California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Prescription Medication Abuse Subcommittee

Ramon Castellblanch, PhD, Chair
Rosalyn Hackworth, Board Member
Lavanza Butler, PharmD
Darlene Fujimoto, PharmD
Gregory Murphy, Board Member

Materials for the November 12, 2014 Meeting

The Communication and Public Education's Prescription Medication Abuse Subcommittee was formed following the February 2013 Joint California Medical Board and Board of Pharmacy Appropriate Prescribing and Dispensing Forum. This subcommittee was formed to continue to explore ways to address the misuse and abuse of prescription medication, particularly of controlled substances. The Medical Board has formed its own subcommittee to work on similar issues.

1. **Report on National Coalition Against Prescription Drug Abuse, Presented by April Rovera, Founder/CEO of the National Coalition Against Prescription Drug Abuse**

   April Rovero retired from Lucent Technologies as a National Program Management Director in 2001 after a 30 year career in telecommunications. She has a Bachelor of Science degree in Business Administration and a Masters Certificate in Program Management from Stephen's Institute of Technology. She founded NCAPDA as a result of her son, Joey's, accidental death on December 18, 2009 from a lethal mixture of alcohol and prescription drugs while attending Arizona State University. April leads and oversees all aspects of the organization and is the chair of both the Contra Costa County Prescription Drug Abuse Prevention Coalition and the California Prescription Drug Abuse Workgroup.

2. **Presentation on the Connection Between The Abuses of Prescription Pain Medications and Heroin, Presented by Writer Jason Smith**

   Attachment 1

   Jason Smith is a writer, business owner and a pain medication addict, who is in recovery and has been sober for two years. Mr. Smith spoke at the August 2014 committee meeting about addiction and at this meeting will present two articles that provide evidence of the connection between pain medication abuse and heroin abuse.

A copy of a portion of the *Journal of the American Medical Association* article and *New England Journal of Medicine* article are included in **Attachment 1**, along with Mr. Smith's recent articles on the CURES system.

3. **Report on Marin County's Efforts to Fight the Opioid Epidemic, Presented by Matt Willis, M.D., MPH, Marin County Public Health Officer**

Attachment 2

Marin County Public Health Officer Dr. Matt Willis earned several advanced degrees in public health and medicine including Internal Medicine Residency, Cambridge Hospital, Harvard Medical School; Masters of Public Health from Harvard School of Public Health; Doctorate of Medicine from Temple School of Medicine; and a BA in Medical Anthropology from Brown University. He will present information on Marin County's efforts to battle the opioid epidemic and Marin County's New Community-wide Standards for Prescribing Opioid Pain Medications.

Attachment 2 contains a bio for Dr. Willis, his PowerPoint presentation and documents on their New Community-wide Standards for Prescribing Opioid Pain Medications.

4. **Report on Orange County and Santa Clara County Lawsuits Against Five Pharmaceutical Companies for False Advertising and Unfair Competition**

Attachment 3

The District Attorney Offices from Orange County and Santa Clara County have joined together to file a complaint against Purdue Pharma and a number of other pharmaceutical companies claiming they used deceptive marketing tactics in their promotion of the use of opioids for long-term use to treat chronic non-cancer pain and misrepresented the risks associated with opioid use. Information on the lawsuit will be presented during the meeting by Greta Hansen of the Santa Clara County Counsel's office.

Attachment 3 contains a copy of the complaint and the support documents used in the lawsuit.

5. **Report on Medical Board's Updated Pain Management Guidelines and California Prescription Drug Abuse Work Group Headed by the Director of the State Department of Public Health**

Attachment 4

At their October meeting, the Medical Board unanimously approved their revised Pain Management Guidelines, which will soon be posted on their website. The California Prescription Drug Abuse Work Group, headed by the director of the State Department of Public Health, will use the revised guidelines to launch statewide educational efforts on

prescription drug abuse and overdose. The goal of the group is to unify a focused policy that can be articulated by state agencies in efforts on opioid abuse education and prevention. Work group members include the Medical Board, Dental Board, Pharmacy Board, Department of Public Health, Department of Health Care Services, Department of Justice CURES, Emergency Medical Services Authority, Department of Education and the California Conference of Local Health Officers.

A copy of the draft revised Pain Management Guidelines is included in **Attachment 4.**

6. **Review of Additions to the Board of Pharmacy Prescription Drug Abuse Prevention Website Page**

Attachment 5

The Board of Pharmacy created a prescription drug abuse prevention page on the board website that contains free, downloadable information on prescription drug abuse for teens, college students, parents, educators and pharmacists. The page also includes helpful website links. The page can be found at http://www.pharmacy.ca.gov/consumers/rx_abuse_prevention.shtml.

The page was recently updated to include a number of recommendations that were made by Dr. Rabia Atayee and Dr. Nathan Painter from the University of California, San Diego School of Pharmacy, at the May subcommittee meeting held in San Diego.

Screenshots of the updated prescription drug abuse prevention page are included in **Attachment 5**.

7. **Review and Discussion of Articles Documenting the Issues of Prescription Medication Abuse**

Attachment 6

Attachment 6 contains a number of articles addressing prescription drug abuse, the heroin epidemic, abuse of ADHD medications, recovery and other related issues. Of note is a DEA press release on the recent Drug Take Back Day with 2,411 tons of drugs collected. Of that, California had the highest amount collected – with 56,695 pounds (more than 28 tons).

8. **Public Outreach to Address Prescription Drug Abuse**

- Aug. 25: Executive Officer Virginia Herold and the executive officer for the Medical Board presented to the Dental Board
- August 28: Committee Chair Dr. Ramon Castellblanch presented at the Generation Rx educational event at Touro University, in Vallejo
- Aug. 29: Ms. Herold and Public Information Officer Joyia Emard attended the California Prescription Drug Abuse Work Group meeting

- Sept. 2-3: Ms. Herold and the Los Angeles Field Division of the Drug Enforcement Administration held two days of pharmacist training on "What every pharmacist should know to prevent drug diversion."
- Sept. 11: Ms. Emard attended the messaging meeting for the California Prescription Drug Abuse Work Group
- Oct. 13: Ms. Emard attended the California Prescription Drug Abuse Work Group meeting
- Oct 17: Ms. Herold presented prescription drug abuse information to the California Dental Association
- Oct. 21: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Oct. 27: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Nov. 3: Ms. Emard participated in the messaging meeting for the California Prescription Drug Abuse Work Group
- Nov. 4: Ms. Herold and Ms. Emard attended the California Prescription Drug Abuse Work Group meeting

9. <u>Public Comment for Items Not on the Agenda, Matters for Future Meetings*</u>

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment **2 p.m.**

Attachment 1

Driven by Prescription Drug Abuse, Heroin Use Increases Among Suburban and Rural Whites

Bridget M. Kuehn, MSJ

The face of heroin use in the United States is changing dramatically. A study published in *JAMA Psychiatry* in late May found that compared with previous generations of heroin users, newer initiates are more likely to be older, to be white, to live in nonurban areas, and to have previously abused prescription painkillers (Cicero TJ et al. *JAMA Psychiatry*. doi:10.1001/jamapsychiatry.2014.366[published online May 28, 2014]).

Anecdotal reports from law enforcement and substance abuse treatment professionals have long suggested that many individuals who become addicted to prescription painkillers eventually move on to heroin when it becomes too difficult or expensive to access prescription opioids. Recent data from the Substance Abuse and Mental Health Services Administration support this anecdotal evidence (Kuehn BM. *JAMA*. 2013;310[14]:1433-1434).

In addition to providing additional data suggesting that opioid dependence resulting from abuse of prescription opioids is driving a resurgence in heroin use, the latest study provides evidence of major shifts in the demographics of heroin users. Using survey data from a national sample of 2797 patients entering substance abuse treatment, the researchers found that although individuals who began using heroin in the 1960s were mostly young men in their mid-teens whose first opioid drug was heroin, more re-

MediImage/www.sciencesource.com

Heroin use appears to be increasing among nonurban whites who previously abused prescription opioids.

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doi:10.1001/jama.2014.9323.

Senate Starts Group to Take on Prescription Drug Abuse

JAMA. 2014;311(22):2264.
doi:10.1001/jama.2014.6829.

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Driven by prescription drug abuse, heroin use increases among suburban and rural whites. *JAMA* 2014;312(2):118-9.

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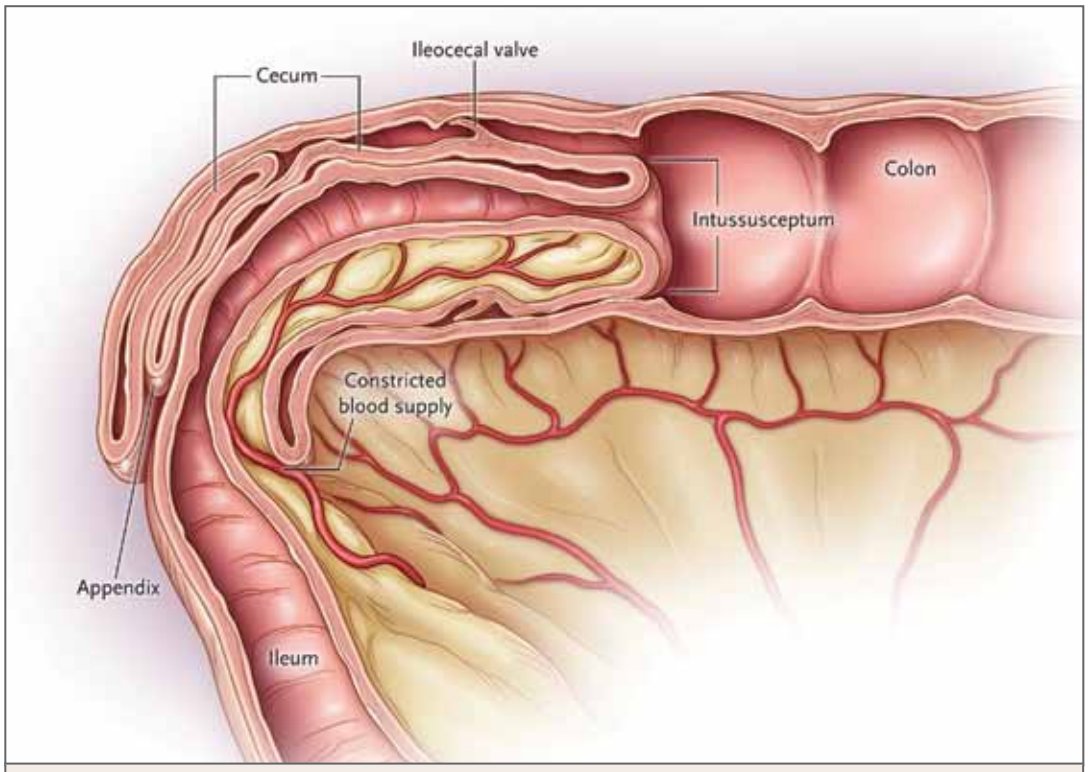

Figure 1. Idiopathic Ileocecal Intussusception.

interpreted by an experienced (pediatric) radiologist, is a better screening test for both intussusception and other intraabdominal processes.

Sjirk J. Westra, M.D.
Allan M. Goldstein, M.D.
Lauren M. Allister, M.D.
Massachusetts General Hospital
Boston, MA

Since publication of their article, the discussants report no further potential conflict of interest. Dr. Goldstein reports no potential conflicts of interest relevant to this reply.

1. Gilsanz V. Displacement of the appendix in intussusception. AJR Am J Roentgenol 1984;142:407-8.

DOI: 10.1056/NEJMc1205522

Effect of Abuse-Deterrent Formulation of OxyContin

TO THE EDITOR: In August 2010, an abuse-deterrent formulation of the widely abused prescription opioid OxyContin was introduced. The intent was to make OxyContin more difficult to solubilize or crush, thus discouraging abuse through injection and inhalation. We examined the effect of the abuse-deterrent formulation on the abuse of OxyContin and other opioids.

Data were collected quarterly from July 1, 2009, through March 31, 2012, with the use of self-administered surveys that were completed anonymously by independent cohorts of 2566 patients with opioid dependence, as defined by the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition, who were entering treatment programs around the United States and for whom

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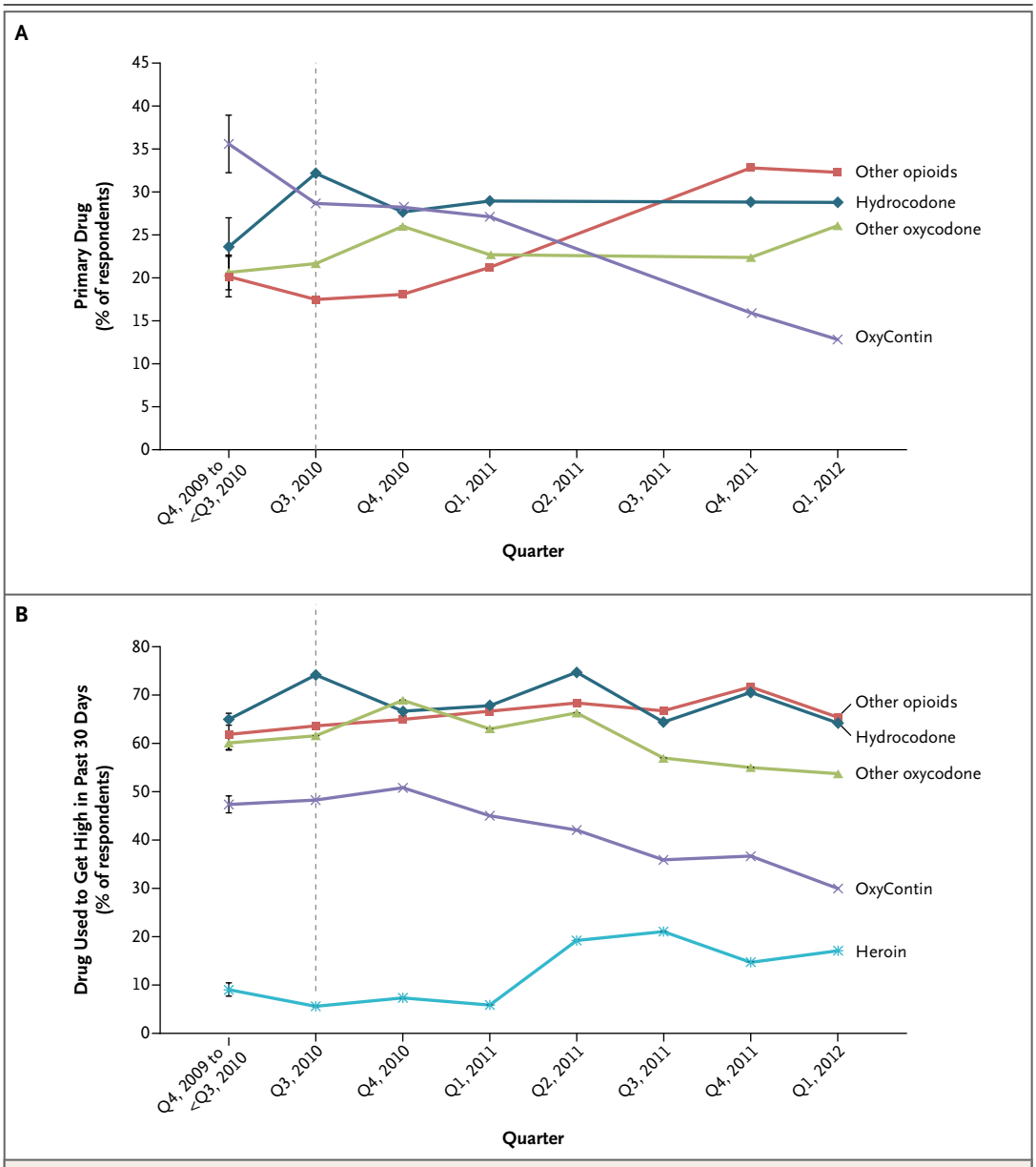

Figure 1. Effect of Abuse-Deterrent OxyContin.

Panel A shows the percentage of respondents in each quarter who selected a specific prescription opioid as their primary drug (used most often and preferred over all others). Respondents could make only one choice. Heroin was not included as a primary drug to limit the population to those who primarily used prescription opiates. Panel B shows the use of opioids to get high at least once in the past 30 days from July 1, 2009, through March 31, 2012. Respondents could select as many drugs as were applicable, and hence the percentages sum to more than 100. In both panels, the dashed vertical line represents the quarter in which the abuse-deterrent formulation of OxyContin was introduced, and the first point the mean (±SE) for the four quarters before the introduction of the abuse-deterrent formulation.

a prescription opioid was the primary drug of abuse (i.e., heroin use was acceptable but could not be the patient's primary drug). Of these patients, 103 agreed to online or telephone interviews to gather qualitative information in order to amplify and interpret findings from the structured national survey.

As shown in Figure 1A, the selection of OxyContin as a primary drug of abuse decreased from 35.6% of respondents before the release of

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the abuse-deterrent formulation to just 12.8% 21 months later (P<0.001). Simultaneously, selection of hydrocodone and other oxycodone agents increased slightly, whereas for other opioids, including high-potency fentanyl and hydromorphone, selection rose markedly, from 20.1% to 32.3% (P=0.005). Of all opioids used to "get high in the past 30 days at least once" (Fig. 1B), OxyContin fell from 47.4% of respondents to 30.0% (P<0.001), whereas heroin use nearly doubled.

Interviews with patients who abused both formulations of OxyContin indicated a unanimous preference for the older version. Although 24% found a way to defeat the tamper-resistant properties of the abuse-deterrent formulation, 66% indicated a switch to another opioid, with "heroin" the most common response. These changes appear to be causally linked, as typified by one response: "Most people that I know don't use OxyContin to get high anymore. They have moved on to heroin [because] it is easier to use, much cheaper, and easily available." It is important to note that there was no evidence that OxyContin abusers ceased their drug abuse as a result of the abuse-deterrent formulation. Rather, it appears that they simply shifted their drug of choice.

Our data show that an abuse-deterrent formulation successfully reduced abuse of a specific drug but also generated an unanticipated outcome: replacement of the abuse-deterrent formulation with alternative opioid medications and heroin, a drug that may pose a much greater overall risk to public health than OxyContin. Thus, abuse-deterrent formulations may not be the "magic bullets" that many hoped they would be in solving the growing problem of opioid abuse.

Theodore J. Cicero, Ph.D.
Matthew S. Ellis, M.P.E.

Washington University in St. Louis
St. Louis, MO
cicerot@wustl.edu

Hilary L. Surratt, Ph.D.

Nova Southeastern University
Coral Gables, FL

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Disclosure forms provided by the authors are available with the full text of this letter at NEJM.org.

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CORRECTIONS

Case 12-2012: A 10-Month-Old Girl with Vomiting and Episodes of Unresponsiveness (April 19, 2012;366:1527-36). A correction is described in the Correspondence section of this issue of the *Journal* (Case 12-2012: An Infant with Vomiting [July 12, 2012:367:186-7]).

Niacin in Patients with Low HDL Cholesterol Levels Receiving Intensive Statin Therapy (December 15, 2011;365:2255-67). In Table 2 (pages 2262 and 2263), the values listed in the columns labeled "Baseline" were actually from the first of three screening samples specified in the protocol. The values varied from baseline values by no more than 2.5 mg/dl in any mean or median reported in the table; they have been replaced with baseline values online. The article is correct at NEJM.org.

NOTICES

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The broken cure – Part I: Docs, drug abusers cheat system

State's CURES system too underfunded, complicated
By: Jason Smith for The Press Tribune
http://www.auburnjournal.com/article/9/24/14/broken-cure-%E2%80%93-part-i-docs-drug-abusers-cheat-system

"Steven White" is not your typical drug dealer. "Steven" is not his real name, nor does he put "drug dealer" on his tax returns, but rest assured Steven moves a lot of product throughout the region.

Operating out of the Arden-Arcade area of Sacramento, his clientele consists of a segment of society that doesn't fit the drug-addict stereotype. They have college degrees, successful careers, and letters after their names.

Steven deals to doctors.

"Crystal meth — I have quite a few doctors who come to me. They say they can't work without it," he says, pausing, looking as if contemplating how much more he should tell. "They say they got hooked in medical school to stay awake. You'd be surprised, man."

He reaches into his pocket. "They'll write me a (prescription) for whatever I want for a few of these," he adds, holding up the drug.

From his backseat he pulls out a newly-received prescription for 360 Norco, a powerful narcotic opioid.

"I traded $100 in meth for this," he explains. "These sell for $4.25 apiece. You do the math."

"It's easy, man," he says, shaking his head. "It's really easy."

It's not supposed to be so easy

Unscrupulous doctors are nothing new. In January 2014, Granite Bay doctor Nicholas J. Capos Jr. was charged by federal officials with illegally distributing opiate painkillers and running a criminal enterprise. His practice extended from Grass Valley to Yuba City.

An LA Times investigation in December 2012, found a number of doctors connected to prescription drug overdoses in Southern California, where 71 doctors prescribed medications that caused or contributed to 298 deaths between 2006 and 2011.

Known as “pill-mills,” doctors writing inordinate numbers of prescriptions have reportedly gone largely unchecked by any state or law enforcement agency in recent years, with offending physicians and pharmacies often being investigated only after a patient overdoses.

Catching doctors and doctor-shoppers, or patients who visit multiple doctors for the same prescription, is one of the goals of the state’s Controlled Substance Utilization Review and Evaluation System, or CURES.

Having declared prescription drug abuse an epidemic in 2012, the Centers for Disease Control recommended state participation in a Prescription Drug Monitoring Program, or PDMP. While remaining autonomous, every state but Missouri has independently created a PDMP to meet the objective of curtailing prescription drug abuse and catching doctors and patients who abuse the system: Patients like those who have died of overdoses in Placer County; doctors like those who trade prescription drugs for street drugs with Steven White.

Theory vs. reality

To many, California’s program – CURES – is a good idea in theory. Before writing a prescription for a narcotic, a doctor would check CURES to make sure the patient hadn’t visited any other doctor or pharmacy for the prescription he or she is about to write. After issuing the prescription, the doctor would put the patient’s name and the drug into the system. After filling the prescription, the pharmacy would do the same thing. The Department of Justice would oversee the entire process, making sure suspicious entries or quantities were investigated properly.

In theory.

In reality, CURES has proven to be useless to many of the doctors and pharmacists who have tried to use it.

“It’s notoriously dysfunctional,” said Dr. Ramon Castellblanch, a professor of Health Education at San Francisco State University and Public Member of the California Board of Pharmacy. “(CURES) is cumbersome and error-prone.”

According to Castellblanch, California’s decision to have the Department of Justice run CURES has made the process impossibly difficult. While most states run their programs through their departments of health, California is one of only seven states to administer the program through its Department of Justice.

“Public Health could handle it better than law enforcement,” Castellblanch said. “But California has gone the other way.”

Apparently under-funded, under-resourced, and understaffed, the Department of Justice, as of 2013, has had only one full-time employee to handle over 100 million prescriptions and 800,000 practitioner inquiries a year.

Ivan Petrzelka, President and General Counsel of NoRxAbuse.org and practicing pharmacist in Redding, concurs with Dr. Castellblanch’s findings, having discovered nothing but frustration when trying to register.

“You mail the (notarized) application, wait two months, and no response,” Petrzelka said. “Send email inquiry – no response. Call the number on the website – no answer or pre-recorded message saying there is a backlog of several months. Send a certified mail inquiry – they tell you your application was not received and to start over again. You go to the site to start over again – it tells you your log-in already exists, that you cannot submit again.”

Mike Small, the DOJ Administrator tasked with handling these issues, has, according to Castellblanch, made no secret about his inability to work with individual doctors or pharmacists who encounter problems. Castellblanch recalls Small, who was barred by the DOJ from being interviewed for this story, speaking at a joint Pharmaceutical Board/Medical Board forum in February 2013, telling the group that he would not return any phone calls, and that he would only meet with groups of 20 or more to explain the registration process.

Further exacerbating the frustration, says Petrzelka, is the ease with which doctors and pharmacists in neighboring states have signed up for their respective PDMPs.

“Contrast (CURES) with Nevada, where access is granted within a week of submitting the application,” Petrzelka pointed out.

Leticia Tanner, a Department of Justice data analyst, defends the DOJ handling of CURES and its implementation.

“We do return emails and field replies,” Tanner said. “But the funding has been gradual. Since Senate Bill 809, the system has begun to work more smoothly.”

Senate Bill 809, the legislature’s latest patch for CURES, mandates an annual $6 fee to all doctors and pharmacists to fund CURES. That funding, according to Tanner, has helped ease the congestion of the current system.

Petrzelka’s experience, however, has been different.

“My personal signup for California took about three months to complete,” he explained. “(And that was) without technical difficulties.”

As for the DOJ’s claims of improvements since the passing of SB 809, Petrzelka is skeptical.

“Given that it is largely manual process at the DOJ and the mandate for all providers to sign up by 2016, it is hard to imagine that it has improved much.”

More money, more problems

CURES’ flaws extend beyond its registration process. There is a three-week lag time between when information is put into the system and when it is viewable. Often times, data put into the system is never seen again, leaving the pharmacist or doctor to either try and get a hold of someone at the DOJ to fix the problem, or simply let it go.

SB 809 may have thrown more money at CURES, but its ambiguous language leads to even more questions.

According to the bill, the deadline for doctors and pharmacists to “obtain approval to access information stored” regarding controlled substance history of a patient is Jan. 1, 2016.

SB 809 mandates that doctors and pharmacists register with the DOJ to have access to the information in the system. Nowhere is there a mandate for a doctor or pharmacist to actually view, or use, the patient information in the system prior to writing prescriptions for narcotics; they are only required to have access.

California Proposition 46, on the ballot this November, would, among other things, mandate all doctors and pharmacists consult the CURES system prior to authorizing or dispensing controlled substances.

Bob Pack, author of Prop 46, says that it's only logical for practitioners to use the information being provided to them.

"In the past 10 years, the sheer number of prescriptions has skyrocketed," Pack said. "We've gone from 3 million in 2002 to 50 million last year. But the pharmaceutical lobby is fighting this hard."

Prop 46 is facing coordinated resistance from "Vote No on 46," which argues CURES could not handle the burden of being accessed by every doctor and pharmacist in the state.

"The infrastructure is not robust enough to handle it," said Tom Sugarman, former president of the California American College of Emergency Physicians and opponent of Prop 46. "It'd be too much on the system and would overload the database. It's not ready."

Business as usual

As for drug dealer Steven White, he doesn't seem too concerned with the state politics surrounding the product he sells. As far as he's concerned, his business will be booming regardless of any new regulations.

No laws are going to stop doctors looking for a fix, according to White, nor will they curb the public's appetite for prescription narcotics.

"Best-case scenario – nothing changes and the pill-game stays hot," he explains.

When pressed for a worst-case scenario, he pauses, thinking long about the question.

“Worst-case scenario – this pill game dries up,” he says, holding up a different prescription than the one he flashed before, “and this (stuff) gets more expensive.”

Asked what that will mean for his business long-term, he smiles.

“All those addicts aren’t just going to just disappear. They’re still going to need something.”

The broken cure – Part II: State cops, overseers hobbled against pharm abuse

Regardless of problems, the CURES system now has little enforcement
By: Jason Smith for the Press Tribune
Editor's note: This is the second in a three-part investigative series.

2011 just wasn't Robert Rothman's year. His pharmacy popped up on the radar of the Bureau of Narcotics Enforcement, implicating him in a complicated prescription drug ring.

According to the Department of Consumer Affairs and an official accusation by the California Board of Pharmacy, Rothman filled large quantities of prescription narcotics, often without doctor approval, which were subsequently transported to San Diego and smuggled into Tijuana.

San Diego law enforcement said the drug ring then sold the pills in bulk to various Tijuana pharmacies for around $3.50 apiece so Mexican pharmacies could re-sell them for around $6 a pop to American addicts who crossed the border.

This was not Rothman's first brush with the law. According to documents obtained in this investigation, the California Board of Pharmacy suspended Rothman's pharmacist's license for 90 days in 1987 for dispensing drugs without a prescription, and placed him on three years of probation.

As of April 8, 2011, Rothman had gone 18 months without a single report to CURES. Discovering that fact in CURES data, and given Rothman's past convictions, the BNE grew suspicious. Mining the little data Rothman and his pharmacy did provide CURES proved to be enough for the bureau to launch an investigation.

BNE took the lead, coordinating with local law enforcement and U.S. Immigration and Customs Enforcement to shut down the prescription drug ring. The primary doctor involved, Carlos Estiandan, was convicted of 13 felony counts of illegally prescribing controlled substances, for which he was sentenced to five years in prison.

Rothman's hearing before the Board of Pharmacy and Department of Consumer Affairs is scheduled for October.

As prescription drug abuse in the state of California mirrored a rise throughout the rest of the nation, the BNE was busy.

Al Cardwood, the President of the Association of Special Agents for the Department of Justice, worked narcotics for the BNE for 20 years.

"We used CURES to track and monitor suspicious activity," Cardwood said. "It was a great tool for investigation."

Law enforcement agents work within their respective jurisdictions. Drug smugglers do not. The most valuable facet of the BNE was its ability to form task forces comprised of multiple agents in multiple jurisdictions, then track, follow and ultimately shut down drug rings like the one in which Rothman is implicated.

According to Cardwood, agents found even more satisfaction in taking down corrupt doctors than busting dealers on the corner.

"Doctors are trusted members of society," he said. "They took an oath. There's no excuse for that."

When legislative Democrats pushed forward a plan in 2009 to close a $24 billion budget gap by cutting the BNE by one third, then-Attorney General Jerry Brown called it a "terrible budgetary decision." Brown was a strong advocate of CURES. In 2009 his office worked closely with Proposal 46 author Bob Pack, who lost two children to a hit-and-run driver high on prescription medication.

Pack worked directly with Brown's office, using Pack's background in technology to help design the current CURES system.

"I brought the idea of an electronic version of CURES, with information available in real time," Pack said. "We brought it to the (Medical Board) and the legislature, and it was approved."

With CURES having been updated and the BNE using the real-time data to shut down doctors, pharmacists and patients who were abusing the system, the outlook back then, according to Pack, was good.

The gubernatorial election of 2010 would change all that.

It all falls apart

Candidate Brown's opponent in that election was Meg Whitman, and she was making big promises. Whitman promised that her plans for pension reform would not apply to law enforcement.

Brown would not make that promise.

As a result, the California Statewide Law Enforcement Association (CSLEA), which includes the BNE, officially endorsed Meg Whitman, giving $500,000 to her campaign and spending millions on media spots.

During the election, Brown, after leaving a message for CSLEA President Alan Barcelona, forgot to hang up the phone. While unknowingly being recorded on voicemail, someone in the room called Meg Whitman a "whore." Barcelona released this recording to the media.

Some in law enforcement worried things were getting personal. The CSLEA backed the wrong horse in what proved to be a consequential race. Brown won the election and did an about-face on both CURES and the BNE. He did as governor what he had warned against doing as attorney general: reassigned those he'd previously called "some of the best-trained agents in the world."

J.D. Palmer, spokesman for the California Department of Finance, said budget cuts were not Brown's decision. The legislature, according to Palmer, handed Brown the budget. He just signed it.

Regardless of the reasons for the cuts, or whose decision they were, the BNE was slashed in half to less than 200 agents.

"Bottom line was, Governor Brown was handed a financial mess," Pack said. "BNE was cut by $70 million, and 200 narcotics officers were taken off of the street at the peak of the prescription drug epidemic."

The 52 drug task forces throughout California – comprised of local law enforcement and lead by BNE agents tasked with everything from shutting down unscrupulous doctors to the chemical clean-up of meth labs – were suddenly slashed. Today only 17 task forces remain, statewide.

Cardwood said the remaining 200 BNE agents were reassigned to other areas.

“We literally at this moment have agents who worked their whole careers fighting narcotics, assigned to aluminum can theft, elder abuse and internet crimes,” he said.

Cardwood can speak personally to this. He has been taken off of narcotics, where he spent his career on the meth-lab and special operations teams, and where he ran a task force.

Today he works for the Bureau of Gambling Control in Fresno.

“Brown believes narcotics enforcement is a local law enforcement issue,” Cardwood said. “Here in Fresno, we have cases that are not being worked because there is nobody to work them. There’s nobody to coordinate across the various departments and jurisdictions.”

Brown’s office did not respond to a request for interview on this issue.

In October 2012, a Rocklin CVS pharmacy on Granite Drive found that it was missing over 20,000 prescription narcotics. Search warrants were also issued for Fairfield, Dixon, Turlock and Modesto CVS pharmacies. In the broader scope of the drug ring, more than 37,000 pills went missing over the course of a year, and no state law enforcement agency caught the discrepancy between prescribed pills and inventory. The case was eventually cracked by federal DEA agents.

“Now they have civilian data analysts looking at all of the information provided by CURES,” Cardwood said, “where before you had the BNE analyzing it.”

“What good is a collection of data if you don’t know what to do with it?"

The broken cure – Part III: Far-reaching strategy for 'scripts' lags behind

Even if CURES is improved, data and experts see more problems
By: Jason Smith for the Press Tribune
-A +A
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Editor's note: This is the third in a three-part series.

Aaron Fechter is an ‘ideas guy.’ He’s an engineer, an entrepreneur. He’s an inventor.

In 1973 he founded Creative Engineering, which produced his most well-known invention. It’s nearly impossible to go into an arcade, Chuck-E-Cheese or any other place where adults take children to run around, eat pizza, and play video games, and not glimpse his creation.

But he could never have envisioned that the Drug Enforcement Agency, the US government, state legislatures and local law enforcement would one day play his game on perpetual rotation, after Richard Nixon declared a “war on drugs” in 1971.

Aaron Rechter invented the game “Whack-a-Mole.”

The law of unintended consequences

Following the Centers for Disease Control and Prevention’s recommendation in 2013 that each state create its own Prescription Drug Management Program, or PDMP, to curtail prescription drug abuse, California started the Controlled Substance Utilization Review and Evaluation System, or CURES.

The goal of the program is to get prescription drugs off the streets and stop addicts from obtaining them by going to multiple doctors for the same prescription.

And if history is any indication, CURES could potentially have dire consequences.

Everything changed in 2010. Purdue Pharmaceutical had been selling OxyContin since 1996, and according to a Therapeutics and Clinical Risk Management report from 2005, the drug was being abused rampantly from the late 1990s through the early 2000s. In October 2010, after receiving pressure from the Drug Enforcement Agency, Purdue changed the makeup of OxyContin to deter those who were abusing it. When crushed, the new tablet turned into a gummy-like ball instead of a powder, making snorting, smoking or injecting nearly impossible.

It worked. But there were consequences.

In July 2012, the New England Journal of Medicine documented an immediate rise in heroin use, with an inverse correlation between OxyContin and heroin abuse. Tracking 2,500 dependent users, researchers found that between March 2009 and July 2012, OxyContin abuse dropped 17 percent while heroin use doubled.

A July 2014 study from the Journal of the American Medical Association surveyed 2,800 addicts entering treatment. The study found that 75 percent of heroin addicts who began using in the 2000s had abused prescription drugs first, and of those, 94 percent said they switched to heroin because prescription drugs became more expensive to buy on the street and more difficult to find.

Both studies proved that cutting off the supply of a widely-abused prescription narcotic like OxyContin did not stop addicts from using. Instead, it simply forced addicts of a prescription narcotic like OxyContin to fall back on a street narcotic like heroin.

Theodore Cicero, the lead researcher of the JAMA, study told ABC News, “Substance abuse is like a balloon: If you press in one spot, it bulges in another.”

Should CURES be successful, California will once again hit the supply side of prescription drug abuse with force, pressing on the metaphorical balloon described by Cicero. And once again, if the OxyContin-to-heroin model holds true, there will be consequences – consequences the California Department of Justice is not prepared to handle without more law enforcement and more incarceration. In the last eight months, Roseville and Granite Bay have experienced three armed robberies at pharmacies in which the assailant demanded opiate pills rather than cash.

Nicholas Pacilio, spokesman for the California Department of Justice, is unaware of any plan in place to catch addicts whose supply will be cut off by CURES data.

“It’s a database,” explained Pacilio. “I’m not sure I even understand what one has to do with the other.”

When pressed further as to what will happen with the millions of prescription drug addicts once CURES data is used to cut off their supply, Pacilio responded, “I’ll have to get back to you on that.”

Despite repeated attempts, Pacilio has not returned with a comment on this issue.

Different state, different approach

Not all states are preparing to use law enforcement to treat the potential health crisis.

Chris Baumgartner is the head of the Prescription Drug Management Program for the state of Washington, which runs its PDMP through the Department of Health. Believing in a proactive approach, Washington has created the Unintentional Poison Workgroup, tasked with creating a strategic plan to deal with the addicts who will maintain their demand for narcotics despite the PDMP's cut into the supply.

"The PDMP is important, but it's not the only tool," said Baumgartner. "We have to take a holistic approach. There is no 'silver bullet' to combat prescription drug abuse."

Washington's Unintentional Poison Workgroup works directly with the state's PDMP, offering treatment options and doctor support to patients addicted to prescription drugs in an attempt to keep them from simply turning to street drugs like heroin as a replacement.

Washington has also created pain management guidelines for physicians – written by physicians, not law enforcement – that advise prescribers on treating chronic pain, giving dosage guidelines, notifying practitioners whose scope of practice does not include treating chronic pain, and referring patients to pain management.

"So far we've seen tremendous success," says Baumgartner. "The PDMP is just a database. You have to have something in place to treat patients based on that data, with patient health being the primary focus."

At the moment, California has no such plan in place.

DOJ approach short-sighted

Neither Ivan Petrzelka, President and General Counsel of NoRxAbuse.org and practicing California pharmacist, or Ramon Castellblanch, Public Member of the California Board of Pharmacy, are aware of any Department of Justice directive on what to do when a doctor-shopper is identified, other than refuse to fill the prescription and send them on their way.

"To the best of my knowledge," Petrzelka said, "there is no hard-and-fast standard for this decision-making process."

Both are unaware of any DOJ effort to combat the demand that will remain intact in a post-CURES California.

Leticia Tanner, a DOJ analyst for CURES, is also uncertain about what to do.

"The DOJ role is not fully developed," she explained.

When pressed to explain why the DOJ's role is not fully developed when it's the one responsible for creating the roles, she responded:

"It's complicated."

COMMENTS:

- There is an innovative poverty alleviation program in New York (City) that says to the parents "We can't fix your circumstances, but if you commit to the program we can move your children to a successful path". In the same way you have to consider future patients of the medicated pain alleviation system as separate from those already addicted by it. The new forms of drugs that can't be injected are a signpost for keeping newbies from addiction by misuse; these include the forms of OxyContin that gum up on crushing, and the clever drug SubOxone that combines naloxone with opioids in a way that can't be injected but engineered so that it will provide relief. So what to do about current overusers still in the medication system? Clearly the 'instant karma' model of CURES will do more harm than cure. I never understand why these programs are not designed with tapering in mind. An acquaintance of mine spent a year reducing the enormous dosage of painkiller prescribed to a twentieth with no ill effects and clearly the author's own experience show that there is a way out; this must be especially so while users are still in the medication system and CURES should recognize that and plan for it.
There are always boffos who blurt out nostrums like "It's just a matter of willpower; I don't see the problem"; and that's the problem; they have never really seen it, and the advice is useless without being part of a program that offers hope and a method.
Reply · Like · 3 · Follow Post · Yesterday at 8:55am

-

  Rhonda Bricker · Top Commenter · Nobody at Retired but still busy!

  John - I would like to hear more about the CURES system. I thought it was just a tracking database. You certainly caught my ear when you speak of solutions and right thinking. Please keep it coming :)

  Reply · Like · 22 hours ago

-

  John Sisson · Top Commenter

  Rhonda Bricker - parts I and II of this are where the CURES system is described; the consequences of its implementation are the issue; the sudden influx of persons who will be identified as abusive and cut loose into the illegal drug jungle. J.Smith is the source for all this knowledge and perceptive writing.

Reply · Like · 22 hours ago

-

  Jason Smith · Top Commenter · Auburn, California

  John Sisson, you bring up a great point. The term "prescription drug" abuse really has two distinct branches to it: prevention and abuse. On one hand, you have the prevention of another generation falling to drugs that were prescribed too loosely for too long. Programs like CURES, prescribing guidelines for physicians, a board that makes sure physicians are acting within their scope of practice - these are all things that would be beneficial. But on the other branch, we're left dealing with the current situation, with the question of "what do we do with all of the current addicts?" Right now there are two ways in which the addictions can be maintained - legal and illegal. While the addicts are still in the legal column, they can receive help. They can receive treatment. They can receive medical detox, taper-downs, etc. That's a controllable environment. But once they shift over to illegal, then treatment becomes a whole lot costlier and a whole lot more complicated.

  Reply · Like · 1 · 20 hours ago

View 2 more

-

Robert Vaughan · Top Commenter
"Cutting off...OxyContin...forced addicts...to fall back on...heroin." The author is in the camp of no personal responsibility. I used to play a game with my children. I would ask them to raise their arms, and then to lower them. I would tell them that they control their arms, and they would agree. I would tell them that they are responsible to control themselves. No one is forcing these addicts to take drugs. They do it as a choice.
Reply · Like · 3 · Follow Post · September 27 at 11:17am

-

  Jason Smith · Top Commenter · Auburn, California

  Robert you bring up a very good point. The language you quote isn't my own. That's the findings in the new England journal of medicine and the JAMA study cited in the article, and the language of the addicts used in the survey. My own personal belief is that individual responsibility is paramount. If you get a chance, read part 3 of my previous article Heroin in the Foothills. That's my thesis. Having said that, stepping back from the individual plane and looking at the problem from a more existentialist position, there will

be a problem once we cut the supply with CURES and we'd be better served following what Washington state has done.

Reply · Like · September 27 at 11:44am

-

Robert Vaughan · Top Commenter

Jason Smith It appears that there is no easy answer to drug abuse. I wonder sometimes if we would be better off as a society if we moved the money we now pay for law enforcement to therapeutic programs and made drugs safe and over-the-counter. That would never work politically because of the vested interests of those who make money off of illegal drugs on the illegal and well as the legal side.

Reply · Like · 3 · September 27 at 1:01pm

-

Rhonda Bricker · Top Commenter · Nobody at Retired but still busy!

Jason Smith - I am encouraged that you focus on personal responsibility in your later series. Perhaps in future stories, you can share with the readers about how people get addicted in the first place. Maybe you could research and discuss the dangers & signs of drug addiction, side effects from prescriptions and how people can take responsibility for their own personal prescriptions rather than to put that responsibility totally on the doctors who still do not have all that they need to better manage their own patient loads, like this CURES database. I would like to see some articles based on the physicians viewpoint...not just stories of a few rogue doctors and pharmacies. Some statistics might also be helpful, such as age groups, income levels, etc. You might also research programs that actually have a high success rate of reduced recidivism, that can give hope to those who have fallen into addiction and the families that suffer when one of their own has slipped through the cracks.....

Reply · Like · 1 · 22 hours ago

-

Aaron Blackwood · San Jose State University
The premise is way off. The US has a vested interest in keeping drugs available on the street. The idea that any of this problem will be solved by the government is laughable.
Reply · Like · 2 · Follow Post · September 27 at 11:18am

Attachment 2

Contact:
Matt Willis
PUBLIC HEALTH OFFICER
Health and Human Services

Marin County
Address
Suite 104
San Rafael, CA 94903
415 473 4163 T
CRS Dial 711
MWillis@marincounty.org
www.marincounty.org/hhs

Biography: Matt Willis, MD MPH

In December, 2012, Dr. Matt Willis assumed the role of Public Health Officer in Marin County, where he had served as an Internal Medicine Physician at Marin Community Clinics, and where he was raised.

Dr. Willis earned several advanced degrees in public health and medicine including:

- Internal Medicine Residency, Cambridge Hospital, Harvard Medical School
- Masters of Public Health, Harvard School of Public Health
- Doctorate of Medicine, Temple School of Medicine
- BA, Medical Anthropology, Brown University

Willis spent six years in the U.S. Public Health Service, serving in the Indian Health Service and the CDC.

Operating on the principle that every person deserves the highest attainable standard of health, he worked to improve systems of care as the Director of Ambulatory Care for the Fort Defiance Service Unit on the Navajo Reservation.

Willis then transferred to the CDC in Atlanta where he served in the Epidemic Intelligence Service, conducting outbreak investigations and researching tuberculosis and HIV in the U.S, Rwanda, India and Kazakhstan. He also helped develop the outbreak detection system in post-earthquake Haiti.

As health officer in Marin County, his epidemiologic training and history as a primary care provider helped guide a departmental focus toward the problem of prescription drug abuse.

Before entering college he spent four years racing on the U.S. National Cycling Team. He credits his passion for promoting wellness to lessons learned mainly outside of the classroom.

Willis lives in Marin County with his wife and three children.

COUNTY OF MARIN

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Promoting and protecting health, well-being, self-sufficiency, and safety of all in Marin County.

MARIN HEALTH & HUMAN SERVICES
Health, Well-being & Safety

Larry Meredith, Ph.D.
DIRECTOR

Matthew Willis, M.D., MPH
PUBLIC HEALTH OFFICER

899 Northgate Drive
Suite 104
San Rafael, CA 94903
415 473 4163 T
415 473 2326 F
415 473 3232 TTY
www.marincounty.org/hhs

PUBLIC HEALTH ADVISORY

July 10, 2014

New Community-wide Standards for Prescribing Opioid Pain Medications

There were 49 drug overdose deaths in Marin County in 2012, according to recently released California Vital Statistics data. This was the highest ever number of drug overdoses for Marin, and was more than four times the number of motor vehicle accident deaths in that year.

The number of prescriptions written for narcotics in Marin County more than doubled between 2004 and 2013. This mirrors national trends in prescribing patterns and correlates to increased drug overdoses and addiction services admissions.

To help address this emerging public health problem, Marin County Emergency Departments have adopted community-wide standards for prescribing opioid pain medicines. These are available below. The standards, collaboratively developed by all of Marin County's Emergency Departments, the Department of Health and Human Services, and Emergency Medical Services, are designed to balance the commitment to safe pain control with measures to limit the harm of prescription drug misuse. Because the majority of pain killer prescriptions are written in Primary Care settings, a similar set of standards will be developed in collaboration with Primary Care providers.

With a common understanding of what can be expected in opioid prescribing as a community, patients and providers can better coordinate care to ensure safe and effective pain management.

SAFE PAIN MEDICINE PRESCRIBING IN EMERGENCY DEPARTMENTS

- We care about you. We are committed to treating you safely.
- Pain relief treatment can be complicated. Mistakes or abuse of pain medicine can cause serious health problems and even death.
- Our emergency department is committed to providing safe pain relief options. Many types of pain can be safely and effectively managed without prescription medications.

For your SAFETY, we follow these rules when treating your pain:

1. We look for and treat emergencies. We use our best judgment when treating pain. These recommendations follow legal and ethical advice.
2. You should have only one provider and one pharmacy helping you with chronic pain. We do not usually prescribe pain medication if you already receive pain medicine from another health care provider.
3. If prescription pain medication is needed, we generally only give you a small amount.
4. We do not refill lost or stolen prescriptions. If your prescription is stolen, please contact the police.
5. We do not prescribe long-acting pain medicines: OxyContin, MSContin, Fentanyl (Duragesic), Methadone, Opana ER, Exalgo and others.
6. We do not provide missing doses of Subutex, Suboxone, or Methadone.
7. We do not usually give shots for flare-ups of chronic pain. Medicines taken by mouth may be offered instead.
8. Health care laws, including HIPAA, allow us to ask for your medical records. These laws allow us to share information with other health care providers who are treating you.
9. We may ask you to show a photo ID when you receive a prescription for pain medicines.
10. We use the California Prescription Drug Monitoring Program, called CURES. This statewide computer system tracks narcotic and other controlled substance prescriptions.

If you need help with substance abuse or addiction, call

(415) 755-2345

for confidential referral and treatment.

These standards were developed by Marin County Department of Health and Human Services, Marin County Emergency Medical Services and all Marin County hospital Emergency Departments.

Rx SAFE MARIN
MARIN COUNTY PRESCRIPTION DRUG MISUSE AND ABUSE INITIATIVE

MARIN HEALTH & HUMAN SERVICES
Health, Well-being & Safety

COUNTY OF MARIN

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MOBILIZING A COMMUNITY

TO PREVENT PRESCRIPTION DRUG MISUSE AND AB

County Health Rankings:
Marin Ranks High In Most Indicators

Marin County ranked in the top 5% in:
- Premature death rate
- Adults self reported health
-Mentally unhealthy days
- Adult obesity
- Teen birth rate
- Uninsured adults
- Primary care physicians per capita
- High school graduation
- Unemployment
- Children in poverty
- Physical activity
- Violent crime rate
High food environment index
-Low rate of preventable hospital stays
-Low violent crime rate

Ranked in the top 25% in:
-Low number of physically unhealthy days
- Adults without social/emotional support
- Low percent driving alone to work

Ranked in the top 10% in:
-Low percent of adults reporting fair or poor health

-Low average number of mentally unhealthy days

-High access to exercise opportunities

-High dentists per capita

-High mental health providers per capita

-High percent with some college

Ranked in the top 15% in:
-Low percent of adults who smoke
- Low percent of children in single-parent households
- Low average daily air pollution

County Health Rankings & Roadmaps
A Healthier Nation, County by County

Marin County ranked in the bottom 50% in:

- [1]Excessive Drinking

-[2]Drug poisoning mortality rate

[1] Data collected from Behavioral Risk Factor Surveillance System 2006-2012 (2005-2010 for social support indicator) and may vary from other local sources used in county health reports and factsheets.

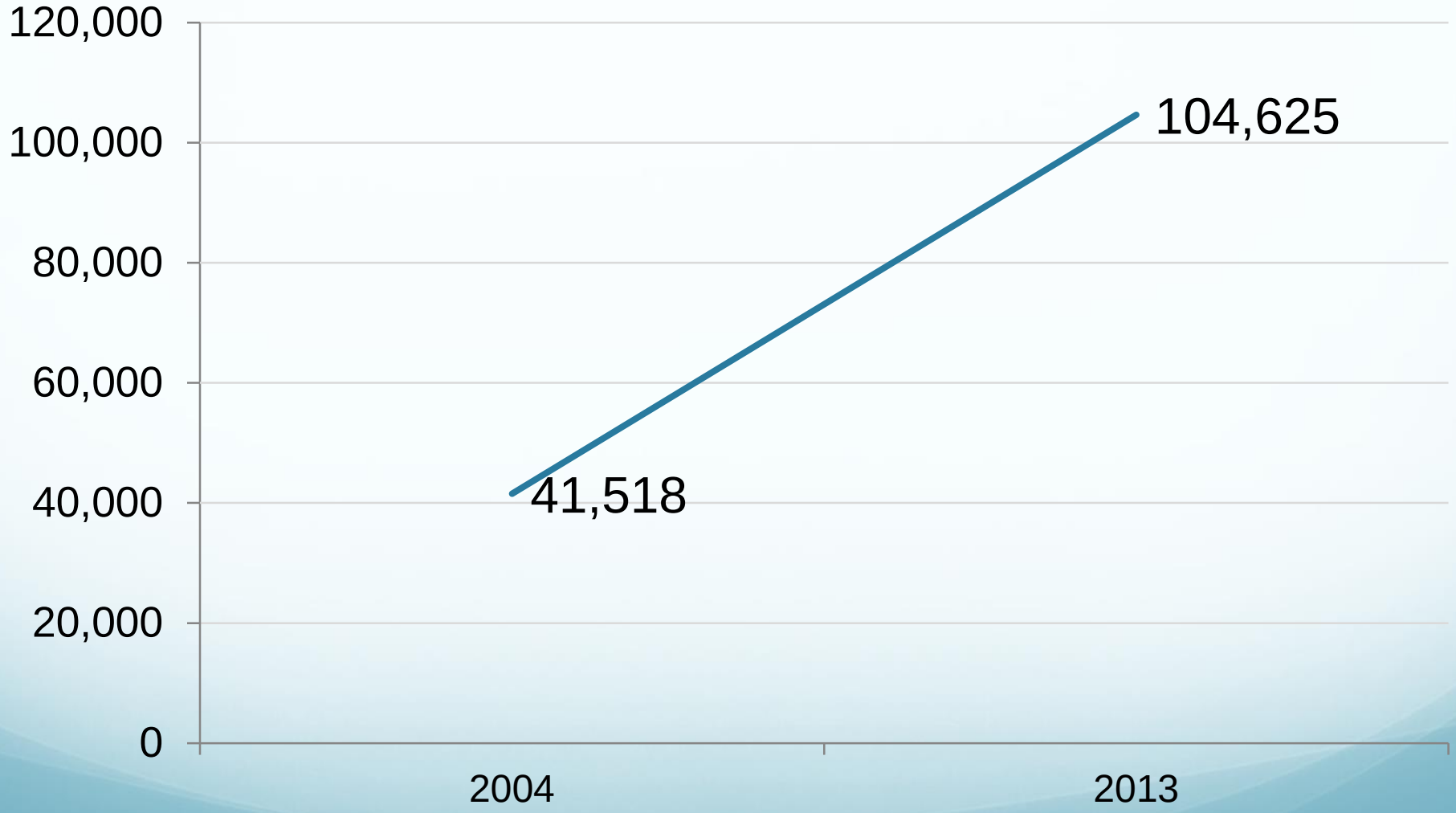
[2] Drug poisoning deaths was an additional measure and did not contribute to the overall county health rankings.

County Health Rankings & Roadmaps

A Healthier Nation, County by County

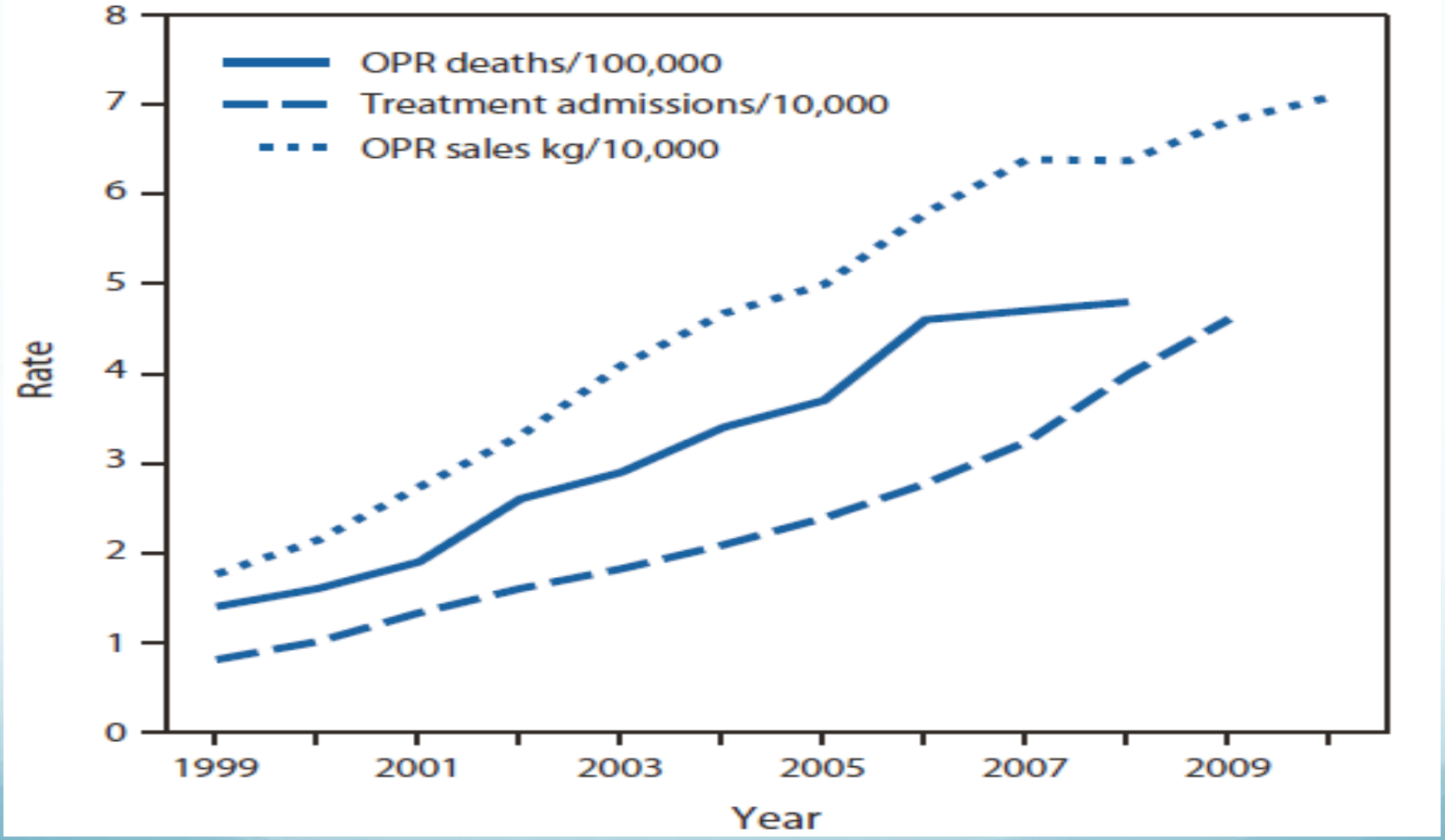
NUMBER OF SCHEDULE II NARCOTIC PRESCRIPTIONS :

MARIN COUNTY, 2004-2013



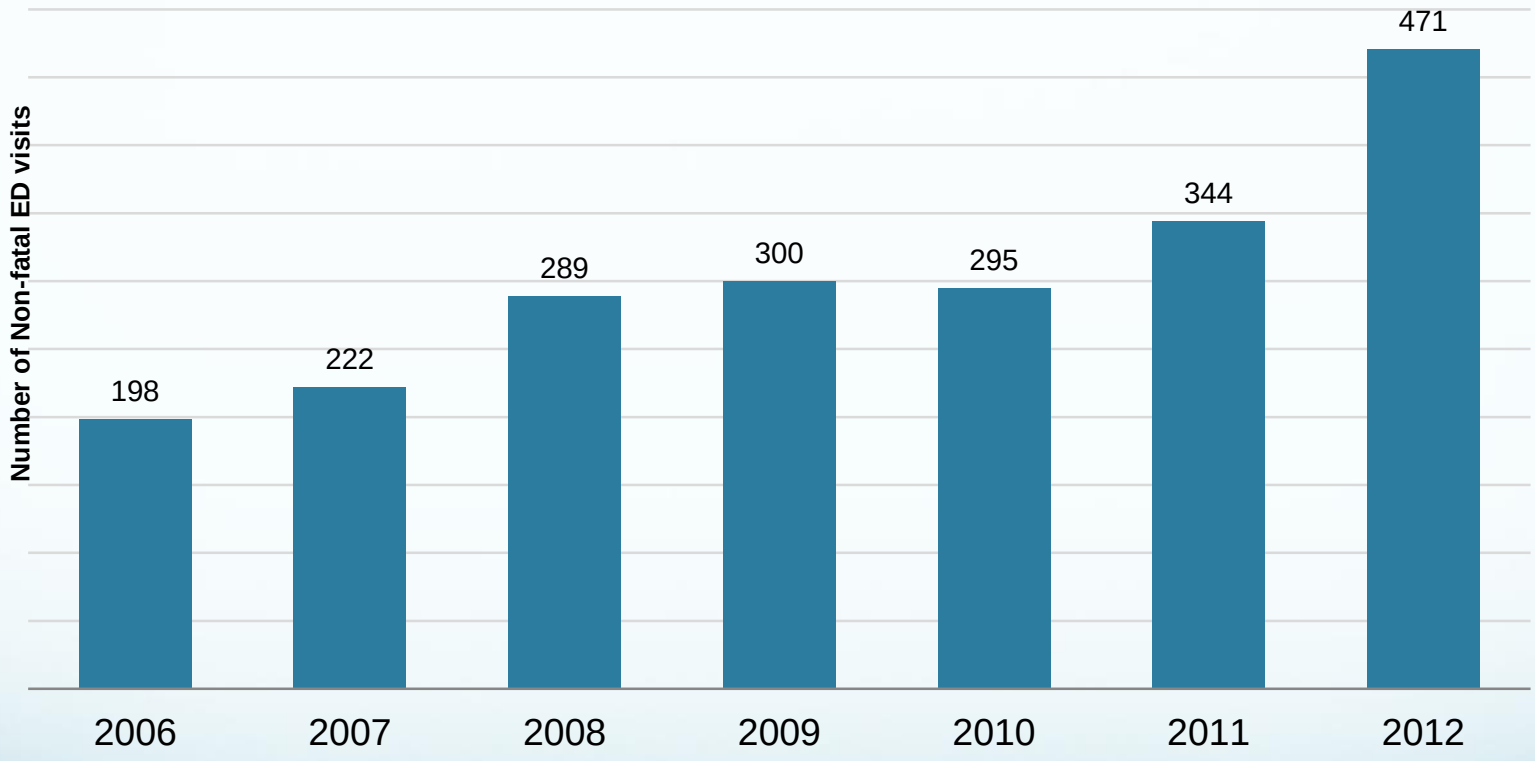
Source: California Department of Justice, Controlled Substance Utilization Review and Evaluation System (CURES)

KILOGRAMS OF OPIOIDS SOLD, OVERDOSE DEATHS AND ADDICTION, U.S. 1999-2010

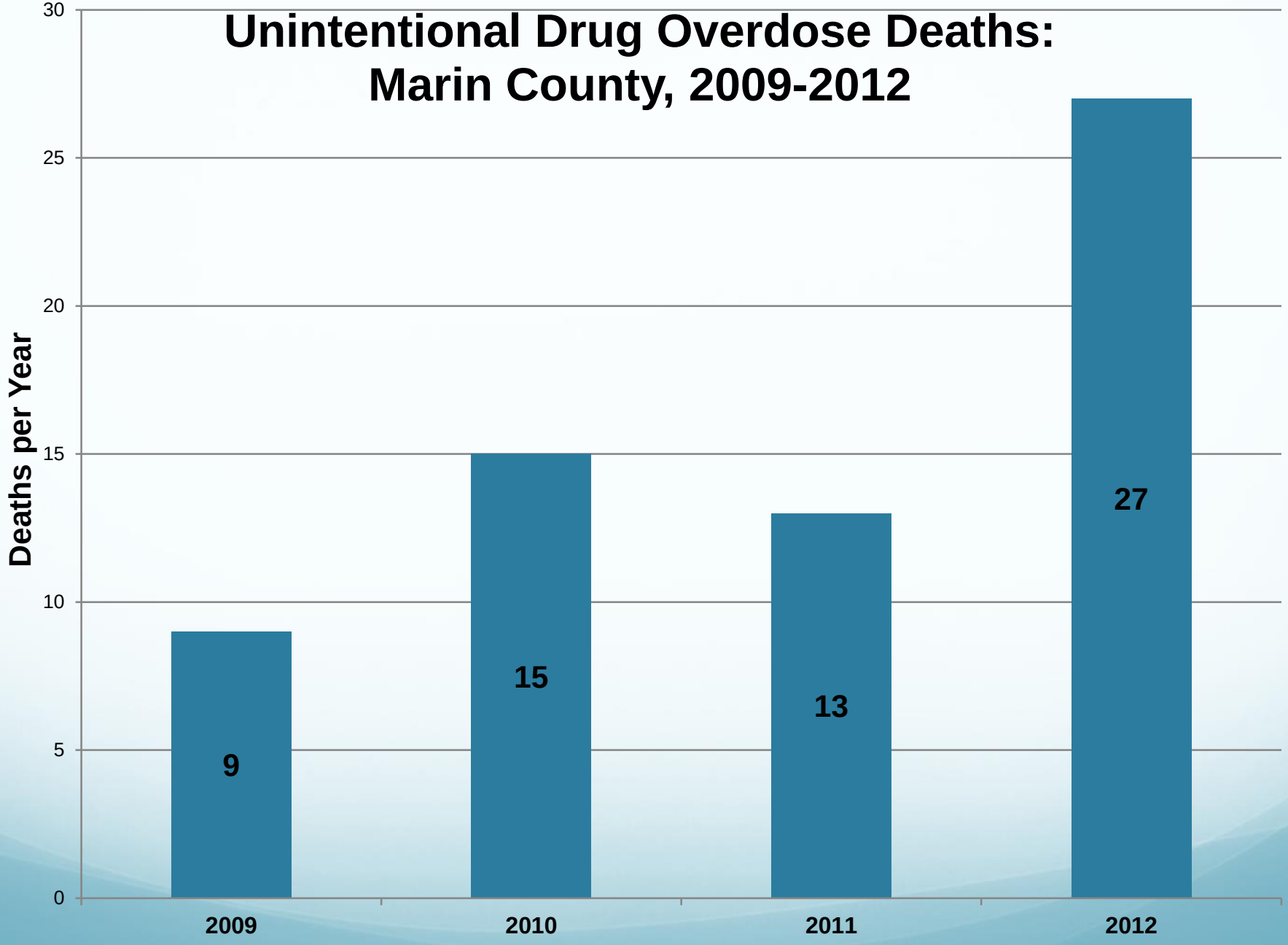


SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009
http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html

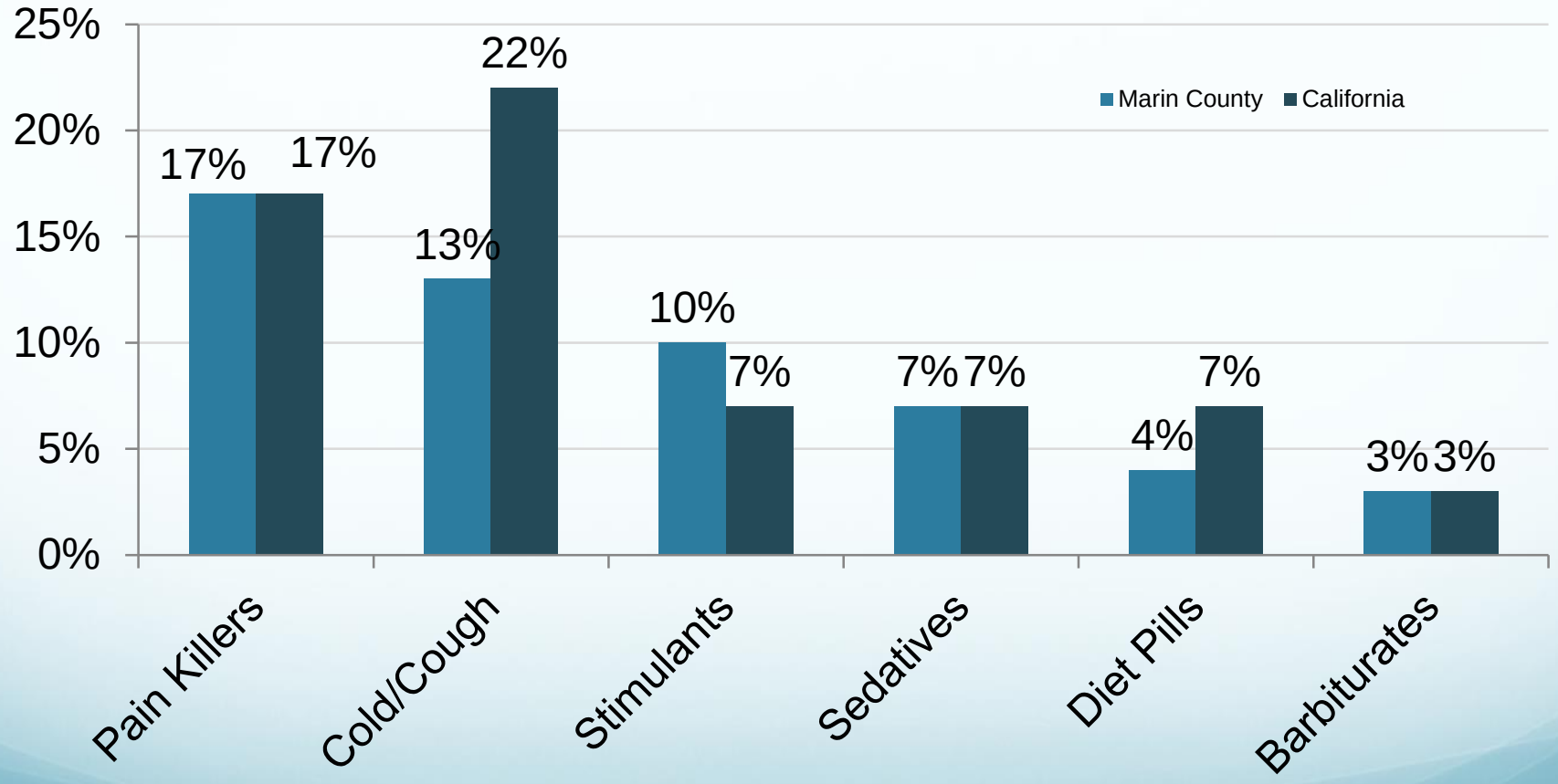
Non-Fatal Emergency Department Opioid-Related Visits: Marin County, 2006-2012



Data Source:
Office of Statewide Health Planning & Development (OSHPD). Emergency Department Data. Prepared by California Department of Public Health, Safe and Active Communities Branch


Unintentional Drug Overdose Deaths:
Marin County, 2009-2012
Deaths per Year
30
25
20
15
10
5
0
9
15
13
27
2009
2010
2011
2012

NON-MEDICAL USE of RX and OTC DRUGS AMONG 11TH GRADERS, MARIN COUNTY 2009-2011



Source: California Healthy Kids Survey, 2009-2011

Comprehensive Approach

Prevention

Education

Surveillance

Monitoring (PDMPs)

Diversion Control

Law Enforcement

Licensure

Treatment

Recovery

PRESCRIPTION
DRUG MISUSE &
ABUSE STRATEGIC PLANNING

HOSTED BY THE MARIN COUNTY HEALTH & HUMAN SERVICES PREVENTION HUB

FEBRUARY 5TH, 2014
7:15AM - 1:00PM

WELCOME

What can we do as a community to prevent and stop prescription drug misuse and abuse and save lives?

SHERATON FOUR POINTS
1010 NORTHGATE DRIVE
SAN RAFAEL 94903

The Life of a Pill: Opportunities for Influence

Manufacture

Marketing

Pharmacists

Prescribers

Community

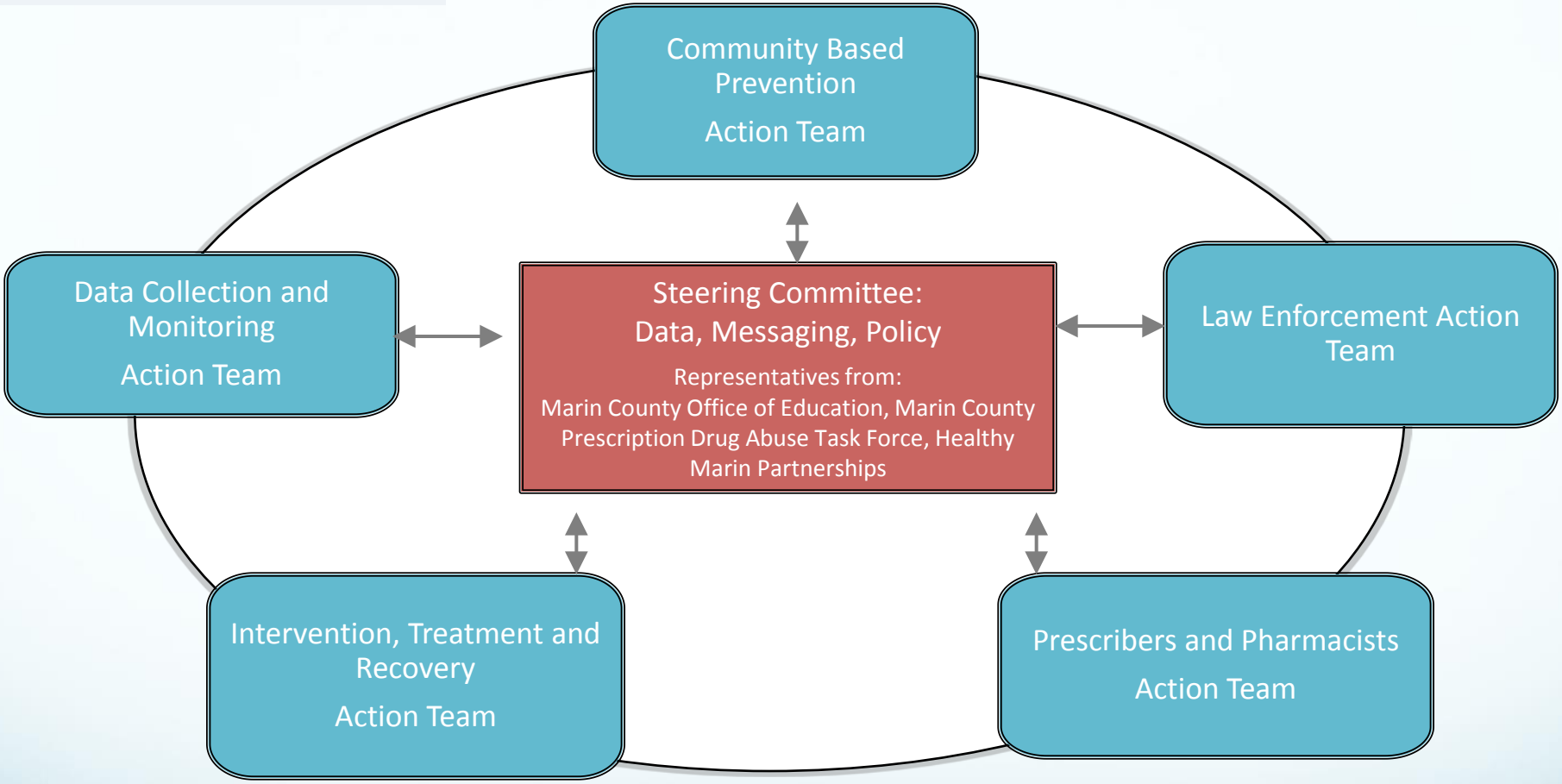
Safe Use

Disposal

Unsafe Use

Public Health Crisis: Over 31 deaths from drug overdoses in Marin Annually

Strategic Plan Implementation Structure



Backbone Support: HHS

Action Team Example: Prescribers and Pharmacists

Goal: 15% fewer narcotics will be prescribed in Marin County in 2015, compared to 2013

- 1:All Emergency Departments will have common prescribing standards by December 31, 2014
- 2: All Primary Care clinics will have common prescribing standards by June 30, 2014

SAFE PAIN MEDICINE PRESCRIBING IN EMERGENCY DEPARTMENTS

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SAFE Rx MARIN

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Action Team Example: Data Collection & Monitoring

Vision: Marin County will have county-wide relevant data on prescription drug misuse and abuse

- A1: Report card generated and disseminated by December 31, 2014
  - A1i: Identify 5-7 common data pieces for report card
  - A1ii: Complete report card and share with stakeholders

State Data Sources

Agency	Type
Office of Statewide Health Planning and Development (OSHPD)	• ED visits • Hospitalizations
California Department of Justice/ CURES	• Controlled substance Rx
Vital Statistics	• Drug poisonings
CalOMS Treatment	• Treatment admissions

Local Data Sources

Agency	Type
Office of the District Attorney (DA)	• Drug possessions
Environmental Health Services (EHS)/ Drug Enforcement Agency (DEA)	• Safely disposed Rx
Emergency Medical Services (EMS)	• Naloxone doses administered

Potential Indicator 2: Non-Fatal Opioid-Related Emergency Department Visits

Why this matters:

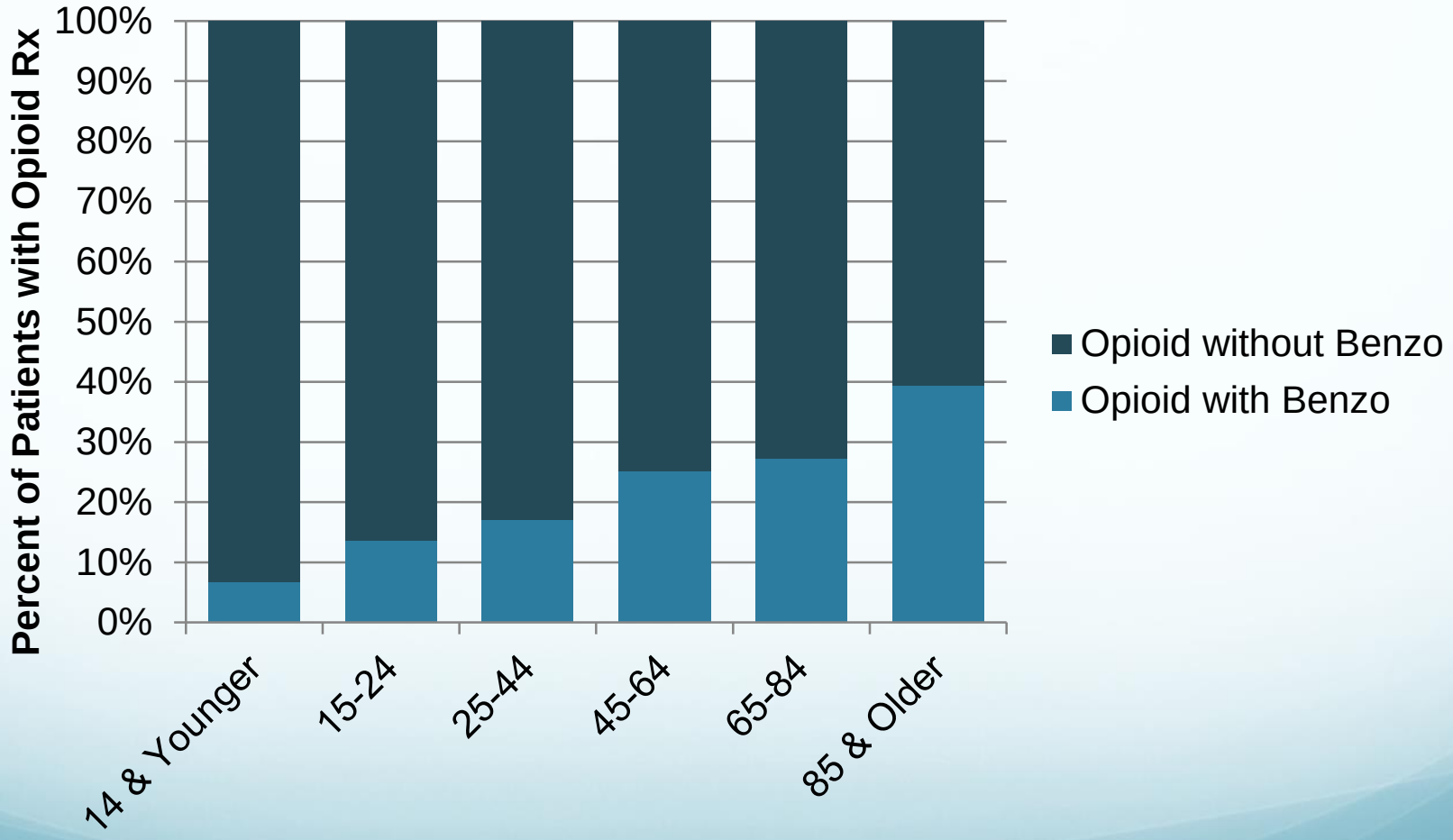
The Centers for Disease Control and Prevention (CDC) reports that in 2011, drug misuse and abuse caused about 2.5 million emergency department (ED) visits. Of these, more than 1.4 million ED visits were related to pharmaceuticals. In the United States, prescription opioid abuse costs were about $55.7 billion in 2007. Of this amount, 46% was attributable to workplace costs (e.g., lost productivity), 45% to healthcare costs (e.g., abuse treatment), and 9% to criminal justice costs.

Report Card Data:

Indicator	2006	2007	2008	2009	2010	2011	2012
Non-Fatal Opioid-Related Emergency Department Visits	198	222	289	300	295	344	471

Data Source:
Office of Statewide Health Planning & Development (OSHPD). Emergency Department Data. Prepared by California Department of Public Health, Safe and Active Communities Branch

Patients Receiving Both Opioid and Benzodiazepine Prescriptions Simultaneously — Marin County, 2010-2013



Potential Indicator 3: Total Number of Prescriptions for Controlled Substances

Why this matters:

The quantity of narcotic prescriptions in a population has been associated with abuse, diversion and overdoses in various populations. Prescriber practices, pharmaceutical companies and patient behavior (such as "doctor shopping") are all factors influencing the quantity of controlled substance prescriptions. This indicator allows us to track controlled substance prescriptions over time.

Report Card Data:

Indicator	2010	2011	2012	2013
Total Number of Prescriptions for Controlled Substances	**396,518**	**403,561**	**416,777**	**412,356**

Data Source*: Controlled Substance Utilization Review and Evaluation System (CURES), California Prescription Drug Monitoring Program (PDMP)*

RxSafe Marin Report Card: DRAFT

	Data Indicators	2009	2010	2011	2012	2013
1	**Unintentional drug poisoning deaths**	9	15	13	27	
2	**Non-fatal opioid-related emergency department visits**	300	295	344	471	
3	**Student self-report Rx painkiller use**	17%				
4	**Number of controlled substance prescriptions**		396,518	403,561	416,777	412,356
5	**Median number of pills per narcotic prescription**		50	45	50	56
6	**Number of Practitioners and Pharmacists Registered with CURES** •Practitioners •Pharmacists		54 4	95 9	121 11	149 42
7	**Pounds of safely disposed medications** •Via take back events •Via EHS collection sites	2,941	4,638	390 4,555	634 5,202	1,085 6,433
8	**Possession of controlled substance without a prescription**		8	9	13	28
9	**Narcan administrations by Emergency Medical Services (from March 1 through December 31)**					115
10	**Adult treatment admissions (fiscal year, 2009 represents July 2008 - June 2009, etc.)** •Total adult treatment admissions •% of clients reporting opiate use (including heroin) at time of admission		2,065 29.7%	1,628 28.5%	1,399 32.6%	1,600 32.5%

Key elements:

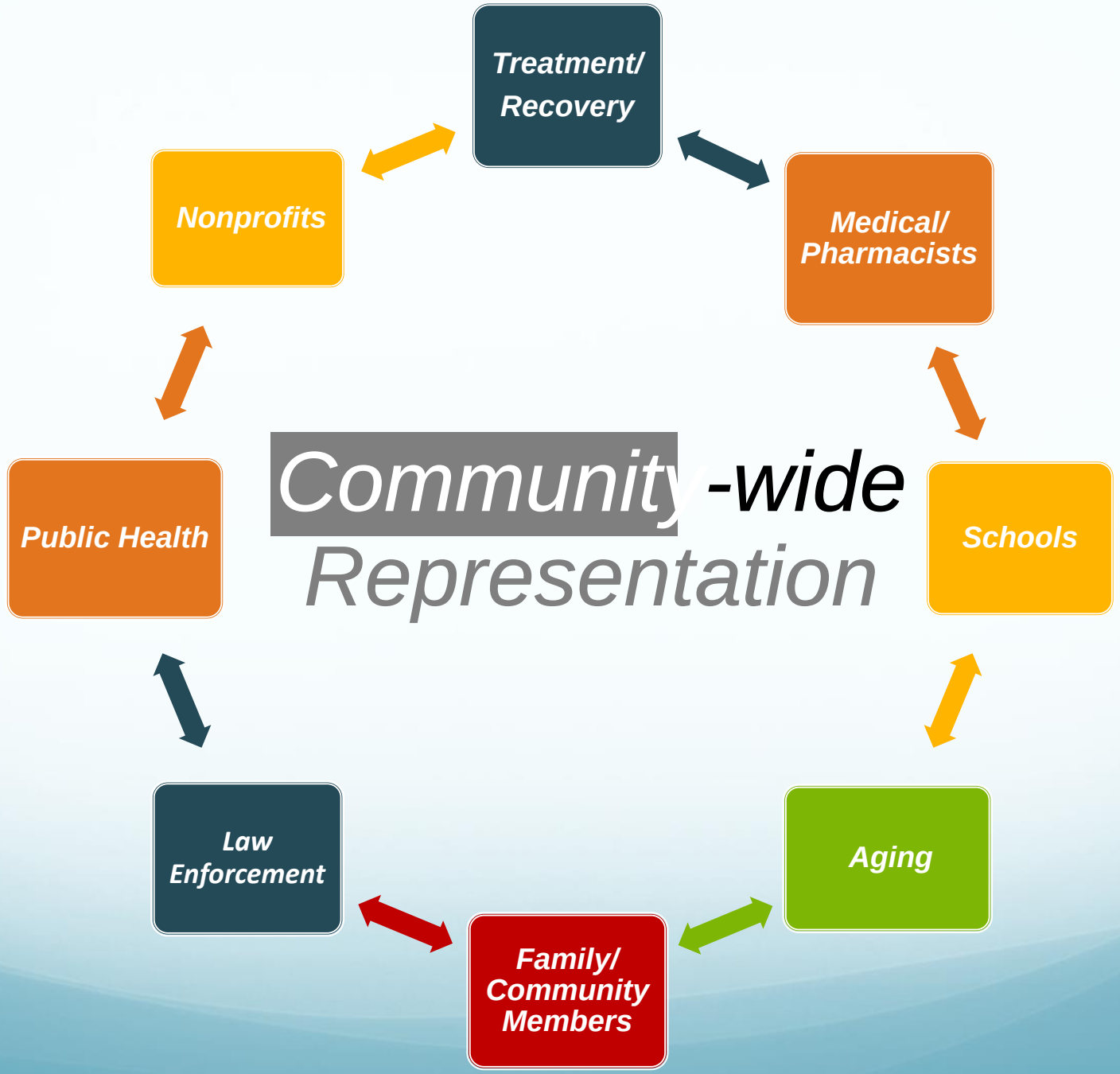
- Community as a “system” with many parts
- Data driven
- New conversations and partnerships
  - Law enforcement
- Centralized support
  - Coordinating and tracking Action Team efforts
  - Cheerleading
- Mutual accountability
  - Tracking progress with established metrics
  - Goals are transparent, measurable and public
- Acknowledge personal and professional dimension
- Political will and support

Thank you

EXTRA slides for reference from other presentation

How do we begin?

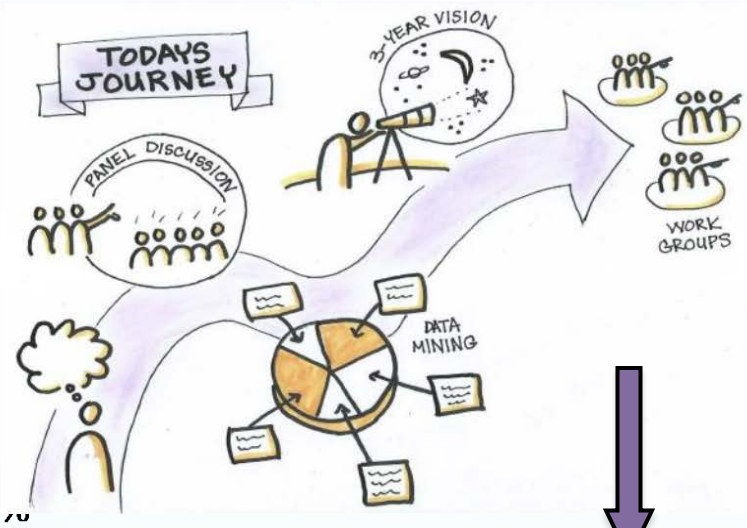
- Approach as a Public Health priority
- Recognize influences are throughout communities:
  - Law enforcement, Prescribers, Pharmacists, Schools, Families, Treatment/recovery, Waste management and others
- Address multiple factors simultaneously and in parallel
- Wide cross sector engagement

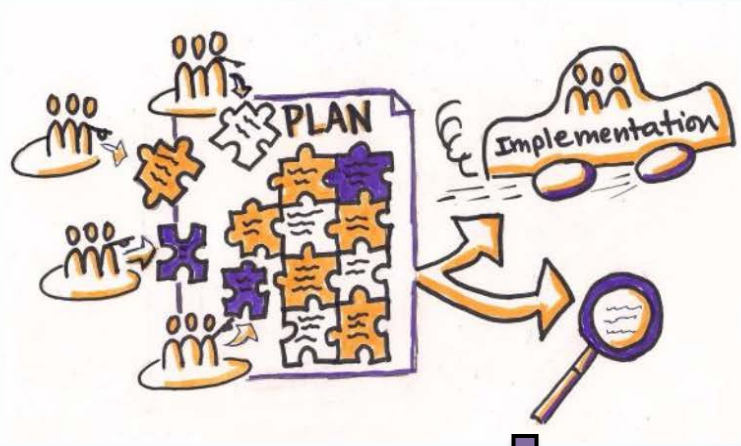

Treatment/ Recovery
Medical/ Pharmacists
Schools
Aging
Family/ Community Members
Law Enforcement
Public Health
Nonprofits
Community-wide Representation

Formation of RxSafe Marin

- Prior efforts:
  - Marin County Prescription Drug Abuse Task Force
  - Youth Leadership/Friday Night Live
- Marin County Health and Human Services
  - Mental Health and Substance Use
  - Public Health
- Marin County Office of Education
- HHS funded, facilitated initiative
- Design Team formed Fall 2013
  - Monthly meetings
  - Community Kick-off February 5, 2014

RxSafe Marin: Road Map





Feb 2014

Kick off:
1st Community Wide Meeting

- Reflected on data
- Created our 3 Year Vision
- Workgroups formed

March-May 2014

Workgroups

Part 1
- Identify driving and restraining forces
- Determine Strategic Goals

Part 2
- Asset mapping
- Identify Strategies

June 2014

2nd Community Meeting

- Preview the Strategic Framework
- Identify priorities
- Create 12 month action plans

Current

a.Action Teams
- Determine and carry out first year action plans

b.Steering Committee
- Monitor plan progress
- Media / messaging
- Policy efforts

c.HHS Backbone
- Coordinate logistical support to Implementation Teams and Steering Committee

Community Launch:
MARIN COUNTY PRESCRIPTION DRUG MISUSE AND ABUSE INITIATIVE

June 19, 2014 / 8:30am-12:30pm

Sponsoring Agencies: Marin Health and Human Services, Healthy Marin Partnership, Marin County Prescription Drug Abuse Task Force, County of Marin

Prepared by:

www.abinadergroup.com

Measurable Strategies and 12-Month Action Plans

In 3 years Marin County will reduce prescription drug misuse and abuse through..

County wide relevant data on Prescription drug misuse and abuse

- Report card generated and disseminated
- New prescribing data identified and collected

Fully funded continuum of services from intervention through treatment and recovery

- Full continuums of services are affordable, accessible, and individualized
- County Health Rankings on drug overdose deaths improve.

Increased coordination and alignment of prescription drug misuse and abuse prevention strategies across all sectors

- Sustainable, coordinated infrastructure supports Rx misuse/abuse prevention efforts
- Current Rx drug related policies implemented, monitored and enforced; new policies created

Cultural norm where prescription drug misuse and abuse is unacceptable

- Residents make informed, responsible Rx choices
- Rx prevention is a recommended standard of practice in all public schools
- Media outlets promote norms change

Intensive, measurable drug awareness learning and skill building across all stakeholder groups

- Community's perceptions align with Rx misuse/abuse realities

Prevention of drug diversion and availability

- Law Enforcement and Providers collaborate on drug diversion and availability
- Increased opportunities for safe, convenient disposal

Mandatory policy and procedures for physicians and pharmacists implemented and enforced

- Narcotic prescription decreased by 15%
- Pharmacists are aware of and have practices and protocols in place to minimize drug diversion

Agenda

Launch Aims:

- Celebrate and share the Strategic Framework
- Invite community input on prioritizing strategic goals and strategies
- Launch the implementation teams and move to action

Breakfast / Networking

Welcome: Moving from Plan to Action

Agenda Review

The Strategic Framework

Walkabout – Preview Strategic Framework

Prioritization and Action Planning: Action Teams

Walkabout - Preview Action Plans

Action Team Accomplishments and Next Steps

Closing Remarks

TEN RULES OF ORDER FOR CENTURY XXI

- Everyone has wisdom to share.
- We need everyone's wisdom for the best result.
- The whole picture comes through hearing and understanding all the perspectives
- There are no wrong answers
- The wisdom of the whole is greater than the sum of its parts
- The more people we engage through participation, the wiser we can all become.
- Participation blows out our images of what is possible.
- People commit to what they create. So the people who implement a plan are the best ones to create the plan.
- Participation in planning creates a sense of self-worth, enthusiasm, respect and accomplishment.

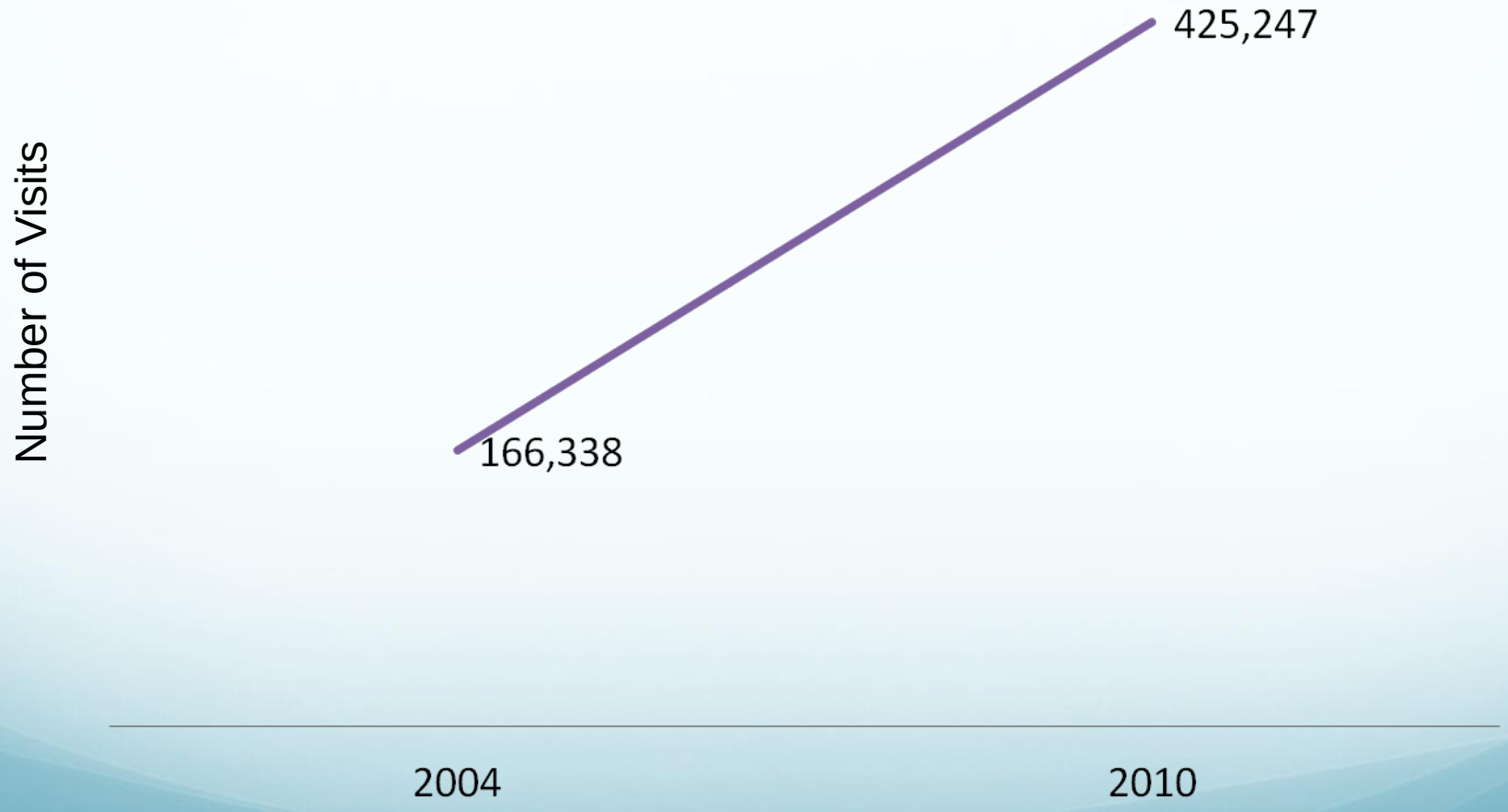
Jo Nelson and Brian Stanfield

ED Prescribing Standards Process

- ED Directors meeting May, 2014
  - Local Data and Evidence presented, discussed
  - Draft guidelines proposed
- Email and phone based co-editing of guidelines
- Adopted and disseminated July 2014
- Public Health Advisory July 10, 2014

Do you know the ER prescribing standards in your county?

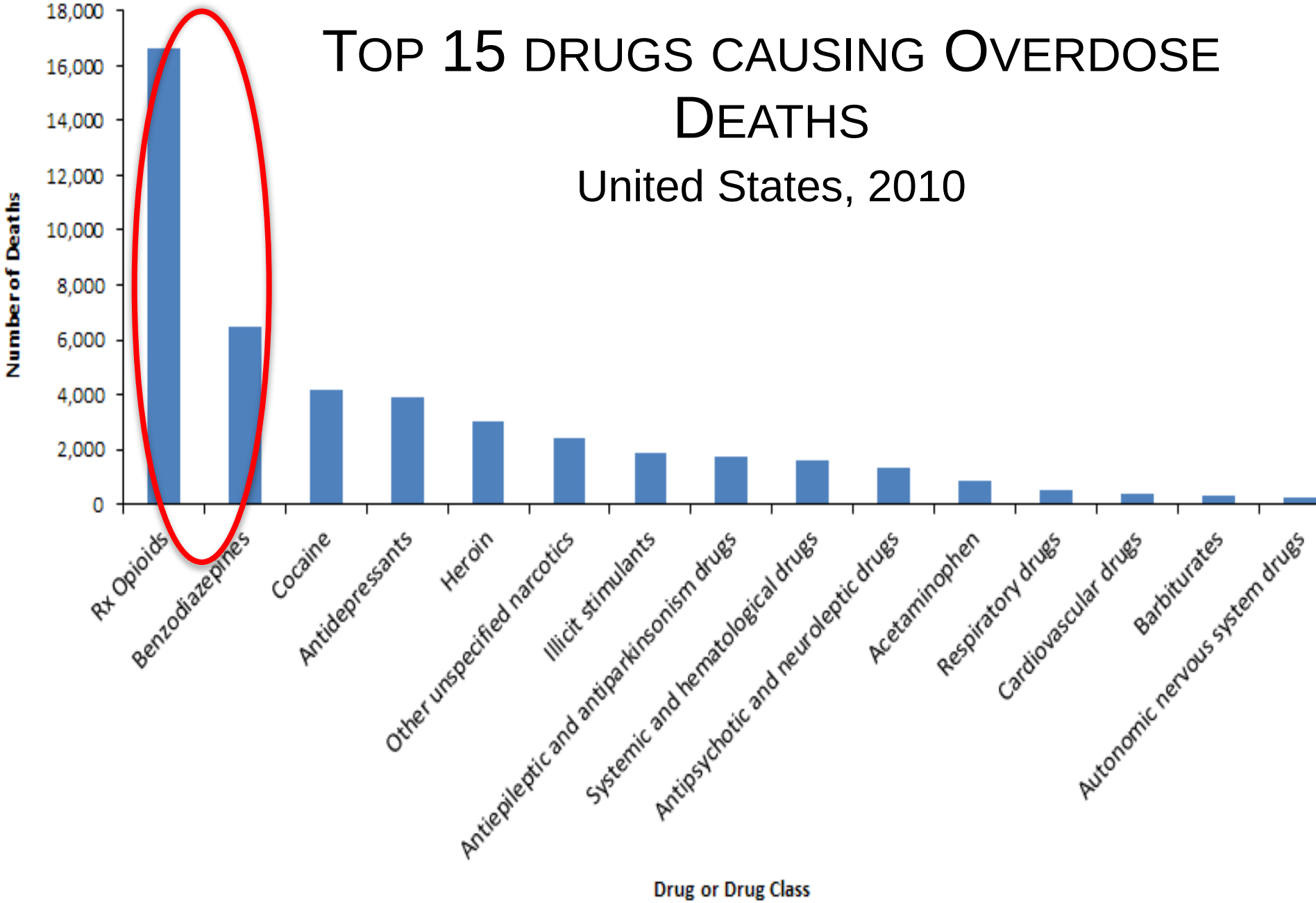
TREND IN ED VISITS FOR NONMEDICAL USE OF NARCOTIC PAIN RELIEVERS, U.S. 2004-2010



Source: SAMHSA Drug Abuse Warning Network (DAWN), 2010

Top 15 drugs causing Overdose Deaths

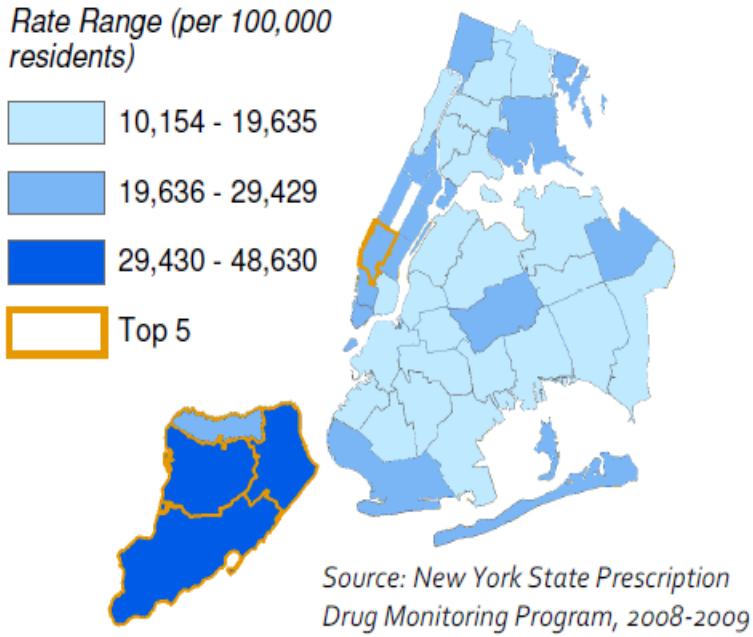
United States, 2010



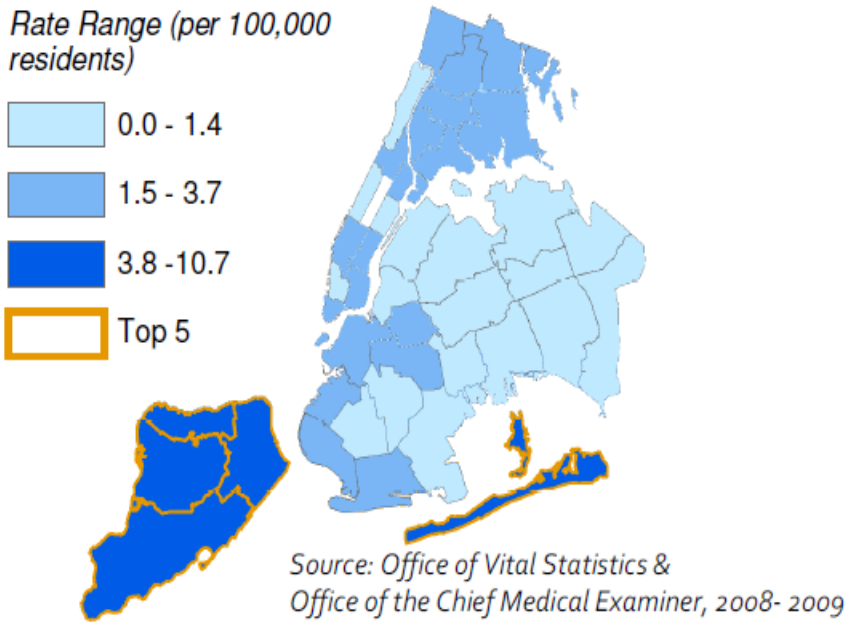
Jones et al Pharmaceutical overdose deaths, United States, 2010. JAMA 2013 and CDC/NCHS NVSS MCOD 2010.

Neighborhoods with Highest Rates of Opioid Prescriptions Also Have the Highest Rates of Overdose Deaths, 2008-2009

Rates of hydrocodone and/or oxycodone prescriptions filled by NYC neighborhood[5]



Rates of unintentional opioid analgesic poisoning (overdose) deaths by NYC neighborhood[4]

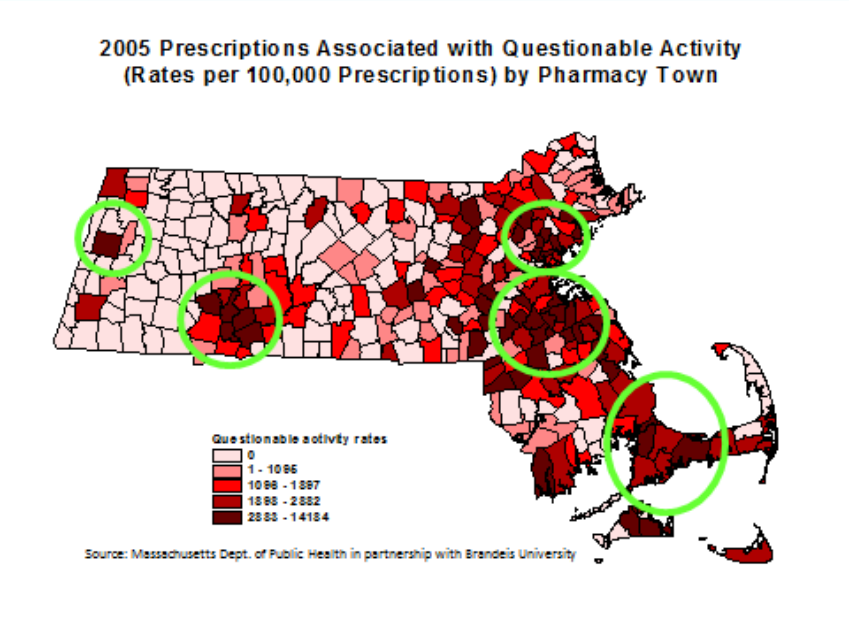


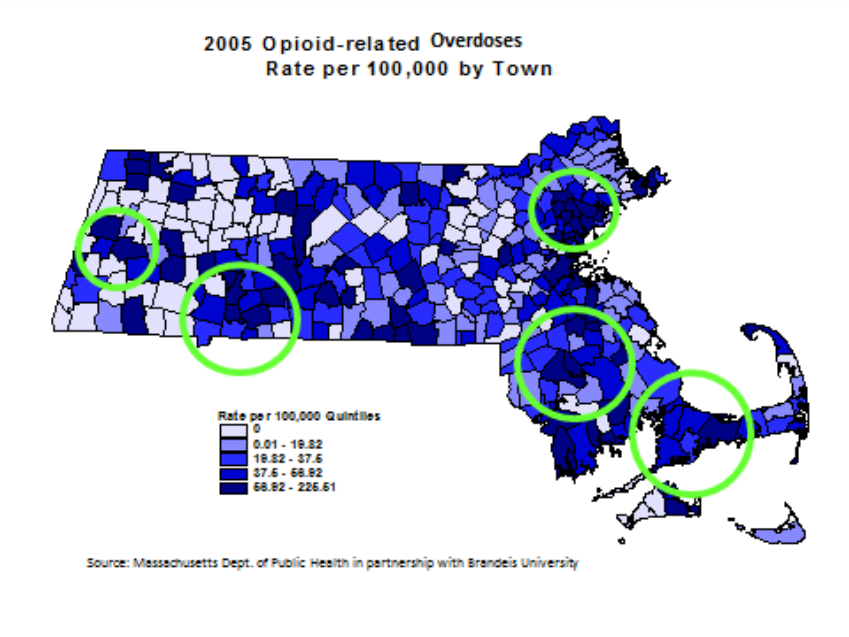
Definitions: The United Hospital Fund (UHF) classifies NYC into 42 neighborhoods, comprised of contiguous zip codes. Income is defined by the percent of households below 200% of the federal poverty level (Census 2000) and separated into three groups: low-income (43%-70%), medium-income (30%-43%) and high-income (13%-30%). To ensure rate stability, two years of prescription and death data were combined for neighborhood analyses.

Source: http://www.nyc.gov/html/doh/downloads/pdf/epi/epi-data-brief.pdf

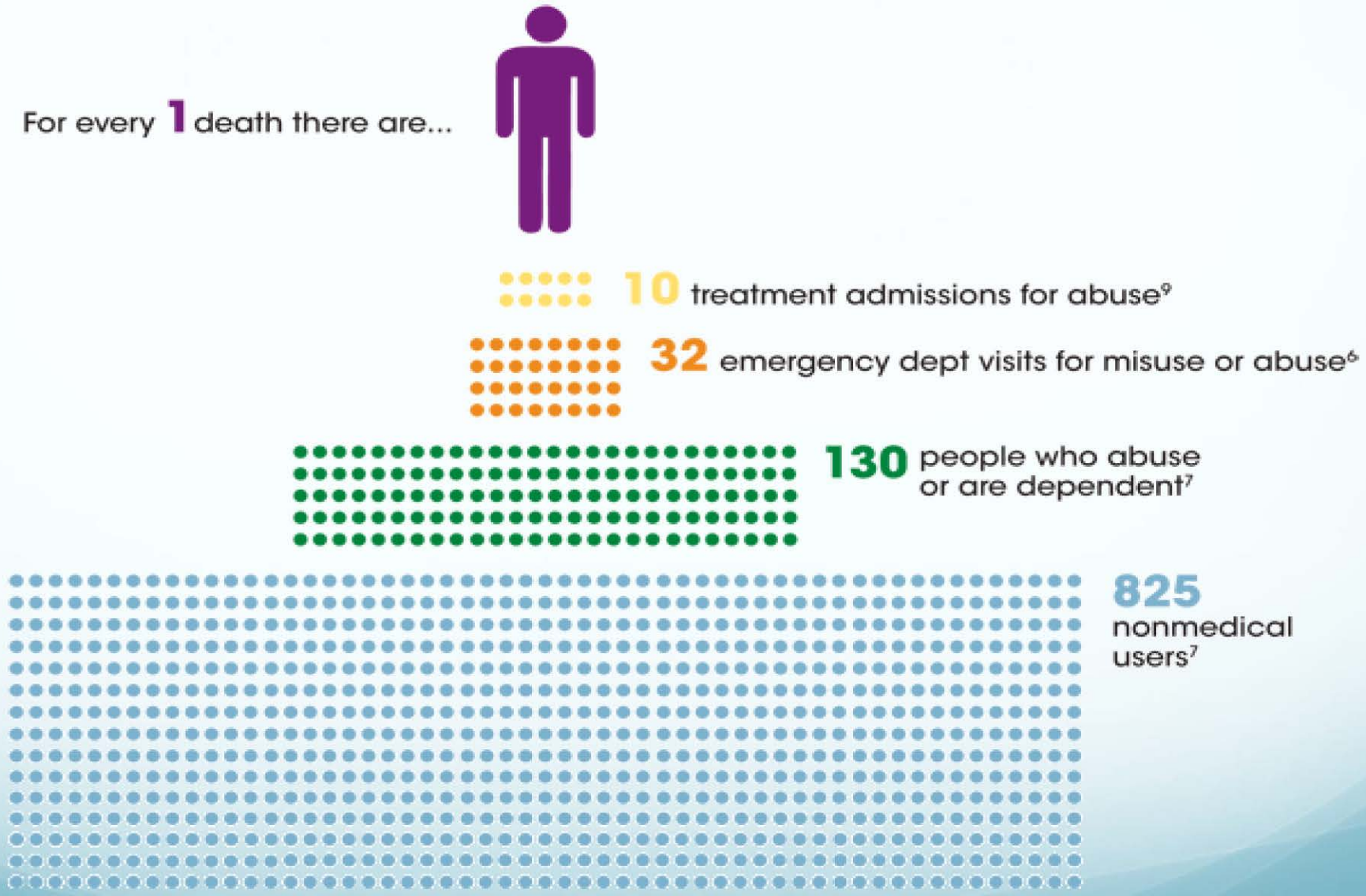
“Shopping” as a portion of all prescriptions

Overdoses in ED Data



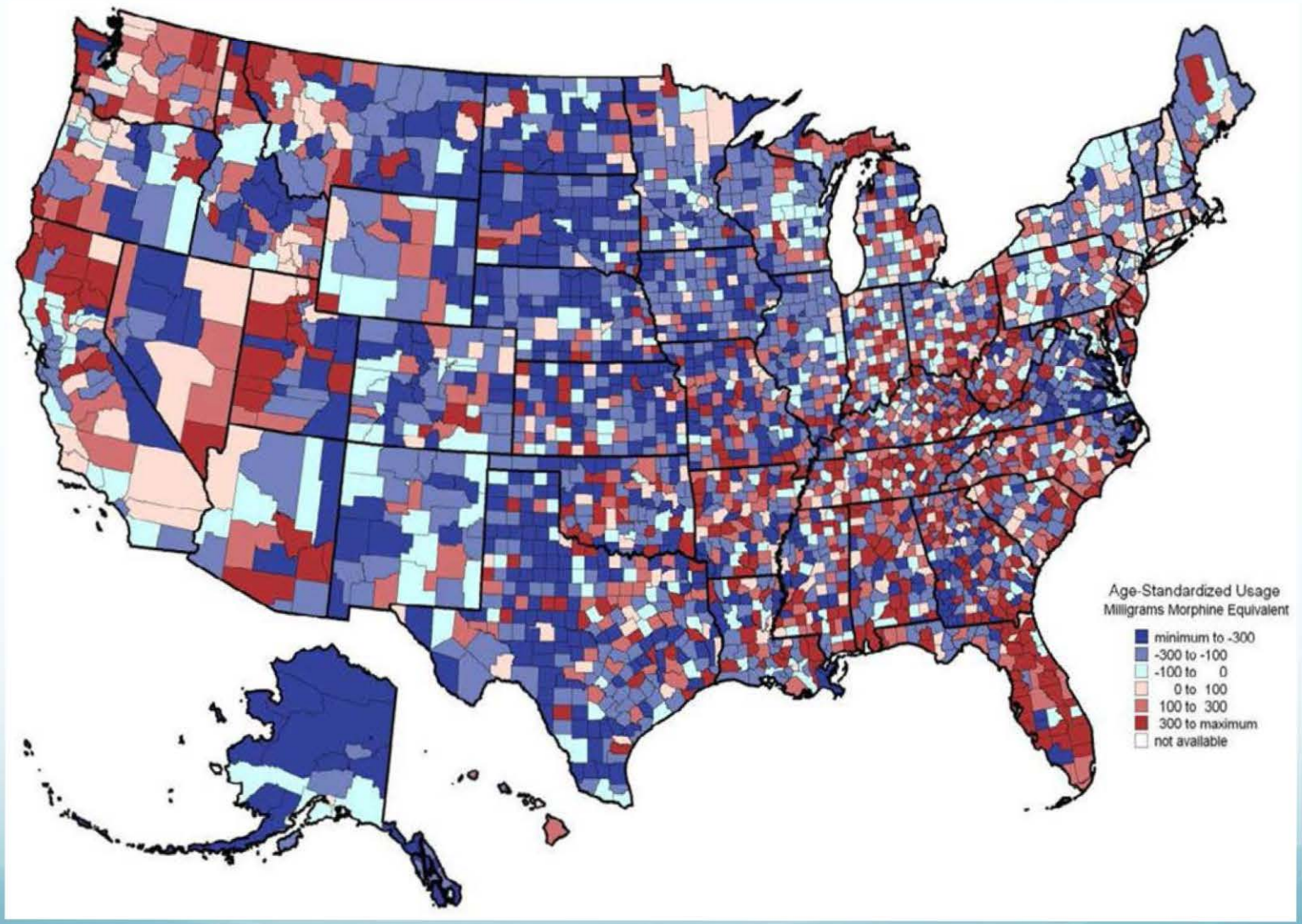


Slide provided courtesy of Peter Kreiner, PMP Center of Excellence at Brandeis. Doctor shopping, the questionable activity, was defined as 4+ prescriber s and 4+ pharmacies for CSII in six months.



Source: CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008. CDC Policy Impact: Prescription Painkiller Overdoses. Available at: www.cdc.gov/homeandrecreationalsafety/rxbrief/

Regional Variation in Prescribing Norms



Attachment 3

OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA
Orry P. Korb (SBN 114399)
Danny Y. Chou (SBN 180240)
Greta S. Hansen (SBN 251471)
Kavita Narayan (SBN 264191)
Marlene Dehlinger (SBN 292282)
70 West Hedding Street
East Wing, 9th Floor
San Jose, CA 95110
Telephone: (408) 299-5900
Facsimile: (408) 292-7240

ORANGE COUNTY DISTRICT ATTORNEY
Tony Rackauckas, District Attorney
Joseph D'Agostino, Senior Assistant District Attorney
Consumer and Environmental Protection Unit
Tracey Hughes (SBN 180494)
Deputy District Attorney
401 Civil Center Drive
Santa Ana, CA 92701-4575
Telephone: (714) 834-3600
Facsimile: (714) 648-3636

[Additional Counsel Listed on Signature Page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ORANGE

THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas, Plaintiff, v. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS, PLC;	No. 30-2014-00725287-CU-BT-CXC FIRST AMENDED COMPLAINT FOR VIOLATIONS OF CALIFORNIA FALSE ADVERTISING LAW, CALIFORNIA UNFAIR COMPETITION LAW, AND PUBLIC NUISANCE, SEEKING RESTITUTION, CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF [FILED CONDITIONALLY UNDER SEAL PER CRC 2.551(d) SUBJECT TO A MOTION TO FILE UNDER SEAL]

ELECTRONICALLY FILED
Superior Court of California
County of Orange
06/09/2014 at 04:19:00 PM
Clerk of the Superior Court
By Irma Cook,Deputy Clerk

ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; AND DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

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I. INTRODUCTION

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. Defendants broke these simple rules.

2. By the 1990s, Defendants had the ability to cheaply produce massive quantities of opium-like painkillers ("opioids"), but the market was small. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. They knew – and had known for years – that opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer),[1] particularly because their effectiveness waned with prolonged use and because of the substantial risk of significant side effects and addiction, especially with high-dose use.[2] They also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

3. Even the doctors who published articles suggesting that opioids might be useful for chronic pain treatment recognized the substantial concerns about long-term opioid use and counseled for "[a]stute ongoing assessment of functional outcomes if opioids are administered."[3]

4. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, are narcotics. They are derived from or possess properties similar to opium and heroin – which is why they are regulated as controlled substances. Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

---

[1] Chronic pain, as used in this Complaint, refers to chronic non-cancer pain.

[2] R.K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, Progress in Pain Research and Management, Vol. 1, ed. H.L. Fields & John C. Liebeskind, IASP Press, Seattle, 1994.

[3] *Id.*

5. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea-change in medical and public perception that would permit the use of opioids for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches. Opioid makers Purdue, Janssen, Endo, Cephalon, and Actavis, through a common, sophisticated, and deeply deceptive marketing campaign that continues to the present, set out to, and did, reverse the popular and medical understanding of opioids.

6. Beginning over 20 years ago, Defendants seized on anecdotal accounts of opioid use to treat chronic pain to begin a reeducation campaign about opioids. They spent millions of dollars funding, assisting, and encouraging doctors and front groups that would pioneer a new and far broader market for their potent and highly addictive drugs – the chronic pain market. Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs and unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. They overstated the benefits of using opioids long-term to treat chronic non-cancer pain, promising improvement in patients' function and quality of life, and dismissed or minimized the serious risks and adverse outcomes of chronic opioid use, including the risk of addiction, overdose, and death. There was and is no reliable scientific evidence supporting Defendants' marketing claims at issue, and there is a wealth of scientific evidence to the contrary. They also deceptively marketed the drugs for indications and benefits that were prohibited by the drugs' labels.

7. Defendants' efforts were wildly successful; the United States is now awash in opioids. In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits result in the prescription of an opioid (nearly double the rate in 2000).[4] Opioids – once a niche drug – are now the most prescribed class of drugs – more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they have

[4] Daubresse M, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, Medical Care, 2013; 51(10):870-878.

consumed 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[5] Together, opioids generated $8 billion in revenue for drug companies in 2010.

8. Roughly 87% of these prescriptions are for chronic opioid therapy – a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates.

9. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic." Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010 – more than twice as many deaths as heroin and cocaine combined and surpassing motor vehicle accidents as a cause of death. In Orange County alone there is an opioid-related death every other day.[6] For every death, more than 30 individuals are treated in the emergency room. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

10. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors or from the secondary criminal market, and a pipeline of drugs that can be diverted to supply them. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[7] According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in the past year, and adolescents are abusing opioids in alarming numbers.

11. In addition, opioid abuse has triggered a resurgence in the use of heroin, which has imposed additional burdens on the public and the state and local agencies that serve them. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid

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[5] Manchikanti, *et al*., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective, Pain Physician*, 2010; 13:401-435.

[6] David Whiting, *Whiting: FDA Finally Starts to Tackle Opioid Epidemic*, ORANGE COUNTY REGISTER, Oct. 26, 2013, *available at* www.ocregister.com/articles/fda-533176-drug-country.html.

[7] Katz M, *Opioids After Thousands of Years, Still Getting to Know You*, Clin J Pain 2007; 23:303-306.

pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person started on prescription opioids for a back injury, to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

12. Dr. Robert Dupont, former director of the National Institute on Drug Abuse and the former White House drug czar, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. … [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.

13. To shift medical convention and unleash this epidemic, Defendants engaged in a campaign of deception that: (1) misrepresented the efficacy of opioids, (2) trivialized or obscured their serious risks and adverse outcomes, and (3) overstated their superiority, compared with other treatments. Defendants supported, encouraged, and directed employees, front groups, and doctors they identified as "Key Opinion Leaders" ("KOLs") to publicize biased and misleading studies and promotional materials and conduct thousands of medical education programs that were deceptive and lacked balance. These "educational" efforts were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic non-cancer pain outweighed their risks and that opioids could be used safely by most patients.

14. Defendants' representations regarding the benefits, risks, and relative superiority of opioids were – and are – untrue and unsupported by competent scientific evidence. In fact, even Defendants' KOLs initially were very cautious about whether opioids were safe and effective to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers and physicians who have sounded the alarm on the long-

term use of opioids to treat chronic non-cancer pain, Defendants continue to disseminate their false and misleading marketing claims even today.

15. Defendants' marketing not only ignored contrary evidence, but also failed to acknowledge risks disclosed on their own labels and sometimes exceeded the approved indications. Defendant Cephalon, for example, marketed its opioid, Fentora, for chronic non-cancer pain even though it was approved *only* to treat cancer pain. Defendants also promised that opioids would improve patients' ability to function, even though such benefits had not been proven and were specifically disputed by the FDA.

16. Many of Defendants' strategies are modeled on the standard promotional activities for prescription drugs that have been deemed unlawful, and for which the drug companies have paid billions of dollars in settlements and judgments. What makes this effort particularly nefarious – and dangerous – is that unlike most other prescription drugs, opioids are highly addictive controlled substances. Defendants deceptively engaged a patient base that – physically and psychologically – could not turn away from their drugs; many of whom were not helped by the drugs or were profoundly damaged by them.

17. There are millions of Californians who suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived California patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payers of the chance to exercise informed judgment, and subjected them to enormous suffering and costs.

18. Defendants' course of conduct, individually and collectively, has violated and continues to violate one or more of the following laws of the State of California:

- California False Advertising Law, BUS. & PROF. CODE § 17500, in that Defendants made and disseminated untrue, false, or misleading statements about the use of opioids to treat chronic non-cancer pain, or caused untrue, false, or

misleading statements about opioids to be made or disseminated to the public;

- California Unfair Competition Law, BUS. & PROF. CODE § 17200, in that Defendants engaged in unlawful, unfair, and fraudulent business acts and practices and deceptive, untrue, and misleading advertising in their promotion of opioids to treat chronic non-cancer pain; and

- California Public Nuisance Law, CAL. CIV. CODE §§ 3479, 3480, in that Defendants, through their untrue, misleading, false, fraudulent, and deceptive promotion of opioids, have created or assisted in the creation of a condition that is injurious to health and substantially interferes with the comfortable enjoyment of life and property of the people of Santa Clara and Orange County and the State of California.

19. To redress and punish these violations of law the People of the State of California, by and through Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas, seek a judgment requiring Defendants to pay restitution, civil penalties, and attorneys' fees, costs, and expenses. The People also request that the Court issue an order requiring Defendants to cease their unlawful promotion of opioids, to correct their misrepresentations, and to abate the public nuisance they have created, in addition to granting any other equitable relief authorized by law.

II. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over the People's claims for restitution, including disgorgement of profits, civil penalties, trebling of relief, injunctive relief, and other equitable relief under the California Unfair Competition Law (BUS. & PROF. CODE § 17200, *et seq.*), California False Advertising Law (BUS. & PROF. CODE § 17500, *et seq.*), and California Civil Code section 3345; and over the People's claim for abatement under the California Public Nuisance law (CAL. CIV. CODE §§ 3479, 3480).

21. This Court has personal jurisdiction over Defendants under California Code of Civil Procedure § 410.10. Defendants have submitted to jurisdiction by conducting and transacting business in Santa Clara and Orange Counties on a regular and continuous basis, by marketing and selling opioids to doctors, pharmacies, payers, and patients in Santa Clara and Orange Counties,

and by committing acts within Santa Clara and Orange Counties against their citizens and residents that are in violation of the laws of California and the United States.

22. Venue as to each Defendant is proper in this judicial district, pursuant to California Code of Civil Procedure §§ 395 and 395.5.

III. PARTIES

A. Plaintiff

23. Plaintiff is the People of the State of California, acting by and through Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas ("the People").

24. The People bring this action for violations of the Unfair Competition Law pursuant to California Business and Professions Code Sections 17200, 17204, and 17206, and for violations of the False Advertising Law pursuant to California Business and Professions Code Sections 17500, 17535, and 17536.

25. The People bring this action to abate a public nuisance pursuant to California Code of Civil Procedure Section 731.

B. Defendants

26. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware, Defendant Purdue Pharma, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut, and Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with is principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids, including OxyContin, its largest selling opioid, in both California and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

27. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – at the time, one of the largest

settlements with a drug company for marketing misconduct. Pursuant to its misbranding settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing is fair and accurate and to monitor and report on its compliance with the Agreement.

28. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Pharmaceutical Industries, Ltd. acquired Cepahlon, Inc. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc., collectively are referred to herein as "Cephalon"). Cephalon is in the business of manufacturing, selling and distributing pharmaceutical drugs, including opioids Actiq and Fentora, nationally and in California.

29. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful marketing to cancer patients experiencing pain "with malignancies who had developed a tolerance to less dangerous therapies." The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug "must not be used in opioid non-tolerant patients" and must be prescribed solely to cancer patients by oncologists and pain specialists specifically trained in the use of Schedule II opioids to treat pain in cancer patients. In 2008, Cephalon plead guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

30. Cephalon also entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of sales representatives; to post payments to

doctors on its web site; and to regularly certify that the company has an effective compliance program.

31. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn, was formerly known as Defendant Janssen Pharmaceutica Inc. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., and Johnson & Johnson, collectively are referred to herein as "Janssen.") Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in California and nationally, including the opioids Duragesic, Nucynta, Ultracet, and Ultram. Duragesic is the largest selling opioid of the group, with revenue of $1 billion in 2008, which dropped to $589 million in 2011. Sales of Janssen's opioids collectively commanded between $1.3 billion in revenue in 2009 and $1.2 billion in 2012 – a total of $4.7 billion dollars over the four-year period.

32. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc., collectively are referred to herein as "Endo.") Endo develops, markets, and sells prescription drugs, including opioids Opana, Percocet, and Percodan, in California and throughout the U.S. These opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion between 2008 and 2012, and alone accounted for 10% of Endo's total 2012 revenue.

33. Defendant Actavis plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc was established for the purpose of facilitating the business combination between Actavis, Inc. and Warner Chilcott plc. Defendant

Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012 and the combined company name was changed to Actavis, Inc. as of January 2013, and then Actavis plc in October 2013. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is wholly owned by Actavis, Inc. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., now known as Actavis, Inc. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Throughout the First Amended Complaint (the "Complaint"), "Actavis," collectively refers to Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. During the relevant time period, Actavis engaged in the business of marketing and selling opioids in California and across the country, including the branded drug Kadian and generic versions of Duragesic and Opana.

34. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to CCP § 474. Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

35. At times relevant herein, each of the defendants acted in concert with or conspired with one or more of the remaining defendants in committing the violations of law alleged herein. Each of the defendants was the agent, employee or principal of each of the remaining defendants and was acting within the course and scope of his or her agency and/or employment.

IV. FACTUAL ALLEGATIONS

A. Before Defendants' Deceptive Marketing Campaign, Opioids Were Rarely Prescribed by Physicians Because of Their Known Serious Side Effects and Substantial Risk of Addiction

36. Opioids have long been approved and accepted for the treatment of chronic cancer pain. Opioids are appropriate for this use given the severity of pain often associated with cancer and the recognition that the benefits of treating that pain outweigh the potential risk of addiction, especially for terminal patients. The same is not true for chronic non-cancer pain. Among other differences, the pathology responsible for cancer pain is distinct from the pathology that causes chronic pain. For patients with cancer, the source of their pain is likely to be the tumor and pressure on, or erosion of nerves or bones, which can be extremely painful, while chronic pain arises from multiple sources – including musculoskeletal (from joints, ligaments, or muscles), neuropathic (or nerve-related, occurring in diseases like diabetes or shingles), headache, or functional pain (arising from disease states such as irritable bowel) – that respond differently (or not at all) to opioids.

37. However, over the past twenty years, fueled by aggressive marketing from the pharmaceutical industry, opioid use for the management of chronic non-cancer pain has become commonplace. As set forth below, use of opioids for long-term non-cancer pain management is based on "unsound science and blatant misinformation … and dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[8]

38. As admitted in 1994 by Dr. Russell Portenoy, a KOL who went on to tirelessly promote opioid therapy for the treatment of chronic non-cancer pain (also called chronic nonmalignant pain), the medical consensus before Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> ***The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs***. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid

[8] *Available at* http://www.ncbi.nlm.nih.gov/pubmed/22786464?report.

> drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects.*** There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.[9]

39. Dr. Portenoy left no doubt about the 1994 state of knowledge concerning the safety and efficacy of opioid therapy for long-term chronic non-cancer pain:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain…[10]

40. But the lack of any credible science supporting opioid therapy for chronic non-cancer pain did not stop Defendants from marketing opioid therapy for that use. Working with and through KOLs like Dr. Portenoy, Defendants seized on anecdotal accounts of opioid efficacy in limited populations and methodically, through numerous publications, programs, and spokespeople, overstated the benefits and understated the risks of opioids in order to create and defend a broad market for opioids that never should have and never would have come to exist absent Defendants' concerted, deliberate, and patently misleading efforts.

B. Defendants' Marketing of Opioids for Long-Term Use to Treat Chronic Non-Cancer Pain was False, Misleading, Imbalanced, and Unsupported by Science

41. For years, Defendants systematically violated state laws requiring that the promotion of pharmaceutical drugs not be false or misleading. Defendants manipulated and ignored scientific evidence to formulate and broadcast the misrepresentations described below, each of which was instrumental in: (1) overcoming longstanding medical and legal barriers to opioid therapy for chronic pain; and (2) making high-dose, long-term opioid use the new "gold standard" of treatment of chronic non-cancer pain.

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[9] Portenoy, R.K., *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, Progress in Pain Research and Management, Vol. 1, p. 247, ed. H.L. Fields & John C. Liebeskind, IASP Press, Seattle, 1994 (emphasis added).

[10] *Id*. at 278 (emphasis added).

42. Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid drug name. Upon information and belief, Defendants used these unbranded materials, which are not reviewed by the FDA, to disseminate messages that were inaccurate, were inconsistent with their branded marketing materials and the drugs' labels and package inserts, and would not pass muster with the FDA. Had they relied on branded materials, the FDA-required drug labels and package inserts would have been included to more fully describe the risks and administration of opioids (such as OxyContin).

43. Defendants marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. Defendants targeted particularly vulnerable, but usually well-insured, groups of patients, such as veterans and the elderly. Defendants leveraged and funded patient organizations and communities – promoting opioids particularly for common conditions, such as headaches, arthritis, fibromyalgia, and back pain. Unlike other direct-to-consumer marketing, Defendants, as a group, focused on unbranded advertising – promoting opioids for chronic pain knowing that the creation of a new, expansive market for opioids would benefit all manufacturers.

44. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Through misleading medical education programs, treatment guidelines, and other efforts, Defendants "reeducated" general practitioners and family doctors, knowing that these doctors reach the vast majority of patients with common chronic pain complaints, but are less likely than specialists to have the time or knowledge to evaluate Defendants' deceptive messages or to closely monitor patients for signs of improvement or adverse outcomes (such as addiction).

45. Individually and collectively, Defendants promoted a series of misrepresentations aimed broadly at reversing the ultimately well-founded fears and beliefs of doctors and patients.

1. Defendants' misrepresentations regarding the benefits of opioids for chronic pain.

46. Defendants deceptively promoted opioids as improving chronic non-cancer pain patients' function by allowing them to get back to "normal" and reducing their pain long-term. Defendants misrepresented the efficacy of opioids in an effort to persuade doctors and patients that their benefits outweigh their risks.

47. Although opioids may initially improve patients' function by providing pain relief in the short term, there were – and are – no controlled studies of the use of opioids beyond 16 weeks and no evidence that opioids improve patients' function in the long-term. Indeed, research such as a 2008 study in *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work. Despite this lack of evidence, and evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life.

48. The FDA has recognized that claims that opioids improve patients' function are misleading. For example, a company claimed that its opioid "Improved Overall Function" and offered "Long Lasting Improvements in Physical Function" and would enable patients to be better able to engage in a list of daily activities, such as walking, standing, and climbing stairs. In a warning letter sent March 24, 2008, the FDA publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities … as not been demonstrated by substantial evidence or substantial clinical experience."

49. In marketing Kadian, Actavis made implied claims that the drug would allow chronic pain patients to return to work, relieve "stress on your body and your mental health," and help them enjoy their lives. The FDA found the Actavis had misrepresented the scientific evidence: "[W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together

with any drug-related side effects patients may experience … results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[11]

50. Janssen also distributed a series of posters to doctors' offices that showed pictures of people dressed for a variety of active professions suggesting that doctors prescribe Ultracet because "Pain doesn't fit into their schedules." Despite the lack of scientific evidence in support of such a claim, the posters falsely implied that Ultracet was appropriate for help in maintaining an active lifestyle. Several of the posters contained the tagline "Ultracet lets them perform."

51. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored the *Policymaker's Guide*, published by the American Pain Foundation ("APF"), which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. To support this claim, APF cited *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, a review published in 2006 in the Canadian Medical Association Journal. However, the review concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-sponsored *Guide* failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks, and therefore could not support the long-term use of opioids.

52. Defendant Janssen, working with APF, created a national patient advocacy campaign titled *Let's Talk Pain*. Upon information and belief, the campaign consisted of a series of television segments, a website, online videos, literature and events. In 2009, one of the campaign's marquee components was a "first-of-its-kind Web-based series called the *Let's Talk Pain* show hosted by veteran TV journalist Carol Martin. The resource brings together medical doctors, nurses, psychologists, social workers and people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain."

[11] Feb. 18, 2010 Warning Letter.

53. The *Let's Talk Pain* talk show was orchestrated (through Ketchum, Inc., Defendant Janssen's public relations firm) and sponsored by Janssen, and is still available online. In the very first episode of this talk show, the following exchange took place:

> **Teresa Shaffer (APF Action Network Leader)**: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Dr. Al Anderson (AAPM Board of Directors)**: The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones who need to have their pain controlled enough so that they can increase their quality of life.
>
> **Teresa Shaffer**: This is what has allowed me to continue to function and is what has allowed me to have somewhat of a normal life, is the opioids.[12]

There simply is no scientific evidence that opioids taken long-term improve function or quality of life for chronic pain patients, and there is significant evidence that opioids impose significant risks and adverse outcomes on long-term users.

54. Similarly, the National Initiative on Pain Control ("NIPC"), an APF initiative sponsored by Endo, ran a facially unaffiliated website called www.painknowledge.org. NIPC billed itself as "an integrated education initiative" and promoted its expert leadership team, including "nationally respected experts in the pain management field." Endo's involvement was not disclosed on the pages describing either the NIPC or painknowledge.org. Painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.[13]

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[12] *Available at* http://www.youtube.com/watch?v=zeAlVAMRgsk (0:35 to 1:09).
[13] www.painknowledge.org_patiented_pdf_8679_PatientHandout_Final.

55. APF's *Policymaker's Guide*, supported and sponsored by Purdue and published only two years ago, also includes claims that opioids "help alleviate pain, restore functioning and improve quality of life."

56. Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and low back pain. For instance, research indicates that as many as 30% of patients who suffer from migraines have used opioids to treat their headaches.[14] Despite this, users of opioids had the highest increase in headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[15] A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[16] Studies of the use of opioids long-term for chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[17]

57. There also is evidence that, over the long-term, opioid therapy fails to lessen, and sometimes increases, patients' pain – important facts that Defendants fail to include in their marketing literature. For example, Defendants have failed to disclose scientific evidence that establishes that many patients on chronic opioid therapy continue to experience significant pain and dysfunction.[18] Defendants also have failed to disclose research and clinical experience demonstrating that: (1) the analgesic (pain relieving) efficacy of opioids often declines over time;

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[14] Buse D, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, Headache: The Journal of Head and Face Pain, 2012, 52: 18-36.

[15] *Id*.

[16] Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment, National Headache Foundation, http://www.headaches.org/press/NHF_Press_Kits/Press_Kits_-_Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments.

[17] Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain*, Cochrane Database System Review, 2013, *available at* http://www.ncbi.nlm.nih.gov/pubmed/23983011.

[18] Mark D. Sullivan, *et al*., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain*, 149(2) Pain 345-353 (2010); Jørgen Erikson, *et al*., *Critical issues on opioids in chronic non-cancer pain*, 125(1-2) Pain 172-179 (2006); *see also*, IOM, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research, Comm. on Advancing Pain Research, Care, & Educ. Board on Health Sci. Policy, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, Institute of Medicine (2011); Dillie KS, *et al*., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample*, J Am Bd Fam Med, 21:108-117 (2008).

(2) patients on opioids long-term may develop greater sensitivity to pain ("hyperalgesia"); and (3) research showing that because they develop tolerance to the medication over time, many chronic pain patients require ever higher doses of opioids to obtain relief and are on doses that doctors have described as "frighteningly high."[19]

58. Consistently, in their marketing, Defendants failed to disclose the lack of evidence to establish that opioids are safe and effective long-term, as well as the growing body of evidence that the risks of opioids increase and their benefits decline over time. The studies relied on by Defendants in marketing their drugs are short-term, typically for less than 12 weeks. For example, an ad run by Janssen in the October 2010 issue of *American Family Physician* included the claim: "Opioid efficacy meets unexpected tolerability in patients with end-stage degenerative joint disease of the hip or knee." The study cited was only conducted over a five-day period, and thus provided no support for long-term efficacy.

59. As one California pain specialist noted in an article titled, *Are We Making Pain Patients Worse*, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[20] Additionally, epidemiological data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

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[19] Katz M, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, Arch Intern Med 2010; 170(16):1422-1424.

[20] Gomes, *Opioid dose and drug-related mortality in patients with nonmalignant pain*, Arch Intern Med 2011;171:686-691A; Dunn KM, *et al*., *Opioid prescriptions for chronic pain and overdose: a cohort study*, Annals of Int. Med. 2010;152:85-92. Most overdoses were medically serious and 12% were fatal. *Id*. *See also*, Braden JB, Russo JE, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD, *Emergency Department visits among recipients of chronic opioid therapy*, Arch Intern Med, 2010; 170(16): 1425-1432 (finding that higher doses of opioids doubled the risk of adverse drug events).

2. Defendants' misrepresentations regarding the adverse outcomes and risks of opioids.

60. In an effort to persuade doctors to prescribe opioids for chronic non-cancer pain, Defendants deceptively overstated the safety and minimized the adverse outcomes, particularly the risk of abuse and addiction, of using opioids long-term.

a. Risk of addiction and abuse.

61. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic non-cancer pain patients, Defendants had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk – condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have posed a nearly insurmountable challenge.

62. Remarkably, Defendants were able to do it. Even though opioids are controlled substances – classified under the federal Controlled Substances Act as having "high potential for abuse" and a "risk of severe psychological and physical dependence"[21] Defendants: (1) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (2) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk – and Defendants' own FDA labels – compelled disclosure.

63. Contrary to Defendants' claims, numerous studies support that, though these patients may not presently show signs of abuse or addiction, at least 15% and as many as 40% of patients will become addicted to opioids.[22] Research has shown that opioids are even more

[21] 21 U.S.C. § 812(b).

[22] *E.g.*, Boscarino, J, Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, Addiction 2010 (105): 1776-1782; Boscarino J, Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria, J Addict Dis. 2011, 30(3): 185-194; Prescription Drugs: Abuse and Addiction, National Institute on Drug Abuse, http://www.drugabuse.gov/sites/default/files/rrprescription.pdf.

addictive than cocaine and alcohol. One in three to five users who self-administer short-acting opioids will become addicted, versus one in eight to 15 for users of cocaine or alcohol.[23]

(1) Minimizing the risk of addiction.

64. In order to answer questions about increasingly well-publicized incidents of opioid addiction, Defendants falsely reassured doctors and patients that, when taken properly under a doctor's supervision, opioids are not addictive. Defendants' representations that opioid addiction can be effectively managed by competent physicians not only had the effect of increasing the number of opioid prescriptions, but also deflected the responsibility from Defendants' marketing to doctors' prescribing and treatment practices.

65. Defendants' efforts to minimize the risk of addiction from taking opioids long-term are evident in their unbranded materials, which dramatically understate or deny the risk of addiction, as compared to their branded materials, overseen by the FDA, which include stronger addiction warnings from the drugs' labels. Upon information and belief, Defendants took advantage of this less regulated marketing channel to disseminate their deceptive messages regarding the risk of addiction from long-term opioid use. For example (emphasis added):

Pain: Opioid Therapy (2009)	**What You Should Know About Treating Your Pain With Opioids (2012)**	**Opana ER Advertisement (2011/2012/2013)**
purported NIPC publication funded by Endo	unbranded patient education material created by Endo	branded Endo advertisement
"People who take opioids **as prescribed usually do not become addicted**."	"**The risk of becoming addicted to your opioid medicine is reduced** if you take your medicine exactly as prescribed by your healthcare provider.	"contains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

[23] Kreek, *et al*., *Pharmacotherapy of Addictions*, 1:710-726, 2002.

66. Defendants also sought to deceptively downplay the risk of addiction to chronic pain patients by defining opioid addicts as people who get the drugs illicitly and take them improperly – not patients taking drugs they were prescribed. According to Defendants, patients who take opioids prescribed to them are not addicted. A 2004 Endo patient education publication edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is still available online, answers the hypothetical patient question: "What should I know about opioids and addiction?" by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

67. More graphically, a Purdue brochure, still provided to doctors today, makes the point visually in advising doctors of *Indications of Possible Drug Abuse*; the brochure shows the stigmata of injecting or snorting opioids – skin popping, track marks, or perforated nasal septa.[24] In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassured doctors that as long as they did not observe those signs, they need not worry that their patients were becoming addicted to opioids.

68. These deceptive messages gave doctors and patients a false sense of security that as long as patients are only taking opioids a doctor gives them – regardless of the dose or frequency ingested – and not manipulating them, snorting, or injecting them, they are not addicted. That is dangerously false. Many opioid users who become addicted to the drugs began using them when a doctor prescribed them. Pain patients and opioid addicts are not separate universes, but overlapping circles. As one study noted, "a potential side effect from chronic use can be abuse and addiction … [I]n fact, correct use and abuse of these agents are not polar opposites – they are complex, inter-related phenomena."[25] A review of studies of urine drug monitoring for opioid

[24] *Providing Relief, Preventing Abuse*, p. 13.

[25] Compton/Volkow, Major increases in opioid analgesic abuse in the United States: Concerns and Strategies (2006), p 106.

patients showed that at least 11% of patients with chronic pain were misusing opioids and at least 12% were not taking their medication as prescribed.[26]

69. Dr. Scott Fishman, another KOL previously funded by opioid makers, acknowledged that data supporting the contention that addiction is rare "have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are high enough that they should be considered a significant potential adverse effect."[27] Despite these acknowledgements, Defendants continued to market opioids to doctors and patients as rarely addictive and failed to disclose the significant risk of addiction.

(2) Claiming the risk of addiction can be identified and managed.

70. Defendants continue to maintain to this day that *most* patients can safely take opioids long-term for chronic pain without becoming addicted. However, over time, needing to explain why so many doctors encountered chronic pain patients addicted to opioids, Defendants admitted that *some* patients *could* become addicted. Defendants claimed that if doctors use screening tools or questionnaires with their patients to identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse), opioids can be given safely and addiction can be avoided.[28]

71. Dr. Russell Portenoy, a pro-opioid, Defendant-funded KOL described above, appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat non-cancer chronic pain. He claimed that, "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a

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[26] Katz N, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, AmJManagCare, April 19 2013, p. 8, *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers/.Katz, AmJManagCare.

[27] *Responsible Opioid Prescribing: A Clinician's Guide* (2012).

[28] The FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics directs doctors to "assess each patient's risk of abuse." However, it does not excuse drug companies' misrepresentations that the screening tools allow them to prevent low-risk or high-risk patients from abusing or becoming addicted to opioids.

history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

72. A guide created by Cephalon, *Opioid Medications and REMS: A Patient's Guide*, similarly promised: "Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

73. Pro-opioid KOL Lynn Webster developed a basic five-question risk screening tool called the Opioid Risk Tool. In 2011, Dr. Webster presented, via webinar, a program sponsored by the American Academy of Pain Management and defendant Purdue, titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in California during the relevant limitations period.

74. An Endo-sponsored 2007 supplement to the *Journal of Family Practice* contained an article, *Pain Management Dilemmas in Primary Care: Use of Opioids*, by a physician who was on all of Defendants' speakers bureaus, which recommends risk screening by use of the Opioid Risk Tool (developed by another pro-opioid KOL, Dr. Lynn Webster), or the Screener and Opioid Assessment for Patients with Pain. Medium to high-risk patients should be treated by "a maximally structured approach" including toxicology screens and pill counts.

75. That same doctor also gave a Purdue-sponsored continuing medical education presentation ("CME") in 2012, *Chronic Pain Managing and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, in which he discussed the treatment of a high-risk chronic pain patient demonstrating aberrant behavior, recommending screening, reducing the prescription fills, and also switching to a different opioid as management strategies – all to maintain a course of chronic opioid therapy.

76. There are three fundamental flaws in Defendants' assurances that doctors could identify and manage the risk of addiction. First, there is no reliable scientific evidence that

screening alone substantially limits the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients can be given opioids safely, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients without red flags can take opioids long-term without significant danger of addiction.

77. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions, but who lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. Defendants have made a concerted effort to reach GPs through continuing medical education programs ("CMEs"), office visits, and literature specifically aimed at them, and most opioids are prescribed by primary care physicians like GPs.[29]

78. Further, GPs do not have the specialized training to fully address the needs of patients taking opioids long-term for chronic non-cancer pain. Defendants put together training for GPs on prescribing opioids to chronic pain patients, but provided no guidance on recognizing opioid abuse or weaning patients off opioids. Since GPs are especially reliant on CMEs to equip them to manage patients on opioids, this critical learning gap makes it even less likely that, once on opioids, chronic pain patients will have the chance to get off them.

(3) Deflecting attention to "undertreated" pain.

79. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about that risk as unfairly denying treatment to needy patients. They claimed that purportedly overblown worries about addiction caused pain to be under-treated and opioids to be over-regulated and under-prescribed. One APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & its Management*, stated that: "[u]nfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for

[29] Wolters Kluwer Health, *Sharp rise in opioid drugs prescribed for non-cancer pain*, ScienceDaily, Sept. 16, 2013, http://www.sciencedaily.com/releases/2013/09/130916091218.htm.

difficulty in obtaining adequate care include … misconceptions about opioid addiction." The Purdue *Guide* further alleged that resulting regulatory constraints (like the FDA's recently mandated prescriber education program, or REMS ("Risk Evaluation and Mitigation Strategies")) have a "chilling effect" on prescribing and that abuse of opioids injured and "jeopardize[d] effective pain management by impeding patient access to opioids."

80. Janssen-sponsored *Let's Talk Pain* – a multi-media patient education campaign – warned that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program went on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients … This prescribing environment is one of many barriers that may contribute to the under treatment of pain, a serious problem in the United States."

81. For example, under the heading of "Protecting Access," *In the Face of Pain*, a Purdue website, complained through at least mid-2013 that policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed; "restricting access to patients with pain who also have a history of substance abuse;" "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[30] This unsupported and untrue rhetoric aimed to portray doctors who did not prescribe opioids as uncaring, protecting themselves at the expense of their patients.

(4) Physical dependence vs. addiction.

82. In an effort to underplay the risk and impact of addiction, Defendants frequently explain that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal.

[30] *Available at* www.inthefaceofpain.com_content_uploads_2011_12_factsheet_ProtectingAccess.

83. For example, in the April 2, 2010, version of its OxyContin label, Purdue states: "**Cessation of Therapy.** When the patient no longer requires therapy with OxyContin, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient." The APF *Policymaker's Guide* (2011) funded by Purdue states: "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation." These representations are false and misleading.

84. Defendants' so-called guidance overstates the ease of withdrawing from long-term use of opioids and the adverse effects that accompany their discontinuance. Withdrawal from opioids after long-term use can trigger severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. The dependence on opioids can be so severe that withdrawal symptoms may persist for months, or even years, after a complete withdrawal from opioids.

85. Defendants also fail to disclose that long-term opioid use often causes psychological, as well as physical, dependence. Addiction is not a switch that is either off or on. Indeed, as the most recent, authoritative Diagnostic and Statistical Manual of Mental Disorders ("DSM-V") acknowledges, there is a spectrum of disorders that range from misuse and abuse of drugs to addiction, and patients suffer negative consequences wherever they fall on that spectrum.[31]

86. This is certainly true of opioids. Anxiety over ending opioid use can trigger cravings for opioids, even after a patient is no longer physically dependent and despite the fact that he or she is not deriving benefits from the treatment. As Dr. Andrew Kolodny, Chief Medical Officer of Phoenix House, a national addiction treatment program, explains, opioids "hijack[] the brain's reward system," convincing users that "the drug is needed to stay alive."[32] Even absent

[31] For that reason, references to "addiction" in this Complaint refer to this spectrum of substance abuse disorders.

[32] David Montero, *Opioid deaths plague O.C.; Actor's overdose shows danger of drugs that claim a local life every two days*, ORANGE COUNTY REGISTER, February 4, 2014.

physical dependence, a patient's fear of the unpleasant effects of discontinuing opioids can cause patients to seek the drugs.[33]

87. Thus, ending opioid therapy is not, as Defendants claim, simply a matter of gradually lowering a patient's dosage over time. In fact, one of the significant risks in beginning chronic opioid therapy is that, once patients become physically dependent, it will be difficult for them to ever stop using opioids. According to one study, more than half of patients who continuously use opioids for more than 90 days remain on opioids after more than five years.[34] Most patients who become physically dependent after long-term use will require opioid maintenance (through methadone or buprenorphine) for years or decades.

88. A publication in Purdue's current catalog of publications for providers, *Providing Relief, Preventing Abuse*, cautions against the "common error" of confusing physical dependence with addiction. It analogizes physical dependence on opioids to physical dependence on antihypertensives (blood pressure medicine) or decongestants.

89. This analogy has no basis in fact. With non-addictive drugs, like blood pressure medicine, patients may experience withdrawal symptoms, but they are rarely difficult to get over, and there is no craving for the drug. However, with long-term use of opioids, even in the absence of a formal diagnosis of addiction, patients often crave the drug long after they have discontinued use. Patients on opioids long-term will often experience symptoms that arguably may not qualify as full blown addiction, but are certainly not mere physical dependence. Defendants' marketing failed to acknowledge the spectrum of substance abuse disorders short of full blown addiction, which are also cause for concern, and created the sense that doctors need only concern themselves with signs of addiction.

90. As with the claimed low incidence of addiction, the misrepresentation that chronic opioid therapy is easy to stop is important to Defendants' fraudulent marketing scheme. Honestly

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[33] Ballantyne J., *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids*, IASP, 2013 Dec.; 21(5), p. 2.

[34] BC Martin, *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, J Gen Intern Med 2011 Dec.; 26(12):1450-7, *available at* www.ncbi.nlm.nih.gov/pubmed/21751058.

describing the difficulty of removing patients from opioids after long-term use and the complexity of patients' dependence would rebalance the risk-benefit analysis and stoke doctors' and patients' well-grounded concerns that once on opioids, severe physical and psychological dependence would make it extremely difficult for patients to ever stop their use. It might also motivate the general practitioners to whom Defendants generally marketed opioids for long-term use to refer patients requesting opioids to pain management specialists who would not so easily prescribe them. Defendants also gave GPs a false sense of confidence that they could identify addiction, distinct from physical dependence, which, again, allowed them to believe that they could continue to responsibly prescribe opioids. Defendants chose not to tell the truth so that they could sell more drugs.

(5) Pseudoaddiction.

91. Defendants needed a way to explain why so many chronic pain patients on opioids seem to be addicted: they ask for drugs by name, seek refills earlier than their supplies should have run out, hoard drugs, or self-escalate their doses. Defendants, led by Purdue, managed masterfully to turn these recognized signs of addiction into a way to sell more opioids through the concept of "pseudoaddiction."

92. Purdue discussed pseudoaddiction in a publication called *Providing Relief, Preventing Abuse*, in which it falsely and misleadingly claimed that the concept of pseudoaddiction had "emerged in the literature" "to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." And Purdue went even farther, saying that pseudoaddiction is unproblematic and may occur "occasionally even with successful opioid therapy for pain." This gave doctors confidence that signs of addiction that do not resolve when more opioids are prescribed might not be cause for concern. It also misled doctors into believing that the proper response to pain that has not been "effectively treated" through opioid prescriptions is *more* opioids. Purdue's unbranded website – PartnersAgainstPain.com – also issued a pamphlet in 2005 titled, *Clinical Issues in Opioid*

Prescribing, that included a list of conduct including "illicit drug use and deception" as examples of unproblematic pseudoaddiction-related behavior, not problematic addiction.

93. Defendants also managed to work the misleading concept of pseudoaddiction into medical literature. In a 1994 article, Defendant-sponsored KOL Russell Portenoy described common signs of addiction as potential signs of mere *therapeutic dependence* – which he likened to a diabetic's response to insulin – or *pseudoaddiction*.[35] Portenoy claimed that "*Pseudoaddiction* describes a specific phenomenon that has also been observed in the population with cancer pain." But his authority for this statement was limited to a single citation to an article by another KOL and later Purdue executive J. David Haddox.[36] Dr. Haddox's article did not concern a population study at all, but rather, simply reported the possible phenomenon in a single cancer (leukemia) patient with pneumonia and chest wall pain.[37]

94. Portenoy took the deception of pseudoaddiction one step farther, separating from a list of commonly accepted signs of drug addiction those he claimed were "probably less predictive of addiction."[38] Portenoy's "less predictive of addiction" list included:

i. Aggressive complaining about the need for more drugs;

ii. Drug hoarding during periods of reduced symptoms;

iii. Requesting specific drugs;

iv. Openly acquiring similar drugs from other medical sources;

v. Unsanctioned dose escalation or other noncompliance with therapy on one or two occasions;

vi. Unapproved use of the drug to treat other symptoms;

vii. Reporting psychic effects not intended by the clinician; and

viii. Resistance to a change in therapy associated with 'tolerable' adverse effects with expressions of anxiety related to the return of severe symptoms.

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[35] Portenoy, R.K., *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, pp. 266-67.

[36] *Id*. at 267.

[37] Haddox, J.D. and Weissman, D.E., *Opioid pseudoaddiction – an iatrogenic syndrome*, Pain, 36 (1989) pp. 363-366.

[38] Portenoy, R.K., *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, p. 267, Table III.

95. Portenoy cited no authority for his "less predictive of addiction" conclusion and is not himself a specialist or authority in addiction medicine. Yet his list encouraged doctors to ignore obvious signs of addiction and prescribe more opioids.

96. Similarly, in his book, *Responsible Opioid Prescribing* (2007), which was funded by Defendants Cephalon and Purdue and is still distributed in California, Dr. Scott Fishman asserts: "It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence should be considered before a judgment is made." Thus, according to Defendants, even patients at high risk for opioid addiction should be given the benefit of the doubt (and more opioids).

97. Defendants' common marketing messages and concerted efforts were evident in the nearly identical language they used to describe pseudoaddiction (emphasis added):

***Let's Talk Pain* (2009)**	***A Policymaker's Guide* (2011)**	***Clinical Issues in Opioid Prescribing* (2005)**
funded by Janssen	funded by Purdue	funded by Purdue
"A related term is pseudoaddiction, which refers to patient behaviors that may occur when **pain is under-treated** … Pseudoaddiction is **different from true addiction** because such behaviors can be resolved with effective pain management."	"Pseudo-addiction describes patient behaviors that may occur when **pain is undertreated** … Pseudo-addiction can be **distinguished from true add[i]ction** in that this behavior ceases when pain is effectively treated."	"Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when **pain is undertreated** … Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be **distinguished from true addition** in that the behaviors resolve when the pain is effectively treated."

98. Despite Defendants' claims, pseudoaddiction has no scientific basis; there is no competent study documenting its existence. Indeed, the list of behaviors that Defendants identified as the symptoms of pseudoaddiction are the same symptoms of addiction. Based on a single cancer pain case observed by Purdue executive and KOL David Haddox, Defendants have counseled doctors to treat chronic pain patients on opioids who seem to be addicted *with more opioids*.

99. KOL Dr. Lynn Webster recommended just this course in his book, *Avoiding Opioid Abuse While Managing Pain* (2007). He advised giving patients more medication when unsure whether a patient is showing signs of addiction or untreated pain. He asserted that pseudoaddiction was the cause "*in most cases and should be the clinician's first response*." Lynn R. Webster, Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007) (emphasis added). Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication.… It led us down a path that caused harm. It is already something we are debunking as a concept."

b. Other adverse effects.

100. Defendants also misrepresent the risks of long-term opioid use by describing them as minor and short-term. Defendants most frequently highlight the risk of constipation, which they advise can be addressed with laxatives or other treatments. The other side effects Defendants typically disclose are drowsiness, nausea and vomiting, mental clouding (sometimes disclosed), and itching, though Defendants promise that these symptoms will go away in a matter of days.

101. Below is a representative example of how Defendants disclose potential side effects from opioid use in unbranded material. This is taken from a 2009 patient education publication distributed by the NIPC and funded by Endo and which was distributed in California during the applicable limitations period:

> **As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**
>
> - Constipation
> - Drowsiness
> - Confusion
> - Nausea
> - Itching
> - Dizziness
> - Shortness of breath
>
> Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

102. Notably absent from this list are far more significant adverse outcomes linked to long-term opioid use, including: hyperalgesia, immunologic and hormonal dysfunction, respiratory depression, apnea, tolerance/loss of analgesic efficacy, endocrinopathies (most notably testosterone depletion, which, among other impacts, may decrease pain tolerance and the effectiveness of opioids),[39] cognitive impairment, dependence, and addiction. These adverse outcomes can result in an increase in falls and fractures in the elderly (which can shorten the lives of elderly patients), overuse, overdose, and death. Defendants also fail to disclose the risk that infants born to pregnant women using opioids will be dependent on opioids as well, suffering a condition called neonatal abstinence syndrome when they painfully withdraw from the drug after birth.[40] In addition, though the labels for opioids contain numerous warnings about use of opioids for patients who have certain conditions, are opioid naïve (new to opioids), or use other drugs, Defendants' marketing materials contain no similar cautions.

103. These omitted side outcomes are not, as Defendants claim, fleeting or minor. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[41] Defendants were aware of this high drop-out rate as they pushed the FDA to allow them to exclude these patients from clinical trial data, a method of research known as "enriched enrollment," which allowed drug companies to study only those patients who could tolerate opioids.

104. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In an ad that Janssen currently is running, including on its website, it claims that

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[39] Daniell HW, *Hypogonadism in men consuming sustained-action oral opioids*, J Pain, 3:377-384 (2002); Katz N, Mazer M, *Impact of opioids on the endocrine system*, Clin J Pain, 25:170-175 (2009).

[40] The FDA now requires a boxed warning on all extended release and long acting opioids, cautioning that chronic use of those drugs by pregnant women can result in neonatal opioid withdrawal syndrome ("NOWS"), which may be life-threatening and require specialized care.

[41] Noble M, *et al*., *Long-term opioid management for chronic noncancer pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 2010.

Nucynta ER has "Efficacy you need, Tolerability you want." However, each of the studies included in the drugs approval were only conducted over a 12-week period, using a pre-seeded patient group; thus none provide support for a claim of long-term efficacy in the population at large.

105. Defendants' misleading treatment of the serious risks of opioid treatment in unbranded materials directly contradicts the disclosures they made on their own labels. The label for Purdue's OxyContin, for example, acknowledges that its use may increase the risk of serious adverse reactions "including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock[.]" Likewise, the label for Janssen's Duragesic includes the warning that "[r]espiratory depression is the chief hazard of" Duragesic, and it "has a narrow indication and should be prescribed only by healthcare professionals who are knowledgeable in the administration of potent opioids and management of chronic pain." The labels even include warnings for interactions with substances as commonly used as alcohol, as in the Nucynta ER label, which says that the drug "may be expected to have additive effects when used in conjunction with alcohol … [and] respiratory depression, hypotension, and profound sedation, coma or death may result." Yet upon information and belief, these risks are not highlighted in the educational programs and marketing materials Defendants have sponsored and disseminated; materials that are much more widely read and relied on than the drug labels.

106. The table below (emphasis added) highlights the differences, described above, between how Defendants (in this instance, Janssen) disclosed side effects in unbranded materials and front-group materials versus how they disclosed side effects in their branded advertisements:

Finding Relief: Pain Management for Older Adults (2009)	**Let's Talk Pain Website (2009)**	**Nucynta IR Advertisement (2010)**
unbranded publication funded by Janssen	APF website funded by Janssen	branded Janssen advertisement
"At first, the drugs can cause **upset stomach or sleepiness**. These side effects often go away as you get used to the drugs. Some other side effects, such as **constipation**, don't lessen with time. Constipation can be	"The most common side effects of opioids include **constipation, nausea and vomiting, sedation (sleepiness), mental clouding, and itching**. Some people may also experience **dizziness** or difficulty urinating … The good	Prescriber information in the ad states: "**Respiratory depression** is the **primary risk** of mu-opioid agonists."

prevented or lessened by taking a laxative on a regular basis."	news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is likely to persist."	

107. In a 2008 warning letter, the FDA recognized that these strategies deceptively represented the side effects of opioids – in that case, Avinza. The FDA complained that one of the company's marketing materials (a file card) lists common adverse effects "including constipation, nausea, and somnolence," but omitted all of the other risks listed in the drug's package insert. According to the FDA, the file card with a page headed "Managing Side Effects"

> creates the misleading impression that the risk information contained in that section is a comprehensive presentation of the risks associated with Avinza therapy and the steps needed to address those risks. The fact that the File Card contains no other disclosure of drug risks reinforces this misleading impression. Furthermore, the File Card – in direct contradiction of the [Package Insert] for Avinza – implies that no serious or life-threatening risks (e.g., risk of respiratory depression, overdose, or death) can be caused by Avinza, both by disclosing only 'common adverse events' (e.g., constipation, nausea, and somnolence) and by emphasizing the drug's 'proven safety and tolerability' throughout the piece. Finally, by framing its discussion of common adverse reactions as one of 'managing' them, and by providing no disclosure to the contrary, the File Card misleadingly implies that common adverse reactions associated with the use of Avinza may ordinarily be alleviated or mitigated, and therefore do not pose a risk to patients…. Your minimization of the serious risk profile associated with your drug raises significant public health concerns.

108. In promoting their opioids, Defendants have engaged in the same marketing practices warned against by the FDA – highlighting only minor risks, emphasizing the ability to manage those risks, failing to disclose serious risks, and generally declaring the safety of their drugs. As the FDA made clear, that message is dangerously deceptive. By deliberately understating the risks of opioids, Defendants exposed patients to extremely dangerous adverse effects and deprived doctors and patients of the ability to make informed, appropriate choices about using opioids.

109. Defendants' pattern of understating the risks of chronic opioid therapies marred the continuing medical education programs and studies they funded or sponsored and left providers with the impression that opioids were much safer than they are and should be used more

frequently. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded article on opioids versus another group who reviewed a non-industry-funded article. The industry-funded article did not mention opioid-related death once; the non-industry-funded article mentioned opioid-related death 26 times. A summary of the study notes that students who read the industry-funded article more frequently cited the impression that opioids were underused in chronic pain. Those reading the non-industry-funded article, in reporting their "take-aways," mentioned the risk of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[42]

3. Misrepresentations regarding superiority.

110. Defendants' deliberate misrepresentation of the risks of opioids is particularly evident when compared to Defendants' description of the risk of over-the-counter nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal and renal risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks make their omissions regarding the risks of opioids all the more striking and misleading. In the Cephalon and Purdue-sponsored 2007 APF *Treatment Options*, which was distributed in California during the applicable limitations period, NSAIDs are described as "life threatening," – a term never used in connection with opioids – and are said to have caused 10,000 to 20,000 deaths each year. The CDC reports that the actual number of deaths even possibly related to the use of NSAIDs in 2008, the most recent year available, is roughly 3,400, and that number includes all gastrointestinal bleeding deaths regardless of cause.[43] The Janssen-funded brochure, excerpted below, included similar misrepresentations

[42] Fugh-Berman A, *Marketing Messages in Industry-Funded CME*, Pharmedout, June 25, 2010, *available at* http://pharmedout.org/conferencematerials.htm.

[43] John Fauber, *NSAID Bleeding Risk: Smoke But No Fire*, MedPage Today, May 30, 2012, *available at* www.medpagetoday.com/Geriatrics/PainManagement/32971.

and likewise was distributed to doctors and patients in California during the applicable limitations period:

Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are a large family of medicines that work in a similar way to aspirin by relieving both pain and swelling. This class includes drugs such as ibuprofen, naproxen, and celecoxib. Some are available without a prescription.

Advantages

- Relieve mild to moderate pain, fever, headaches, and swelling

Disadvantages

- Can cause stomach upset or bleeding in stomach or intestines
- Can cause kidney or liver damage if taken at high doses or for a long time
- May cause adverse reactions in people with asthma
- Can increase the risk of heart attack and stroke

Topical anesthetics

Topical anesthetics are used to numb the surface of a body part. They can be used to numb the front of the eye, the inside of the nose, the throat, the skin, the ear, the anus, and the genital area. Topical anesthetics are available in creams, ointments, aerosols, sprays, lotions, and jellies. They are used to relieve many types of pain and itching, such as that caused by sunburn, minor burns, insect bites or stings, nerve damage, or conditions such as hemorrhoids.

Opioid medications

Medicines containing opioids have been used for centuries. *Opioids* are strong pain medicines for moderate to severe pain. Today, opioids come in many forms and strengths. Some work very quickly but don't last very long. Some give long-lasting pain relief. And some are less likely to be addictive.

All opioids require a prescription. Talk to your doctor about what type of opioid would be best for you.

Opioids usually produce side effects. At first, the drugs can cause upset stomach or sleepiness. These side effects often go away as you get used to the drugs. Some other side effects, such as constipation, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis.

Used properly, opioid medications can make it possible for people with chronic pain to "return to normal"—get back to work, walk or run, play sports, and participate in other activities.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

1 - *Finding Relief: Pain Management for Older Adults*, sponsored by Defendant Janssen (2009)

111. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.[44]

C. Defendants, Directly and Through Their Agents and Front Organizations, Made and Caused Their Misrepresentations to Be Made and Broadly Disseminated

112. Defendants have polluted virtually every resource for information on the use of opioids to treat chronic non-cancer pain, and have created a deceptively solid foundation of core materials, cited and relied upon by others, to minimize the risks and overstate the benefits of using opioids to treat chronic pain. Both directly and indirectly – through doctors, medical education courses, seemingly independent patient advocacy groups, and professional societies – Defendants have ensured that their messages reach and expand the market for opioids. Upon information and

[44] Olfson M, *et al.*, *National trends in the office-based prescription of schedule II opioids*, J Clin Psychiatry, 2013 Sept.; 74(9):932-9, *available at* http://www.ncbi.nlm.nih.gov/pubmed/24107767.

belief, these strategies and players are deployed according to marketing plans that Defendants developed. Defendants have identified, encouraged, and compensated high profile KOLs to give talks and advice and author books and articles. Defendants' KOLs offer and serve on the program committees that choose continuing medical education programs, and develop and promote treatment guidelines that promote chronic opioid therapy. Many of these groups and KOLs have been misled by Defendants in the same manner as general practitioners and family doctors.

113. Directly and through public relations firms they hire and advocacy groups and professional societies they finance and influence, Defendants have funded, drafted, edited, approved, published, and distributed websites, books, patient education brochures, videos, and other materials that carry their misrepresentations to targeted groups of doctors (such as family doctors), and patients – particularly veterans and the elderly. Defendants carry out their fraudulent promotions both individually and in concert with industry front groups and each other, and make and disseminate these misrepresentations throughout the State of California.

1. Method 1: Key opinion leaders ("KOLs").

114. Defendants routinely rely on a small circle of doctors to promote the use of opioids for the treatment of chronic pain. These doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research in order to support the broad use of opioid therapy for chronic non-cancer pain. Known by industry shorthand as "KOLs," they have written, consulted on, edited, and lent their names to books and articles and given speeches and continuing medical education programs supportive of chronic opioid therapy. They served on committees that developed treatment guidelines that, even while acknowledging the lack of evidence for their positions, strongly encourage the use of opioids to treat chronic pain.

115. Defendants' KOLs have served on the boards of the advocacy groups and professional societies that develop and offer continuing medical education programs and publish patient education materials on opioids.

116. What Defendants and the KOLs rarely disclose is the substantial sums of money Defendants have paid to the KOLs for consulting and speaking arrangements and to serve on

various panels and boards; as well as through purported "research grants." Some KOLs have even gone on to become direct employees and executives of Defendants. Dr. Haddox, for example, was a KOL who, as a physician in private practice, promoted widespread opioid use for common non-cancer chronic pain. He was a paid speaker and consultant for Purdue, then became a Purdue employee and executive.

117. While some KOLs may initially have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the opioid therapy market. Defendants selected and funded doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[45] These doctor's professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

118. The KOLs' association with Defendants provided not only money, but also prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community. Upon information and belief, using these KOLs is a central part of Defendants' marketing plans and critical to persuading regulators and doctors – who rely heavily and more uncritically on their peers – that the benefits of chronic opioid therapy outweigh its risks.

119. Dr. Russell Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and co-opted to further their marketing campaign. With Defendants' support, Dr. Portenoy was dubbed the "King of Pain" by Time Magazine. He co-authored *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases (1986)*, which asserted, based solely on 38 cases, that chronic opioid therapy was a safe and effective treatment for patients with intractable non-malignant pain. His 1994 writings also strongly promoted opioid use long-term for

[45] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used key opinion leaders in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

non-cancer pain, although even he suggested opioid therapy should be used for chronic pain only as a last resort, after an initial limited trial period and with intense observation.[46]

120. Dr. Portenoy thus helped to open the door for the use of opioids to treat chronic pain. He served on the American Pain Society/American Academy of Pain Medicine Guidelines Committee, which endorsed the use of opioids to treat chronic pain, and the FDA Anesthetic and Life Support Drugs Advisory Committee, one of a host of FDA advisory committees that serve to provide expertise and technical assistance to assist the FDA decision-making. While he held these positions he also was receiving "research support," consulting fees or honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

121. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research. He is a Senior Editor of the *Pain Medicine* Journal, which published numerous articles supportive of chronic opioid therapy. He was President, and is a current board member, of the American Academy of Pain Medicine, an ardent supporter of chronic opioid therapy.

122. Dr. Webster is the author of numerous CME programs, sponsored by Defendants, that contained virtually all of Defendants' misrepresentations described above. At the same time, Dr. Webster was receiving significant funding from Defendants.

123. Dr. Webster has been under investigation by the U.S. Drug Enforcement Administration, which raided Dr. Webster's clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses. Ironically, Dr. Webster created and promoted an opioid risk tool, which purportedly allows a doctor to manage the risk that their patient will become addicted to or abuse opioids.[47]

124. In a striking blow to Defendants' marketing campaign, Drs. Portenoy and Webster recently acknowledged shortcomings in their pro-opioid positions. Dr. Webster has admitted that the concept of pseudoaddiction – taking patients at their word and assuming they are not addicts,

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[46] Portenoy, R.K., *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, pp. 274-75, Table IV.

[47] Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN HEALTH, Dec. 30, 2013, *available at* http://www.cnn.com/2013/12/20/health/pain-pillar/.

but just need more pain relief "– obviously became too much of an excuse to give patients more medication[.]"[48] Dr. Portenoy has admitted that he gave "innumerable lectures in the late 1980s and '90s" in which he asserted that fewer than 1% of patients would become addicted to opioids that "weren't true." Because the primary goal was to "destigmatize" opioids, he said, "we often left evidence behind." Dr. Portenoy also conceded that "data about the effectiveness of opioids does not exist."

2. Method 2: Co-opting of chronic pain advocacy and research groups to promote opioid use.

125. A key component of Defendants' plans to promote the long-term use of opioids was co-opting pain management organizations and societies and pain patient advocacy groups. Taking a page from the tobacco industry's play book, which had created and used front groups to proclaim tobacco was not harmful, Defendants harnessed and warped existing organizations to disseminate their deceptive messages with the expectation that these messages would circulate among and influence the conduct of prescribing physicians and other members of the medical community. These front organizations appeared to be legitimate scientific and patient advocacy organizations (and perhaps started out as such) and publicized seemingly scientific, balanced, and accurate information on opioid use. In fact, the information was false and misleading and paid for and encouraged by Defendants for the purpose of creating a vast market for the use of opioids for chronic pain.

126. The role of these organizations in promoting opioid use and their ties to opioid makers was highlighted when, on May 8, 2012, Senators Grassley and Baucus wrote to a half-dozen of these organizations:

> There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic [of opioid use and abuse] by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the

[48] Silverman E, *Opioids & An Overdue Senate Probe: Kolodny Explains*, Pharmalot.com.

> American Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[49] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers … helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient litigators, position statements, books and doctor education courses."[50]

127. These front groups, aided by millions of dollars in grants from Defendants and assistance from public relations firms hired by Defendants, spread the misrepresentations central to Defendants' fraudulent promotion of opioids. Indeed, Defendants influenced, if not outright controlled, the messages disseminated by many of these front groups.

a. American Pain Foundation.

128. The most prominent of Defendants' front groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from Defendants from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.3 million and $1.7 million, respectively.

129. APF issued education guides for patients, reporters, and policymakers that promoted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, described in greater detail below; promotion of opioids to treat veterans has contributed to high rates of addiction among our returning soldiers. APF engaged in a significant multimedia campaign –

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[49] ProPublica, *The Champion of Painkillers*, Dec. 23, 2011, *available at* http://www.propublica.org/article/the-champion-of-painkillers.

[50] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/ MEDPAGE TODAY Feb. 19, 2012, *available at* http://www.medpagetoday.com/Neurology/PainManagement/31256.

through radio, television and the web – to educate patients about their "right" to pain treatment – namely opioids. KOLs funded by Defendants, including Drs. Perry Fine, Scott Fishman and Kathleen Foley, also served on APF's Board of Directors.

130. In 2009 and 2010, more than 80% of APF's operating budget came from industry sources. Including industry grants for specific projects, in 2009, APF received about $2.3 million from industry sources out of total income of about $2.85 million; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

131. But the control was even more direct than the money. As a condition of one grant from Defendant Purdue, APF agreed that "APF and Purdue will work collaboratively to develop and approve key messages. The expert and APF will agree to follow the reasonable instructions and direction of Purdue in the form of a media training session to implement this project and to deliver key messages and presentation points on back pain and Partners Against Pain, and Purdue patient education and advocacy program." APF also did paid consulting work directly for Purdue under a Master Consultant Services Agreement which gave Purdue – but not APF – the right to terminate any project for any reason.

132. One grant request to Endo to create an opioid "tool-kit" for the National Initiative on Pain Control and to promote painknowledge.org, demonstrates APF's willingness to assist with Defendants' marketing efforts: "Some of these people [in chronic, intractable pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided $747,517 to the project, which included two of Defendants' key misrepresentations:

> - After starting opioid therapy, you may see the following positive improvements: - Your pain level may decrease[;] -Your level of function should improve: you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse[;] - Your sleep may improve.

- People who take opioids as prescribed usually do not become addicted.

133. At a July 2007 hearing before the Senate Judiciary Committee, "evaluating the propriety and adequacy of the oxycontin criminal settlement," APF aggressively defended Purdue, repeatedly denying that patients prescribed opioids abuse or become addicted to the drugs. APF's board chairman, Dr. James Campbell, described addiction as a "rare problem" for chronic pain patients and asserted that "the scientific evidence suggests that addiction to opioids by legitimate chronic pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of oxycontin and the abuse and diversion of the drug."

134. Despite APF's unequivocal pro-opioid positions, participants in a roundtable convened by APF and funded by Defendant Endo acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to **appropriate opioid management** [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."[51]

135. On May 8, 2012, Senators Grassley and Baucus wrote the Chairman of APF seeking information about the source of its funding and asked for a response by June 8, 2012. APF shuttered its offices and dissolved before that deadline.

b. American Academy of Pain Medicine.

136. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs critical to Defendants' deceptive marketing of chronic opioid therapy. Upon information and belief, the American Academy of Pain Medicine received significant funding from opioid manufacturers in a two-year period.

[51] Brown M, Highlights from the American Pain Foundation's Roundtable. Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management, *available at* http://www.cecentral.com/assets/817/men08061-04_content_FINAL.pdf.

137. The American Academy of Pain Medicine maintained a corporate relations council, whose members paid $25,000 a year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with the American Academy of Pain Medicine's marquee event, its annual meeting in Palm Springs. The American Academy of Pain Medicine describes the annual event as an "exclusive venue" for offering education programs to doctors. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

138. The American Academy of Pain Medicine and American Pain Society issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Defendant Purdue; three years later, he became Vice President for Health Policy at Purdue. American Academy of Pain Medicine and APS revised their guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the guidelines, including KOL Dr. Portenoy, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Upon information and belief, the consensus statement remained on The American Academy of Pain Medicine's website until 2011, and was taken down only after a doctor complained.

3. Method 3: Treatment guidelines.

139. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts in, nor trained in, the treatment of chronic pain. Treatment guidelines used in making treatment decisions are cited throughout the scientific literature and are referenced by third-party payers in determining whether they should cover treatments for specific indications.

140. Initially, even Defendants' KOLs were reasonably balanced and cautious in their proposed guidelines. For example, Dr. Portenoy's 1994 proposed guidelines stated as follows:

Table IV
Proposed guidelines in the management of opioid maintenance therapy for nonmalignant pain

1. Should be considered only after all other reasonable attempts at analgesia have failed.
2. A history of substance abuse, severe character pathology and chaotic home environment should be viewed as relative contraindications.
3. A single practitioner should take primary responsibility for treatment.
4. Patients should give informed consent before the start of therapy; points to be covered include recognition of the low risk of true addiction as an outcome, potential for cognitive impairment from the drug alone or from co-administration of sedative/hypnotics, likelihood that physical dependence will occur (abstinence possible with acute discontinuation), and understanding by female patients that children born when the mother is receiving opioid drugs will likely be physically dependent at birth.
5. After drug selection, doses should be given on an around-the-clock basis; several weeks should be agreed upon as the period of initial dose titration, and although improvement in function should be continually stressed, all should agree to at least partial analgesia as the appropriate goal of therapy.
6. Failure to achieve at least partial analgesia at relatively low initial doses in the non-tolerant patient raises questions about the potential treatability of the pain syndrome with opioids.
7. Emphasis should be given to attempts to capitalize on improved analgesia by gains in physical and social function; opioid therapy should be considered complementary to other analgesic and rehabilitative approaches.
8. In addition to the daily dose determined initially, patients should be permitted to escalate dose transiently on days of increased pain; two methods are acceptable: a) Prescription of an additional 4-6 "rescue doses" to be taken as needed during the month;
b) Instruction that one or two extra doses may be taken on any day, but must be followed by an equal reduction of dose on subsequent days.
9. Initially, patients must be seen and drugs prescribed at least monthly. When stable, less frequent visits may be acceptable.
10. Exacerbations of pain not effectively treated by transient, small increases in dose are best managed in the hospital, where dose escalation, if appropriate, can be observed closely and return to baseline doses can be accomplished in a controlled environment.
11. Evidence of drug hoarding, acquisition of drugs from other physicians, uncontrolled dose escalation, or other aberrant

behaviors must be carefully assessed. In some cases, tapering and discontinuation of opioid therapy will be necessary. Other patients may appropriately continue therapy within rigid guidelines. Consideration should be given to consultation with an addiction medicine specialist.

12. At each visit, assessment should specifically address:
    a. Comfort (degree of analgesia)
    b. Opioid-related side effects
    c. Functional status (physical and psychosocial)
    d. Existence of aberrant drug-related behaviors
13. Use of self-report instruments may be helpful but should not be required.
14. Documentation is essential and the medical record should specifically address comfort, function, side effects and the occurrence of aberrant behaviors repeatedly during the course of therapy.[52]

141. The measured precaution evident in Dr. Portenoy's early guidelines was excluded from later guidelines funded and sponsored by Defendants. As noted above, in 2009 the American Pain Society, together with the American Academy of Pain Medicine, issued their *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain*. Though Dr. Portenoy served on the panel, the Guidelines represented a marked departure from previous guidelines for the promotion of opioids. The APS/AAPM guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients with and without past abuse histories. One member of the panel, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and the founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions by Defendants to the sponsoring organizations and committee members. These guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but the body of scientific evidence on opioids; the APS/AAPM guidelines have been cited 732 times in academic literature that was disseminated in California during the applicable limitations period are still available on the internet, and were reprinted in the *Journal of Pain* in 2009.

[52] Portenoy, R.K., *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, pp. 274-75, Table IV.

142. In 2009, the American Geriatric Society ("AGS") revised its guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. Upon information and belief, these guidelines were funded by Defendants Purdue and Janssen, and included the following recommendations:

- "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of evidence, strong recommendation)."
- "[Th]e risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence and they are contrary to Dr. Portenoy's 1994 guidelines which noted opioid therapy as a last resort and required disclosure of the risk of addiction and other significant risks of the therapy.

143. According to one news report, the American Geriatric Society received $344,000 in funding from opioid makers since 2009.[53] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants and investing in Defendants' stock.[54]

144. In contrast, treatment guidelines that did not receive industry backing are much more reserved and endorse chronic opioid therapy only in narrow circumstances. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians, included a remarkable disclaimer that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in

[53] John Fauber, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE JOURNAL SENTINEL, May 30, 3012.

[54] The Institute of Medicine recommends that, to ensure an unbiased result, that fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

fact, be facilitating it." The American Society of Interventional Pain Physicians Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." They recommend long-acting opioids in high doses only "in specific circumstances with severe intractable pain … with continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

145. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against "routine use of opioids for treatment of chronic pain patients," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

146. Industry supported guidelines, in contrast, separate the strength of the recommendation from the strength of evidence supporting the recommendation. For instance, most of the "strong" recommendations of the APS/AAPM guidelines are backed by only weak evidence. Further, the guidelines Defendants supported fail to adequately take into account the potential adverse effects and specific label warnings that a physician should take into consideration in deciding on a treatment for any medical condition. As a result, they present a distorted picture of treatment options.

4. Method 4: Continuing medical education.

147. The millions of doctors and other health care professionals[55] who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants have sponsored thousands of CME programs that promote chronic opioid therapy and support and

[55] Schwart, *et al*., *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine*, JAMA Intern Med., Dec. 18, 2012, p. 2507.

disseminate the deceptive and biased messages described in this Complaint. Upon information and belief, Defendants' grant making to fund and sponsor CMEs has been influenced by their marketing strategies and harnessed to the goal of increasing opioid sales. Upon information and belief, Defendants are more than passive funders of these programs, which reached tens of thousands of doctors; they have influenced, if not outright controlled, the messages on topics and in the fields of practice Defendants targeted.

148. Defendants have long-standing relationships with the professional associations, advocacy organizations, presenters, and CME development companies that select and develop opioid-related CMEs. These organizations have depended upon Defendants' financial support for their activities and, in some cases, their very existence. It stands to reason that each of these organizations and the individuals running them know and believe that future financial support from Defendants depends upon producing programs that support the use of Defendants' products.

149. Defendants are able to influence CMEs because they funded: (1) the KOLs who serve on the program committees of the professional societies that select the presentations and speakers and promote the views on which the presentations rely; (2) the KOLs who serve as speakers for the CMEs; and (3) the professional societies that host the conferences at which the presentations are given. Upon information and belief, many of these programs focus exclusively on prescribing opioids, and do not fairly present reasonable alternative treatments (except to discount them), nor do they fairly present (or present at all) the risks or benefits of chronic opioid therapy, nor how to take patients off opioids, once prescribed.

150. Defendants' sales representatives participated in these conferences, encouraged doctors to attend the programs, and held auxiliary events that reinforced and amplified the distorted messaging of the CMEs. The CMEs themselves, however, buttressed by printed disclaimers by Defendants, were marketed to appear evidence-based and unbiased. In fact, like KOLs, the CMEs are particularly effective for disseminating Defendants' messages because

doctors rely on these peer-led professional events to deepen their understanding of clinical issues.[56]

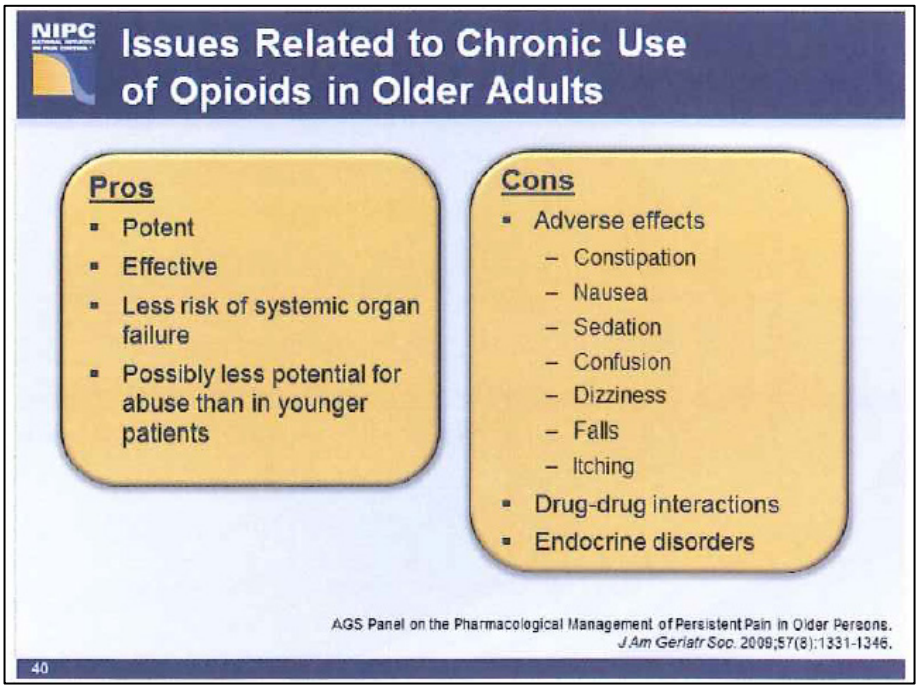
151. *Path of the Patient, Managing Chronic Pain in Younger Adult at Risk for Abuse*, a CME program sponsored, in part, by Purdue and edited by KOL Dr. Perry Fine, provides one example of Defendants' use of CMEs to spread deceptive messages supportive of chronic opioid therapy. *Path of the Patient* aimed to educate primary care doctors about managing chronic pain with opioids. The presentation is devoted entirely to opioid prescribing and, despite its title, presents *no other* potential treatments. Far from a therapy of last resort, as conventional medical thought advised, *Path of the Patient* promotes opioid therapy as the only solution, even for common chronic pain issues such as back pain. This CME was available on-line for California physicians, and others, to view during the relevant statute of limitations period.

152. In a role play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills a day as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Even given these facts, an authoritative narrator notes that, because of a condition known as pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid.

153. An Endo-sponsored continuing medical education program put on by the American Pain Foundation's National Initiative for Pain Control, *Persistent Pain in the Older Adult*, also reprises several of Defendants' misrepresentations. The program was first made available on-line, including to California residents, in 2011 and continued to be available during the relevant statute of limitations period. The CME describes fear of addiction, safe use, and drug-drug interactions – all factors relating to addiction, abuse, and overdose – as the most significant barriers to treating

[56] This is especially true in the Counties and State since all California-licensed physicians (except pathologists and radiologists), beginning in 2001, have been required to take a full-day course on "pain management."

"persistent" or chronic pain in the elderly. The presentation counsels that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse outcomes, including severe liver injury and anaphylaxis (shock). Citing the American Geriatric Society's treatment guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and notes "possibly less potential for abuse than in younger patients." Its listed adverse outcomes simply omit addiction, overdose, respiratory depression, or death, among others, and the slides note that tolerance to opioids more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients (see below).



154. In 2012, the American Academy of Pain Medicine offered a *Safe Opioid Prescribing Course* in connection with its annual conference. The course promised that participating doctors would "get the answers from the leading experts in pain" and offered up to 36 hours of CME credit. The course was sponsored by Defendants Purdue and Endo, and the faculty included noted pro-opioid KOLs such as Drs. Fine, Fishman, Haddox and Webster. Indeed, Dr.

Webster, two other doctors from Dr. Webster's clinic, and Dr. Haddox, a Purdue executive, all served on the course program planning committee.

155. The course materials included a 560-page syllabus, which contained selected studies, literature and slide decks from the presenters. The syllabus also contained numerous misrepresentations including, for example: pseudoaddiction; risk of addiction can be managed (use of screening tools; high-risk patients may be considered for chronic opioid therapy); taking opioids long-term to treat chronic non-cancer pain improves quality of life and physical function; promotion of the American Academy of Pain Medicine's guideline recommendations.

156. Dozens of CMEs, that were and continue to be available to doctors in California and during the relevant limitations period, also promoted the false concept that the risk of addiction to opioids is low and that doctors can identify and manage patients at higher risk of addiction. The programs train doctors to use specific risk training tools without disclosing that the tools are unproven or the lack of evidence that high-risk – or any – patients can take opioids long-term without becoming addicted.

5. Method 5: Scientific articles.

157. Defendants rely on misleading and deceptive citation of purported authorities to overstate the benefits of chronic opioid therapy and minimize its serious risks and fail to disclose contrary evidence. For instance, APF's *Policymaker's Guide* (2011) makes the particularly callous representation that less than 1% of children prescribed opioids will become addicted. In support of this contention it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain. The purpose of the *Guide* was to support opioid therapy generally; it was not focused on or restricted to cancer pain patients – the only population addressed in Dr. Foley's article, which also did not reference pediatric cancer patients or include *any* statistics on addiction rates. Defendants funded and distributed the Guide with this misleading citation, knowing that there was no evidence to support the general assertion that children will not become addicted to opioids, even when taken

long-term. The Guide was disseminated in the State of California within the applicable limitations period.

158. Similarly, a 2003 scientific study funded by Purdue and co-authored by a Purdue employee concluded that OxyContin is "effective and safe for the management of [chronic diabetes-related pain] and improves QOL [quality of life]." The study asserts that there is "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The authors cite a single article by Porter and Jick, *Addiction Rare in Patients Treated with Narcotics*, published in the prestigious New England Journal of Medicine. What the authors fail to disclose is that the "evidence" is actually a letter to the editor, not a peer reviewed article. Moreover, the letter describes not a study but a chart review of hospitalized patients; if medical charts failed to note that the patients exhibited documented signs of addiction while on opioids, the authors concluded that they were not addicted. Not only did the study not support the authors' assertion, but the authors' misleading citation of it created a false impression of its reliability. The Porter and Jick letter and the 2003 Purdue study have been cited 819 and 455 times, respectively, in the medical literature since 2008.

159. Practicing doctors, particularly the busy family doctors and general practitioners targeted by Defendants, do not have the time to look behind seemingly authoritative sources, particularly in scientific literature. They do – and must be able to – rely on citations to scientific literature, a fact that Defendants use to their advantage. Moreover, the misleading use of studies – to give them weight or meaning they do not have – is like a virus; once embedded in the literature, it takes on a life of its own. Studies that assert addiction is rare, relying either on the Foley or Porter-Jick analyses, themselves are cited for the proposition. Thus, with a few key manipulations and deceptive citations, Defendants were able to seed a scientific consensus supportive of chronic opioid therapy.

6. Method 6: Patient education.

160. Defendants reach chronic pain patients through written publications, websites, and videos designed to present the purported "facts" about opioids in a simple, user-friendly manner.

As Defendants know, these materials are accessed by both patients doing their own research and doctors, who read them when distributing them to patients. The materials Defendants produced concerning opioids include numerous fraudulent representations, overstate the benefits of chronic opioid therapy and fail to fully disclose its risks, particularly the risks of addiction.

161. For example, Janssen funded a patient education pamphlet produced by public relations firm Conrad & Associates. The pamphlet, *Finding Relief: Pain Management for Older Adults*, 2009 (also sponsored by AGS, and American Academy of Pain Medicine) is unbranded.

162. Because the piece is general and does not seem to promote a particular drug, and because it is co-sponsored by a credible and seemingly neutral professional organizations (the American Geriatric Society and the American Academy of Pain Medicine), patients are more likely to read and credit it. The pamphlet was distributed in the State of California within the applicable limitations period.

163. *Finding Relief* promises: "Used properly, opioid medications may make it possible for people with chronic pain to "return to normal" – get back to work, walk or run, and play sports, and participate in other activities." *Finding Relief* describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse … you will probably remain on the same dose or only need small increases over time." As described above, these contentions are wholly lacking in scientific or clinical support. Upon information and belief, Defendants were involved in developing and approving the deceptive messages in patient education booklets such as this one.

164. Defendants created campaigns – including literature, websites, community groups, and programs – related to chronic non-cancer pain from illnesses such as low back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia and multiple sclerosis. These conditions affect significant numbers of people, who have formed affinity groups and on-line communities for support in seeking to address conditions that produce persistent pain and may necessitate long-term treatment. Defendants used this community-building to promote the use of opioids in the treatment of these conditions, despite the fact that there was little or no scientific

evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more benefit from pain relief than harm from the many known and significant opioid treatment risks. None of these conditions reflect indications approved to appear on Defendants' drug labels, supporting the inference that Defendants did not have evidence to obtain such approval.

165. In addition to their general marketing efforts, Defendants made special efforts to market to two particularly vulnerable patient groups: the elderly and veterans. While obvious markets for chronic pain medications, each of these patient populations has risk factors that make long-term opioid use particularly dangerous.

(1) Elderly patients.

166. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels, occurs more frequently in elderly patients.[57] A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Defendants' targeted marketing to the elderly and the absence of cautionary language in its promotional materials flies in the face of scientific evidence and even their own labels.

167. In their effort to reach elderly patients, who experience pain associated with arthritis and other aging-related conditions, Defendants supported the American Geriatric Society, which produced the treatment guidelines discussed at ¶¶ 140-41 and education materials focused on elderly patients. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored by Janssen, repeated the same unsubstantiated, deceptive statements that opioids are "rarely addictive" and increase patients' function, allowing them to get back to work or participate in recreational activities.

[57] Saunders/Dunn, *et al.*, *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, J Gen Intern Med 2010; 25:310-5.

168. Defendants also promoted the notion – also without adequate scientific foundation – that the elderly are particularly unlikely to become addicted to opioids. The American Geriatric Society's 2009 Guidelines, for example, described addiction rates as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study that examined overdoses among long-term opioid users found that the largest number of patients among those with serious overdoses were 65 or older.[58]

169. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

(2) Veterans.

170. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005 and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they did in 2001. Although, upon information and belief, many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving Veterans' Administration ("VA") services nationally in a single year (2005), 1,013 had died of accidental drug overdoses – double the rate of the civilian population. Between 2001 and 2012, the VA hospital in Santa Clara County – the Palo Alto Health Care System – provided 80.3 opioid prescriptions for every 100 patients. That amounts to 681,290 patients who received 546,793 prescriptions – in a single hospital in one county.[59]

171. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have higher incidence of adverse clinical outcomes, like overdoses and self-

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[58] Dunn, *et al*., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, Annals of Internal Medicine. 2010, *available at* http://www.rsds.org/2/library/article_archive/pop/DunnKM_AnnInternMed_2010.pdf.

[59] Aaron Williams, *et al*., *Veterans Affairs: Painkillers*, U.S. Census Bureau, Sept. 28, 2013, *available at* http://va-opiates.apps.cironline.org/#/system/118.

inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.[60] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and failed to disclose in their promotional materials the known, serious risks opioids posed to them.

172. Defendants have targeted veterans with fraudulent and unproven representations. As early as 2001, a Purdue promotional plan described spending hundreds of thousands of dollars to target the Veterans Administration and admitted that it was using "education" for what was actually marketing.[61] "Corporate initiatives and partnering efforts were very successful with the Veterans Administration. In addition to building sales for OxyContin Tablets, it also positioned Purdue as the leader in pain management education."[62]

173. *Exit Wounds*, a 2009 publication sponsored by Defendants Purdue, Endo and Janssen but framed and promoted as a personal narrative by one veteran writing to others, describes opioids as "under-used" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "*increase* your level of functioning" (emphasis in original) and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards." The U.S. Federation of State Medical Boards itself received support from Defendants during the time it created and published its guidelines for prescription of opioids. Upon information and belief, *Exit Wounds* was disseminated in the State of California within the applicable limitations period.

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[60] Seal KH, *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, JAMA Intern Med., 2012; 307(9); 940-947.

[61] *Critics say pharmaceutical firms spurred the increase in prescriptions for narcotic painkillers*, STATESMAN.COM, Sept. 29, 2012, *available at* http://www.statesman.com/news/news/local-military/critics-say-firms-spurred-painkiller-prescriptions/nSPNL/.

[62] *Id*.

174. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with anti-anxiety medications taken by a significant number of veterans. It was not the unbiased narrative of a returning war veteran. It was pure marketing, sponsored by Purdue, Endo, and Janssen. Janssen, for example, supported the marketing effort despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma." A similar warning is found on the labels of other Defendants' opioids.

175. The deceptive nature of *Exit Wounds* is made obvious in comparing it to guidance on opioids published by the VA and Department of Defense ("DOD") in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses or using multiple doctors for prescriptions and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death – none of which are disclosed in *Exit Wounds*. *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the DOD, discloses that its review "revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps … include: lack of effectiveness studies on long-term benefits and harms of opioids …; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification …; lack of evidence on the utility of informed consent and opioid management plans …; and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse." These disclosures are missing from Defendants' marketing to veterans.

D. Defendants Often Acted Together in Promoting Opioids, Opposing Regulation, and Facilitating Supportive Standards to Approve Opioids

176. As laid out above, Defendants supported, assisted, encouraged and/or facilitated the same front groups and KOLs to disseminate the same deceptive messages about the use of opioids to treat chronic pain. In fact, the similarity of their messages, language, and even their formatting

(*e.g.*, the myth/fact formulation) suggests that Defendants participated in a common scheme to disseminate misleading information about opioids.

177. This inference is supported by Defendants' cooperation in other activities to promote opioids, including successful efforts to set standards for measuring and treating pain, training and regulating doctors, and approving new opioids.

178. Defendants' efforts to shift the paradigm on opioids and pain treatment began soon after their branded opioids were launched. In 2000, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), in conjunction with the University of Wisconsin Pain and Studies Group, declared that pain was the "5th Vital Sign" and required all healthcare practitioners to make pain assessment and management a priority in daily practice.

179. Upon information and belief, the impetus behind the new pain standard began with June Dahl, then a professor of pharmacology at the University of Wisconsin-Madison. Dr. Dahl approached JCAHO with a proposal and helped identify pain management experts and key organizations to act as advisors to JCAHO, as well as promoters of Pain as the 5th Vital Sign. Those experts and key organizations are many of the same heavily funded KOLs and front groups that ultimately helped bring about the change in attitudes towards opioids and, subsequently, the rise in opioid prescribing. Purdue was one of two companies that paid for programs across the country to educate hospital physicians and staff about complying with the new pain standards and had exclusive rights to distribute certain education materials to JCAHO members.[63]

180. Once health practitioners were required to consider a patient's pain along with other vitals, the next step was to convince practitioners that all pain must be treated – preferably with opioids. In 2004, the Federation of State Medical Boards revised and updated its Model Policy for the Use of Controlled Substances for the Treatment of Pain. In support of those efforts, noted KOL Dr. Scott Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide*.

[63] GAO, *OxyContin Abuse and Diversion*, Dec 2003, *available at* http://www.gao.gov/htext/d04110.html.

181. The Guide was sponsored by Defendants Endo and Purdue, and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals and physicians across the country, including in California. The 2007 *Physician's Guide* contained many of the misrepresentations described above, notably the concept of "pseudoaddiction" and the claim that opioids improve function.

182. Defendants also worked together to promote opioids through the Pain Care Forum, which is comprised of representatives from opioid manufacturers and distributors (including each of the Defendants); doctors and nurses in the field of pain care; health care professional organizations (*e.g.*, the American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF, American Chronic Pain Association, and the Northern California Pain Initiative); and other like-minded organizations (*e.g.*, Federation of State Medical Boards and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants. Upon information and belief, the Pain Care Forum was started, and continues to be run, by Defendant Purdue's in-house lobbyist Burt Rosen, previously in conjunction with APF. The group meets regularly in-person and via teleconference. There also is an email listserv that is used to share information.

183. Upon information and belief, Defendants collaborated on a common campaign to build a market for opioids for chronic non-cancer pain.

E. Defendants Also Acted Individually to Deceptively Promote Their Opioids for Chronic Pain

184. In addition to participating in a shared campaign to expand the market for opioids by reaching chronic pain patients and conditions, each Defendant acted on its own to deceptively market its specific opioids for chronic pain and to capture a larger share of the chronic pain market. Separately, in their branded materials and on seemingly independent websites, they each overstated the benefits and understated the risks of their drugs (including the risk of addiction) in the various ways described above, often causing the FDA to formally admonish them. On top of this, Cephalon engaged in additional unlawful conduct, marketing its opioid Fentora for unapproved chronic pain uses despite only recently settling a case involving almost identical

activities with respect to its predecessor, Actiq. Likewise, Purdue also quickly began to violate a consent judgment with the federal government and State of California by continuing to misrepresent the risks and benefits of OxyContin and its other opioids.

1. Cephalon fraudulently marketed Actiq and Fentora.

185. Cephalon also engaged in a distinctive effort to market its opioids for chronic pain despite having labels that specifically limited their use to cancer pain. As a result of its successful marketing efforts, Cephalon reaps significant revenue from selling its opioids for treatment of chronic pain. However, neither of its two opioid drugs – Actiq or Fentora – is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die.

a. Cephalon launches its fraudulent marketing scheme of Actiq.

186. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." [64]

187. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, that is, patients who have taken specific dosages of opioids for a week or longer and whose systems have acclimated to the drugs.

[64] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs,* WALL STREET JOURNAL, Nov. 3, 2006.

188. In 1995, the FDA approved Actiq "**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Emphasis in FDA document.) Because of Actiq's dangers, wider, off-label uses – as the FDA label makes clear – are not permitted:

> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients."
>
> Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.) Unlike other drugs, where off-label uses are permitted but cannot be promoted by the drug maker, Actiq is so potent that off-label use to opioid naïve patients is strictly forbidden.

189. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic pain – an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

190. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b. Cephalon engaged in deceptive, off-label marketing efforts to expand the use of Actiq.

191. Cephalon knew that Actiq's market potential for the treatment of breakthrough cancer pain in opioid-tolerant patients with malignancies was limited. Rather than seek FDA approval for a broader set of indications, Cephalon launched an illegal marketing campaign to capture the lucrative chronic pain market. Cephalon also actively concealed the illegal means that it used to market the drug.

192. Despite the FDA's mandate that Actiq be prescribed only by oncologists or pain specialists skilled in the use of Schedule II opioids to treat cancer pain, Cephalon implemented a marketing scheme aimed at a wide range of doctors, including general practitioners, neurologists and sports medicine specialists. Cephalon failed to disclose the fact that Actiq was not approved or safe for the treatment of general aches and pains and is inappropriate for anything besides persistent cancer pain in certain opioid-tolerant cancer patients.

193. Cephalon drove Actiq prescriptions by providing coupons to doctors in this wide range of specializations. According to the WALL STREET JOURNAL, an ImpactRx survey showed that Actiq sales visits to non-cancer physicians increased six-fold between 2002 and 2005. The surveyed doctors reported more than 300 Actiq sales visits in both 2004 and 2005. One general practitioner reported that a Cephalon sales representative visited his office once a month, delivering 60 to 70 coupons for free Actiq at a time. Each coupon was good for six Actiq lollipops. A package of 30 Actiq lollipops, each containing 200 micrograms of fentanyl, would otherwise cost about $500.

194. Within two years, Cephalon's off-label marketing campaign had borne fruit. According to data from NDCHealth, a health-care information company, Actiq prescriptions in the United States rose from 77,478 in 2001 to 321,463 in 2003. By 2003, 26% of Actiq prescriptions were written by family-practice doctors or internists – five times the number written by that same group in 2001. During the first six months of 2006, 99% of the prescriptions for Actiq filled by retail pharmacies were prescribed by non-oncologists. According to one physician survey, 80% of patients who were prescribed Actiq between June 2004 and October 2006 were non-cancer patients.[65]

195. Cephalon even targeted workers' compensation programs, which usually handle relatively few cases of cancer. By 2003, Actiq catapulted to 15th on The Hartford Financial Services Group's list of total medication costs in workers' compensation claims. Just two years earlier, it ranked 66th.

[65] According to Cephalon, at its peak, there were 9,000 Actiq prescriptions filled per week.

196. A June 16, 2007 report by Prime Therapeutic LLC, a company dedicated to providing pharmacy solutions for third-party payers, also confirm the off-label marketing scheme. The study analyzed a Midwestern commercial health plan's Actiq claims for April through June 2005. Of the 95 patients who received prescriptions for Actiq during that period, only 21 had a diagnosis of cancer or AIDS. And only 10 of 21 patients were taking a long-acting opioid painkiller (opioid tolerant). Altogether, 84 of the 95 Actiq prescriptions – nearly 90% – were for off-label purposes. The study also found that more than 15% of Actiq prescriptions exceeded the FDA's recommended 120 lollipops per month, signaling widespread overuse of the drug.

c. Government investigations also confirm Cephalon's deceptive marketing strategy.

197. Internal company documents uncovered during an investigation by the State of Connecticut revealed that:

a. Cephalon instructed its sales representatives to ask non-cancer doctors whether they had the potential to treat cancer pain. Even if the doctor answered "no," the Cephalon-created decision tree instructed the sales representatives to give the physician free Actiq coupons to distribute to their patients.

b. Cephalon encouraged neurologists to prescribe Actiq to patients with migraine headaches. An internal document titled *Actiq in Migraine*, instructed salespersons to tout the berry-flavored narcotic as "an ER on a stick."

c. Outside pain management specialists were enlisted to pitch Actiq to non-cancer physicians. A retained "independent" pain management specialist would accompany the Cephalon salesperson on sales calls to non-cancer physicians. The "independent" pain management specialist would deceptively assure the physician that Actiq did not cause patients to feel "high" and, unlike other narcotic painkillers, carried a low risk of diversion toward recreational use.

d. Cephalon set sales quotas for its sales and marketing representatives that could be met only by promoting Actiq for off-label uses.

e. Cephalon encouraged physicians to ignore the label's maximum dosage, which limited new patients to six lollipops containing a 200-microgram dose of fentanyl, and instead encouraged physicians to start patients with 24 lollipops containing 400 micrograms.

f. Cephalon promoted Actiq by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for nonmalignant pain. CME topics included "Opioid Use in Headache" and "Use of Actiq in Opioid-Naïve Patients."

g. Cephalon paid speakers' fees and expenses to present topics promoting off-label uses for Actiq at these conferences.

h. Cephalon also funded, promoted, and distorted studies to promote Actiq for noncancer pain. The methodologies used in the studies would not pass scientific muster. For example, two Cephalon-touted studies tested fewer than 28 patients and had no control group. One of the doctors involved in the studies pitched Cephalon products in paid speaking engagements; another received help from Cephalon with conducting his study. At least one of the studies was published in the medical journal "Headache."

198. Actiq's widespread use led the FDA's Office of Criminal Investigations and the U.S. Attorney for the Eastern District of Pennsylvania to investigate Cephalon's marketing practices. That investigation found that from 2001 through at least 2006, Cephalon promoted Actiq off-label to treat migraines, back pain, and even injuries. The investigation also confirmed that Cephalon had structured its sales quotas and bonuses such that a sales representative could only reach sales goals by selling the drug for chronic non-cancer pain. In 2008, Cephalon entered a criminal plea for its off-label promotion of Actiq.

d. Cephalon attempted to cover-up evidence of its deceptive, unlawful scheme.

199. The FDA conditioned its approval of Actiq upon Cephalon's agreement to conditions enumerated in the FDA's Risk Management Program. This Program required Cephalon to: (1) make sure that informational packets describing the limited uses for Actiq were given to everyone who was prescribed Actiq; (2) conduct patient surveys and spot check pharmacies to ensure that the informational packets were being distributed; (3) monitor prescribing physicians to make sure only appropriate patients received Actiq; and (4) if it turned out that more than 15% of the prescriptions were written by doctors who should not have been prescribing Actiq, Cephalon was to report that fact to the FDA and embark on a physician training program to stop and prevent physicians from prescribing Actiq for broader use.

200. But a report drafted by a compliance auditor hired by Cephalon revealed that Cephalon was failing to meet the Program's conditions. Rather than come into compliance,

Cephalon buried the report.[66] The report was submitted to the company in October 2003, and various management members directed the auditor to remove from the report his conclusion that Cephalon was not in compliance with the Program. He refused and was terminated.

e. Cephalon fraudulently marketed Actiq's successor drug, Fentora.

201. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application (NDA) to the FDA for approval.

202. Like Actiq, Fentora is an extremely powerful opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth. Like Actiq, Fentora is a rapid onset opioid.

203. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already receiving and were tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

204. Fentora's inherent danger is confirmed by the unusually strong and detailed black box warning label – the most serious medication warning required by the FDA. The warning makes clear that, among other things:

> Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdosing.
>
> *FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
>
> FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients,"

[66] The allegations in this section are made on information and belief based on the allegations in the Second Amended Complaint filed on April 7, 2005 in the lawsuit *David Brennan v. Cephalon, Inc.*, No. 4 CV 3241 (D.N.J.).

…

> *FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.)

f. October 1, 2006 – Cephalon launches Fentora and immediately begins deceptive marketing campaign.

205. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label.

206. Cephalon's marketing of Actiq "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally – not breakthrough cancer pain in particular – from Actiq.

207. On February 12, 2007, only five months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[67]

208. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities" – treating breakthrough cancer pain and:

[67] *See* http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (last visited Jan. 28, 2014).

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain….
>
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication…. Noting that opioids are "widely used in the treatment of … non-cancer patients," Roche continued:
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[68]

g. September 2007 – Reports of death and serious side effects lead the FDA to issue a public health warning for Fentora.

209. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection *(e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution." The warning did not acknowledge Cephalon's deliberate role in the "improper patient selection."

210. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora only should be prescribed for approved conditions and that dosage guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label use. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including

[68] *See* http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript (last visited Aug. 23, 2010).

migraines, post-operative pain or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.

h. Cephalon sponsored CMEs used to promote the off-label use of Actiq and Fentora – 2007-2008, in spite of the FDA warnings.

211. Cephalon also used the CME programs it sponsored to promote the off-label use of their Actiq and Fentora. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora, and only Actiq and Fentora, as "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs only use the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME would know to prescribe Actiq or Fentora.

212. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn R. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid onset opioid when it cannot. The only examples of rapid onset opioids then on the market are oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well*." (Emphasis added.)

213. Similarly, *Breakthrough Pain: Improving Recognition and Management*, offered between March 31, 2008, and March 31, 2009, by Medscape, LLC completely omitted tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like the "Optimizing Opioid Treatment" CME, taught that Actiq and Fentora were the only

products on the market that would take effect before the breakthrough pain episode subsided. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, *Opioid-Based Management of Persistent and Breakthrough Pain*, with Dr. Christine A. Miaskowski, Professor and Associate Dean for Academic Affairs, Department of Physiological Nursing, University of California – San Francisco. They instruct their audience, "Clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommend "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including specifically in patients with chronic non-cancer pain.[69]

214. Dr. Miaskowksi disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines that she served on Cephalon's speakers' bureau. Dr. Fine and Dr. Webster also received funding from Cephalon for consulting services, and upon information and belief, Drs. Fine and Webster continued to receive funding from other opioid manufacturers, too.

i. May 6, 2008 – The FDA rejects Cephalon's request for expanded approval of Fentora.

215. Cephalon filed a supplemental new drug application, (sNDA), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. To support its application, Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[70] Cephalon argued for the expanded approval even though, as it acknowledged, "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

[69] *See Opioid-Based Management of Persistent and Breakthrough Pain*, Aug. 20, 2008, pp. 9-10.

[70] *See* Joint Meeting: Anesthetic and Life Support Drugs, Advisory Committee and Drug Safety and Risk Management Advisory Committee, May 6, 2008, *available at*, http://wwvv.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (last visited Aug. 17, 2010).

216. The FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[71] By a vote of 17-3, the relevant Advisory Committee – a panel of outside experts – voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of its already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that up with a supplemental request, asking that the company submit a Risk Evaluation and Mitigation Strategy for Fentora as well.

j. March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora.

217. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

218. On March 26, 2009, the DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. Specifically, the Warning Letter asserted that a direct-to-patient advertisement found on the internet was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy … when this is not the case." DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."** (Emphasis in original.) DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening

[71] *See* Review of Fentora® and Actiq® Adverse Events from the Adverse Event Reporting System ("AERS") Database, May 6, 2008, *available at*, http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations.ppt#289,1 (last visited Aug. 17, 2010).

hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original.) DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original.)

k. Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses.

219. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

220. Yet Cephalon continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists. This only makes sense because the off-label sales are so vast that missing out on 90% of the potential on-label market is inconsequential to Cephalon's bottom line.

221. Cephalon-set sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label. The general pain sales representatives have, from the outset, been required to adhere to call lists that include numerous pain doctors and other

physicians who do not, and would not, prescribe Fentora on-label. These same call lists contain few, if any, oncologists.

222. A 2009 PowerPoint presentation by Kathy Roman, Cephalon's Associate Director of Oncology for Strategic Analysis & Planning, reported that only 4% of Fentora prescriptions were written by oncologists.

223. Cephalon's conduct in marketing Actiq and Fentora for chronic pain, despite their clear (and deadly) risks and unproved benefits, was an extension of, and reaped the benefits of, Cephalon's generally deceptive promotion of opioids for chronic pain.

2. Purdue's role in deceptively promoting opioids for treatment of chronic pain.

224. Like Cephalon, Purdue also undertook its own separate campaign to deceptively market opioids. Purdue is the maker of OxyContin, which, over time, has been the most used and abused opioid. Today, with one exception, all of the drugs marketed by Purdue are opioids.

a. Purdue's marketing of OxyContin was deceptive from the start.

225. OxyContin was approved by the FDA in 1995 for "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." Purdue immediately began promoting OxyContin as less addictive than other opioids. The drug's extended-release mechanism, according to Purdue, meant it was less likely to provide a euphoric high, and therefore was less likely to be abused, create addiction, or cause withdrawal. However, Purdue "did not have, and did not provide the FDA with any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications." When crushed, dissolved in water, or injected, OxyContin's extended-release mechanism could be bypassed to produce a heroin-like high. In fact, OxyContin was more likely than other opioids to be abused and diverted because it had more oxycodone than other non-controlled release opioids (and oxycodone already is twice as potent as morphine).

226. Purdue's marketing persuaded primary care physicians that it was safe to prescribe OxyContin for chronic pain. By 2003, according to the Government Accountability Office

("GAO"), general practitioners represented half of all OxyContin prescribers. A GAO report noted that, between 1997 and 2002, OxyContin prescriptions for non-cancer pain increased nearly ten-fold, from 670,000 to 6.2 million, versus an increase in prescriptions for treatment of cancer pain from 250,000 to 1 million; non-cancer prescriptions represented 85% of total OxyContin prescriptions. At the same time, Purdue doubled the number of its sales representatives, who received bonuses based on sales quotas and were directed to target the most prolific opioid prescribers. Total sales bonuses in 2001 were $40 million, up from $1 million in 1996. Purdue also used speakers bureaus, which put on programs at resort locations, starter coupons to attract new patients, funded new front group websites, and, even distributed plush toys and hats, which the Drug Enforcement Administration ("DEA") says had never been done before for a controlled substance. The DEA blamed Purdue's "aggressive marketing of OxyContin" for "fuel[ing] demand for the drug and exacerbat[ing] the drug's diversion.

227. In 2001, the FDA required Purdue to narrow its approved indication to "moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time" and added new warnings relating to the drug's potential for misuse and abuse. In August of that year, the FDA wrote to Purdue to make clear that all promotional materials should prominently disclose the new label information. Yet, not 18 months later, in January 2003, in response to two ads Purdue ran in the Journal of the American Medical Association, the FDA issued a sharply worded warning letter to Purdue:

> Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug

and the serious, potentially fatal risks associated with its use is especially egregious and alarming in its potential impact on the public health.[72]

228. The FDA's strong language seemed to have little impact on Purdue's behavior. In 2007, Purdue entered into a $635 million settlement with the federal government to resolve civil and criminal allegations relating to its marketing of OxyContin. This is a drop in the bucket compared to the $27 billion in sales revenue generated since the introduction of OxyContin in 1996.[73] News reports assert that federal prosecutors originally intended to charge the company with multiple felonies, including conspiracy, mail and wire fraud and money laundering, but that the Department of Justice agreed to allow Purdue to plead guilty to a single felony count of misbranding. Purdue's chief executive officer, chief medical officer, and general counsel individually pled guilty to misdemeanor counts of misbranding and subsequently left the company. Purdue admitted in its plea that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.

229. As part of its settlement, Purdue entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services-Office of Inspector General ("HHS-OIG"). Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the Agreement, monitor its own compliance, and report its compliance (both independently and through an independent review organization or "IRO") to HHS-OIG.

230. In 2007, Purdue also agreed to pay $19.5 million to 26 states, including California, to settle these states' consumer protection claims which likewise stemmed from Purdue's promotion and marketing of OxyContin. As part of the consent judgment with California and the other states ("Consent Judgment"), Purdue likewise agreed to, among other things, refrain from deceptively marketing OxyContin; to refrain from providing to health care professionals written information describing off-label use of OxyContin; to disclose any educational or research grants relating to OxyContin; and to refrain from sponsoring any event that will discuss off-label use.

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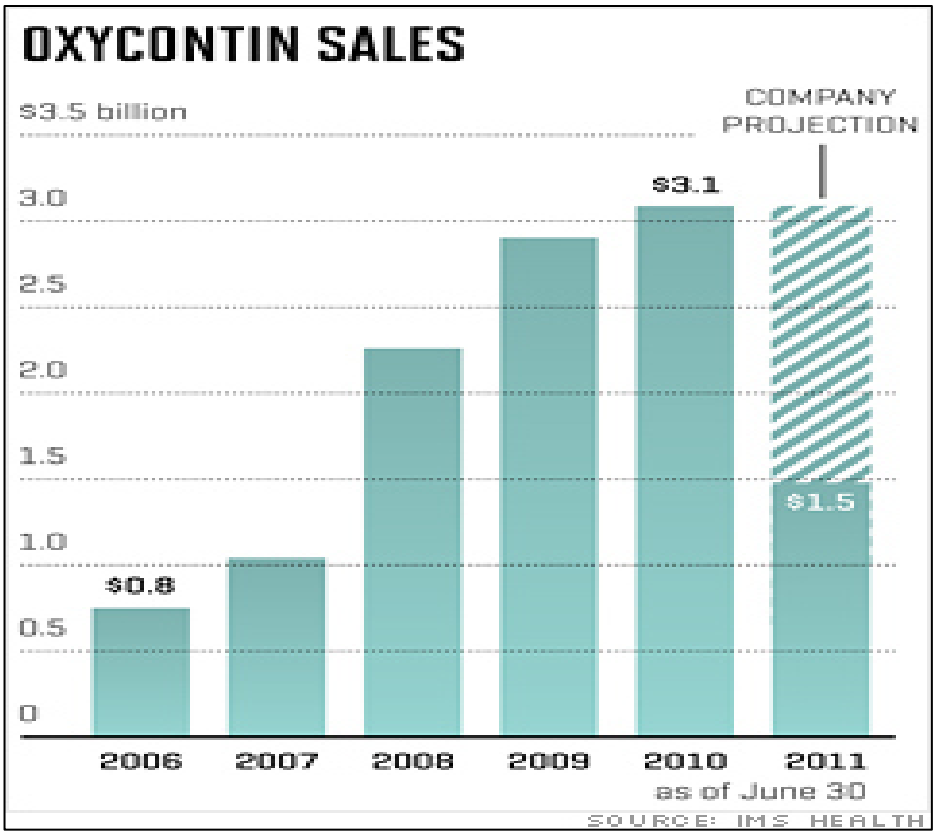
[72] January 17, 2003 Warning Letter from Thomas W. Abrams, Director, Division of Drug Marketing, Advertising, and Communications , U.S. Food and Drug Administration, to Michael Friedman, Executive Vice President and Chief Operating Officer, Purdue Pharma L.P.

[73] *See* http://www.latimes.com/opinion/la-ed-oxycontin-overprescribing-database-20130-001-photo.html.

b. Purdue continued to engage in false marketing, misrepresenting OxyContin's benefits and the risk of addiction when taken long-term for chronic pain.

231. Despite its guilty plea, Purdue continued to deceptively market opioids. And, as a result, its sales continued to grow. OxyContin yielded $3.1 billion in revenue for Purdue in 2010, up four-fold from its 2006 sales of $800 million.



232. Purdue's direct misrepresentations and its relationship with front groups and KOLs who advanced its deceptive marketing, are described above. Upon information and belief, Purdue deployed these doctors and front groups according to marketing strategies it developed, and also funded, directed, shaped, approved, and disseminated their misrepresentations regarding the risks, benefits, and superiority of opioids' use to treat chronic pain.

c. Purdue was aware of, and has profited from, misuse and diversion of its opioids.

233. According to the GAO, the first public news of diversion and abuse of OxyContin became known in 2000. Among them were reports of patients arriving in emergency rooms with

severe withdrawal or overdoses, hundreds of deaths, and increases in drug treatment admissions for individuals on OxyContin. Since 2000, there have been countless news reports, lawsuits, and government and other data describing the rising toll of addiction, overdose, and death from OxyContin specifically and opioids generally.

234. In 2010, Purdue reformulated OxyContin to reduce tampering and make it less subject to abuse. The new OxyContin cannot be reduced to a powder and does not dissolve; when water is added to it, it becomes gelatinous and cannot be injected.

235. While an important step, Purdue knew that even the reformulation of OxyContin did not resolve issues of abuse and addiction. A recent article in the LOS ANGELES TIMES revealed that Purdue – since 2002 – has kept a database of 1,800 doctors suspected of inappropriately prescribing its drugs, but did not alert law enforcement or medical authorities to all but a few of these doctors.[74] This database, according to the news report, was whittled down from 3,200 doctors reported as suspicious by Purdue's sales representatives (conduct that must have been so egregious that the sales representatives forewent the chance to earn commissions on the doctors' prescriptions).

236. Purdue did not use its database of problem doctors to reduce OxyContin abuse, to rein in dangerous doctors, or to stop the potentially unlawful distribution of a controlled substance. Instead, the company presented the evidence of rogue prescribing in an effort to persuade the FDA that generic drug makers should not be allowed to copy the earlier, non-tamper resistant version of OxyContin – the same OxyContin that Purdue originally promoted as less addictive – as it is too subject to abuse.

237. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services said in the LOS ANGELES TIMES article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." Instead, on information and belief, Purdue continued to

[74] Scott Glover and Lia Girion, *Oxycontin maker closely guards is list of suspect doctors*, LA TIMES, Aug. 11, 2013.

profit from the prescriptions of these suspicious prescribers. Psychologist, researcher, and Stanford University professor Keith Humphreys noted, "[t]hose doctors are a gold mine for Purdue Pharma. And the whole time they're taking the money, knowing that something is wrong, and not telling anyone until it gives them a market advantage to do so. That is really disgusting."[75]

F. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded, and Dangerous and would Harm California Residents

238. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were untrue and unproven. The history of opioids, as well as research and clinical experience over the last 20 years, established that they were deeply addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to address nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

239. Moreover, Defendants knew and should have known about the harm that their efforts had caused. Defendants closely monitored their sales and the habits of prescribing doctors, which allowed them to see sales balloon, overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended continuing medical education programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to and also watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

[75] *Id.*

240. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic non-cancer pain. However, the FDA's approval did not give Defendants license to misrepresent the risks, benefits, or side effects of opioids; if that were the case, there would be few limits on what a drug company could say about its product and little use for the FDA's rules on fair promotion.

241. Nor is Defendants' causal role broken by the involvement of doctors, professionals with the training and responsibility to make individualized medical judgments for their patients. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness – and indeed hijack – what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

G. Defendants Fraudulently Concealed their Misrepresentations

242. At all times relevant to this Complaint, Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.

243. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and relied on them to vouch for the accuracy and integrity of Defendants' untrue and unsupportable statements about opioid use for chronic pain.

244. Upon information and belief, while Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Upon information and belief, Defendants exerted their considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with key opinion leaders, front groups, and public relations companies that were not, and have not yet become, public.

245. Contrary to their competitive interest in promoting their own opioid products, Defendants disseminated their deceptive messages through websites that were unbranded (did not promote a specific drug) and therefore could not easily be tied to a particular drug company sponsor. Unbranded messaging created the appearance of neutrality and gave Defendants' marketing messages the appearance of neutral medical science. One example is painknowledge.org, ostensibly run by the National Initiative on Pain Control, which did not disclose Endo's involvement. Upon information and belief, Defendants, including Purdue and Janssen, ran similar websites that masked their own direct role in developing the content.

246. Upon information and belief, Defendants also obscured their participation by extensively using the public relations companies they hired to work with front groups to produce and disseminate deceptive materials. Also upon information and belief, Defendants may have created their own seemingly independent public relations or marketing companies to create campaign and education materials for opioids.

247. Much of Defendants' deceptive marketing occurred at medical conferences and through continuing medical education programs that were open only to registered medical professionals. Therefore, the People would have had no access to or awareness of their content.

248. Further, in addition to hiding their own role in the deceptive conduct, Defendants manipulated their promotional materials to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the People. Only in recent months have some of the KOLs whom Defendants relied upon and promoted to spread their deceptive messages acknowledged the lack of support for their positions.

249. Important elements of Defendants' unlawful conduct are only now becoming known. Revelations, for example, of Defendants' role in paying third parties for access to the

FDA and a voice in formulating standards for the clinical trials for approving new opioid drugs and indications was revealed only recently in an article in the WASHINGTON POST.[76] Defendants were well-aware of their activities, intent, and impact, but hid their influence from the public and from law enforcement and regulatory agencies.

250. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their marketing strategy, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the People now assert. The People were not alerted to the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the People of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

H. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to California Communities

251. Defendants' misrepresentations prompted doctors to prescribe, patients to take, and payers to cover opioids for the treatment of chronic pain. Defendants set out to overcome barriers to widespread prescribing of opioids – and succeeded – through a series of deceptive messages designed to address fears that opioids were dangerous for long-term use and addictive.

252. Defendants' fraudulent marketing caused consumers to purchase and use opioids believing they were safe and effective. In addition, consumers have had to bear the costs of the immediate and foreseeable results of chronic opioid therapy, including addiction treatment, emergency department admissions, intensive care treatment for infants born addicted to opioids, and other hospitalizations.

253. Defendants' deceptive marketing caused the use of opioids to explode. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the

[76] Peter Whoriskey, *Pharmaceutical firms paid to attend meetings of panel that advises FDA*, THE WASHINGTON POST, Oct. 6, 2013, *available at* http://www.washingtonpost.com/business/economy/pharmaceutical-firms-paid-to-attend-meetings-of-panel-that-advises-fda-e-mails-show/2013/10/06/a02a2548-2b80-11e3-b139-029811dbb57f_story.html.

population over 45 have used opioids."[77] Indeed, "[o]pioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid."[78] A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 even though the number of office visits in which patients complained of pain did not change; prescribing of non-opioid pain medications decreased over the same time.[79] For back pain alone – one of the most common chronic pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.[80] This increase corresponds with, and was caused by, Defendants' marketing push.

254. The sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse.[81] "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[82] Opioids are involved in 40% of fatal drug overdoses – including overdoses due to illegal drugs.[83] Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[84] According to the CDC, the 80% of opioid patients who take low-

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[77] Stagnitti, M.N., *Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006*, Statistical Brief #235, Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2006).

[78] Grady D, *et al*., *Opioids for Chronic Pain*, 171 Arch. Intern. Med. 1426, 1426 (Sept. 2011).

[79] Daubresse M, *et al*., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, Med. Care 2013; 51(10):870-78.

[80] Mafi J, *Worsening Trends in Management and Treatment of Back Pain*, JAMA Intern Med., 2013; 173(17):1573-1571.

[81] Cicero T, *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States*, Pharmacoepidemiology and Drug Safety, 2007; 16:827-840.

[82] Grady D, *et al*., *Opioids for Chronic Pain*, 171 Arch. Intern. Med. 1426, 1426 (Sept. 2011).

[83] Margaret Warner, Ph.D., Li Hui Chen, M.S., Ph.D., & Diane M. Makuc, Dr. P.H., *Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006*, U.S. Dep't of Health & Human Servs., 2 (Sept. 2009), *available at* www.cdc.gov/nchs/data/databriefs/db22.pdf.

[84] U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.[85] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

255. In California, the numbers are equally dramatic. There were just over 10 deaths from opioids for every 100,000 California residents in 2008, amounting to roughly 4,000 people.[86] That is almost double the number of homicides in the state (2,143) in the same year.[87] Santa Clara and Orange Counties have not been spared from this rise in opioid-related deaths. Indeed, in Orange County prescription opioids are responsible for a death every other day.[88]

256. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users.[89] Recent analysis by the CDC has documented increased rates of opioid abuse and addiction among women; nationally, every three minutes a woman goes to the emergency department for prescription painkiller misuse or abuse.[90] Every year since 2005, opioid use has caused 1,000 additional emergency room visits in California.[91] Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).[92]

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[85] Paulozzi L, *et al*., *CDC Grand Rounds: Prescription Drug Overdoses, a U.S. Epidemic*, Morbidity and Mortality Weekly Report, Jan. 13, 2012; 61(1):10-13.

[86] *Opioid Analgesics in California: Relieving Pain, Preventing Misuse, Finding Balance*, CMA, June 2013, at p. 4.

[87] Edmund G. Brown, Jr., Attorney General, *Homicide in California 2008*, California Department of Justice, 1 (March 2010), ag.ca.gov/cjsc/publications/homicide/hm08/preface.pdf.

[88] David Whiting, *Whiting: FDA Finally Starts to Tackle Opioid Epidemic*, ORANGE COUNTY REGISTER, Oct. 26, 2013, *available at* www.ocregister.com/articles/fda-533176-drug-country.html.

[89] Wilson M. Compton, M.D., M.P.E., *Prescription Drug Abuse: It's Not What the Doctor Ordered*, Nat'l Inst. On Drug Abuse, 11 (May 3, 2013), *available at* www.apa.org/about/gr/science/spin/2013/05/prescription-drug-abuse.pdf.

[90] CDC, Prescription overdose deaths are a growing problem among women, *available at* http://www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/.

[91] Substance Abuse and Mental Health Services Administration [SAMHSA], Treatment Episode Data Set [TEDS] 2000-2010, State Admissions to Substance Abuse Treatment Services, Table 1.9.a.

[92] *See* http://www.samhsa.gov/data/dawn/nations/Nation_2011_NMUP.xls.

257. The deceptive marketing and overprescribing of opioids also have had a significant detrimental impact on children in California. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. One study documented over 9,000 children nationally exposed to prescription opioids, with a median age of two years old; the number of exposures in young children correlated to the number of prescriptions in the area.[93] In addition, surveys of adolescents have shown that an alarming percentage of California teenagers have used prescription painkillers illicitly. The most recent California State Survey, conducted by the Attorney General, found that 12% of 9th graders and 19% 11th graders had used an opioid without a prescription and finds that opioids are "the most popular class of drugs after marijuana among high school students." Four percent and 7% of students, respectively, reported using opioids seven or more times.[94] Other research has found that more than half of the teenagers obtained the drugs from their own home and report that the drugs are easy to obtain.[95] A significant percentage of adolescents' suicide attempts are carried out with opioids.

258. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born and cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of

[93] Bailey, JE, Campagna, E, Dart, RC, *The under recognized toll of prescription opioid abuse on young children*, Ann. Emerg. Med., 2009 Apr. 53(4), 419-24.

[94] *See* http://www.wested.org/online_pubs/hhdp/css_13th_highlights.pdf.

[95] *See* http://www.adp.ca.gov/director/pdf/PDM_Tips_for_Educators.pdf.

impulse control, and a higher risk of future addiction.[96] When untreated, NAS can be life-threatening.[97] In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.[98] According to data from Tennessee, which has most closely studied the issue, 52% of mothers of NAS newborns used only drugs prescribed to them; another 20% used a mix of their own prescriptions and illicitly obtained drugs.[99]

259. Opioid addiction is the primary reason that individuals seek substance abuse treatment at California facilities, and admissions into treatment facilities more than doubled from 2006-07 to 2010-11.[100] Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction – buprenorphine and naltrexone – were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payers at $72.5 billion.[101]

260. Defendants' creation through false and misleading advertising of a virtually limitless opioid market has imposed significant burdens on the community at large. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplied both ends of the secondary market for opioids – providing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that "substantial increases in the nonmedical use of opioids is a predictable adverse effect of substantial increases in

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[96] Roland Gray presentation to FDA; *See* citations in FDA decision on Docket Nos. FDA-2013-P-1288 and FDA-2013-P-1289.

[97] *See*, FDA decision on Docket Nos. FDA-2013-P-1288 and FDA-2013-P-1289.

[98] Patrick S, *et al*., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures, United States 2000-2009*, JAMA Intern Med. May 9, 2012; 307(18).

[99] Jonel Aleccia, *'Just Flooding US': Tenn. Spike in drug-dependent newborns is warning to nation*, NBC NEWS, October 11, 2013.

[100] California Department of Alcohol and Drug Programs (ADP), Fact Sheet: Prescription Opioid Users in Treatment, Oct. 2012, at p. 2.

[101] Katz N, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, AmJManagCare, April 19 2013, p. 2, *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers/.

the extent of prescriptive use."[102] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[103]

261. In California counties like Orange County, the street value for a single tablet of OxyContin may range from $10 to $15. These prices have given rise to a significant black market in prescription opioids, which have not only created and supplied additional addicts, but fueled other criminal activities. In Orange County, for example, rings of "cappers and handlers" prey on homeless, indigent and seniors to buy their Medicare numbers or MediCal information to get prescription opioids.

262. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. According to one user interviewed by a local television station, "If you're doing 4, 5, 6, 7 Vicodin a day, you're already spending $30 or $40 on the pills. You know a bag of heroin is $20." Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids.[104] Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street." In the words of one federal Drug Enforcement Agency official, "[w]ho would have ever thought in this country it would be cheaper to buy heroin than pills and obtain them more easily. That is the reality we're facing."[105]

263. The toll on patients who abuse or become addicted to opioids does not lend itself to quantification, or even easy descriptions. Many of them will lose their jobs and some of them will

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[102] Alexander, *et al*., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, JAMA Intern Med., Nov. 14, 2012; 208(18):1865-66.

[103] Katz N, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, AmJManagCare, April 19 2013, p. 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

[104] NPR Staff, *With Rise of Painkiller Abuse, A Closer Look At Heroin*, NPR, Nov. 2, 2013, *available at* www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[105] Matt Pearce and Tina Susman, *Philip Seymour Hoffman dies amid major comeback of heroin in the U.S.*, LA TIMES, Feb. 3, 2014.

lose their homes and their families. Some of them will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. As noted above, some will become so desperate for drugs that they will switch to heroin – moving from taking prescription drugs, to buying and even injecting illegal drugs. Of those who continue to take opioids, some will overdose – some fatally, some not. Others will die prematurely from related causes – falls, traffic accidents, or assaults or from premature heart or neurological disease that hastens their death by 10 or 20 years.

FIRST CAUSE OF ACTION

FALSE ADVERTISING

Violations of California Business and Professions Code Section 17500, *et seq*.
Against all Defendants

264. The People reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

265. California Business and Professions Code Section 17500 ("Section 17500") makes it unlawful for a business to make, disseminate, or cause to be made or disseminated to the public "any statement, concerning … real or personal property … which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

266. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Section 17500 by making and disseminating untrue, false, and misleading statements about the use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to the general public. In addition, Defendants repeatedly failed to disclose material facts about the risks of opioids.

267. Defendant Purdue made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Posting misleading statements and pamphlets, concerning the risk of addiction and the misleading concept of pseudoaddiction;
- Distributing brochures to doctors that included misleading statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributed and assisted in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleading concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and

- Exclusively disseminating misleading statements in education materials to California hospital doctors and staff while purportedly educating them on new pain standards created by JCAHO.

268. Defendant Endo made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials and programs that contained misleading statements;
- Facilitating the posting of misleading statements and pamphlets concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations – including over $10 million to the most egregious organization – that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleading concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life; and
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

269. Defendant Janssen made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials and programs that contained misleading statements concerning the risk of addiction;

- Facilitating the posting of misleading statements and pamphlets, concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;
- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain; and
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

270. Defendant Cephalon made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Endorsing, directly distributing and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain, and which did not concern cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded Cephalon's opioids (approved only for cancer pain) are safe and effective for the long-term treatment of chronic non-cancer pain; and
- Targeting its marketing to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs.

271. Defendant Actavis made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Providing significant financial support to pro-opioid key opinion leader who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain.

272. Such omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. All of this conduct, separately and collectively, was likely to deceive California payers who purchased, or covered the purchase of, opioids for chronic pain.

273. Defendants engaged in the widespread promotion of opioids for the treatment of chronic pain directly through their own publications and employees, and indirectly through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements

and representations to doctors and patients. Defendants made untrue, false, and misleading statements and representations about the benefits, risks, and superiority of opioids.

274. Defendants knew, or by the exercise of reasonable care should have known, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the benefits, risks, and superiority of opioids.

275. Pursuant to California Business and Professions Code Section 17535, Plaintiff requests an order from this Court enjoining Defendants from any further violations of Section 17500, *et seq*.;

276. Pursuant to California Business and Professions Code Section 17535, Plaintiff requests restitution of any money acquired by Defendants' violations of Section 17500, *et seq*.;

277. Pursuant to California Business and Professions Code Section 17536, Plaintiff requests an order assessing a civil penalty of two thousand five hundred dollars ($2,500) against Defendants for each violation of Section 17500, *et seq*.

SECOND CAUSE OF ACTION

UNFAIR COMPETITION

Violations of the Unfair Competition Law
California Business and Professions Code Section 17200
Against all Defendants

278. The People reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

279. Each Defendant is named in this Count for its activities that occurred within four years of the filing of this action.

280. California Business and Professions Code Section 17200 ("Section 17200") prohibits any "unlawful, unfair or fraudulent business act or practices." Defendants have engaged

in unlawful, unfair and fraudulent business practices in violation of Section 17200 as set forth above.

281. Defendants' practices as described in this Complaint are deceptive business practices that violate Section 17200 because the practices are likely to deceive consumers in California. Such practices include, but are not limited to, the following:

> Defendants engaged in the widespread promotion of opioids for the treatment of chronic pain directly through their own publications and employees, and indirectly, through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements and representations to doctors and patients. Defendants' untrue, false, and misleading statements and representations involve overstating the benefits of opioids to treat chronic pain and their superiority over alternate treatments and minimizing their serious risks, including the risks of addiction, overdose, and death.

282. Defendants knew, or by the exercise of reasonable care should have known, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

283. Such omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids false, and misleading. All of this conduct, separately and collectively, was likely to deceive California payers who purchased, or covered the purchase of, opioids for chronic pain.

284. Defendants' practices as set forth in this Complaint are also unlawful business practices that violate Section 17200. These unlawful practices include, but are not limited to:

a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 110390.

b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 110395.

c. Defendants advertised misbranded opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 110398.

d. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 110400.

e. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 111440.

f. Defendants misbranded opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 111445.

g. Defendants received in commerce opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 111450.

h. Defendants proffered for delivery opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, CAL. HEALTH & SAFETY CODE § 111450.

i. Defendants failed to adopt a Comprehensive Compliance Program in violation of CAL. HEALTH & SAFETY CODE § 19402.

j. Defendants represented that opioids had sponsorship, approval, characteristics, ingredients, uses, or benefits which they did not have in violation of the Consumer Legal Remedies Act, CAL. CIV. CODE § 1770(a)(5).

k. Defendants represented that opioids were of a particular standard, quality, or grade when they were of another in violation of Consumer Legal Remedies Act, CAL. CIV. CODE § 1770(a)(7).

l. Defendants disparaged the goods of another by false or misleading representation of fact in violation of Consumer Legal Remedies Act, CAL. CIV. CODE § 1770(a)(8).

m. Defendants made or disseminated, directly or indirectly, untrue, false, or misleading statements about the use of opioids to treat chronic pain, or causing untrue, false, or misleading statements about opioids to be made or disseminated to the general public in violation of Section 17500.

n. Defendants formed and operated a conspiracy, committed wrongful acts pursuant to that conspiracy, and damaged the People in violation of the California Common Law of Civil Conspiracy.

o. Defendant Purdue continued to deceptively market OxyContin after 2007, in violation of the terms of the 2007 Consent Judgment with the State of California.

285. Defendants' practices as set forth in this Complaint are also unfair business practices that violate Section 17200 because they offend established public policy, and because the harm they cause to consumers in California greatly outweighs any benefits associated with those practices.

286. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Unfair Competition Law described in this Complaint.

287. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained a competitive unfair advantage over similar businesses that have not engaged in such practices.

288. Each time a Defendant marketed opioids in violation of Section 17200 constituted a separate violation. CAL. BUS. & PROF. CODE § 17206(b). Plaintiff therefore seeks civil penalties up to $2,500 per violation pursuant to Section 17206 for each violation of Section 17200. Plaintiff also seeks civil penalties up to $2,500 per violation under Section 17206.1.

THIRD CAUSE OF ACTION

PUBLIC NUISANCE

Violations of California Civil Code Section 3479, *et seq.*
Against all Defendants

289. The People reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

290. California Civil Code Section 3479 provides that "[a]nything that is injurious to health … or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property … is a nuisance."

291. California Civil Code Section 3480 defines a "public nuisance" as "one which affects at the same time an entire community or neighborhood, or any considerable number of

persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."

292. Pursuant to Section 731 of the California Civil Code, this action is brought by the People to abate the public nuisance created by the Defendants.

293. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Californians or interferes with the comfortable enjoyment of life in violation of California Civil Code Sections 3479 and 3480.

294. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused harm to the community, includes, but is not limited to:

a. Upwards of 30% of all adults have used them. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths. In recent years, California deaths from opioids have exceeded deaths by homicide by nearly a factor of two.

b. Children too have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among California teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Californians who have never taken opioids also have suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. More broadly, opioid use and misuse have driven Californians' health care costs higher.

e. Employers have lost the value of productive and healthy employees who suffered from adverse consequences from opioid use.

f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids have increased the demands on emergency services and law enforcement in the Counties.

i. All of this has caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the People of California.

k. The Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

295. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

a. Defendants have engaged in massive production, promotion and distribution of opioids for use by the People of the State of California.

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

c. Defendants misrepresented the benefits of opioids for chronic pain and by fraudulently concealing, misrepresenting, and omitting the serious adverse effects of opioids, including the addictive nature of the drugs.

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

296. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the least, a substantial factor in

doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

297. The health and safety of the citizens of the jurisdictions, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the jurisdictions' citizens and residents.

298. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

299. Defendants' conduct has affected and continues to affect a considerable number of people within the Counties and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

300. Pursuant to California Code of Civil Procedure Section 731, Plaintiffs request an order from the Court on behalf of the People of the State of California providing for abatement of Defendants' ongoing violations of California Civil Code Sections 3479 and 3480, and enjoining Defendants from future violations of California Civil Code Sections 3479 and 3480.

301. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury and each Defendant is jointly and severally liable for abating it.

V. PRAYER FOR RELIEF

THE PEOPLE pray that the Court:

302. Declare that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law.

303. Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law.

304. Order Defendants to pay restitution of any money acquired by Defendants' false and misleading advertising, pursuant to Business and Professions Code sections 17500 and 17535 of the False Advertising Law.

305. Order Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to Business and Professions Code Sections 17500 and 17536 of the False Advertising Law.

306. Declare that Defendants have engaged in unlawful, unfair, and deceptive business acts and practices in violation of the Unfair Competition Law.

307. Enjoin Defendants from performing or proposing to perform any acts in violation of the Unfair Competition Law.

308. Order Defendants to pay restitution of any money acquired by Defendants' unlawful, unfair, and deceptive business practices, pursuant to Business and Professions Code section 17203 of the Unfair Competition Law.

309. Order Defendants to pay civil penalties for each act of unfair and unlawful competition, pursuant to Business and Professions Code section 17206 of the Unfair Competition Law.

310. Order Defendants to pay civil penalties for each act of unfair and unlawful competition perpetrated against senior citizens or disabled persons, pursuant to Business and Professions Code section 17206.1 of the Unfair Competition Law.

311. Order Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code section 3345.

312. Declare that Defendants have created a public nuisance in violation of California Civil Code Sections 3479 and 3480.

313. Enjoin Defendants from performing any further acts in violation of California Civil Code Sections 3479 and 3480.

314. Order Defendants to abate the public nuisance that they created in violation of California Civil Code Sections 3479 and 3480.

315. Order Defendants to pay the cost of the suit, including attorneys' fees.

316. Provide such further and additional relief as the Court deems proper.

DATED: June 6, 2014.

OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA

By_____
for Danny Chou

70 West Hedding Street
East Wing, 9th Floor
San Jose, CA 95110
Telephone: (408) 299-5900
Facsimile: (408) 292-7240

ORANGE COUNTY DISTRICT ATTORNEY

By_____
Tony Rackauckas

401 Civil Center Drive
Santa Ana, CA 92701-4575
Telephone: (714) 834-3600
Facsimile: (714) 648-3636

ROBINSON CALCAGNIE ROBINSON SHAPIRO DAVIS, INC.
Mark P. Robinson, Jr. (SBN 54426)
mrobinson@rcrlaw.net
Kevin Calcagnie (SBN 108994)
kcalcagnie@rcrlaw.net
Daniel S. Robinson (SBN 244245)
drobinson@rcrlaw.net
Scot D. Wilson (SBN 223367)
swilson@rcrlaw.net
19 Corporate Plaza Drive
Newport Beach, CA 92660
Telephone: (949) 720-1288
Facsimile: (949) 720-1292

315. Order Defendants to pay the cost of the suit, including attorneys' fees.

316. Provide such further and additional relief as the Court deems proper.

DATED: June 6, 2014.

OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA

By_____
Danny Chou

70 West Hedding Street
East Wing, 9th Floor
San Jose, CA 95110
Telephone: (408) 299-5900
Facsimile: (408) 292-7240

ORANGE COUNTY DISTRICT ATTORNEY

By Tony Rackauckas
Tony Rackauckas

401 Civil Center Drive
Santa Ana, CA 92701-4575
Telephone: (714) 834-3600
Facsimile: (714) 648-3636

ROBINSON CALCAGNIE ROBINSON SHAPIRO DAVIS, INC.
Mark P. Robinson, Jr. (SBN 54426)
mrobinson@rcrlaw.net
Kevin Calcagnie (SBN 108994)
kcalcagnie@rcrlaw.net
Daniel S. Robinson (SBN 244245)
drobinson@rcrlaw.net
Scot D. Wilson (SBN 223367)
swilson@rcrlaw.net
19 Corporate Plaza Drive
Newport Beach, CA 92660
Telephone: (949) 720-1288
Facsimile: (949) 720-1292

COHEN MILSTEIN SELLERS & TOLL PLLC
Linda Singer
lsinger@cohenmilstein.com
Pro hac to be submitted
Eric Harrington (SBN 257178)
eharrington@cohenmilstein.com
1100 New York Ave NW, Suite 500 West
Washington, DC 20005
Telephone: (202) 408-4600
Facsimile: (202) 408-4699

HAGENS BERMAN SOBOL SHAPIRO LLP
Steve W. Berman
steve@hbsslaw.com
Pro hac to be submitted
Thomas E. Loeser (SBN 202724)
tomloeser@hbsslaw.com
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

HAGENS BERMAN SOBOL SHAPIRO LLP
Elaine Byszewski (SBN 222304)
elaine@hbsslaw.com
301 North Lake Avenue, Suite 203
Pasadena, CA 91101
Telephone: (213) 330-7150

HAGENS BERMAN SOBOL SHAPIRO LLP
Jennifer Fountain Connolly
jenniferc@hbsslaw.com
Pro hac to be submitted
1701 Pennsylvania Ave., NW, Suite 300
Washington, DC 20006
Telephone: (202) 248-5403
Facsimile: (202) 580-6559

A Policymaker's Guide
to Understanding Pain & Its Management

American Pain Foundation
A United Voice of Hope and Power over Pain

Pain is a complex experience that differs enormously from one person to another, even among those with seemingly identical injuries or illnesses.

ABOUT THE AMERICAN PAIN FOUNDATION

Founded in 1997, the American Pain Foundation (APF) is an independent, nonprofit 501(c)3 and the largest national advocacy organization serving people affected by pain. APF speaks out with people living with pain, caregivers, health care providers and allied organizations, working together to dismantle the barriers that impede access to quality pain care for all.

OUR MISSION

The American Pain Foundation educates, supports and advocates for people affected by pain.

A Policymaker's Guide
to Understanding Pain & Its Management

PURPOSE OF THIS GUIDE

Policymakers within the federal or state government and regulatory agencies must keep in mind that they represent Americans who live with pain, many of whom have pain every day of their life.

Because pain can and should be treated as a legitimate medical condition just like diabetes, hypertension, obesity and cancer, the American Pain Foundation (APF) has developed this guide as a primer on pain and its management to help meet the informational needs of busy policymakers and their staff members. We know pain is a complex topic, and hope you will find this to be a useful resource in your work to help shape positive, balanced pain policies.

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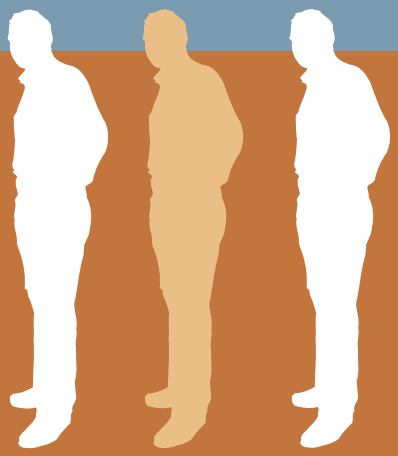
PAIN AFFECTS EVERYONE

Chronic pain affects
1 in 3
Americans, according to the Institute of Medicine.



Consider the following…

- Most Americans eight in 10 will suffer from back pain at some point in their lives.
- As we age, arthritis hinders the normally smooth sliding motion of our joints and connective tissues, resulting in stiffness and discomfort. Arthritis is the leading cause of disability in people over the age of 55.
- Pain associated with pediatric immunizations is a significant source of anxiety for children receiving immunizations, and evidence suggests that the way children and parents cope can set the stage for future pain responses.
- Damage to or dysfunction of the central nervous system due to stroke, multiple sclerosis and brain or spinal cord injuries also stimulates pain pathways. Undertreated or poorly treated acute pain can manifest as chronic pain for the same reasons.
- An estimated 30 to 50 percent of individuals undergoing active treatment for cancer and 70 percent of those with advanced stages of the disease experience significant levels of pain and may be reluctant to discuss their pain with their health care providers.
- Pain continues to rank among the top medical complaints of active duty military personnel and veterans. An estimated nine out of 10 Iraq and Afghanistan veterans reportedly return home with some type of pain.

Sources: The American Academy of Physical Medicine and Rehabilitation, Arthritis Foundation, Mayday Fund, National Institute of Neurological Disorders and Stroke, National Cancer Institute.

Introduction

Everyone has experienced pain — whether it is a pounding headache at the end of a long day, a throbbing toothache warning of a cavity or infection, a cut or sprained ankle from a fall, or a stinging burn from touching a hot pan. There are also hundreds of pain syndromes, and pain is often a chief complaint with most chronic medical conditions, including cancer, diabetes, arthritis, fibromyalgia and a host of neurological disorders.

While acute pain serves as nature's biological red flag that something is wrong, pain that persists beyond the expected point of healing has no physiological value — in a sense, the nervous system has broken. For many Americans, pain is a constant and unwanted companion and it's only when someone is in the grips of pain that they truly know how agonizing and life-limiting it can be.

If untreated, pain can significantly infringe on a person's quality of life and productivity. Aside from the human suffering, untreated pain exacts a tremendous financial toll on individuals and society at large.

COMMON TYPES OF PAIN

Acute Pain — usually has a clear cause and signals a problem	**Chronic — continues beyond the expected point of recovery**
• Postoperative pain • Dysmenorrhea (severe menstrual pain) • Chest pain signaling a heart attack • Post-traumatic pain: Cuts, scrapes, bruises, fractures • Mild stress or sinus headache • Epigastric pain from cardiac problems, gastroesophageal reflux disease (GERD) or other digestive disorder • Sudden, severe headache signaling stroke or brain aneurysm	• Persistent back or neck pain from an injury • Migraine • Arthritis • Phantom limb pain • Shingles/postherpetic neuralgia • Neuropathic pain due to damage to the central nervous system from diabetes, cardiovascular disease, cancer treatment (surgery, chemotherapy, radiation therapy), spinal cord injury, stroke, blast injury

BURDEN OF PAIN IN AMERICA: AN EVOLVING PUBLIC HEALTH CRISIS

Pain is a serious and costly public health issue. Chronic pain affects 116 million American adults that's one out of every three yet it remains misunderstood. It afflicts more people than diabetes, heart disease and cancer combined, and is a leading cause of disability in the United States. Even though pain is one of the most common reasons patients consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering and poor patient outcomes.

Untreated or poorly managed pain can compromise every aspect of life including a person's:

- physical and mental health,
- social and intimate relations,
- ability to sleep and perform everyday tasks,
- work productivity, and
- financial well-being.

Chronic pain is not only emotionally and physically debilitating for the individual, it also places a tremendous burden on family members and caregivers, and contributes to excessive health care costs. Pain costs the U.S. an estimated $635 billion in health care expenses and lost productivity each year.[1]

Health care providers and policymakers will soon see a substantial increase in the number of people needing treatment for chronic pain when the 75 million baby boomers move into their late 60s and 70s in the coming years. This uptick will not only affect providers, but it is also expected to increase the cost of chronic pain in the U.S.

[1] Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. June 2011 brief report. Available at www.iom.edu/relievingpain.

Treating and managing pain is an integral part of clinical care in primary care settings and across all specialties. Pain management matters; **it guards against needless suffering, improves quality of life and productivity and can cut health care costs.**

Even though pain is one of the most common reasons patients consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering and poor patient outcomes. It also costs the nation $635 billion in medical treatment and lost productivity every year.

SOME COMMON MISCONCEPTIONS ABOUT PAIN

Pain is "all in your head." Although our brains process the perception of pain, this does not mean that pain is imaginary when the source of pain is not well understood. Pain is all too real to the person who lives with it on a daily basis.

Pain is inevitable; you must learn to tolerate it and suffer in silence. Pain traditionally has been viewed as an inevitable consequence of a disease or condition. The fact is most pain can be relieved with proper pain management.

Pain is a natural part of growing older. While pain is more common as we age, because conditions that cause pain (e.g., arthritis, degenerative joint diseases, cancer, shingles, osteoporosis) are more frequent in older adults, it should not be something people have to endure untreated.

All pain is the same. Many studies failed to find that similar pain stimuli will produce the same pain level intensity. There is an individual difference when sensation is first recognized as painful (pain threshold). There is a difference with pain intensity that each person is able to accept (pain tolerance). Identical injuries can be described differently by sensation and intensity.

The best judge of pain is the physician or nurse. There is little relationship between what a physician or nurse might "guess" about a person's pain and their actual pain experience. The person with pain is the authority on the existence and severity of his/her pain. His or her self-report is the most reliable indicator.

Seeking medical care for pain is a sign of weakness. Pain carries a stigma, and many people are hesitant to talk about their pain and how it affects their daily life; they also don't want to be considered a "bad" or high-maintenance patient.

Use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit www.painsafe.org.

Pain is complex and frequently misunderstood by the public, policymakers, and even health care providers. The issue of pain is riddled with myths and misconceptions, which makes the task of informing and educating people about pain and its management that much more challenging.

Unfortunately, too many Americans are not getting the pain care they need and deserve.

Some common reasons for difficulty in obtaining adequate care include:

- Lack of access to care because of too few trained professionals and problems with insurance coverage.
- Limited or no professional training in pain management, which leaves health care providers ill-equipped to respond effectively to their patients' reports of pain.
- Cultural norms and the stigma associated with admitting pain.
- Restrictive or ambiguous state laws governing health care practice relating to pain care.
- Misconceptions about opioid addiction.
- Concerns among providers about prescribing pain medications for chronic pain, and fears of scrutiny by regulators or law enforcement.
- Persisting disparities leaving certain populations vulnerable to denials of appropriate pain treatment (e.g., infants and children, women, minorities and certain ethnic groups, the elderly, the institutionalized including those in the prison system).

While pain is a symptom of many chronic diseases and is expected after many surgical procedures, persistent pain should not be viewed simply as a symptom. Ongoing pain is a sign that something is wrong in the body.

POLICY AFFECTS PAIN MANAGEMENT PRACTICE

Regulation and legislation can have a significant effect on the practice of pain management and access to care, much like it does for other health conditions such as HIV/AIDS and breast cancer. Policymakers and health care regulators play an active role in the development of laws governing pain treatment; however, a number of factors can influence the content and messages of such policies, affecting public access to pain care treatment options. For example, availability of prescription opioid analgesic medications especially may be hindered by restrictive state policies, and therapeutic switching and/or step therapies imposed by insurance companies may limit pain treatment options.

KEY CHALLENGES TO CONSIDER WHEN WORKING TO IMPROVE PAIN-RELATED POLICY

- Persisting social stigma of pain management and the medical use of opioid pain medications, especially among legal and government regulatory bodies.
- Lack of awareness of current state policy content.
- Predominant focus on abuse and diversion of opioid analgesics. While abuse and diversion of prescription pain medication is certainly a problem that can have tragic consequences, so too are policies that hinder access to safe and effective pain care for those with legitimate medical need. The little attention paid to access to care for those with addictive disease or mental health disorders compound this issue.
  - As a group, lawmakers, educators, health care providers, the pharmaceutical industry, and caregivers could address the dual public health crises of the undertreatment of pain and rising prescription drug abuse together.[2]
- Outdated terminology that confuses physical dependence with addiction and has the potential to stigmatize people with pain as addicts and restrict prescribing practices.
- Lack of sufficient treatment resources and no clear definition of what constitutes a pain expert.
- Lack of reimbursement or support for pharmacological and nonpharmacological treatments for pain. Yet, there is increasing evidence that a multimodal treatment approach leads to better outcomes, gets people back to work sooner and costs less over the long run.
- Poor communication and/or implementation of policy that may unintentionally harm patients or limit access to pain therapies. Even if the substance of a policy upholds pain treatment as integral to the provision of quality medical care, sometimes the implementation of a policy can negatively affect the clinical practice of pain care. Intractable pain treatment acts are one example (see APF's *Pain Care Policy Topic Brief* for more information).

[2] American Pain Foundation. Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management — A Roundtable Discussion. April 2008. Available at www.painfoundation.org.

BURDEN OF PAIN IN AMERICA: AN EVOLVING PUBLIC HEALTH CRISIS

Pain is a serious and costly public health issue. It affects more American adults than diabetes, heart disease and cancer combined, and is a leading cause of disability in the United States. Even though pain is one of the most common reasons people consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering, poor outcomes and reduced quality of life and productivity.

Pain is a complex perception that differs enormously from one person to another, even those with seemingly identical injuries or illnesses.

Untreated or undertreated or inappropriately treated pain can compromise every aspect of life, including a person's physical and mental health, social and intimate relations, ability to sleep and perform everyday tasks, work productivity and financial well-being.

Persistent pain is not only emotionally and physically debilitating for patients, it also places a tremendous burden on families and caregivers, and contributes to excessive health care costs. Chronic pain costs the nation an estimated $635 billion in medical treatment and lost productivity each year. As the 75 million baby boomers move toward retirement, the epidemic of untreated or undertreated pain is expected to rise.

Chronic pain affects 1 out of 3 Americans — or an estimated 116 million adults, according to the Institute of Medicine.

PAIN BASICS

The International Association for the Study of Pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. In 1968, Margo McCaffery, RN, a pioneer in the field of pain management nursing, stated pain is "whatever the experiencing person says it is, existing whenever and wherever the person says it does."

COMMON PAIN CONDITIONS

In a National Center of Health Statistics survey, the following are common types of pain:

- low back pain (27 percent)
- severe headache or migraine pain (15 percent)
- neck pain (15 percent)
- facial ache or pain (4 percent)

See: http://www.painfoundation.org/media/resources/pain-facts-figures.html.

At its best, acute pain is the body's natural alarm system, alerting us to injury (or further injury if already injured). It prompts us to stop a harmful behavior or seek medical attention. For example, lifting too much weight might result in a piercing pain in a person's back. Within moments of touching a hot surface, the fiery sensation of a burn warns us to quickly pull away. Worsening abdominal pain may be a sign of appendicitis or other serious infection. The experience of pain also beckons the injured person to rest, promoting healing.

At its worst, persistent pain robs people of their livelihood and well-being. When pain persists, it is often a sign that the body's alert system has broken down. In other words, pain signals remain active. Over time, this heightened response may:

- Harm the nerves, blood vessels and organs
- Suppress immune function
- Result in excessive inflammation
- Delay healing

Since the brain remembers pain, pain may be imprinted into the nerve tissue and continue to send pain sensations even in the absence of painful stimuli. This change in the nervous system means that pain has now evolved into disease state with no physiological meaning or value.

Chronic Pain-Brain Connection

New research is unraveling how chronic activation of the biological pathways transmitting pain is associated with structural and chemical changes in the brain. A recent study suggests that constant pain signals can result in mental rewiring that affects the frontal cortex — the area of the brain mainly associated with emotion and attention. According to researchers, this provides the first objective proof of brain disturbances in people with chronic pain that is unrelated to the sensation of physical pain. Functional magnetic resonance imaging reveals changes in brain activity and sensitization in people with pain.

TYPES OF PAIN

	Acute	Chronic
Cause	Generally known	May be known, but often unknown
Duration	Short, well described	Prolonged beyond healing ≥ 3 months
Onset	Usually sudden	Sudden or gradual development
Treatment	Resolve underlying cause; self-limiting	Focus on underlying cause, if known, and pain disorder: pain reduction, function improvement, minimize side effects
Prognosis	Total relief typically possible	Total relief often impossible

Acute pain occurs suddenly due to illness, inflammation, injury or surgery. It has a short duration that subsides when the injured tissue heals. The cause of the pain can usually be diagnosed and treated.

Persistent (chronic) pain is pain that lasts long enough (after normal healing or for at least three months), or is intense enough, to affect a person's normal activities and well-being. Failure to treat acute pain promptly and appropriately at the time of injury, during initial medical and surgical care or at the time of transition to community-based care, contributes to the development of chronic pain syndromes. Every time someone undergoes surgery in which nerves and tissue are cut, he or she is at risk for ongoing pain if their initial pain is not addressed or their pain processing is altered during healing.

With chronic pain, pain signals may remain active in the nervous system for weeks, months or even years. Unlike acute pain, chronic pain has no value or benefit; it is a disease in its own right. It can also be especially challenging to treat.

PAIN ASSESSMENT

Timely access to quality pain management is the best way to minimize the suffering and disability often associated with undertreated pain and to avoid additional problems down the road.

Most hospitals, nursing homes and other health care facilities are now required to assess and treat pain. To correctly diagnose pain, a health care professional will:

- Perform a thorough physical exam
- Complete a pain assessment
- Ask detailed questions about the individuals's medical history and lifestyle
- Order blood work, X-rays, electrical tests to detect nerve damage, or other diagnostic and laboratory tests

Pain is a subjective experience, and it is critical for health care providers to have a complete picture of the patient's pain history. He/she may ask about seven characteristics of pain to help LOCATE the pain and make the correct diagnosis.

L the exact Location of the pain and whether it travels to other body parts
O Other associated symptoms such as nausea, numbness or weakness
C The Character of the pain, whether it's throbbing, sharp, dull or burning
A Aggravating or Alleviating factors. What makes the pain better or worse?
T the Timing of the pain, how long it lasts, is it constant or intermittent?
E the Environment where the pain occurs, for example, while working or at home

The type of pain someone is experiencing is often a clue to its cause; for example, persistent pain that is burning or tingling is often the result of nerve disease (neuropathy).

EFFECTS OF UNRELIEVED PAIN ON PHYSICAL AND MENTAL HEALTH

If untreated, pain can have serious physiological, psychological and social consequences. It can:

- Limit the ability to work, sleep, exercise or perform everyday tasks (for example, dressing, going to the grocery store, lifting a child)
- Reduce mobility
- Impair strength
- Diminish appetite
- Make it difficult to recover from an injury or fight infection by weakening the immune system
- Aggravate other health problems
- Lead to depression and/or anxiety, which often worsen pain sensations
- Make it difficult to concentrate or reason
- Place added strain on relationships and interfere with intimacy
- Result in a loss of self-esteem and independence

Pain intensity scales are additional tools available to help individuals with pain describe only one feature of their pain, its intensity These assessment tools help health care providers better understand the level of pain experienced at rest, during activities and how it varies throughout the day. These include numeric, verbal or visual scales.

With **numerical scales**, patients use numbers from 0 to 10 (0 being no pain and 10 being the worst pain ever) to rate the intensity of the pain.

Verbal scales contain commonly used words such as "mild," "moderate" and "severe" to help patients' describe the severity of the pain.

Visual scales use aids like pictures of facial expressions, colors or gaming objects, such as poker chips, to help explain the severity of pain. One type, the Wong Baker Faces Pain Rating Scale, shows six different facial expressions from happy (no hurt) to agony (hurts the worst) to help show health care providers how much pain a patient feels. Body diagrams may also be used to help pinpoint where the pain occurs.

From Hockenberry MJ, Wilson D, Winkelstein ML: *Wong's Essentials of Pediatric Nursing*, ed. 7, St. Louis, 2005, p. 1259. Used with permission. Copyright, Mosby.

Multidimensional pain assessment tools, such as the McGill Pain Questionnaire (MPQ) and the Brief Pain Inventory (BPI), have been developed to quantify different aspects of pain, including location and quality of pain and its effect on mood and function. However, these take longer to administer than the simpler scales and some patients who are cognitively impaired or poorly educated may find them difficult to complete. They are generally used in pain research, and have been adapted for clinical use in many settings.

The processing of pain is complex. A basic explanation is that the pain signals of acute pain are initiated when receptors on the skin, within an organ, tissue or nerve are triggered by injury or disease, known or unknown. A series of events follow: an electrical impulse, or pain message, is generated that is then carried on nerve fibers to the spinal cord. The spinal cord transmits the pain signal to various levels of the brain for interpretation and response. At any time during the transport of pain messaging, these noxious signals can be blocked, enhanced or modified. Signaling associated with chronic pain is much more complicated than acute pain as science is beginning to show.

TREATING PAIN

Successful pain management aims to:

1) lessen the pain,
2) improve functioning and
3) enhance quality of life.

Pain treatment should be:

- patient-centered — tailored to the individual
- multimodal — use a variety of pain treatment options
- multidisciplinary — involve a team of health care providers working directly with the person with pain, caregivers and family members as needed

Not one treatment strategy will work for everyone — a "cookie cutter" approach to pain care is ineffective.

Treatment options may include:

- Medication (anti-inflammatory medicines, opioids or other classes of medications called adjuvants)
- Psychosocial interventions (cognitive-behavioral counseling, guided imagery)
- Rehabilitative approaches (exercise, application of heat/cold, myofascial release, occupational therapy, if needed)
- Complementary alternative medicine (massage, acupuncture, hypnosis)
- Injection or infusion therapies
- Implantable devices and surgical procedures

Research shows that pain can affect one's emotions and behavior and interfere with the ability to concentrate, manage everyday tasks and cope with stress. Likewise, stress and emotional pressures can make pain worse, provoking "flare ups" and contributing to alterations in the immune system response. These relationships are not always easily recognized or readily fixed by medical procedures or medications alone.

New treatments under investigation are aimed at the physical, psychological and environmental components of chronic pain. Research is also examining the role of genetic predisposition and the immune system in mitigating pain signals.

For a detailed description of the different treatment modalities for managing pain, please refer to the America Pain Foundation's *Treatment Options: A Guide for People Living with Pain.*

PainSAFE (Pain **S**afety & **A**ccess **f**or **E**veryone), www.painsafe.org, includes information and tips for consumers and clinicians on the safe and appropriate use of pain therapies.

MEDICATIONS & PAIN MANAGEMENT

Medications play an important role in the treatment of pain. There are three major classes of medications for pain control:

Non-opioids: nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen

Opioids: morphine, oxycodone, methadone, codeine and fentanyl are examples

Adjuvant analgesics: a loose term referring to the many medications originally used to treat conditions other than pain, but now are used to help relieve specific pain problems; examples include some antidepressants and anticonvulsants. Some of these medications have been shown to work well for specific types of pain.

Medications that have no direct pain-relieving properties may also be prescribed as part of a pain management plan. These include medications to treat insomnia, anxiety, depression and muscle spasms, and can help a great deal in the overall management of pain in some individuals.

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Topic Brief

THE FDA, REMS AND THE POTENTIAL IMPACT ON ACCESS TO PAIN TREATMENTS

The U.S. Food and Drug Administration (FDA) regulates new drug approvals, product labeling for both prescription and over-the-counter (OTC) medications and the manufacturing process. When reviewing new drug applications, the agency carefully weighs the benefits and risks of each medication.

New laws also give the FDA authority to regulate these products after they have been approved. Such expanded jurisdiction over prescription and OTC medications is well-intended to help ensure additional oversight of medications after they come to market and provide extra safeguards for medication safety.

Because of its role in regulating controlled substances, including ingredients in pain medication, the Drug Enforcement Agency (DEA) is also influential in shaping federal pain policy and regulations. The non-medical use and abuse of prescription drugs has become a serious public health issue. Both FDA and DEA are involved with pain medication regulation in an attempt to curb the misuse and diversion of these medications, while at the same time ensuring access for people with legitimate medical need. The challenge — and concern — is that new policies to curb the non-medical use of various prescription medications could end up interfering with legitimate access to treatments for certain patient populations, most notably people living with persistent pain.

POST-APPROVAL DRUG REGULATION

In 2007, the Food and Drug Administration Amendments Act (FDAAA) gave the FDA authority to regulate drugs after they are approved.

As part of this charge, the FDA has been working with the pharmaceutical industry and consumer stakeholders to develop Risk Evaluation and Mitigation Strategies, or REMS, for a number of classes of medications, including opioid analgesics. Opioids are often a necessary part of a comprehensive pain management plan for certain patients with moderate to severe pain to help alleviate pain, restore functioning and improve quality of life. See APF's *Chronic Pain and Opioid Therapy Topic Brief* for more information.

In February 2009, the FDA sent letters to the manufacturers of 24 short- and long-acting opioid medications announcing they will be required to institute REMS to ensure the benefits of the medications outweigh the risks, such as those related to misuse, abuse and overdose. New opioid medications will require REMS; some of the long-acting and rapid-onset opioids that are currently available by prescription already have REMS.

As of March 2010, more than 100 medications have REMS in place. Strategies for reducing risk of harm or misuse can range from providing basic patient and prescriber information and education packets or mandating continuing education for pharmacists and prescribers to restricting channels of distribution for certain medications and requiring patients to sign on to a registry.

It is well documented and widely understood that pain is undertreated or poorly treated for millions of people. FDAAA states that REMS should not place undue burden on access to care for those with legitimate need. The REMS process is well-intended and is meant to ensure the safe use of medications in part by helping to ensure proper patient selection (an opioid tolerant individual who has low risk for misuse or becoming addicted) and requiring patient education on how to safely store and dispose of these medicines so they don't fall into the wrong hands. However, the American Pain Foundation (APF) — along with other leading consumer and provider organizations in the pain community — is concerned that the REMS process, while well-intentioned, will erect new barriers to timely and appropriate pain care.

REMS MAY UNINTENTIONALLY THREATEN ACCESS TO CARE FOR PEOPLE WITH PAIN

While well-intentioned, REMS have the potential to further limit access to opioid pain medication. There is not clear evidence that the proposed strategies will reduce abuse or misuse of prescription medication. Such strategies may cause people living with pain to

not receive the medications that are most appropriate for their needs.

Currently, REMS recommended by the FDA would only be required for long-acting opioids – not short-acting. This can affect prescribing choices. By making it more difficult for a health care provider to prescribe one class of medication and easier to prescribe another, prescribers may gravitate toward less stringently-regulated products. In some cases where a long-acting opioid could greatly improve the life of a person with pain, they may be prescribed a short-acting opioid because it is "easier" for the prescriber, yet more burdensome and less efficacious for their patient. This is not optimal pain care and may diminish the quality of life for the person in pain. It also does not address the underlying problem of prescription drug abuse, as those with substance use disorder or participants in criminal diversion will simply move to products that have fewer restrictions and are easier to obtain.

Additionally, from the clinician perspective many may choose not to treat people with pain who require opioid therapy amid such onerous requirements. These protocols serve to reinforce the fear that their medical license and livelihood are at risk each and every time they write a prescription. Regulations can be so restrictive that they deter health care professionals from the practice of pain care altogether.

A CALL FOR BALANCE

Prescription drug abuse is a serious public health issue — one that may make it more difficult for people with pain to access medication that can make their lives worth living; ideally, REMS can be a part of the solution in terms of making abuse and misuse of pain medication more difficult. However, regulations designed to reduce prescription drug abuse should not come at the expense of people with a legitimate medical need.

As such, REMS must protect and not interfere with patient access to these important medicines. Negative stereotypes about individuals with pain and fear of ramifications of opioid prescribing can prevent early and effective treatment. Any strategies that further interfere with the ability of prescribers and other appropriate health care practitioners to responsibly develop, provide and adjust pain management regimens for their patients, including regimens that use opioid medication, will prove detrimental to patient care and are financially burdensome.

The cost of pain not only includes direct costs associated with health care provider visits, diagnostics and medication, but indirect costs such as lost wages and productivity of people with pain, as well as family members and caregivers. Aside from stealing livelihoods, untreated pain has been shown to shorten the lives of those who suffer. Some, who no longer consider their lives worth living, see suicide as their only option. These lives and livelihoods lost to pain are worth no less than lives and livelihoods lost to prescription drug misuse or abuse.

RATIONAL AND OUTCOME-BASED SOLUTIONS DESPERATELY NEEDED

Access to appropriate medicines should not be disrupted. As REMS evolve, the elements or strategies included should be proven to reduce the risk of abuse, misuse or diversion.

APF endorses recommendations made to the FDA to provide a balanced solution that will measurably curb the non-medical use and diversion of opioids, while ensuring and protecting patient access to opioid pain medications for those who medically need them. Recommendations include:

1) REMS should not interfere with the ability of prescribers and other appropriate health care practitioners to responsibly develop, provide and adjust pain management regimens for their patients.

2) REMS elements should be designed so they can be measured to determine their effectiveness in reducing risk of abuse, misuse and overdose.

3) Appropriate metrics are needed to determine successful outcomes for patient care as well as abuse, misuse, and diversion. Success thresholds should be predefined, reasonable and achievable. The following questions should be answered:

   a. Is there convincing data to show a direct link between the non-medical use and abuse of prescription drugs to the prescribing behaviors of responsible health care professionals and use by people with pain who legitimately require opioids as part of their pain treatment plan?

   b. Does the increase in prescriptions for legitimate medical use provide a surplus of prescription opioid analgesics in medicine cabinets and mailboxes for others to divert?

For example:

- To differentiate accidental overdose by those who are prescribed opioids and overdoses caused as a result of non-medical use, abuse or diversion, REMS metrics should capture more detail about prescribers and patients (similar to cancer, stroke, or trauma registries) so there is insight on who is prescribing (family practice, rural, urban, etc), at what doses, and to what types of patients.
- Improved metrics are needed to better understand the national prevalence data that separates out incidents of accidental overdose due to inadequate knowledge (of the prescriber and their patients), misuse, abuse and diversion by the patient population as compared to the non-medical use by the public at large.
- More information is needed to identify sources for non-medical access to prescription medications, as it relates to unintentional and intentional overdose, misuse, abuse and diversion.
- Impact on access to pain care from REMS requires data collection and analysis to monitor for unintentional harm to people living with pain who require opioid therapy as one of their pain treatment options.

4) Short-acting opioids should also be subject to the class-wide REMS to eliminate any inclination to substitute short-acting for long-acting opioids.

5) New patient registries should not be a part of REMS for opioids. Restrictive, punitive systems such as patient "registries" further stigmatize people with pain and create additional hardships and new barriers to effective pain care.

6) Prescriber and dispenser risk mitigation education should be conducted as effectively as possible, and tied to DEA registration requirements or otherwise incentivized to encourage responsible prescribing and ensure compliance. Educational efforts directed to the prescriber, the dispenser and the intended end user need to focus on the safe use, safe storage and safe disposal of medicines to prevent prescription opioid medication from entering illicit channels of distribution.

7) Patient education materials can be developed for individual products to help prescribers and dispensers provide patients with appropriate use, storage, and disposal information, as well as any specific precautions relating to individual products.

Conclusions/Next Steps

Regulators, health care providers and people with pain all face a difficult challenge in the current environment. Balancing policies in such a way that they effectively address two concurrent and sometimes conflicting public health crises is extraordinarily difficult. REMS is not the sole solution to this dilemma, but it can be one incremental step in the direction of resolving it. For this to happen, it is necessary for policymakers to continually remind themselves that there are two groups of people at risk of morbidity and even mortality in this situation, and to continually ask if policy proposals will serve the needs of both groups.

In part, this challenge is so difficult because we have never addressed a pair of problems so diametrically opposed and have never thoroughly evaluated the outcomes to determine the extent to which the solutions were, in fact, solutions. It is imperative that such outcome studies be conducted with any REMS for opioids, so that we implement policies that protect both the millions of people with chronic pain and the millions of people with substance use disorders. Failure to conduct such an evaluation could leave us spending huge amounts of time and effort — not to mention money — implementing policies that are, in fact, harmful rather than helpful. Intervening in the manner evidence indicates is best is not just necessary in the practice of medicine, but also in the practice of public policy.

As FDA implements the new REMS for long-acting opioids and evaluates its effect, it is important to recognize that the lives and livelihoods lost to uncontrolled pain are worth no less than those who misuse or abuse prescription medications.

For more information, visit www.painfoundation.org.

STATE-BASED PAIN CARE POLICY

A Snapshot of State-Based Policies Affecting Pain Care

Untreated pain is a silent epidemic in America. Chronic pain significantly and negatively affects the lives of an estimated one out of every three Americans, and costs the nation as much as $635 billion in added health care expenses and lost productivity each year, according to the Institute of Medicine. This figure does not begin to cover the physical, emotional and economic strain of pain on the individual and caregivers.

As with efforts to advance the prevention, diagnosis and treatment of other diseases — for example HIV/AIDS and cancer — legislative and regulatory policies can strengthen or hinder efforts to improve pain care — a fundamental tenet in medicine.

In June 2011, the Institute of Medicine (IOM) released a seminal consensus report, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research," and called for a comprehensive, population-level strategy to address pain as a complex disease, not just a symptom of injury or illness.

Included among the IOM's recommendations to improve pain management are:

- **Developing a comprehensive plan by the U.S. Department of Health and Human Services** with specific goals, actions and timeframes by the end of 2012;
- **Reducing barriers** to access — whether legal, regulatory, reimbursement or cultural;
- **Educating the public** on prevention, treatment and self-management;
- **Improving professional education** across the spectrum of disciplines, and throughout the continuum of undergraduate, graduate and continuing health professions training; and
- **Focusing pain research efforts at the National Institutes of Health (NIH)**, and coordinating that research with other government agencies and the private sector to speed the development of **new therapies**, foster **interdisciplinary approaches**, increase **longitudinal research** of people in pain, and **increase the number of pain researchers**.

For more information, see IOM (Institute of Medicine) 2011. Relieving Pain in America: *A Blueprint for Transforming Prevention, Care, Education and Research*, Washington, DC; The National Academies Press. Available at http://iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx.

Of course, federal and state elected officials, along with members of regulatory and licensing bodies, play a role in many of these areas and help shape the practice of pain management throughout the United States through the passing of federal and state policy.

At the same time, the non-medical use and diversion of prescription medications — including opioid analgesics — is also an important public health and safety issue that has influenced many policies in this area. For this reason, most of the policies discussed in this topic brief relate to the medical use of opioids, and the restrictions affecting the safe and appropriate provision of opioids for the treatment of moderate to severe pain. This in no way diminishes the importance of a multidisciplinary, multimodal therapeutic approach to pain management; opioids are only one tool within a broad range of treatment options. Indeed, many policies governing opioid therapy recognize the benefits of a multidisciplinary clinical approach. Moreover, policy responses to prevent the non-medical use of any therapy should not only protect the public from harm, but also maintain access to treatment for those with legitimate medical needs.

State-based Legislation and Regulatory Policy

State governments have the authority to adopt policies that provide the legal basis for health care practice, including professional practice relating to pain management and the medical use of opioids. Legislatures create statutes that are broad and general, and then depend on the relevant regulatory agency to interpret and implement the statutes through regulations. In the field of medicine, for example, the state legislature grants authority to the state medical board to define and implement its laws through regulations that are consistent with legislative provisions.

Although these laws can establish requirements and prohibitions affecting treatment decisions about pain care, including chronic non-cancer pain, regulations are designed to be revised periodically to keep pace with changing practice standards. Conversely, legislation has been slow to change in reaction to updated professional standards. Please refer to the section below titled *Challenges to Policies Promoting Safe and Effective Use*, which provides examples of pain-related statutes or regulations relating to opioid prescribing that contain potentially restrictive or ambiguous language.

Well-crafted pain policy promotes acceptable medical treatment, including pain management and the appropriate use of pain medications, and assures that the non-medical use of medications is clinically monitored and addressed effectively. However, overly restrictive prescribing requirements or prohibitions may create barriers to adequate pain treatment. Policies relating to the access of pain medications, therefore, must balance the public's health with protecting public safety through appropriate and effective drug control. Minimizing drug abuse and diversion must not interfere with the availability of medications for legitimate medical and scientific purposes.

Policies that promote the safe and effective use of pain medications are adopted and implemented within the context of two public health issues: (1) the under-treatment of pain and (2) the abuse of prescription pain medications. The story most commonly communicated to the public is too often focused on fears of substance abuse and diversion of opioids.

When the perception of undue risk outweighs therapeutic benefit, detrimental clinical consequences will occur. People with pain will be unable to access pain treatment options that enable them to be more functional and have an optimal quality of life. On the other hand, the abuse and diversion of opioids constitute a serious public health problem, and policies must be developed to reduce the resultant morbidity and mortality.

For more information, read the American Pain Foundation (APF) *Chronic Pain and Opioid Therapy* topic brief.

POLICIES CAN AND DO INFLUENCE PAIN CARE

Policies of any kind may either directly or unintentionally stigmatize individuals and/or make it harder for them to get appropriate pain care, which is already difficult to obtain for clinical or systemic reasons. In addition, health care professionals generally are hesitant to engage in policy change activities because of a lack of guidance about how best to approach and interact with policymakers around these issues.

Furthermore, good policy does not necessarily equal good practice. Once good policy is in place, a number of actions must follow to translate it into practice. Policymakers, health care professionals and people with pain must understand what constitutes good pain management and what certain policies allow. Any policy responses must be thoughtfully approached and uphold access to humane care that prevents needless suffering and improves quality of life.

A Snapshot of State Pain Laws and Policies that Influence Pain Management

The ability to effectively and responsibly manage pain is influenced by federal laws, state statutes, regulations, regulatory guidelines and policy statements.

The following provides a snapshot of some of the existing policies that can affect pain care at the state level.

Some state-based laws and policies that can influence the provision of pain care:

- Prescription Monitoring Programs
- Professional Licensing Board Regulatory Policies
- Mandated Continuing Education in Pain/Palliative Care
- Intractable Pain Treatment Acts
- Controlling Pharmaceutical Costs in Medicaid Programs
- Workers' Compensation
- Step Therapy (Fail First) and Therapeutic Switching Insurance Policies

- **Prescription Monitoring Programs** (PMPs, also called prescription drug monitoring programs [PDMPs])

PDMPs are state-based programs that aim to reduce the abuse and diversion of prescription medications. These programs track controlled substances prescribed by authorized practitioners and dispensed at pharmacies. PDMPs can help identify individuals who obtain similar medications from multiple prescribers or pharmacies (also called "doctor shopping" or "pharmacy hopping"). Not only can PDMPs provide early warnings of drug abuse hot spots (especially when considered with other data) and help investigators uncover diversion and insurance fraud, they also can be a useful clinical practice tool to improve patient care.

By mid-2011, 36 states had operational PDMPs; another eight states have adopted laws authorizing the creation of these programs.

In its recent report, "Epidemic: Responding to America's Prescription Drug Abuse Crisis," the White House supports the expansion of state-based PDMPs to all 50 states as a "promising approach" to help curtail prescription drug diversion and abuse (See http://www.whitehousedrugpolicy.gov/publications/pdf/rx_abuse_plan.pdf), but also recognizes the need for improvements, stating that "more work is needed to determine how to maximize their effectiveness." In particular, PDMPs currently are limited by their inability to:

- Share inter-state data to determine whether an individual has obtained medications from other states (although this may soon change);
- Authorize electronic access to prescribers; or
- Provide "real-time" data to prescribers and dispensers.

There also is a need to effectively promote the appropriate use of PDMPs when they become available so that prescribers can better utilize the PDMP data to inform their treatment decisions when prescribing opioids. For information about the current status of PDMPs, visit http://www.aapainmanage.org/aboutus/Advocacy.php.

APF outlines key considerations for policymakers when drafting or reviewing PDMP legislation, and calls for research to study the effect of PDMPs on physician prescribing practices, pain management and drug diversion and misuse. To read APF's statement, visit http://www.painfoundation.org/about/position-statements/pmp.html.

- **Professional Licensing Board Regulatory Policies**

Most states have avoided enacting pain legislation. Instead, states promote health care regulatory board regulations, guidelines or policy statements.

These policies typically promote the message that pain management and the safe and effective use of controlled substances is an accepted part of professional practice. Another goal of such policies is to reassure clinicians that they have nothing to fear from their licensing agency if reasonable professional practices are followed when using controlled substances for patient care. Much of this recent policy activity was prompted in 2004 by the Federation of State Medical Boards' creation of the model policy to promote consistency in state medical board policy (see http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf). Now, 45 states have some type of medical board policy to address pain relief.

Other states have joint statements on pain management, palliative care or end-of-life care adopted by health care boards. Examples are:

- Minnesota: http://www.phcybrd.state.mn.us/forms/jspm.pdf;
- Kansas: http://www.state.mn.us/mn/externalDocs/BMP/BMP_Joint_Policy_Statement_091404112418_Joint%20Statement%20on%20Pain%20Management.htm;
- Oregon: http://www.painpolicy.wisc.edu/domestic/states/OR/joint.pdf;
- South Carolina: http://www.painpolicy.wisc.edu/domestic/states/SC/scjoint.pdf

- **Mandated Continuing Education in Pain/Palliative Care**

Some legislatures and regulatory boards either mandate or strongly encourage that continuing education (CE) for health care professionals to renew their license include pain and palliative care education. Such policies have been deemed necessary based on evidence that many health care professionals lack knowledge about pain management and receive little training in medical school.

These mandates should incorporate outcomes research to demonstrate the value of CE, including data to show whether and to what extent the curriculum and teaching methods improved pain treatment. Such research also may suggest how CE programs could be modified to increase their effectiveness.

- **Intractable Pain Treatment Acts (IPTAs)**

IPTAs are a class of statutes intended to provide immunity to health care professionals who prescribe opioids to treat intractable pain. Although the intent of IPTAs is commendable, the statutes historically have contained restrictions or ambiguities that may limit clinical decision-making practices. For example, these laws may require people living with pain to have a consultation with one or more health care professionals before their pain can be treated when the goal should be to make it easier for clinicians to treat pain.

Additional problematic language includes implying that opioids are outside legitimate professional practice; providing immunity only for individuals living with persistent pain that does not respond to other treatment options; prohibiting prescribing to people with substance use disorder; and confusing addiction with physical dependence. IPTAs also tend to omit clear statements supporting enhanced pain management and access to care.

In recognizing these issues, several states have repealed such requirements and ambiguities — including the term and definition of "intractable pain," in effect extending the immunity of this law to treating all types of pain.

- **Controlling Pharmaceutical Costs in Medicaid Programs**

Medicaid programs control which medications are on a drug formulary by establishing preferred drug lists (PDLs) to accomplish cost containment. Medications not included on the PDL remain available only with prior approval, which can delay access to the medically recommended medication. Pharmaceutical companies are often required by Medicaid to provide supplemental rebates to have their product included in the formulary.

Ideally, states should make decisions based on safety, clinical efficacy, and cost, rather than solely on the cost as the primary criteria in determining which medications are included in a PDL.

"The struggle for pain relief can ill-afford any more unnecessary obstacles, even those masquerading as fiscal responsibility. It is never responsible to exchange pain and suffering for a per-pill cost ledger. Without also taking efficacy, expediency, and safety into account along with overall cost, this committee will also need to be accountable for unnecessary pain and suffering among the most vulnerable citizens in Maryland, a toll for which each member can justly feel responsible."

— 2005 Maryland P & T Committee Testimony by F. Michael Gloth, III, MD.

Another mechanism that can be used by Medicaid to both control costs and enhance patient safety is a "lock-in" program, in which an individual may be assigned a single practitioner and single pharmacy from which to obtain pain medication.

The premise behind lock-in programs is that heightened tracking helps ensure Medicaid recipients receive appropriate treatment, while controlling costs by reducing visits to hospitals, clinics, physician offices and emergency rooms, as well as duplicative or unnecessary prescriptions. North Carolina enacted a lock-in program specific to opioid pain medication in 2010. Other states, like Wisconsin, monitor controlled substances, including benzodiazepines and stimulants as well as opioids. Lock-in requests can be made by pharmacists when the prescription recipient is suspected of non-medical use.

- **Workers' Compensation**

Workers' compensation, like Medicaid, is a very expensive area for government health care funding. Some states have established extensive guidelines for workers' compensation-related pain treatment, as a means of controlling both costs and the risk of non-medical use of medications and diversion. Unfortunately, some of these guidelines are extremely restrictive and run the risk of impeding effective and appropriate pain treatment.

For example, in Washington state, the Health Technology Clinical Committee has denied coverage of several pain care devices and treatments for those enrolled in state-paid medical plans: Medicaid, workers' compensation and Uniform Medical. As of May 2011, coverage denials include the use of intrathecal pumps, transcutaneous electrical nerve stimulator (TENS) units and spinal cord stimulators. The decisions to deny reimbursement for these three chronic pain devices affects approximately 330,000 public employees and retirees, 70,000 individuals in the Basic Health Program, 900,000 in the Medicaid program, and 2.5 million workers with approximately 130,000 claims (Labor & Industries, Workers' compensation).

This is a complex area of work — one that deserves more focused attention from the pain community and policymakers alike. Third-party payer policies and practices that usurp the "doctor-patient" relationship, deny pain care access to vulnerable groups, or are developed primarily for cost savings supersede the best interest of patient care. These actions serve as an inappropriate and unacceptable form of health care rationing.

For more information, read APF's Access to Care Position Statement.

- **Step Therapy (Fail First) and Therapeutic Switching — Insurance Policies**

Step or **fail first therapy** requires alternate medications, which in some cases includes over-the-counter medication, or other therapies to be used before the health care provider-recommended medication is approved for reimbursement. These patients can be required to "fail" numerous other treatment options before the insurer will grant reimbursement access to the treatment option that was originally prescribed by the clinician. This protocol is used as a cost-saving measure for the insurer.

Step therapy often sets the stage for forced "off-label" use of medications that may no longer be appropriate nor provide optimal efficacy for an individual's medical condition. This policy can actually increase costs for the insurer because the delay in recommended care may decrease the person's response to treatment or cause other health complications.

Therapeutic switching (or "therapeutic substitution") is when the *insurer* substitutes less expensive medications or alternate medications. These are not the medications prescribed by the health care professional and the individual is not usually aware of the change until he or she arrives at the pharmacy to pick up their medication. These medications may have more side effects or be less effective for the person with pain. Pharmacists and clinicians are put in the unfortunate predicament of confronting insurers to defend the medication therapy that they prescribed. This is different than "therapeutic interchange," where exchanges are in accordance with previously established and *medical* staff-approved written guidelines or protocols, within a drug formulary system.

It is understandable that insurance companies try to cut costs and avoid unnecessary medical interventions; however, the clinical judgment of the direct care provider to an individual's health care must not be undermined. Legislative and

regulatory ruling must help correct this by placing prescribing power back in the hands of health care professionals in charge of their patient's care. APF supports the American Medical Association's official statement on this issue:

> …[T]he AMA accepts the concept of therapeutic *interchange*; i.e., the authorized exchange of therapeutic alternates in accordance with previously established and medical staff-approved written guidelines or protocols, within a drug formulary system. …[T]he AMA clearly differentiates therapeutic interchange from therapeutic *substitution*; i.e. the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber, and reaffirms its strong opposition to therapeutic substitution in any patient care setting.

For more information, read APF's position statements on therapeutic switching and step therapies.

Challenges to Policies Promoting Safe and Effective Use

Pain generally is poorly understood by the public, policymakers, and even many health care professionals. An integral part of pain care policy is educating people — and in some cases reeducating people — about how pain affects lives, its cost to society and the tremendous toll it can exact on families, the workplace and the community. Such efforts to improve the awareness and understanding of pain treatment issues, however, may be undermined by policies included in the previous section and also by requirements and language found in other policies.

Addiction terminology

One of the most common problematic provisions remaining in state policy today is archaic terminology that confuses physical dependence with addiction. As of mid-2011, 41 states have adopted language clarifying the distinction between these clinical phenomena. Such up-to-date terminology is typically contained in health care regulatory guidelines or policy statements; however, the statutes of 14 states and the health care regulations in two states continue to classify physical dependence as synonymous with addiction. As a result, these states have conflicting standards about what constitutes addiction, which may create ambiguity and has significant clinical implications.

When such archaic standards are applied in practice, they have the potential to stigmatize people with pain as "addicts" and restrict prescribing practices, leading to inadequate pain management for those who need opioid pain medication for management of their pain condition.

ADDITIONAL RESOURCES FOR APPROPRIATE DEFINITIONS

American Pain Foundation issued an At-a-glance page defining each of these terms in its *Chronic Pain and Opioid Therapy* topic brief.

The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine released a consensus document about this issue. These professional organizations recognize the following definitions and recommend their use. See http://www.ampainsoc.org/library/bulletin/mar99/president.htm for additional information.

- **Addiction**
  Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
- **Physical Dependence**
  Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
- **Tolerance**
  Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

For additional resources, see the Federation of State Medical Boards' influential Model Policy for the Use of Controlled Substances for the Treatment of Pain. Responsible Opioid Prescribing: A Physician's Guide at www.fsmb.org/pain-model-policy.html.

Reporting People Who are Prescribed Opioids

The laws in some states contain problematic language relating to the reporting of people being treated with opioids. For example:

- In Pennsylvania, pharmacies must report the identity of every person being treated with schedule II controlled substances to the state attorney general (28 Pennsylvania Code § 25.131).
- A law in North Carolina requires all health care practitioners who treat "drug dependent persons" to report their patients to the state Department of Health and Human Services. This law may classify individuals as "drug dependent" if they are taking opioids for a legitimate medical purpose and are physically dependent on the medication. It seems, therefore, that practitioners prescribing opioids to treat people with pain could be subject to this requirement (North Carolina General Statutes § 90-109.1(c)).
- Finally, the California Department of Justice can assign a physician to examine any person taking a schedule I, II, or III medication, or who has an addiction to a controlled substance. The person must submit to the examination, or could be found guilty of a misdemeanor (California Health & Safety Code § 11453).

Excessive Prescribing

A frequent dictate on health care practice is the creation of ambiguous practice standards, such as defining unprofessional conduct to include "excessive prescribing" without operationalizing the term or defining how it would be determined. Such vague standards need to be clarified in or removed from state laws.

Pain Management and the Legal System

Prescribers frequently cite fear of prosecution and loss of license as reasons they fear treating people with pain. If legal or regulatory sanction is perceived as a significant risk, it presents a barrier to proper pain management. All health care professionals need to know how to assess and treat pain knowledgeably. Prescribers must know how and when to add opioid-based medications to the pain treatment plan. They must be aware of federal and state laws governing the prescribing and handling of controlled-substance pain medications to avoid contributing to abuse and diversion. At the same time, legislators and regulatory officials should successfully address prescription drug abuse and diversion without limiting the availability of any pain treatment option, including opioid analgesics that are warranted for legitimate medical use.

HOW POLICIES MAY HAVE UNINTENDED CONSEQUENCES

In Washington state, three polices have been problematic for people living with pain and their health care professionals:

- ESHB 2876 — a new opioid prescribing law that went into effect in June 2011, adds barriers to prescribing opioids to people living with pain by adding burden and cost to practitioners and patients.
- HTA— Washington state's Health Technology Assessment Committee denied coverage of three technologies (spinal cord stimulation, intrathecal drug delivery systems and TENS units) for people with pain in the public payer system and voted to cover four out of five spinal injections in early 2011.
- HB1311— proposes the creation of a committee that may decide to limit options for pain care, contributing to this disturbing climate in Washington state. In each of these instances, well-intentioned laws can have consequences not only for people with pain and those with a substance use disorder, but also for anyone receiving a controlled substance to treat a medical condition.

Ironically, this policy activity was promoted as an effective response to the abuse and overdose deaths related to prescription pain medications, without evidence that such public health issues result from inappropriate prescribing by health care professionals. Of course, initiatives to safely and successfully reduce the non-medical use of prescription opioids are essential, but only to the extent that they avoid undermining clinical decision-making practices and legitimate patient care. Unfortunately, such policy activity encourages similar policy adoption in other states before its impact either on non-medical use and overdose deaths or on the treatment of patients with legitimate medical conditions is known.

Non-Governmental Regulations Promoting Good Pain Management

Not all policy affecting pain management comes from government agencies. The Joint Commission, a voluntary, independent, not-for-profit organization, provides accreditation services to more than 18,000 health care facilities and programs in the United States. Joint Commission accreditation is, in many ways, the "gold standard" of achievement for health care organizations, and recognizes the adherence to high standards in many aspects of patient care.

In 2001, thanks largely to the efforts of Dr. June Dahl and her colleagues from the University of Wisconsin, the Joint Commission issued its first set of standards focused specifically on a symptom or disorder: pain. The standards for pain assessment and treatment required organizations to

- regularly assess and document the presence, severity, and qualities of pain;
- provide appropriate treatment for pain when it is present;
- educate patients, their caregivers, and practitioners about pain treatment; and
- engage in performance improvement efforts related to pain management, among other standards.

These standards resulted in many institutions adopting "pain as a fifth vital sign" policies.

Evaluating State Policies

Pain advisory committees (also known as pain commissions or pain task forces) play a role in evaluating state pain care policies. These state-level workgroups are used to improve pain management practices by evaluating state laws and regulations that could interfere with access to adequate pain care and to develop recommendations for corrective action.

To be most effective, pain advisory committees should comprise a multidisciplinary team of individuals representing state agencies and health care organizations, health care professionals with pain expertise, people with pain, caregivers and public citizens. They should also serve an advisory and educational function, surveying the status of pain policy and practice in the state and recommending changes to policymakers about achieving better balance in policy and improved practice of pain management. As a result, successful collaborations between committee members and policymakers can influence a state's legislative or regulatory agenda to diminish or avoid establishing barriers to pain management, as well as reduce the non-medical use and diversion of prescription pain medications. One successful model to consider is the pain management commission for the state of Oregon, established in 1999 (see http://www.oregon.gov/OHA/OHPR/PMC/index.shtml/).

In addition, the University of Wisconsin Pain & Policy Studies Group (PPSG) created a criteria-based evaluation related to opioid analgesics to quantify and assign grades representing the quality of each state's pain policies aimed at preventing drug abuse, regulating professional practice, and improving patient care. These criteria can then be used to compare all states and track policy changes over time. Five evaluations over an eight-year period by PPSG show continuous improvement in state policies governing the medical use of opioid medications. See: http://www.painpolicy.wisc.edu/Achieving_Balance/PRC2008.pdf

Grades range from A to F, including mid-point grades (e.g., B+, C+, D+). Higher grades are associated with state policies that are more balanced and consistent with modern medicine. A lower grade means that a state's policies contain potential barriers to patient pain relief (i.e., language that creates ambiguous practice standards or contradicts current medical knowledge, policies that are not consistent with the policy guidance recommendations from authoritative sources and fail to communicate the appropriate messages about pain management to professionals, patients and the public). See the table below for a list of states' most recent grades related to the content of statutes, regulations, and health care regulatory board guidelines/policy statements involving opioids.

State Grades for 2008

State	2008 Grade	State	2008 Grade
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+
Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

PPSG provides a database of state statutes, regulations and other government policies affecting pain management. Visit www.painpolicy.wisc.edu/matrix.htm to find pain management policies in your state.

What's Next to Improve Policy Content Related to Pain Care

We all must thoughtfully consider existing and proposed legislation and regulatory policies to find requirements that might unduly impede access to pain management, while also maintaining the potential to protect against harm from the inappropriate use of any treatment modality. To guide efforts within a state to create new or modify existing policies that both promote the safe and effective treatment of pain and minimize the public health consequences of the non-medical use of prescription opioids, we encourage policymakers to:

- Identify the policy needs/issues in your state by engaging with the constituencies governed/affected by such policy
- Ask questions of pain experts and people affected by pain
- Focus on removing archaic or ambiguous language/requirements
- Avoid legislation that establishes standards that are slow to change in reaction to professional developments
- Anticipate how policies, even if not directly related to pain management, could influence pain care
- Support efforts to evaluate outcomes of policy change to determine if the intended goals were met, if unintended consequences need to be addressed, and if there is a way to modify policy to achieve more intended and fewer unintended consequences.
- Use available resources to guide policy changes/recommendations, such as the American Pain Foundation (www.painfoundation.org) or the Pain & Policies Study Group state policy evaluation findings (http://www.painpolicy.wisc.edu/Achieving_Balance/EG2008.pdf). These resources could provide an idea about what other states may have done to address similar issues, or could point to the existence of policy templates that are available.

STATE POLICY WATCH

State policies influencing pain management continue to evolve. Policymakers, health care professionals and the public need to be mindful about unintended consequences that could introduce hardships for prescribers, dissuade well-meaning health professionals from providing pain and palliative care, and hinder access to quality and timely pain care. Experts expect the following to be ongoing policy topics in the years to come:

- Expanding and improving consistency of prescription monitoring programs, especially efforts to link these programs across state lines and evaluate outcomes to make them more effective.
- Shutting down "pill mills," which contribute to prescription drug trafficking, endanger individuals receiving medications from these illegal clinics and threaten the communities where they are located, through dedicated legislation.
- Increasing the number of community-based take back programs to ensure proper disposal of expired and unused prescription medications and, in turn, prevent diversion and non-medical use.
- Developing regulatory policies aimed at health care professionals to promote the safe and effective treatment of pain.
- Creating policies aimed to curb morbidity and mortality from prescription medication abuse that might impede efforts to protect access to quality pain management.

LEGISLATORS CAN USE THE FOLLOWING TIPS AND QUESTIONS, DEVELOPED BY PPSG, TO HELP IMPROVE PAIN MANAGEMENT IN THEIR STATES.

What can state legislatures do to improve pain management?

First, study the problem. Create a multidisciplinary task force, commission or committee with public hearings to study carefully the barriers to pain management for all types of pain in the state (cancer, chronic non-cancer, post-surgical, sickle cell, AIDS, etc.); review relevant state policies outlined below; make and implement recommendations inlegislation, leadership, public information, education, training, program development, etc.

1. Drug, pharmacy, controlled substances policy

- Does the state controlled substances act recognize the essential medical uses of controlled substances as in federal law and as recommended by the National Conference of Commissioners on Uniform State Laws?
- Does state law or regulations unduly restrict prescribing of controlled substances, e.g., government-required prescription forms; exclusion of addicts even if they have pain; require second opinion, consultation or informed consent; legal terminology confusing addicts with pain patients/addict reporting, limit number of dosage units of controlled substances (e.g., opioids) that can be prescribed at one time, or limit unrealistically the period of validity of a prescription for a scheduled substance?
- Does state policy allow physicians and pharmacists to take full advantage of the flexibility in federal controlled substances regulation regarding faxing and partial dispensing of controlled substances prescriptions?

2. Medical policy

- Does the medical practice act or regulations contain any policies with regard to prescribing controlled substances which are unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain? (i.e., no prescribing to addicts, even if they have pain?)
- Does the medical board have a policy statement or guidelines which clarifies that the board recognizes that the use of controlled substances for the treatment of chronic pain is accepted medical practice and clarifies the principles which a physician can follow to confidently avoid the risk of discipline or arrest by any agency in the state?

3. Facility regulation (hospice, nursing home, home care, etc.)

- What is the attitude of the state facility regulators: is pain a priority or is the priority only reducing the use of controlled drugs?
- Do certification and inspection criteria include assessment and treatment of pain and training of patient care staff; is technical assistance on pain and symptom management available?

4. State health policy

- Does the state cancer control program include a funded emphasis on pain management and palliative care for cancer patients in the state?
- Is there a state pain initiative and does it have adequate support?
- Does the public have access to information about pain and symptom management including chronic non-cancer pain, and where to go for help?
- Do toll free numbers for other chronic conditions, like cancer or diabetes, include information about pain management?
- Do managed care organizations have adequate policies: pain assessment, treatment, reimbursement, appropriate access to specialists?
- Does state Medicaid policy reimburse the controlled medications used in pain and symptom management?
- Does workers' compensation adequately address the needs of people with chronic severe pain?

5. Drug enforcement policy

- Do the agencies in the state which are involved in drug law enforcement and monitoring of controlled substances prescribing, dispensing and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who prescribe and dispense legitimate controlled substances?

CHRONIC PAIN AND OPIOID THERAPY

Effective management of chronic pain often requires a step-wise, coordinated and integrated trial of different treatment options, a team of health care providers and social support from family and friends. Health care providers may start with behavioral and non-pharmacological interventions (e.g., hot/cold therapy, physical therapy, relaxation techniques) when devising pain treatment plans. Strong prescription pain relievers like opioid analgesics may be recommended as one of the treatment options to help reduce moderate to severe pain so that function and quality of life can be improved. According to the American Pain Society, the American Academy of Pain Management and the American Geriatrics Society, individuals with severe or functionally limiting pain that is not sufficiently relieved by other means should be considered for a trial of opioid therapy.

Key Issues

- An estimated 116 million Americans suffer with chronic pain.[1] The consequences of unmanaged persistent pain are devastating for individuals and their families. Sadly, many people with chronic, debilitating pain are made to feel as though the pain is "just in their head."
- For some people, opioids are a necessary and integral part of a comprehensive pain management plan to help relieve pain, restore functioning and improve quality of life.[2,3]
- Unfortunately, access to these medications may be hindered by unduly restrictive state policies, persisting social stigma surrounding their use, as well as therapeutic switching and/or step therapies imposed by insurance companies. For more information about policies that directly or unintentionally affect access to pain care, read the *State-Based Pain Care Policies Topic Brief*.
- Unless a person with pain has a past or current personal or family history of substance abuse, the likelihood of addiction is low when opioids are appropriately prescribed, taken as directed and monitored by a responsible and knowledgeable health care provider. Although more well-controlled studies are needed, current evidence indicates that addiction prevalence in pain patients may be no different from prevalence of addiction in the general U.S. population.[4,5]
- Rising rates of non-medical use of prescription medications and emergency room admissions related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide.[6] The main source of drug diversion is from theft by family members, friends and workers in the home or from the sharing and selling of medications though often with good intentions.[7]
- Diverse players (e.g., lawmakers, educators, health care providers, the pharmaceutical industry, caregivers) must come together to address the dual public health crises of the undertreatment of pain and rising prescription drug abuse.[8]
- Alleviating pain remains a medical imperative — one that must be balanced with measures to address rising non-medical use of prescription drugs and to protect the public health.[8]

Opioids 101

Opioids include morphine, oxycodone, oxymorphone, hydrocodone, hydromorphone, methadone, codeine and fentanyl. Opioids are classified in several ways, most commonly based on their origin and duration of effects.[9]

Common classifications for opioids[9,10]

SOURCE	**Natural or semisynthetic:** Contained in or slightly modified (semisynthetic) from chemicals found in poppy resin	Synthetic: Synthesized in the laboratory
DURATION OF RESPONSE	**Short-acting:** Provide quick-acting pain relief and are used primarily as "rescue medication," as in acute pain	Long-acting: Provide longer duration of pain relief and are most often used for stable, chronic pain

One of the advantages of opioids is that they can be given in so many different ways. For example, they can be administered by mouth, oral mucosal or sublingual delivery systems, rectal suppository, intravenous injection (IV), subcutaneously (under the skin), transdermally (in the form of a patch) or into a region around the spinal cord. Patches, IV injections and infusions are very important for patients who cannot swallow, or whose GI tracts are not working normally.[11]

Opioids are believed to work by binding to specific proteins (opioid receptors), which are found in specialized pain-controlling regions of the brain and spinal cord. When these compounds attach to certain opioid receptors, the electrical and chemical signals in these regions are altered, ultimately reducing pain.[9]

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain[12]

However, some types of pain, such as pain caused by nerve compression or destruction, do not appear to be relieved by opioids.[10]

Adverse Effects

Side effects of opioids result primarily from activation of opioid receptors outside and within the nervous system. Activation of opioid receptors in the gut, for example, may cause constipation, nausea and vomiting, and other gastrointestinal effects. Tolerance to nausea and vomiting usually develops within the first few days or weeks of therapy, but some people are intolerant to opioids and experience severe adverse side effects.[10] Other side effects include drowsiness, mental clouding and, in some people, euphoria.[9] Recent research shows that genetic variations may influence opioid metabolism.

Depending on the amount taken, opioids can depress breathing. However, this effect usually is not present after someone has taken opioids over time. The risk of sedation and respiratory depression is heightened when opioids are taken with other sedating medications (e.g., antihistamines, benzodiazepines), reinforcing the need to carefully monitor individuals who are taking such combinations..

Careful Monitoring and Open Communication

People taking opioids must be carefully selected and monitored by a knowledgeable and responsible prescriber. People with pain should speak openly with their health care provider about noticeable improvements in functioning, as well as side effects and other concerns (e.g., constipation, fears of addiction).

The American Pain Foundation's *Targeting Chronic Pain* materials help facilitate open dialogue between people who live with pain and their health care team, and give prescribers tools for selecting, monitoring and following their patients. To access these resources, visit www.painfoundation.org and click on Publications under the Learn about Pain tab.

The Four "A's"

The Four "A's" of pain management are used by clinicians to measure key treatment outcomes — pain relief, psychosocial functioning, side effects and addiction-related outcomes.

Analgesia – Is the pain relief clinically significant? Is there a reduction in the pain score (0-10)?

Activity levels – What is the patient's level of physical and psychosocial functioning? Has treatment made an improvement?

Adverse effects – Is the patient experiencing side effects from pain relievers? If so, are they tolerable?

Aberrant behaviors – Are there any behaviors of concern such as early refills or lost medication? Does the patient show signs of misuse, abuse or addiction? What is the plan of action?

Source: Passik & Weinreb, 1998; Passik & Portenoy, 1998

Dual Public Health Crises: Balancing Medical Imperative to Relieve Suffering and Protect Public Safety

Pain affects more Americans than diabetes, heart disease and cancer combined, and it is one of the leading causes of disability in the United States. Recognition of pain as a growing public health crisis has led to the establishment of specialized pain clinics, treatment guidelines for certain types of pain, as well as greater use of treatment strategies to effectively alleviate pain and improve functioning, including prescription pain medicines.

As the therapeutic use of opioids has increased to appropriately address pain, there has been a simultaneous and dramatic rise in non-medical use of prescription drugs.[13] When misused — that is, taken by someone other than the person for whom the medication was prescribed, or taken in a manner or dosage other than what was prescribed — prescription medications can produce serious adverse health effects and can lead to addiction, overdose and even death.

People who abuse opioids typically do so for the euphoric effects (e.g., the "high"); however, most abusers are ***not*** patients who take opioids to manage pain.[14] Rather, they are often people within the social network of the person who possesses a lawful prescription. In fact, 71 percent of people abusing prescription pain relievers received them from a friend or family member without a prescription.[7] Prescription pain relievers are frequently illegally stolen from medicine cabinets, purchased or shared in schools, or simply given away.

Picture of Prescription Drug Abuse in America

- In 2009, 16 million Americans 12 years of age and older had taken a prescription pain reliever, tranquilizer, stimulant or sedative for non-medical purposes at least once in the previous year.[14]
- The rate of non-medical use of medications has risen among teenagers. In fact, prescription drugs are now the second most abused category of drugs behind marijuana.[15]
- In 2007, 93 percent of unintentional poisoning deaths in the U.S. were caused by drugs. Opioid pain medications, such as methadone, hydrocodone, or oxycodone, were most commonly involved, followed by cocaine and heroin.[16]
- Most people who use prescription drugs nonmedically (7 out of 10) get them from friends or family; very few obtain them from drug dealers or the Internet.[14]

Nonmedical use includes misuse, abuse or otherwise not taking a drug as prescribed.

The growing prevalence of prescription drug abuse not only threatens the lives of abusers; concerns about misuse, abuse and diversion may also jeopardize effective pain management by impeding appropriate access to opioids for legitimate medical need. Concern about scrutiny by regulators or law enforcement, and specific action by some agencies, has had a "chilling effect" on the willingness of some doctors, nurse practitioners and physician assistants to prescribe opioids.[8,17]

Moreover, high profile reports of drug abuse, diversion and addiction, or of legal actions taken against prescribers have helped perpetuate a negative — and often false — picture of chronic pain management.[8] Over time, these reports overshadow the stories of people with pain — those whose lives have been shattered by unrelenting pain — who get needed pain relief from these medications. Understanding the difference between tolerance, physical dependence, abuse and addiction is also critical to telling the story. According to medical experts, use of the term "narcotic" in news reports may further reinforce the myths and misconceptions of this class of drugs, given the negative connotation.[8]

"Clinicians continue to approach opioid prescribing with a spectrum of highly diverse practices, from complete avoidance to alacrity. Both extremes ignore either patient-specific indications and context for opioid therapy or the risks associated with such therapy. Idiosyncratic approaches need to give way to principles-based practices, focusing on well-established therapeutic goals and clinical indications, risk stratification and matched structuring of care, titration and stabilization, ongoing monitoring and outcomes (safe and effective use)."

— Perry Fine, MD, Topics in Pain Management

Strategies to Address Twin Public Health Crises

Systematic and targeted approaches are essential to address the growing prevalence and complexity of the non-medical use of prescription drugs, while simultaneously ensuring that people with legitimate medical needs receive effective treatment.

These approaches can generally be categorized as follows:

- Legislative strategies to create balanced and consistent laws and improve state-based prescription drug monitoring programs.
- Educational efforts to raise awareness about prescription drug abuse and its dangers among schools, families, health care providers, patients and potential abusers.
- Greater public awareness and acceptance of pain and the need to be able to access appropriate treatment with medical oversight.
- Medical strategies to help identify and monitor people with pain who require opioid management, incorporating risk management into the treatment plan (e.g., informed consent, appropriate pain assessment, diagnostic testing and monitoring, transition planning, collaborative practice with addiction medicine and behavioral health specialists as indicated).
- Pharmaceutical industry strategies to help prevent misuse, abuse and diversion by developing new tamper resistant packaging and/or formulations (e.g., tamper-resistant bottles, electromagnetic chips to track medication, new formulations that could resist or deter common methods of opioid abuse).

For additional recommendations, see the American Pain Foundation's report outlining critical barriers to appropriate opioid prescribing for pain management, *Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management.* This 16-page report calls for a more balanced perspective of the risks and benefits of these medications in practice and policy and summarizes key challenges and actionable solutions discussed by leading pain experts at a roundtable meeting hosted by APF.

Making the Grade: Evaluation of State Policies

The Pain & Policy Studies Group (PPSG) report "Achieving Balance in State Pain Policy: A Progress Report" graded states on quality of its policies affecting pain treatment and centered on the balance between preventing abuse, trafficking and diversion of controlled substances and simultaneously ensuring the availability of these medications for legitimate medical purposes. PPSG researchers evaluated whether state pain policies and regulations enhance or impede pain management and assigned each state a grade from 'A' to 'F.'

State Grades for 2008

State	2008 Grade	State	2008 Grade
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+
Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

Source: The Pain & Policy Studies Group, http://www.painpolicy.wisc.edu/Achieving_Balance/PRC2008.pdf.

At a Glance: Differentiating physical dependence, tolerance, abuse and addiction

Unfortunately, confusion between normal physiological responses to opioids (physical dependence and analgesic tolerance) and pathological phenomena such as addiction or substance abuse persist. Such misunderstandings not only reinforce the stigma surrounding medical use of these medicines, they also fuel fears of addiction and, in turn, may impinge on access to these medications for legitimate medical need. Although opioids have an abuse liability, clinical studies have shown that the potential for addiction is low for the vast majority of individuals using opioids for the long-term management of chronic pain.[19] As with any medication, there are risks, but these risks can be managed.

"Universal agreement on definitions of addiction, physical dependence and tolerance is critical to the optimization of pain treatment and the management of addictive disorders."

— Consensus document from the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine

Physical dependence is characterized by biological changes that lead to withdrawal symptoms (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) when a medication is discontinued. Physical dependence differs from psychological dependence, or the cravings for the euphoria caused by opioid abuse. Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation.[9]

Analgesic tolerance is a biological process in which a patient requires increasing amounts of a medication to achieve the same amount of pain relief. Dose escalations of opioid therapies are sometimes necessary and reflect a biological adaptation to the medication. Although the exact mechanisms are unclear, current research indicates that tolerance to opioid therapy develops from changes in opioid receptors on the surface of cells.[9] Thus, the need for higher doses of medication is not necessarily indicative of addiction.[3]

Addiction is a disease characterized by preoccupation with and compulsive use of a substance, despite physical or psychological harm to the person or others.[3] Behaviors suggestive of addiction may include: taking multiple doses together, frequent reports of lost or stolen prescriptions, and/or altering oral formulations of opioids.

Abuse is the intentional self-administration of a medication for a non-medical purpose, such as to obtain a high.[3] Both the intended patient and others have the potential to abuse prescription drugs; in fact, the majority of people who abuse opioids do not suffer from chronic pain.[14]

Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately "drug seeking," which may be misidentified as addiction by the patient's physician. Pseudo-addiction can be distinguished from true adduction in that this behavior ceases when pain is effectively treated.[3]

MISUSE VS. ABUSE

- **Medication Misuse**: Legitimate use of a valid personal prescription but using differently from provider's instruction, such as taking more frequently or higher than the recommended doses. Use may be unintentional and considered an educational issue.
- **Medication Abuse**: Using a valid personal prescription for reasons other than its intent, such as to alleviate emotional stress, sleep restoration/prevention, performance improvement, etc. Use may be unintentional and considered an educational issue.
- **Prescription Drug Misuse**: Intentional use of someone else's prescription medication for the purpose of alleviating symptoms that may be related to a health problem. The use may be appropriate to treat the problem but access to obtain this drug may be difficult/untimely or may have been provided from a well-intentioned family member or friend.
- **Prescription Drug Abuse**: Intentional use of a scheduled prescription medication to experiment, to get high or to create an altered state. Access to the source may be diversion from family, friends or obtained on the street. Inappropriate or alteration of drug delivery system, used in combination with other drugs or used to prevent withdrawal from other substances that are being abused are included in this definition.

Source: Carol J. Boyd PhD, MSN, RN; Director: Institute for Research on Women and Gender, Substance Abuse Research Center, University of Michigan

Risk factors for opioid addiction include, but are not limited to:[2,3]

- Personal or family history of prescription drug or alcohol abuse
- Cigarette smoking
- History of motor vehicle accidents
- Substance use disorder
- Major psychiatric disorder (e.g., bipolar disorder, major depression, personality disorder)
- Poor family support
- History of preadolescent sexual abuse

NOTE: Unless an individual has a past or current history of substance abuse, the potential for addiction is low when opioid medications are appropriately prescribed by a licensed health care provider and taken as directed. Those with chronic pain and addictive disease deserve the same quality of pain treatment as others and will require greater structure and resources in their care.

WEB RESOURCES

PainSAFE
www.painsafe.org

Opioid RX
http://pain-topics.org/opioid_rx/

Tufts Health Care Institute Program on Opioid Risk Management
http://www.thci.org/opioid/

Emerging Solutions
http://www.emergingsolutionsinpain.com/index.php?option=com_continued&cat=37&Itemid=303

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Topic Brief

PAIN MANAGEMENT & DISPARITIES

The undertreatment of pain in America is a growing public health crisis, especially among underserved populations, including ethnic minorities, women, older Americans and those who are socioeconomically disadvantaged.

Despite an overall improvement in health for most Americans, certain segments of the population continue to experience poor health status.[1] There is compelling evidence that minorities are less likely to have access to routine, coordinated medical care or health insurance than whites. They are also more likely to receive inappropriate or insufficient care, resulting in poorer health outcomes.

As the U.S. population becomes increasingly diverse, there is an urgent need to eliminate health disparities. Patients have a right to appropriate assessment and treatment of their pain without regard to race, ethnicity or other factors.

"Of all the forms of inequality, injustice in health is the most shocking and the most inhumane."
–Martin Luther King, Jr.

Health Disparities Defined

According to the National Institutes of Health, health disparities are defined as "differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States."

Disparities in health care are complex and multifaceted resulting from:

- Patient/personal factors (e.g., low socioeconomic status, communication barriers)
- Health care provider factors (e.g., bias, cultural insensitivity)
- Systematic/health system factors (e.g., health insurance status, access to care)

Snapshot of U.S. Population, An Older and More Diverse Nation

According to projections by the U.S. Census Bureau:

- Minorities now comprise roughly one-third of the U.S. population.
- By 2023, more than half of all children will be from minority groups.
- Minorities are expected to become the majority in 2042.
- In 2050, the nation is projected to be 54 percent minority.
- The Latino population, already the nation's largest minority group, will triple in size between 2005 and 2050.
- The nation's population of elders will more than double in size from 2005 through 2050 as the baby boom generation enters traditional retirement years.

Source: U.S. Census Bureau, 2008, http://www.census.gov/PressRelease/www/releases/archives/population/012496.html; Pew Hispanic Center.

Disparities in Pain Care

Pain is widely recognized as an undertreated health problem in the general population.[2] However, a growing body of research reveals even more extensive gaps in pain assessment and treatment among racial and ethnic populations, with minorities receiving less care for pain than non-Hispanic whites.[3,4,5,6,]

Differences in pain care occur across all types of pain (e.g., acute, chronic, cancer-related) and medical settings (e.g., emergency departments and primary care).[3,4,5,6,7] Even when income, insurance status and access to health care are accounted for, minorities are still less likely than whites to receive necessary pain treatments.[3,4,8]

Minorities are less likely to:

- Have access to pain management services and treatments
- Have their pain documented by health care providers
- Receive pain medications

And more likely to:

- Use the emergency department for pain care, but less likely to receive adequate care
- Experience greater severity of pain
- Experience and report physical disability
- Experience poorer health and quality of life related to pain

There are clear variations in the way pain is assessed and managed among all minority populations. Significant gaps exist in the provision of effective quality pain care due to the lack of research and medical training focused on pain care disparities.[3,4,9]

Research also shows gender differences in the experience and treatment of pain. Most chronic pain conditions are more prevalent among women; however, women's pain complaints tend to be poorly assessed and undertreated.[3]

Additionally, gender differences have been identified in patient responsiveness to analgesics and pain stimuli. While estrogen and progesterone play a role in how pain signals are received in men and women, psychology and culture may also account for some of the difference. For example, children may learn how to respond to pain later in life depending on how their pain complaints were treated in their formative years (e.g., receiving comfort and validation versus being encouraged to tough it out or dismiss the pain).[14] For more information, see the *Special Considerations: Pain in Specific Populations Topic Brief.*

In response to the overwhelming discrepancies in pain treatment among minority groups, the Joint Commission issued a statement recognizing the rights of all patients to receive appropriate assessment and management of pain, and the World Health Organization has declared that pain relief is a human right.

RESEARCH ON DISPARITIES IN PAIN CARE HAVE SHOWN:

- Blacks were less likely than whites to receive pain medication and had a 66 percent greater risk of receiving no pain medication at all.[5,6,7,9]
- Hispanics were twice as likely as non-Hispanic whites to receive no pain medication in the emergency department (55 percent of Hispanics received no pain medication vs. 26 percent of non-Hispanic whites).[7,10]
- Minority patients were less likely to have pain recorded relative to whites, which is critical to providing quality patient care.[11]
- Only 25 percent of pharmacies in predominantly nonwhite neighborhoods had opioid supplies that were sufficient to treat patients in severe pain, as compared with 72 percent of pharmacies in white neighborhoods.[12]
- In a study of minority outpatients with recurrent or metastatic cancer, 65 percent did not receive guideline-recommended analgesic prescriptions compared with 50 percent of nonminority patients ($P < 0.001$). Hispanic patients in particular reported less pain relief and had less adequate analgesia.[13]

Patient and provider factors drive pain disparities

Multiple factors contribute to racial and ethnic disparities in pain care, including beliefs about pain, preconceived bias and cultural insensitivity and poor patient-provider communication.

Positive physician-patient interaction and communication is critical in accurate pain assessment.[2] Some research has shown that patients take a more active role in their own pain treatment when their health care providers are of similar ethnic backgrounds.[3,4]

"Pain is a complex, subjective response with several quantifiable features, including intensity, time course, quality, impact, and personal meaning. The reporting of pain is a social transaction between caregiver and patient."[15]

Patient sources of racial and ethnic disparities:[3]

- Low socioeconomic status
- Patients' attitudes or beliefs regarding pain and patient-level decision making and preferences
  - Stoicism and the belief that pain is an inevitable part of disease
- Minority patients more likely to:
  - Refuse recommended pain therapies
  - Poorly adhere to treatment regimens
  - Delay seeking medical care
- Mistrust of physicians or previous negative experiences with health care system
- Limited health literacy
- Language barriers that hinder communication with providers

Physician sources of racial and ethnic disparities:[3]

- Perceptions of race and ethnicity
- Racism or bias
- Poor cross cultural communication skills/cultural insensitivity
- Underrepresentation of physicians from racially/ethnically diverse backgrounds/lack of cultural sensitivity

HOT TOPICS

Disparities & Pain: HOT TOPICS

- Aging and increasingly diverse U.S. population could lead to greater disease burden if pain remains untreated
- Undertreatment of minorities in emergency departments
- Minority pain complaints receive less attention than others
- Impact of pain on productivity and quality of life among minority patients
- Pain relief as a human right

Minorities lack access to effective pain care

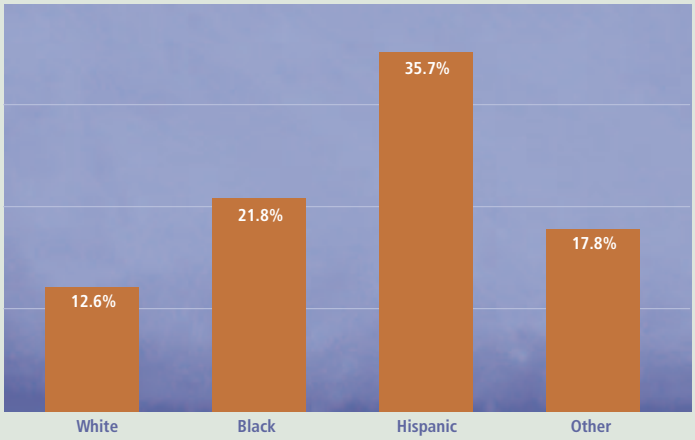
Limited access to pain care services is a key contributor to poorer pain treatment among minorities.

- Overall, minorities tend to be financially poorer than non-Hispanic whites.
- Socioeconomic factors can impede access to health insurance and primary health care services, and minorities are less likely to have access to pain treatment services than the general population.[3,4,7,16,17]
- Racial and ethnic minorities are at increased risk of having their pain complaints ignored by health care providers, thereby limiting their options for accessing appropriate pain treatment.[3,4,6,7]

According to the Robert Wood Johnson Foundation, 46 million Americans, including 9 million children, are living without health care coverage. More than eight out of 10 are from working families. The consequences of being uninsured are widely recognized and include: lack of access to health care, poor quality care, lost economic productivity, as well as financial burdens on individuals and society overall. As the minority population in the U.S. continues to grow, it becomes increasingly important to address the numbers of uninsured and underinsured among racial and ethnic groups.

Barriers also exist in patient access to pain medications. Research shows that physicians may be less likely to prescribe pain medications for minority populations [6,7,16,18] and pharmacies in neighborhoods with large minority populations often do not carry opioid medications.[3,4,12]

PERCENTAGE UNINSURED AMONG THE NONELDERLY POPULATION BY RACE AND ETHNIC ORIGIN, 2006



Sources: Employee Benefit Research Institute estimates from the March Current Population Survey, 2007 Supplement. Cover the Uninsured, www.covertheuninsured.org.

"Inequities in access can contribute to and exacerbate existing disparities in health and quality of life, creating barriers to a strong and productive life."

— The Commonwealth Fund

More extensive research needed to close disparities gap

While national attention has become increasingly focused on health disparities, less attention has been given specifically to inequities in pain care.[19,20] However, the growing interest in health disparities in general provides pain treatment providers, researchers and advocates with an opportunity to raise awareness about disparities in pain management and the need for additional pain disparities research. Currently, the social impact of pain on patients, their families and communities is largely absent in most federal research plans.[3,4]

Additional studies and a comprehensive pain research agenda are needed to:

- Understand the role of stereotypes and bias in doctor-patient interactions
- Improve training for health care providers
- Plan educational interventions for patients
- Understand the differences in patient behaviors that may contribute to pain care disparities
- Develop culturally sensitive pain assessment tools
- Raise consciousness about disparities in pain management and barriers to effective health care overall

WEB RESOURCES

CDC Office of Minority Health and Health Disparities
http://www.cdc.gov/omhd/

Cover the Uninsured: a Project of the Robert Wood Johnson Foundation
http://covertheuninsured.org/

American Pain Society: Racial and Ethnic Identifiers in Pain Management: The Importance to Research, Clinical Practice, and Public Health Policy
http://www.ampainsoc.org/advocacy/ethnoracial.htm

Agency for Health care Research and Quality: Addressing Racial and Ethnic Disparities in Health Care
http://www.ahrq.gov/research/disparit.htm
http://www.ahrq.gov/qual/nhdr03/nhdrsum03.htm

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Topic Brief

SPECIAL CONSIDERATIONS: PAIN IN SPECIFIC POPULATIONS

Although pain is a significant problem among all Americans, certain populations are more susceptible to and at greater risk for undertreatment, including children, minorities and those with advanced, life-limiting medical illness. Studies conducted in emergency departments suggest that women receive less attention in response to reports of severe pain than men. Also, due to military training and culture which teaches service members to be tough, and the complex nature of pain and post-traumatic stress, active duty military personnel and veterans tend to experience greater challenges achieving optimal pain relief than the civilian population.

In order to provide the most effective pain care possible and minimize pain-related morbidity, characteristics of vulnerable populations must be taken into consideration when performing pain assessment and implementing treatment plans. Health care professionals must also become aware of their own biases and understand that, regardless of demographic or social position, every individual with pain requires evaluation and treatment tailored to his or her specific clinical circumstances.

Children and Pain

Every child will experience pain at one time or another, whether it's from everyday bumps and bruises, or more chronic conditions such as headaches, gastrointestinal problems or diabetes. In fact, chronic pain affects up to 38 percent of children.[1]

Pediatric pain stems from a wide range of chronic conditions. For example:

- Each year, 1.5 million children have surgery, and many receive inadequate pain relief. In 20 percent of cases, the pain becomes chronic.[2]
- Of children aged 5 to 17 years, 20 percent suffer headaches.[2]
- More than one-third of children complain of abdominal pain lasting two weeks or longer.[3]
- Juvenille arthritis, which causes joint inflammation and aches, affects nearly 250,000 people under the age of 16 years.[4]
- About one in 1,000 U.S. children are cancer survivors and may have to deal with late and long-term effects of treatment (e.g., chronic fatigue and pain syndromes, nerve damage).[2]
- Recent evidence reveals reduced pain sensitivity is a common feature of children with autism and Asperger's syndrome.[2]
- Musculoskeletal pain can result from "growing pains," a normal occurrence in about 25 to 40 percent of children.[5]

COMMON CAUSES OF PAIN IN CHILDREN

- Abdominal pain (e.g., irritable bowel syndrome, ulcerative colitis)
- Headaches
- Scrapes and bruises
- Needlestick pain from immunizations (most children receive up to 24 immunizations by their 2nd birthday)
- Sports injuries (e.g., sprains, concussion, fractures)
- Chronic illnesses (e.g., sickle cell disease, type I diabetes)

According to the American Medical Association, children and infants are at increased risk of inadequate pain management, with age-related factors playing a major role. Physical and psychological changes that occur during childhood development can make understanding and managing pain in children significantly more complicated than treating pain in adults.

Many things affect the way a child experiences, communicates and responds to pain, including their:

- age
- beliefs and understanding of what is causing the pain
- ability to cope
- activity and anxiety levels
- previous experiences with pain and how they learned to respond
- support from parents and siblings
  - parental pain, stress and family functioning may also play a role in pediatric pain
  - preliminary data suggest that a mother's anxiety may be transmitted more strongly to her daughters than her sons, resulting in increased anxiety and pain in girls, but not boys.[6]

If pain is not addressed and treated early on, it can greatly impact a child's quality of life by interfering with mood, sleep, appetite, school attendance, academic performance, and participation in sports and other extracurricular activities. Furthermore, if unrelieved, childhood pain can pave the way to more pain later in life.[7] It is essential that health care providers

begin to approach pediatric pain so that appropriate strategies can be devised to target and reduce children's distress and pain-related disability.

Unaddressed pain can also result in significant financial stress for families who not only have to cover health care expenses, but who may also have to miss work to care for a sick child.[8]

Inadequate prevention and relief of pediatric pain are still widespread. Many obstacles exist to providing appropriate pain care to children and adolescents:[10]

- Beliefs and attitudes about the experience of pediatric pain.
- General lack of understanding about the best course of action for treating children in pain.
- Belief that pain should be treated less aggressively in children than adults.
- Pediatric pain management research has not been effectively translated into routine clinical practice.
- Pain in children with disabilities or other special health care needs may be more difficult to assess.

MYTHS AND TRUTHS ABOUT PAIN IN CHILDREN

MYTH: Children who are playing or sleeping must not be in pain.

TRUTH: Children cope with pain by distracting themselves, often through play. Sleep may also be a coping mechanism, and/or because they are exhausted.

MYTH: Young infants do not feel pain because their nervous systems are immature and unable to perceive and experience pain the way adults do.

TRUTH: Decades ago it was believed that a newborn couldn't feel pain, and surgery was routinely performed on infants without anesthetic. Today, we know that the central nervous system of a 26-week-old fetus has the capability of experiencing pain. There is strong evidence that children experience increasing anxiety and perception of pain with multiple procedures or painful stimuli.[8]

MYTH: Children can easily become addicted to pain medications.

TRUTH: Less than 1 percent of children treated with opioids become addicted.[9]

MYTH: Children will tell adults when they are having pain.

TRUTH: Children may not have the words to express pain (e.g., hurt, "ouch") or know to point to where it hurts. They may also be afraid of the consequences (e.g., extra visits to the pediatrician, shots, medicine). There are many tools available to assess pain in children. Adults need to recognize how children of different ages express pain in both behaviors and words.

Potential barriers to the effective treatment of pain in children[10]

- The myth that children, especially infants, do not feel pain the way adults do;
- Lack of routine assessment for the presence of pain in children;
- The idea that treating pediatric pain takes too much time and effort;
- Fears of adverse effects of analgesic medications, including respiratory depression and addiction;
- Differing personal values and beliefs of health care professionals about the meaning and value of pain in the development of the child (e.g., the belief that pain builds character).

WEB RESOURCES

American Pain Society
www.ampainsoc.org

International Association for the Study of Pain
Pain in Children
http://childpain.org

UCLA Pediatric Pain Program
www.mattel.ucla.edu/pedspain/home.php

American Academy of Pediatrics
www.aap.org

Whole Child Foundation
www.wholechildla.org

Gender and Pain

Although it has long been thought that women and men have similar pain experiences, recent research reveals significant differences in the way male and female brains process pain,[1] as well as in women's expression of pain and their responsiveness to analgesics and pain stimulus.[2,3]

Historically, women have been categorized as being emotional and overly sensitive; often influencing the way physicians assessed and managed their pain.[4] Even though research now shows that chronic pain conditions are generally more prevalent among women, they continue to be treated less aggressively for their pain than men.[5,6] And while women are more likely than men to seek treatment for their pain, they are less likely to receive it.[7]

Women report pain more often than men do and in more body regions, and they also tend to have more severe, recurrent and persistent pain, as well as a reduced pain threshold when compared with men.[3] However, despite their increased pain burden, women reportedly cope with pain better than men, possibly due to the fact that they experience pain more often throughout the course of their lives (e.g., menstruation, pregnancy and child birth, and other health issues specific to women).[3]

Female hormones are also likely to play a role in pain perception. Some pain conditions like migraine tend to vary with a woman's menstrual cycle, and many of the observed gender differences in pain appear to diminish following the reproductive years.[8]

Hormones May Influence Pain Experience

- Estrogen administration in women and in men can increase the incidence of chronic pain conditions.[9,10]
- Variations in women's estrogen levels, like those that occur during the menstrual cycle or during pregnancy, may regulate the brain's natural ability to suppress pain.[11]
- Some pain conditions such as migraine and fibromyalgia tend to fluctuate with a woman's menstrual cycle.
- Observed gender differences in pain appear to diminish following menopause.

Additionally, cultural conditioning may impact the expression of pain among women and men. As children, girls are more likely to be permitted to express pain and show emotion than boys, and attitudes about the social acceptability of gender and pain often carry into adulthood.[3]

Potential Sources of Gender Differences in Pain

Biological factors including:

- sex hormones
- genetics
- anatomical differences

Psychosocial influences including:

- emotion (e.g., anxiety, depression)
- coping strategies
- gender roles
- cultural conditioning
- health behaviors
- use of health care services

As advances in brain imaging technology provide further insights into gender variations in the experience of pain, it is becoming evident that different pain experiences among men and women will call for different approaches to pain management.

Ongoing research is essential to achieve:

- A better understanding of the biological and psychosocial factors that influence gender differences in pain
- A greater appreciation of the different health needs of men and women
- More effective and targeted pain treatments for women

PAIN DISORDERS WITH HIGHER PREVALENCE IN WOMEN

- Migraine
- Irritable bowel syndrome
- Fibromyalgia
- Chronic pelvic pain
- Interstitial cystitis
- Temporomandibular joint disorder (TMJ)
- Breast pain (mastalgia)
- Autoimmune disorders (e.g., lupus and chronic fatigue syndrome)
- Rheumatoid arthritis
- Osteoarthritis

WEB RESOURCES

International Association for the Study of Pain: Real Women, Real Pain
www.iasp-pain.org

National Institutes of Health: Gender & Pain
http://painconsortium.nih.gov/genderandpain/summary.htm

HealthyWomen.org
www.healthywomen.org/

Society for Neuroscience: Gender & Pain
www.sfn.org/index.cfm?pagename=brainBriefings_gender_and_pain

Older Adults and Pain

As we age, pain becomes a more common problem due to the high prevalence of chronic and progressive pain-producing conditions associated with aging. It is estimated that up to 50 percent of older persons living in the community have pain that interferes with normal function, and 59 to 80 percent of nursing home residents experience persistent pain.[1,2] Alarmingly, being older than 70 is the leading risk factor for inadequate pain management.[3]

Diagnosing and treating pain in older adults can be challenging. Those 65 and older often present with multiple medical and nutritional problems, take multiple medications and have many potential sources of pain. Older persons with dementia or communication problems are at even greater risk of undertreatment of pain due to difficulties communicating their pain.[4] Use of certain medications in older persons becomes problematic because of physiological changes.[5]

The most common cause of persistent pain in older adults is musculoskeletal in nature, typically from osteoarthritis or other bone, joint and spine disorders. According to the Arthritis Foundation, arthritis affects up to 80 percent of older adults, who report being fearful of recurring pain and disability. But the predilection for painful conditions does not mean that older adults need to live with uncontrolled pain. Quite the opposite; older adults can be effectively treated, and in so doing, pain-related morbidity — and even premature mortality — can and should be obviated.

COMMON PAIN CONDITIONS IN OLDER ADULTS

- Arthritis
- Lower back and neck pain; vertebral compression fractures from osteoporosis
- Abdominal pain (e.g., gallstones, bowel obstruction, peptic ulcer disease, abdominal aortic aneurysm)
- Cancer-related pain (symptom of disease or effect of nerve damage from treatments)
- Neuropathic pain due to diabetes, herpes zoster ("shingles"), kidney disease or other medical problems
- Muscle cramps, restless leg pain, itchy skin and sores due to circulatory problems or vitamin D deficiency
- Fibromyalgia
- Complex regional pain syndrome (CRPS), a neuropathic pain condition which can develop after an illness or injury and often affects the extremities
- Injuries, especially from falls

WEB RESOURCES

Handbook of Pain Relief in Older Adults — An Evidence-Based Approach
By Gloth III, F. Michael
http://www.amazon.com/Handbook-Pain-Relief-Older-Adults/dp/1607616173#reader_1607616173

American Medical Association
Assessing and Treating Pain in Older Adults
http://www.ama-cmeonline.com/pain_mgmt/module05/index.htm

American Geriatrics Society Foundation
The Management of Persistent Pain: Resources for Older Adults and Caregivers
http://www.healthinaging.org/public_education/pain

End-of-life and Pain

Pain control is one of the most challenging aspects of end-of-life care.[1] Terminal illness is often accompanied by severe pain, and a significant number of people suffer needlessly at the end-of-life. While the goal of end-of-life care should be making the terminally ill more comfortable, the health care system has been designed to take a curative approach to disease, rather than focusing on symptom relief.[2] Hospital research reveals that health care providers continue to inadequately treat pain, and tend to under-medicate terminal pain.

Individuals at end-of-life may have their pain undertreated for variety of reasons, including a lack of knowledgeable and experienced physicians and myths about addiction to pain medication, leading unnecessarily to patient and family suffering.[3]

Despite advances in research on end-of-life pain treatment, health care providers remain influenced by social and legal concerns, as well as misconceptions about medications including addiction, overdose, lasting side effects and diminished physical capacity.[5] The terminally ill and their families may also hesitate to begin using pain medications as they often associate such treatment with imminent death, thereby allowing patient suffering to worsen and continue.[4]

However, thorough and ongoing pain assessment, paired with well-designed and aggressive medication plans, as well as counseling for patients and their families can have a significant impact on pain relief and side effects among dying patients.[4,5]

END-OF-LIFE PAIN MAY BE EXACERBATED BY MANY OTHER SYMPTOMS INCLUDING:

- Dry mouth
- Nausea
- Water retention and swelling
- Lack of appetite
- Shortness of breath
- Mental distress and anxiety caused by fear or denial of impending death

Effective pain management at the end-of-life requires addressing the total pain experience, including physical causes, as well as interpersonal and spiritual pain.[3,4]

Pain associated with terminal illness often requires special treatment that can be best provided by hospice and palliative care programs available in many medical facilities. Hospice focuses on relieving symptoms and supporting patients who are nearing the end of their life, while palliative care is designed to provide comfort and pain relief at any time during a person's illness.[7] The goal of both programs is to alleviate physical, emotional, spiritual pain and suffering while respecting the dignity of the individual with a life-limiting illness.

"When someone is dying, time is a luxury and wait-and-see is not an option. What matters most in the final days is that patients are free of crippling pain and unbearable suffering so that they can finish their lives in ways that bring comfort, peace, and completion. Concerns about lasting side effects or diminished physical capacity from months of using a drug become secondary to making a patient comfortable. No one has to die in pain."

— *Dr. Scott Fishman*

"Suicidal wishes in patients with advanced disease are closely linked to unrelieved pain and to mood alterations such as depression and anxiety, which like pain, frequently respond to clinician treatment if the clinician identifies and addresses them."[2,6]

Essential Components of End-of-life Care[8]

- Continual assessment and management of pain and other physical symptoms
- Assessment and management of psychological and spiritual needs
- Helping the individual identify personal goals for pain treatment and end-of-life care
- Assessment of the person's support system

WEB RESOURCES

American Academy of Family Physicians: Challenges in Pain Management at the End of Life
www.aafp.org/afp/20011001/1227.html

American Pain Society: Treatment of Pain at the End of Life
www.ampainsoc.org/advocacy/treatment.htm

Discovery Health Center: End of Life Q&A with Dr. Scott Fishman
http://health.discovery.com/centers/pain/endoflife/endoflife.html

National Hospice and Palliative Care Organization
www.nhpco.org/i4a/pages/index.cfm?pageid=3254

Military/Veterans and Pain[1]

Pain is a major issue among military personnel and veterans, who are at heightened risk for injury and combat wounds. Although modern body armor and rapid evacuation to medical care is saving lives, there are more maimed and shattered limbs than ever before, with instances of amputation nearly doubling since before the Vietnam War. Hundreds of thousands of returning veterans will seek medical care and claim disability compensation for a wide variety of injuries and health problems they sustained during their tours of duty. It is estimated that the U.S. will be paying the cost of related medical care and disability claims for the next 40 years.

Veterans are more likely to experience psychological distress and other medical conditions, including post-traumatic stress disorder, depression, amputations, traumatic brain injuries, substance abuse and other injuries, which further complicate effective pain management.

COMMON PAIN CONDITIONS AMONG MILITARY MEMBERS

Post-traumatic stress disorder (PTSD) commonly affects soldiers returning from war, and is triggered by exposure to a situation or event that is or could be perceived as highly threatening to a person's life or those around him/her. PTSD may not emerge for years after the initial trauma.

It is a normal reaction to an abnormal situation. Not every service member will be diagnosed with a disorder, but most will experience some level of post-traumatic stress which can exacerbate pain conditions.

Chronic pain symptoms and PTSD frequently co-occur and may intensify an individual's experience of both conditions. Together, they result in fear, avoidance behaviors, anxiety and feelings of isolation.

Amputations have long been a tragic, unavoidable consequence of combat — "one of the most visible and enduring reminders of the cost of war," according to the Amputee Coalition of America. While there have been major advances in medicine, prosthetics and technologies that allow amputees to lead more independent lives, most of these patients continue to need specialized long-term or lifelong support. Managing wound, post-operative, phantom and stump pain is important to reduce suffering and improve quality of life.

A **traumatic brain injury** (TBI) is a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain and is a major cause of lifelong disability and death. Managing pain in veterans with TBIs may be complicated by memory lapses affecting medication management, difficulty organizing and following complicated and sometimes even simple pain management regimens, and difficulty learning new coping skills. Rehabilitation should incorporate efforts to relieve associated pain.

Veterans have significantly worse pain than the general public, and while military medical care is among the best in the world, there are still long-term problems and challenges with managing disability and chronic pain.

Military culture may also present a significant barrier to appropriate pain care. The persisting stigma around pain and pain treatment is particularly pronounced in the military, and pain is often perceived as a sign of weakness leading many individuals to choose to suffer in silence. Seeking mental health care for PTSD and depression, which so often accompany pain is important; pain is best managed when depression and PTSD are treated simultaneously.

A recent analysis found that the Veterans Health Administration (VHA) is already overwhelmed by the sheer number of returning veterans and the seriousness of their health care needs. Without increased staffing and funding for veterans medical care, it will not be able to provide quality care in a timely fashion.

However, after the 2009 passage of the military and veterans pain care laws, the Department of Defense and the Veterans Health Administration have begun to work together to improve pain care for service members. They jointly developed a pain management task force and issued a report: *Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize the Care for Warriors and their Families* outlining more than 100 recommendations to improve pain care within these health care systems. To find out more, visit http://www.health.mil/Libraries/HA_Policies_and_Guidelines/11-003.pdf.

Barriers to optimal pain management among veterans and military personnel may include fears about:

- No longer being physically capable of fulfilling their duties
- Being discharged and no longer having a sense of purpose
- Letting down or losing the respect of their peers
- Becoming addicted to pain medications
- Experiencing personality changes or problems with sexual relations due to pain medications
- Losing their benefits/pension if they acknowledge a pain condition

The U.S. Veterans Health Administration is instructing physicians and nurses who treat veterans to regard pain as a "fifth vital sign," to be routinely assessed along with blood pressure, pulse, temperature and respiration.

WEB RESOURCES

American Pain Foundation: Military/Veterans and Pain
www.painfoundation.org
www.exitwoundsforveterans.org

Amputee Coalition of America
www.amputee-coalition.org

Defense and Veterans Brain Injury Center
www.dvbic.org

Disabled American Veterans (DAV)
www.dav.org

U.S. Department of Veterans Affairs
www.va.gov

HOT TOPICS

Children & Pain

- Maternal anxiety influencing daughters' experience of pain
- Some neonatologists still do not treat pain in pre-term low birth weight babies because they "won't remember it"
- Investigations into "chronic daily headaches" in children
- Unraveling pediatric pain conditions and their impact into adulthood (e.g., whether complex regional pain syndrome in children leads to adult CRPS, whether irritable bowel syndrome in adolescents is this the same as IBS in adults)
- Complementary and alternative medicine: how and what is safe to use in children with chronic pain?
- Factors leading to pain-related disability in children (e.g., missing school, not sleeping, avoiding physical and social activities, not eating)

Gender & Pain

- Prevalent pain conditions in women (e.g., fibromyalgia, chronic pelvic pain)
- Interface of hormones and the pain experience
- Brain imaging, uncovering routes of pain transmission and tolerance
- Differential effects of medicines across genders
- Impact of chronic pain on sexuality and self-image

HOT TOPICS

Older Adults and End-of-life Care & Pain

- False belief that pain is an inevitable part of aging
- Vitamin deficiencies and musculoskeletal pain
- Limited consumer awareness of the options that exist other than traditional "acute care" approaches (e.g., doctor's office visits, ER visits, hospitalizations)
- Insufficient numbers of adequately trained and skilled health care professionals to manage the myriad issues confronting patients/families with advanced medical illness; limited number of providers with specialty in geriatrics
- Variability in delivery of hospice and palliative care services across the country
- Lack of clinical research data on pain care among elders

Military/Veterans & Pain

- DOD/VA responds to the Military and Veterans Pain Care Acts of 2009
- Emerging Options: Interdisciplinary approaches to pain care
- Acupuncture now being incorporated into treatment plans at Walter Reed Army Medical Center
- Competitive athletics as a form of therapy

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201 N. Charles St., Suite 710 • Baltimore, MD 21201-4111 • 1-888-615-PAIN (7246)
www.painfoundation.org

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Dedicated to eliminating the undertreatment of pain in America.

Treatment Options: A Guide for People Living with Pain

American Pain Foundation

Dedicated to eliminating the undertreatment of pain in America.

WHO WE ARE

Founded in 1997, the American Pain Foundation is an independent nonprofit 501(c)3 organization serving people with pain through information, advocacy and support. Our mission is to improve the quality of life of people with pain by raising public awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management.

WHAT WE DO

Serve as an information clearinghouse and resource center for people with pain, their families and their caregivers, the general public, healthcare professionals, policymakers and the media.

Promote recognition of pain as a critical health issue; correcting damaging myths about pain and pain management, and seeking to remove the stigma often experienced by those with pain.

Advocate for changes in professional training, regulatory policies, and health delivery systems to ensure that people with pain have access to high quality care.

Encourage healthcare professionals to assess pain routinely and provide immediate, ongoing, effective care.

Mobilize organizations and individuals who care about better pain management.

HOW YOU CAN HELP

If you would like to further our mission, please visit our web site, www.painfoundation.org, and join the growing number of APF members. Membership is free and open to all. APF members receive online support and resources and useful publications like the *Pain Community News*, which features the latest news about pain and the *Pain Monitor*, which provides updates on pain news and policy issues.

Dear Friend:

As you pick up this publication, you may be asking yourself lots of questions: Can my pain be better controlled? Are there options available that I don't know about? How do various treatments differ? What non-drug therapies are used to manage pain? What questions should I ask my doctor, nurse, pharmacist or social worker about pain?

Treatment Options was written to help answer these and other questions related to pain care. Whether you've just started experiencing pain, have lived with it for several years, or are a caregiver to someone in pain, this guide was written to serve as a useful resource. Each subsection provides easy-to-understand information about a variety of treatment options from medications to psychosocial interventions, rehabilitation therapies, surgical interventions and much more. Words boldfaced in **green** are some common pain terms and are defined at the end of the book.

We trust this will inspire hope and help you in your quest for better pain care. You should not have to suffer with your pain. As always, it is important to talk to your healthcare provider to decide what approach is right for you. Please feel free to share your thoughts and comments by sending an e-mail to info@painfoundation.org.
We will update the online version of this book periodically, so check for new tips and information at **www.painfoundation.org.**

Will Rowe
Executive Director
American Pain Foundation

Whether you are a newcomer searching for information to improve your pain care or a seasoned explorer looking for what's new and different, this guide is for you.

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The content was developed, edited and reviewed in collaboration with the following expert advisors:

Terry Altilio, MSW, LCSW
Social Worker, Department of Pain Medicine and Palliative Care
Beth Israel Medical Center (NYC)

Michael Brennan, MD
Private Practice,
Physical Medicine and Pain Management

June Dahl, PhD
Professor of Pharmacology,
University of Wisconsin School of Medicine and Public Health

Annabel Edwards, MSN, ARNP
Nurse Practitioner, Massachusetts General Hospital

Judith Fouladbakhsh, MSN, APRN, BC, AHN-C, CHTP
Assistant Professor, Wayne State University College of Nursing
Certified Advanced Practice Holistic Nurse,
Healing Touch Practitioner

Francis Keefe, PhD, Professor,
Department of Psychiatry and Behavioral Sciences,
Associate Director for Research,
Duke Pain and Palliative Care Program,
Duke University Medical Center

Jacqueline Levin, RN, MS, AHN-C, CHTP
Clinical Nurse Specialist in Holistic Nursing,
NYU Medical Center (NYC)
Certified Pilates Instructor

Bruce Nicholson, MD
Chief of Service; Mid-Atlantic Pain Specialists

Cassie Snyder, MS, RN
Director of Center for Pain Management at Lehigh Valley Hospital

American Pain Foundation Board: Physician Reviewers

Scott Fishman, MD
Chief, Division of Pain Medicine at the University of California, Davis
Professor of Anesthesiology, Department of Anesthesiology and Pain Medicine
Vice Chairman of the APF Board of Directors

Russell Portenoy, MD
Chairman, Department of Pain Medicine and Palliative Care,
Beth Israel Medical Center (NYC)
Professor of Neurology and Anesthesiology,
Albert Einstein College of Medicine
Member of APF Board of Directors

Pain Community Reviewers

Don Freeman
Pain Community Advisory Committee (PCAC) Leader

Mary Anne Stabile
PainAid Online Community Team Leader

Mary Vargas, Esq.
PCAC Member

Nick Wilson
PainAid Online Community Team Leader, PCAC Member

American Pain Foundation Project Staff

Micke A. Brown, BSN, RN
Director of Advocacy and Project Team Leader

Yvette Colón, MSW, ACSW, BCD
Director of Education & Internet Services

Susan McLean
Former Media Director 2004-2005

Lisa Nuth
Support Specialist, Certified Massage Therapist

The following organizations are represented by those who helped create this publication:

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Jacqueline Levin, RN, MS, AHN-C, CHTP

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READ THIS BOOK TO FIND OUT:

- Why pain management is important
- How to talk with your healthcare provider about pain
- Information about a variety of drug and non-drug treatment options
- Important goals of therapy
- Benefits and drawbacks of various treatments
- Promising new treatments

As you are reading, remember some approaches span various treatment settings and specialists. For example, some psychosocial interventions, such as hypnosis and guided imagery, may also be advocated for and used by specialists in complementary medicine. This is also true for some rehabilitative techniques (e.g., Rolfing, myofascial therapy).

WHY IS MANAGING PAIN IMPORTANT?

Persistent pain can interfere with your enjoyment of life. It can make it hard to sleep, work, socialize with friends and family and accomplish everyday tasks. When your ability to function is limited, you may become less productive. You may also find yourself avoiding hobbies and other activities that normally bring you happiness in order to prevent further injury or pain. Ongoing pain can cause you to lose your appetite, feel weak and depressed.

Try not to allow your physical illness or pain to take over your life. Pain *is* a part of you, but it is *not* YOU. It is *not* who you are. Managing your pain is an important step to reclaim your life and ensure it does not control you.

ESTABLISHING A DIAGNOSIS AND ASSESSING YOUR PAIN

To correctly diagnose your pain, your healthcare provider may:

- Perform a complete physical exam
- Complete a pain assessment
- Ask detailed questions about your medical history and lifestyle
- Order blood work, X-rays and other tests

Note: Because of the current state of medical science and limited pain research, there are some causes of pain which might not be able to be confirmed with current medical technology and diagnostic tests.

It is important to give your healthcare provider a complete picture of your pain history. This information will help him or her to determine the right treatment plan for you. To complete a pain assessment, your healthcare provider may ask the following questions about your pain:

- Location
- Intensity
- Description of the sensation(s)
- Nature: Onset, duration, fluctuations
- What makes it better?
- What makes it worse?
- How does it affect your sleep, mood, appetite, activity?

Pain can affect your emotional outlook, your ability to concentrate, your energy level and your sense of self.

If you keep a pain journal, be sure to share it with your healthcare provider. If you don't, consider starting one today. The American Pain Foundation's Pain Notebook is an easy-to-use tool to help you keep a record of your pain (when it occurs, for how long, the level or type of pain, etc.), response to various treatments over time, improvements in daily function and side effects. The *Pain Notebook* can help guide your communication with your healthcare provider and is available by calling 1-888-615-PAIN (7246).

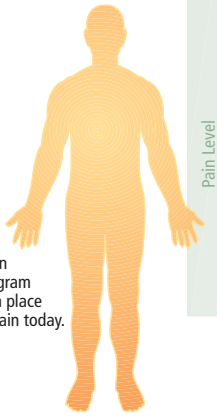
Finding good pain care and taking control of pain can be hard work. As a person with pain, you should become your own best advocate. Learn all you can about pain and possible treatments, and insist on the care you need and deserve.

Use descriptive language when explaining your pain. Describe your pain with words like: sharp, crushing, throbbing, shooting, deep, pinching, tender, aching, among others. Your healthcare provider may also use a pain scale to help assess your pain. Pain scales are tools that can help you describe the intensity of your pain and help your doctor or other healthcare providers diagnose or measure your level of pain. Three types of scales are commonly used: numeric, verbal and visual.

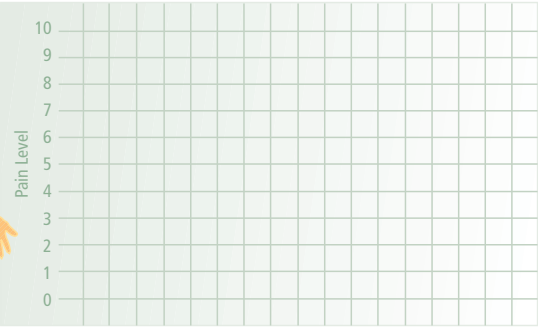
With **numerical scales**, you use numbers from 0 -10 (0 being no pain and 10 being the worst pain ever) to rate the intensity of your pain.

Verbal scales contain commonly used words such as "mild," "moderate" and "severe" to help you describe the severity of your pain.

Visual scales use aids like pictures of facial expressions, colors or gaming objects such as poker chips to help explain the severity of your pain. One type, the Wong Baker Faces Pain Rating Scale, features facial expressions to help you show your healthcare provider how much pain you feel. Body diagrams may be used to help pinpoint where your pain is located.



Put an "X" on the body diagram to show each place you've had pain today.



Mapping a Treatment Plan

Pain is complex and unique to each individual. For this reason, your healthcare team will consider many aspects of your pain and daily life before recommending a treatment program, including:

- Type of pain (whether it is **acute** or **chronic**)
- Category of pain (**nociceptive** or **neuropathic**)
- Intensity of your pain
- Your physical condition, coping ability and challenges
- Your lifestyle and preferences for treatment

YOUR PAIN MANAGEMENT TEAM

Common pain problems can often be managed by your primary care provider or treating healthcare professional. This individual could be a physician, nurse practitioner or physician's assistant. When pain is more difficult to treat, help from additional healthcare professionals and others with specialized training in pain may be required. Some of these disciplines may include, but are not limited to:

- Specialty physicians from the fields of neurology, neurosurgery, physical medicine, anesthesia, orthopedics, psychiatry, rheumatology, for example.
- Nurses
- Pharmacists
- Social Workers
- Psychologists
- Case Managers
- Chiropractors
- Physical Therapists, Occupational Therapists, Physiatrists
- Complementary/Alternative Medicine Practitioners

Remember, a therapeutic relationship is a two-way street. It develops over time and trust and open communication are essential. Be sure to find a healthcare professional who is not only trained to treat your pain disorder, but is also willing to work with you to manage your pain. At each follow-up visit, a re-assessment of your pain and pain management plan is very important in order to evaluate the effectiveness of your treatment.

GOALS OF PAIN THERAPY

Your pain management team will work with you to map out a treatment plan tailored to your specific needs. Successful pain management aims to:

1. Lessen the pain
2. Improve functioning
3. Enhance your quality of life

These are considered the hallmarks of pain management and "best practices."

In some cases, pain is best managed using a combination of treatments. This is referred to as a "multi-modality" approach. For example, your healthcare provider may prescribe a medication along with activities to reduce stress (e.g., yoga, deep-breathing exercises). To improve daily functioning, specific therapies may be suggested to increase muscle strength and flexibility, enhance sleep and reduce fatigue, and assist you in performing usual activities and work-related tasks.

While there are a variety of treatment options available for those living with pain, different therapies might not work for everyone. Finding the right combination may take time, but often makes the critical difference in your care. As always, it is important to weigh the risks and benefits of different pain treatments and consult your healthcare provider before starting or changing any treatment.

Pain management is an ongoing process, not just a one-time concern. Finding the right combination of therapies may take time, but often makes the critical difference in your care.

There are factors that can interfere with therapies, including:

- How different drugs interact with each other when taken together
- How different foods might affect how a drug works when taken together
- How different treatments can either complement each other or cause harm
- How your general health and personal habits can play a role in pain treatment (for example, smoking tobacco can interfere with pain treatment and increase pain levels)

TREATING THE WHOLE PERSON

The impact of pain requires an understanding that the whole person experiences pain; that is, the mind, body and spirit. Integrative medicine supports the use of "conventional" treatments, for example, drugs, counseling, exercise or surgery, along with "complementary" pain-relieving techniques like acupuncture, bio-feedback, massage or chiropractic manipulations. This allows healthcare providers to offer more **holistic care.**

TREATING THE CAUSE OF YOUR PAIN

Whenever possible, your healthcare provider should make every effort to treat the cause of your pain. For example:

- If you are a diabetic, it is important to control your blood sugar, because that may prevent nerve and blood vessel damage that can result in a variety of painful problems commonly seen with this disease.
- If you have rheumatoid arthritis, you may be prescribed drugs to treat the arthritis itself because pain medicines will not prevent the disease from damaging your joints.
- If you have migraine headaches, there are medicines that can prevent or reduce the frequency and severity of headaches, reducing the need to use pain medications.
- If you have osteoporosis, your provider may recommend that you take medications to strengthen your bones to help prevent fractures that could result in pain and disability.
- Surgery also plays a critical role in pain control. Replacement of a knee or hip may provide relief of pain and reduce or eliminate the need for analgesics.

Pain is complex and involves every aspect of your being. Because it is not just a physical experience, there is no magic pill to take away the pain.

HELPFUL HINTS ON YOUR ROAD TO PAIN RELIEF

Keep the following tips in mind as you seek treatment for your pain:

- **Chronic pain** can result in physical and psychological challenges. It is important to accept support from loved ones — you need and deserve all the help you can get.
- Be sure to seek treatment as early as possible to avoid further problems.
- Do not allow your physical illness or pain to take over your life. Pain is a part of you, but it should not define who you are.
- Try not to let past frustrations of failed treatments stand in your way; there are a wide range of treatments available as detailed in this guide. While your pain might not go away completely, there are ways to reduce it so that it is bearable and you can reclaim parts of your life.
- Keep a pain journal.
- Only you know the extent of your pain and how it's impacting your life. Don't be afraid to speak up.
- Before going to your appointments, write down any questions you might have and take them with you; it's easy to forget things and you may not have much time with your provider.
- Bring a relative or friend to your appointments to provide any support you might need. They can also take notes and help you to remember things that were said.
- Be certain there is someone on the healthcare team that you can call if you have any questions or concerns after you have been taking your medicine for awhile. Make sure you know how to get in touch with them.
- Know your treatment options. Your healthcare provider should share information about your condition, pain and possible treatment options, but you should also inform yourself.

AVAILABLE TREATMENT OPTIONS

The following areas of pain treatment should be considered:

- Pharmacotherapy (drug options)
- Psychosocial Interventions (coping, counseling, etc.)
- Rehabilitation Techniques (re-conditioning, re-training and lifestyle changes)
- Complementary and Alternative Medicine (CAM)
- Injection and Infusion Therapies
- Implantable Devices and Surgical Interventions

Healthcare professionals who treat pain may not have experience in using or performing every treatment option available. Some pain treatment options require special areas of expertise or training. Referrals to those specialists may be required. Insurance coverage of pain treatment options vary widely, if covered at all.

The information in this guide is provided to help readers find answers and support. Readers are encouraged to share and discuss this information with their doctor.

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Pharmacotherapy
{Drug Options}

USING MEDICINES TO CONTROL PAIN

An overview of pharmacotherapy

Medications play an important role in the treatment of pain. Many different medicines can be used to help relieve pain. A few, such as aspirin, ibuprofen and acetaminophen, can be purchased in a pharmacy or supermarket without a prescription, but most pain relievers are only available with a prescription from your healthcare provider. Some medications used to treat pain are not usually thought of as pain medicines, but they have been shown to relieve specific types of pain. For example:

- Some drugs used to manage depression or seizures can be used to treat neuropathic or nerve pain.
- Some steroid medications, such as prednisone and dexamethasone, may be used to treat pain caused by inflammation or bone disease.
- Some medications used to relax muscles or treat insomnia or anxiety may be used in the overall management of pain.

Don't be afraid to ask your healthcare provider questions about prescribed medications. Be certain to address the following:

- Why a particular medicine was chosen to manage your pain problem.
- The associated risks and benefits of the drug; common side effects, as well as recommended steps should these side effects appear.
- Exactly how you should take your pain medicine, including the dosage (how much) and how often.
- Whether there are other drugs, foods, drinks, vitamins or herbal supplements that you should not take at the same time. For example, grapefruit juice has been shown to interfere with the action of many medications.

Some pharmacies do not carry every type of pain medication. You can always call your pharmacy to find out if the drug or drugs you are prescribed are available and whether they are covered by your health insurance plan. Tell your provider if you cannot afford to pay for your medicine. Sometimes he/she may be able to prescribe a less expensive medication that works in the same way or help you access the medication at a reduced cost or, sometimes, at no cost. Several pharmaceutical companies have special programs that will assist people with financial need.

CLASSES OF ANALGESICS FOR PAIN CONTROL

There are three major classes of medications for pain control:

Non-opioids: non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen

Opioids (may also be called **narcotics**): codeine and morphine are examples

Adjuvant analgesics: a loose term referring to the many medications originally used to treat conditions other than pain, but now also used to help relieve specific pain problems; examples include some antidepressants and anticonvulsants. Some of these drugs have been shown to work well for specific types of pain.

Drugs that have no direct pain-relieving properties may also be prescribed as part of a pain management plan. These include medications to treat insomnia, anxiety, depression and muscle spasms. They can help a great deal in the overall management of pain in some persons.

THE NON-OPIOIDS

NSAIDs

There are many different drugs in this family of pain relievers. They all relieve mild to moderate pain and reduce fever and inflammation. They decrease the formation of natural substances in the body called prostaglandins. Prostaglandins serve to protect a number of areas in the body such as the stomach and kidneys. They are also produced at sites of injury or inflammation and allow pain receptors in the surrounding area to become more sensitive to pain. *By decreasing prostaglandins, NSAIDs lessen the sensation of pain and reduce inflammation.*

Classes of NSAIDs

Aspirin (acetylsalicylic acid) is the oldest NSAID and was introduced into medicine in 1899. A large number of aspirin-like drugs have been developed since that time. Aspirin, ibuprofen, naproxen and ketoprofen are the only NSAIDs available over-the-counter (OTC) without a prescription. A different class of NSAIDs, the selective COX-2 inhibitors (or coxibs), were not marketed until quite recently and were developed to reduce the risk of ulcers caused by NSAIDs. Only one selective COX-2 inhibitor, celecoxib, is still available at this time.

Clinical uses

NSAIDs are effective against mild to moderate pain, and are important for the management of both acute and chronic pain. For example, an NSAID may be the only analgesic needed to control pain after a minor injury or surgical procedure. They are often used in combination with other drugs such as opioids for treating pain after surgery because, when combined in this way, the pain can often be well controlled with a smaller dose of the opioid. This may help to avoid some of the common side effects of opioids. NSAIDs are especially effective for relieving pain due to inflammation or pain in persons whose cancer has spread to the bone. There is no research evidence that they relieve **neuropathic pain** or are of particular benefit for treating the pain of fibromyalgia.

There is no evidence that one NSAID is a better pain reliever than another; however, each individual may get better pain relief from one than from another. Finding the right NSAID to treat persistent pain is a matter of trial and error. It may take awhile for the drug to work, so you and your provider will need to allow an adequate trial of the drug before judging its benefit. NSAIDs have an important limitation, called a dose *ceiling*. Taking doses above the ceiling dose will significantly increase the risk of serious side effects, such as kidney failure, which can be life threatening.

Common side effects of NSAIDS

- GI distress
- Stomach ulcers
- GI bleeding
- Delayed blood clotting
- Decreased kidney function
- Possible increased risk of stroke or heart attack with selective COX-2 inhibitors

How to take these medicines

All NSAIDs are effective when taken by mouth. Different NSAIDs last for different lengths of time, so one must be careful to follow dosing instructions. There is one NSAID, ketorolac (Toradol®), available for injection into a muscle or a vein, which makes it useful to treat pain after surgery or trauma especially when persons may not be able to take medicines by mouth. Others that can be given by injection may be available in the near future.

In an attempt to avoid some of the serious side effects of NSAIDs, topical preparations have also been developed. Topical NSAIDs work at

the site of pain and inflammation and do not get into the blood stream like medications taken by mouth. One topical NSAID is a solution that is rubbed on the skin, another is in the form of a patch. Topical NSAIDs have been shown to decrease pain and increase function in persons with osteoarthritis and to relieve **acute pain** associated with soft tissue injuries such as sprains and strains. Be very cautious about buying topical NSAIDs from the Internet as the consistency of their delivery systems and the actual dose delivered are unproven and may result in unsafe or unsatisfactory results.

Side effects

The most common side effects of NSAIDs involve the gastrointestinal (GI) tract. They can produce anything from heartburn to ulcers to bleeding. Serious problems, like ulcers or bleeding, can occur without warning. While taking these medicines with food or milk may reduce stomach upset, this will not protect you against the development of ulcers or bleeding from the GI tract. The risk of a GI bleed is increased in older adults, in those who are also taking aspirin or a steroid such as prednisone, and in those who have had ulcers or any kind of NSAID-induced GI problem in the past. The risk of bleeding from an ulcer is also greater if you are taking a blood thinner such as warfarin (Coumadin). Your healthcare provider may tell you to check your stools for hidden blood. If you ever notice that your stool contains blood or appears darker than usual, contact your healthcare provider immediately.

Your doctor can prescribe medications to protect your stomach from NSAIDs, but some of these can be expensive and also have their own side effects. The most effective are the proton pump inhibitors, including omeprazole, which are available over-the-counter. The selective COX-2 inhibitors were designed to be easier on the stomach and avoid GI problems common to the older NSAID drugs. Unfortunately, recent studies show that if you take COX-2 inhibitors with aspirin, you are likely to have as many stomach problems as if you were taking one of the older drugs.

NSAIDs may also decrease kidney function, which is a significant problem in elders. As a result, the body may retain water, which would be dangerous in persons who have high blood pressure or heart failure. The older NSAIDs interfere with blood clotting and have to be discontinued hours to days before surgery. An advantage of the COX-2 inhibitors is that they do not affect blood clotting. NSAIDs can cause "hypersensitivity reactions" with symptoms similar to an allergic reaction. Some cause headaches or slow thinking.

Recently, concern has been raised about the possibility that NSAIDs, including the COX-2 selective inhibitors, may increase the risk of heart attack and stroke. Although the research is still limited, there is evidence that a small increased risk of these complications occurs whenever an NSAID is taken for a period of time. Two COX-2 inhibitors (Vioxx® and Bextra®) were taken off the market in response to this concern.

Should I take these pain medicines?

It's been known for a long time that NSAIDs can cause life-threatening side effects in some persons. There are 10,000 to 20,000 deaths each year because of the side effects of this class of medicines. In spite of that, these drugs are widely used. A third of Americans over the age of 65 take NSAIDs daily. If you are taking NSAIDs for musculoskeletal pain, keep in mind that there are a variety of non-drug and drug therapies available that are helpful as well. The risks from NSAIDs are greater if higher doses are used or if these drugs are taken for more than a period of months. Discuss these risks with your healthcare provider, particularly if you may be at risk because of a

history of heart disease, stroke, peripheral vascular disease, hypertension, kidney disease or ulcers. Whenever an NSAID is taken for pain, it is prudent to use the lowest effective dose and to stop the therapy unless it is clearly needed over time. Though NSAIDs are commonly used medications, they do have dangers and must be used appropriately.

Acetaminophen

Acetaminophen can be used to relieve mild to moderate pain and treat fever, but it is not an NSAID and does not reduce inflammation. It produces few, if any, side effects at the doses that can relieve pain, but it can damage the liver when used in large doses. Acetaminophen overdose is a medical emergency. The labeling specifies an upper limit of 4 grams in 24 hours (which is equivalent to just eight Extra Strength Tylenol®). Persons with liver disease or a history of alcohol abuse should limit their use to much less than this and should consult their healthcare provider about the safest and most appropriate dose to use.

There are many combination pain medicines that contain an opioid with acetaminophen. Be careful with these drugs as they contain different amounts of acetaminophen. Be sure to check the amount with your pharmacist. Don't decide to take extra acetaminophen on your own if a combination pain medicine is not controlling your pain because you may end up using too much acetaminophen and that could cause liver damage. Be aware that many OTC cough, cold and sinus remedies and combination pain relievers also contain acetaminophen, meaning you could be taking more of the drug than you realize. You should also be aware there is a risk of kidney damage if you take acetaminophen for months or years, especially if you take it together with an NSAID.

OPIOID ANALGESICS (NARCOTICS)

Opioid analgesics are another important class of medications that are very effective pain relievers. As mentioned before, they may also be called "narcotics." Unfortunately, this term is used by law enforcement to refer to drugs that are abused. Cocaine and heroin are called narcotics even though they are very different kinds of drugs. Calling opioid analgesics "narcotics" reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines. In the pain treatment world, the word opioid is used when speaking about this class of medications.

Clinical uses

Opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer. They may also be an important part of the management of persistent pain unrelated to cancer. These medicines block pain messages in the body, but they also affect the way we feel about our pain and help us better tolerate it. Our body produces natural opioids (endorphins) as part of its survival response to danger and injury. Because the medications of this class work in the same way as endorphins, they work very well in blocking pain.

Despite the great benefits of opioids, they are often under-used. For a number of reasons, providers may be afraid to give them and the public may be afraid to take them. Some feel opioids should not be used to treat persistent pain except in persons

who are dying. Others are concerned that the average person will become addicted to these drugs. These concerns lead to confusion and hesitation on the part of some providers to prescribe these for pain control. Adding to the problem is the increase in abuse of prescription drugs in the U.S. Persons with addictive disease (in the past, the term "addicts" was used) have obtained and misused these drugs. Others have taken them illegally through pharmacy thefts or under false pretenses in order to sell them "on the street" for profit.

Obviously, it is very important to get the facts about these effective and powerful pain medicines because their under-use has been responsible for much unnecessary suffering. Those affected by pain, providers, patients and family alike, need to be well-informed to be sure that myths and misunderstandings do not get in the way of effective pain control.

Classes of opioid analgesics

Familiar medicines in this family of drugs are codeine and morphine. But there are several others that your provider might use for different pain problems. These include hydrocodone, oxycodone, hydromorphone, meperidine, methadone, propoxyphene and fentanyl. Generic and brand name drugs are available, so you may have heard hydrocodone referred to as Vicodin® and oxycodone as Percocet®. Both of these products contain acetaminophen. Opioid pain medicines are not all alike. They differ in how well they control pain, how much you have to take, how long they last and in the routes by which they can be given.

Some opioids such as codeine, hydrocodone and propoxyphene usually are not preferred for the management of severe pain. Tramadol, although not classified as an opioid, is another drug that has some opioid effects and can be beneficial for mild to moderate pain. Persons taking an antidepressant or an antipsychotic drug along with Tramadol may be at increased risk of seizures.

The side effects of codeine become unacceptable if given at high doses. Some people do not make the natural enzyme that breaks codeine down into a pain relieving chemical in the body. In those people, taking codeine for pain is like taking a sugar tablet.

The dose of hydrocodone is limited because it only comes in combination with acetaminophen and, as was mentioned before, acetaminophen can be toxic to the liver in large doses. In the doses usually prescribed for pain, propoxyphene is only as effective as aspirin or acetaminophen. High doses may not be tolerated and toxic doses are associated with serious risk of heart problems.

Meperidine is another opioid for which dose and length of use must be limited because it is metabolized (breaks down) to a chemical that can cause tremors, twitches or even seizures. Although it can provide relief of severe pain, it should only be used in small doses and for short periods (less than 3 days) in healthy adults. More and more hospitals are either restricting or avoiding its use.

The other opioids can relieve severe pain. Their doses can be gradually increased over time. There is no ceiling dose as there is with the NSAIDs. As pain worsens, these medications continue to be useful unless side effects occur. It is a myth that opioids, like morphine should only be used at the final stages of a seriously painful disease. When pain is severe, opioids should be considered.

Ways to take these medicines

One of the advantages of opioid drugs is that they can be given in so many different ways. For example, they can be given by mouth, rectal suppository, intravenous injection (IV), subcutaneously (under the skin), transdermally (in the form of a patch) or into a region around the spinal cord. Patches, IV injections and infusions are very important for patients who cannot swallow or whose GI tracts are not working normally.

Many people benefit from having some form of control in taking their pain medications, whether they are at home or in the hospital. Your healthcare provider may give you the option of taking doses of the opioid on an "as needed" basis at home. You may wish to discuss this option with your healthcare provider.

Another way of allowing you to control the dosing of an opioid is called "patient-controlled analgesia" or PCA. You may have heard of intravenous or subcutaneous patient-controlled analgesia (IV-PCA; SQ-PCA) that is used after surgery or sometimes for severe pain in persons with cancer (*see Infusion Therapy section*). On the horizon is a new patch delivery system that gives an extra dose of medication across the skin; this is called a patient-controlled transdermal system (PCTS).

Pain medicine can also be delivered into your back through a very small tube called an epidural or intrathecal catheter. This may be an excellent way to give an opioid if you are having major surgery of the chest, stomach, pelvis or limbs. Opioids may be given through an intrathecal catheter for chronic pain if a person has not responded to more conservative approaches to treatment.

The duration of opioid pain relief

In the absence of a special "extended-release" formulation, most opioids provide just several hours of pain relief after a dose. The extended-release formulations (also called "modified-release," "controlled-release," "sustained-release" and sometimes "long-acting") can be pills or patches and can provide pain relief from eight to as long as 24 hours. NEVER crush, chew or take these long-acting medications differently than prescribed. These changes can destroy the time-release feature and cause an overdose.

Fentanyl is available in a patch worn on the skin for the treatment of persistent pain. The drug is absorbed slowly under the skin and then is absorbed into the blood stream. The patch can give pain relief for as long as 72 hours. DO NOT put heat on the patch after you have placed it on the skin because the drug could get into your blood very quickly and cause side effects, and even a possible overdose. Fentanyl is also available in a lozenge. In this formulation, it has a quick onset and short duration of effect that makes it especially useful for the treatment of "breakthrough" pain.

Pain is considered "breakthrough pain" when it "breaks through" the pain medication being used to treat persistent pain. Breakthrough pain (BTP) can occur suddenly—in bursts and may last for short periods of time. BTP can also be experienced during pain-producing activities. BTP can result when the dose of a long-acting opioid begins to wear away.

Opioids can be given as the only treatment for pain, but as mentioned earlier, they are often prescribed in combination with non-opioids or with one of the adjuvant analgesics. A long-acting drug may be used to treat persistent pain. It may be the only medication required to keep pain under control. When moments of increased pain occur two or three times a day or more, a short-acting (SA) medication may be added.

Side effects

The most common side effects of opioids include constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching. Some people may also experience dizziness or difficulty urinating. Respiratory depression, a decreased rate and depth of breathing, is a serious side effect associated with overdose.

The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is most likely to persist. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, poor diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. Always make certain to drink plenty of fluids and be as active as possible.

If any of the other side effects don't go away, they can also be treated. Be certain to tell your provider if you are having any problems. Serious side effects such as delirium or respiratory depression can occur if the dose is increased too quickly, especially in someone who is just starting to take opioids. Tell your provider if you are unable to concentrate or think clearly after you have been taking an opioid for a few days. Report other medications you may be taking that make you sleepy. Do not drive when you first start taking these drugs or immediately after the dose has been increased. Most persons will adapt to these medicines over time and can drive safely while taking them for pain control. If side effects remain troublesome, your provider may switch you to a different opioid. The amount of pain relief can be maintained after such a switch and often the side effects can be reduced.

Common drugs that can cause physical dependence

- Opioids
- Stimulants
- Sedatives
- Steroids
- Certain Antidepressants
- Certain Heart Medications
- Caffeine

Tolerance, physical dependence and addiction

You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. *Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted. In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.

If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.

Persons who have an addiction have lost control over use of the drug and continue to use it even when the drug is doing them or others harm. The term addiction now refers to a medical diagnosis and is defined as a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and expression. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving (From the American Pain Society, American Academy of Pain Medicine and American Society of Addiction Medicine http://www.asam.org/pain/definitions2.pdf).

People with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches.

Some people who are not substance abusers also engage in these types of behavior. Even if this results in part from a desperate desire to obtain pain relief, it is unacceptable and your healthcare provider must intervene to stop the behavior.

Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction. However, your provider may establish very clear guidelines to ensure that you take the opioid as prescribed. Some physicians will require you to sign an agreement (*see Table 1*) before opioids are prescribed.

Table 1: COMMON FEATURES OF AN OPIOID AGREEMENT

- Sign an opioid agreement to be kept in your medical file (ask for your own copy)
- Obtain prescriptions from only **one** doctor
- Have your prescriptions filled at **one** pharmacy
- Come in for regular office visits (every 2-4 weeks or so)
- Agree to have periodic urine drug screening
- Bring your pills in to be counted during visits
- Follow any additional rules not listed above

Once your prescription is filled, it is of the utmost importance that these medications are kept in a secured location to prevent access to children or others. According to law enforcement reports, theft of personal supplies of pain medications stored in the home does occur. If this happens to you, report it immediately to your local police department. Ask for a copy of this report, so you may share it with your healthcare provider. It is very important to remember that drugs of all kinds have a potential to hurt us, but when used properly and with supervision they can be life-savers and give all of us a quality of life we deserve.

ADJUVANT ANALGESICS

Adjuvant analgesics are drugs that are used to treat other illnesses, but have been found to provide relief for certain kinds of pain. These include certain antidepressants, anticonvulsants, corticosteroids and some other drugs used by pain specialists. Adjuvant analgesics are particularly important for the treatment of neuropathic pain. This kind of

pain may be difficult to treat. Drugs recommended for the treatment of neuropathic pain are listed in *Table 2*. You will notice opioid analgesics and tramadol are listed. Finding the drug that works best for you is a matter of trial and error. Your provider will consider your age, your general health and the cost of the medications. Combining different drugs may give the best results. For example, a recent study confirmed that combining gabapentin and morphine gives better relief for neuropathic pain than using either one alone.

Table 2: MEDICATIONS FOR NEUROPATHIC PAIN

Medication	Uses and Impact on Pain
Opioid analgesics and tramadol	These medications were discussed earlier.
Lidocaine patch	Put the patch where it hurts and follow your healthcare provider's instructions about changing it on a daily basis. Do not place it on areas of broken skin.
Antidepressants* Tricyclics such as amitriptyline, nortriptyline, desipramine, doxepin	Dose is increased gradually. These have many possible side effects such as sleepiness, dry mouth, blurred vision, weight gain, decrease in sexual desire or performance.
Venlafaxine and duloxetine	Generally, these have fewer side effects than tricyclics; your doctor will gradually increase the dose of these as well.
Certain anticonvulsants† Gabapentin	Usually needs to be increased gradually over a period of time.
Pregabalin	Increasing the dose to the effective range can be done more quickly and requires fewer steps than gabapentin.

*There are many other antidepressants, but they don't work as well for pain.
†Older anticonvulsants such as carbamazepine, phenytoin and valproic acid may have benefit; newer drugs are also being used in some patients.

Corticosteroids may be useful for treatment of severe inflammatory pain. They can be taken by mouth or injected where there is inflammation. These can cause serious side effects so your provider will use the lowest effective dose for the shortest possible time period. Typical examples include prednisone and dexamethasone. Ask about the potential side effects of corticosteroids. Be sure to notify your healthcare provider if you experience new or worsening joint pain after using prescribed corticosteroids.

Muscle relaxants may decrease muscle pain, but often causes sleepiness. They are usually used for a short period time, such as following a muscle injury or with some diseases that may cause muscle spasms.

Topical Analgesics
There are other drugs that are effective when used topically. One of these topical analgesics is capsaicin, which comes from chili peppers. It must be applied several times a day for about six weeks to get benefit. It can cause burning where it is applied, so you have to be very careful that you don't get it in your eyes. There are many other ointments that you can buy in the pharmacy; some contain menthol and may be helpful for musculoskeletal pain.

Local Anesthetics
Local anesthetics are very important for providing pain control and can be used in many different ways. Many persons have had an injection of lidocaine before having dental work or before having stitches. Longer term administration of a local anesthetic can be done alone or in combination with opioids to block pain in specific regions of the body; this is usually administered in the spine through a catheter. Chronic pain can be treated with a lidocaine patch, as mentioned above. There are also local anesthetic preparations that can be applied to skin and open wounds in the form of a cream or ointment to prevent pain from a needle stick. Disposable devices can be used as another way to deliver anesthetics around an incision or site of injury.

Drugs for Anxiety, Depression and Sleep
Persons with persistent pain may become anxious or depressed or they may have trouble sleeping. Treatment of anxiety and depression may decrease the need for pain medicines. On the other hand, relief of pain may significantly reduce anxiety and depression. There are many effective drugs for depression; as mentioned previously, some are helpful with pain, others are not. Selective serotonin reuptake inhibitors (SSRIs) are often used for depression; they are also beneficial to persons who are anxious. The dose of these drugs needs to be increased slowly over time so they can take a while to begin to work. If persons are extremely anxious, they can get quick benefit from the use of a benzodiazepine. The drug diazepam (Valium®) is a member of that class. There are several medications to treat sleep problems. Several that are available without a prescription contain antihistamines. Others that are more likely to help are available only with a prescription.

Table 3: IMPORTANT CONSIDERATIONS THAT HELP GUIDE THE USE OF PAIN MEDICINES

1. A thorough understanding of your pain (a pain assessment) is essential to any decision about what pain medicines you should take.
2. The severity and type of pain will guide the choice of medications. You may have more than one type of pain.
3. The dose of a medication and the time between doses is based on the specific properties of the medication and how a person responds to the drug. These things can vary from one drug to another and from one person to another. With some drugs, the dose needs to be slowly increased over time before it is known if it will help to control pain.
4. Your provider may combine two or more pain medicines that work in different ways in order to provide the best pain relief with the fewest side effects.
5. Some medications take time to begin to work; this is especially true for some drugs used to treat persistent pain: it can take days, weeks or even sometimes months to know what drug will work best for you.
6. If your pain is chronic and usually present, your healthcare provider will probably offer you medication on a regular schedule. Preventing pain from returning or getting worse is the best way to control it. Your provider may refer to this as "staying on top of the pain" or "staying ahead of the pain."
7. The addition of non-drug therapies, both physical and behavioral (*see additional sections in this publication*), may result in better pain relief and fewer side effects.
8. The purpose of pharmacotherapy is to relieve pain and improve function. Improved function after surgery means, for example, being able to cough, breathe deeply and move about. Improved function in persons living with persistent pain may mean being comfortable while engaging in work or the activities of daily living.

Pain management is complex and often requires several attempts with different combinations of medications to find the best treatment plan for an individual. Medications are often one part of a person's pain management plan and can be quite effective when used properly. *Table 3* discusses helpful tips that guide the use of pain medicines. Remember, using medication to relieve pain is only one treatment option. They work well when combined with other approaches as discussed throughout this book.

Psychosocial Interventions

PSYCHOSOCIAL INTERVENTIONS

Pain is complex and unique to each individual. As with other aspects of life, each of us brings pre-existing thoughts, feelings, beliefs, expectations and behavior patterns to any health experience. Understanding the impact of pain requires that we expand our view to consider the whole person — the mind, body and spirit.

Research shows that pain can affect your emotions and behavior and interfere with your ability to concentrate, manage everyday tasks and cope with stress. Likewise, stress and emotional pressures can make pain worse, provoking "flare ups" and contributing to alterations in the immune system response. These relationships are not always easily recognized or readily fixed by medical procedures or medications alone.

As the science of pain moves forward, there is growing evidence that interventions (drug and non-drug) used to influence emotions, thinking and behavior can aid in the reduction of pain and associated distress. For example, studies are uncovering a biological link between the brain systems involved in depression and pain regulation. Some antidepressant medications may have analgesic properties, which may be because these systems have shared properties. Some people experience depression due to chronic pain. Others may begin to realize that depression was present before their pain began. Depression can make the experience of living with persistent pain more difficult and should be diagnosed and treated.

Others may falsely believe that referral for psychological pain treatment means that their pain is not physical, or feel they are being labeled as having a mental illness rather than a physical problem. You may feel hesitant to try psychosocial therapies due to the associated stigma, or the fear that your provider will no longer treat the physical symptoms of your pain or try new treatment options. Don't let these fears interfere with your willingness to try a broad class of potentially safe and effective treatments. Consider these a gift to yourself — an investment in your peace of mind and quality of life.

PSYCHOLOGICAL CONSULTATION, COUNSELING & STRESS MANAGEMENT

Consultation

Many people believe knowledge is *power*. In fact, you may be reading this book to increase your pain knowledge and put it to good use. While reading, ask yourself:

1. How does your pain affect the way you think and act?
2. How does your pain affect your loved ones and co-workers?
3. How do they react to you?
4. Does this help or hinder your recovery and healing?
5. Are there ongoing stressors in your life?

For example, you may find that previous relationship patterns are no longer working for you. Stress and emotions, such as fear and anger, increase pain, which can then heighten stress levels. These kinds of cycles are important to recognize and modify. This action may decrease your pain and, at the same time, boost your sense of control over your life. Change is difficult. Working with a skilled therapist who understands chronic pain may help you recognize the "unhealthy" stressors in your life and guide you through making necessary life changes.

Your healthcare providers may recommend that you consult a behavioral health professional. This could be a social worker, psychologist or psychiatrist, or a therapist with special training in chronic pain. No, they do not think that "you are crazy" or that your pain is "only in your head." This evaluation may include testing and interviews to help assess how you cope with pain. It is important to:

- Identify how your pain interferes with your daily life and relationships
- Understand the stressors that worsen your pain and distress
- Determine which coping skills are helpful and which are harmful

When people have had pain for a long time, they develop ways to deal with pain, which are called coping strategies. Some of these strategies may help, while other may not. As a result, you may need to learn new ways to cope. There are a range of strategies that can help in this process. The following therapies may be recommended:

- Relaxation Therapy (relaxation, mindfulness, imagery)
- Biofeedback Training
- Behavioral Modification
- Stress Management Training
- Hypnotherapy
- Counseling (individual, family or group)

COGNITIVE TECHNIQUES

Some techniques used in stress management include relaxation training, meditation, hypnosis, biofeedback and behavior modification. Common to these approaches is the belief that people have the ability to self-manage some aspects of pain, such as changing attitudes, thoughts feelings or behaviors.

Relaxation therapies teach people how to relax tense muscles, reduce anxiety and alter their mental state. Both physical and mental tension can make pain worse. Headaches or back pain, muscle tension or spasms can be part of the problem. Meditation, which aims to produce a state of conscious relaxation, is sometimes combined with therapies that assist you in thinking of pain as a distant part of you. This skill of detachment helps to regain a sense of control. This approach may be particularly helpful when fear or anxiety accompanies pain.

- **Mindfulness Meditation** is a concentration practice during which people focus their attention on a specific object, most commonly on breathing patterns. For example, the focus might be on the experience of the breath entering the nostrils when inhaling and again when exhaling. When our minds wander off the breath (which is natural to do), we acknowledge that it has wandered and bring it back to the breath. Conscious awareness can bring about a sense of calm, patience, reduced muscle tension and pain and a clear sense of reality. When beginning this practice, you may experience anxiety or increased pain. This is because you may not have spent time being quiet with yourself. It is best to start a meditation practice with the help of a meditation teacher who can give you suggestions on how to proceed when these feelings arise.

Once mastered, meditation can be used in many situations, such as reducing the intensity of pain during flare ups, decreasing anxiety while sitting in the dentist chair and reducing the urge to scream during a traffic jam.

- **Guided Imagery** is a conscious meditation technique. Advocates of imagery believe our imagination is a potent healer, which has been overlooked by practitioners of Western medicine. Imagery may help relieve pain, promote healing from injury or illness, and/or ease depression, anxiety and sleeplessness. Thoughts have a direct influence on feelings and behavior. Negative thoughts may promote sadness and hopelessness, while positive thoughts breed pleasure and drive.

  Imagery has been found to be very effective for the treatment of stress. Imagery relaxes the body by aiding the release of brain chemicals that serve as the body's natural tranquilizers. These chemicals lower blood pressure, heart rate and anxiety levels. Practitioners who specialize in imagery may recommend it for a variety of different conditions such as headaches, chronic pain in the neck and back, high blood pressure, spastic colon and cramping due to premenstrual syndrome. Several studies suggest that imagery can also boost the immune system and, therefore, promote healing.

  Most guided imagery techniques begin with relaxation followed by the visualization of a mental image. For example, imagine a color for pain and then gradually replace that color with one that is more pleasing. Another is visualizing a peaceful scene, such as the ocean surf, wooded forest, fishing at a quiet pond or watching the sunset. Practicing guided imagery with music or aromatherapy may enhance the overall experience. This eventually may stimulate the ability to relax and create a mental image when those favorite sounds or scents are present.

- **Biofeedback training** teaches people how to recognize their physical reaction to stress and tension by using a variety of monitoring procedures and equipment. Physical responses that might be monitored include brain activity, blood pressure, muscle tension and heart rate. These involuntary responses generally increase with stress (known as the "stress response"), which can accompany pain. By measuring these physical reactions, you can learn relaxation and breathing techniques to help return these responses to normal levels of activity. Often when the stress response is lowered, so is the intensity of pain.

- **Behavioral modification** (sometimes called operant conditioning) is aimed at changing habits, behaviors and attitudes that can develop from living with chronic pain. Some people are overwhelmed by pain and may become dependent, anxious, homebound or perhaps even bedridden. Living with pain is influenced and sometimes complicated by social, family, legal, insurance and political factors. For example, some people are told they will lose financial benefits or other types of critical support if they improve. Those involved in lengthy lawsuits may hesitate to get better or gain function due to the fear that they will lose any chance of financial compensation,

which they believe they deserve. In some instances, pain has spurred an unhappy employee to leave a job in which they never felt valued. At times, having pain becomes a way of saying "no" to situations or people we have never been able to refuse. In some families, pain becomes a way to express anger, get care or be excused from responsibilities. These situations are damaging far beyond what is happening in your body. It is very important to understand how pain fits into the larger context of your life so you can identify ways to diminish harmful influences.

When appropriate, vocational counseling and rehabilitation can help to create a gradual path to more productive, fulfilling employment so that worries about the loss of compensation are replaced with possibilities. Behavioral modification can help people separate the multitude of issues surrounding pain and devise a step-by-step approach to confronting challenges through behavior change and shifting attitudes.

STRESS MANAGEMENT

Stress and anxiety can influence pain in ways you may not realize. Additionally, depression and feeling disheartened influences the ability to cope with pain and any other challenging life experience. When pain levels increase and the usual relief methods do not work as well as before, anxiety and catastrophic thoughts can cause more distress. This can result in a vicious cycle, which can often be avoided or managed. A first step in gaining control over this cycle is to create a process to observe your thoughts and understand your unique, individual pattern. This can be a beginning step in changing how much pain is allowed to rule your quality of life.

Simple Stress Management Suggestions

- **Structure and Predictability:** Try to set and keep a routine schedule of activities, rest and medications. Some people find that controlling the pace and abruptness of change reduces stress. While it is sometimes difficult to predict change, you may find aspects of your daily routine that you can control.

- **Activity:** Find an activity or exercise program that you like and make it part of your daily routine. It might be Tai Chi, yoga, walking or water aerobics. Talk with your pain practitioner for guidance about how to introduce any of these into your pain management regimen. It has been said that once you repeat something at least 25 times, it becomes a new habit.

- **Positive Outlook ("Self-talk")**: Many people living with persistent pain may wonder how to have a positive attitude about their situation when they haven't done so before. Some may find the pain experience too devastating and overwhelming. Others believe they can move beyond their pain to use positive language or think thoughts that give a sense of power rather than those that seem discouraging. You may have to practice this skill over and over and experiment with the results but … *First you need to hear yourself*…and perhaps you may need to ask those who know you well about how they hear you. You may want to consider the following suggestions as you think about your personal "*self-talk.*"

- Practice POSITIVE self-talk: You are a whole person with a past and a future, with special talents and accomplishments. Do not allow pain to take that away from you.
- Celebrate your successes, no matter how small they may appear!!!
- Concentrate on being around people and places that make you feel valued and *GOOD about yourself.*
- Think about those friends, family members, social settings, projects and/or work situations that bring meaning, joy and satisfaction to your life; surround yourself with these influencers.
- Think about the situations and/or people who cause you to feel badly and either limit your exposure to them or learn to interact with them so they do not affect your body, your pain and your feelings about yourself.

- **Balance:** Learn how to live in the moment. Experience the now, by shutting off the constant chatter in your mind: your thoughts, plans and perceptions; quiet the pressures caused by expectations from yourself as well as from others.
  - Coping techniques that help you relax may already be part of your life and it will be easy to build them into your pain management plan. You may want to learn from others. These techniques might include meditation, prayer, walking, nature, soothing music or scents (lavender, cinnamon, ylang-ylang, vanilla).
  - Practice deep breathing whenever you feel stressed:
    * Inhale slowly and deeply through your nose, hold for a count of five.
    * Exhale slowly (through your nose helps slow you down) for a count of ten.
    * Repeat three to four times until you feel relaxed.
  - Remember what is really important to you in life and make this a priority.

HYPNOTHERAPY/HYPNOSIS

Therapeutic or medical hypnosis is a method of directing one's focused attention inward to achieve benefits like relaxation and the lessening of pain and/or anxiety. With a skilled hypnotherapist, you can explore your own potentials for greater control over your experience of pain. Once you have practiced with the hypnotherapist, self-hypnosis can be taught.

Although hypnosis has been shown to reduce **pain perception**, it is not clear how the technique works. Some studies have shown that a proportion of those with moderate to severe pain were able to achieve total relief while under hypnosis. Other studies report that hypnosis reduces anxiety and depression.

COUNSELING

Living with pain can evoke a range of feelings from fear and anger to hopelessness, confusion and isolation. Family and other significant people in your life may have similar feelings. Counseling for you and, in some cases, with your family can help. Working either in private sessions or within support groups may be suggested. Most of us are familiar with acute pain and react to our loved ones and friends with the expectation that over time the pain will go away. When that doesn't happen, we may continue to act as if it will eventually go away if we ignore it long enough or seek additional medical input to search for the cause and cure. It is very difficult to imagine that persistent pain may be a lifelong condition. Many find tremendous benefit from individual or group counseling specifically focused on pain and related worries. Trained professionals can teach useful skills, and provide needed emotional support and guidance. When choosing a therapist, working with a counselor with experience in pain management is preferable.

Physical Rehabilitation *for* Pain Management

PHYSICAL REHABILITATION FOR PAIN MANAGEMENT

Physical methods have been used for pain relief for centuries. Reportedly, Hippocrates (420 BC) — considered the father of medicine — used a warm water bag to treat pain from sciatica. Today, there are a variety of skilled healthcare professionals with specialized training in the use of physical techniques that help reduce pain. Many work in the field of rehabilitative medicine, and include physiatrists (physicians who specialize in physical medicine), physical therapists, occupational therapists and exercise physiologists.

- **Physiatry**

  Physiatry — also called Physical Medicine and Rehabilitation — is a branch of medicine focusing on the diagnosis, treatment and management of disease primarily using "physical" methods of care, such as physical therapy and other methods. Physiatrists provide a wide variety of treatments for the musculoskeletal system (the muscles and bones) and do not perform surgery. Because the back is the core of the musculoskeletal system, many physiatrists are considered specialists in treating back pain. A number of physiatrists have additional training in special areas, like sports medicine, brain (e.g., stroke) or spinal cord injury, pain management or pediatric medicine.

  Some physicians of rehabilitative medicine have had different training than others. They may be Doctors of Medicine (MDs) or Doctors of Osteopathy (DOs). A DO has attended an independent medical school and received identical training in basic science and clinical medicine as MDs; however, they are trained to use a holistic approach to healthcare that includes an additional 300-500 hours of training in osteopathic manipulative medicine (OMT). Most DOs practice no differently than MDs, and not all continue to use OMT. To find a DO who uses OMT in their practice, you must ask if they specialize or have additional interest in osteopathic manipulative medicine.

  DOs are different than chiropractors (*see CAM section*). Chiropractors are independent practitioners with limited licenses to practice spinal manipulation and may incorporate nutrition into their practices. Unlike DOs or MDs, they cannot prescribe prescription medications, admit patients to hospitals or perform surgery.

- **Physical Therapy**

  Physical Therapists (PTs) provide services that help restore function, improve mobility, relieve pain and prevent or limit permanent physical disabilities of those suffering from injuries or disease. They restore, maintain and promote overall fitness and health. They work with accident victims, as well as individuals with disabling conditions such as low-back pain, arthritis, heart disease, fractures, head injuries and cerebral palsy.

  Therapists first examine medical histories and then test and measure the individual's strength, range of motion, balance and coordination, posture, muscle performance, respiration and motor function. They help determine one's ability to be independent and assist with the return to the community/workplace after an injury or illness. The overall goal is to improve and maximize how an individual performs in their work setting and at home.

  Physical therapists use a variety of treatment methods to relieve pain and reduce swelling including electrical stimulation, hot packs, cold compresses, traction, deep-tissue massage and ultrasound. They also teach patients to use assistive or adaptive devices, such as crutches, prostheses and wheelchairs. Exercise training is often

provided, which can be performed at home to help advance recovery by reducing immobility and improving flexibility, strength and/or endurance. As treatment continues, physical therapists document the individual's progress, conduct periodic examinations and modify therapies when necessary. Besides tracking progress, they help identify areas that may require more or less attention.

PTs consult and practice with a variety of other professionals, such as physicians, dentists, nurses, educators, social workers, occupational therapists, speech-language pathologists and audiologists. Some treat a wide range of conditions; others specialize in areas such as pediatrics, geriatrics, orthopedics, sports medicine, neurology, pain management and cardiopulmonary physical therapy.

- **Occupational Therapy**

  Occupational therapists (OTs) help people perform tasks required for daily living and in the work setting. They work with those who have mentally, physically, developmentally or emotionally disabling conditions. OTs help to improve their basic movement and thinking skills, as well as adaptive behaviors when there is a permanent loss of function. Their overall goal is to help individuals have independent, productive and satisfying lives.

  Occupational therapists assist in performing activities of all types, ranging from using a computer to mastering everyday needs such as dressing, cooking and eating. Physical exercises may be used to increase strength and skillfulness. Therapists instruct those with disabilities in the use of adaptive equipment, including wheelchairs, splints and aids for eating and dressing. They can design or make special equipment needed at home or at work.

  Some occupational therapists treat individuals whose ability to perform in a work environment has been impaired. OTs can help arrange for work re-training and/or new employment, and may team up with the individual and the employer to evaluate the work environment, plan work activities, and provide a progress report on work performance. If needed, they help modify the work environment so that work can be successfully completed.

- **Exercise Physiology**

  Exercise physiologists (EP) are commonly seen working in wellness or fitness centers. Their duties include developing exercise routines and educating people about the benefits of exercise. EPs may also work in clinical settings prescribing exercise for individuals with special risks, such as cardiac and pulmonary disease. Services they may provide include:

  - Assessment of functional abilities, including monitoring cardiovascular and metabolic state
  - Risk profile for various exercise modes and intensities
  - Health-behavior change counseling and management
  - Specific physical activity prescription (to accommodate current health status)
  - Exercise supervision or delivery for individual or group settings

They provide the pain management team regular reports on individual progress.

REHABILITATIVE TECHNIQUES

The most common physical methods for pain management offered by rehab services are:

- **Exercise**

  Exercise and physical activity are beneficial not only for the body, but also the mind, spirit and soul. Making a commitment to carve out a little time for exercise everyday is challenging for those who do not live with pain. It is much more difficult when simple movements like walking and changing positions causes pain.

  Exercise not only keeps you healthy, it also helps reduce pain over time. Weight-bearing and cardiovascular exercise strengthens your heart, lungs, bones and muscles. This becomes even more important as we age. Physical activity protects against falls and bone fractures in older adults. Research also suggests that exercise may help control joint swelling and pain caused by arthritis. If we don't "use it, we lose it." Exercise helps preserve strength, agility and independence as we age.

  The benefits of exercise are not only physically tangible; exercise has a profound effect on your mental state as well. Regular physical activity helps you cope with stress, improve your self-image, and ease anxiety and depression by releasing pleasure chemicals in our brains called endorphins. Research even suggests that physical fitness can make you more mentally alert. By incorporating group exercise with friends or family into your routine, you can also use exercise to strengthen your bonds with others. Connecting with friends and family is a key aspect of good emotional health. Too often, living with pain, leads to isolation.

Here are a few tips:

- Find something that you enjoy.
- Remember your routine need not start out at a vigorous pace. Try walking. Look into yoga classes to help you stretch and become more flexible. Tai Chi offers a low impact workout that promotes physical and mental well-being.
- Ask your instructors if they have experience working with those who live with chronic pain.
- Consult your healthcare professional before beginning any exercise program.

- **Hydrotherapy, Heat and Cold**

  Hydrotherapy is the use of water to maintain health or promote healing. Water has been part of healthcare since the beginning of civilization. Today, aspects of hydrotherapy are taught as part of healthcare training. Also known as Aquatic or Pool Therapy, the use of therapeutically warm water and exercise may help ease painful muscles and joints. Gentle movement may help build strength, relax stiff joints and sore muscles. Water buoyancy greatly reduces the pressure on joints, making it easier to perform range of motion exercises.

  The use of ice packs, hot water bottles, heating pads and counter-irritant preparations, like Tiger Balm, Icy Hot or Ben Gay, are familiar in popular culture. For example, many use the application of ice to a sprained ankle or soaking in a hot

tub to soothe sore muscles. Steam can open clogged sinuses; ice packs can relieve swelling. Cold-based hydrotherapies, such as ice packs and cold compresses, decreases swelling and pain by constricting blood vessels and numbing nerve endings. On the other hand, heat-based hydrotherapies, such as whirlpools and hot compresses, have the opposite effect. As the body attempts to throw off the excess heat and keep body temperature from rising, dilation of blood vessels occurs, providing increased circulation to the area being treated. This helps relax muscle spasms and relieve pain.

Today hydrotherapy is a part of the physical therapy department of virtually every hospital and medical center. Various techniques using water are considered standard strategies for rehabilitation and pain relief. Many forms of hydrotherapy are also available at health spas and resorts. Be sure to check with your healthcare provider and verify the credentials of the spa before going.

- **Myofascial Therapy**

  A gentle blend of stretching and massage, myofascial release therapy uses hands-on manipulation of muscle and skin to relieve pain and promote healing. According to practitioners of myofascial release, scarring or injury to this network of connective tissue and muscle is a major cause of pain and restricted motion. The easy stretch is aimed to alleviate these problems by breaking up, or releasing, constrictions or snags in the fascia. People with longstanding back pain, fibromyalgia, recurring headaches, sports injuries and other chronic pain disorders may benefit from this technique.

  Myofascial release is part of a larger philosophy of healing that emphasizes the importance of mind-body interactions and preventive care. It is based on the idea that poor posture, physical injury, illness and emotional stress can throw the body out of alignment, which causes the fascia and muscle to become tight and constricted. Scarring or adhesions form. The gentle and sustained stretching of myofascial release is believed to free adhesions and soften and lengthen the fascia. The stretch may be held for one to two minutes, and sometimes for up to five minutes, before a softening, or "release," is felt. The release indicates that the muscle is relaxing, fascial adhesions are slowly breaking down, or the fascia has realigned to its normal position. The process is then repeated until the tissues are fully elongated.

  Sessions typically last 30 minutes to an hour and may be given one to three times a week depending on your condition. Some people immediately feel better - even free of pain - and are able to move their joints more freely as soon as the session is over. Others feel some discomfort that night or the next day. Any soreness should subside within a day or two, and you should feel less pain and be able to move more easily than you did before.

  Exercises are tailored to your individual needs, and you should be given exercises to do at home. Unlike stretching routines for specific sports, these exercises will be designed to lengthen the muscles and connective tissues in various directions. To relieve tightness in the pelvic region, for instance, you may lie with your hip resting on a small foam ball for several minutes.

- **Osteopathic Manipulation Treatment (OMT)**

  Osteopathic medicine is a form of conventional medicine that highlights diseases arising in the musculoskeletal system. This practice follows an underlying belief that all of the body's systems work together, and disturbances in one system may affect function elsewhere in the body. The use of a hands-on technique called osteopathic manipulation treatment (OMT) may be considered to help reduce pain, restore function and promote health and well-being.

  OMT covers a wide range of services including spinal manipulation, connective tissue release, soft-tissue techniques, muscle energy and cranial osteopathy. It is considered more comprehensive than a chiropractic spinal adjustment. OMT works to release blockages in a person's body to promote health. By removing restrictions in the muscles, nerves, blood vessels, ligaments, etc., the patient's body is able to move more freely allowing it to heal itself more effectively. As previously stated, some DOs practice osteopathic manipulation, particularly those who specialize in physical medicine.

- **Splints**

  Casts, splints and braces are more commonly known as tools to support and protect injured bones and tissue following an injury. By shielding the injury, they allow for more rapid healing and help prevent further injury. They can also help reduce pain, swelling and muscles spasms.

  At times, pain from inflammation, like in arthritis, causes swelling, which, in turn, increases pain. Your provider may suggest a splint to help you rest the affected area. Periodic rest with support and elevation may help to reduce the swelling and pain that has already occurred.

  Wearing splints or braces during certain activities may also be recommended to help prevent pain, particularly when repetitive motion is a primary cause. Whether you are advised to wear a splint all day or only at night, this technique may help decrease additional irritation and lessen the degree of swelling and pain that might occur without one.

  Protective devices such as light compression gloves/socks or splints, may be recommended if you have neuropathic pain that affects your hands and/or feet. These may help reduce swelling and decrease pain from light touch or light pressure.

- **Transcutaneous Electrical Nerve Stimulation (TENS)**
  TENS is a method commonly managed by physical therapy as a means to decrease pain without needles or surgery. The TENS unit is designed to block or prevent pain by providing opposing stimulation to compete with the unpleasant signals that cause pain. The TENS sensation(s) interrupt pain signals in the body. The mechanisms by which TENS can relieve pain are not understood.

  TENS can be used in the treatment of acute and chronic pain, including pain of the lower back, neck, pelvis, nerves (CRPS/RSD, **neuritis**) and muscles (fibromyalgia, myofascial).

  Used properly, TENS units are very safe, and do not hurt to apply or wear. The best time to wear TENS is during activities or times of the day when your pain is generally the most severe. The sensation should feel comfortable or pleasurable when the unit is turned on. They are battery-operated (9-volt). A TENS unit will NOT electrocute you. To prevent an unintentional shock, they should NOT be worn in the shower or bath tub or be turned up too high. It is not recommended to be used with a demand-type cardiac pacemaker. Also, there are specific areas of the body that should be avoided, like over the larger blood vessels (arteries) in the neck.

ADDITIONAL PHYSICAL METHODS

There are other physical methods that may be offered to aid in pain reduction and improvement of movement. Depending on the practice size, location and experience of the providers may determine the scope of services. These methods may be performed by a physical therapist with special training or a complementary practitioner (*see CAM section*).

- **Chiropractic** (*See CAM section*)

- **Craniosacral Therapy**
  A gentle form of manipulation, **craniosacral therapy**, is a hands-on healing technique typically practiced by physical therapists, massage therapists and chiropractors. Craniosacral therapists believe the movement of spinal fluid within and around the central nervous system creates a vital body rhythm, no less important to health and well-being than the heartbeat or breath. Health problems develop, they contend, when blockages occur. Practitioners assert that craniosacral therapy reestablishes the normal flow of fluids and thus restores health.
  By law, craniosacral therapists are not allowed to make a medical diagnosis. For this reason, the technique should not be confused with cranial osteopathy, a diagnostic and therapeutic method of treatment that is practiced by highly trained osteopathic physicians. A session usually lasts from 20 minutes to an hour.

- **Feldenkrais (Functional Integration)**
  The ***Feldenkrais Method*** is a form of somatic education that uses gentle movement and directed attention to improve movement and enhance human functioning. Through this method, you learn to improve your ease of motion, increase your range of motion, expand your flexibility and coordination, and rediscover your ability to move gracefully and effectively. These improvements may enhance functioning in other aspects of your life such as pain reduction.

  The *Feldenkrais Method* is based on principles of physics, biomechanics and an understanding of learning and human development. By expanding the self-image through movement sequences that bring attention to the parts of the self that ***are out*** of awareness, the method enables you to include more of yourself in your everyday activities.

- **Rolfing (Structural Integration)**
  Rolfing emerged from the concept that humans function most efficiently and comfortably when key parts of the body, such as the head, torso, pelvis and legs, are properly aligned. There are different versions of Rolfing. Rolfing is a form of myofascial massage guided by the contours of the body. Rolfers use their fingers, hands, elbows and knees to place deep pressure and shift bones into proper alignment. Their goal is to increase range of motion and make movement easier by correcting posture misalignments. Rolfing can sometimes be painful.

- **Trager Approach**
  The Trager Approach is a form of movement consisting of a series of gentle, passive movements, along with rotation and traction of arms and legs to relieve muscular tightness without pain. This was technique was developed in the early 1900s to help polio victims. Some with chronic pain due to muscle spasm have reported noticeable pain relief beginning with the first session.

  The practitioner moves select parts of the body in a light rhythmical fashion so that you can experience the feeling of this light, effortless movement. The goal of each session is to help reduce stress and to find more effective ways to deal with stressful situations. Added benefits are enhanced conscious awareness, greater flexibility, improved self image, greater energy and reduced constriction and rigidity.

Icing. Ideal for pain related to recent injury, re-injury of inflammation like with strains, sprains and bruises. It can easily be done anywhere. Cold has a numbing effect. However, placing ice directly on your skin can cause nerve damage. Be sure to place a thin towel or pillow case between your skin and the cold source, whether using ice cubes in a plastic bag, a frozen pack of peas (or corn) or a gel pack. Ice for 20 minutes, and then remove it until the surrounding skin returns to normal temperature before re-applying. This can be repeated on a regular basis every two hours throughout the day.

Compresses. To make a wet compress soak a cloth in hot or cold water and squeeze out the excess until the desired amount of moisture remains. Single or double compresses may be used. Grain pillows, gel-packing and certain heating pads (follow the manufacturer directions) can be used. A single compress involves the use of the wet cloth over the affected area. A double compress includes placing a dry material such as wool or flannel over the wet compress.

A cold compress can be used to decrease swelling, reduce blood flow to an area or inhibit inflammation. Cold should not be used in the presence of circulation disorders, like peripheral vascular disease, certain heart conditions and diabetes, unless pre-approved by your healthcare professional.

A hot compress can have an analgesic effect, thereby decreasing pain. When using hot water, the double compress serves to retain the heat. Hot compresses can also be used to lessen the discomfort from muscle cramping or spasm and improve blood flow to a particular part of the body. Separate, alternating or simultaneous use of hot or cold compresses can be applied for pain relief depending on the individual preference. When using a microwave to heat a gel pack or grain pillow, please follow the directions to avoid extreme heat that could cause skin burn.

Baths. Either immersing the entire body or simply the affected part of the body can be helpful. Hot full-immersion baths can help with arthritic discomfort and conditions where muscles are in painful spasm, such as fibromyalgia. For a neutral (or tepid) bath the temperature should be neither too hot nor too cold. These are mainly used for relaxation purposes and to treat stress-related ailments such as insomnia, anxiety and nervous exhaustion. Cool baths can relieve swelling or inflammation.

Sitz baths. Taking sitz baths involves partially immersing the pelvic region. A hot sitz bath can help reduce pain from hemorrhoids, abdominal cramping or sciatica. A special sitz bath seat can be purchased at most pharmacies.

Cold friction rubs. A friction rub involves massaging a particular area of the body with a rough washcloth, terry towel or loofah that has first been place in ice water. Friction rubs have a toning effect that helps to increase circulation and tighten muscles.

Counter-irritants. Better known as heating or cooling creams, lotions or salves applied to the skin over the painful area. They are either gently rubbed around the skin surface or used with massage or myofascial release treatments. They can be used as a single agent for either the preferred heat or cooling effects, alternating between the two sensations or in combination with a therapy that provides the opposite effect.

Alternating. Use one preparation that heats, wait for effect to wear off and skin returns to normal temperature, wash off remaining product before applying opposite preparation that cools.

Combination. Apply product that heats. Be sure to protect the skin by placing plastic wrap over area, then place ice pack on top. Remove ice pack within 15-20 minutes and wait 30 minutes before reapplication of ice pack.

Whenever these preparations are used, it is important to avoid using two therapies that enhance the same temperature effect to avoid heat or cold burns to the skin. For example, if you plan to take a hot shower or apply a heating pad to an area previously treated, wait for the product effect to wear away and wash off any remaining product.

Complementary & Alternative Medicine {CAM}

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

Many Americans are using complementary and alternative medicine (CAM) therapies, and many conventional (allopathic) doctors are incorporating these therapies into their practices. Medical schools across the country — including Yale and Harvard — now offer courses in complementary and alternative medicine (CAM). In 1999, the National Institutes of Health opened the National Center for Complementary and Alternative Medicine (NCCAM) to evaluate these methods. NCCAM was created to advance the scientific study of CAM to help answer questions about safety and the effect on health promotion, disease prevention and/or management of medical disorders.

CAM Therapies and Practices On the Rise

More and more Americans are turning to CAM to help manage and treat various health problems, including pain and stress.

Consider these facts:

- According to surveys, seven out of ten Americans use some form of CAM.
- Americans spend at least $34-47 billion on CAM therapies, exceeding out of pocket expenses for all U.S. hospitalizations. CAM is expected to grow by 15 percent each year.
- People report using CAM because these methods mirror their personal beliefs, values and philosophical orientations toward life.
- Many people use CAM to help relieve back pain, joint pain, severe headache and pain associated with migraines, dental and jaw pain and for a variety of other reasons.
- Being able to deliver integrated medicine, which incorporates proven CAM therapies into "mainstream" care, is increasingly important to consumers and healthcare providers.

CAM: What Is It?

NCCAM defines CAM as "a group of diverse medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine." Most CAM therapies take a *holistic* approach to care — treating the mind, body and spirit. Some of these approaches, such as acupuncture, mind-body therapies (e.g., biofeedback), yoga and massage are widely used and accepted. For this reason, they have been *integrated* into medical care. Integrative approaches may be the most effective for people living with pain. For example, acupuncture, mind-body techniques, energy therapies and chiropractic care can be used along with analgesics (pain

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Much of the information presented in this chapter is adapted from the National Center for Complementary and Alternative Medicine (NCCAM) Web site and educational materials on CAM. For more information, visit nccam.nih.gov.

medication) to reduce pain. Other CAM therapies are not widely accepted by the medical community and some carry risks, so make sure to speak with your healthcare provider about CAM.

CAM is expected to grow as therapies are proven safe and effective, adopted into routine healthcare and new approaches become known.

What is the difference between complementary medicine, alternative medicine and integrative medicine?

Complementary medicine is used **together with** conventional medicine. An example of a complementary therapy is using massage therapy to help lessen a patient's discomfort for the relief of musculoskeletal pain/discomfort.

Alternative medicine is used in place of conventional medicine. An example of an alternative therapy is using a special diet to treat cancer instead of undergoing surgery, radiation or chemotherapy that has been recommended by a conventional doctor.

Integrative medicine combines conventional medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness.

NCCAM classifies CAM therapies into five categories:

1. **Alternative Medical Systems**
   Alternative medical systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the United States. Examples of alternative medical systems that have developed in Western cultures include homeopathic medicine and naturopathic medicine. Examples of systems that have developed in non-Western cultures include traditional Chinese medicine and Ayurveda.
2. **Mind-Body Interventions**
   Mind-body medicine uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms. Some techniques once considered CAM have been part of conventional medicine for decades, like patient support groups and cognitive-behavioral therapy. Other mind-body techniques are still considered CAM, including meditation, prayer, mental healing and methods that encourage creative expression such as journaling, art or music.
3. **Biologically Based Therapies**
   Biologically based therapies involve substances found in nature, such as herbs, foods and vitamins. Some examples include dietary supplements and herbal remedies. This may include the use of other substances that have unsubstantiated scientific value, such as shark cartilage used in cancer treatment.
4. **Manipulative and Body-Based Methods**
   Manipulative and body-based methods are based on manipulation and/or movement of one or more parts of the body such as chiropractic techniques, osteopathic manipulation and therapeutic massage.

5. **Energy Therapies**
   Energy therapies involve the use of energy fields. They are of two types:

   Biofield therapies are intended to affect energy fields that surround and penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include Qigong, Reiki and Therapeutic Touch.

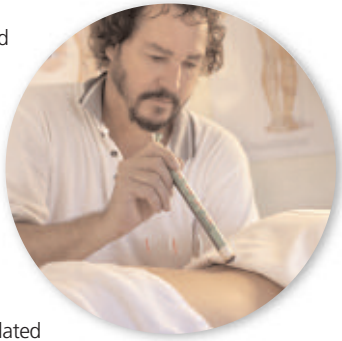
   Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct-current fields.

OVERVIEW OF CAM THERAPIES

Alternative Medical Systems

- **Homeopathic medicine** is an alternative medical system. In homeopathic medicine, there is a belief that "like cures like." Highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses would actually cause those symptoms. To date, there is no scientific evidence supporting the use of homeopathic medicine for pain.
- **Naturopathic medicine**, or naturopathy, is an alternative medical system. Naturopathic medicine proposes that there is a healing power in the body that establishes, maintains and restores health. Practitioners work with the patient with a goal of supporting this power through treatments such as nutrition and lifestyle counseling, dietary supplements, medicinal plants, exercise, homeopathy and treatments from traditional Chinese medicine.
- **Traditional Chinese Medicine (TCM)** is the current name for an ancient system of healthcare from China. TCM is based on a concept of balanced qi (pronounced "chee"), or vital energy, that is believed to flow throughout the body. Qi is thought to regulate a person's spiritual, emotional, mental and physical balance and to be influenced by the opposing forces of yin (negative energy) and yang (positive energy). Disease is believed to result from the flow of qi being disrupted and yin and yang becoming imbalanced. Among the components of TCM are herbal and nutritional therapy, restorative physical exercises, meditation, acupuncture and therapeutic massage.

  Acupuncture is a method of healing developed in China at least 2,000 years ago. Acupuncture has a growing acceptance in the field of conventional medicine. Today, acupuncture describes a family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.



Acupressure is an ancient Chinese healing method that involves applying pressure to certain meridian points on the body to relieve pain. These meridians start at the fingertips, connect to the brain, and then connect to the organ associated with the specific meridian. Acupressure relaxes muscular tension and balances what are thought to be the vital life forces of the body. The patient lies fully clothed on a soft massage table while the practitioner presses gently on points situated on various parts of the body. The session is non-invasive and gentle. An average session lasts for about one hour. However, most people require a number of sessions to complete a treatment.

- **Reflexology** is a healing art based on the principle that specific points on the feet and hands correspond to specific parts of the body. By applying pressure to the feet or hands, an increase in circulation and energy is stimulated to specific bodily and muscular functions. People often experience deep relaxation and sense of well-being.
- **Ayurveda** is an ancient Eastern Indian approach to healthcare that has been practiced primarily in the Indian subcontinent for 5,000 years. Ayurveda includes diet and herbal remedies and emphasizes the use of body, mind and spirit in disease prevention and treatment.

Mind-Body Interventions

The mind is the most powerful healing tool.

Mind-body techniques focus on influencing changes at the higher brain centers where information is processed for the perception of pain, where thought can interrupt the pain message, as well as your feelings and fears. Simple changes in our thoughts can change our behavior. For example, when we learn to turn off our negative "self-talk" and change our internal conversation to a dialogue with positive messages, our mood lifts and we feel better physically, emotionally and spiritually.

Mind-body techniques are powerful options to incorporate into daily living. Examples include distraction, meditation, prayer, guided imagery, hypnosis, relaxation/breathing exercises (commonly used in prepared childbirth classes) and biofeedback.

- **Mindfulness Meditation** (*See Psychosocial section*)
- **Prayer** is often considered a spiritually-focused meditation. Prayer has been shown to have dramatic effects. Prayer is used to promote healing, relieve pain, enhance comfort and relaxation and ease the transition during life changes.
- **Guided Imagery** (*See Psychosocial section*)
- **Hypnosis/Hypnotherapy, Relaxation and Breathing Exercises and Biofeedback** (*See Psychosocial section*)
- **Mind-Body Disciplines** are techniques and practices aimed at integrating mind, body and spirit by achieving physical conditioning, as well as a state of peace, being centered or feeling grounded. Yoga and Tai Chi are centuries old, whereas Pilates was developed in the early 1900s.
- **Pilates** is a method of body conditioning that focuses on the core postural muscles essential to spinal alignment, muscular flexibility and strength. By using spring-based equipment, the person uses their own body's resistance to improve strength,

circulation, posture and breathing, critical to decreasing pain and improving body awareness and muscular tone. A teacher should have experience in working with individuals with chronic pain, be certified through a 400-600 hour certification program and have a fully equipped studio.

- **Tai Chi** is an ancient Chinese discipline. In addition to its physical benefits, there are certain psychological effects as well. Tai Chi also provides a form of meditation. This form of meditation is rooted in self-control, which can come from learning how to create a natural balance (harmony) within yourself. The effect of this harmony is to capture both physical and spiritual well-being.

  Tai Chi, as it is practiced in the West today, can best be thought of as a yoga and meditation combined. There are a number of *forms* (also called 'sets') which consist of a sequence of movements. Many of these movements are originally derived from the martial arts and from the natural movements of animals and birds. Tai Chi is performed slowly, softly and gracefully with smooth and even transitions between forms.

  The concentration used to execute Tai Chi fosters a calm and tranquil mind. Learning Tai Chi forms correctly provides a practical ground for learning balance, alignment, fine-motor control, rhythm of movement and the peace of silence. Tai Chi can help you to better stand, walk, move and/or run. Many practitioners notice benefits in terms of correcting poor postural, alignment or movement patterns which can contribute to tension or injury. The meditative nature of the exercises is calming and relaxing.

- **Yoga** is an ancient Indian discipline that teaches balance, flexibility and meditation. In its most authentic expression, yoga is not exercise or religion, but an ancient method of stilling the mind, cultivating kindness and compassion towards ourselves, and resisting the urge to over-identify with the physical body. There are different forms of yoga. For example, Hatha yoga is considered the oldest comprehensive form of self care — physical, mental, emotional and spiritual — to bring balance and enhanced wellbeing. Hatha yoga includes body positions or poses, breathing techniques, relaxation and sustained concentration or meditation.

  The poses (asanas) improve posture though stretching, toning and strengthening the muscles, joints and the spine. They also stimulate and balance the internal organs, glands, nervous system, and circulatory and respiratory systems. Through proper breathing, the mind is calmed and the whole body is cleansed and revitalized. By learning relaxation techniques before and after yoga poses, the body and mind can experience a new form of rest. A goal of the practice of yoga is to learn how to find the calm, quiet place inside yourself, which can console you during times of stress, pain or the need for restoration.

Biologically Based Therapies

- **Aromatherapy** involves the use of essential oils (extracts or essences) from flowers, herbs and trees to promote health and well-being. Essential oils have been used for thousands of years all over the world, and may be used in a bath, vaporizer, spritzer bottle or in other ways. Most essential oils are diluted for use in water, cream or non-scented oils. Some essential oils may be used topically. When using essential oils, you should be told about the expected benefits and risks and the proper way to use them.

- **Dietary supplements** are products (other than tobacco) taken by mouth that contain a "dietary ingredient" intended to supplement the diet. Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. Dietary ingredients may include vitamins, minerals, herbs or other botanicals, amino acids and substances such as enzymes, organ tissues, and metabolites. Dietary supplements come in many forms including extracts, concentrates, tablets, capsules, gel caps, liquids and powders. They have special requirements for labeling. Under DSHEA, dietary supplements are considered foods not drugs.

  Herbal remedies and supplements are increasingly being used and studied for pain treatment and pain-related symptoms. Ideally, they should be recommended and monitored by a healthcare professional. If you are using them without supervision, please report this to your healthcare provider. Examples are:

  Feverfew: Migraine headache; arthritis

  Glucosamine & Chondroitin: joint pain, like with arthritis or degenerative disease

  Ginger: Anti-inflammatory as with arthritis; reduces nausea

  Gingko Biloba: Migraine headache; lower leg pain due to poor circulation

  Ginseng: Fibromyalgia; Chronic fatigue

  Kava Kava: Tension headache, insomnia, neuropathic pain

  Melatonin: Insomnia

  Pycnogenol: Arthritis

  St. John's Wort: Sciatica, arthritis, and neuropathic pain, depression

  Tiger Balm (Menthol; Camphor): Muscular pain and spasm (used with massage; myofascial release)

  Valerian Root: Insomnia, anxiety, nervousness, spasms, muscle cramps

- **Nutrition.** Maintaining an ideal body weight supports health and well-being and reduces excess burden on painful conditions, including back and knee pain, arthritis and diabetes. If this is a problem for you, a dietician can help you pursue a weight loss program. This can help relieve pain associated with low back pain or joint pain disorders.

  Eliminating nicotine and minimizing alcohol use is also beneficial. There is increasing evidence that smoking tobacco has a strong influence on the prevalence of low back pain. Limiting alcohol lowers the risk of alcohol related neuropathies and pancreatitis. Most medications used for pain treatment should not be taken while drinking alcohol. Excessive alcohol intake changes the liver where the filtering of most pain medications takes place upon entering the bloodstream. As the liver becomes damaged, medication therapy is less effective.

Manipulative and Body-Based Methods

- **Chiropractic Care** is a therapeutic approach that focuses on the relationship between bodily structure (primarily that of the spine) and function, and how this relationship affects the protection and restoration of health. Chiropractors use spinal manipulative therapy as a basic treatment tool.

  The roots of chiropractic care can be traced to the beginning of recorded time. Ancient writings mention spinal manipulation and the adjustment of the lower extremities to ease low back pain. The primary belief of the chiropractic profession supports a natural method of healthcare that includes a deep respect for the human body's ability to heal itself without the use of surgery or medication. Chiropractors give careful attention to the biomechanics, structure and function of the spine, its effects on the musculoskeletal and neurological systems, and the role played by the proper function of these systems in the preservation and restoration of health.

  Chiropractors frequently treat individuals with a variety of pain disorders, such as headaches, joint pain, neck pain, low back pain and sciatica. They also treat patients with osteoarthritis, spinal disk conditions, carpal tunnel syndrome, tendonitis, sprains and strains.

- **Osteopathic Medicine** (*See Rehabilitative section*)

- **Massage** therapists manipulate muscle and connective tissue to enhance function of those tissues and promote relaxation and well-being.

  Massage is an old healing art with many techniques and approaches. Massage acts directly on the nervous system, activating the opposite of the "fight or flight syndrome" and promoting relaxation. It eases painful and tight muscles using stretch that gently separates individual muscle fibers that may have become bound and knotted together. This reduces spasm.

  Massage can help:

  - Increase range of motion in your joints by releasing muscle tension around them;
  - Enhance circulation, cleansing your body of waste products (toxins) that can cause fatigue and soreness;
  - Stimulate the healthy production of the joint's natural lubrication; and,
  - Relieve secondary pain that builds up around a primary pain or injured site.

  Secondary pain has been known to last longer than the primary cause. For example, headaches can be caused from tense shoulder and neck muscles, shooting leg pain can originate from tight low back muscles and stiff hip joints. Massage aids in the release of endorphins (your body's natural morphine) that reduces pain and gives the sensation of feeling good.

  It is most important to drink plenty of water following massage to help rid the body of toxins that are released. Massage also promotes a restful sleep by helping the body and mind relax. At the same time, people experience an overall increase in vitality, energy and alertness.

- **Therapeutic Massage** is the biomechanical manipulation of soft tissue for the purpose of restoring or maintaining balance within and among the various systems of the body-mind complex while the body is at rest and the mind is letting go. Aromatherapy, music therapy and special massage lotions are frequently used. Therapeutic massage should be administered by an individual with special training and certification in this form of body-mind work.
- **Simple Massage** is either self-massage or a focused-area massage performed by a family member, friend or healthcare provider without special certification in therapeutic massage. This type of massage may be used with counter-irritant products, like Tiger Balm, Icy Hot or warmed lotion/creams.

Energy Therapies

- **Biofield (also known as Touch) Therapies** originate from an ancient technique called "laying-on of hands" or the "sharing of energy." The recipient of the therapy may either accept or reject that "healing" energy.
- **Qigong** is a component of traditional Chinese medicine that combines movement, meditation, and regulation of breathing to enhance the flow of energy in the body, blood circulation and immune function.

  The word Qigong is a combination of two ideas: "Qi" means air, breath of life, or vital energy of the body, and "gong" means the skill of working with, or cultivating self-discipline and achievement. The art of Qigong consists primarily of meditation, relaxation, physical movement, mind-body integration and breathing exercises. It is believed that regular practice of Qigong helps to cleanse the body of toxins, restore energy, reduce stress and anxiety, and help individuals maintain a healthy and active lifestyle.
- **Healing Touch** is an energy balancing therapy provided by practitioners to promote healing, relieve pain, increase relaxation, reduce anxiety, prevent illness, manage symptoms of illness and ease dying. Treatments involve light touch on and above the body in the individual's energy field (biofield). Certification of practitioners is provided by Healing Touch International.
- **Reiki** is a Japanese word representing Universal Life Energy. Reiki is a technique used for stress reduction and relaxation that allows one to tap into an unlimited supply of "life force energy" to improve health and enhance the quality of life. Reiki is based on the belief that when spiritual energy is channeled through a Reiki practitioner to another, the spirit can be healed, which in turn heals the physical body. Special training and credentialing is required.

- **Therapeutic Touch** is based on the premise that it is the healing force of the therapist that affects the patient's recovery; healing is promoted when the body's energies are in balance. By passing of the therapist's hands over the patient, they can identify energy imbalances and share energy for healing. Therapeutic Touch involves special training through Nurse Healers Professional Associates International, as well as extensive practice and experience.

Bioelectromagnetic-based therapies

- **Magnet Therapy** uses magnets, which produce a type of energy called magnetic fields, to treat or ease the symptoms of various diseases and conditions, including pain. Most magnets that are used are called "static" magnets because the magnetic field is not changed. Electromagnetic therapy, the use of magnets with electrical currents, is used only under supervision of a healthcare provider.

Including CAM in Your Pain Management Plan: Some Things to Consider
Surprisingly, nearly half of those using complementary and alternative therapies do not tell their primary care doctors about it — either out of embarrassment, fear of being reprimanded and/or not recognizing the importance of informing their providers. But it's important to tell your healthcare providers the whole truth. If you are thinking about incorporating CAM approaches into your pain management plan, here are some things you should do:

- **Consult with your healthcare provider.** Discuss all conventional and CAM treatments you are using. Ask about CAM therapies, and how they can be included in your pain management plan.
- **Assess the safety and effectiveness of the therapy.** A safe therapy does no harm when used as intended. An effective therapy is one that has measurable benefits. Ask your provider about the safety and effectiveness of the therapy you are interested in. He or she may not be familiar with the type of therapy you are using or plan to use, so bring as much information as you can.
- **Seek out the evidence.** Research studies evaluating CAM therapies are ongoing. Scientific evidence for the benefits of some CAM therapies is extensive, while for others it may be lacking and/or in progress.
- **Talk to the practitioner.** Ask about his or her education, additional training, licenses, and certifications — both conventional and CAM. Will he or she provide you with information about the therapy (e.g., how it is administered, its purpose, any possible side effects)?
- **Investigate the practitioner's expertise, background, qualifications and competence.** Contact your state or local regulatory agency with authority over the type of treatment you are seeking. Check to see if the practitioner is licensed to deliver services he or she claims to provide. Talk to your provider and other patients about the practitioner.
- **Consider the quality of service delivery.** Learn about how and where the therapy is given, and whether it meets regulated standards for medical safety and care. Visit the practitioner's setting. Ask about how many patients he or she sees, and how much time is spent with patients. It is important to know that some therapies take longer to provide a significant effect; however, more lasting results may occur. Give yourself a timeframe in which you think you should see results based on information you have gathered.
- **Think about the costs.** Learn about which treatments will be reimbursed by your medical insurer. Many CAM treatments are not covered yet. Contact several practitioners and see what they're charging for similar therapies.

- **Look at YOURSELF.** Consider what you can do on your own first. Eliminate or significantly decrease potentially harmful habits commonly used to relieve stress: drinking too many caffeinated beverages (coffee, tea, sodas), using alcohol, smoking cigarettes and eating comfort foods. These may be rewarding in the short-term, but when used repeatedly, they significantly contribute to the pain problem. Begin to change those habits by pursuing activities that are rewarding, satisfying and relaxing: walking in the park, listening to music, gardening, playing with your children or pets. Group social support is also extremely beneficial. Group therapy can be as simple as talking with close friends and loved ones, who will listen. Remember to do the same for them.
- **For safety, know the source of your products.** Explore the company that is making the products you chose to use. Ask questions about their standards for manufacturing of the product, quality control and standardization of active ingredients in the product.

Injection and Infusion Therapies

INJECTION AND INFUSION THERAPIES

Injection and infusion therapies may be used for the management of both acute and chronic pain. Acute pain, which you might experience after surgery or a major trauma, may be controlled optimally with pain medications delivered directly into your vein (intravenous) or your spine (intraspinal, which includes epidural or intrathecal), or with local anesthetics injected prior to your procedure (regional anesthesia). Persistent or chronic pain, which is defined as pain lasting longer than three months, may require injection (nerve block) or infusion therapies if other therapies (oral medications, physical therapy, etc.) do not provide adequate pain relief. In this section, we will discuss injection therapies, neuroablative therapies, minimally invasive surgical procedures, infusion therapies and implantables.

Injection Therapies

Injection therapies may be used to treat painful conditions in many areas of the body. The term nerve block was originally used for an injection that targeted specific nerves. It is now associated with any procedure involving placing a needle into a muscle, joint, spine, or around a specific group of nerves, followed by the injection of medication(s) or delivery of some other treatment such as electricity, heat or cold.

Nerve blocks can be used to:

- *Diagnose pain (diagnostic nerve blocks)* – This can help determine if your pain is coming from a nerve, muscle or joint. It may also help identify nerve pathways causing your pain.
- *Predict the effects of permanent nerve blocks (prognostic nerve blocks)* – Certain nerve blocks are first done with a numbing (local anesthetic medication). If you have relief from this type of block, a more permanent type of block, which will provide longer lasting pain relief may be recommended. The local anesthetic block may "predict" what kind of result you will have with the permanent block.
- *Prevent development of chronic pain syndromes (prophylactic nerve blocks)* – Development and spread of certain types of sympathetic nerve pain conditions may be slowed or stopped by using prophylactic nerve blocks.
- *Provide pain relief (therapeutic nerve blocks)* – When the cause of your pain is known, a therapeutic nerve block may provide a reduction in pain that serves as a complement to other pain treatment options.

Prior to any procedure, your pain specialist may perform a complete pain assessment in order to select the most appropriate injection therapy. This usually includes a complete physical exam and a review of your full medical history, including any testing you may have had (X-rays, CT scans, MRIs, etc.), as well as your personal preferences. This will allow your provider to develop a treatment plan tailored to your specific condition and needs. Your pain specialist should go over the type of block, benefits and risks, and potential side effects in detail before getting your consent to perform the procedure.

The most common medications injected include local anesthetics, corticosteroids and neurolytic drugs. (*For additional information, see Pharmacotherapy section*).

- *Local anesthetics* can numb a painful area by "blocking" sensory and pain pathways. Commonly used local anesthetics are lidocaine and bupivacaine.
- *Corticosteroids* reduce inflammation around the nerves to decrease pain. Commonly used corticosteroids are methylprednisolone acetate and triamcinolone.

- *Neurolytic drugs* destroy nerve pathways to produce a more permanent effect. These drugs include absolute alcohol and phenol, which are otherwise not commonly used in chronic pain management.

In all cases, the area to be injected will be cleaned with an antiseptic solution before any medication or solution is injected into the affected area, which will be numbed with a local anesthetic. Fluoroscopy (a special X-ray) is used for some nerve blocks in order to guide the placement of the needle.

What to Expect Prior to the Procedure (Preparation)
What you may need to do to prepare for each injection therapy will depend on the type of injection and the setting in which the pain specialist will perform the procedure (private office, ambulatory surgery center, hospital center, etc.). Particularly for nerve blocks or minimally invasive surgery, you might need to consider:

- Food and liquids – you **may** be asked to refrain from eating or drinking for a certain period of time prior to your procedure.
- Transportation – you **may** be asked to have someone drive you home after the procedure.
- Medications – you **may** be asked to stop certain medications (blood thinners) prior to your procedure.
- Intravenous (IV) – you **may** have an IV placed prior to your procedure with or without IV fluids running.
- Conscious sedation – you **may** be given medications either before or during your procedure to calm you, make you sleepy while remaining aware and able to follow directions, or to relieve your pain. You should be given specific instructions prior to receiving any type of sedation. These medications may interfere with your memory and functioning, which is why you need to bring a friend or family member with you to listen to your discharge instructions and drive you home.
- Positioning – you **may** be asked to get onto an exam or X-ray table and lie still for a period of time. Be sure to let the pain specialist know if you will require any special assistance.
- Allergies – it is very important that you report if you are allergic to any medications, especially any reactions you may have had to local anesthetics, corticosteroids, iodine, IV dye or shellfish.
- Risk of exposure to radiation (if X-ray/fluoroscopy is used); this is a particular concern in pregnancy.

General Risks
As with any procedure, there are risks of serious complications. While these are uncommon, your pain specialist will be prepared to treat them immediately. Admission to the hospital for at least an overnight observation could be recommended for any of the following:

- Uncontrolled bleeding
- Unplanned perforation of a vital organ located close to the treatment area
- Unplanned nerve damage causing weakness or numbness to the surrounding area of treatment
- Allergic reaction from the local anesthetic causing difficulty breathing

Types of Injection-Based Therapies (e.g., Nerve Blocks) and How They are Used

Diagnostic Injection

- **Discogram**
  A discogram is a procedure used to determine which disc(s) in your lower back is causing your back or leg pain. Fluoroscopy is used and X-ray pictures of the discs are taken. This procedure may be performed by a pain specialist or a specialty trained radiologist. You may be asked to take copies of your X-rays back to the physician who ordered the discogram for their review if that is preferred over a written report of findings by the performing physician.

  Conscious sedation is commonly used for this procedure. You will be placed in the prone (face down) position on an X-ray table. A thin needle will be placed into each disc being tested and solution will be injected to increase pressure in the disc in an attempt to recreate your pain. You will be asked if the injection of the solution "reproduces" your pain or not. If it does, then this may be the disc that is causing your pain and further treatment options may be available.

Injections

- **Botulinum Toxin Injection**
  An injection of botulinum toxin into the muscle/muscle group causing you pain. This toxin causes temporary paralysis of these muscles. This injection may be done if you have dystonia, a disorder characterized by cramping muscles, certain headaches or other conditions where muscles are in chronic spasm causing pain.

  The dosage of botulinum toxin is very small. The relief effect takes time to notice. It may take 2-3 days before muscle relaxation is achieved. This effect generally lasts months, but requires follow-up before a repeat injection is recommended. If a poor response or no response occurs with a previous injection, the value of proceeding with further injections should be reviewed first.

- **Sacroiliac (SI) Joint Injections**
  An SI joint injection is the injection of medication into the sacroiliac joint in your buttock region. This may be done if you have a certain type of low back/buttock pain.

  Fluoroscopy may be used to guide placement of a needle into the SI joint, and inject a local anesthetic or local anesthetic/steroid solution.

- **Trigger Point Injections (TPI)**
  TPIs are the injection of medications into your muscles. These muscle "trigger points" are usually painful when you press directly on them.

  TPIs may be done to treat trigger point pain from chronic spasm, Myofascial Syndrome or Fibromyalgia. A needle will be inserted into the painful trigger points and a local anesthetic with or without steroid will be injected.

Nerve Blocks

The nerve blocks described below are a representation of the most common nerve blocks done for pain conditions. Ask your healthcare provider about these and nerve blocks not discussed in this section.

- **Axillary Block**
  An axillary block is an injection of a local anesthetic around a group of nerves located in your underarm area. This type of block may be done if you have Complex Regional Pain Syndrome (CRPS), nerve pain in your arm, or for diagnostic purposes.

  You will lie flat with the affected arm stretched out with your palm up. A needle will be inserted into your underarm and a local anesthetic is injected. You may feel a sharp tingling sensation at the time of injection. Don't worry, this is normal. This confirms that the needle is in the proper place.

- **Celiac Plexus/Hypogastric Plexus Block**
  These blocks involve the injection of a local anesthetic into the area of a group of nerves which supply the abdominal organs, called celiac plexus nerves. These blocks are performed most commonly for the treatment of upper abdominal pain due to chronic pancreatitis, cancer and pelvic pain. Fluoroscopy is used to guide the placement of needle to the area. After the needle is in the proper area, local anesthetic will be injected in the area of the celiac plexus nerves.

- **Epidural Steroid Injection (ESI)**
  An ESI is the injection of a small amount of steroid into the epidural space that surrounds the spinal cord and spinal nerves. This can be done in the neck (cervical), mid back (thoracic) or low back (lumbar or caudal).

  An ESI may be performed if you have back and/or leg pain, neck and/or arm pain. The pain may be due to a herniated spinal disc, spinal stenosis (narrowing of the spinal canal space), or degeneration of your spinal bones (vertebrae) or compression fractures. All of these conditions may cause irritation and inflammation, which may be the root cause your pain.

  Fluoroscopy is commonly used as a guide for needle placement, so typically, you will be lying face down on an X-ray table. If X-ray is not used, you may be sitting or lying on your side during the procedure. Conscious sedation may be optional and would require IV placement prior to the procedure. Sometimes, IV placement is required for the first procedure, or if you have a history of fainting or sudden drops in your blood pressure during medical procedures (better known as a vagal response).

  The needle may not be placed in exactly the same site as your pain; the medication injected will "float" to coat the nearby nerves. You may feel some pressure in the area of the injection or some re-creation of your pain symptoms as the medication (steroid or steroid/local anesthetic) is injected. This feeling is normal and will go away in a short period of time.

- **Facet Nerve Blocks**
  A facet nerve block is performed if it is suspected that your back or neck pain may be caused by irritation or inflammation of the small nerves near the facet joints of the spine. Pain from facet nerves can occur from injuries that involve twisting and straining while lifting heavy objects or falling. Facet joints are on the back of your spine, one on each side, near the boney spine, but not near the spinal cord.

  Fluoroscopy is used to guide the placement of needles to the area. After correct needle placement is confirmed, a small amount of local anesthetic will be injected near the facet nerve.

- **Intercostal Nerve Blocks**
  An intercostal nerve block is the injection of a local anesthetic or a neurolytic agent in the area between two ribs. This may be performed for pain due to nerve injury around the rib area. A needle will be inserted into the intercostal space and a local anesthetic, local anesthetic/steroid, or neurolytic solution is injected.

  Because the pain specialist is working close to your lung, you should be made aware that a pneumothorax (collapsed lung) is a possible complication. A highly, skilled practitioner, a calm, quiet environment, along with very small and short needles are used to avoid this complication. It is very important that you do not move during the injection phase of this procedure.

- **Lumbar Sympathetic Block**
  A lumbar sympathetic block is the injection of local anesthetic around a group of nerves (lumbar sympathetic "nerve chain" or plexus) in your low back (lumbar) region. This is typically recommended if you have Complex Regional Pain Syndrome/RSD, severe peripheral vascular disease, or neuropathic pain (pain coming from the nerves). Fluoroscopy is used to guide the placement of the needle to the area. After the needle is in the proper area, local anesthetic will be injected in the area of the lumbar plexus nerves.

- **Stellate Ganglion Block**
  A stellate ganglion block is the injection of local anesthetic around a group of nerves (cervical sympathetic "nerve chain" or plexus) in the base of the front of your neck. This type of block may be done if you have Complex Regional Pain Syndrome/RSD or severe peripheral vascular disease.

  You may experience a temporary drooping of your eyelid, blurred vision on the side that was injected or minor swallowing difficulties. You should be monitored closely by skilled healthcare professionals until these go away and you are able to swallow liquids without difficulty.

- **Occipital Nerve Block**
  An occipital nerve block is the injection of local anesthetic around the occipital nerves, which are located in the back of your neck near the base of the skull. This may be useful in the diagnosis and treatment of headache and jaw pain. A needle is inserted around your occipital nerve and a local anesthetic or local anesthetic/steroid solution is injected.

- **Selective Nerve Root Block**
  A nerve root block is the injection of a local anesthetic/steroid solution around a nerve root after it leaves the spine, also called the paraspinal region. This may be performed to diagnose a particular pain problem (to determine if your pain is coming from a nerve, muscle or joint) or as an alternative treatment approach to an epidural steroid injection (for a herniated spinal disc or spinal stenosis, which is the narrowing of the spinal space).

  Fluoroscopy is used to guide the placement of a needle to the area of the involved nerve root. You may experience a small electric shock-like sensation (similar to when you hit your "funny bone"). This will confirm if the needle is in the right place. A small amount of local anesthetic/steroid or steroid solution will be injected.

OTHER

- **Epidural Blood Patch**

  An epidural blood patch is done when a person has a spinal headache, usually from a myelogram or lumbar puncture. This type of headache can occur when there is a hole or tear in the dura (the covering of the spinal fluid/spinal cord), which causes spinal fluid to leak through. A severe headache results. This headache is usually different from a typical headache; it usually is not present when you lie down and painful when you stand up. Nausea and vomiting commonly occur when the pain is severe.

  The blood patch is the injection of your own blood, which is first taken from your arm, into the epidural space in your spine. An IV (intravenous) will be started in your arm prior to the procedure.

  The pain specialist will insert a needle into the epidural space in your spine. An assistant will then draw blood from your arm through the IV. This is done in sterile conditions. Your blood is then injected through the needle in your back. That needle is removed. The blood remains in your epidural space where it will clot or "patch" the hole/tear.

What to Expect After a Procedure

Different injection procedures will have all, some or none of the following considerations. The antiseptic solution will usually be washed off of the area that was injected, and a small dressing (band-aid®) will be placed over the injection site. Your provider may monitor your vital signs (blood pressure, pulse, respirations, etc.) for a period of time. If you had an IV, it will be removed. You will be given instructions of what to expect when you go home, which might include:

- *Numbness* – common if a local anesthetic was used. Use caution with any area that is numb. Do not walk or drive with a numb leg, or apply heat or ice to the area until all feeling has returned.
- *Soreness* – common at the injection site after any type of injection. You may put ice on the area.
- *Low Blood Pressure* – may be common for a short period of time if you have had a sympathetic block. You will be monitored until your blood pressure is within your normal limits.
- *Mild to Moderate Headache* – may be from steroids if they were used. An over-the-counter medication of your choice may be used. If you have a severe headache, with or without nausea and vomiting, please call your pain specialist as soon as possible.
- *Increase in pain level or change in pain location* – common for the first 24 hours after the injection/block.
- *Hot flashes, facial redness, mood changes, increased appetite and menstrual irregularities* – common for the first few days to weeks post injection/block. This is due to the effects of the steroid that was injected. These will go away with time.
- *Increased blood sugar* – If you are a diabetic, your blood sugar may be higher than normal for the first 3-5 days after an injection/block. Please contact the healthcare provider who treats your diabetes for any advice before the procedure is scheduled to make plans on what to do when/if this happens after the procedure.
- *Activity* – after a Blood Patch, your activity should be minimal for the first 24 hours. Rest is necessary so as not to dislodge the patch. All other injections/blocks often do not restrict activity. Use your judgment and be careful not to overdue it just because you may be feeling better; this can prevent re-injury.

Please call your pain specialist if you experience any of the following:

- Redness, swelling or drainage around/from the injection/block site
- Persistent bleeding from injection/block site
- Severe headache (may or may not be accompanied by nausea and vomiting)
- Fever
- Stiff neck
- Weakness not present prior to the injection

NEUROABLATIVE THERAPIES

Neuroablative therapies usually produce a longer lasting effect than nerve blocks. These therapies use thermal (heat or cold) or chemical agents (alcohol or phenol) to "destroy" certain nerves or nerve chain pain pathways, thereby providing you with prolonged pain relief. Your pain specialist might choose one of the following therapies if your pain is severe, expected to persist, and cannot be lessened by other therapies. However, in some cases, special cautions must be given about potential nerve damage and return of pain that can be the same or even worse than before.

THERMAL THERAPIES

- **Radiofrequency Facet Rhizotomy**

  A facet rhizotomy destroys facet nerve(s) either in the lower back (lumbar) or the neck (cervical) region, using radiofrequency (heat) waves. This procedure is done if you have pain due to disease in the facet joints of your spine, and you have had pain relief from your facet nerve blocks.

  You will be placed in the prone position. Your back or neck will be cleaned with an antiseptic solution and the skin area will be numbed with a local anesthetic. Fluoroscopy is used to guide the placement of the needle probe to the area of the facet nerve. Radiofrequency waves are transmitted to lesion (destroy with heat) the involved nerve(s). This temporarily stops sensation from that area, which may last for an average of 6 months or more.

- **IntraDiscal ElectroThermal Therapy (IDET)**

  IDET may be considered if you have "cracks" or fissures in the wall of one of your spinal discs, or if the inner disc tissue has "herniated" into the fissure. Since these fissures are filled with small nerve endings, this may be a source of chronic back pain.

  IDET is the application of thermal energy (heat) to a section of a spinal disc wall. This may result in the contraction or closure of that "crack" in the spinal disc wall or a reduction in the bulge of the inner disc material.

  An IV will be placed in your arm and you will be given sedation. You will be placed in the prone position on an X-ray table. Fluoroscopy is used to guide a needle into place. An electrothermal treatment catheter is inserted through the needle, and the heating element is started. Once the heating is done, the catheter and needle are removed.

  You should be given special instructions after this procedure with regard to activity, physical rehabilitation and other considerations.

- **Cryoanalgesia**
  Cryoanalgesia is the application of thermal energy (cold) to a nerve or nerve chain to "freeze" it with nitrous oxide or carbon dioxide gas. Cryoanalgesia may still be available in some pain specialty practices, but it is limited due to the unavailability of equipment from old or new manufacturers.

  Cryoanalgesia may be done if you have rib pain, pain after lung/chest surgery, facial pain or pain from a neuroma.

  Your positioning will depend on the area being treated. The cryoanalgesia probe will be placed around the nerve to be "frozen" when the gas is activated. This process forms an "ice ball" around the nerve to freeze it. This temporarily stops sensation from that area, which may last for an average of 3-6 months and sometimes more.

CHEMICAL THERAPIES

- **Celiac Plexus (Destructive) Block**
  A celiac plexus destructive block is the injection of an alcohol or phenol in the area of a group of nerves which innervate (supply) the abdominal organs. It is performed most commonly for the treatment of upper abdominal pain due to chronic pancreatitis or cancer, and *usually after you have had pain relief from a diagnostic celiac plexus block.*

  After the needle is in the proper area, alcohol or phenol will be injected in the area of the celiac plexus or hypogastric plexus nerves.

- **Lumbar Sympathetic (Destructive) Block**
  A lumbar sympathetic block is the injection of alcohol or phenol around a group of nerves (lumbar sympathetic nerve chain) in your low back (lumbar) region. This may be done if you have Complex Regional Pain Syndrome/RSD, severe peripheral vascular disease, or neuropathic pain (pain coming from the nerves) and *you have had pain relief from a diagnostic lumbar sympathetic block.*

  Fluoroscopy is used to guide placement of a needle to the grouping of nerves in your low back. After correct needle placement, alcohol or phenol will be injected.

MINIMALLY INVASIVE SURGERY

- **Vertebroplasty (therapeutic)**
  Percutaneous **vertebroplasty** is a procedure that allows health professionals to stabilize vertebrae damaged by compression fractures by injecting bone cement into the collapsed vertebrae. The aim of a vertebroplasty is to improve the strength and stability of the injured vertebrae and to eliminate pain.

  When conservative treatment fails to alleviate pain associated with vertebral

compression fractures, this method may be suggested. The most common complication following vertebroplasty is a transient increase in pain at the injected level. This is readily treated with NSAIDs and typically resolves within 48 hours.

Your care after any of these procedures will be similar to that after having an injection/nerve block. Your pain specialist may provide you with additional instructions depending on the type of procedure performed.

- **Kyphoplasty**
  Like Vertebroplasty, kyphoplasty is used to treat bone fractures due to osteoporosis — the loss of calcium from bones resulting in weakened bone structure that increases the risk of fracture. Kyphoplasty includes an additional step when compared to vertebroplasty. Prior to injecting the cement-like material, a special balloon is inserted and gently inflated inside the fractured vertebrae. The goal of this step is to restore height to the bone thus reducing deformity of the spine. Pain is reduced which allows you to return to normal daily activities after either procedure.

INFUSION THERAPIES

Infusion therapies, especially intravenous (IV) drug delivery, are a convenient and effective way to control your pain. Giving pain medications through a catheter placed in your vein or spine means you may get faster and more effective pain relief, especially after surgery, injury or trauma. The following are common infusion therapies.

- **Subcutaneous (SC)**
  The SC route is usually used for chronic pain, not acute pain because pain medication given this way will take longer to work. A small needle is placed under your skin into your subcutaneous or "fatty" tissue. The needle is connected to a hollow tubing and infusion pump, which will deliver the pain medication into the SC tissue. The medication is then absorbed by your body and distributed to relieve your pain. SC infusion can successfully be used in the home setting, but require visits from home health personnel.

- **IV Bolus**
  Small amounts of pain medication are given through an IV catheter by a doctor or nurse. IV boluses are good for fast control of severe or acute pain on a short-term basis. IV boluses can provide immediate pain relief, but this might only last for 45-60 minutes, so additional boluses will have to be given. IV boluses are usually only used in a hospital setting.

- **IV Continuous Infusion**
  When moderate to severe pain over a long period of time (i.e. a few days after surgery) is expected, a continuous infusion may be used. A continuous dose of pain medication is delivered through an IV by an infusion pump, which means you will have a constant level of pain relief. This is usually started after your pain has been controlled with IV boluses. IV continuous infusions are usually only used in a hospital setting, where a healthcare provider can monitor you.

- **IV Patient-controlled Analgesia (PCA)**
  IV PCA is a method of pain relief to help you feel comfortable. It is routinely used after surgery or during a painful illness. By pushing the patient control button for the PCA infusion pump, you can give yourself small amounts of pain medication. Your doctor will order the amount of pain medication and indicate how often you can have it. The benefits of PCA are rapid pain relief when you need it, the possibility of using less pain medicine and having fewer side effects, and a sense of control over your pain. You will be given specific instructions on using PCA by your provider. IV PCA is usually used in a hospital setting, but may be used at home for severe, chronic pain.

- **Intraspinal Drug Delivery**
  Infusing pain medications and/or local anesthetics directly into the epidural — in front of the spinal fluid space (epidural analgesia) or spinal fluid space (intrathecal analgesia) — is a method of pain relief used after surgery, painful injury or illness. This can help you get better pain relief and help you move better after surgery. It is also possible to use less pain medicine and have fewer side effects, which should help your recovery. With epidural analgesia, a small hollow tube (catheter) is placed in the space between the covering around the spinal cord and the bones of the spine; with intrathecal analgesia, the catheter is placed in the spinal fluid. The catheter may be inserted in the operating room before surgery, on a hospital floor/intensive care unit, or as an outpatient in a pain center or outpatient surgical center. A dressing will be put over the area where the catheter goes into your skin, and the catheter will be taped along your back up to your shoulder. An anesthesiologist (doctor specializing in giving anesthesia), or pain management specialist will order the amount of pain medicine to be given by a specialized infusion pump. Special training is required for nurses who assist in the monitoring and care of this infusion system.

  Epidural/intrathecal analgesia is usually used in a hospital setting, but may be used at home for cancer pain.

- **IV Regional Blocks**
  IV regional blockade, also known as a Bier Block, is a method of producing pain relief (analgesia) in an arm or leg by injecting medications intravenously, while the blood supply (circulation) in the arm or leg is cut off (occluded). This may cause temporary numbing (anesthesia) of the extremity, if a local anesthetic drug is used. Many patients are sent for physical therapy after the block, so their arm or leg can be exercised without pain. Your doctor may recommend this type of block if you have severe pain from Complex Regional Pain Syndrome or nerve injury.

- **Anesthetic Infusions**
  IV Anesthetic Infusion is the infusion of a local anesthetic such as lidocaine through an IV catheter. This method can be used to treat chronic neuropathic pain (pain coming from nerves). The local anesthetic is given over a 30-60 minute period of time; you will be monitored for a period of time after that determined by your pain specialist. This may be done in an outpatient or ambulatory care setting.

- **Disposable Anesthetic Systems**
  PainBuster and ON~Q are two of the systems available that provide a continuous infusion of local anesthetic directly into the surgical wound. Your healthcare provider might recommend this method of pain control if you are having knee, hip, shoulder or abdominal surgery. The advantage to this system is it can be used on an outpatient basis. A small catheter is place directly into the surgical site, and your skin closed around the catheter. A small device will deliver local anesthetic to the wound site for 24-48 hours. You will be instructed on care and removal of the catheter.

Implantable Devices and Surgical Interventions

IMPLANTABLES

Advances in medical technology have greatly impacted pain management delivery systems. Pumps and stimulators have been designed so they can be surgically placed under the skin. This helps reduce the risk of infections that is more common with external devices and provides targeted pain relief to major nerves and the spinal cord, depending on the system selected. External devices tend to be recommended for short-term pain problems when pain relief is expected to decrease over time. Internal (implantable) devices may be more appropriate for persistent pain problems that require long-term pain reduction.

SPINAL CORD STIMULATION (SCS)

SCS therapy may be used to treat chronic pain that has been objectively confirmed in the neck or arms, chest, mid to low back or legs. It is most effective in treating pain coming from the nerves (nerve damage). Your pain specialist will perform a SCS "trial," a test so see if the therapy will help to relieve your pain. If the trial is successful, a surgical procedure will be required to "implant" the SCS system.

Physicians require special training to insert either temporary or permanent SCS. Often, nurses who specialize in pain management are trained in adjusting and monitoring these systems following placement.

SCS uses a small battery-type device, called a pulse generator or receiver, to deliver electrical impulses to a "lead" (catheter with electrodes along the tip), which is placed near nerves along the spinal cord. The electrical impulses, or stimulation, interfere with the transmission of pain signals to the brain. In successful cases, the brain perceives the more pleasant tingling sensation (stimulation) and not the pain sensation.

SCS therapy may be used to treat: chronic pain in the neck or arms, chest, mid to low back and legs that has been objectively confirmed. It is most effective in treating pain coming from the nerves (nerve damage). Your pain specialist will perform a SCS "trial," a test to see if the therapy will help to relieve your pain. If the trial is successful, a surgical procedure will be required to "implant" the SCS system.

There are two types of SCS systems, *Implantable Pulse Generator (IPG)* or *Radiofrequency (RF)*.

The IPG system is known as an internal system; all components (generator connected to the lead) are implanted under your skin. The IPG is typically implanted in your buttock or abdomen, with the lead in your spine. You or your pain specialist may program the system using a programmer held over the generator. In older systems, the IPG will need to be replaced when the generator becomes depleted (battery wears out). This usually requires an outpatient surgical procedure. Newer systems have battery/generators that are rechargeable by placing a small device over the generator. Many patients prefer this system, which is advantageous in terms of not having to have repeat surgery for battery changes. The IPG systems offer great advantages in supporting daily activity (can be used while showering, bathing, swimming) along with cosmetic features (nothing can be seen on the outside).

The RF system, on the other hand, is known as an external system. It uses a rechargeable type battery, located in a small controller called a transmitter. The transmitter is connected to an antenna, which must be placed on your skin over a receiver (usually implanted in your buttock or abdomen). The receiver is then connected to the lead, which is placed in your spine. Some advantages to this system include: no additional surgical procedures required and higher power outputs may be possible.

Disadvantages are that it cannot be used while showering, bathing, or swimming, the transmitter and antenna must be worn continuously outside the body to receive the stimulation, and wardrobe issues may be present.

Prior to undergoing a SCS trial, your pain specialist should provide you with detailed information on the therapy, system components, benefits and risks, and potential complications. This information can help you decide if SCS is right for you.

IMPLANTED INTRASPINAL DRUG DELIVERY SYSTEMS

Intraspinal Drug Delivery is the continuous infusion of pain medications, possibly including opioids, local anesthetic drugs, baclofen, or other drugs into your spinal fluid via a catheter and implanted infusion pump. Physicians require special training to insert implantable systems. Often, nurses who specialize in pain management are trained in filling, adjusting and monitoring these systems following placement.

Your pain specialist may choose this type of advanced pain treatment therapy if you have chronic pain due to cancer, or other chronic pain condition that has been objectively diagnosed. As in SCS therapy, this option should be considered only after conservative methods have been tried and failed. There are many similarities to SCS therapy: a trial infusion of the opiate medication will usually be done to assess your response; a surgical procedure will be required to implant the system; the system lies totally beneath the skin; from time to time the infusion pump must be replaced when the battery is depleted.

The implanted drug delivery system consists of a small flexible catheter, placed in the spinal fluid, connected to a drug infusion pump, and implanted in your abdomen. The medication is placed into the pump via a small port (covered opening) in the top of the pump. Your pain specialist will decide which drug is right for you based on your trial.

A computerized program is used to tell the pump which drug is being used and how much of the drug you are to receive per day.

Prior to undergoing a drug infusion trial, your pain specialist should provide you with detailed information on the therapy, system components, benefits and risks, and potential complications. This information can help you decide if intraspinal drug delivery is right for you.

Looking Forward with Hope

LOOKING FORWARD WITH HOPE!

What's in the Pipeline?

Over the years, new medications and technologies have emerged for the treatment of pain. A variety of pharmaceutical and medical technology companies have been carefully working within their research and development departments to improve drugs and delivery systems and create new treatment options for pain. They work closely with some of the best and brightest pain researchers and pain clinicians. As pain research advances, new ideas are generated and explored. There is hope in the future!

We have seen new preparations of "old" opioids expand with the introduction of longer acting versions in pill form. Work continues so that eventually every opioid that traditionally comes in a short-acting form will have a long-acting version. Today, we have morphine and oxycodone options. Next, hydrocodone, oxymorphone and hydromorphone will be an option. Also, new combination drugs that contain opioids along with other medications are entering clinical trials. Some of these preparations are expected to enhance pain relieving effects. Others are expected to eliminate the "sought after" pleasurable effects when long-acting versions are improperly altered by those who would misuse.

Patch therapy has gained popularity, whether in the form of an opioid, NSAID or anesthetic. Generic versions of fentanyl have entered the market. Hopefully, offering other medications or combination of medications in patch form will be created. The introduction of transbuccal delivery systems for fentanyl has launched a new concept. Some companies are working on improving the onset of oral drug action by speeding it up. Research is underway that uses an effervescent delivery system to create more rapid onset versions of short-acting drugs. One such preparation has been reported to taste like taking a teaspoon of a gentle carbonated cola or soda (pop). This may be very appealing to those who experience breakthrough pain and would prefer faster relief.

Although two of the three COX-2 inhibitors have been taken off the market because they increased the risk of heart attack and stroke in some persons, research is in process to improve the safety of these drugs. It wouldn't be surprising to find new preparations of NSAIDs become available in the next few years.

New adjuvants, such as gabapentin, pregabalin and duloxetine for neuropathic pain, are showing great promise as they may provide better pain relief with fewer side effects. Anesthetic patches, creams and solutions have helped with local pain problems, such as open wounds, diabetic neuropathy and shingles pain. The release of a shingles vaccine was announced in May 2006. This approach is expected to decrease the occurrence of shingles in older or immune-compromised individuals and hopefully reduce the incidence and severity of shingles pain. More research in neuropathic pain will generate new treatment options.

We can expect the introduction of drugs that work by unique mechanisms. For example, Ziconotide, from a snail toxin, was introduced in 2004. Though this must be given through an implantable infusion pump, it has helped in the treatment of severe pain disorders that have not responded to other therapies. More substances that block pain in newly discovered ways are being investigated. Drugs that work on nicotine and capsaicin receptor sites in the nervous system might be the next breakthrough. Others are investigating drugs to "turn off" parts of nerve cells that become "irritated" in the presence of pain stimuli or when some pain relieving drugs, like morphine have been used for a long period of time.

Emerging medical technology is another promise of hope. Creating new and improving current infusion devices and stimulators is on the rise. Recently, a rechargeable battery for implantable pumps was introduced to the marketplace. This should help to decrease the need to replace pumps every five years. That is a cost savings in pain, suffering and healthcare dollars. The creation of smaller, more compact pumps and stimulator systems will not only help decrease the discomfort of implantation, but expand this option for very thin persons and the younger population living with persistent, complex pain. New stimulator devices for the brain and the periphery are undergoing clinical trials now.

There is much to look forward to, but for those in pain the future cannot come fast enough.

CONCLUSION

In summary, understanding and effectively managing pain can be challenging. Since you may have consulted several medical professionals already, you are well aware of the difficulty in receiving adequate pain diagnosis and care. It is very important for you and your healthcare providers to work as a TEAM to treat your pain effectively. Asking for help from professionals who have more experience in specialized areas may be recommended. That way, a pain management program can be designed to meet your needs.

As part of the pain "investigation," a comprehensive pain assessment should be completed. Knowing as much information as possible about your pain experience will make it easier for your provider to diagnose and decide if your pain condition is treatable by behavioral changes, medication adjustments and/or the inclusion of other specialists or techniques.

When there is a challenging pain problem to address, working with well-trained and experienced pain management specialists is ideal. There are many more complicated therapies than those discussed here that could be helpful to some.

Fortunately, there are also some pain problems that are easily managed, and a primary care provider often can handle the problem very well. The main point is to understand that most pain can be managed, and that all people have the right to have their pain problems addressed.

Disability Determination

The overall goal for pain management is to reduce pain and improve function so that each individual living with persistent pain may regain a quality of life. When pain cannot be adequately reduced or when function is impaired, other options may need to be pursued. Pain experts in rehabilitative medicine (*See Rehabilitative section*) are often trained experts in the evaluation of those who may require some form of disability classification. This process is better known as a disability determination. More information about disability evaluations and the government sponsored program under Social Security can be found at **http://www.ssa.gov/disability/professionals/bluebook/** or by calling **1-800-772-1213**.

Common Pain Terms

Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (IASP/APS 1992); The inability to identify tissue damage sufficient to explain the pain is not proof that the pain is of psychological origin (Portenoy, Kanner 1996); Pain is whatever the experiencing person says it is, existing whenever said it does (McCaffery 1968). Pain is personal and subjective (APS 1999), therefore, the individual's self-report on pain is the single most reliable indicator of pain (AHCPR 1992).

Acute Pain: pain of sudden onset usually from a single, "fixable" event commonly seen with surgery, accidental injury or inflammation, however, can be from unknown cause; short duration from days to less than 3-6 months as associated with healing; considered our biological red flag that sends warning signals through the nervous system that something is either wrong within the body or that a hurtful activity should be avoided to prevent further or repeat damage.

Allodynia: pain caused by a stimulus or action that does not normally cause pain, like light touch or pressure, subtle temperature change, gentle breeze on skin (Mersky 1986).

Breakthrough Pain: pain that flares up or emerges through the comfort state obtained from drug and/or non-drug pain relief methods.

Central pain: pain started or caused by damage to the central nervous system (spinal cord, brain); this is a disorder of the nervous system or a disruption of normal nervous system activity.

Chronic Pain: pain lasting longer than expected healing time, may last for many months, years or a lifetime, may be constant or in intervals; cause may be unknown or result of recent or previous acute pain episode; may be related to another chronic disorder, such as arthritis, peripheral vascular disease, diabetes, or cancer (disease, treatment or aftermath as a survivor); often cancer-related pain and non-cancer-related pain are discussed as separate, distinct pain problems.

Deafferentation Pain: pain due to alteration or damage to the central nervous system (central pain or neuropathic pain) or may be alteration of nervous system within larger nerves or nerve roots before entry into central nervous system.

Escape Pain: another term used to describe breakthrough pain.

Hyperalgesia: an increased response to a stimulus that normally would induce a mild discomfort (Mersky 1986).

Intractable Pain: old term (outdated) used to describe chronic pain resistant to pain treatment; may be seen as diagnosis of those experiencing chronic persistent pain.

Lacinating Pain: stabbing, knifelike pain (Portenoy and McCaffery 1999).

Neuralgia: pain along a nerve or nerves (Mersky 1986).

Neuritis: pain caused from the inflammation of a nerve or nerves (Mersky 1986).

Neuropathic Pain: pain started or caused from alteration of the nervous system (McCaffery and Pasero, 1999).

Nociceptive Pain: another term used to describe acute pain as a response to a noxious (unpleasant) stimulus activating nerve cells to send pain signals along the nervous system for recognition and response. The nervous system is working appropriately.

Pain Flares: pain that suddenly erupts or emerges with or without an aggravating event or activity.

Pain Perception: the natural process of recognizing, defining and responding to pain (McCaffery and Pasero, 1999).

Pain Threshold: the least experience of pain that is recognized (or) the lowest level of stimulus that is perceived as painful (Mersky 1986).

Pain Tolerance: the greatest level of pain that an individual is prepared to (or willing to) tolerate (Mersky 1986).

Paroxysmal Pain: pain that occurs in waves or patterns, intermittent in nature; may be related to muscle spasm or visceral pain disorders.

Peripheral Neuropathic Pain: pain started or caused from alteration of nerves or nerve roots (McCaffery and Pasero, 1999).

Persistent Pain: pain that lasts 12 or more hours every day.

Radicular Pain (Radiculopathy): pain from an alteration within one or more nerve roots (Bonica 1990).

Somatic Pain: pain within the muscles and/or bones (McCaffery and Pasero 1999).

Visceral Pain: pain within internal organs (McCaffery and Pasero 1999).

REFERENCES

Definitions Related to the Use of Opioids for the Treatment of Pain
American Society of Addiction Medicine
http://www.asam.org/pain/definitions2.pdf

MedlinePlus
National Library of Medicine
http://medlineplus.gov/

National Center for Complementary & Alternative Medicine
National Institutes of Health
http://nccam.nih.gov/health/

National Institutes of Health
http://www.nih.gov/

Pain & Policy Studies Group
University of Wisconsin
http://www.medsch.wisc.edu/painpolicy/

Pain Management Guidelines for the Older Persons
American Geriatric Society
http://www.americangeriatrics.org/products/positionpapers/JGS5071.pdf

RxList: The Internet Drug Index
http://www.rxlist.com/

Use of Opioids for the Treatment of
Chronic Pain
American Pain Society
http://www.ampainsoc.org/advocacy/opioids.htm

Note: Many resources and a more comprehensive list of links relating to this Treatment Options Book can be found through the American Pain Foundation's Web site or toll-free telephone information service.

RESOURCES - FIND A PAIN SPECIALIST

American Academy of Medical Acupuncture
(323) 937-5514
http://www.medicalacupuncture.org/acu_info/generalinfo.html

American Academy of Pain Management
(209) 533-9744
http://www.aapainmanage.org/info/Patients.php

American Academy of Pain Medicine
http://www.painmed.org/membership/

American Academy of Physical Medicine and Rehabilitation
(312) 464-9700
http://www.aapmr.org/

American Association of Naturopathic Physicians
(866) 538-2267
http://www.naturopathic.org/

American Chiropractic Association
(703) 276-8800
http://www.amerchiro.org/level1_css.cfm?T1ID=13

American Holistic Medical Association
(505) 292-7788
http://www.holisticmedicine.org/public/public.shtml

American Holistic Nurses Association
(800) 278-2462
http://www.ahna.org/practitioners/index.html

American Osteopathic Association
(800) 621-1773
http://www.osteopathic.org/index.cfm?PageID=findado_main

American Pain Society
(847) 375-4715
http://www.ampainsoc.org

American Society of Addiction Medicine
(301) 656-3920
http://www.asam.org/search/search2.html

American Society of Interventional Pain Physicians
(270) 554-9412
http://www.asipp.org/

American Society for Pain Management Nursing
(888) 34-ASPMN / (888) 342-7766
http://www.aspmn.org/

American Society of Regional Anesthesia & Pain Medicine
(847) 825-7246
http://www.asra.com/

RESOURCES

American Alliance of Cancer Pain Initiatives
(608) 265-4013
http://www.aacpi.wisc.edu/

American Cancer Society
(800) ACS-2345
http://www.cancer.org

American Chronic Pain Association
(800) 533-3231
http://www.theacpa.org/

American Pain Foundation
(888) 615-PAIN (7246)
http://www.painfoundation.org

Beth Israel Medical Center
Department of Pain Medicine and Palliative Care
http://www.stoppain.org/

Cancer*Care*
(800) 813-HOPE (4673)
http://www.cancercare.org

City of Hope Pain/Palliative Care Resource Center
http://www.cityofhope.org/prc/

Mayday Pain Project
http://www.painandhealth.org/index.html

National Chronic Pain Society
(281) 357-HOPE (4673)
http://www.ncps-cpr.org/

National Family Caregivers Association
(800) 896-3650
http://www.thefamilycaregiver.org/

National Pain Foundation
(303) 783-8899
http://www.nationalpainfoundation.org/

Pain Assessment Scales
http://www.partnersagainstpain.com/index-mp.aspx?sid=3&aid=7825

Pain Assessment Scales for Children
http://www.childcancerpain.org/content.cfm?content=assess07

Pain Assessment Scales in Multiple Languages
http://www.partnersagainstpain.com/index-mp.aspx?sid=3&aid=7692

Pain Clinical Trials Resource Center
http://www.centerwatch.com/ctrc/PainFoundation/default.asp

Pain.com
http://www.pain.com/

Partnership for Prescription Assistance
(888) 4PPA-NOW / (888) 477-2669
https://www.pparx.org/Intro.php

Patient Advocate Foundation
(800) 532-5274
http://www.patientadvocate.org/

Spine Universe
http://www.spineuniverse.com/

Whole Health MD Therapies Reference Library
http://www.wholehealthmd.com/ME2/Default.asp

Yoga for Chronic Pain
http://www.painfoundation.org/page.asp?file=ManageYourPain/Yoga/Intro.htm

BOOKS

*Managing Pain Before It Manages You, Revised Editio*n – M.A. Caudill-Slosberg (Guilford Press, 2001).

The War on Pain – S. Fishman & L. Berger, (Harper Collins, 2001).

The Savvy Woman Patient: How and Why Your Sex Matters to Your Health - P. Greenberger & J. Wider, Eds. (Capital Books, 2006)

Pain: Clinical Manual, 2nd edition – M. McCaffrey, & C. Pasero (Mosby, 1999).

Mayo Clinic on Chronic Pain, 2nd edition – J. Rome, Ed. (Mayo Clinic Health Information, 2002).

The Truth About Chronic Pain: Patients And Professionals On How To Face It, Understand It, Overcome It – A. Rosenfeld (Basic Books, 2004).

Cognitive Therapy for Chronic Pain: A Step-by-Step Guide – B.E. Thorn (Guilford Press, 2004).

Disclaimer Statement: This information in this book is provided for educational and information purposes only. Readers are encouraged to discuss it with their families and with their health-care providers. Always consult with health-care providers before starting or changing any treatment. APF is not engaged in rendering medical advice or professional services and this information should not be used for diagnosing or treating a health problem. APF makes no representations or warranties, expressed or implied. Providing references to other organizations or links to other resources or websites does not imply that APF endorses the information or services provided by them. Those organizations are solely responsible for the information they provide.

An amazing document.
—Jackie Levin RN, MS

First, let me say how much I enjoyed reading this publication—it is very well developed and informative. I couldn't think of a thing that might have been missed. I think it will be very well-received by the general public. Y'all have done an exemplary job!!
— MaryAnn Stabile, Person Living with Pain

REFRIGERATOR REMINDER

Medication Schedule For: _____

Date: _____

Medication	Dose	Action	Breakfast @_____	Lunch @_____	Supper @_____	Bedtime @_____	Other @_____

www.painfoundation.org

1-888-615 PAIN (7246)

This is a very good resource for the pain patient.
— Russell Portenoy, MD

What a great job! Finally, a full consumer resource created for patients with pain. A "must have" for every physician's waiting room. — Scott Fishman, MD

This is one heck of a guide. Most of the therapies I have had or heard of but there were a few that popped in that I had not heard about. It is a great overall introduction, explanation and summary of complex issues and multi-disciplinary approaches to pain treatment. — Nick Wilson, Person Living with Pain

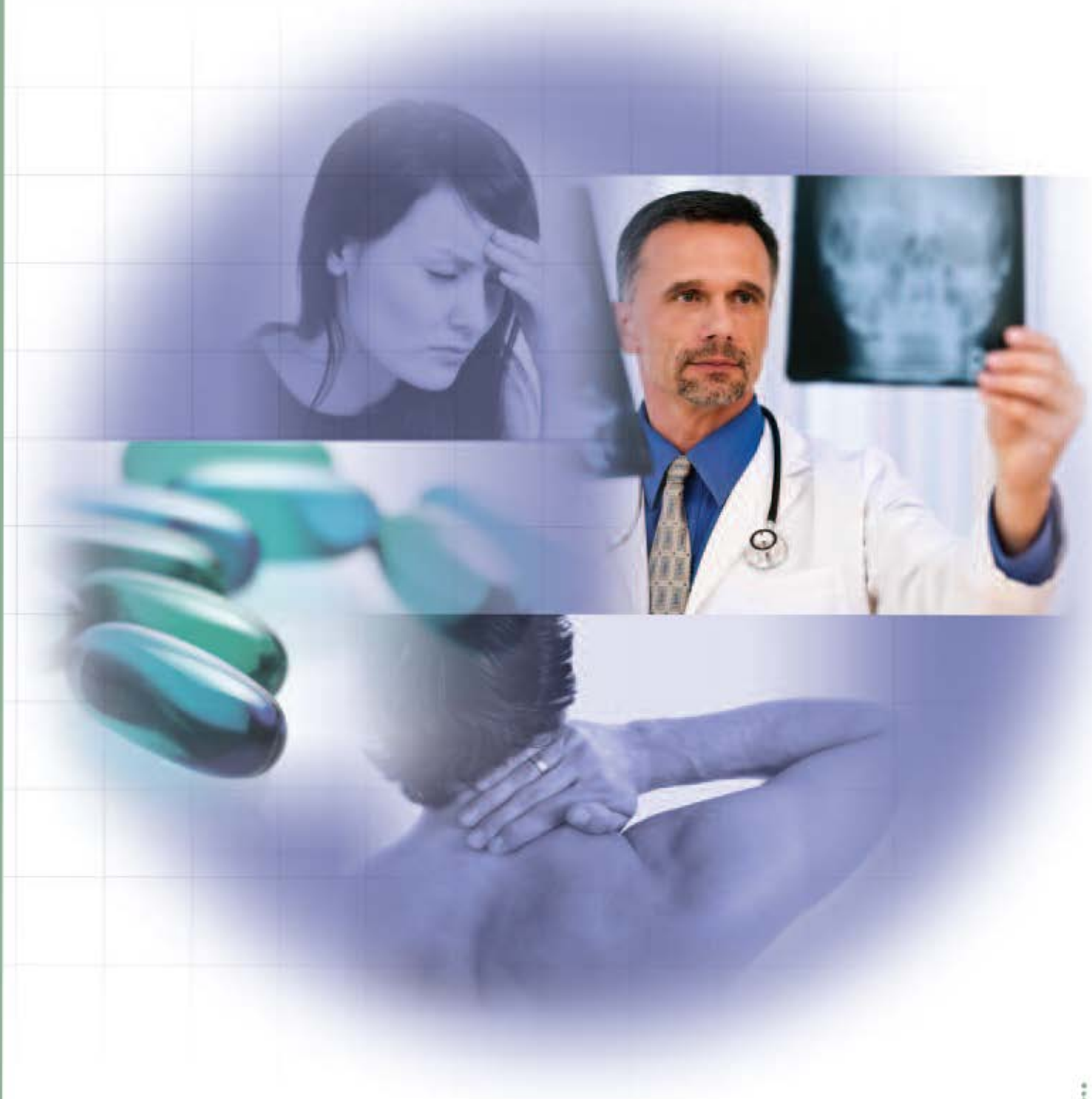
This book is just AWESOME, AWESOME, AWESOME. It makes me so mad I didn't have this when my family and I were trying to understand different therapies and getting hopelessly confused! You all should be SO proud of what you have done here.
— Mary Vargas, Person Living with Pain

American Pain Foundation

Dedicated to eliminating the undertreatment of pain in America.

American Pain Foundation
201 North Charles Street,
Suite 710
Baltimore, MD 21201-4111

American Pain Foundation
A United Voice of Hope and Power over Pain



A Reporter's Guide:
Covering Pain and Its Management

Pain is a complex perception that differs enormously from one person to another, even those with seemingly identical injuries or illnesses.

Introduction

Everyone has experienced pain—whether it's a pounding headache at the end of a long day, a throbbing toothache warning of a cavity or infection, an open wound or sprained ankle from a fall, or a stinging burn from touching a hot pan.

There are hundreds of pain syndromes, and pain is often a chief symptom of most chronic conditions, including cancer, diabetes, arthritis, fibromyalgia and a host of neurological disorders. For millions of Americans, pain persists, interfering with everyday activities and enjoyment of life. People living with chronic pain will often avoid certain movements or activities, fearful they will cause more injury or to avoid the anxiety of anticipated pain.

Pain is complex and frequently misunderstood by the public. The issue of pain is riddled with myths and misperceptions, which makes the task of informing and educating people about pain and its management that much more challenging.

SOME COMMON MISCONCEPTIONS ABOUT PAIN

- **Pain is "all in your head."** Although this is partially true because we need our brains for the perception of pain, that does not mean pain is imaginary when the source of pain is not well understood. Pain is all too real to the person who lives with it day in and out.
- **Pain is just something one has to live with**—an inevitable part of a disease or condition. The fact is most pain can be relieved with proper pain management.
- **Pain is a natural part of growing older**. While pain is more common as we age because conditions that cause pain (e.g., arthritis, degenerative joint diseases, cancer, shingles, osteoporosis) are more frequent in older adults, it should not be something people have to struggle with.
- **The best judge of pain is the physician or nurse.** Studies have shown that there is little correlation between what a physician or nurse might "guess" about someone's actual pain. The person with pain is the authority on the existence and severity of his/her pain. The self-report is most reliable indicator.
- **Seeking medical care for pain is a sign of weakness.** Pain carries a stigma, and many people hesitate talking about their pain and how it affects their daily life; they also don't want to be considered a "bad" patient.
- **Use of strong pain medication leads to addiction.** Many people living with pain and even some healthcare providers falsely believe opioids (strong pain medicines) are universally addictive. Studies have shown that the risk of addiction is small when these medicines are properly prescribed and taken as directed. As with any medication, there are risks, but these risks can be managed.

Key Reporting Challenges

A limited and informal survey of reporters, editors and producers revealed the following challenges when researching and covering the pain/pain management story:

- Stigma of pain management, especially among legal and government regulatory bodies
- Hesitancy on the part of patients and providers to discuss opioids for legitimate chronic pain management given misperceptions about opioids and addiction
- Ability to find unbiased, credible information about pain
- Limited number of randomized controlled trials
- Finding pain patients who live with the type of pain and/or use the pain management approach being reported in the news story
- Accurately characterizing the pain experience given that every person experiences pain differently, even if they have a similar injury or illness

THE UBIQUITOUS NATURE OF PAIN

Consider the following…

- Most Americans (80%) will suffer from back pain at some point in their lives.
- As we age, arthritis hinders the normally smooth sliding motion of our joints and connective tissues, resulting in stiffness and discomfort. Arthritis is the leading cause of disability in people over the age of 55.
- Pain associated with pediatric immunizations is a significant source of anxiety for children receiving the immunizations, and evidence suggests that the way children and parents cope can set the stage for future pain responses.
- Damage to or dysfunction of the central nervous system, due to stroke, multiple sclerosis, epilepsy, brain or spinal cord injuries or Parkinson's disease, also stimulates pain pathways.
- An estimated 30 to 50% of patients undergoing active treatment for cancer and 70% of those with advanced stages of the disease experience significant levels of pain and may be reluctant to discuss their pain with their doctors.

Sources: The American Academy of Physical Medicine and Rehabilitation, Arthritis Foundation, Mayday Fund, National Institute of Neurological Disorders and Stroke, National Cancer Institute.

Purpose of This Guide

The American Pain Foundation (APF) has developed this Guide as a primer on pain and pain management to help meet the informational needs of busy reporters, editors and producers covering the pain story. We know it's a complex topic, and hope you will find this to be a useful resource.

INSIDE YOU WILL FIND:

Page

- A basic overview of the burden of pain in America, consequences of unmanaged pain, pain assessment tools and treatment options *4*
- Pain Stats & Facts *10*
- Special Topic Briefs covering
  - *Special Considerations: Pain in Specific Populations* *13*
  - *Pain Management and Disparities* *23*
  - *Chronic Pain and Opioid Therapy* *27*
    At a Glance: Differentiating addiction, physical dependence and tolerance
  - *Integrative Medicine: Non-Drug Treatment Options for Pain Management* *35*
- Pain A to Z: Common Pain Terms and Syndromes *40*
- Online Pain Resource *43*

Be sure to visit the Newsroom section of the American Pain Foundation's web site at www.painfoundation.org to download additional copies and to check for posted updates and new Topic Briefs as they are added. Here you will also find recent news releases, press statements and background information on a wide variety of issues related to pain care.

ABOUT THE AMERICAN PAIN FOUNDATION

APF's mission is to improve the quality of life for people with pain by:

- Raising public awareness;
- Providing practical information, education and support;
- Advocating to remove barriers and increase access to effective pain management; and,
- Promoting research.

Since its founding in 1997, the American Pain Foundation (APF) has been at the forefront of advocating for people living with a wide variety of pain conditions and their caregivers.

Our grassroots effort, *Power Over Pain Action Network,* is now active in nearly 40 states and is comprised of people living with pain, caregivers, healthcare providers and advocates, who are working hard to call attention to the urgent need for positive changes in pain policy, practice and research investment.

EXPERTS AVAILABLE FOR INTERVIEW

APF can connect reporters with a wide array of leading pain experts, as well as people living with pain and their caregivers. Whether you are working on a national or local story, we can help coordinate interviews about pain-specific conditions and other important issues related to pain (e.g., depression, coping skills, financial matters, disparities, treatment options).

If you are interested in interviewing someone at APF or need additional resources, please contact Tina Regester, APF's communications manager, at (443) 690-4707 or tregester@painfoundation.org.

A Primer on Pain and Its Management

BURDEN OF PAIN IN AMERICA: AN EVOLVING PUBLIC HEALTH CRISIS

Pain is a serious and costly public health issue. It affects more Americans than diabetes, heart disease and cancer combined, and is a leading cause of disability in the United States. Even though pain is one of the most common reasons patients consult a healthcare provider, it is often inadequately assessed and treated, resulting in needless suffering and poor patient outcomes.

PAIN IS WOEFULLY UNDERTREATED FOR A VARIETY OF REASONS, INCLUDING:

- Misconceptions about opioid addiction
- Lack of access to care
- Cultural norms and the stigma associated with admitting pain
- Limited or no professional training in pain management, which leaves healthcare providers ill-equipped to effectively respond to patients' reports of pain
- Concerns among physicians about prescribing pain medications for chronic pain, and fears of scrutiny by regulators or law enforcement
- Inadequate funding for pain research (less than 2% of NIH research budget was dedicated to pain studies)

Untreated or poorly managed pain can compromise every aspect of life, including a person's physical and mental health, social and intimate relations, ability to sleep and perform everyday tasks, work productivity and financial well being.

Chronic pain is not only emotionally and physically debilitating for patients, it also places a tremendous burden on families and caregivers, and contributes to excessive healthcare costs. The economic toll of chronic pain exceeds $100 billion each year in the United States alone. As the 75 million Baby Boomers move toward retirement, the epidemic of untreated or undertreated pain is expected to continue.

More than one-quarter of Americans (26%) age 20 years and over—or, an estimated 76.5 million people—report that they have had a problem with pain. This number does not account for acute pain.

Source: National Center for Health Statistics,2006.

PAIN BASICS

The International Association for the Study of Pain defines pain as: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

COMMON PAIN CONDITIONS

- Headaches or migraine
- Back pain and sciatica
- Neck and shoulder pain
- Joint pain due to arthritis, bursitis, fibromyalgia or degenerative joint disease
- Muscle pain from overuse or strain, injury or fibromyalgia
- Post-surgical pain

For definitions of these and other pain conditions, as well as common pain terms, please refer to the Pain A to Z listing at the back of this resource.

At its best, pain is the body's natural alarm system, alerting us to injury (or further injury if already injured). It prompts us to stop a harmful behavior or seek medical attention. For example, lifting too much weight might result in a piercing pain in a person's back. Within moments of touching a hot surface, the fiery sensation of a burn warns us to quickly pull away. Worsening abdominal pain may be a sign of appendicitis or other serious infection. Pain also triggers inflammation, which directs healing cells to the area of injury. The experience of pain also beckons the injured person to rest, promoting healing.

At its worst, unrelenting pain robs people of their livelihood and well being. When pain persists, it is often a sign that the body's alert system has broken down. In other words, pain signals remain active. Over time, this heightened response may:

- Harm the nerves, blood vessels and organs
- Suppress immune function
- Result in excessive inflammation
- Delay healing

Since the brain remembers pain, pain may be imprinted into the nerve tissue and continue to send pain sensations even in the absence of painful stimuli.

Chronic Pain-Brain Connection

New research is unraveling how chronic activation of the biological pathways transmitting pain is associated with structural and chemical changes in the brain. A recent study suggests that constant pain signals can result in mental rewiring that affects the frontal cortex, the area of the brain mainly associated with emotion and attention. According to researchers, this provides the first objective proof of brain disturbances in patients with chronic pain that is unrelated to the sensation of physical pain.

ACUTE VS. CHRONIC PAIN

There are two main types of pain: acute and chronic.

	ACUTE PAIN	CHRONIC PAIN
Onset	Usually sudden	Sudden or gradual development
Cause	Typically linked to an event, such as an injury or disease	Contributing factors are less certain
Duration	Temporary (up to 3 months)	Persistent (beyond usual healing time or longer than 3 months)
Pain Identification	Painful areas are generally well identified	Painful areas are less easily differentiated
Pattern	Self-limiting or readily corrected	Continuous or intermittent; intensity may vary or remain constant
Course	Pain usually lessens over time	Pain usually increases over time
Response	Stress response may be present (increased heart and/or breathing rate, increase in blood pressure)	Stress response often absent
Prognosis	Total relief typically possible	Total relief often impossible

Adapted from: McCance K, Huether SE, eds. Pathophysiology: the biologic basis for disease in adults and children. 5th ed. New York, NY: Elsevier, 2006:447-489.

Acute Pain occurs suddenly due to illness, inflammation, injury or surgery. It has a short duration that subsides when the injured tissue heals. The cause of the pain can usually be diagnosed and treated.

Chronic Pain is pain that lasts long enough (after normal healing or for at least three months), or is intense enough, to affect a person's normal activities and well-being. Failure to treat acute pain promptly and appropriately at the time of injury, during initial medical and surgical care or at the time of transition to community-based care, contributes to the development of chronic pain syndromes.

With chronic pain, pain signals may remain active in the nervous system for weeks, months or even years. Unlike acute pain, chronic pain has no value or benefit; it is a disease in its own right. It can also be especially challenging to treat.

PAIN ASSESSMENT

Timely access to quality pain management is the best way to minimize the suffering and disability often associated with undertreated pain and to avoid additional problems down the road. Science is revealing the role of unrelieved acute pain in the development of chronic, persistent pain.

Most hospitals, nursing homes and other healthcare facilities are now required to assess and treat pain. To correctly diagnose pain, healthcare professional will:

- Perform a thorough physical exam
- Complete a pain assessment
- Ask detailed questions about the patient's medical history and lifestyle
- Order blood work, X-rays, electrical tests to detect nerve damage, or other diagnostic and laboratory tests

Pain is a subjective experience, and it is critical for healthcare professionals to have a complete picture of the patient's pain history. He/she may ask about seven characteristics of pain to help LOCATE the pain and make the correct diagnosis.

L the exact Location of the pain and whether it travels to other body parts
O Other associated symptoms such as nausea, numbness, or weakness
C The Character of the pain, whether it's throbbing, sharp, dull or burning
A Aggravating or Alleviating factors. What makes the pain better or worse?
T the Timing of the pain, how long it lasts, is it constant or intermittent?
E the Environment where the pain occurs, for example, while working or at home

The type of pain someone is experiencing is often a clue to its cause; for example, chronic pain that is burning or tingling is often the result of nerve disease (neuropathy).

EFFECTS OF UNRELIEVED CHRONIC PAIN ON PHYSICAL AND MENTAL HEALTH

If untreated, pain can have serious physiological, psychological and social consequences. It can:

- Limit the ability to work, sleep, exercise or perform everyday tasks (for example, dressing, going to the grocery store)
- Reduce mobility
- Impair strength
- Diminish appetite
- Make it difficult to recover from an injury or fight infection by weakening the immune system
- Aggravate other health problems
- Lead to depression and/or anxiety, which often worsen pain sensations
- Make it difficult to concentrate or reason
- Place added strain on relationships and interfere with intimacy
- Result in a loss of self-esteem and independence

Pain scales are additional tools available to help patients describe the intensity of their pain. These assessment tools help healthcare professionals diagnose or measure a patient's level of pain. These include numeric, verbal or visual scales.

With **numerical scales**, patients use numbers from 0-10 (0 being no pain and 10 being the worst pain ever) to rate the intensity of the pain.

Verbal scales contain commonly used words such as "mild," "moderate" and "severe" to help patient's describe the severity of the pain.

Visual scales use aids like pictures of facial expressions, colors or gaming objects, such as poker chips, to help explain the severity of pain. One type, the Wong Baker Faces Pain Rating Scale, shows six different facial expressions from happy (no hurt) to agony (hurts the worst) to help show healthcare professionals how much pain a patient feels. Body diagrams may also be used to help pinpoint where the pain occurs.

From Hockenberry MJ, Wilson D, Winkelstein ML: *Wong's Essentials of Pediatric Nursing*, ed. 7, St. Louis, 2005, p. 1259. Used with permission. Copyright, Mosby.

Multidimensional pain assessment tools, such as the McGill Pain Questionnaire (MPQ) and the Brief Pain Inventory (BPI), have been developed to quantify different aspects of pain, including location and quality of pain and its effect on mood and function. However, these take longer to administer than the simpler scales and some patients who are cognitively impaired or poorly educated may find them difficult to complete. They are generally used in pain research, but can be adapted for clinical use if appropriate and valuable.

Our processing of pain is complex. A basic explanation is that the pain signals of acute pain are initiated when receptors on the skin, within an organ, tissue or nerve are triggered by injury or disease, known or unknown. A series of events follow: an electrical impulse, or pain message, is generated that is then carried on nerve fibers to the spinal cord. The spinal cord transmits the pain signal to various levels of the brain for interpretation and response. At any time during the transport of pain messaging, these noxious signals can be blocked, enhanced or modified. Signaling associated with chronic pain is much more complicated than acute pain as science is beginning to show.

TREATING PAIN

Successful pain management aims to:

1) lessen the pain
2) improve functioning and
3) enhance quality of life

Pain treatment needs to be individualized and, in most cases, requires a team of providers, as well as social support from family and friends. Most often, an integrative approach is needed to provide pain relief, which includes a combination of treatment options; this also encourages patients to actively participate in self-care. Treatment options may include:

- Medication (anti-inflammatory medicines, opioids or other classes of drugs)
- Psychosocial interventions (cognitive-behavioral counseling, guided imagery)
- Rehabilitative approaches (exercise, application of heat/cold, myofascial release, occupational therapy, if needed)
- Complementary alternative medicine (massage, acupuncture, hypnosis)
- Injection or infusion therapies
- Implantable devices and surgical procedures

Research shows that pain can affect patients' emotions and behavior and interfere with the ability to concentrate, manage everyday tasks and cope with stress. Likewise, stress and emotional pressures can make pain worse, provoking "flare ups" and contributing to alterations in the immune system response. These relationships are not always easily recognized or readily fixed by medical procedures or medications alone.

New treatments under investigation are aimed at the physical, psychological and environmental components of chronic pain. Research is also examining the role of genetic predisposition and the immune system in mitigating pain signals.

For a detailed description of the different treatment modalities for managing pain, please refer to the America Pain Foundation's *Treatment Options: A Guide for People Living with Pain*.

MEDICATIONS & PAIN MANAGEMENT

Medications play an important role in the treatment of pain. There are three major classes of medications for pain control:

Non-opioids: non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen

Opioids: morphine, oxycodone, methadone, codeine and fentanyl are examples

Adjuvant analgesics: a loose term referring to the many medications originally used to treat conditions other than pain, but now also used to help relieve specific pain problems; examples include some antidepressants and anticonvulsants. Some of these drugs have been shown to work well for specific types of pain.

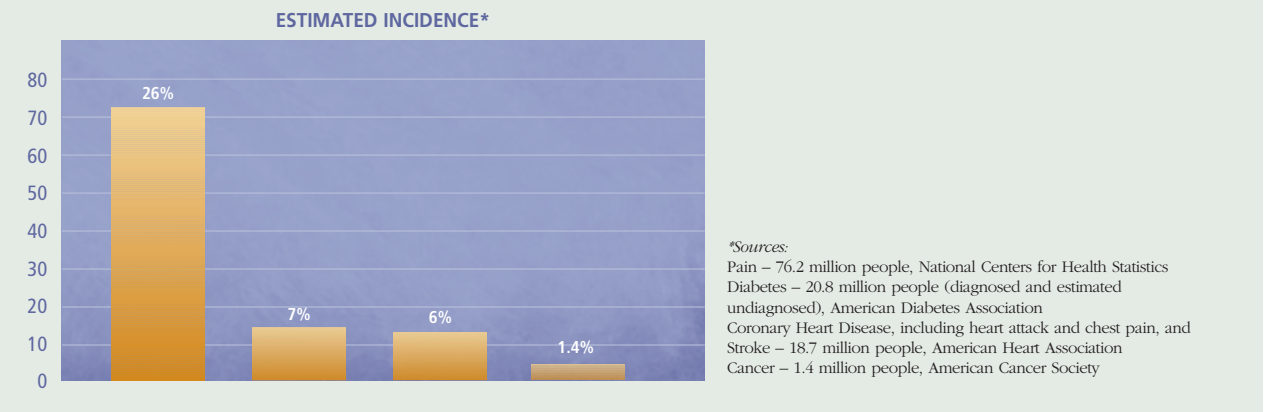
Drugs that have no direct pain-relieving properties may also be prescribed as part of a pain management plan. These include medications to treat insomnia, anxiety, depression and muscle spasms, and can help a great deal in the overall management of pain in some persons.

Pain Facts & Stats

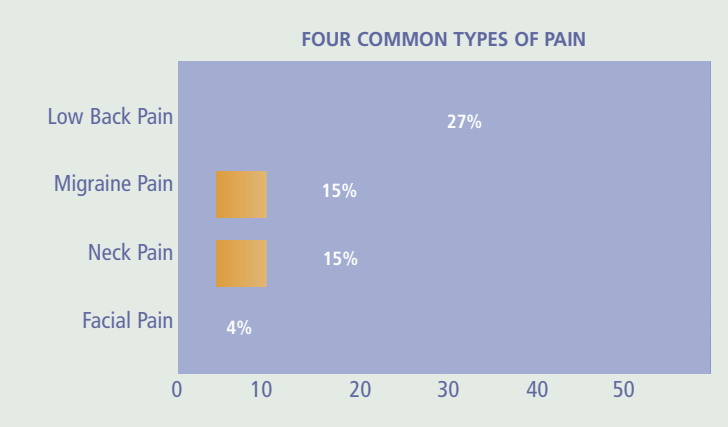
PREVALENCE OF PAIN

Pain is a serious and costly public health problem.

- A hallmark of many chronic conditions, pain affects more Americans than diabetes, heart disease and cancer combined.

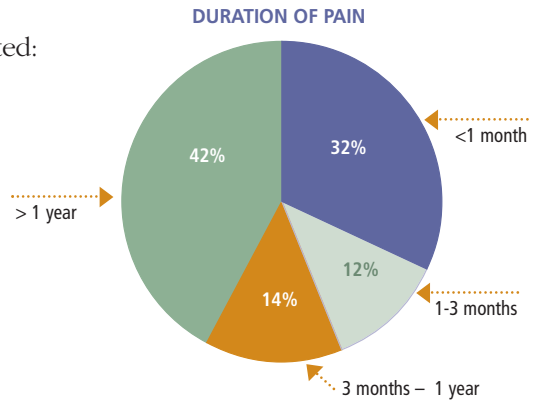


- More than one-quarter of Americans (26%) age 20 years and over—or, an estimated 76.5 million Americans—reported that they have had a problem with pain of any sort that persisted for more than 24 hours in duration. This number does not account for acute pain.[1]
- About one-third of people who report pain indicate that their pain is "disabling," defined as both severe and having a high impact on functions of daily life.[2]
- More women (27.1%) than men (24.4%) report that they are in pain.[1]
- Non-Hispanic white adults reported pain more often than adults of other races and ethnicities (27.8% vs. 22.1% Black only or 15.3% Mexican).[1]
- Adults living in families with income less than twice the poverty level reported pain more often than higher income adult.[1]
- When asked about four common types of pain, respondents of a National Institute of Health Statistics survey indicated that low back pain was the most common (27%), followed by severe headache or migraine pain (15%), neck pain (15%) and facial ache or pain (4%).[1]



DURATION OF PAIN

- Adults 20 years of age and over who report pain said that it lasted:
  - Less than one month – 32%
  - One to three months – 12%
  - Three months to one year – 14%
  - Longer than one year – 42%



ECONOMIC AND WORKPLACE BURDEN OF PAIN

- The annual cost of chronic pain in the United States, including healthcare expenses, lost income, and lost productivity, is estimated to be $100 billion.[3] However, more recent studies have indicated that costs associated with low back pain alone are an estimated $85.9 billion.[4] The total cost of arthritis—the nation's leading cause of disability—is estimated at $128 billion.[5]
- Undertreated pain drives up the cost of healthcare because it extends lengths of stay in hospitals, increases emergency room visits and results in unplanned clinic visits.
- Pain is the second leading cause of medically related work absenteeism, resulting in more than 50 million lost workdays each year.[6]
- Lost productive time due to headache, arthritis, back pain and other musculoskeletal conditions is estimated to cost $61.2 billion per year.[7]
  - Headache was the most common (5.4%) pain condition resulting in lost productive time. It was followed by back pain (3.2%), arthritis pain (2.0%), and other musculoskeletal pain (2.0%).
  - Most (76%) of the pain-related lost productive time was in the form of reduced performance occurring while the employees were at work, rather than absenteeism.
  - Workers who experienced lost productive time from a pain condition lost an average of 4.6 hours per week.

MUCH WORK REMAINS

- Currently, less than 2% of the NIH research budget is dedicated to pain.
- More than half of all hospitalized patients experienced pain in the last days of their lives and although therapies are present to alleviate most pain for those dying of cancer, research shows that 50-75% of patients die in moderate to severe pain.[8]

For more statistics and research findings, see our **Topic Briefs** on:

- Special Considerations: Pain in Specific Populations
- Disparities and Pain Management
- Integrative Medicine: Non-Drug Treatment Options for Pain Management
- Chronic Pain and Opioid Treatment

Be sure to visit the American Pain Foundation at www.painfoundation.org for posted updates and additional Topic Briefs.

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"The moral test of a society is how that society treats those who are in the dawn of life...the children; those who are in the twilight of life...the elderly; and those who are in the shadows of life...the sick, the needy and the handicapped."

—Hubert Humphrey

SPECIAL CONSIDERATIONS: PAIN IN SPECIFIC POPULATIONS

Although pain is a significant problem among all Americans, certain populations are more susceptible to and at greater risk for undertreatment, including children, minorities and those with advanced, life-limiting medical illness. Studies conducted in emergency departments suggest that women receive less attention in response to reports of severe pain than men. As well, active duty military and veterans tend to experience pain differently and present greater challenges to achieving optimal pain relief.

In order to provide the most effective pain care possible and minimize pain-related morbidity, characteristics of vulnerable populations must be taken into consideration when performing pain assessment and implementing treatment plans. Healthcare professionals must also become aware of their own biases and understand that, regardless of demographic or social position, every individual with pain requires evaluation and treatment tailored to his or her specific clinical circumstances.

Children and Pain

Every child will experience pain at one time or another, whether it's from everyday bumps and bruises, or more chronic conditions such as headaches, gastrointestinal problems or diabetes. In fact, research shows that as many as 40% of children and adolescents complain of pain that occurs at least once weekly, and chronic pain affects at least 15 to 20% of children.[1] And pediatric pain stems from a wide range of chronic conditions:

- Each year, 1.5 million children have surgery, and many receive inadequate pain relief. In 20% of cases, the pain becomes chronic.[2]
- Of children aged 5 to 17 years, 20% suffer headaches.[2]
- More than one-third of children complain of abdominal pain lasting two weeks or longer.[3]
- Juvenille arthritis, which causes joint inflammation and aches, affects nearly 250,000 people under the age of 16 years.[4]
- By 2010, 1 in 1,000 U.S. children will be a survivor of childhood cancer and may have to deal with late and long-term effects of treatment (e.g., chronic fatigue and pain syndromes, nerve damage).[2]
- Recent evidence reveals reduced pain sensitivity is a common feature of children with autism and Asperger's syndrome.[2]
- Musculoskeletal pain can result from "growing pains," a normal occurrence in about 25 to 40% of children.[5]

COMMON CAUSES OF PAIN IN CHILDREN

- Scrapes and bruises
- Needlestick pain from immunizations (most children receive up to 24 immunizations by their 2nd birthday)
- Sports injuries (e.g., sprains, concussion, fractures)
- Chronic illnesses (e.g., sickle cell disease, Type I diabetes)
- Headaches
- Abdominal pain (e.g., ulcerative colitis)

According to the American Medical Association, children and infants are at increased risk of inadequate pain management, with age-related factors playing a major role. Physical and psychological changes that occur during childhood development can make understanding and managing pain in children significantly more complicated than treating pain in adults.

Many things affect the way a child experiences, communicates and responds to pain, including:

- Their age
- Their beliefs and understanding of what is causing the pain
- Their ability to cope
- Their activity and anxiety levels
- Previous experiences with pain and how they learned to respond
- Support from parents and siblings
  - Preliminary data suggest that a mother's anxiety may be transmitted more strongly to her daughters than her sons, resulting in increased anxiety and pain in girls, but not boys.[6]

If pain is not addressed and treated early on, it can greatly impact a child's quality of life by interfering with mood, sleep, appetite, school attendance, academic performance, and participation in sports and other extracurricular activities. Further, if unrelieved, childhood pain can enhance a child's vulnerability to pain later in life.[7] It is essential that healthcare providers begin to approach pediatric pain so that appropriate strategies can be devised to target and reduce

children's distress and pain-related disability.

Unaddressed pain can also result in significant financial stress for families who not only have to cover healthcare expenses, but who may also have to miss work to care for a sick child.[8]

Inadequate prevention and relief of pediatric pain are still widespread. Many obstacles exist to providing appropriate pain care to children and adolescents:[10]

- Beliefs and attitudes about the experience of pediatric pain.
- General lack of understanding about the best course of action for treating children in pain.
- Belief that pain should be treated less aggressively in children than adults.
- Pediatric pain management research has not been effectively translated into routine clinical practice.
- Pain in children with disabilities or other special health care needs may be more difficult to assess.

MYTHS AND TRUTHS ABOUT PAIN IN CHILDREN

MYTH: Children who are playing or sleeping must not be in pain.

TRUTH: Children cope with pain by distracting themselves, often through play. Sleep may also be a coping mechanism, and/or because they are exhausted.

MYTH: Young infants do not feel pain because their nervous systems are immature and unable to perceive and experience pain the way adults do.

TRUTH: Decades ago it was believed that a newborn couldn't feel pain, and surgery was routinely performed on infants without anesthetic. Today, we know that the central nervous system of a 26-week-old fetus has the capability of experiencing pain. There is strong evidence that children experience increasing anxiety and perception of pain with multiple procedures or painful stimuli.[8]

MYTH: Children can easily become addicted to pain medications.

TRUTH: Less than 1% of children treated with opioids become addicted.[9]

MYTH: Children cannot effectively communicate their pain; it is difficult to know when they have pain.

TRUTH: Children don't communicate, respond to, or feel pain the same way adults do, so it's difficult for health professionals and parents to understand what they are experiencing. But, it is very real and not something they easily forget about. There are many tools available to assess pain in children. Adults need to recognize how children of different ages express pain in both behaviors and words.

MYTH: Children will tell adults when they are having pain.

TRUTH: Children may not have the words to express pain (e.g., hurt, "ouch") or know to point to where it hurts. They may also be afraid of the consequences (e.g., extra visits to the pediatrician, shots, medicine).

Potential barriers to the effective treatment of pain in children[10]

- The myth that children, especially infants, do not feel pain the way adults do;
- Lack of routine assessment for the presence of pain in children;
- The idea that treating pediatric pain takes too much time and effort;
- Fears of adverse effects of analgesic medications, including respiratory depression and addiction;
- Differing personal values and beliefs of healthcare professionals about the meaning and value of pain in the development of the child (e.g., the belief that pain builds character).

WEB RESOURCES

American Pain Society
www.ampainsoc.org

National Children's Pain Center
www.pediatricpain.org/ncpc.php

Pediatric Pain Sourcebook
http://painsourcebook.ca/

UCLA Pediatric Pain Program
www.mattel.ucla.edu/pedspain/home.php

American Academy of Pediatrics
http://www.aap.org

Gender and Pain

Although it has long been thought that women and men have similar pain experiences, recent research reveals significant differences in the way male and female brains process pain,[1] as well as in women's expression of pain and their responsiveness to analgesics and pain stimulus.[2,3]

Historically, women have been categorized as being emotional and overly sensitive; often influencing the way physicians assessed and managed their pain.[4] Even though research now shows that chronic pain conditions are generally more prevalent among women, they continue to be treated less aggressively for their pain than men.[5,6] And while women are more likely than men to seek treatment for their pain, they are less likely to receive it.[7]

Women report pain more often than men do and in more body regions, and they also tend to have more severe, recurrent and persistent pain, as well as a reduced pain threshold when compared with men.[3] However, despite their increased pain burden, women reportedly cope with pain better than men, possibly due to the fact that they experience pain more often throughout the course of their lives (e.g., menstruation, pregnancy and child birth, and other health issues specific to women).[3]

Female hormones are also likely to play a role in pain perception. Some pain conditions like migraine tend to vary with a woman's menstrual cycle, and many of the observed gender differences in pain appear to diminish following the reproductive years.[8]

Hormones May Influence Pain Experience

- Estrogen administration in women and in men can increase the incidence of chronic pain conditions.[9,10]
- Variations in women's estrogen levels, like those that occur during the menstrual cycle or during pregnancy, may regulate the brain's natural ability to suppress pain.[11]
- Some pain conditions such as migraine and fibromyalgia tend to fluctuate with a woman's menstrual cycle.
- Observed gender differences in pain appear to diminish following menopause.

Additionally, cultural conditioning may impact the expression of pain among women and men. As children, girls are more likely to be permitted to express pain and show emotion than boys, and attitudes about the social acceptability of gender and pain often carry into adulthood.[3]

Potential Sources of Gender Differences in Pain

Biological factors including:

- sex hormones
- genetics
- anatomical differences

Psychosocial influences including:

- emotion (e.g., anxiety, depression)
- coping strategies
- gender roles
- cultural conditioning
- health behaviors
- use of healthcare services

As advances in brain imaging technology provide further insights into gender variations in the experience of pain, it is becoming evident that different pain experiences among men and women will call for different approaches to pain management.

Ongoing research is essential to achieve:

- A better understanding of the biological and psychosocial factors that influence gender differences in pain
- A greater appreciation of the different health needs of men and women
- More effective and targeted pain treatments for women

PAIN DISORDERS WITH HIGHER PREVALENCE IN WOMEN

- Migraine
- Irritable bowel syndrome
- Fibromyalgia
- Chronic pelvic pain
- Interstitial cystitis
- Temporomandibular joint disorder (TMJ)
- Breast pain (mastalgia)
- Autoimmune disorders (e.g. Lupus and Chronic Fatigue Syndrome)
- Rheumatoid arthritis
- Osteoarthritis

WEB RESOURCES

International Association for the Study of Pain: Real Women, Real Pain
www.iasp-pain.org

National Institutes of Health: Gender & Pain
http://painconsortium.nih.gov/genderandpain/summary.htm

National Women's Health Resource Center
www.healthywomen.org/

Society for Neuroscience: Gender & Pain
www.sfn.org/index.cfm?pagename=brainBriefings_gender_and_pain

Older Adults and Pain

As we age, pain becomes a more common problem due to the high prevalence of chronic and progressive pain-producing conditions associated with aging. It is estimated that up to 50% of older persons living in the community have pain that interferes with normal function, and 59 to 80% of nursing home residents experience persistent pain.[1,2] Alarmingly, being older than 70 is the leading risk factor for inadequate pain management.[3]

Diagnosing and treating pain in older adults can be challenging. Those 65 and older often present with multiple medical and nutritional problems, take multiple medications and have many potential sources of pain. Older persons with dementia or communication problems are at even greater risk of undertreatment of pain due to difficulties communicating their pain.[4] Use of certain medications in older patients becomes problematic because of physiological changes.[5]

The most common cause of persistent pain in older adults is musculoskeletal in nature, typically from osteoarthritis or other bone, joint and spine disorders. According to the Arthritis Foundation, arthritis affects up to 80% of older adults, who report being fearful of recurring pain and disability. But the predilection for painful conditions does not mean that older adults need to live with uncontrolled pain. Quite the opposite; older patients can be effectively treated, and in so doing, pain-related morbidity—and even premature mortality—can and should be obviated.

COMMON PAIN CONDITIONS IN OLDER ADULTS

- Arthritis
- Lower back and neck pain; vertebral compression fractures from osteoporosis
- Abdominal pain (e.g., gallstones, bowel obstruction, peptic ulcer disease, abdominal aortic aneurysm)
- Cancer-related pain (symptom of disease or effect of nerve damage from treatments)
- Neuropathic pain due to diabetes, herpes zoster ("shingles"), kidney disease or other medical problems
- Muscle cramps, restless leg pain, itchy skin and sores due to circulatory problems or vitamin D deficiency
- Fibromyalgia
- Complex Regional Pain Syndrome (CRPS), which develops after an illness or injury and often affects the leg, arm, foot or hand
- Injuries, especially from falls

WEB RESOURCES

Handbook of Pain Relief in Older Adults — An Evidence-Based Approach
By Gloth III, F. Michael
http://www.humanapress.com/Product.pasp?txtCatalog=HumanaBooks&txtProductID=1-58829-217-7

American Medical Association
Assessing and Treating Pain in Older Adults
http://www.ama-cmeonline.com/pain_mgmt/module05/index.htm

American Geriatrics Society Foundation
The Management of Persistent Pain: Resources for Older Adults and Caregivers
http://www.healthinaging.org/public_education/pain

End-of-Life and Pain

Pain control is one of the most challenging aspects of end-of-life care.[1] Terminal illness is often accompanied by severe pain, and a significant number of patients suffer needlessly at the end-of-life. While the goal of end-of-life care should be making patients more comfortable, the health care system has been designed to take a curative approach to disease, rather than focusing on symptom relief.[2] Hospital research reveals that healthcare providers continue to inadequately treat pain, and tend to under-medicate terminal pain.

Patients at end-of-life may have their pain undertreated for variety of reasons, including a lack of knowledgeable and experienced physicians and myths about addiction to pain medication, leading unnecessarily to patient and family suffering.[3]

Despite advances in research on end-of-life pain treatment, physicians remain influenced by social and legal concerns, as well as misconceptions about medications including addiction, overdose, lasting side effects and diminished physical capacity.[5] Patients and their families may also hesitate to begin using pain medications as they often associate such treatment with imminent death, thereby allowing patient suffering to worsen and continue.[4]

However, thorough and ongoing pain assessment, paired with well-designed and aggressive medication plans, as well as counseling for patients and their families can have a significant impact on pain relief and side effects among dying patients.[4,5]

IN DYING PATIENTS, PAIN MAY BE EXACERBATED BY MANY OTHER SYMPTOMS INCLUDING:

- Dry mouth
- Nausea
- Water retention and swelling
- Lack of appetite
- Shortness of breath
- Mental distress and anxiety caused by fear or denial of impending death

Effective pain management at the end-of-life requires addressing the total pain experience, including physical causes, as well as interpersonal and spiritual pain.[3,4]

Pain associated with terminal illness often requires special treatment that can be best provided by hospice and palliative care programs available in many medical facilities. Hospice focuses on relieving symptoms and supporting patients who are nearing the end of their life, while palliative care is designed to provide comfort and pain relief at any time during a person's illness.[7] The goal of both programs is to alleviate suffering and ultimately assist patients in achieving a pain-free and dignified death.

"When someone is dying, time is a luxury and wait-and-see is not an option. What matters most in the final days is that patients are free of crippling pain and unbearable suffering so that they can finish their lives in ways that bring comfort, peace, and completion. Concerns about lasting side effects or diminished physical capacity from months of using a drug become secondary to making a patient comfortable. No one has to die in pain."

— Dr. Scott Fishman

"Suicidal wishes in patients with advanced disease are closely linked to unrelieved pain and to mood alterations such as depression and anxiety, which like pain, frequently respond to clinician treatment if the clinician identifies and addresses them."[2,6]

Essential Components of End-of-Life Care[8]

- Continual assessment and management of pain and other physical symptoms
- Assessment and management of psychological and spiritual needs
- Helping patients identify personal goals for pain treatment and end-of-life care
- Assessment of the patient's support system

WEB RESOURCES

American Academy of Family Physicians: Challenges in Pain Management at the End of Life
www.aafp.org/afp/20011001/1227.html

American Pain Society: Treatment of Pain at the End of Life
www.ampainsoc.org/advocacy/treatment.htm

Discovery Health Center: End of Life Q&A with Dr. Scott Fishman
http://health.discovery.com/centers/pain/endoflife/endoflife.html

National Hospice and Palliative Care Organization
www.nhpco.org/i4a/pages/index.cfm?pageid=3254

Military/Veterans and Pain[1]

Pain is a major issue among military personnel and veterans, who are at heightened risk for injury and combat wounds. Although today's body armor and rapid evacuation to medical care is saving lives, there are more maimed and shattered limbs than ever before, with instances of amputation double previous rates. Hundreds of thousands of returning veterans will seek medical care and claim disability compensation for a wide variety of injuries and health problems they endured during their tours of duty. It is estimated that the U.S. will be paying the cost of related medical care and disability claims for the next 40 years.

Veterans are more likely to experience psychological distress and other medical conditions, including post traumatic stress disorder, depression, amputations, traumatic brain injuries, substance abuse and other injuries, which further complicate effective pain management.

COMMON PAIN CONDITIONS AMONG MILITARY MEMBERS

Post traumatic stress disorder (PTSD) commonly affects soldiers returning from war, and is triggered by exposure to a situation or event that is or could be perceived as highly threatening to a person's life or those around him/her. PTSD may not emerge for years after the initial trauma. Chronic pain symptoms and PTSD frequently co-occur and may intensify an individual's experience of both conditions. Together, they result in fear, avoidance behaviors, anxiety and feelings of isolation.

Amputations have long been a tragic, unavoidable consequence of combat injury—"one of the most visible and enduring reminders of the cost of war," according to the Amputee Coalition of America. While there have been major advances in medicine, prosthetics and technologies that allow amputees to lead more independent lives, most of these patients continue to need specialized long-term or lifelong support. Managing wound, post-operative, phantom and stump pain is important to reduce suffering and improve quality of life.

A **traumatic brain injury** (TBI) is a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain and is a major cause of life long disability and death. Managing pain in veterans with TBIs may be complicated by memory lapses affecting medication management, difficulty organizing and following complicated and sometimes even simple pain management regimens, and difficulty learning new coping skills. Rehabilitation should incorporate efforts to relieve associated pain.

Veterans have significantly worse pain than the general public, and while military medical care is among the best in the world, there are still long-term problems and challenges with managing disability and chronic pain.

Military culture may also present a significant barrier to appropriate patient care. The persisting stigma around pain and pain treatment is particularly pronounced in the military, and pain is often perceived as a sign of weakness leading many individuals to choose to suffer in silence. Seeking mental health care for PTSD and depression, which so often accompany pain is important; pain is best managed when depression and PTSD are treated simultaneously.

A recent analysis found that the Veterans Health Administration (VHA) is already overwhelmed by the sheer number of returning veterans and the seriousness of their health care needs. Without increased staffing and funding for veterans medical care, it will not be able to provide quality care in a timely fashion.

Military/Veterans and Pain[1]

Barriers to optimal pain management among veterans and military personnel may include fears about:

- No longer being physically capable of fulfilling their duties
- Being discharged and no longer having a sense of purpose
- Letting down or losing the respect of their peers
- Becoming addicted to pain medications
- Experiencing personality changes or problems with sexual relations due to pain medications
- Losing their benefits/pension if they acknowledge a pain condition

THE UNITED STATES CONGRESS HAS STATED THE FOLLOWING:

(1) Acute and chronic pain are prevalent conditions among active duty and retired military personnel.

(2) Characteristics of modern warfare, including the use of improvised explosive devices, produce substantial numbers of battlefield casualties with significant damage to both the central and peripheral nervous systems.

(3) The successes of military health care both on and off the battlefield result in high survival rates of severely injured military personnel who will be afflicted with significant pain disorders on either an acute or chronic basis.

(4) Failure to treat acute pain promptly and appropriately at the time of injury, during initial medical and surgical care, and at the time of transition to community-based care, contributes to the development of long-term chronic pain syndromes, in some cases accompanied by long-term mental health and substance abuse disorders.

(5) Pain is a leading cause of short- and long-term disability among military personnel.

(6) The military health care systems have implemented important pain care programs at some facilities and in some areas, but comprehensive pain care is not consistently provided on a uniform basis throughout the systems to all patients in need of such care.

(7) Inconsistent and ineffective pain care leads to pain-related impairments, occupational disability, and medical and mental complications with long-term costs for the military health and disability systems, and for society at large.

(8) Research, diagnosis, treatment, and management of acute and chronic pain in the active duty and retired military populations constitute health care priorities of the United States.

From the Military Pain Care Act of 2008

The U.S. Veterans Health Administration is instructing physicians and nurses who treat veterans to regard pain as a "fifth vital sign," to be routinely assessed along with blood pressure, pulse, temperature and respiration.

WEB RESOURCES

American Pain Foundation: Military/Veterans and Pain
www.painfoundation.org/page.asp?file=Veterans/Intro.htm

Amputee Coalition of America
www.amputee-coalition.org

Defense and Veterans Brain Injury Center
www.dvbic.org

Disabled American Veterans (DAV)
www.dav.org

Military Pain Care Act of 2008
http://www.govtrack.us/congress/bill.xpd?bill=h110-5465

U.S. Department of Veterans Affairs
www.va.gov

HOT TOPICS

Children & Pain: HOT TOPICS

- Maternal anxiety influencing daughters' experience of pain
- Some neonatologists still do not treat pain in pre-term low birth weight babies because they "won't remember it"
- Investigations into "chronic daily headaches" in children
- Unraveling pediatric pain conditions and their impact into adulthood (e.g., whether Complex Regional Pain Syndrome in children leads to adult CRPS, whether irritable bowel syndrome in adolescents is this the same as IBS in adults)
- Complementary and alternative medicine: how and what is safe to use in children with chronic pain?
- Factors leading to pain-related disability in children (e.g., missing school, not sleeping, avoiding physical and social activities, not eating)

Gender & Pain: HOT TOPICS

- Prevalent pain conditions in women (e.g., fibromyalgia, chronic pelvic pain)
- Interface of hormones and the pain experience
- Brain imaging, uncovering routes of pain transmission and tolerance
- Differential effects of medicines across genders
- Impact of chronic pain on sexuality and self-image

HOT TOPICS

Older Adults and End-of-Life Care & Pain: HOT TOPICS

- False belief that pain is an inevitable part of aging
- Vitamin deficiencies and musculoskeletal pain
- Limited consumer awareness of the options that exist other than traditional "acute care" approaches (e.g., doctor's office visits, ER visits, hospitalizations)
- Insufficient numbers of adequately trained and skilled healthcare professionals to manage the myriad issues confronting patients/families with advanced medical illness; limited number of providers with specialty in geriatrics
- Variability in delivery of hospice and palliative care services across the country
- Lack of clinical research data on pain care among elders

Military/Veterans & Pain: HOT TOPICS

- President Bush recently signing the Military and Veterans Pain Care Acts into law
- Emerging Options: Interdisciplinary approaches to pain care
- Acupuncture now being incorporated into treatment plans at Walter Reed Army Medical Center
- Competitive athletics as a form of therapy
- New Veteran centers open for drop-in counseling

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PAIN MANAGEMENT & DISPARITIES

The undertreatment of pain in America is a growing public health crisis, especially among underserved populations, including ethnic minorities, women, the elderly and those who are socioeconomically disadvantaged. Despite an overall improvement in health for most Americans, certain segments of the population continue to experience poor health status.[1] There is compelling evidence that minorities are less likely to have access to routine, coordinated medical care or health insurance than whites. They are also more likely to receive inappropriate or insufficient care, resulting in poorer health outcomes.

As the U.S. population becomes increasingly diverse, there is an urgent need to eliminate health disparities. Patients have a right to appropriate assessment and treatment of their pain without regard to race, ethnicity or other factors.

"Of all the forms of inequality, injustice in health is the most shocking and the most inhumane."
–Martin Luther King, Jr.

Health Disparities Defined

According to the National Institutes of Health, health disparities are defined as "differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States."

Disparities in health care are complex and multifaceted resulting from:

- Patient/personal factors (e.g., low socioeconomic status, communication barriers)
- Healthcare provider factors (e.g., bias, cultural insensitivity)
- Systematic/health system factors (e.g., health insurance status, access to care)

Snapshot of U.S. Population, An Older and More Diverse Nation

According to projections by the U.S. Census Bureau:

- Minorities now comprise roughly one-third of the U.S. population.
- By 2023, more than half of all children will be from minority groups.
- Minorities are expected to become the majority in 2042.
- In 2050, the nation is projected to be 54% minority.
- The Latino population, already the nation's largest minority group, will triple in size between 2005 and 2050.
- The nation's elderly population will more than double in size from 2005 through 2050 as the baby boom generation enters traditional retirement years.

Source: U.S. Census Bureau, 2008, http://www.census.gov/PressRelease/www/releases/archives/population/012496.html; Pew Hispanic Center.

Disparities in Pain Care

Pain is widely recognized as an undertreated health problem in the general population.[2] However, a growing body of research reveals even more extensive gaps in pain assessment and treatment among racial and ethnic populations, with minorities receiving less care for pain than non-Hispanic whites.[3,4,5,6,]

Differences in pain care occur across all types of pain (e.g., acute, chronic, cancer-related) and medical settings (e.g., emergency departments and primary care).[3,4,5,6,7] Even when income, insurance status and access to health care are accounted for, minorities are still less likely than whites to receive necessary pain treatments.[3,4,8]

Minorities are less likely to:

- Have access to pain management services and treatments
- Have their pain documented by healthcare providers
- Receive pain medications

And more likely to:

- Use the emergency department for pain care, but less likely to receive adequate care
- Experience greater severity of pain
- Experience and report physical disability
- Experience poorer health and quality of life related to pain

There are clear variations in the way pain is assessed and managed among all minority populations. Significant gaps exist in the provision of effective quality pain care due to the lack of research and medical training focused on pain care disparities.[3,4,9]

Research also shows gender differences in the experience and treatment of pain. Most chronic pain conditions are more prevalent among women; however, women's pain complaints tend to be poorly assessed and undertreated.[3]

Additionally, gender differences have been identified in patient responsiveness to analgesics and pain stimuli. While estrogen and progesterone play a role in how pain signals are received in men and women, psychology and culture may also account for some of the difference. For example, children may learn how to respond to pain later in life depending on how their pain complaints were treated in their formative years (e.g., receiving comfort and validation versus being encouraged to tough it out or dismiss the pain).[14] For more information, see the *Special Considerations: Pain in Specific Populations* Topic Brief.

In response to the overwhelming discrepancies in pain treatment among minority groups, the Joint Commission issued a statement recognizing the rights of all patients to receive appropriate assessment and management of pain, and the World Health Organization has declared that pain relief is a human right.

RESEARCH ON DISPARITIES IN PAIN CARE HAVE SHOWN:

- Blacks were less likely than whites to receive pain medication and had a 66% greater risk of receiving no pain medication at all.[5,6,7,9]
- Hispanics were twice as likely as non-Hispanic whites to receive no pain medication in the emergency department (55% of Hispanics received no pain medication vs. 26% of non-Hispanic whites).[7,10]
- Minority patients were less likely to have pain recorded relative to whites, which is critical to providing quality patient care.[11]
- Only 25% of pharmacies in predominantly nonwhite neighborhoods had opioid supplies that were sufficient to treat patients in severe pain, as compared with 72% of pharmacies in white neighborhoods.[12]
- In a study of minority outpatients with recurrent or metastatic cancer, 65% did not receive guideline-recommended analgesic prescriptions compared with 50% of nonminority patients ($P < 0.001$). Hispanic patients in particular reported less pain relief and had less adequate analgesia.[13]

Patient and provider factors drive pain disparities

Multiple factors contribute to racial and ethnic disparities in pain care, including beliefs about pain, preconceived bias and cultural insensitivity and poor patient-provider communication.

Positive physician-patient interaction and communication is critical in accurate pain assessment.[2] Some research has shown that patients take a more active role in their own pain treatment when their healthcare providers are of similar ethnic backgrounds.[3,4]

"Pain is a complex, subjective response with several quantifiable features, including intensity, time course, quality, impact, and personal meaning. The reporting of pain is a social transaction between caregiver and patient."[15]

Patient sources of racial and ethnic disparities:[3]

- Low socioeconomic status
- Patients' attitudes or beliefs regarding pain and patient-level decision making and preferences
  - Stoicism and the belief that pain is an inevitable part of disease
- Minority patients more likely to:
  - Refuse recommended pain therapies
  - Poorly adhere to treatment regimens
  - Delay seeking medical care
- Mistrust of physicians or previous negative experiences with health care system
- Limited health literacy
- Language barriers that hinder communication with providers

Physician sources of racial and ethnic disparities:[3]

- Perceptions of race and ethnicity
- Racism or bias
- Poor cross cultural communication skills/cultural insensitivity
- Underrepresentation of physicians from racially/ethnically diverse backgrounds/lack of cultural sensitivity

HOT TOPICS

Disparities & Pain: HOT TOPICS

- Aging and increasingly diverse U.S. population could lead to greater disease burden if pain remains untreated
- Undertreatment of minorities in emergency departments
- Minority pain complaints receive less attention than others
- Impact of pain on productivity and quality of life among minority patients
- Pain relief as a human right

Minorities lack access to effective pain care

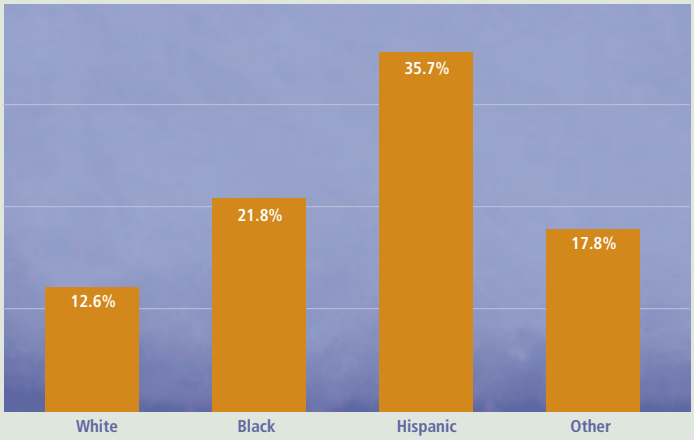
Limited access to pain care services is a key contributor to poorer pain treatment among minorities.

- Overall, minorities tend to be financially poorer than non-Hispanic whites.
- Socioeconomic factors can impede access to health insurance and primary health care services, and minorities are less likely to have access to pain treatment services than the general population.[3,4,7,16,17]
- Racial and ethnic minorities are at increased risk of having their pain complaints ignored by healthcare providers, thereby limiting their options for accessing appropriate pain treatment.[3,4,6,7]

According to the Robert Wood Johnson Foundation, 46 million Americans, including 9 million children, are living without health care coverage. More than eight out of 10 are from working families. The consequences of being uninsured are widely recognized and include: lack of access to health care, poor quality care, lost economic productivity, as well as financial burdens on individuals and society overall. As the minority population in the U.S. continues to grow, it becomes increasingly important to address the numbers of uninsured and underinsured among racial and ethnic groups.

Barriers also exist in patient access to pain medications. Research shows that physicians may be less likely to prescribe pain medications for minority populations [6,7,16,18] and pharmacies in neighborhoods with large minority populations often do not carry opioid medications.[3,4,12]

PERCENTAGE UNINSURED AMONG THE NONELDERLY POPULATION BY RACE AND ETHNIC ORIGIN, 2006



Sources: Employee Benefit Research Institute estimates from the March Current Population Survey, 2007 Supplement. Cover the Uninsured, www.covertheuninsured.org.

"Inequities in access can contribute to and exacerbate existing disparities in health and quality of life, creating barriers to a strong and productive life."

—The Commonwealth Fund

More extensive research needed to close disparities gap

While national attention has become increasingly focused on health disparities, less attention has been given specifically to inequities in pain care.[19,20] However, the growing interest in health disparities in general provides pain treatment providers, researchers and advocates with an opportunity to raise awareness about disparities in pain management and the need for additional pain disparities research. Currently, the social impact of pain on patients, their families and communities is largely absent in most federal research plans.[3,4]

Additional studies and a comprehensive pain research agenda are needed to:

- Understand the role of stereotypes and bias in doctor-patient interactions
- Improve training for healthcare providers
- Plan educational interventions for patients
- Understand the differences in patient behaviors that may contribute to pain care disparities
- Develop culturally sensitive pain assessment tools
- Raise consciousness about disparities in pain management and barriers to effective healthcare overall

WEB RESOURCES

CDC Office of Minority Health and Health Disparities
http://www.cdc.gov/omhd/

Cover the Uninsured: a Project of the Robert Wood Johnson Foundation
http://covertheuninsured.org/

American Pain Society: Racial and Ethnic Identifiers in Pain Management: The Importance to Research, Clinical Practice, and Public Health Policy
http://www.ampainsoc.org/advocacy/ethnoracial.htm

Agency for Healthcare Research and Quality: Addressing Racial and Ethnic Disparities in Health Care
http://www.ahrq.gov/research/disparit.htm
http://www.ahrq.gov/qual/nhdr03/nhdrsum03.htm

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CHRONIC PAIN AND OPIOID TREATMENT

Effective management of chronic pain often requires a step-wise trial of different treatment options, a team of healthcare providers and social support from family and friends. Healthcare providers may start with behavioral and non-pharmacological interventions (e.g., hot/cold therapy, physical therapy, relaxation techniques) when devising pain treatment plans. However, pain relievers, including prescription pain medicines (opioid analgesics), are often prescribed to help alleviate pain and improve function.

Key Issues

- More than 76.5 million Americans suffer with pain.[1] The consequences of unmanaged chronic pain are devastating for patients. It is not uncommon for patients with intractable, debilitating pain—many of whom are often made to feel that the pain is "just in their heads"—to want to give up rather than living one more day in excruciating pain.
- For many patients, opioids are an integral part of a comprehensive pain management plan to help relieve pain, restore functioning and improve quality of life.[2,3]
- Unfortunately, patient access to these medications may be hindered by unbalanced state policies, persisting social stigma surrounding their use, as well as therapeutic switching and/or step therapies imposed by insurance companies.
- Unless a patient has a past or current personal or family history of substance abuse, the likelihood of addiction is low when opioids are taken as prescribed and under the guidance of a physician; however, they have the potential for misuse, abuse and diversion.
- Rising rates of prescription drug abuse and emergency room admissions related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide.[4] The main source of drug diversion is unlikely the prescriber as was once assumed, but rather from theft by family, friends and workers in the home or from the sharing and selling of medications though often with good intentions.[5]
- Diverse players (e.g., lawmakers, educators, healthcare providers, the pharmaceutical industry, caregivers) must come together to address the dual public health crises of the undertreatment of pain and rising prescription drug abuse.[6]
- Alleviating pain remains a medical imperative—one that must be balanced with measures to address rising non-medical use of prescription drugs and to protect the public health.[6]

Opioids 101

Opioids include morphine, oxycodone, oxymorphone, hydrocodone, hydromorphone, methadone, codeine and fentanyl. Opioids are classified in several ways, most commonly based on their origin and duration of effects.[7]

Common classifications for opioids[7,8]

SOURCE	**Natural or semisynthetic:** Contained in or slightly modified (semisynthetic) from chemicals found in poppy resin	Synthetic: Synthesized in the laboratory
DURATION OF RESPONSE	**Short-acting:** Provide quick-acting pain relief and are used primarily as "rescue medication," as in acute pain	Long-acting: Provide longer duration of pain relief and are most often used for stable, chronic pain

One of the advantages of opioids is that they can be given in so many different ways. For example, they can be administered by mouth, rectal suppository, intravenous injection (IV), subcutaneously (under the skin), transdermally (in the form of a patch) or into a region around the spinal cord. Patches, IV injections and infusions are very important for patients who cannot swallow, or whose GI tracts are not working normally.[9]

Opioids are believed to work by binding to specific proteins (opioid receptors), which are found in specialized pain-controlling regions of the brain and spinal cord. When these compounds attach to certain opioid receptors, the electrical and chemical signals in these regions are altered, ultimately reducing pain.[7]

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for patients with chronic pain[10]

However, some types of pain, such as pain caused by nerve compression or destruction, do not appear to be relieved by opioids.[8]

Adverse Effects

Side effects of opioids result primarily from activation of opioid receptors outside and within the nervous system. Activation of opioid receptors in the gut, for example, may cause constipation, nausea and vomiting, and other gastrointestinal effects. Tolerance to nausea and vomiting usually develops within the first few days or weeks of therapy, but some patients are intolerant to opioids and experience severe adverse side effects.[8] Other side effects include drowsiness, mental clouding and, in some people, euphoria.[7] Recent research shows that genetic variations may influence opioid metabolism.

Depending on the amount taken, opioids can depress breathing. The risk of sedation and respiratory depression is heightened when opioids are taken with other sedating medications (e.g., antihistamines, benzodiazepines), reinforcing the need to carefully monitor patients. However, this effect is usually is not present after a patient has taken opioids regularly.

Careful Monitoring of and Open Communication with Patients

Patients taking opioids must be carefully selected and monitored, and should speak openly with their healthcare provider about noticeable improvements in functioning, as well as side effects and other concerns (e.g., constipation, fears of addiction).

The Four "A's"

Analgesia – Is the pain relief clinically significant? Is there a reduction in the pain score (0-10)?

Activity levels – What is the patient's level of physical and psychosocial functioning? Has treatment made an improvement?

Adverse effects – Is the patient experiencing side effects from pain relievers? If so, are they tolerable?

Aberrant behaviors – Are there any behaviors of concern such as early refills or lost medication? Does the patient show signs of misuse, abuse or addiction? What is the plan of action?

Source: Passik & Weinreb, 1998; Passik & Portenoy, 1998

The American Pain Foundation's *Target Chronic Pain* materials help facilitate open dialogue between patients and their healthcare team, and give prescribers tools for selecting, monitoring and following patients. To access these resources, visit www.painfoundation.org and click on the Publications tab.

Dual Public Health Crises: Balancing Medical Imperative to Relieve Suffering and Protect Public Safety

Pain affects more Americans than diabetes, heart disease and cancer combined, and it is one of the leading causes of disability in the United States. Recognition of pain as a growing public health crisis has led to the establishment of specialized pain clinics, treatment guidelines for certain types of pain, as well as greater use of treatment strategies to effectively alleviate pain and improve functioning, including prescription pain medicines.

As the therapeutic use of opioids has increased to appropriately address pain, there has been a simultaneous and dramatic rise in non-medical use of prescription drugs.[11] When abused—that is, taken by someone other than the patient for whom the medication was prescribed, or taken in a manner or dosage other than what was prescribed—prescription medications can produce serious adverse health effects and can lead to addiction, overdose and even death.

People who abuse opioids typically do so for the euphoric effects (e.g., the "high"); however, most abusers are ***not*** patients who take opioids to manage pain.[12] Rather, they are often people within the social network of the patient. In fact, 71% of people abusing prescription pain relievers received them from a friend or family member without a prescription.[5] Prescription pain relievers are usually stolen from medicine cabinets, purchased or shared in schools, or simply given away.

Picture of Prescription Drug Abuse in America

- An estimated 2.2 million Americans abused pain medications for the first time in 2006.[12] The rate of new abuse of opioids has risen most dramatically among teenagers.
- Between 1992 and 2002, reported abuse by teenagers increased by 542%.[13]
- From 1999 to 2004, unintentional poisoning deaths associated with opioids and hallucinogens rose by 55%, and the increase has been attributable primarily to prescription pain relievers.[14]
- According to 2005 and 2006 National Surveys on Drug Use and Health, an annual national average of 6.2% of persons aged 12 or older had used a prescription psychotherapeutic drug non-medically in the 12 months leading up to the survey; an average of 9.1% of youths aged 12 to 17 were past year non-medical users of any prescription psychotherapeutic drug.[12]
- Nearly 600,000 emergency department visits involved non-medical use of prescription or over-the-counter (OTC) pharmaceuticals or dietary supplements. Opiates/opioid analgesics accounted for 33% of the non-medical visits. Anti-anxiety agents (sedatives and hypnotics) accounted for 34% of the non-medical visits.[4]

The growing prevalence of prescription drug abuse not only threatens the lives of abusers; concerns about misuse, abuse and diversion may also jeopardize effective pain management by impeding patient access to opioids. Fear of scrutiny by regulators or law enforcement, and specific action by some agencies, has had a "chilling effect" on the willingness of some doctors, nurse practitioners and physician assistants to prescribe opioids.[6,15]

Moreover, high profile reports of drug abuse, diversion and addiction, or of legal actions taken against prescribers have helped perpetuate a negative—and sometimes false—picture of chronic pain management.[6] Over time, these reports overshadow untold stories of people with pain—those whose lives have been shattered by unrelenting pain—who get needed pain relief from these medications. Understanding the difference between tolerance, physical dependence, abuse and addiction is also critical to telling the story (See page 31-32 for definitions). According to medical experts, use of the term "narcotic" in news reports may further reinforce the myths and misconceptions of this class of drugs, given the negative connotation.[6]

"…[T]he attitude toward opioids has ranged from complete avoidance to widespread therapeutic use with minimal caution. These extremes have been driven by insufficient appreciation of risks by those at one end of the spectrum, and excessive fear of punitive regulatory scrutiny or exaggerated perceptions of addictive risk by those at the other. When opioids are prescribed for pain control in adequately evaluated, selected, and monitored patients, addiction is rare."

— Perry Fine, Topics in Pain Management

Strategies to Address Twin Public Health Crises

Systematic and targeted approaches are essential to address the growing prevalence and complexity of prescription drug abuse, while simultaneously ensuring that people with legitimate medical needs receive effective treatment.

These approaches can generally be categorized as follows:

- Legislative strategies to create balanced and consistent regulation and improve state-based prescription drug monitoring programs.
- Educational efforts to raise awareness about prescription drug abuse and its dangers among schools, families, healthcare providers, patients and potential abusers.
- Medical strategies to help identify and monitor patients who require opioid management, to include the incorporation of risk management into the treatment plan (e.g., treatment agreements, urine testing and monitoring, transition planning, collaborative practice with addiction medicine and behavioral health specialists).
- Pharmaceutical industry strategies to help prevent misuse, abuse and diversion by developing new tamper resistant packaging and/or formulations (e.g., tamper-resistant bottles, electromagnetic chips to track medication, new formulations that could resist or deter common methods of opioid abuse).

For additional recommendations, see the American Pain Foundation's report outlining critical barriers to appropriate opioid prescribing for pain management, *Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management.* This 16-page report calls for a more balanced perspective of the risks and benefits of these medications in practice and policy and summarizes key challenges and actionable solutions discussed by leading pain experts at a roundtable meeting hosted by APF.

Making the Grade: Evaluation of State Policies

The Pain & Policy Studies Group (PPSG) report "Achieving Balance in State Pain Policy: A Progress Report" graded states on quality of its policies affecting pain treatment and centered on the balance between preventing abuse, trafficking and diversion of controlled substances and simultaneously ensuring the availability of these medications for legitimate medical purposes. PPSG researchers evaluated whether state pain policies and regulations enhance or impede pain management and assigned each state a grade from 'A' to 'F.'

State Grades for 2008

State	2008 Grade	State	2008 Grade
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+
Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

Source: The Pain & Policy Studies Group, http://www.painpolicy.wisc.edu/Achieving_Balance/PRC2008.pdf.

At a Glance: Differentiating physical dependence, tolerance, abuse and addiction

Unfortunately, confusion between normal physiological responses to opioids (physical dependence and tolerance) and pathological phenomena such as addiction or abuse persist. Such misunderstandings not only reinforce the stigma surrounding legitimate medical use of these medicines, they also fuel fears of addiction and, in turn, may impinge on patient access to these medications. Although the use of opioids carries some risk of addiction, clinical studies have shown that the potential for addiction is low for the vast majority of patients using opioids for the long-term management of chronic pain.[17] As with any medication, there are risks, but these risks can be managed.

"Universal agreement on definitions of addiction, physical dependence and tolerance is critical to the optimization of pain treatment and the management of addictive disorders."

— Consensus document from the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine

Physical dependence is characterized by biological changes that lead to withdrawal symptoms (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) when a medication is discontinued, and is not related to addiction. Physical dependence differs from psychological dependence, or the cravings for the euphoria caused by opioid abuse. Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation.[7]

Tolerance is a biological process in which a patient requires increasing amounts of a medication to achieve the same amount of pain relief. Dose escalations of opioid therapies are sometimes necessary and reflect a biological adaptation to the medication. Although the exact mechanisms are unclear, current research indicates that tolerance to opioid therapy develops from changes in opioid receptors on the surface of cells.[7] Thus, the need for higher doses of medication is not necessarily indicative of addiction.[3]

Addiction is a disease characterized by preoccupation with and compulsive use of a substance, despite physical or psychological harm to the person or others.[3] Behaviors suggestive of addiction may include: taking multiple doses together, frequent reports of lost or stolen prescriptions, and/or altering oral formulations of opioids.

Abuse is the intentional self-administration of a medication for a non-medical purpose, such as to obtain a high.[3] Both the intended patient and others have the potential to abuse prescription drugs; in fact, the majority of people who abuse opioids do not suffer from chronic pain.[12]

Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately "drug seeking," which may be misidentified as addiction by the patient's physician. Pseudo-addiction can be distinguished from true adduction in that this behavior ceases when pain is effectively treated.[3]

MISUSE VS. ABUSE?

- **Medical Misuse**: Legitimate use of a valid personal prescription but using differently from provider's instruction, such as taking more frequently or higher than the recommended doses. Use may be unintentional and considered an educational issue.
- **Medical Abuse**: Valid personal prescription by using for reasons other than its intent, such as to alleviate emotional stress, sleep restoration/prevention, performance improvement, etc. Use may be unintentional and considered an educational issue.
- **Prescription Drug Misuse**: Intentional use of someone else's prescription medication for the purpose of alleviating symptoms that may be related to a health problem. The use may be appropriate to treat the problem but access to obtain this drug may be difficult/untimely or may have been provided from a well-intentioned family member or friend.
- **Prescription Drug Abuse**: Intentional use of a scheduled prescription medication to experiment, to get high or to create an altered state. Access to the source may be diversion from family, friends or obtained on the street. Inappropriate or alteration of drug delivery system, used in combination of other drugs or used to prevent withdrawal from other substances that are being abused are included in this definition.

Source: Carol J. Boyd PhD, MSN, RN; Director: Institute for Research on Women and Gender, Substance Abuse Research Center, University of Michigan

Risk factors for opioid misuse include, but are not limited to:[2,3,19]

- Personal or family history of prescription drug or alcohol abuse
- Cigarette smoking
- History of motor vehicle accidents
- Substance use disorder
- Major psychiatric disorder (e.g., bipolar disorder, major depression, personality disorder)
- Poor family support
- History of preadolescent sexual abuse

NOTE: Unless a patient has a past or current history of substance abuse, the potential for addiction is low when opioid medications are prescribed by a doctor and taken as directed. Those patients who suffer with chronic pain and addictive disease deserve the same quality of pain treatment as others, but may require greater resources in their care.

WEB RESOURCES

Opioid RX
http://pain-topics.org/opioid_rx/#RiskManage

Tufts Health Care Institute Program on Opioid Risk Management
http://www.thci.org/opioid/

Opioid Risk Management PainEDU
http://www.painedu.org/soap.asp

Emerging Solutions
http://www.emergingsolutionsinpain.com/index.php?option=com_frontpage&Itemid=1

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"The purpose of life…is to be useful, to be honorable, to be compassionate, to make some difference…"

—Ralph Waldo Emerson

INTEGRATIVE MEDICINE: NON-DRUG TREATMENT OPTIONS FOR PAIN MANAGEMENT

Pain management continues to challenge healthcare providers and places added strain on an already fragmented health care system. The U.S. health system was built around acute illness; however, because of advances in modern medicine and increased longevity, many Americans are living longer and with one or more chronic conditions (for example, cancer, diabetes, heart disease and arthritis), which require careful coordination of care and symptom management.

While pain is a symptom of many chronic diseases and is expected after many surgical procedures, persistent pain should not be viewed simply as a symptom. According to experts, the pain itself becomes a disease when the origin of the pain signals fails to shut off due to damage of the pain alarm system, leaving the person with persisting pain.

Whatever the cause, chronic pain transcends the physical hurting. Persistent pain interferes with daily life and relationships, and takes a tremendous toll on a person's mind, body and spirit. It's no surprise that pain and associated problems (e.g., medication side effects, depression and anxiety, limited mobility) are best managed using a combination of treatments tailored to each patient. This is referred to as a "multi-modal" or integrative approach.

Multi-modal Therapeutic Strategies for Managing Pain and Related Disability

Integrative medicine combines conventional medicine with complementary healing techniques, such as massage, yoga and acupuncture, to address the specific needs. Because an interdisciplinary approach to pain management is patient-centered, patients learn how to manage and cope with pain by playing an active role in their treatment plan.

Integrative medicine combines treatments from conventional medicine and complementary and alternative therapies for which there is some high-quality evidence of safety and effectiveness.[1] Being able to deliver integrated medicine, which incorporates proven CAM therapies into "mainstream" care, is increasingly important to consumers and healthcare providers.[4]

Benefits of Combined Treatment Modalities

While medications remain an integral part of pain management plans, non-drug therapies may be used to supplement and enhance the effectiveness of current pain medications. These strategies also offer additional options for those patients at greater risk for, or who are intolerant of, medication side effects.

Moreover, a growing body of research reinforces the benefits of interventions that address the psychosocial aspects of pain, especially given recent evidence of a biological link between the regions of the brain involved with depression and pain regulation. People with pain often suffer from depression, which can affect a patient's thinking, concentration and behavior, and increase pain sensitivity and severity.

Effective pain management may also require lifestyle changes that are supportive of patient mobility and independence.[2] For example, to improve daily functioning, specific therapies may be suggested to increase muscle strength and flexibility, enhance sleep and reduce fatigue, and assist patients in performing usual activities and work-related tasks.

As with the management of other chronic illnesses, patients with chronic pain need to play an active role in their care and incorporate non-drug options and other lifestyle changes (e.g., exercise, proper nutrition) over the long-term.

Patients Seek Complementary Treatments

In their quest for better pain relief, patients are increasingly turning to non-drug approaches to help ease their discomfort and give them a sense of empowerment and control. There are a wide variety of non-drug therapies available to treat pain and related disability including:

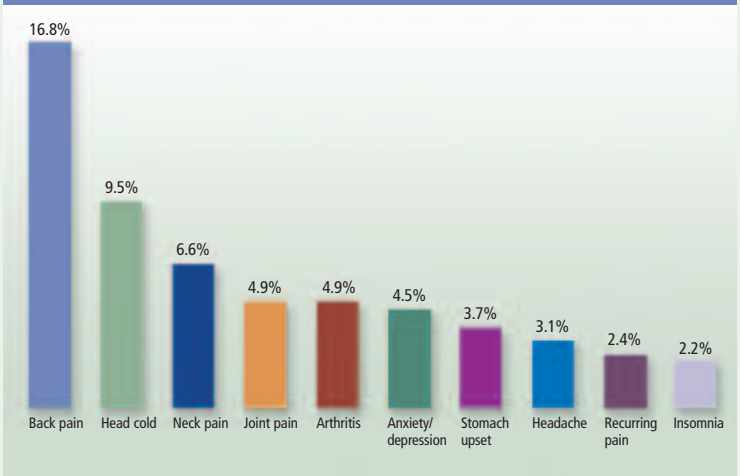
- *Psychosocial interventions* – cognitive behavioral therapy, stress management
- *Rehabilitation techniques* – exercise, heat or cold therapy, physical therapy
- *Complementary and alternative medicine* – meditation, acupuncture, hypnotherapy, yoga, aromatherapy, massage, touch therapy

Not surprisingly, pain conditions are among those most likely to prompt patients to turn to complementary and alternative medicine (CAM) therapies. These practices also give patients a greater sense of control, so they no longer feel that they are solely dependent on a single pill or procedure.

COMMON NON-DRUG OPTIONS FOR PAIN RELIEF

- Stress management techniques (e.g., meditation, deep breathing and relaxation exercises)
- Massage
- Application of heat or cold, including heating pads or ice packs
- Acupuncture
- Visualization
- Physical therapy, including stretching or exercise
- Hypnotherapy
- Psychological and spiritual counseling
- Biofeedback
- Transcutaneous electrical nerve stimulation, also known as TENS

Diseases/Conditions for Which CAM is Used Most Often



Source: NCCAM, *The Uses of CAM in the United States.*

What is CAM?

CAM includes a diverse group of healing systems, practices and products that are not part of conventional medicine. Examples of CAM therapies include acupuncture, massage, meditation, hypnosis, yoga and herbal therapies. These approaches are increasingly used to help manage pain and related issues (e.g., depression, anxiety, fatigue) and enhance patients' quality of life. NCCAM, one of 27 institutes and centers designated by the National Institutes of Health, is the lead agency for scientific research on CAM and groups these therapies into four areas.

CAM DOMAINS DEFINED	
Mind-body medicine	Uses a variety of techniques designed to enhance the mind's ability to affect the body's function and symptoms. Examples include meditation, hypnosis, guided imagery, prayer, as well as art or music therapy.
Biologically based practices	Use substances found in nature, such as herbs, special diets or vitamins. Some examples include dietary supplements or herbal products (e.g., garlic, ginger, Kava Kava).
Energy medicine	Involves the use of energy fields, such as magnetic fields or biofields (energy that some believe surround and run through the body). Examples include qi gong, Reiki and therapeutic touch.

Many CAM practices are gentle methods that tend to have fewer side effects, which is part of their appeal to patients. Patients also use these therapies to help alleviate the associated stress, depression and insomnia that can accompany and worsen pain sensations.

Some CAM practices, such as acupuncture, massage and chiropractic care require the practitioner to be licensed. It's important for patients to research and find a CAM practitioner who is certified, willing and equipped to coordinate with other members of the patient's health team, and has experience working with patients with chronic pain.

When tailored to the individual patient, non-drug approaches to pain management can help:

- Allow patients to take an active role in managing their pain, thereby, improving patient satisfaction
- Address the physical, emotional and spiritual needs of patients
- Reduce pain and manage related symptoms (e.g., pain and anxiety, depression, insomnia, fatigue)
- Enhance the effectiveness and minimize adverse effects of medications
- Reduce health care costs by reducing doctor visits and reliance on medications
- Improve functioning and the ability to perform activities of daily living
- Enhance wellness and quality of life

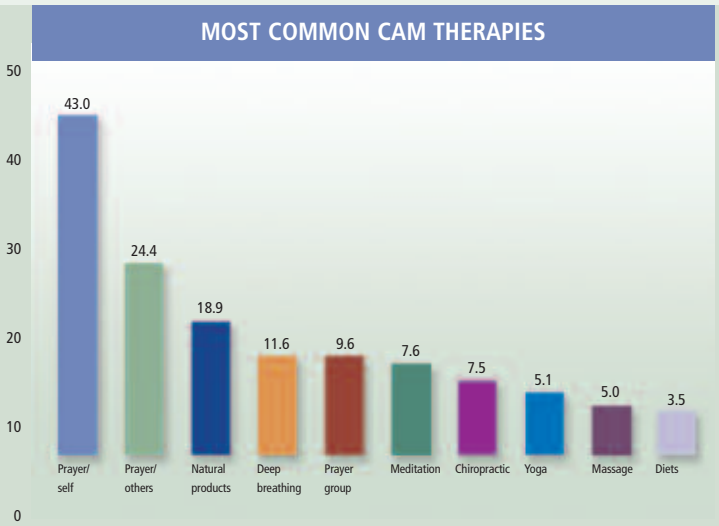
More and more Americans are turning to CAM to help manage and treat various health problems, including pain and distress.

- An estimated 36% of American adults use some form of CAM, and this percentage jumps to 62% if prayer for health reasons and megavitamin therapy are included.[3]
- Americans spend at least $34-47 billion on CAM therapies, exceeding out of pocket expenses for all U.S. hospitalizations. CAM is expected to grow by 15% each year.[3]
- People report using CAM because these methods mirror their personal beliefs, values and philosophical orientations toward life.[4]
- Many people use CAM to help relieve back pain, joint pain, severe headache and pain associated with migraines, dental and jaw pain and for a variety of other reasons.[4]

Barriers to Fully Integrating CAM

Despite CAM's growing popularity, there are barriers to its widespread use. According to CAM experts, these include:

- Limited scientific evidence about the safety and effectiveness of certain therapies. Studies are underway to research specific CAM practices for pain management.
- Lack of professional training in CAM and integrative medicine and limited resources to coordinate services.
- Restricted health insurance coverage. Many CAM therapies are not yet covered by health insurance carriers and are, therefore, only available to patients on an outpatient fee-for-service basis. Insurers tend to restrict reimbursement to "medically necessary" therapies and without the data to back up their effectiveness, these practices are not covered.



Source: Barnes P, Powell-Griner E, McFann K, Nahin R, CDC Advance Data Report #343, *Complemenary and Alternative Medicine Use Among Adults*, United States, 2002. May 27, 2004.

- Lack of education (on the part of consumers and providers) about the appropriate use of CAM therapies and how best to integrate them with standard pain treatments.
- Misperceptions about CAM therapies as "elusive, nonsensical options."

Source: American Pain Foundation, *Pain Community News*, Spring 2008.

Paying for non-drug therapies

The majority of CAM treatments are not currently covered by traditional insurance plans, largely due to the absence of scientific evidence proving the effectiveness of some CAM therapies. When coverage for CAM is offered, it is generally limited to more common therapies such as acupuncture and massage. Most people must pay for CAM services out-of-pocket; however, consumer interest has prompted more insurance companies to consider CAM coverage.

A study in Washington State, where private health insurers are legally required to cover licensed CAM providers, found that a significant number of people were utilizing CAM insurance benefits with only a modest effect on insurance expenditures.[5]

Given the high cost and low insurance coverage of many CAM therapies, it is important that patients, especially those that are no longer able to work, have access to low cost, at-home therapies that provide effective pain relief. These may include heat and cold therapies, relaxation techniques and exercise.

People living with chronic pain are increasingly turning to CAM to help alleviate their suffering and improve their quality of life. The addition of these therapies often results in better pain relief and fewer side effects. However, more research is needed to prove the effectiveness of certain therapies and increase the likelihood that they will be covered by conventional insurance providers and offered as an option to all patients living with pain.

With nearly half of all consumers concerned about the safety of their health care,[6] the use of CAM and other non-drug treatments for pain management is expected to grow as non-drug therapies are proven safe and effective and adopted into routine health care.[7]

For a snapshot of recent research on select CAM therapies, see the Spring 2008 issue of *Pain Community News* at www.painfoundation.org.

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WEB RESOURCES

American Academy of Pain Management
www.aapainmanage.org

American Pain Foundation Treatment Options
www.painfoundation.org/Publications/TreatmentOptions2006.pdf

National Center for Complementary and Alternative Medicine (NCCAM)
www.nccam.nih.gov

The Office of Cancer Complementary and Alternative Medicine
www.cancer.gov/cam

Pain A to Z

Common Pain Terms and Syndromes

Hundreds of pain syndromes or disorders make up the spectrum of pain. There are the most benign, fleeting sensations of pain, such as a pin prick. There is the pain of childbirth, the pain of a heart attack, and the pain that sometimes follows amputation of a limb. There is also pain accompanying cancer and the pain that follows severe trauma, such as that associated with head and spinal cord injuries. A sampling of common pain terms and syndromes follows, listed alphabetically.

Acute Pain occurs suddenly due to illness, injury or surgery. It has a short duration that subsides when the injured tissue heals.

Arachnoiditis is a condition in which one of the three membranes covering the brain and spinal cord, called the arachnoid membrane, becomes inflamed. A number of causes, including infection or trauma, can result in inflammation of this membrane. Arachnoiditis can produce disabling, progressive, and even permanent pain.

Arthritis is the most prevalent cause of chronic disability in the United States. Millions of Americans suffer from arthritic conditions such as osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and gout. These disorders are characterized by joint pain in the extremities. Many other inflammatory diseases affect the body's soft tissues, including tendonitis and bursitis.

Back pain has become the high price paid by our modern lifestyle and is a startlingly common cause of disability for many Americans, including both active and inactive people. Common types of back pain include:

- **Sciatica** — back pain that spreads to the leg (see below).
- **Degenerative or ruptured disc** — type of back pain associated with the discs of the spine, the soft, spongy padding between the vertebrae (bones) that form the spine. Discs protect the spine by absorbing shock, but they tend to degenerate over time and may sometimes rupture.
- **Spondylolisthesis** — back condition that occurs when one vertebra extends over another, causing pressure on nerves and therefore pain.
- **Radiculopathy** — damage to nerve roots is a serious condition that can be extremely painful.

Treatment for a damaged disc includes drugs such as painkillers, muscle relaxants, and steroids; exercise or rest, depending on the patient's condition; adequate support, such as a brace or better mattress and physical therapy. In some cases, surgery may be required to remove the damaged portion of the disc and return it to its previous condition, especially when it is pressing a nerve root. Surgical procedures include discectomy, laminectomy, or spinal fusion. Minimally invasive procedures (vertebroplasty), certain complementary and alternative therapies and implantable devices may also help certain patients.

Breakthrough Pain is intermittent worsening of pain that occurs spontaneously or in relation to a specific activity. The pain increases above the level of pain being treated with ongoing analgesics (pain medications).

Burn pain can be profound and poses an extreme challenge to the medical community. First-degree burns are the least severe; with third-degree burns, the skin is lost. Depending on the injury, pain accompanying burns can be excruciating, and even after the wound has healed patients may have chronic pain at the burn site.

Cancer pain can accompany the growth of a tumor, the treatment of cancer, or chronic problems related to cancer's permanent effects on the body. Fortunately, most cancer pain can be treated to help minimize discomfort and stress to the patient.

Central pain syndrome — see Traumatic Pain below.

Chronic Pain is pain that persists for long periods of time (usually >3 months). Failure to treat acute pain promptly and appropriately at the time of injury, during initial medical and surgical care, and at the time of transition to community-based care, contributes to the development of chronic pain syndromes. In chronic pain, pain signals may remain active in the nervous system for weeks, months or even years. Chronic pain has no value or benefit; it is a disease of the nervous system.

Types of Chronic Pain:

- **Intermittent Pain** - episodic and may occur in waves or patterns.
- **Persistent Pain** - lasts 12 or more hours every day for more than three months.

Complex Regional Pain Syndrome, or CRPS, is a chronic pain condition that typically affects one or more limbs. It is accompanied by burning pain and hypersensitivity to temperature. Often triggered by trauma or nerve damage, CRPS causes the skin of the affected area to become characteristically shiny.

There are two types of CRPS:

- **CRPS I** (formerly known as Reflex Sympathetic Dystrophy Syndrome, or RSDS) is frequently triggered by tissue injury, but with no underlying or identifiable nerve injury.

- **CRPS II** (formerly known as Causalgia) is characterized by the same symptoms, but these cases are clearly associated with a specific nerve injury.

The cause of CRPS is not well understood, but experts believe it is due to a malfunction of the autonomic nervous system following blunt trauma to an arm or leg, after surgical procedures or even from minor injuries such as a sprain or fracture. Nerves begin to misfire, repeatedly sending pain impulses to the brain. The resulting pain seems out of proportion to the severity of the injury.

Deafferentation Pain: pain due to alteration or damage to the central nervous system (central pain or neuropathic pain) or may be alteration of nervous system within larger nerves or nerve roots before entry into central nervous system.

Fibromyalgia is a chronic pain disorder characterized by widespread musculoskeletal pain that has lasted for at least three months. People with fibromyalgia report general tenderness and soreness, muscle stiffness, especially in the morning, as well as fatigue. Stress or lack of sleep can make the symptoms of fibromyalgia worse. An estimated 6 million Americans have fibromyalgia, most of them women.

Headaches affect millions of Americans. The three most common types of chronic headache are migraines, cluster headaches, and tension headaches. Each comes with its own telltale brand of pain.

- **Migraines** are characterized by throbbing pain and sometimes by other symptoms, such as nausea and visual disturbances. Migraines are more frequent in women than men. Stress can trigger a migraine headache, and migraines can also put the sufferer at risk for stroke.
- **Cluster** headaches are characterized by excruciating, piercing pain on one side of the head; they occur more frequently in men than women.
- **Tension headaches** are often described as a tight band around the head.

Head and facial pain can be agonizing, whether it results from dental problems or from disorders such as cranial neuralgia, in which one of the nerves in the face, head, or neck is inflamed. Another condition, **trigeminal neuralgia** (also called tic douloureux), affects the largest of the cranial nerves and is characterized by a stabbing, shooting pain.

Muscle pain can range from an aching muscle, spasm, or strain, to the severe spasticity that accompanies paralysis. Another disabling syndrome is **fibromyalgia**, a disorder characterized by fatigue, stiffness, joint tenderness, and widespread muscle pain. **Polymyositis**, **dermatomyositis**, and **inclusion body myositis** are painful disorders characterized by muscle inflammation. They may be caused by infection or autoimmune dysfunction and are sometimes associated with connective tissue disorders, such as lupus and rheumatoid arthritis.

Myofascial pain syndromes affect sensitive areas known as trigger points, located within the body's muscles. Myofascial pain syndromes are sometimes misdiagnosed and can be debilitating.

Neuropathic Pain – is a type of pain that results from damage to or dysfunction of the nerves in either the peripheral or central nervous system, rather than stimulation of pain receptors (as is the case of somatic and visceral pain). Neuropathic pain can occur in any part of the body and is frequently described as a hot, burning sensation, which can be devastating to the affected individual. It can result from diseases that affect nerves (such as diabetes) or from trauma, or, because chemotherapy drugs can affect nerves, it can be a consequence of cancer treatment. Among the many neuropathic pain conditions are:

- **Diabetic neuropathy**, which results from nerve damage secondary to vascular problems that occur with diabetes;
- **Reflex sympathetic dystrophy syndrome** (see below), which can follow injury;
- **Phantom limb** and **post-amputation pain**, which can result from the surgical removal of a limb;
- **Postherpetic neuralgia**, which can occur after an outbreak of shingles; and
- **Central pain syndrome**, which can result from trauma to the brain or spinal cord.

Nociceptive pain - caused by an injury that stimulates pain receptors. Pain receptors, located on the tips of nerve cells, recognize and react to an unpleasant stimulus (pressure, extreme temperatures [hot or cold], substances released by other cells) and send pain signals through the nervous system for recognition and response. This type of pain may be accompanied by inflammation. Infections, burns, cuts, a severe lack of oxygen in the blood, and stretching of or pressure within an organ, can injure tissues and cause nociceptive pain.

Types of Nociceptive Pain:

- **Somatic Pain** - caused by injury to skin, muscles, bone, joint, and connective tissues. Deep somatic pain is usually described as dull or aching, and localized in one area. Somatic pain from injury to the skin or the tissues just below it often is sharper and may have a burning or pricking quality.
- **Visceral Pain** - originates from ongoing injury to the internal organs or the tissues that support them. When the injured tissue is a hollow structure, like the intestine or the gall bladder, the pain often is poorly localized and feels like cramping. When the injured structure is not a hollow organ, the pain may be pressure-like, deep, and stabbing.

Pain flares. Pain that suddenly erupts or emerges with or without an aggravating event or activity.

Peripheral Neuropathic Pain due to vascular disease or injury-such as vasculitis or inflammation of blood vessels, coronary artery disease, and circulatory problems-all have the potential to cause pain. Vascular pain affects millions of Americans and occurs when communication between blood vessels and nerves is interrupted. Ruptures, spasms, constriction, or obstruction of blood vessels, as well as a condition called ischemia in which blood supply to organs, tissues, or limbs is cut off, can also result in pain.

Reflex sympathetic dystrophy syndrome — see Complex Regional Pain Syndrome.

Repetitive stress injuries are muscular conditions that result from repeated motions performed in the course of normal work or other daily activities. They include:

- writer's cramp, which affects musicians and writers and others,
- compression or entrapment neuropathies, including carpal tunnel syndrome, caused by chronic overextension of the wrist and
- tendonitis or tenosynovitis, affecting one or more tendons.

Sciatica is a painful condition caused by pressure on the sciatic nerve, the main nerve that branches off the spinal cord and continues down into the thighs, legs, ankles, and feet. Sciatica is characterized by pain in the buttocks and can be caused by a number of factors. Exertion, obesity, and poor posture can all cause pressure on the sciatic nerve. One common cause of sciatica is a herniated disc.

Shingles and other painful disorders affect the skin. Pain is a common symptom of many skin disorders, even the most common rashes. One of the most vexing neurological disorders is shingles or herpes zoster, an infection that often causes agonizing pain resistant to treatment. Prompt treatment with antiviral agents is important to arrest the infection, which if prolonged can result in an associated condition known as **postherpetic neuralgia**. Other painful disorders affecting the skin include:

- **Vasculitis**, or inflammation of blood vessels;
- Other infections, including **herpes simplex**;
- Skin **tumors** and **cysts**, and

Tumors associated with **neurofibromatosis**, a neurogenetic disorder.

Somatic pain—see Nociceptive Pain.

Sports injuries are common. Sprains, strains, bruises, dislocations, and fractures are all well-known words in the language of sports. Pain is another. In extreme cases, sports injuries can take the form of costly and painful spinal cord and head injuries, which cause severe suffering and disability.

Spinal stenosis refers to a narrowing of the canal surrounding the spinal cord. The condition occurs naturally with aging. Spinal stenosis causes weakness in the legs and leg pain usually felt while the person is standing up and often relieved by sitting down.

Surgical pain may require regional or general anesthesia during the procedure and medications to control discomfort following the operation. Control of pain associated with surgery includes presurgical preparation and careful monitoring of the patient during and after the procedure.

Temporomandibular disorders are conditions in which the temporomandibular joint (the jaw) is damaged and/or the muscles used for chewing and talking become stressed, causing pain. The condition may be the result of a number of factors, such as an injury to the jaw or joint misalignment, and may give rise to a variety of symptoms, most commonly pain in the jaw, face, and/or neck muscles. Physicians reach a diagnosis by listening to the patient's description of the symptoms and by performing a simple examination of the facial muscles and the temporomandibular joint.

Traumatic pain can occur after injuries in the home, at the workplace, during sports activities, or on the road. Any of these injuries can result in severe disability and pain. Some patients who have had an injury to the spinal cord experience intense pain ranging from tingling to burning and, commonly, both. Such patients are sensitive to hot and cold temperatures and touch. For these individuals, a touch can be perceived as intense burning, indicating abnormal signals relayed to and from the brain. This condition is called **central pain syndrome** or, if the damage is in the thalamus (the brain's center for processing bodily sensations), **thalamic pain syndrome**. It affects as many as 100,000 Americans with multiple sclerosis, Parkinson's disease, amputated limbs, spinal cord injuries, and stroke. Their pain is severe and is extremely difficult to treat effectively. A variety of medications, including analgesics, antidepressants, anticonvulsants, and electrical stimulation, are options available to central pain patients.

Visceral pain – see Nociceptive Pain.

Sources:

American Pain Foundation. *Treatment Options: A Guide for People Living with Pain*. Available at www.painfoundation.org.

"Pain: Hope Through Research," National Institutes of Neurological Disorders and Stroke. Publication date December 2001. NIH Publication No. 01-2406 . Last updated July 31, 2008.

Pain Resources

American Pain Foundation
888-615-7246
www.painfoundation.org

Key Publications

- *Pain Community News*, APF's quarterly newsletter
- *Pain Monitor*, APF's monthly e-news update
- *Treatment Options: A Guide for People Living with Pain*
- *Pain Resource Guide: Getting the Help You Need*
- *Targeting Chronic Pain Notebook* and companion provider resources
- APF Report, *Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management*
- Fact sheets on cancer pain, shingles/PHN, fibromyalgia, military/veterans and pain, among others
- Top 10 Tips Series, including:
  - Finding Quality Health Information Online
  - Exercising for Pain Relief
  - Making the Most of Your Medical Visits
  - Easing Pain Around the Holidays
  - Pain-free Tips for Travelers
  - Helpful Hints on the Road to Pain Relief
- Pain Care Bill of Rights

Special Projects/Initiatives

- APF's grassroots **Power Over Pain Action Network** (POPAN) has 72 POPAN leaders in 36 states tirelessly working to help improve pain care, legislation related to pain care, healthcare access and medical practices.
- **Military and Veterans Pain Initiative**
- **Spotlight Series** on cancer pain, fibromyalgia and shingles
- **Pain & Creativity**
- **Yoga for Chronic Pain**
- ***Let's Talk Pain*** Coalition, www.letstalkpain.org, launched in partnership with the American Academy of Pain Management and the American Society for Pain Management Nursing

For more information about APF's programs and services, see the 2007 Annual Report at http://www.painfoundation.org/About/2007AnnualReport.pdf

To subscribe to print or online publications, please visit www.painfoundation.org, or call Tina Register, Communications Manager, at (443) 690-4707 or tregister@painfoundation.org

Other Consumer Pain Associations

American Chronic Pain Association
800-533-3231
www.theacpa.org

National Pain Foundation
303-783-8899
www.nationalpainfoundation.org

Condition-Specific Pain Organizations

The American Pain Foundation keeps an updated and searchable listing of condition-specific patient advocacy and professional organizations at www.painfoundation.org. These include such groups as the Amputee Coalition of America, Arthritis Foundation, the National Vulvodynia Association, National Fibromyalgia Association and the American Diabetes Association, among others.

Professional Pain Associations

Alliance of State Pain Initiatives
608-262-0978
E-mail: aspi@mailplus.wisc.edu

American Academy Hospice and Palliative Medicine
847-375-4712
www.aahpm.org

American Academy of Pain Management
209-533-9744
www.aapainmanage.org

American Academy of Pain Medicine
847-375-4731
www.painmed.org

American Pain Society
847-375-4715
www.ampainsoc.org

American Society of Addiction Medicine
301-656-3920
www.asam.org

American Society for Pain Management Nursing
913-895-4606
www.aspmn.org

National Hospice & Palliative Care Organization
703-837-1500
www.nhpco.org

Other organizations

Pain Policy Studies

Pain and Policy Studies Group (PPSG)
608-263-7662
www.painpolicy.wisc.edu

Pain Law Studies

Pain and the Law
617-262-4990
www.painandthelaw.org

The Legal Side of Pain
865-560-1945
www.legalsideofpain.com

National Association of Attorneys General
www.naag.org

Drug Abuse/Addiction Groups

National Institute on Drug Abuse
301-443-1124
www.nida.nih.gov

Drug Enforcement Administration
Office of Diversion Control
800-882-9539
www.deadiversion.usdoj.gov

Partnership for a Drug-Free America
212-922-1560
http://drugfreeamerica.com

Substance Abuse and Mental Health Services Administration (SAMHSA)
877-726-4727
www.samhsa.gov

White House Office of National Drug Control Policy
800-666-3332
www.whitehousedrugpolicy.gov

Others

Center for Practical Bioethics
800-344-3829
www.practicalbioethics.org

Federation of State Medical Boards (FSMB)
817-868-4000
www.fsmb.org

National Family Caregivers Association
301-942-6430
www.nfcacares.org

"Pain is inevitable. Suffering is optional."

—Anonymous

201 N. Charles St., Suite 710 • Baltimore, MD 21201-4111 • 1-888-615-PAIN (7246)
info@painfoundation.org • www.painfoundation.org

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American Pain Foundation
A United Voice of Hope and Power over Pain

KEY PROCEEDINGS

Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management— A Roundtable Discussion

Published April 2008

American Pain Foundation
A United Voice of Hope and Power over Pain

Key Proceedings

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Introduction

Untreated or undertreated pain is a growing public health problem and a leading cause of disability. Just over one-quarter of American adults—or, an estimated 76.5 million Americans—report that they have had a problem with pain that persisted for more than 24 hours in the past month. Notably, 57 percent of older adults who reported pain indicated that the pain lasted for more than one year.[1] Even though pain is one of the most common reasons patients consult a healthcare provider, it is often inadequately treated, leading to needless suffering and lost productivity. Chronic pain (pain that persists after normal healing or for at least three months) is not only emotionally and physically debilitating for patients, it also places a tremendous burden on families and caregivers and contributes to excessive healthcare costs. The need for improved pain management will undoubtedly become even more salient given increasing life-expectancy and an aging baby boomer population.

Opioids are strong pain medications and are increasingly used as part of a multi-modality pain management treatment plan. Medications that fall within this class include morphine (e.g., Avinza, Kadian, Morphine Sulfate Contin), oxycodone (e.g., OxyContin, Percodan, Percocet), fentanyl (e.g., Duragesic, Fentora), oxymorphone (e.g., Opana), hydromorphone, methadone, and related drugs. Although the use of opioids has been well studied and accepted in acute, end-of-life and cancer-related pain, there continues to be much confusion and controversy surrounding the use of these drugs in the long-term management of chronic non-cancer pain. A key challenge is the lack of scientific studies that have evaluated long-term safety and efficacy of opioids for non-cancer pain. Another challenge is the undeniable problems of substance abuse, addiction and drug diversion, all of which necessitate regulatory scrutiny of prescribers.

The dramatic rise of nonmedical uses of prescription drugs, which has paralleled the increasing use of opioids for legitimate medical purposes, have fueled fears, and for some, blurred the line between the law and the practice of medicine. As Scott Fishman, MD, wrote in *Responsible Opioid Prescribing: A Physician's Guide:* "...the collision between the War on Pain and the War on Drugs has created a 'perfect storm' of controversy."

Unfortunately, there is reason to believe that a lack of clinician knowledge or skills in selecting patients and managing their therapy restricts access to medically necessary opioid treatments. Even knowledgeable and skilled prescribers are often reluctant to prescribe opioids because of concerns related to regulatory scrutiny or fears about iatrogenic drug abuse or addiction. Historically, there has been a lack of training, particularly for primary care providers, about how to: prudently evaluate candidates for long-term opioid therapy; initiate and adjust therapy; and recognize signs suggestive of aberrant drug behaviors or addictive disorders. Moreover, sensationalized news reports of drug abuse, diversion and addiction, or of legal actions taken against prescribers have helped perpetuate a negative—and sometimes false—picture of chronic pain management.

In an effort to review the challenges surrounding optimal opioid therapy and pain management, the American Pain Foundation (APF) convened a roundtable of leading pain experts in November 2007. The roundtable, which was titled, *Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management,* was supported by an educational grant from Endo Pharmaceuticals. The meeting was intended as an open interchange to describe the ongoing critical barriers to appropriate opioid prescribing and the opportunities that exist to drive a pain treatment agenda forward in a

[1] National Center for Health Statistics. Health, United States, 2006 With Chartbook on Trends in the Health of Americans. Hyattsville, MD: 68-71.

positive and constructive manner. This lively and thoughtful discussion also served as a springboard for actionable solutions that will help elevate the national dialogue about appropriate opioid use within professional and public arenas.

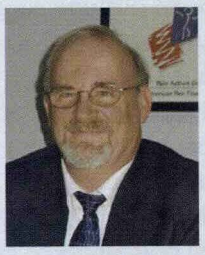
Roundtable participants issued an urgent call to the pain community to begin to reframe the discussion about opioid therapy in a way that incorporates a more balanced perspective of the risks and benefits of these medications.
As part of this paradigm shift, pain leaders recognize the need to engage and collaborate with other stakeholders—health professionals, consumers, the pharmaceutical industry, law enforcement and regulatory agencies, and health policymakers—to arrive at a unified agenda and establish a framework that supports better understanding of the issues surrounding both the essential medical role of this therapy and the benefits and risks of prescribing opioid medication. While the pain community must call attention to the epidemic of chronic pain, its undertreatment, and the utility of opioid therapy as a safe and effective strategy to relieve pain and improve functioning in appropriately selected and monitored patients, it also must acknowledge the societal and public health concerns raised by reports of increasing prescription drug abuse. The ultimate goal, according to several roundtable participants, should be to build collaborations based on a shared understanding of the multifaceted benefits and burdens associated with opioid medications, rather than continuing to operate within silos positioned on the basis of "pro" or "con" attitudes concerning medical use, or an emphasis on risk alone. Attendees focused on the need for education and training, regulation and research strategies that the American Pain Foundation and others could consider adopting in order to lead the movement toward a more balanced view of pain management.

Participants also discussed the key findings of an online survey of 238 primary care physicians, pain specialists, nurse practitioners and physician assistants. The survey, conducted by HCD Research from October 4 – 24, 2007, aimed to gain an in-depth understanding of the prescription practices, knowledge and beliefs of opioid therapy for non-cancer chronic pain. The findings of the survey reinforced many of the ideas presented by participating key opinion leaders.

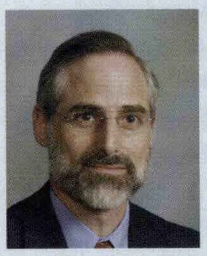
Pain affects more Americans than diabetes, heart disease and cancer combined. Now is the time to build consensus on pain management and opioid use in America and drive perceptions towards a more balanced view. Alleviating pain in patients with legitimate medical needs remains an important medical imperative. Patients deserve optimal pain relief, which includes access to safe and effective pain medications balanced with appropriate risk management. When properly prescribed by a healthcare professional and taken as directed, these medications provide important pain relief and can improve functioning.

Roundtable Participants

Co-Moderators:



Will Rowe
Chief Executive Officer
American Pain Foundation
Baltimore, Maryland



Russell Portenoy, MD
Chairman, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, N.Y.
Professor of Neurology and Anesthesiology, Albert Einstein College of Medicine

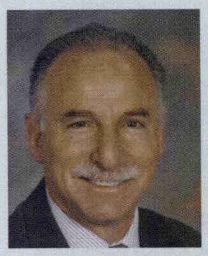
Participants:

Paul Arnstein, RN, PhD, FNP-C
Associate Professor, MGH Institute for Health Professionals, and Clinical Nurse Specialist
Massachusetts General Hospital

Aaron Gilson, MS, MSSW, PhD
Director for U.S. Policy Research, Pain and Policy Studies Group
University of Wisconsin – Madison

Micke A. Brown, BSN, RN
Director of Advocacy
American Pain Foundation
Baltimore, Maryland

Howard Heit, MD, FACP, FASAM
Assistant Clinical Professor
Georgetown University Hospital



Perry G. Fine, MD
Professor of Anesthesiology
University of Utah, Salt Lake City

Todd Sitzman, MD, MPH
Medical Director,
Advanced Pain Therapy
Forrest General Hospital
Cancer Center
Hattiesburg, Mississippi

Scott Fishman, MD
Chief of the Division of Pain Medicine, Professor of Anesthesiology
University of California, Davis

Key Insights

The roundtable discussion initially focused on overarching statements that participants agreed should help frame current and future dialogue about chronic non-cancer pain in America. Although these observations are primarily anecdotal, the panel believes they will be widely accepted by pain specialists in the United States.

PAIN IS UNDERTREATED IN AMERICA.
All members of the roundtable discussion were in agreement that pain is undertreated, despite the availability of safe and effective treatments. Participants suggested that patients with chronic pain are not seeking or receiving the care they need for a variety of reasons. Most physicians have not been trained in chronic pain management, and chronic pain is not recognized as an illness in its own right. As a consequence, a high proportion of patients consult multiple doctors before their pain condition is acknowledged, let alone appropriately managed. For those with disabling chronic pain, access to pain specialists is very limited. This is due to the limited number of specialists and the current systems that support the training and reimbursement of specialists. The panel agreed that there are certain patients with chronic pain who should be given access to opioid therapy, and that outcomes will be favorable, but many physicians are reluctant to consider a therapeutic trial, and many patients are hesitant to accept this therapy.

Although the extent to which undertreatment with opioids occurs in populations with chronic non-cancer pain cannot be determined given current data, the panel accepted that undertreatment exists, is probably substantial, and is multifactorial. Causes include the shame and stigma associated with therapy, and limited access to physicians with the skills to select and manage treatment, and the willingness to accept responsibility for this therapy. There are anecdotal reports of practices either dropping chronic pain patients who are taking opioids or putting a cap on the number of patients served. Furthermore, some pharmacies are electing not to carry opioids. Many pain clinics will offer patients interventional treatments for pain, but will not prescribe oral pharmacological management of pain for economic and other reasons, which need to be studied. Efforts to increase awareness about the pain epidemic in this country may also be complicated by a cultural emphasis on the problems associated with drug abuse.

An important caveat to the evidence of serious undertreatment of pain is a parallel problem of overtreatment or mistreatment. Some patients are over- or mistreated when clinicians perform or prescribe multiple ineffectual, risky, and costly interventions or drug therapies without well-defined, identifiable benefit.

It was generally agreed that optimal outcomes require that opioid therapy be structured as a component of a more comprehensive pain treatment plan—one that integrates psychological, social and functional rehabilitative approaches to care along with medical or interventional treatments. There are often inadequate resources in primary care practice settings, and severe reductions in the numbers of comprehensive chronic pain treatment centers, for this approach. This is a "systems" problem that requires correction in order to maximize the utility of pharmacological therapies and improve the treatment of chronic pain and related disability.

THE CHRONIC PAIN CONVERSATION MUST REMAIN BROAD IN SCOPE.

Although much of the discussion centered on opioid therapy, roundtable participants agreed that for the pain community to move forward in a significant way, the conversation must also focus on pain management as a whole. Just as anesthesiology is not about one inhalational agent, one injectable drug, or one monitoring device, pain medicine is not defined by one procedure, one pharmacologic class of drug, one psychological strategy, or a single physical modality of treatment.

It's also critical to understand that while there is a great deal that is known about non-cancer chronic pain, the practice is still in its infancy and studies are needed to validate how it is best treated initially and over time.

OPIOID THERAPY MUST BE PRESENTED WITH A MORE BALANCED POINT-OF-VIEW.

Unfortunately, the discussion about opioid therapy often is characterized by dogmatic views or one-sided arguments. Those who recognize the likelihood of opioid undertreatment may not speak about the problem of prescription drug abuse, and those whose concern is addiction or diversion may not acknowledge the potential negative impact of law enforcement or regulations on pain management. Roundtable participants agreed that, in order to break the mold, a shift towards a more balanced view that takes into account the full spectrum of issues pertaining to opioid management—"the good, bad and ugly"—is essential to improve patient care and to help shift overriding prescribing fears to a more rational, clinical, science-based appreciation of the risks and benefits of these medicines.

Integral to this is a keener understanding of the intersection of pain medicine and addictive disorders, including the role, and mechanisms, of tolerance, physical dependence, pseudoaddiction and addiction.

"The pain community—the 'we'—has neither the manpower nor the skills to do this," Dr. Portenoy said. "The pain community must figure out who and where the local champions are."

ALL WITH A STAKE IN PAIN MANAGEMENT MUST WORK COLLABORATIVELY.

It will be essential for the entire pain management community, not only pain medicine specialists, to come together and work collaboratively with one unified voice to achieve success. Although several organizations exist to help support pain patients and the healthcare professionals who care for them, they are each engaged in separate campaigns to increase awareness and understanding of pain management. By coordinating these efforts and dovetailing on key initiatives, the pain management community can be much more powerful and effective in delivering messages and outreaching to key stakeholders. In addition, discussions about opioids and pain management have to move beyond the world of pain medicine to bring together experts from a wide variety of fields (e.g., family medicine and other medical specialties, nursing, pharmacy, physician assistants). The field needs to enlist enlist champions within the pharmaceutical, managed care, legislative, regulatory and law enforcement arenas.

"There is an opportunity for us to collaborate and break down the silence and start working towards a common [pain] agenda. We all have different capabilities and strengths, but together we're a phenomenal force."
– Micke Brown, BSN, RN, American Pain Foundation

Discussion Highlights

EDUCATION

Education of healthcare professionals, patients, the news media, elected officials and the public about pain management and opioid use was discussed as a key priority that the pain management community should undertake. Panelists agreed that education of these stakeholders is lacking and that more must be done to encourage more balanced conversations.

Curriculum Advocacy

Roundtable participants called for a coordinated effort that would require pain management training to be part of the core curriculums at schools of Medicine, Nursing and Pharmacy. Appropriate training and resources are needed to ensure that prescribers have the necessary skill set and resources to provide quality pain and opioid management.

"I really feel that [the missing part is] training; it's education at the medical school, pharmacy school, nursing school level," said Aaron Gilson, MSSW, PhD. "If they don't get an understanding of the [principles of] pain management and opioid analgesics at that stage, it's very unlikely they will develop that practice without it."

Dr. Heit added "I think we really have to put the pressure...on medical schools in regards to making this part of the core curriculum." The prevalence of pain, as well as the potential for addiction further justifies the need for a dedicated curriculum in pain management. "If 10 percent of the population has a disease of addiction, and pain is the most common presentation to a doctor's office, why isn't this part of the core curriculum of all medical schools?" Heit asked.

Primary Care Community Engagement

Health professionals in the primary care setting serve as the main providers of pain care and should be at the table during future discussions about opioid therapy. Pain experts agreed that to deliver good pain management, healthcare providers must also have a working understanding of both the skills necessary to optimize the favorable pharmacologic effects of opioids and those needed to assess and manage the risks associated with opioid abuse, addiction and diversion. It is critical that primary care providers be given the training and tools necessary to watchfully monitor and manage risk when treating chronic pain in order to reduce their fears of prescribing.

In summarizing the group's discussion of primary care education, Dr. Russell Portenoy said, "We would all agree that a major barrier [to appropriate pain management] is the lack of education in the primary care community, which has to address most of the chronic pain in the United States."

Paul Arnstein, RN, PhD, added, "There's this fear [among primary care professionals] of causing or feeding an addiction problem. And I think that this fear is really driven by a lack of an appropriate skill set...how do we evaluate patients for aberrant drug behaviors or addiction disorders? How do we treat or refer those types of patients? And how do we have difficult conversations with patients where there may be a conflict or difference of opinion?"

Patient Education

In addition, roundtable participants unanimously agreed that patient education must run parallel to professional education. To make informed pain management decisions, patients must be armed with the information about how to safely use medications, store medications to avoid unauthorized use by others, understand expectations for therapeutic

adherence and communicate with providers. One participant suggested developing self-assessment tools to help patients track their pain relief and understand the difference between tolerance, physical dependence, and addiction.

"I think that one of the real strengths of the APF is the focus on the consumer and the patient," said Perry G. Fine, MD. "And I think that there is some education that needs to be done that hasn't been done to the consumers about the potential benefits or risks."

The Media

The morning of the roundtable, a segment on a national morning news show poignantly illustrated the media's ability to cast a negative, biased light on the subject.

"The other thing we can do to deal with the public perceptions that are out there today—that we heard this morning when the doctor on the Today Show said 'Get your chronic pain treated, but stay away from those narcotics'—is we can watch and provide responses that will move the dime," Dr. Scott Fishman remarked.

Participants agreed the use of the term "narcotic" reinforces the myths and misconceptions of this class of drugs and places emphasis on the drug abuse issue.

Dr. Fishman continued, "We don't have a media watchdog that can help [monitor] and give feedback to those who are [reporting] . . . to [help] maintain a position of balance. With the lack of [statistical] evidence, [we must rely on anecdotal] evidence that people are suffering. Doing nothing has risk."

REGULATION

In light of the barriers created by law enforcement and regulatory bodies for the pain management community, Dr. Aaron Gilson suggested, "to create messages that not only counter the actions that have been taken against the pain management community in recent years [we must] recognize the limitations of what we have, the evidence that we have. We have to be truthful about it."

"I'm for coming together. The DEA is not going to go away. The government is not going to go away. The police are not going to go away. It's an accepted fact and it's better that we join and try to work with them," Dr. Heit said.

Dr. Heit also proposed that law enforcement and regulators invite members of the pain community to their meetings and vice versa. "Let us exchange ideas and educate each other so that we may better serve our patients and communities," he said.

Micke Brown, RN, added that the pain community "needs to push back a little bit or we're going to continue to be taken advantage of to the derailment of the people that we serve."

Roundtable participants voiced their fear that those concerned with criminality related to opioids "might choose to use the lack of safety and effectiveness data as an opportunity to promote an agenda that would be harmful to the patients who might otherwise benefit." This underscores the need for more shared discussion and understanding of the problem.

RESEARCH

As the pain management community continues to move forward, so too must the research that supports specific guidelines and policy. Participants called for an aggressive research agenda to generate long-term studies of the effects of pain-management therapies, as well as studies that demonstrate the effectiveness of different processes (e.g., documentation, opioid rotation, multimodal therapy). Without this data it will be difficult to make a strong case for appropriate use of pain medicine.

"We have to recognize that there's probably more that we don't know than we do know—and be upfront about that," said Dr. Heit. "But, we also have to recognize that those who are in academic positions, that have the ability to do clinical studies, these studies have to be done in order to validate what we're doing now."

The absence of controlled clinical trials evidence must not be misinterpreted to be "lack of evidence." As defined by the principles of evidence-based medicine, the cumulative experience of myriad practitioners and their patients presents a robust body of evidence; however, the need for better science in this area is abundantly clear.

NOTE: In recognition of the above, the Mayday Fund, in partnership with the Milbank Foundation, supported a "research conclave" in March 2008. This forum was led by C. Richard Chapman, Soledad Cepeda, Perry G. Fine, and John Loeser, with an invited multidisciplinary panel of researchers, methodologists, and others. The purpose is to define a research agenda around key unanswered questions, as further defined and reinforced by roundtable participants.

KOL Perspectives: What Are the Most Pressing Issues to Achieving Appropriate Opioid Prescribing and Management?

In addition to the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, roundtable participants called attention to other real and perceived barriers to opioid prescribing. These include:

- **Persisting stigma and shame** felt by patients around opioid use and the inappropriate conclusion that opioid therapy equals addiction. Stigmatization may lead to communication problems between patients and providers, which may drive undertreatment or inappropriate prescribing.
- **Limited public awareness and education** about opioid pain relievers. As part of a broad imperative to educate consumers about the risks and benefits of all pain relievers, myths about opioids must be addressed. The messages must be about the balance between the potential for long-term reduction in pain and the risks related to side effects and the phenomena of tolerance, physical dependence and addiction.
- **Lack of education and training in pain medicine**, especially among primary care providers, who are on the frontlines of the pain epidemic. There is an urgent need to increase the number physicians willing to care for patients with chronic pain and competent to assess and manage patients with a broad array of therapies, including opioid medications. At present, there is only one pain specialist for every 21,000 patients. As a result, access to competent pain care may be limited, forcing patients to go from doctor to doctor to find relief. "We're asking people to do a job they're not trained to do, and then trying to give them technical support after the fact," said one panelist.

- **Absence of standards of care** for effective use of opioids for long-term non-cancer pain management. Unlike the uniform, systematic approaches to other illnesses, such as diabetes, there is an unacceptable degree of variation in the approach to patients with chronic pain. As a result, it is likely that the phenomena of undertreatment and overtreatment are occurring simultaneously in the health care system.

- **Discussions around opioid prescribing patterns** and challenges need to extend beyond the world of pain and academic medicine. It will be especially important to engage the primary care profession and share best practices for pain management, including the best ways to prescribe, dispense and monitor pain medications.

- **State, legal and regulatory barriers** interfere with the medical use of opioids for pain relief. Fear of scrutiny by regulators or law enforcement, and specific actions by some agencies, have had a "chilling effect" on the willingness of doctors to prescribe opioids. Pain management professionals voice concern that this may hinder legitimate patient access to medications. "The prescriber must know that federal regulations, as written, are not a barrier to effective pain management with opioids, if indicated," said Dr. Heit.

- **Inadequate reimbursement of pain medications** due to the impact of formulary restrictions, rising co-pays and Medicare Part D policies, among other factors may hinder access.

- **Need to shift focus from a reactive, "fear-based" prescribing strategy** to a proactive, "risk-based" strategy for opioid medications. The discourse around opioids needs to shift from the fear of prescribing to the need to judge the potential benefits and burdens for the individual patient and the approaches that must be in place to monitor effectively and encourage responsible medication use over time. Opioids, like all other medications, have a risk profile. Prescribers must understand the risks—including side effects and the risks associated with the abusability of these drugs—and acquire the skills necessary to perform a risk assessment. Based on this assessment, patients can be risk stratified, and prescribing—if the assessment supports a therapeutic trial—can be undertaken with the degree of control and monitoring appropriate to risk. Transition planning (exit strategy) should be considered when opioids are initially offered as a treatment option.

- **News media coverage and sensationalized case reports** of young lives being destroyed because of non-medical access to prescription medications, including opioids, are damaging because they pit one public health problem against another. Drug abuse, diversion and addiction often take center stage in news reports of pain management which perpetuates a negative—and sometimes false—picture of chronic pain management. Such reports fuel fears and the stigma associated with opioids.

"The undertreatment [of pain] is accepted by all of us based on anecdotal observations that suggest very limited access [to pain care], stigmatization of patients, lack of competence among physicians, non-clinical decisions being made by physicians based on perceptions of personal risk and other factors."
–Dr. Russell Portenoy

Recommendations & Next Steps

The group set forth a number of short-term and long-term strategies to reframe the discussion around opioid therapy. All of these strategies must be framed from the perspective of a balanced approach to these drugs—one that recognizes the necessity to ensure access to legitimate opioid treatment for pain, while also addressing the public health and law enforcement concerns related to drug abuse, addiction and diversion. Importantly, this balanced perspective at a societal level can be mirrored by clinical practice through balance at the bedside.

Overall, roundtable participants suggest greater transparency in discussions about the risks and benefits of opioid therapy. To be successful, the pain community must work collaboratively with other important stakeholders, including other healthcare professionals, patients and families, health policymakers, pharmaceutical industry, regulatory and law enforcement agencies. The pain community needs to come together and identify local champions—those individuals who can help move other organizations, agencies, and the public at large. The National Pain Care Policy Act represents an important step and includes strong language about the need for professional education and training, a dedicated research agenda and consumer outreach and awareness program.

The group also agreed the American Pain Foundation (APF) is well positioned to take the lead in advancing many of these issues, especially as it relates to patient values—an often neglected ingredient of evidence-based medicine. Roundtable members stressed that understanding and meeting patient needs is integral to good medicine, which is demonstrated by the shift to patient-centered care. APF stated its commitment to establish programming priorities in 2008 and beyond that elevate the national dialogue about opioid use within professional and public arenas.

Roundtable participants shared concerns that the pain management field is losing ground as drug abuse, diversion and addiction have continued to take center stage. Concurrently, funding for comprehensive pain care is waning. Practitioners and patients are the ones suffering as a result. The emphasis must change to the perspective of balance in communication, education, practice, regulation, and research.

ROUNDTABLE PARTICIPANTS OFFERED THE FOLLOWING RECOMMENDATIONS:

Defining the Issue

Roundtable participants agreed there needs to be a more accurate assessment of opioid prescribing patterns and perceptions among primary care professionals, which could help inform future initiatives. A similar effort to gauge the public's view of opioids for pain management would also be valuable.

- Create a targeted, scientifically valid survey that aims to better understand/define the barriers that exist for healthcare professionals treating pain with opioid therapy that can be administered to a representative sample of professionals; conduct a companion omnibus survey to assess public opinion and gain insight into important gaps in communication and understanding about opioid therapy; use these survey results to drive additional research, regulatory and educational initiatives.

Inspiring Consensus

- Develop an opinion paper to examine the *State of Opioid Therapy in Pain Management* that includes relevant historical perspectives, challenges and solutions, and an overview of "what we know and what we don't know." This document could be developed in collaboration with key stakeholder organizations to gain greater consensus and acceptance and provide a road map for the future. NOTE: perhaps link this to 2008 publication of APS-AAPM Guideline for chronic opioid therapy in non-cancer chronic pain.

Educating Healthcare Professionals

- Develop a strategy to engage top-tier medical schools to discuss core curriculum and the integration of pain management into the curriculum.
- Explore a strategic partnership with a well respected professional medical organization to collaborate on a direct-to-PCP campaign which focuses on increasing knowledge about pain management and provides PCPs with the necessary tools to appropriately prescribe pain medications.
- Conduct an audit of select third party/professional medical organizations to determine opportunities to collaborate (e.g., existing communications vehicles, programming initiatives, medical meetings/panels) and integrate information about chronic pain management.
- Develop a template article, tentatively titled, *Balance at the Bedside: Pain Management and Opioid Therapy* and other related news items, for publication in select third party/professional member organization publications, e-newsletters or web content; Roundtable participants suggest focusing initial efforts on PCP trade publications.

Launching a Patient-Provider Educational Platform

- Develop a module within the American Pain Foundation's larger consumer outreach campaign, *My Pain, My Decision*, to highlight opioids and other medications in pain management. This module could include:
  - Pain & Opioids Fact Sheet
  - FAQs about Opioid Use
  - Tip Sheet to differentiate tolerance, physical dependence and addiction to include vignettes to ensure health literacy
  - Self-assessment tests to help facilitate medical decisions and other communication tips to educate patients and encourage ongoing, open dialogue with providers
  - Pain Aid related chat/webinar
  - National (omnibus) survey on pain and opioids
  - Peer-to-peer seminar-in-a-box (Power Point presentation, summary booklet, worksheet, sample promotional materials and feature article, resources and other program materials)
  - Video stories from pain experts and consumers to highlight key issues (importance of communication, safe use and storage, multi-modal approach to pain care)
- Develop a parallel interactive program to arm healthcare professionals, particularly PCPs, with the resources/tools that enhances providers' ability to select, dose, monitor and exit patients, educate patients and facilitate communication and necessary documentation.

Responding to Negative News Reports

Members of the roundtable believe there should be a coordinated effort to rapidly respond to emerging issues and inaccuracies surrounding news media coverage of pain management and opioids.

- Establish a Speakers' Bureau of expert pain leaders equipped to respond to newspaper and trade media stories and speak about issues in real time.

Issuing a Call to Action for Expanded Research

- Develop a status of pain management opinion paper that examines current research and standards, and makes recommendations for advancing an aggressive research agenda that includes the key unanswered questions about the safety and effectiveness of long-term opioid therapy. This would also draw from other ongoing efforts, including reports from Dr. Chapman's efforts supported by the Mayday Fund.
- Drive a research agenda through a call to action for additional data to support current methods and begin focusing on future methods and issues as well.

Bridging Divide: Reaching out to Regulatory and Law Enforcement Agencies

- Review existing relationships with key government organizations to better understand how to further engage them and use the process to identify any organizations which are not currently engaged.

ABOUT THE AMERICAN PAIN FOUNDATION

Founded in 1997, the American Pain Foundation (APF) is the nation's leading independent non-profit 501(c)3 organization serving people with pain. Our mission is to improve the quality of life for people with pain by:

- Raising public awareness
- Providing practical information, education and support
- Advocating to remove barriers and increase access to effective pain management
- Promoting research

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info@painfoundation.org • www.painfoundation.org

AVINZA®—
Get Patients Back to Active Living

- Proven efficacy with continuous 24-hour pain control[1]
- Significant improvement in physical and social function[1]
- Proven safety and tolerability[2]
- Simplified drug accountability

24-Hour Pain Relief Available in Multiple Dosing Strengths

30 mg | 60 mg | 90 mg | 120 mg

Capsules are shown at actual size.

Please see full Prescribing Information enclosed.
For questions regarding *AVINZA*, please call the *AVINZA* Information Service at 1-888-8-AVINZA.

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Organon

AVINZA® (morphine sulfate extended-release capsules)

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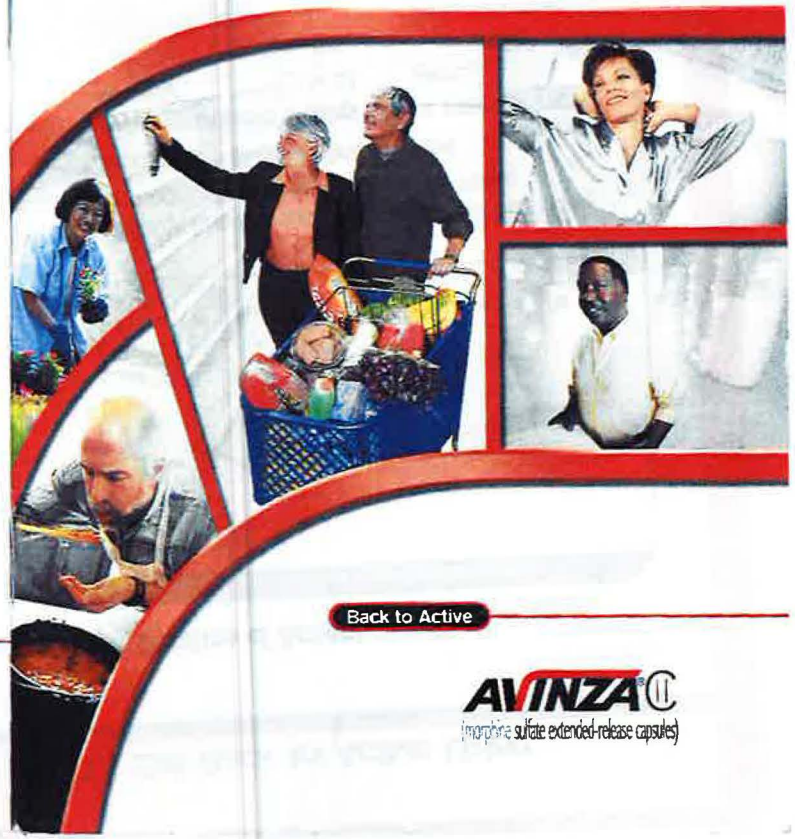
AVIN512-RCW 0106 AVI-3052

AVINZA® Treatment Guide

For Chronic Moderate-to-Severe Pain

Continuous 24-Hour Pain Relief To Get Back to Active Living



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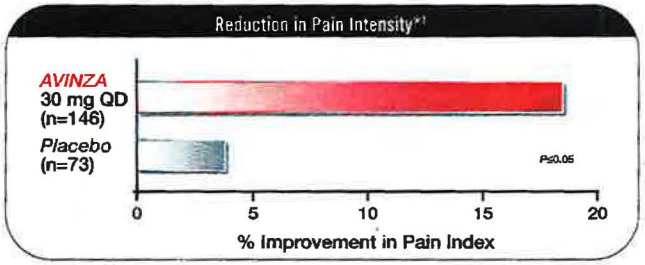
AVINZA®— Proven Efficacy

To Get Back to Active Living

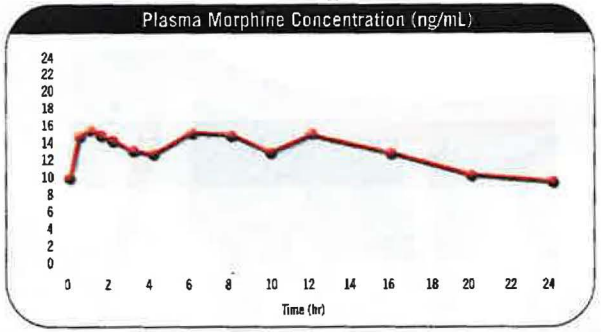
The Benefits of Continuous 24-Hour Pain Control and Long-Lasting Relief



*Double-blind, placebo-controlled, fixed-dose, parallel-group trial of 295 patients with moderate to severe pain due to osteoarthritis (OA) of hip and/or knee. Statistically significant reductions in pain were seen with *AVINZA* as compared to placebo. Results with *AVINZA* reflect average of AM and PM dosing.

- Simplified drug regimen and accountability
  - — One dose per day makes it easy to keep track of capsules and prescriptions for physicians, office staff, patients, and caregivers
- Reduces need for clock-watching
- Less interruption to daytime activities and nighttime rest

Long Duration of Action[2]



- *AVINZA* has a unique delivery system that slowly and consistently releases over 24 hours
- More stable plasma concentration
- Pharmacokinetic profiles may or may not imply efficacy[2]

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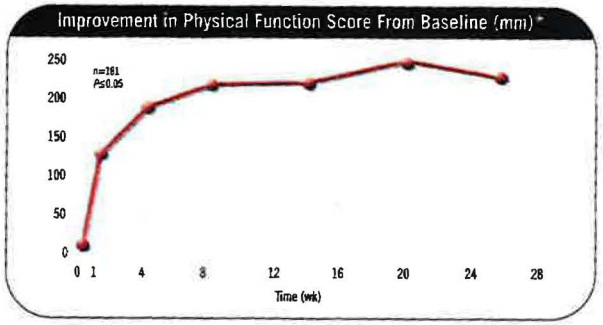
AVINZA®
(morphine sulfate extended-release capsules)

AVINZA®— Improved Overall Function

Long-Lasting Improvements in Physical Function[1]



* Improvement measured by the Western Ontario and McMaster Universities (WOMAC) OA Index Pain Scale, a comprehensive, well-validated, self-administered questionnaire consisting of subsets of questions that are answered by the patients. Results with *AVINZA* reflect average of AM and PM dosing. Week 0 (baseline) is Week 4 of the double-blind trial. For some patients, titration occurred over the 26-week period to achieve optimal pain relief.

- Improvement seen as early as Week 1
- Sustained improvement over 6 months

To Get Back to Active Living

Improvement in Daily Activities Includes[†1]

- Walking on a flat surface ✓
- Standing or sitting ✓
- Climbing stairs ✓
- Getting in and out of bed or bath ✓
- Ability to perform domestic duties ✓

† Results from a 26-week, open-label extension trial involving patients who successfully completed a 4-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel trial comparing the safety and efficacy of once-daily *AVINZA* 30 mg and twice-daily MS Contin® 15 mg. Upon entering the extension trial, patients were randomized to receive *AVINZA* 30 mg once daily in the morning (*AVINZA* QAM) or *AVINZA* 30 mg once daily in the evening (*AVINZA* QPM). If optimal pain relief was not achieved, the *AVINZA* dose was allowed to be increased.

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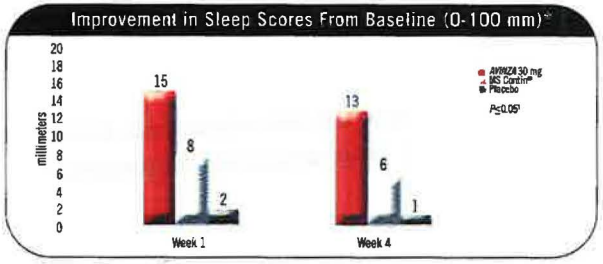
(morphine sulfate extended-release capsules)

AVINZA®— Improved Sleep Quality

Improvement in Quality of Sleep[1]



* Results from a 4-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel trial. Upon entering the trial, patients were randomized to 1 of 4 treatments: *AVINZA* 30 mg once daily in the morning (*AVINZA* QAM), *AVINZA* 30 mg once daily in the evening (*AVINZA* QPM), MS Contin® 15 mg twice daily, or placebo twice daily.

† *P* value for *AVINZA* vs placebo.

To Get Back to Active Living

Improved Quality of Sleep Includes[1]

- Sustained sleep improvement over 6 months
- Reduced need for sleep medication
- Increased ability to fall asleep
- Increased duration of sleep each night
- Less awakening at night

Back to Active

AVINZA® (morphine sulfate extended-release capsules)

AVINZA®— Convenient Dosing

Continuous 24-Hour Pain Relief in A Single Daily Dose[3]

Vicodin®
(hydrocodone/acetaminophen CIII):
6 times a day[4]

30 mg* *AVINZA* Once Daily[3]

* Equianalgesic ratio of morphine to hydrocodone is 1:1.5.[3] Rounded down to the nearest *AVINZA* dose.

Simplified drug regimen and accountability

- 30 Days = 30 Doses
- One dose per day makes it easy to keep track of capsules and prescriptions to physicians, office staff, patients, and caregivers

For Simplified Accountability

Individualization of Dosage[2]

- In all patients, the dose of *AVINZA* should be titrated to achieve a balance between therapeutic and adverse effects
- As with any opioid, it is critical to adjust the dose of *AVINZA* for each individual patient, taking into account the patient's prior analgesic treatment experience
- Practitioners should consider other factors when starting a patient on opioid therapy (eg, age, medical history, concomitant medications)
- *AVINZA* has been proven to be safe and well tolerated

Back to Active

AVINZA® CII
(morphine sulfate extended-release capsules)

Dosing and Conversions

- All *AVINZA* doses are intended to be administered once daily. Treatment should be individualized using a progressive plan of pain management such as outlined by the
  - World Health Organization
  - American Pain Society
  - Federation of State Medical Boards Model Guidelines
- The following guidelines should be considered for reference only. As with any opioid, it is critical to adjust the dose of *AVINZA* for each individual patient. Because every patient responds differently to opioid drugs and formulations, a conservative approach is advised when determining the total daily dose of *AVINZA*
- 30 mg capsules are indicated for opioid-naïve patients. 60 mg, 90 mg, and 120 mg capsules are for use in opioid-tolerant patients only
- When selecting the initial dose of *AVINZA*, it's advisable to pay attention to
  - The patient's prior experience with analgesic treatment, including
    - The total daily dose, potency, and specific characteristics of the opioid previously taken
    - The reliability of the relative potency estimate used to calculate the equivalent morphine dose needed
  - The patient's degree of opioid tolerance
  - The general condition and medical status of the patient
  - Concomitant medications
  - The type and severity of the patient's pain

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AVINZA® C
(morphine sulfate extended-release capsules)

AVINZA®— Convenient Dosing

For Simplified Accountability

Important: Conversion From Non-Morphine Opioids

In general, it is safest to administer half of the estimated daily morphine requirement as the initial *AVINZA* dose once per day, and then manage insufficient pain relief by supplementation with immediate-release morphine or other short-acting analgesics. Clinical judgment is advised when dosing for each individual patient.

Titration

In all patients, the dose of *AVINZA* should be titrated to achieve a balance between therapeutic and adverse effects.

Tolerance and Reassessment

Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). As with all opioids, some degree of tolerance may occur, requiring a dosage adjustment. When it does, the total dose of *AVINZA* should be increased until pain relief is reached or clinically significant opioid-related adverse reactions occur.

Managing Side Effects

Common adverse events seen on initiation of therapy with *AVINZA* are dose dependent, and are typical opioid-related side effects, including constipation, nausea, and somnolence.

In general, *AVINZA* has been proven to be safe and well tolerated.

Physicians should start patients on a bowel regimen from the onset of therapy to manage opioid-induced constipation.

Discontinuation of *AVINZA* Therapy

In general, opioids should not be abruptly discontinued. Instead, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient.

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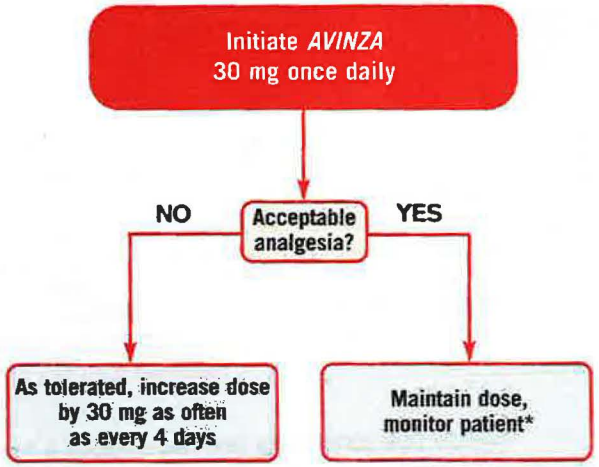
(morphine sulfate extended-release capsules)

Titrating *AVINZA*®



Continually monitor the patient; manage adverse events as needed.

If breakthrough pain occurs, supplement with immediate-release medication (5% to 15% of total daily dose of morphine equivalent).

***For unacceptable side effects, reassess/reduce the dose.**

For Opioid-Naïve Patients

Individually Assess Each Patient and Titrate to the Optimal *AVINZA* Dose

- Assess patient's medical condition and *AVINZA* therapy objectives
- Initial dose: 30 mg once daily
- Administer at 24-hour intervals
- Do not increase dosing frequency
- Dose adjustment: no more than 30 mg every 4 days[1]

[1]Steady-state concentrations of morphine are achieved 2 to 3 days after initiation of once-daily *AVINZA*. In some cases, steady state may be reached in 4 to 5 days.

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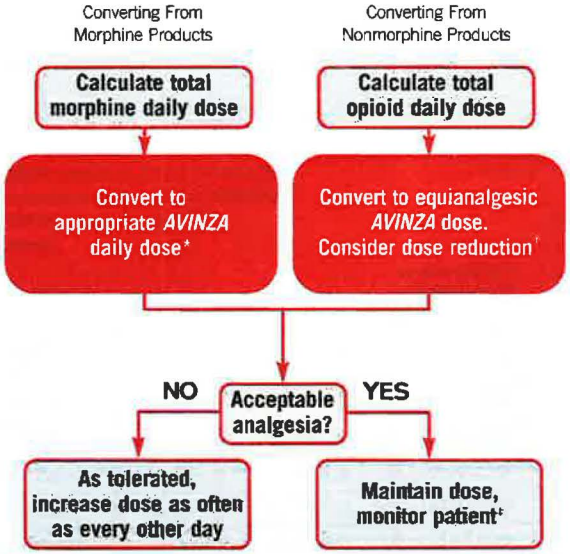
For Opioid-Tolerant Patients



Continually monitor the patient; manage adverse events as needed.

If breakthrough pain occurs, supplement with immediate-release medication (5% to 15% of total daily dose of morphine equivalent).

**From oral morphine:* The amount of morphine absorbed from *AVINZA* following oral administration is similar to that absorbed from other oral morphine formulations. *From intravenous (IV) morphine:* A reasonable starting dose of *AVINZA* would be approximately 3 times the daily IV morphine requirement. (3 mg to 6 mg of oral morphine may be required to provide pain relief equivalent to 1 mg of IV morphine.)

Individually Assess Each Patient and Titrate to the Optimal *AVINZA* Dose

- Assess patient's medical condition and *AVINZA* therapy objectives
- Review the product information of prior medication regarding conversion to other opioids
- Titration frequency: as often as every other day
- Dose should be taken at 24-hour intervals
- Do not increase dosing frequency
- Steady-state concentrations of morphine can be achieved 2 to 3 days after initiation of once-daily *AVINZA*. Therefore, it may take 3 to 4 days to see the clinical benefit of increased dosage

† *From oral nonmorphine opioids:* Use the equianalgesic table in the following section to determine the daily dose of *AVINZA* based on current opioid total daily dose. Due to interpatient variability and incomplete cross-tolerance, it is generally safest to administer half of the estimated daily morphine requirement as the initial *AVINZA* dose once per day, and then manage insufficient pain relief by supplementation with immediate-release morphine or other short-acting analgesics.

‡ **If excessive side effects occur, reduce the *AVINZA* dose and reassess.**

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AVINZA®— Convenient Dosing

These tables should be considered for guidance only, providing the total daily cumulative equianalgesic dosing for various opioids.

Morphine Agents to *AVINZA*

Immediate Release	IV dose/day	Extended Release	*AVINZA**
5 mg q4h	10 mg	15 mg q12h	30 mg q24h
10 mg q4h	20 mg	30 mg q12h	60 mg q24h
15 mg q4h	30 mg	45 mg q12h	90 mg q24h
20 mg q4h	40 mg	60 mg q12h	120 mg q24h
25 mg q4h	50 mg	75 mg q12h	150 mg q24h
30 mg q4h	60 mg	90 mg q12h	180 mg q24h
35 mg q4h	70 mg	105 mg q12h	210 mg q24h
40 mg q4h	80 mg	120 mg q12h	240 mg q24h
45 mg q4h	90 mg	135 mg q12h	270 mg q24h
50 mg q4h	100 mg	150 mg q12h	300 mg q24h

Equianalgesic ratio is 1:1[5]

*Consider the need for dose reduction.

Morphine Products:

Immediate Release: MSIR® Roxanol™

IV: Morphine sulfate (including Infumorph®, Duramorph®).

Extended Release: Kadian®, MS Contin®, Oramorph SR®

Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

Equianalgesic Tables

These tables should be considered for guidance only, providing the total daily cumulative equianalgesic dosing for various opioids.

Oral Oxycodone Agents to *AVINZA*

Immediate Release	Controlled Release	*AVINZA**
5 mg q6h	10 mg q12h	30 mg q24h
10 mg q6h	20 mg q12h	60 mg q24h
15 mg q6h	30 mg q12h	90 mg q24h
20 mg q6h	40 mg q12h	120 mg q24h
25 mg q6h	50 mg q12h	150 mg q24h
30 mg q6h	60 mg q12h	180 mg q24h
35 mg q6h	80 mg q12h	240 mg q24h

Equianalgesic ratio is 1:1.5[5]

*Consider the need for dose reduction.

Oxycodone Products:

Immediate Release: Oxy IR® Oxydose™, Oxyfast®, Roxicodone® Intensol, Roxicodone®, Endocet®, Percocet®, Roxicet™ Tylox® Endodan® Percodan®

Controlled Release: OxyContin®

For oxycodone combination products with acetaminophen, higher doses may exceed maximum recommended daily doses of acetaminophen (4 g)

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Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

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AVINZA®— Convenient Dosing

Equianalgesic Tables

Hydromorphone Agents to *AVINZA*

Oral Hydromorphone	*AVINZA**
2 mg q4h	30 mg q24h
2 mg q6h	30 mg q24h
4 mg q4h	90 mg q24h
4 mg q6h	60 mg q24h
6 mg q4h	120 mg q24h
6 mg q6h	90 mg q24h
8 mg q4h	180 mg q24h
8 mg q6h	120 mg q24h
10 mg q4h	240 mg q24h
10 mg q6h	150 mg q24h

Equianalgesic ratio is 1:4.[3]

*Consider the need for dose reduction.

Oral Hydromorphone Products:
Dilaudid®, Dilaudid®-5.

Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

Hydrocodone Agents to *AVINZA*

Oral Hydrocodone	*AVINZA**
5 mg q4h	30 mg† q24h
7.5 mg q4h	60 mg† q24h
7.5 mg q6h	30 mg† q24h
10 mg q4h	90 mg q24h
10 mg q6h	60 mg q24h
15 mg q4h	120 mg† q24h
15 mg q6h	90 mg q24h
20 mg q4h	180 mg q24h
20 mg q6h	120 mg q24h

Equianalgesic ratio is 1:1.5.[3]

*Consider the need for dose reduction.

Combination Oral Hydrocodone Products:
Anexsia®, Bancap® HC, Lorcet® 10/650, Lorcet® Plus, Lortab® Lorcet®-HD, Norco® (Vicodin®, Vicodin HP® Vicodin ES®), Zydone®

Rounded down to nearest *AVINZA* dose.
For hydrocodone combination products with acetaminophen, care should be taken not to exceed recommended daily doses of acetaminophen (4 g).[6]

Back to Active

Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

AVINZA® (morphine sulfate extended-release capsules)

AVINZA®— Convenient Dosing

Fentanyl Transdermal System to *AVINZA*

Fentanyl Transdermal System	*AVINZA**
25 mcg/h	60-90 mg q24h
50 mcg/h	90-180 mg q24h
75 mcg/h	180-270 mg q24h
100 mcg/h	270-360 mg q24h

*Consider the need for dose reduction.

AVINZA doses are suggested equianalgesic ranges based on American Pain Society recommendations.[5]

Fentanyl Transdermal System Product:
Duragesic®

Conservatively, 30 mg of *AVINZA* could be substituted for each 25 mcg/h fentanyl transdermal patch for initial conversion

After patch removal, 17 hours or more are required for a 50% decrease in serum fentanyl concentrations in healthy individuals.[7] *AVINZA* treatment can be initiated 18 hours following removal of the transdermal fentanyl patch, or as clinically indicated.

References: 1. Caldwell JR, Rapoport RJ, Davis JC, et al. Efficacy and safety of a once-daily morphine formulation in chronic moderate-to-severe osteoarthritis pain: results from a randomized, placebo-controlled, double-blind trial and open-label extension trial. *J Pain Symptom Manage.* 2002;23:278-291. **2.** *AVINZA* [prescribing information]. San Diego, Calif: Ligand Pharmaceuticals Inc.; Rev. 10/05. **3.** Brookoff D. Chronic pain: 2. The case for opioids. Available at: http://www.hosppract.com/issues/2000/09/brook.htm. Accessed December 29, 2005. **4.** Vicodin [prescribing information]. North Chicago, Ill: Abbott Laboratories; Rev. June 2002. **5.** American Pain Society. *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain.* 5th ed. Glenview, Ill: American Pain Society; 2003. **6.** Gilman AG, consulting ed; Hardman JG, Limbird LE, eds. *Goodman & Gilman's The Pharmacological Basis of Therapeutics.* 10th ed. New York, NY: McGraw-Hill; 2001. **7.** Duragesic [package insert]. Titusville, NJ: Janssen Pharmaceutica Products, L.P.; 2003.

Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

Equianalgesic Tables

Other Oral Medications to *AVINZA*

Oral Methadone	Oral Meperidine	*AVINZA**
	50 mg q4h	30 mg q24h
	100 mg q4h	60 mg q24h
5 mg q4h	150 mg q4h	90 mg q24h
	200 mg q4h	120 mg q24h
10 mg q4h		180 mg q24h
15 mg q4h		270 mg q24h
Equianalgesic ratio.[1]	Equianalgesic ratio is 1:0.1[5]	*Consider the need for dose reduction.

[1]The half-life of methadone varies from 15-40 hours and, with chronic administration, methadone accumulates in body tissue.[6] Use care when rotating patients from methadone to other opioids.[5]

Oral Methadone Products:
Dolophine® HCL, Methadose®, Methadone HCL, Methadone HCL Intensol™, Methadose®.

Oral Meperidine Products:
Demerol® HCL, Meperidine Hydrochloride.

Anexsia® is a registered trademark of Mallinckrodt Inc. Bancap® HC is a registered trademark of Forest Pharmaceuticals Inc. Demerol® is a registered trademark of Sanofi-Synthelabo Inc. Dilaudid® and Dilaudid®-5 are registered trademarks of Abbott Laboratories. Dolophine® is a registered trademark of Roxane Laboratories Inc. Duragesic® is a registered trademark of Janssen Pharmaceutica Products, L.P. Duramorph® is a registered trademark of Elkins-Sinn. Endocet® is a registered trademark of Endo Pharmaceuticals. Endodan® is a registered trademark of Endo Pharmaceuticals. Infumorph® is a registered trademark of Elkins-Sinn. Kadian® is a registered trademark of US Oral Pharmaceuticals Pty Ltd. Lorcet®-HD, Lorcet® Plus, and Lorcet® 10/650 are registered trademarks of Forest Pharmaceuticals Inc. Methadone HCL Intensol™ is a trademark of Roxane Laboratories Inc. Lortab® is a registered trademark of UCB Pharma, Inc. Methadose® is a registered trademark of Mallinckrodt Inc. MS Contin® and MSIR® are registered trademarks of The Purdue Frederick Company. Norco® is a registered trademark of Watson Pharma, Inc. Oramorph® SR is a registered trademark of aaiPharma. OxyContin®, OxyFast®, and Oxy IR® are registered trademarks of Purdue Pharma L.P. Oxydose™ is a trademark of Ethex Corp. Percocet® and Percodan® are registered trademarks of Endo Pharmaceuticals. Roxanol™ is a trademark of aaiPharma. Roxicet™ is a trademark of Roxane Laboratories Inc. Roxicodone® is a registered trademark of aaiPharma. Tylox® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc. Vicodin® Vicodin HP® and Vicodin ES® are registered trademarks of Abbott Laboratories. Zydone® is a registered trademark of Endo Pharmaceuticals.

Back to Active

AVINZA® (morphine sulfate extended-release capsules)

Note: Confirm the actual opioid dosage being taken per day to determine the total daily *AVINZA* dose.

Exhibit 5

PARTNERS AGAINST PAIN®

CLINICAL ISSUES IN OPIOID PRESCRIBING

Considerations for the practitioner in the use of opioids in managing moderate to severe pain

Partners Against Pain

www.partnersagainstpain.com

OPIOID PRESCRIBING

Opioids are an effective and established treatment for moderate to severe pain. Yet they are frequently underdosed—or even withheld due to a widespread lack of information and appropriate education about their use among healthcare professionals. Underuse of opioid analgesics and other treatments for pain has prompted pain expert C. Stratton Hill, MD, to declare: "All types of pain in all parts of the world are inadequately treated."*

"Clinical Issues in Opioid Prescribing" offers information on many of the most important issues related to appropriate prescribing and dosing of opioids for moderate to severe pain. Clear understanding and discussion of the concepts highlighted in this booklet can help pave the way for more effective opioid therapy in appropriate patients.

* Hill CS Jr. [editorial.] *JAMA.* 1995;274:1881-1882.

KEY TERMS IN PAIN MANAGEMENT

Addiction

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[1]

Physical Dependence

Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood levels of the drug, and/or administration of an antagonist.[1]

Tolerance

Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[1]

Pseudoaddiction

Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.[1]

Misunderstanding of this phenomenon may lead the clinician to inappropriately stigmatize the patient with the label 'addict.' ... In the setting of unrelieved pain, the request for increases in drug dose requires careful assessment, renewed efforts to manage pain, and avoidance of stigmatizing labels.[2]

Key Terms References: 1. *Definitions Related to the Use of Opioids for the Treatment of Pain.* A consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine. The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, February, 2001. 2. Cherny NI . Opioid analgesics: Comparative features and prescribing guidelines. *Drugs.* 1996;51:713-737.

CLINICAL ISSUES IN OPIOID PRESCRIBING

1	**Respiratory Depression**	*Does the risk of respiratory depression make opioids too dangerous?*
2	**Addiction**	*What is the risk of addiction associated with opioids used to treat patients with moderate to severe pain?*
3	**Tolerance**	*Does development of tolerance to opioids necessitate increasingly higher doses?*
4	**Constipation**	*When opioids are dosed adequately to control pain, does constipation become unmanageable?*
5	**Antiemesis**	*Is routine prophylactic antiemesis required for the majority of patients taking opioids?*
6	**Sedation**	*Is sedation a common side effect associated with opioid therapy?*
7	**Dosing Schedule**	*What is the most appropriate dosing schedule for controlling moderate to severe pain?*
8	**Controlled-Release Opioids**	*When are controlled-release opioids specifically indicated?*
9	**Titration**	*What are the challenges associated with controlled-release opioids in terms of initiating therapy and titrating dosage?*
10	**Parenteral Opioids**	*When are parenteral opioids most appropriate for pain management?*
11	**Plasma Opioid Concentration**	*What is the correlation between plasma opioid concentration and analgesia?*

Does the risk of respiratory depression make opioids too dangerous?

While respiratory depression is the most serious risk with all opioid agonist preparations, clinically significant respiratory depression rarely occurs in patients treated for pain, when opioid doses are appropriately prescribed, administered, and titrated to effect.[1]

The federal Agency for Healthcare Research and Quality (AHRQ), in its Clinical Practice Guideline for the management of cancer pain, states that "patients receiving long-term opioid therapy usually develop tolerance to the respiratory depressant effects of these agents."[2]

If opioid doses are gradually increased, high dosages are generally well tolerated and not associated with respiratory depression.[3] Studies in cancer patients have shown that when morphine is properly titrated against pain, respiratory failure is "neither common nor severe."[4]

Respiratory depression is rare in patients who have been receiving chronic opioid treatment. It can occur, however, in opioid-naive patients with severe pain who require high opioid doses.[5,6]

In the absence of underlying pulmonary dysfunction, clinically significant respiratory depression is rarely seen when morphine doses are properly titrated.[7] However, morphine and related opioids must be used cautiously in patients with compromised respiratory function including emphysema or cor pulmonale.[7] In patients with chronic cor pulmonale, therapeutic doses of morphine have even caused death.[7]

What is the risk of addiction associated with opioids used to treat patients with moderate to severe pain?

In a 2001 consensus document, the American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine provide the most current thinking on often-confused terminology in pain medicine. The following is an excerpt:[8]

> "Most specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders. However, the actual risk is not known and probably varies with genetic predisposition, among other factors. Addiction, unlike tolerance and physical dependence, is not a predictable drug effect, but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals. ... Addiction is a primary chronic disease and exposure to drugs is only one of the etiologic factors in its development.
>
> "Addiction in the course of opioid therapy of pain can best be assessed after the pain has been brought under adequate control, though this is not always possible. Addiction is recognized by the observation of one or more of its characteristic features: impaired control, craving and compulsive use, and continued use despite negative physical, mental, and/or social consequences."

The consensus statement also stresses that behavior that may suggest addiction is sometimes in reality a reaction to unrelieved pain or is an indication of problems unrelated to addiction.[8] Good clinical judgment

is required to assess whether or not a certain behavior set indicates true addiction or reflects other issues.[8] (For *Definitions of Key Terms*, see page 2).

Pain expert C. Stratton Hill, Jr, MD, has noted that "scientific data show that almost all patients with painful medical conditions requiring opioids for treatment discontinue their use after the medical condition for which opioids were needed no longer exists."[9]

Proper assessment of the patient, proper prescribing practices, periodic reevaluation of therapy,[6,10] and proper dispensing and storage are appropriate measures that can help limit abuse of opioid drugs.[10]

It should be noted that, among terminally ill patients with pain, concern about addiction is largely irrelevant and may interfere with proper palliative care.[11,12]

While preventing drug abuse is an important societal goal, there is consensus, by law enforcement agencies, healthcare practitioners, and patient advocates alike that it should not hinder patients' ability to receive the care they need and deserve.[13]

Does development of tolerance to opioids necessitate increasingly higher doses?

When discussing tolerance in the context of opioid therapy, it is important to differentiate between analgesic tolerance and tolerance to non-therapeutic adverse effects.

Analgesic Tolerance

"Clinical experience indicates that tolerance to opioid therapy (i.e., the continued need for dose escalation to maintain the same level of pain relief in the absence of disease progression or other external factors) does not represent a common or major impasse in pain medicine."[14]

Analgesic tolerance is an important element in the concept of opioid responsiveness.[3] If a patient complains of increasing pain which is traced to disease progression or other sources, opioid analgesic tolerance cannot be inferred.[3] Conversely, if dose escalation is required "in the absence of other obvious causes, tolerance may be the explanation."[3] Thus, while increasing dose requirements are most consistently correlated with progressive disease, stable disease does not usually require increasing doses.[2]

With pure opioid agonist analgesics, there is no defined maximum dose: the ceiling to analgesic effectiveness is imposed only by side effects, the most serious of which is respiratory depression.[2]

Tolerance to Opioid Adverse Effects

Even if opioid doses need to be gradually increased in a patient, common adverse effects may often decrease.[1] Sedation is a frequent side effect of initial opioid administration, but tolerance to this effect usually develops rapidly. Sedation may also be a transitory side effect when opioid doses are increased substantially, but tolerance to sedation usually develops quickly in these instances as well.[2] Tolerance also may develop quickly to the nausea and vomiting that can be common side effects of initial opioid therapy or when opioid doses are increased.[1]

Most patients, however, do not develop tolerance to constipation, which is a universal side effect of treatment with opioids.[2] (See the following page for a detailed discussion of opioid-induced constipation.)

When opioids are dosed adequately to control pain, does constipation become unmanageable?

While constipation is a nearly universal side effect of opioid treatment — oral, transdermal or parenteral — it can be effectively managed. Constipation is not a reason to withhold opioid pain control from patients who need it.[1,2]

The AHRQ recommends a bowel protocol for patients who may experience marked constipation when taking opioids, which includes administering a stimulant laxative agent.[2]

Oral laxatives can be taken at bedtime, and rectal suppositories used in the morning if needed.[2] Stool softeners, while not useful alone, are effective in combination with stimulant laxatives, to allow water to enter hard, dry stools. Laxatives should be taken under a physician's direction.

Is routine prophylactic antiemesis required for the majority of patients taking opioids?

While nausea can be a common side effect of opioid treatment for pain, it is usually transient and typically diminishes over the first few days of therapy.[1]

In patients taking opioids, it is important to determine the cause of nausea and vomiting.[1,2] Sometimes, and particularly in cancer patients, nausea and vomiting can result from chemotherapy or disease progression, not just from opioid therapy.[1,2]

Nausea and vomiting should be managed according to the underlying cause. As the AHRQ notes, antiemetics can be used "when patients complain of nausea after opioid administration has begun."[2]

To manage nausea and vomiting, antiemetic therapy can be administered on a fixed schedule for several days.[2] After that, the dose of antiemetic can usually be provided on an as-needed basis.[2] Ultimately, antiemetic therapy may be discontinued as nausea and vomiting is alleviated.[1,2] Relief of constipation can also help mitigate nausea.[1,2]

Prophylactic antiemetic therapy is discouraged due to associated sedation and other potential side effects.[1]

Is sedation a common and/or unmanageable side effect associated with opioid therapy?

Although sedation or somnolence is a frequently reported side effect of opioid therapy, it is usually self-limited and does not persist beyond the first few days of treatment.[1,2]

Typically, sedation occurs after initiation of opioid therapy or after upward titration to a new dose, after which tolerance usually develops.[1,6] If sedation persists, patients and prescriber can work together to titrate a dosage that balances pain relief and side effects.[6]

Sedation is a common effect when patients initially receive opioid analgesics or after a significant increase in dose. This usually improves over the first few days. In cancer patients who are taking opioid medication, there are often other possible causes or contributors to sedation such as infection, metabolic disturbance, renal impairment, dehydration, CNS involvement, or concomitant use of other sedative drugs. Underlying contributing factors should be addressed.[6]

Patients should be advised that opioids may impair mental and/or physical ability required for the performance of potentially arduous tasks (e.g., driving operating heavy machinery), and these activities should not be attempted until a patient knows how a given opioid affects alertness.

What is the most appropriate opioid dosing schedule for controlling moderate to severe pain?

In choosing an appropriate analgesic dosing schedule to treat pain, it is important to assess both intensity and duration. Duration may be reasonably predicted, as with postsurgical or postinjury pain, or may become relatively unpredictable. When choosing an effective dosing schedule, one must also consider pain intensity, often characterized as mild, mild to moderate, moderately severe, or severe.[2,6,15-17]

Any proposed systemic regimen must be individualized for the patient, and inflexible reliance should not be placed on any "standard" mixture of medications and/or dosing regimens. For patients with moderate or severe pain, opioid therapy is recommended. Once an opioid and a route of administration are chosen, the dose should be increased until a favorable response occurs or when unmanageable or intolerable adverse effects ensue.[15]

Please note that while precise definitions of many terms commonly used to characterize pain remain a topic of international discussion, those used here are taken from sources relevant to the topic of opioid dosing schedules.

Acute pain is most often associated with injury to the body (e.g., surgery, trauma, etc.); it decreases over time and resolves with healing.[16]

There is no universal agreement on when an acute pain state ends and the pain becomes *chronic*. However, the two chronologic markers most commonly used to identify pain as chronic are 3 months and 6 months since the onset of pain,[16] although these distinctions are described as arbitrary.[16] Often the cause of chronic pain cannot be removed or oth-

erwise treated and it may be associated with a long-term, incurable condition.[16]

In temporal terms pain can also be described as *persistent* — existing continuously [throughout the day] or as *intermittent*, also referred to as recurrent pain.[16] Intermittent or recurrent pain is episodic, with each episode lasting a relatively short period of time but recurring over an extended period of time (e.g., sickle cell crisis).[16] In some cases, recurrences may be separated by completely pain free periods (e.g., migraine).[16]

Opioid medications are the major class of analgesics used to treat *moderate to severe pain*, whether acute, intermittent, persistent, or chronic.[2,5]

When treating *persistent* pain that is either acute or chronic, the ideal opioid dosing schedule is one that not only relieves pain, but that also prevents it from returning.[2] The AHRQ recommends that persistent or daily pain that is moderate to severe be treated with opioids "on a regular schedule rather than only 'as needed.'" An "around-the-clock" (ATC) fixed-dosing schedule is preferred to PRN dosing because it helps maintain a constant blood level of medication, which helps prevent the recurrence of pain.[2,5] ATC "administration of analgesics allows each dose to become effective before the previous dose has lost its effectiveness."[2]

Acute persistent pain that is moderate to severe, such as initial post-surgical pain, is also best initially treated on a regular, around-the-clock schedule.[17]

For patients taking controlled-release opioids on a fixed dose, around-the-clock schedule, it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing of controlled-release opioids or to prevent pain that occurs regularly during specific patient activities (incident pain).[2,5]

Pain that does not require around-the-clock analgesia — such as an episode of intermittent pain that is mild or mild to moderate, or acute pain that is mild-to-moderate and not expected to last — can be treated with acetaminophen, NSAIDs, tramadol, or short-acting opioids.[18]

When are controlled-release opioids specifically indicated?

It is a common misconception among healthcare providers that opioid analgesics are indicated solely for the treatment of cancer-related pain.[19-24]

Use of controlled-release opioids is often not dependent on a specific disease state, but is based on the severity and the chronicity of pain. Controlled-release opioids are most often indicated for moderate to severe pain in patients requiring continuous, around-the-clock analgesia for an extended period of time, which may be weeks to months or longer. The aim is to prevent recurrence of pain by maintaining adequate analgesia.[9]

The consensus statement *The Use of Opioids for the Treatment of Chronic Pain* issued by the American Academy of Pain Medicine and the American Pain Society[25] and the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* from the Federation of State Medical Boards of the United States[10] both serve as guides for practitioners who choose to treat chronic pain with opioids.

What are the challenges associated with controlled-release opioids in terms of initiating therapy and titrating dosage?

Initiation and titration of oral opioid therapy should be individualized according to the patient's needs.[5,6,15]

Physicians should tailor treatment using a progressive plan of pain management such as one of those outlined by the World Health Organization,[26] the American Pain Society,[5] and the Federation of State Medical Boards Model Policy.[10]

In treating pain, it is vital to assess the patient regularly and systematically. Therapy should also be regularly reviewed and adjusted based upon the patient's own reports of pain and side effects and the health professional's clinical judgment.[6,10] The appropriate dose for an individual patient is one that relieves pain throughout the dosing cycle without causing intolerable side effects.

A controlled-release dosing regimen should be initiated on a patient-by-patient basis, taking into account the patient's prior opioid and non-opioid analgesic treatment. Attention should also be given to other relevant clinical factors.

- In patients already taking other opioids, convert from the prior opioid to an equianalgesic dose of controlled-release opioid, using an appropriate equianalgesic conversion guide. Provide immediate-release medication to be used prn for exacerbations of pain. Whenever possible, use the short-acting form of the long-acting, ATC opioid.[27]

- In either case, when a dose increase is needed, calculate the increase based on current total opioid dose (i.e., ATC dose + any prn doses) taken in the previous 24 hours.[27] Increase both ATC and prn doses.[27]

During any period of changing analgesic requirements, including initial titration, regular communication should be maintained between the treating physician, other members of the healthcare team, the patient, and family and/or caregivers.[2]

Once therapy is initiated, pain relief and other opioid effects should be frequently assessed in all patients.[2,6,10] Dose titration may be required periodically because of the natural history of the primary disease or the development of tolerance.[15]

Individualized care involving titration of the opioid according to response is the best way to ensure optimal treatment for each patient. Patients should be titrated to adequate effects (generally mild or no pain); patients may also require rescue doses of supplemental analagesia.[6,27]

Ongoing assessment should take place at regular intervals, when pain changes (worsens or new pain develops) and when treatment is changed.[2,6,10]

Periodic reviews should assess the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.

When the patient no longer requires therapy with controlled-release opioids, doses should be tapered gradually, to prevent signs and symptoms of withdrawal in the physically dependent patient.[5]

When are parenteral opioids most appropriate for pain management?

Parenteral administration (e.g., intravenous or subcutaneous) of opioids benefits certain patients including those requiring rapid incremental doses of analgesia, those with persistent nausea and vomiting, with severe dysphagia or swallowing disorders and those with mental status changes accompanied by impaired ability to swallow.[2] Parenteral analgesia may also be more effective for patients who need high doses of oral medications requiring large numbers of tablets and for those who have undesirable side effects after each dose of a PRN medication.[2]

Both intraspinal and intraventricular opioid administration require implantation of a permanent device. These methods are most often reserved for intractable pain that has proved resistant to all other reasonable methods[2] and routes of administration.

It is important to remember, however, that established guidelines for use of analgesics in the treatment of pain support oral administration as the preferred route.[2,5,26] Other less invasive routes, such as rectal or transdermal, should be tried when patients cannot take an opioid by mouth.[2] The AHRQ suggests that, "Parenteral routes should be used only when simpler, less demanding methods are inappropriate or ineffective."[2]

For example, in medical emergencies such as hospital admission for rapid pain control, parenteral analgesia may be necessary,[2] either by continuous infusion or patient controlled analgesia. The American Pain Society Guideline for the Management of Acute Pain in Sickle Cell Disease[28] indicates administration of either intravenous or subcutaneous opioids upon hospital admission for severe acute pain, titrated to stable pain control then dosed around the clock.[28] When it is determined that a pain crisis has passed and that a patient (with sickle cell disease or rapidly escalating pain from another illness) can be maintained at home with oral medications, the IV around-the-clock opioid

dose can be used to determine conversion requirements for an oral regimen that will maintain satisfactory analgesia.[2]

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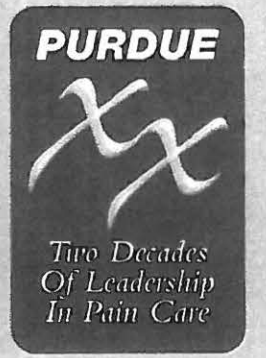

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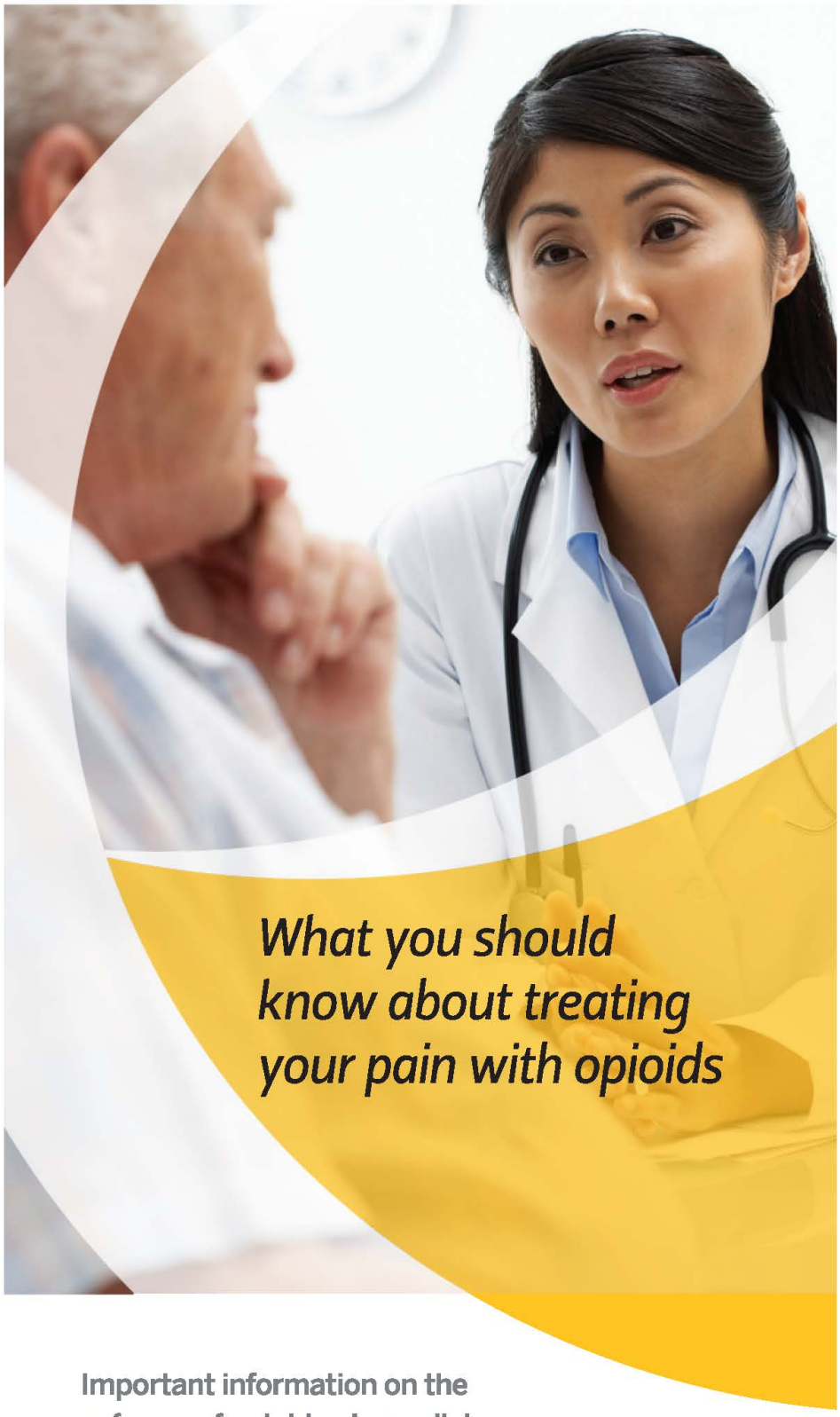

What you should know about treating your pain with opioids

Important information on the safe use of opioid pain medicine.

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If your healthcare provider has determined that opioid therapy is right for you, it is important to read this entire brochure.

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Introduction to opioids and the possible risks from taking them

Opioids (OH-pee-oyds) are strong pain medicines that are used to treat moderate-to-severe around-the-clock pain. When pain is not adequately managed by other treatments, opioids can be useful therapy; however, opioids can harm you if you use them the wrong way. The risk of harm goes hand-in-hand with the benefit of pain relief. The good news is that these risks can usually be managed and this brochure will help educate you on these risks.

Possible risks from taking opioids include:

- Adverse events
- Misuse
- Abuse
- Physical dependence
- Addiction

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What are the side effects of opioid therapy?

Opioids can help reduce both sudden (acute) and ongoing (chronic) pain. But there are some possible side effects with opioid therapy:

- Breathing problems
- Constipation
- Confusion
- Itching
- Drowsiness
- Nausea
- Dizziness

Serious side effects, such as breathing problems or death, have been associated with opioid therapy. Get emergency medical help if you have trouble breathing; shortness of breath; fast heartbeat; chest pain; swelling of your face, tongue, or throat; extreme drowsiness; or if you are feeling faint.

Your healthcare provider can help to explain and, in some cases, minimize side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or feeling sleepy (drowsiness), may go away within a few days without the need for more treatment. If you notice any side effects, you should let your healthcare provider know right away.

What are the differences between misuse, abuse, physical dependence, and addiction?

Misuse is when a prescription drug is used for relief or treatment, but in a way other than directed by a healthcare provider. Think of it as trying to treat yourself. Misuse involves taking more or less drug than needed, taking it at different times than prescribed, or taking it for a different condition. Taking a drug that has been prescribed for someone else is also misuse.

Abuse is when a drug is intentionally used to get high or relieve anxiety, and not to treat the medical condition it was prescribed for. This pattern of drug use could result in bad outcomes, such as illness, physical discomfort, or even death; failure to perform at work, school, or home; legal issues; or problems with loved ones.

Physical dependence refers to changes in the way your body responds to a drug. Long-term use can also result in your body being dependent on that drug. In this case, if you quickly reduce the dose or stop taking the drug, your body will have uncomfortable symptoms called "withdrawal."

Common symptoms of withdrawal include nausea, diarrhea, coughing, sweating, or increased blood pressure or breathing. Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your healthcare provider. You should not change your dose on your own. Speak with your healthcare provider if you feel that you need to have your medicine adjusted. However, just because you develop withdrawal symptoms if you miss a dose does not mean that you are addicted.

In some cases, withdrawal symptoms could be very dangerous. Life-threatening symptoms could include breathing problems, such as shortness of breath, shallow breathing, dizziness, or confusion. If any of these symptoms occur, call your healthcare provider or get medical help right away.

Addiction involves a group of behavioral, mental, and emotional issues that can occur after using substances for a period of time.

Who may be at greater risk for addiction?

Addiction and abuse are more likely to happen if you smoke, already have a drug or alcohol problem, or if you have used illegal drugs in the past. If you have abused alcohol or drugs in the past, you may need to work with an addiction specialist while being treated with opioid medicine. Your healthcare provider can recommend an addiction specialist to help you manage the use of opioids to relieve your pain.

Patients who become addicted to opioids will show the following behaviors, known as the **4 C's**:

- Loss of **c**ontrol over drug use
- **C**ompulsive drug use
- **C**ontinued drug use even when it damages the body, the mind, or relationships
- **C**raving

Opioid medicine has been proven effective for millions of patients suffering from severe pain. The risk of becoming addicted to your opioid medicine is reduced if you take your medicine exactly as prescribed by your healthcare provider.

There is help for people recovering from active addiction. It is important to reach out to your healthcare provider for assistance and recognize that sometimes several rounds of addiction treatments are necessary. Therefore, it is important not to give up.

Take your opioids as prescribed

Your healthcare provider will tell you how to take your medicine and how many doses you need to take.

Remember to:

- Never adjust the amount or frequency of your medicine without discussing with your healthcare provider
- Never mix your medicine with alcohol
- Always tell your healthcare provider about all medicines you are taking or plan to take, including over-the-counter medicines and supplements
- Keep track of when you take all of your medicines
- Always ask for help when it is needed

Just because your opioid medicine comes from a healthcare provider does not automatically make it safe. It is extremely important to take opioids only as instructed by your healthcare provider and never share your medicine, even with someone who is suffering from the same pain as you.

It is important to know what to expect while taking an opioid medicine. Opioids provide effective relief for many short-term and chronic conditions, but should not always be expected to completely relieve all your pain. Taking more tablets than prescribed in order to relieve all of your pain is dangerous because of the life-threatening side effects and the risk of physical dependence.

Help is available if you need more relief

You may find over time that your medicine is not working as well to relieve your pain as when you first started taking it. This may be because your body has built up a *tolerance* to the medicine.

Tolerance means that your body gets used to the medicine so that the opioid does not control your pain as well as it used to. The pain may come back sooner.

If you need more pain relief, are having trouble sleeping, or are feeling depressed, tell your healthcare provider. Treatments may be available, but a healthcare provider must always be the one to add medicine, change a prescription, or adjust the dose. Medication may be one part of the solution. Other important options include exercise and physical therapy, stress reduction techniques such as biofeedback and hypnosis, and interventional alternatives, which include injections or surgery.

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To be successful on your opioid treatment, you need a plan

Your healthcare provider will do a physical examination and may ask you questions about your illness or injury and your pain. He or she may ask about your and your family's health history, and may even collect blood samples and do other tests. With this information, your healthcare provider can talk to you about your treatment options.

Your healthcare provider will work with you to develop a treatment plan or agreement. This plan may include:

- Treatment goals
- The right way to take opioid medicines
- Information about other treatment options and specialists
- How to avoid misuse and abuse

It can be helpful to write down 2 or 3 things that pain is stopping you from doing and develop a goal for treatment. It may be helpful to discuss this goal as well as the expectations of your treatment at each visit with your healthcare provider in order to determine if your current therapy is appropriate. Use the space below to take notes.

_____

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Starting treatment

Many people start opioid treatment on a trial basis. During this time, healthcare providers can see how well the medicine is working and if you have any side effects. Most people start with a low dose of opioid medicine. Your healthcare provider may adjust that dose until your pain is controlled.

Opioids do not work for everyone. An opioid may not take away all of your pain. Treatment goals should be discussed with your healthcare provider before you begin the medication.

Monitoring

You will need to see your healthcare provider for regular checkups. During these visits, your healthcare provider will ask you how the medicine is working to relieve your pain and if you are experiencing any side effects. Your healthcare provider will also talk with you to learn if changes to your treatment plan are needed. The purpose of treatment is to make progress toward the goals you identified in your treatment plan or agreement. You should be prepared to discuss how the treatment is helping you do the things you need and want to do.

Your healthcare provider may also ask you about your use of the medicine to make sure you are taking it correctly. You may also have to provide a blood or urine sample to confirm that you are taking the medicine as prescribed. These requests are common in opioid treatment.

What to expect from your healthcare provider

Pain is a very personal experience that can be difficult to explain to other people. Many patients with pain worry that they are not being taken seriously. Your healthcare provider is used to dealing with people in pain, and he or she is trained to:

- Listen to you when you describe and explain your pain
- Understand the pain you have described
- Explain why you have pain

You and your healthcare provider will work together to determine what treatment option is right for you and to ensure your pain is treated as effectively and safely as possible.

Patient responsibilities while taking opioids

Healthcare providers have expectations of patients as well, especially those taking opioids. When meeting with your healthcare provider, be prepared to:

- Provide accurate and detailed information, including past medical records
- Discuss treatment goals and expectations
- Follow your healthcare provider's directions
- Keep all medicines safe and secure
- Agree upon a treatment plan with your healthcare provider
- Use the same healthcare provider and pharmacy for any of your opioid medicines

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Keeping your medicine safe is as important as taking it as directed

Thousands of people die every year because of opioid misuse and abuse. Drug theft is a common way people obtain prescription drugs for illegal use. People steal drugs for their own misuse and/or to sell illegally.

For people who are not prescribed opioids by a healthcare provider, taking an opioid can be harmful and, in some cases, deadly. Opioids are strong pain medicines that can cause life-threatening problems when not taken correctly.

You are responsible for your medicine and for keeping it in a safe place where it cannot be stolen.

Steps for the safe and proper storage of opioid medicine:

- Do not share your medicine with anyone
- Limit access to your opioid medicine to you and your caregivers only
- Lock your medicine in a cabinet or box and secure the key
- Keep all medicines out of reach of any children
- Do not use a bathroom cabinet because they rarely lock and are the first place any stranger or visitor in your house will look
- Make sure that you have the correct number of tablets when you get your prescription and count the number you have left on a regular basis. If tablets are missing, discuss it with your immediate family or anyone else you share your house with
- Evaluate the risk you have in your home, including such possible situations as:
  - Presence of young children
  - Presence of teens or young adults
  - Visitors or family who may have a history of drug abuse, addiction, or mental health problems
- Dispose of your unused opioid pain medicine as soon as it is no longer needed
  - Ask your pharmacist or read the disposal instructions located in the package insert that came with your medicine

Using opioids safely is important to get proper pain relief and to avoid potentially serious side effects

- When starting a new opioid medicine, discuss goals and expectations with your healthcare provider
- Take your medicine only as instructed, never take it more often
- Meet with your healthcare provider regularly to discuss how well the medicine is relieving your pain
- Keep your medicine safe and never share it with anyone else

Resources to help you safely and successfully manage your chronic pain

- **painACTION** (www.painaction.com) is an organization dedicated to helping people with chronic pain better manage their treatment
- **Opioids911-Safety** (www.opioids911.org) offers help for safely using opioid pain relievers

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Exit Wounds

A Survival Guide to Pain Management

for Returning Veterans and Their Families

By

Derek McGinnis, U.S. Navy veteran, Iraq War

Brenda Murdough, MSN, RN-C

with Stephen R. Braun

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Foreword by Chester "Trip" Buckenmaier, MD, Walter Reed Medical Center

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Resources

Introduction

Pain is a powerful thing. It changes everything. Your whole life is altered to accommodate it. In military hospitals all around the nation I witnessed strong young infantrymen, medics, and snipers buckle under its crushing weight. Exhausted emotionally and physically they cried out in pain.

— Captain Jonathan D. Pruden, US Army, Iraq veteran, amputee

Hope

Pain is tough. It can be a sneaky, elusive, stubborn, and sadistic enemy. If you or a loved one has battled chronic pain, you already know this first-hand. This book is a weapon against pain. It is a tool—the only tool currently available—that is specifically designed for the unique needs and perspectives of veterans of the wars in Iraq and Afghanistan and their families. In these pages you'll find hope. Hope that the pain you or a loved-one is feeling can fade or disappear. Hope that you can regain lost function, frayed relationships, and lost happiness. It's possible. How do we know? Because we've seen it with our own eyes, felt it in our own lives.

In this book we will speak with a single voice—"we"—most of the time because the information here is based on both of our experiences and skills (as well as leaders in the field of pain medicine). But we want to introduce ourselves individually here:

Derek: I was serving as a Navy corpsman with the Marines 3rd Light Armored Reconnaissance Battalion in Iraq. During the second battle of Fallujah in November, 2004, my Humvee ambulance was hit with an IED that nearly killed me and wounded several others in the vehicle. I was saved by the tremendous skills of many military doctors, nurses, and others—many of whom I have never met. But my recovery was hell. I experienced pain beyond anything I had previously endured. There were times, as you will see, that I gave up, gave in,

and sat down. But those were temporary setbacks. I kept fighting, and, today, I am blessed with as full and satisfying a life as I could want.

The first chapter of this book is my story. It is told in third-person for two reasons. One is that because of the brain trauma I sustained from the explosion, I don't have any memory of the first month or so of my recovery—so I can't tell that part of the story myself. But, also, although it's my story, it's not just about me. My wife, my folks, and others who supported me are vital pieces of the story too. Their voices deserve to be heard too, because, again, this book isn't just for vets—it's for those who love and support them.

I hope that by telling my story with as much honesty and detail as I can, that others will gain understanding, comfort, and hope. My fundamental message is: if I can do it, so can you. But you can't give up. Never give up. No matter how bad things seem to be, there's always hope, always a way to move forward, even if you can't see it right now.

Brenda: Like Derek, I know that hope is real. For the past decade I have worked as a clinical nurse specialist in pain management for the Dartmouth-Hitchcock health system in Keene, New Hampshire. I treat patients in pain every day—and I've learned first-hand how pain can be controlled, subdued, and successfully managed.

I also know what it's like to have a child go to war. In fact, more than that--I'm as engaged with the military as a person can be without actually serving. Let's start with my son, Robert, who served 15 months in Iraq. My brother, Michael, served in Operation Desert Storm. My Edward is a retired Army colonel. My sister's two daughters are both the military, one recently returned from Afghanistan. These deep connections have taught me a lot about the role of family members in the support of returning service members. I know that things are rarely as easy or simple as they may seem on the surface. I know the stress of having a love-one deployed. I know that the emotions surrounding separation and reunification can be complicated and contradictory. And I've seen first-hand the many ways that military attitudes—which are so critical and helpful on the battlefield—can become roadblocks or landmines on the home front. I feel very fortunate to be involved in this book. I hope that by sharing some of the lessons I've learned in the clinic and my own life others will get the help they need to manage their pain and return to their lives.

Why This Book?

We are writing this book because both of us want passionately to help those who have given so much to our country and whose pain is so often un-recognized or inadequately treated. We both have seen too much unnecessary pain—and not just among veterans. The problem of inadequate pain treatment is just as acute in the civilian world. But seeing veterans in pain is particularly wrenching because these men and women willingly put their lives on the line in defense of ideals that many civilians take for granted. Nobody deserves to be in pain, but all of our veterans have an extraordinary right to be free of disabling pain. They have a right to the best possible treatments, the highest standards of care, and the most comprehensive of services.

The military health care system has taken great strides in recent years toward these goals. Is it perfect? Of course not. But it is far better than is often portrayed in the media, and every day the knowledge of effective, innovative pain management practices spreads a little further among the clinicians working in these massively complex federal health institutions.

We don't want to sound naïve. We are perfectly aware that the VA, the military hospitals, and the many other health care systems tied to the Department of Defense have their weaknesses and limitations. But we are convinced that, armed with the information and tools provided in this book, you or a loved one can achieve the goal of reducing your pain and improving your function. Here, without jargon or needless technical details, you will learn about the different types of pain and the many treatment options that now exist to deal with it. You'll see that beating pain is about much more than pills, or IVs, or surgery. Pain is complicated. People are complicated. The strategies you use to combat pain must, therefore, address these complications. Your strategy must be flexible, tailored to your specific needs, and broad enough to cover both mind and body.

In addition to laying out the facts about pain and providing you with new knowledge, we hope this book instills in you an appropriate attitude toward pain management. You will hear us say this more than once in this book: *you* are the real key to success. Your doctors cannot simply cure you or heal you with a wave of their medical wand. You should view your doctors as expert consultants who offer their skills and recommendations and who will work with you at every step on your journey to overcome pain. But, in the end, you are in command and the responsibility for your success rests, ultimately, on your shoulders.

Your mental and emotional attitude is a critical component of your mission. You will need to call upon the courage, discipline, and drive that your military training instilled in you. You will need to advocate for yourself, or for a loved-one, fight for the attention and treatment you deserve, and persevere even when progress seems slow or non-existent. If you stick with it and don't give up, we are convinced that your ultimate victory is assured.

The Big Picture

In the civilian world, complaints about pain are the #1 reason people go to the doctor. Pain affects more Americans than diabetes, heart disease, and cancer combined. The same facts apply—with an even greater urgency—to the men and women returning from military operations in Iraq and Afghanistan. A recent study of soldiers enrolled in VA Polytrauma Centers showed that more than 90% have chronic pain, that most have pain in more than one part of the body, and that pain is the most common symptom in returning soldiers. One reason the incidence of pain is so high is that more servicemen and women are surviving very serious wounds, thanks to improved body armor and advanced medical care in the field.

The statistics on pain are sobering when you consider that more than 33,000 soldiers have been wounded in action thus far in Operation Enduring Freedom and Operation Iraqi Freedom. And that's just the visible tip of the iceberg. To date, roughly 1,350,000 men and women have been deployed to Iraq or Afghanistan. Without question, a significant fraction of this population are either suffering now, or will be suffering in the future from injuries not severe enough to count as "wounds."

Throughout this book we will emphasize the importance of getting help for pain as rapidly as possible. Research shows that unrelieved pain, regardless of its initial cause, can be an aggressive disease that damages the nervous system, and causes permanent abnormal changes in nerves, the spinal cord, and the brain. We now know that it doesn't take long for pain to become "hardwired" in the body. When it does, the consequences are serious, both for the person in pain and those around him or her. People with untreated or poorly-treated chronic pain cannot live the lives they want. Their pain and their constant search for relief affects their function, their relationships with those they love, their ability to work effectively, and often their self esteem. Chronic pain is often accompanied by or leads to sleep disorders, emotional distress, anxiety,

depression, and even suicide. Tragically, in 2007, 115 soldiers killed themselves, which is the highest suicide rate since the Army began keeping statistics in 1980.

Complicating the care and treatment of wounded veterans is the fact that pain is often poorly understood by those who suffer and by those around them. Pain is even misunderstood by many health care professionals. Unfortunately, the science of modern pain management is still relatively young That means many physicians never learned pain management in medical school and have not been able to keep abreast of all the exciting developments that have taken place in the field over the past decade. By reading this book, you may be learning things that are unfamiliar to your health care providers!

A Larger Project

Exit Wounds is just one piece of a larger project by the American Pain Foundation. The overall mission of the APF is to improve the quality of life of people with pain by raising public awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. Several years ago the APF began a specific push to reach out to veterans and members of the military precisely because of the pain statistics we have just been discussing. The APF has also been lobbying hard on behalf of veteran for more and better treatment of pain. Encouragingly, in the fall of 2008 two major pieces of legislation were signed into law that will do just that. The bills call for the establishment of a pain care program in *all* inpatient Veteran's Administration (VA) facilities and requires the VA to provide the necessary pain management for long-term chronic pain disabilities. The law will also require providing education and training to VA healthcare professionals on how to assess and treat pain, as well as increasing research on pain care.

The APF is also supporting a valuable extension of the book you have in your hands. A special website companion to this book has been created (www.exitwounds.org), which contains more detailed information about most of the topics we cover. You'll find extensive resources about types of pain and specific pain treatments, which would be too cumbersome to include in the book itself.

Finally, a word about the title "Exit Wounds." It's a nice punchy phrase, of course, but it shouldn't be taken literally. Obviously some returning vets *are* in pain from wounds that involved projectiles that entered and exited the body. But that's not the point. The title is meant to convey

the point that the book is concerned about wounded veterans who are “exiting” the war and entering life back home. Our goal is to give you the information—and the inspiration—that you need to “exit” from any pain you or a loved one may be in. And we’ll begin that process in the next chapter with Derek’s story, which will introduce and vividly illustrate so many of the main ideas of this book.

Chapter 1
To Hell and Back

It is late August, 2008. An American flag flies from a short pole mounted to the front of Derek's house in the small town of Waterford, California. On one wall of his office in that house are three glass-faced triangular frames, each holding a folded American flag that had been used in the military funeral of Derek's two grandfathers and a step-grandfather. On another wall of the office, pinned wide, is a flag covered with hand-written notes from 19 of his Marine buddies. And when he sees a house or a building displaying the flag, as he drives his red Ford F-150 pickup down the quiet streets of Waterford, he says, almost to himself, "That's nice…nice to see that respect."

Flash back to a chilly March evening three years earlier. Derek was in a wheelchair, rolling himself along a path on the sprawling grounds of the National Naval Medical Center in Bethesda, Maryland. It was dusk, and a Navy sailor was lowering the flag from a pole—a ceremony called "evening colors." A sailor himself, Derek knew perfectly well that he was expected to stop, face the flag, remain silent, and salute until the "carry on" signal was given. What Derek did next, therefore, testifies to the brutal power of chronic pain to grind down a human soul.

"I was coming back from a meeting were nobody was listening to me," Derek recalls. "And I was in such pain…nothing they were doing was working. And I'm just pissed, I'm like, 'fuck it, fuck this place, I'm outta here.' It was my lowest point…and it was something I would never do normally, because you think of all those people who have gone before you, and they fought for that flag, and that's what colors is all about, thinking about the people who have gone before you. But I didn't stop. I just rolled right through colors and went inside."

This is the story of how Derek came back from a point where he no longer cared about one of the most sacred things in his life, overcame the pain, and returned to life.

California Boy

Derek grew up in Hayward, California, a suburb of Oakland on the eastern side of San Francisco Bay. He was a natural athlete and took up skimboarding, surfing, and skateboarding. In school he played defensive end and tight end on the football team, and played defense on the soccer team. But track was his favorite sport. "I liked track because it was individual," he says. "You're kinda fighting yourself, trying to beat yourself."

When he would focus on something--"lock on" as he likes to say--he was tenacious. He locked on to biology, for example, and got A's. But, aside from sports, his friends, and his sweetheart Christie, he didn't lock on to much in school. By his junior year, Derek was feeling aimless and itchy.

"I didn't know what I wanted to do with my life," he says. "I knew I wasn't ready for college. But I wanted to leave the house, get my independence, do my own thing."

With veterans on both sides of his family, Derek saw the military as a logical and natural choice. He wanted to go for the Marines, but his mom, Barbara, was pushing hard for him to learn a skill in the military that he could build on when he came out. The skill Derek wanted to learn was emergency medicine. Problem was, the Marines have never had their own medical corps like the other branches of the military. As an advance attack force that had evolved out of the Navy, the Marines have historically relied on Navy corpsmen who train and fight with the Marines. In the famous photograph of Marines raising the US flag on Iwo Jima in World War II, one of the six men, John H. Bradley, was the Navy corpsman assigned to that platoon.

So Derek chose the Navy because corpsman training was more extensive than the training given to medics in other branches of the military. Also, there were the beaches.

"I mean, I'm from California, right?" he grins. "I don't want to end up in the middle of nowhere, and the Navy bases, heck, there're always on the water, on a beach somewhere, which was cool."

So Derek locked onto a career in the military. It was 1996, five years after Operation Desert Storm drove Saddam Hussein's Iraqi troops out of Kuwait. Saddam had been whipped good…though not driven from power. The US was at peace. In New York City, the twin towers

were simply taken for granted; an everyday part of the skyline. The chance that Derek would ever see combat, much less be wounded, seemed remote.

Sailor

It was still dark in early hours of July 2, 1996, when a Navy recruiter picked up Derek at his home and drove him to the airport for the flight to boot camp. Derek already looked the part…his good friend Tim had shaved his head several days before.

He flew to the Navy's Recruit Training Command on the shore of Lake Michigan, about 30 miles north of Chicago. There he began an 8-week transformation from civilian to sailor.

"They break you down, take away your individuality," Derek recalls. "Then they bring you back up as a team. The whole mental game to get the team working. Your culture changes, your vocabulary changes, everything changes. Still to this day I say 'hatch' for 'door' and 'head' for 'bathroom'."

Derek readily accepted the changes. It didn't take long, however, for him to realize that his lack of a college degree was a liability.

"So, in boot camp, you're on the very bottom rank, right?" he says. "And you're looking up the ranks, at the officers, and thinkin' man, all he did was go to school for 4 years and he can be an officer? Man, I can do that.' I wanted to be the officer, you know? I want to be in charge. But I'm there scrubbin' toilets. So I'm thinkin', 'this sucks…I should have gone to college'."

He locked on to a new goal: a college degree. But before he could start taking courses, he had to become a corpsman. After boot camp, Derek flew to the Naval School of Health Science in San Diego to begin his training. It was hard academic work—classes in anatomy, physiology, pharmacology—of a caliber he hadn't experienced before.

"You really had to focus, because this was a big deal," he says. "If you don't stay engaged, or do well, they kick you out and you go back into the fleet…you're a regular seamen. So I was really nervous."

When he wasn't studying, he was surfing with his buddies or enjoying "liberty" in San Diego and Tijuana, just over the border.

"It was cool…here I was, back in California, and now I was with some close buddies from boot camp," he says. "So you have that sense of unit integrity and culture. You do PT

together, chow together…it's your family. You get into trouble together and get out of trouble together, you know? We had some crazy good times down there."

Derek pulled through with decent grades and graduated as a Navy Corpsman, level HC3, in January, 1997. He then moved on to Camp Pendleton, north of San Diego, for three months of additional training to join the Marines as a Fleet Marine Force Corpsman.

"Some guys didn't want to go with the Marines," he says. "But, for me, I was good to go, locked on. It was awesome training. You're doing major PT, humpin' 12-mile patrols with gear, doing weapons training, field emergency care, land navigation, night operations--everything to get you to have the stamina and mentality and knowledge of a Marine. Because if you're not up to that level, you could fail the mission."

The mission

After his training with the Marines and for the next four years, "mission" was a metaphor for "personal goal" not a battlefield order with life-or-death consequences. He made steady progress toward his bachelor's degree, taking courses whenever, and wherever, he could. He worked in military medical clinics in California, Guam, Spain, and Hawaii. He married, and soon divorced, his high school sweetheart.

"I wanted to see the world, have an adventure," he says. "So I sort of choose military service over Christy."

When his five years of service were up, he re-enlisted for another five years. And, in 2001, he fell in love with a pretty Navy servicewoman named Andrea O'Malley. In the summer of 2004, they were married in a luau ceremony on his favorite surfing beach in Hawaii, where they were both stationed at the time. Two months later, Andrea was pregnant with a son, whom they named Sean Patrick even before he was born.

Then "mission" took on an entirely new—and menacing—significance. It was late summer, 2004. Operation Iraqi Freedom had stalled. A year after "shock and awe" and the toppling of Saddam's statue in Baghdad, Iraqi insurgents aiming to destabilize the government and pressure the US to withdraw had re-organized and begun a series of deadly attacks using Improvised Explosive Devices (IEDs)—bombs strapped to a body or a car and detonated to inflict maximum carnage.

The Marine 1st Division was in Iraq, and they needed corpsmen. In Hawaii, word went out: corpsmen could volunteer for a 7-month deployment, or they could wait to be ordered to deploy.

"Andrea and I sat down and talked about it," Derek says. "They were hurtin' for corpsmen, so we knew I'd have to go at some point. If I volunteered, I could be home for Sean's birth. It was a hard call. I wanted to be there for Andrea, of course, but I also wanted to do my job, do my duty, get the job done and get home. And I wanted to be with the Marines, on the offensive. I felt it was my time to do what I'd been trained to do."

Andrea, who had already served a stint in Iraq and Kuwait coordinating purchasing and logistics for the Navy, was equally torn. She knew what it meant to serve, knew Derek's desire to help out…but she was pregnant, dealing with bouts of morning sickness, and afraid of what Derek might face in Iraq.

"I had really mixed emotions," she says. "I had a really horrible feeling about his deployment from day one. I don't know why. I knew things were getting worse in Iraq, and knew he'd be in an infantry unit on the front line. I guess I just assumed the worst."

In the end, she agreed that he should go sooner rather than later.

Like Andrea, Derek's parents were worried, but they were relieved when he told them his orders were to serve far from Baghdad in a small hospital near the Syrian and Jordanian borders. When they learned that Derek would need a month of combat-readiness training at the 29 Palms Marine base in the southern California desert, they decided to fly down to see him before he shipped off to Iraq. On the visit, Derek showed them the 14,500-pound Light Armored Vehicles (LAVs) that were the mainstay of the Marines 3rd Light Armored Reconnaissance Battalion (3rd LAR), in which he would be imbedded. And he showed them his gear and the Kevlar body armor that would protect his chest, abdomen, and groin.

"So I put on his helmet and the flak jacket," Barb says. "And it was heavier than heck…but I'm thinking to myself, what about the arms? What about the legs? I wanted the knight suit, you know?…the full suit of armor."

After the brief visit, Dave and Barbara flew back home, worried, but determined to do what they could to support Derek.

"Our goal was that he would receive the most mail and the most care packages of anybody," Barb says. "So we sent out 250 letters to all our family and friends asking them to write to Derek. We wanted him to be bombarded with mail."

Before dawn, one day in early September, Derek climbed on a bus at 29 Palms to begin the trip to Iraq. His parents had left, and Andrea was in Hawaii, so he said no goodbyes himself. But for many of the Marines getting on the bus, 29 Palms was home to girlfriends, wives, and children.

"It's a pretty sad scene," Derek recalls. "All the families that are living there are saying goodbye and giving hugs, and it's dark, early in morning. Then you're on the bus, and it takes off. It's dark inside, dark outside. Everybody's in full battle gear, ready to go…you've got your weapon—I had a 9 millimeter pistol. And the bus is dead quiet, everybody just thinking to themselves…it was the quietest thing you've ever heard."

Fallujah

The initial mission of the 3rd LAR was to provide security and patrols in the enormous Anbar Province of western Iraq. Anbar is roughly 50,000 square miles of high, windswept desert, cultivated here and there with wheat, corn, vegetables, and other crops. After a series of flights to Kuwait, a bus convoy into Iraq, a flight on a C-130 cargo jet, and finally a helicopter flight, Derek landed in a tiny village near the Syrian border hundreds of miles west of Baghdad. The Marines had established a forward operating base just outside of town. The base—a motley collection of huts and improvised shelters—was surrounded by high dirt berms and guarded by short watch towers.

For the next three months Derek worked in the Battalion Aid Station (BAS)—where wounded Marines were brought directly from the field. Marines with minor wounds would be patched up and sent back. Those with serious injuries would be stabilized, if possible, and air-lifted to the nearest military hospital. If they needed more advanced medical attention, they would be transferred to Landstuhl Medical Center in Germany, which is the largest military hospital outside of the continental US. But at the time Derek arrived, the BAS was quiet. There were no battles going on…in fact, the Marines stationed there were mostly engaged in "hearts and minds" missions; helping re-build infrastructure, provide security, and restore trust levels with local Iraqis.

Within the base, Derek was relatively safe. The danger lay whenever he and the Marines went beyond the berms on supply runs or patrols—which was frequent.

"I got there right when the use of IEDs was really starting," he says. "On patrols we'd alternate our speeds to make it harder for them to time when to trigger a bomb. Everyone was constantly scanning for the trigger man."

Derek went along on many small-scale missions to clear specific buildings of suspected insurgents, but it wasn't until he made a supply run to a sister BAS that he encountered real casualties.

"When we got up to their forward aid station it was extremely busy, lots of casualties coming in, and that's when you realize…damn…this is for real," he says. "And I saw some marines standing around three pairs of boots, each with an M-16 and a helmet, and I knew they'd lost their buddies. But you're thinking, 'that's not gonna happen to me, I'm not gonna get hurt or injured,' And then you just start thinking about other things…training, talking to your buddies and telling stories, and try to forget about it right away. You don't want to dwell on that shit…you focus…you're good to go."

The next few weeks were a blur of patrols, tending to minor injuries from accidents around the base, and building the bond between himself and the Marines under his care.

"You know, the majority of the job isn't healthcare," he says. "For me, it was more about talking to the guys, letting them talk to you. They want somebody to ask them how they're doing, you know? Because most of the time it's just people telling them to 'do this, do that, do this.' So I'd go around and just say 'Hey man, how's it going? How're your feet?' Because that's big…you gotta take care of your feet or you can't march, you can't walk, you're worthless. And it's a conversation starter, really…you end up being like a counselor to the guys."

He also took time to talk and sing into a portable tape recorder, sending messages both to Andrea and Sean. Back in Hawaii, Andrea would listen to the messages and then put the speaker of the tape player on her belly, so that Sean would hear the sound of his father's voice.

Then rumors of a new mission began to circulate through the base. Fallujah was heating up again. After being initially secured by US forces and turned over to the new Iraqi army, Fallujah had disintegrated into chaos. It was now home base for insurgent activity. Rumor was that the US would attack Fallujah again…soon. That would mean urban warfare—house-to-house, close-quarters fighting against an enemy impossible to distinguish from ordinary Iraqi

civilians. US airpower and advanced technology would help in a battle like this, but, in the end, the job would fall to individual soldiers picking their way through a dense warren of buildings. It was the most deadly kind of warfare an infantryman—or corpsman—could face.

In the first week of November, Derek was swept up in the most massive deployment of US forces since the war had begun. Four Marine regiments and two Army regiments prepared to attack Fallujah from the north. The 3rd LAR would attack early, from the west, both to distract the insurgents and secure a key position: a hospital and three nearby bridges spanning the Euphrates. As he was moved, in stages, from western Anbar Province to a position just outside of Fallujah, Derek learned that his specific mission would be to provide care to the Marines attempting to seize the hospital. During the fight, he would be expected to drive an un-armored ambulance—basically a Humvee rigged with four stretchers in the back—into a live battle to pick up wounded Marines, stabilize them, and bring them back to a Forward Aid Station.

On the night of November 7, Derek was at the station, waiting. It was nearly pitch black because the US had cut electricity to Fallujah. Suddenly, the sky blazed as the initial air bombardment of the city began.

"It's pure dark, then all of a sudden you hear the rocket fire and see the explosions and hear the planes and missiles going right over your head. We could see that Fallujah was getting hammered."

The next day, platoons from the 3rd LAR began advancing on the city, but the main invasion wasn't to begin until the 9th, so all Derek could do was check and re-check his supplies, monitor the radio, and prepare as best he could.

In the pre-dawn of November 9th, the invasion of Fallujah began in earnest with all regiments attacking from north and west. At around 10 a.m. the radio in the aid station crackled with an urgent request for a corpsman and ambulance. Several Marines from 3d LAR had been hit near the hospital with shrapnel from an exploding 82mm mortar round.

"I say, 'OK, let's go guys, let's go, we got casualties'," Derek says.

He grabbed an M-16 and hopped into the passenger seat of the Humvee ambulance across from the driver. As they roared down the road, Derek had his M-16 in his right hand, sticking out the window, and the radio in his left hand. A new order came through the static: an LAV had been hit with an IED and several more Marines were injured…Derek was to link up with a convoy of LAV's and another ambulance to transfer wounded. They were driving north, toward

the Euphrates, and a line of Iraqi civilian cars were pulled to the side of the road to let them pass. Concentrating on the radio, and the map, and the welter of orders coming over the radio, Derek had no time to wonder if the civilians he was passing were innocents or insurgents.

"We were just driving down the road," he says. "I could see activity up ahead, and I was on the radio. I had just turned to tell the driver to speed up or something…and…BOOM… I got blown up. That's the last thing I remember."

According to an account written by his Captain, Matt T. Good, Derek's ambulance was hit on the right front side with an explosive-laden silver Mercedes Benz. The driver of the Mercedes was killed instantly. The explosion severed Derek's left leg above the knee, severely fractured his right foot, sent shrapnel ripping through his arms, neck, left leg, both eyes, and his mouth, and slammed his skull so violently that the right side of his brain shut down, paralyzing the left side of his body.

Emerging from the rear of the mutilated Humvee, himself wounded with shrapnel, was Derek's fellow-corpsman Ed Ronquillo. Seeing Derek's leg injury, Ronquillo immediately crawled over to him and applied a tourniquet, which staved off immediate death.

"The sights and smells that I encountered as I ran up to the ambulance will be with me for the rest of my life," Commander Good wrote. "I saw corpsman Ronquillo treating Derek's wounds. Derek was in shock. I'll never forget his eyes as he lay there. I'll never forget the cold feel of his hands and forehead as I tried to comfort him. I'll never forget wondering if it made me a bad man to lie to him in my efforts to bring him peace. Ronquillo was sobbing and working furiously."

The battle of Fallujah would rage for another two weeks and "mopping up" operations would take months longer. Fifty-one US servicemen would die in the battle, and 425 would be seriously wounded. An estimated 1200 insurgents were killed and the operation succeeded in returning civilian governance and a sense of security to the city.

But, for Derek, the external battle had ended. The internal battle had just begun.

Waiting

Derek, Ronquillo, and the other wounded Marines were taken back to the Forward Aid Station, then immediately transferred to the Baghdad military hospital. Derek's wounds were so

severe and life-threatening that he was quickly transferred to Landstuhl. His gravest threat was not his leg, but his brain. As with any other tissue, the brain swells when it is injured. Encased in the skull, however, the pressure can permanently damage parts of the brain that were initially un-injured. If the swelling hits the brainstem, which controls breathing and heartbeat, Derek would die quickly.

The doctors in Landstuhl drilled a hole in Derek's skull to relieve as much of the pressure as possible and inserted a drain tube there. They also cleaned and sutured his many wounds as best they could. For what remained of Derek's left leg they applied temporary treatments and dressings. Amputations due to combat wounds are left open at first because they are often heavily contaminated with dirt, debris and shrapnel, and premature closure would increase the risk of infection. In addition, it can take days for tissue to show signs of necrosis (tissue death), hence the limb is left open so that dead tissue can be surgically removed prior to closure.

While the doctors in Germany were working on Derek, notification of his injury was sent to the Naval Support Center in Millington, Tennessee. There, if fell to a Navy Lieutenant to pick up the phone and dial Andrea's number.

"It was about 4 a.m. Hawaii time when the phone rang," Andrea says. "The lieutenant told me Derek had been hurt, that he'd been hit by an IED and that he was in Germany. I asked him how badly Derek was wounded, but he said he didn't know…that he didn't have any more information."

Andrea hung up, shaken, and immediately called her mother, Kathy, in Arizona.

"I talked to my mom for a long time, and just cried…because of course you assume the worst," she said.

As soon as she thought someone would be in the office, Andrea drove to the base.

"I walked right up to my master chief's office and said, 'master chief, I just got a phone call that Derek got hurt' …and I remember saying 'I don't care if he doesn't come home with any legs, I just want him to come home'."

She returned home, and as the news spread, friends and the wives of her commanders came to be with her as she waited for more news. Meanwhile, her mother, assuming that Andrea had called Derek's parents with the news, called Barbara, who was getting ready for work.

"So the phone rings, and it's Kathy, who I hadn't seen since the wedding," Barbara says. "And so I'm all cheerful and say, 'oh, hi, how are you doing?' And she asks me how I'm doing

with the news about Derek…and I say 'what news?' So she tells me… I just sat down on the floor and broke down. You break…you totally break. That's the only way I can describe it."

Barbara pulled herself together enough to call a girlfriend so she wouldn't be alone, then call Dave, who hadn't yet gotten to work. And then she called Andrea, not only out of concern for her, but out of a powerful need to protect what might be her most tangible link to Derek.

"This is going to sound weird," Barbara says, "But at that point, all I knew was that Derek was either dead, or could die. And so my main concern shifted to Andrea and Sean Patrick. I was afraid she wouldn't go to term, and then I'd have nothing. I had to help that baby. Because Sean had part of Derek in him."

Hours passed. Then, around noon in Hawaii, a friend of Andrea's who worked in the intelligence wing of the Army managed to find the name and phone number of the doctor in Germany who had treated Derek. His name was Major Mann. Andrea immediately picked up the phone. To this day she has kept the scrap of paper on which she furiously scribbled while Dr. Mann gave her the status report:

Breathing machine
Hit in head
Eye surgery, drops in eyes
Monitoring intracranial pressure
Face peppered with burn injuries
Shrapnel in neck
Lower arms injured, bandaged
Antibiotics
Lower left leg amputated

The doctor said there was no way to tell yet how serious Derek's brain injuries were, nor whether he would ever see again.

When Andrea called Dave and Barbara to relay the news, Derek's older brother, Trevor, answered. He can come as soon as he heard the news and was now fielding the calls of sympathy and support than were flooding in.

"I told Trevor the list of injuries," Andrea says, "and he said, 'hold on, I'll go tell Barb and Dave'…and then I heard Barb's scream…"

Dave recalls the moment vividly. "When Andrea told me about Derek's leg…I'm, like, well…ok…people have prosthetics," he says. "Then she talked about lacerations on his arms, and that they weren't sure if he was going to be able to keep his hands…and that was devastating…because he could get around without his leg but you can't replace his fingers."

Barbara, who says she had "melted on the floor" once more, was worried about other things.

"For me it was his eyes," she says. "And the burns…in my head…all I could think of was Kentucky fried chicken…that's what I thought he was going to look like."

Andrea caught a red-eye flight to California that evening, and for the next four days they waited, getting daily updates, hoping for the best, fearing the worst. Finally they got the call that Derek was being transferred from Germany to the Navy's primary hospital in Bethesda, Maryland. The Navy took care of all the arrangements to fly Andrea, Dave, and Barbara to Bethesda, and to set them up for an indefinite stay.

It was after midnight when they finally reached the hospital and took the elevator up to the ward where Derek lay. A nurse greeted them and told them Derek was sedated, doing OK. He was in a room with another wounded soldier, in the bed closest to the window, surrounded by a curtain.

Dave and Andrea went first.

"I don't know if I was holding her up or if she was holding me up," Dave says. "We came around the certain and I saw him and thought…he's OK…it's Derek."

Derek was laying back on a pillow, a week's growth of beard on his face and battlefield dirt still under his fingernails. He looked sunburned, with "raccoon eyes" from where his goggles had protected his skin from the blast.

"He looked much better than I thought," Andrea says. "Because the doctor had told me so many awful things…burns on his face, so I'm thinking he's going to be disfigured or something, but it was just these little pepper burns. He was really skinny, and his left leg was really swollen…it was like a foot wide. Both of his arms were bandaged up past his elbows."

There was no question, by this time, that Derek's body would survive. The unknown was whether Derek himself—his memories, personality, and abilities—was still alive in his seriously damaged brain.

Hero

For the next month, except when he was in surgery, somebody who loved Derek was always by his bedside. Andrea's parents Kathy and Steve O'Malley arrived on November 16. They took the night shift while Dave and Barbara took the daytime. This allowed Andrea, now 26 weeks pregnant, to come and go as she pleased.

Very quickly, Derek began waking for short periods. His entire left side remained paralyzed, he could barely see, and he was on a powerful cocktail of opioid pain killers, antibiotics, and anti-seizure medications. He couldn't chew or swallow solid food because of lacerations to his tongue. But he was alive, he could speak, and he seemed able, at times, to understand others. But he was also, often, utterly confused, incoherent, or agitated.

On November 18th, Andrea wrote in a diary she began to keep:

> *He tried to pull his catheter out and was yanking on this drain tubes. I couldn't control him. He kept yelling 'hello' trying to get help. He'd pull the curtains back. This was all at about midnight or so. After he calmed down, I went in the waiting room to let him sleep. Turns out he was up doing that all night. The doctors all say not to worry, that they see this every day and it's very normal. I'm scared he's going to hurt himself, especially when he kicks his injured foot at the end of the bed.*

As the days passed, however, Derek's mind slowly cleared. He recognized Andrea, his parents, his brother, and his in-laws, though it wasn't clear he knew that Andrea was pregnant. And he could even be funny. On November 19th, the Commandant of the Marine Corps visited Derek and other wounded Marines. He was a four-star general and most people treated him with reverent dignity. Derek, however, was in rare form when the general came to his bedside.

> *Derek was absolutely hysterical! Grinning from ear to ear! When he found out that the General used to be stationed in Hawaii, Derek bursts out with a huge smile and tells him they most definitely have to go surfing together, go do a luau, just hang out on the beach! Golf too. The General was laughing and asks Derek, as far as golf goes, if he as any handicaps. And Derek says, "Oh yes, sir, many…" So everyone is laughing.*

Moments of hilarity, however, were rare. The day before Thanksgiving, he got an infection, his body swelled with fluid, and he spiked a high, dangerous fever. He was rushed to the ICU and pumped full of antibiotics. It was a close call, but the antibiotics worked, his fever cooled, and the swelling subsided.

Derek was also dealing with periods of intense pain. It wasn't that he was getting poor care—he and his relatives all praise the care he got at this time—it was simply that he was recovering from massive wounds which required frequent interventions that re-stimulated his nerves. For example, every three days he underwent a "washout" of all his wounds and the remaining part of his left leg. This involved cleaning and removal of any dead tissues. Although he felt nothing during the actual procedures, the disruption of the tissues would send massive bolts of pain shooting through his body which even the heaviest doses of morphine were unable to dull.

"He'd come out of the washouts in so much pain," Andrea recalls. "I remember going with him into pre-op one day, and he told me, 'why are you doing this to me? I just want to die.' Because I don't think he understood what was going on. All he knew was that he was in a lot of pain."

Most of the time, however, the medications did control the pain, though that left him sometimes in an opioid-induced fog. At one point, for example, Derek looked up at a nurse tending to him and asked her if people were going to spit on him when he returned home, as some people did to returning Vietnam vets. "No," she assured him, "You're a hero."

One day President Bush visited the ward to personally hand out Purple Hearts. Derek did not yet have a prosthesis, and he still had metal pins in his right foot to help it heal. He wanted to be able to shake the President's hand, so he spend all morning practicing standing up, using Andrea as a crutch. A picture on the wall of Derek's office captures the moment, later that day: Derek, thin, but smiling, being held tight by Andrea as he and President bush shook hands.

In early December, things were looking up. His remaining left leg was finally closed and it began to heal. The doctors did not expect him to need further surgery. He also had successful surgery to repair the cornea and lenses in his eyes. His left eye had been only lightly damaged, but that eye had been impaired since childhood. It as his good, right eye that took the hardest hit, but, fortunately, the damage was to the outer parts of the eye, not the retina, and so the doctors said they expected him to see well enough to drive and to read with glasses.

Best, of all, neurological testing showed that his brain was recovering well, though he would need many weeks of physical and cognitive rehabilitation to recover lost functions. Nonetheless, his short-term memory remained "broken." Derek himself can recall nothing from this period. Not the pain, not the jokes, not shaking the President's hand.

"It's all a story," he says. "Everything's a report from other people I asked to tell me what happened."

One of the earliest things he can remember, after being "blown up," was waking up at night in a hospital in Palo Alto where he had been transferred so he could continue his rehabilitation closer to home.

"I remember waking up and thinking I was in a nut ward somewhere," he says. "Because I could hear the other patients, hear what was going on, hear the moaning and the cries…and I thought, Oh god, I must be so messed up if I'm here too."

But with increasing speed, over the course of the next month, his mental faculties came back online. He had to re-learn basic things such as how to use a checkbook, and he also had to master new skills, such as using a wheelchair. Derek now locked on to a new mission: to run again. It was a very ambitious goal. It is very difficult to learn to run for people who lose their leg below the knee. But it is far harder for people, like Derek, who no longer have their knee joint. They have to learn an entirely different way to run.

But before he could run, he had to learn to walk, and before that, he had to be fitted with a prosthetic. At the time, the best place in the world for that task was Walter Reed Army Hospital, which is just down the street from the hospital in which Derek initially recovered in Bethesda. And so, on January 11, Derek and Andrea, now 8 months pregnant, flew east.

Agony

At Walter Reed, Derek began intensive physical therapy to get him to the point of using his prosthesis. He had to learn an entirely new gait, using hip muscles in new ways, as well as the muscles remaining in his limb.

He was ferociously determined to make progress, but he was experiencing increasing amounts of pain from his prosthesis, which was a "bucket" molded to the contours of his remaining limb. Attempting to reduce his pain, the prosthetic designers created small "blow outs" in the bucket to try to reduce pressure. But still the pain came, shooting from the tender tip

of his limb. The doctors raised the dose of his medications. But that made him sleepy…and didn't stop the pain.

"It was a hard time," Derek says. "I was so sad and upset and angry. With the meds, I'd feel sick and between my head injury and the medications I'd just sleep all the time. We lived in a one-bedroom kitchenette type of thing and I wasn't helpful. All we'd do is PT, read, and try to get ready for the baby."

In early February, Derek and Andrea had just finished buying the car seat, crib, and diapers they would need for Sean when Andrea learned she had dangerously high blood pressure. The doctors recommended that she be induced early, and so, on February 15, 2005, Sean Patrick McGinnis was born at Bethesda Navy Hospital.

"It was awesome," Derek recalls. "I was there in my wheelchair…it was a big room with a pull-out bed for dads. Andrea did great…it was really emotional. And it re-invigorated me to carry on, because, it was like, 'Sean's here now, I gotta get this shit squared away. I gotta get my leg locked on."

But for all his determination, and despite a very high pain threshold, he couldn't use the prosthesis. Derek could feel something hard at the end of his limb, inside, and he thought that was what was causing his pain. But, at first, his doctors were skeptical.

"I felt something there, in the stump," he says. "And I thought initially they had put my kneecap in there or something and didn't tell me. But on an x-ray they couldn't see anything…just this sort of cloudy stuff. That was just so frustrating. I knew there was something going on here, so I was pushing for surgery…and they were like, 'no, we've got to wait…we're going to try to build the prosthetics.' Every time I'd leave I'd be pissed off. And they're frustrated too…they got hundreds of patients and they had 15 minute slots and running late…they were busy."

Finally, the pain became so searing that the prosthesis was useless. It was the end of his dream to run, unless the doctors agreed to another surgery. Derek pushed, argued, and stayed in the doctor's faces until they agreed to take a look with a more sophisticated type of scan that gave clearer pictures of bone and soft tissues. When the scans of his limb came back, the doctors were stunned.

At the cut end of Derek's left femur was a massive "bloom" of random, pathological bone growth. The medical term for this out-of-control bone growth is hypertrophic ossification. It was one of the worst cases the doctors had ever seen.

Within a week, Derek was back in surgery. The ossification was cut out, the femur end was cleaned up, and limb was re-closed. The doctors again said Derek should need no further surgeries.

Rock Bottom

Full of hope, Derek waited for the normal post-surgical pain to pass and for the incisions to heal so he could return to his mission of using a prosthetic. But the pain didn't pass. It got worse.

"Only a week later, I started noticing something was still wrong," he says. "I could tell…I'd say, 'guys, there's something extremely wrong here.' And they said, 'well, we've done everything we can.' So they started increasing my medications…because now the pain was twice as bad, three times as bad. I couldn't get anybody to listen."

The failure of the surgery, coupled with the pain, and the fact that Derek, on his own, decided to scale back his use of medications, sent him into an emotional tailspin. He was depressed and the depression painted everything in his life in shades of black.

"I was at the point where I said to Andrea, 'babe, it's time for you to seriously think about leaving…this ain't working…this isn't going to get better. It's time for you to leave. You can find another wonderful man'."

Andrea recognized Derek's despair, but she was caring for Sean Patrick and getting pressure from her commander to return to her post in Hawaii. Her belief in the reality of Derek's pain was also being eroded by comments made by some of his care givers.

"A social worker called and told me, 'I believe the pain is all in his head'," she says. "It was awful. Why would she say something like that?"

"So I'm mad because nobody believes that I have this pain," Derek says. "I'm just really pissed off. I don't appreciate my uniform anymore, don't appreciate my service."

The losses were stacking up for Derek. His leg, his dream of running, his self-esteem, and now Andrea and Sean who would have to return soon to Hawaii. Plus he was still in desperate pain.

This was when he snapped that evening, wheeling past the flag pole, when he didn't stop, didn't salute, didn't care.

"I'm not a liar!"

Andrea, ordered to return to Hawaii and unable to do anything to ease Derek's misery, was feeling awful too.

"Going back to Hawaii was the hardest thing I've ever done," she says. "Because the doctors were doing everything they could to make him comfortable, but nothing was working. They tried everything…acupuncture, Botox injections in his stump, different medications…but he'd move it in any direction and just scream with pain."

All Andrea could do, at that distance, was to urge him not to give up and to keep looking for somebody who would believe him. The messages managed to cut through the fog of Derek's pain and frustration. Despite the lingering effects of his brain injury, Derek decided to forge on with his mission of obtaining a bachelor's degree in business administration.

"I started school again…Andrea and Sean were gone, and I needed something to focus on," he says. "I was living in the barracks, alone, I still couldn't drive, couldn't do anything, so school was like therapy."

And then he connected with a social worker named Ansel who had been assigned to Derek's case.

"Ansel was the only guy who would listen to me," Derek says. "He was straight forward and talked to me at my level—I made a bonding relationship with him. He basically said, 'Look, they're not going to do another surgery on your leg here, they think the pain is in your head, you miss your family…so let's get you back to Hawaii. Take some liberty'."

So Derek flew home and was greeted with a big party by his friends and family. For the next 30 days, he relaxed around the condo, went to physical therapy, and tried to help as best he could.

"He had adapted to the pain somewhat by not wearing his prosthetic," Andrea says. "He used a wheelchair, and he'd scoot up the stairs of condo. He'd try to do things around the house, try to weed the garden."

The time off revived Derek's determination to run. He began to research the options available to him through the military's healthcare system. He discovered a new multi-

disciplinary amputee care center at the Brook Army Medical Center (BAMC) in San Antonio. It looked like a viable alternative to Walter Reed. Perhaps there he might find a doctor who would believe he was in pain. He found that he could get a transfer there…but there was one major catch.

"Andrea asked for a humanitarian transfer to BAMC," Derek says, "but BAMC is an Army base…Andrea's command tried hard to find something nearby in the Navy, but there just wasn't anything. So she was faced with a hard decision. Leave the service to be with me, or stay in Hawaii."

Andrea had been in the Navy since 1998. She had served with distinction in Iraq, Kosovo, Thailand, and on other deployments. She was as proud of her uniform as Derek, and she had many long-time friends in the military. But she says the decision wasn't difficult.

"I went to my boss and said, 'look, my husband's depressed—beyond depressed—he needs me, what are my options?' My only choice was to apply for a hardship discharge, honorably. So I said, 'ok, give me that hardship discharge'."

Within a month the condo in Hawaii was sold, Andrea and Sean were in San Antonio, and Derek was under the care of Dr. Robert Granville, Director of Amputee Services, who took a fresh look at Derek's complaints.

"Right away, Dr. Granville and the therapist welcomed me in," Derek says. "I told them I'm still having extreme amounts of pain. And they start trying to diagnose it, using ultrasound, trying to find out what's going on."

One of the first things Dr. Granville did was to use an injection of anesthetic to temporarily block a nerve leaving from Derek's severed limb. It was both a diagnostic and therapeutic technique—and the effect was dramatic: the pain was gone.

"I remember Derek hopping around in the hallway with a big ol Kool-Aid grin on his face after they gave him that nerve block," Andrea recalls. "He was so happy…finally somebody figured out what was wrong with him. He was shouting, 'I'm not a liar! I'm not making it up!'"

The nerve block was only a temporary fix—the pain gradually returned. But between the results of the nerve block and the imaging he was doing, Dr. Granville suspected that Derek's pain was related to the formation of small, misshapen pockets of fluid called bursa. He was willing to perform another surgery to confirm his hunch and, if possible, fix the problem.

In the OR, with the limb opened, the problem was obvious. Not only were there abnormal bursa that needed to be removed, but there were three sharp, bony spikes growing from the end of Derek's femur which were probably the major reason he couldn't put any weight on the limb. The spikes and the bursa were removed, the femur end was again smoothed off, and the nerve that had been identified by the nerve block was severed.

This time, as the post-surgical pain faded, no new pain emerged. Within a week Derek could put some weight on the limb, and within a month he was in his prosthetic learning to walk."

"I'll be grateful to Dr. Granville forever," Derek says. "He listened. He didn't care what the other doctors said before. He gave me a new look, from his own perspective. If he didn't do that and just followed the course, I wouldn't be walking. Every time I saw him I'd thank him, I'd tell him 'thank you for listening.' I probably got damned annoying to him after a while. After that surgery, everything just started going up, up, up."

Soon Derek was tackling new challenges—stairs, ramps, obstacles. He began his coursework again, did physical therapy to improve his balance, and passed the vision test that allowed him to drive once more.

Derek also worked on the non-physical side of his recovery. He did some one-on-one counseling as well as group therapy with other wounded veterans.

"We all had this cool bond," he says. "We were all young, from different branches of the service, and we'd all been blow up, you know? They'd bring in pizza, and it would be just a conversation. It was really helpful. Because you're talking about all the stuff you've been through…and you see that you're normal. I found solace and comfort in it. We were helping each other grow."

With things finally looking up and Derek making so much progress, Andrea broached a topic that, until then, had been off the table.

"I begged him for another baby," she says. "Because Sean was so good and we were having so much fun with him, and I wanted him to have a sibling close in age. I don't think Derek was 100% behind it, but he still did it for me."

Later that year, Derek achieved the goal he thought, in his lowest point, was impossible: he learned to run. He was fitted with an entirely different kind of leg from the one he used for walking. This one had a curving, flexible "cheetah foot" which absorbed impact and provided

something like the natural spring of a foot and lower leg. Before long, he could run 5 kilometers. He began entering local races, for the motivation they provided. He was an early member of Team Semper Fi, a group of Marine and Navy combat veterans who compete together in road races and triathalons.

In the summer of 2006 Derek locked on to a new goal: surfing. Searching the Internet, he discovered Rodney Roller, a surfer who had lost a leg in a fork lift accident. Roller taught himself to surf again and went on to win several surfing competitions and now gives clinics to other amputees. Derek called him up. Within a month Derek and 12 other wounded vets from BAMC were on the white sand of Pismo Beach on a foggy August morning, listening to Roller explain the basics of surfing. Derek's goal was to stand up on his board within 30 minutes. A cheer went up on the beach as he succeeded, right at the 30 minute mark.

Although his passion for surfing and running and racing is, in part, an expression of a competitive spirit he has had since childhood, Derek says there's also a newer motivation.

"Maybe all the running and stuff is a way to say thank you to all the doctors and nurses and everyone who cared for me," he says. "They all used their skills so that I can walk, so I can see. It's almost like my duty not to waste what they gave me. They gave me my vision and my life."

With the birth of Ryan, in December, 2006, Derek and Andrea decided it was time to move closer to their families in California. They found a new single-story house in Waterford, and one of the first things Derek did when they moved in was install a bracket on the front porch to hold a flag. For awhile he would put the flag out every morning and take it in at night, because it is improper etiquette to leave a flag up overnight, unless it is lighted in some way. Then he mounted a light so the flag could remain in place day and night.

Their life in Waterford is relatively simple and quiet. Derek's brother Trevor lives the next town over with his wife and five girls. They go to a small local church on Sundays, and take walks to the park down the street, where the boys like to chuck rocks into the clear water of the Tuolumne River. Andrea looks after the boys, runs a small business from the house re-selling designer clothes on Ebay, keeps in shape by running and going to the gym.

In late August, 2008, Derek drove over to nearby California State University at Stanislaus to pick up supplies he needed for a new mission: a Masters degree in social work. Having obtained his bachelor's degree in Texas, he decided that he wanted to help other vets overcome

the kinds of challenges he himself has mastered. Once he gets his degree, he hopes to land a job in a VA hospital somewhere nearby.

Walking through the campus in shorts, and a T-shirt, with his short-cropped hair and sunglasses, he would pass for any other college student except for his artificial leg and the slight unevenness of his gait. At the bookstore, he buys a stack of books for his upcoming courses: *Pedagogy of the Oppressed*, *The Expanded Family Life Cycle*, and four others. The books—and the courses—are all paid for by the military, and though the transactions go smoothly, he says that wasn't coincidence.

"Do you know how many calls I've made to make sure everything goes ok?" he says. "I worked with the vocational rehab folks at the VA and I was, like, on them all the time. You just gotta be proactive."

It's a message Derek delivers constantly, both in his part-time work for the American Pain Foundation and in his daily life. An example: the previous evening Derek went to the regular meeting of the Waterford VFW, where he is, by far, the youngest member. When he entered the room, an old veteran walked slowly over to him with a smile on his face and shook Derek's hand. Derek had helped the man with the paperwork required to file for veteran's benefits—which are provided on the basis of an assessment of disability, ranging from 0%--not at all disabled—to 100%--full disability. Like many older vets, this man had simply never bothered to file.

"I'm glad you're here," the old man said in a raspy voice. "I got 100 percent."

"That's awesome man!" Derek says. "You earned it."

It's not the first person Derek has helped navigate the medical bureaucracy. He tries to use what he's learned through his own battles to help other vets he comes in contact with.

"My advice to any wounded veteran is to self-advocate big time," he says. "Know the rules. Be intelligent. You need to know what's going on. And do not quit—never quit. If something's not happening for you, keep pushing. You need to fight for everything you need, because the decisions you make today will affect you the rest of your life."

Ultimately, the distance Derek has come from laying near death on the side of a road in Fallujah, is measured most accurately not by the academic degrees he's earned or running trophies he's won, but by small, ordinary moments…the kind that many civilians take for granted. Pulling into his driveway one evening after picking up some take-out Mexican food,

Derek swings out of the drivers seat and walks into his house. There he is tackled by Sean and Ryan, and hugged by Andrea, who is in shorts, ready for a run. He sets the food on the kitchen counter and goes over to look at some drawings Sean has done.

It has been another typically hot day with near-zero humidity, and the plants in the backyard need watering, especially three small, recently-planted trees: a lemon, mandarin orange, and pear. Derek stands up, opens the sliding glass door, grabs a son in each hand, and says, "C'mon guys, let's make the trees happy."

Chapter 2
Coming Home in Pain

Chapter Recon:

This chapter will answer the following questions:

- How many veterans have been wounded and how many are still in pain?
- What types of pain are veterans experiencing?
- Why is coming home often so stressful for vets?
- What kinds of re-entry "attitude adjustment" can help reduce the risk of experiencing chronic pain?
- How are "wounds of the mind" related to pain from physical wounds?

The Price of Survival

Derek's story vividly illustrates many of the themes you will hear in the chapters to come about pain, what it can do to a person, how it can be treated, and the role you play in your own recovery. In this chapter we want to explore the phase of life that often sets the stage for a veteran's experience of pain: coming home. For vets like Derek who are severely wounded, this transition is primarily about survival and recovery. For those less seriously wounded—or who are "wounded" in less visible ways by stress or exposure to traumatic events—the transition home can be fraught with un-expected complications.

The good news, of course, is that so many of our brave young men and women *are* coming home: the survival rate for those wounded in Iraq and Afghanistan is better than 90%. That's a medical success story that the military can be proud of and that the soldiers and their loved ones can be thankful for. The historically high survival rate is due to three factors: improved body armor,

surgical care deployed far forward on the battlefield, and rapid evacuation of the wounded to major hospitals on aircraft equipped with advanced life support systems. That so many service men and women survive is all the more remarkable because the wounds in OIF/OEF are so often the result of bombs, not bullets—about 65% of the roughly 33,000 soldiers wounded to date were injured by IEDs, land mines, or other "blast phenomena."

The flip side of this medical triumph, however, is an unusually high percentage of service men and women returning home from Iraq and Afghanistan in pain. For example, of those thousands of soldiers, like Derek, who are wounded by blasts fully 60% suffer traumatic brain injury (TBI)—a rate much higher than was seen in previous wars. The wounds from explosions also typically injure multiple body parts or systems, which increases the chances that the veteran will experience chronic pain of some kind. And because large numbers of Reserve and National Guard units have been deployed in these wars, the average age of service men and women has risen to 33.4 years. This, too, increases the risk for experiencing chronic pain.

Several studies have found that nearly half of all veterans seeking care from the VA report some degree of pain. Here's where that pain is being felt:

Headaches	58%
Back	47%
Knee	19%
Shoulder	9%
Neck	6%
Ankle	6%
Head	5%
Hand/wrist	2%

Since roughly 1,350,000 men and women have served in OIF/OEF thus far, we're talking about hundreds of thousands of veterans returning home and dealing not just with the ordinary stresses of re-adjustment, but with the additional stress of coping with pain. The pain itself as well as the side-effects of pain treatments (such as sleepiness, sexual difficulties, or mood changes) can amplify and complicate the entire process of returning to civilian life.

Re-Entry Stress

To soldiers at war, "home" takes on an almost mythic quality, and the prospect of returning to spouses, children, families, and "normal life" can be both deeply appealing and, inevitably, somewhat romanticized. Welcome-home parties, loving embraces, sex, and the resumption of fun activities all shimmer on the horizon of a soldier's mind like an oasis. (It is also true, of course, that for some warriors, deployment is actually preferred to "home" and their feelings about returning are considerably more complicated.)

But returning home is seldom the un-mixed joy most service men and women envision. Here are just some of the things that can make re-entry to civilian life challenging:

- **You've changed.** Military service can cause long-lasting changes in personality, temperament, and outlook. Some of those changes can be good: serving your country, putting yourself in harms way for others, learning responsibility and discipline—these are aspects of war that can leave a deep sense of honor and self-respect. You may have surprised yourself by how much you accomplished in your service, and that may build confidence that you can achieve other goals in civilian life. And the bonds of friendship that soldiers build with each other can be a source of strength and support for the rest of their lives.

  But, of course, there can be negative changes as well—and flip sides to even some of the positive changes. For example, the emotional bonds with brothers- or sisters-in-arms can be so deep, so strong, and so comforting that other relationships—even with a spouse—can feel shallow or less candid in comparison. The need to push strong emotions such as fear as far in the background as possible in order to accomplish a mission can become so ingrained that it becomes difficult to express—or even feel—emotions of any kind. Or your experience of the reality of war may change your beliefs about the value of war, the validity of the war's goals, or your faith in government. These are just a handful of examples—the number of ways people change as a result of combat are as numerous as the number of people who serve!
- **They've changed.** Many servicemen and women are separated from their loved ones for long periods of time in both OIF and OEF, either because of multiple deployments or deployment extensions. During their time away, spouses, children, family members all continue to grow, develop, and change in response to normal—and abnormal—life events.

In other words, the person a soldier dreams of returning to may not, in fact, exist when the longed-for reunion actually happens.

- **You're severely wounded.** Obviously, if you suffered a major wound such a head injury or a wound that required an amputation, you will face a host of challenges upon returning home. You may need to modify your home…or move altogether, to accommodate your new abilities. Like Derek, your new life may be consumed by the demands of treatment and rehab. You may need to change careers, get new training, or go back to school. Hardly anything in your life will be as it was before you left.
- **Civilians can't understand.** The difference between war and the life led by almost any U.S. civilian is so vast it is difficult to describe—though easy enough to feel for returning vets. War strips away many upper layers of culture and personality. Warriors live at the most primal level of human existence where it is kill or be killed. The vast majority of civilians have never been the target of bullets, bombs, and mortars. Most are spared the horror of seeing a buddy killed or seriously wounded before their eyes. And most civilians never train a weapon at another human being and fire.

> *I miss all the guys. If they were all around me, piled into bunk beds, I would be laughing right now. We always laughed no matter how lousy things were. You didn't think about the bad stuff -- well you thought about it just enough to make jokes about it.*
>
> --Derek McGee, former Marine gunnery sergeant in Iraq.

But it's not just the most brutal aspects of war that are incomprehensible to most civilians—the ordinary realities of military life are still a light-year away from the way most civilians live. The regimentation, discipline, and command structure of the military, and the lack of privacy and freedom that follow are also difficult for civilians to understand.

Finally, the mere fact that most service men and women willingly choose to risk their lives for an ideal such as freedom, or for a goal such as liberation from dictatorship is foreign to many civilians in an era when public service of any kind is not widely held up as honorable or desirable.

- **Your buddies are gone.** Bonds of friendship formed in war are difficult to duplicate in civilian life. Not having those comrades around—the people you could tell anything to, the people you could joke with, swear with, endure hell with—can be hard.
- **No adrenaline.** Although it can be terrifying, war can also be exciting, exhilarating…a rush. That level of adrenaline high just doesn't happen much in civilian life, which is why some vets pursue extreme sports such as hang gliding, rock climbing, white-water kayaking, or motorcycle racing. The contrast in the intensity level of life in Iraq or Afghanistan and life in the US can be disorienting.
- **No mission.** In the military, the mission is everything—and it is delivered to you in the form of orders from above. The mission is also usually crystal clear—even if the way to accomplish the mission is not. In civilian life, there may be no clear mission…and if there is, you must usually generate it yourself.
- **No structure.** Not having the order, structure, and rigor that you got used to in the military may at first feel great but then feel foreign or uncomfortable. Fitting back into the workplace, classroom, or community can be more anxiety-provoking than you expected simply because there are so relatively few rules to follow compared to the military.

This short list of potential re-entry stressors is hardly exhaustive, but it illustrates the point: coming home is likely to be different than you imagined—more emotionally complicated, more stressful, and more open-ended. Untreated or inadequately-treated pain adds additional layers of complexity to the re-entry process. Severe pain may mean you can't do your job or can't enjoy recreational activities you once did. Less severe pain may still be corrosive. It can sap your energy, distract your attention, and leaves you with less patience and cheerfulness than you'd like. In later chapters, you'll learn much more about how pain can affect your life—and how you can reduce or eliminate such pain. Right now, however, we want to focus on something many veterans bring home with them from war, something they may not even be aware of but which may be one of the biggest barriers standing between them and getting relief from their pain.

Attitude Adjustment

Military service in general—and active combat in particular—require a host of mental attitudes that serve to protect you from harm and allow you to complete your mission. Being able to

overlook discomfort and pain is one of these attitudes. Throughout basic training you are urged to "push through the pain" to reach higher levels of physical ability. Both training and deployment can involve all sorts of discomfort—freezing cold, blistering heat, blowing sand, sweat, dirt, fatigue, and soreness. Being able to push discomfort to the background—or even deny to yourself that they're even uncomfortable—is an excellent way to adapt. And, on the battlefield, the "pain is not an option" attitude is an essential survival skill. The culture of the military encourages these attitudes, and fighters who continue to shoot, continue to drive on, or continue to help others even when badly wounded and in severe pain are held up as the models of heroism and service that they are.

> *For many, becoming a Marine represents one of the last all-male adventures left in America. Among them, few virtues are celebrated more than being hard—having stronger muscles, being a better fighter, being more able to withstand pain and privation. They refer to extra comforts—foam sleeping pads, sweaters, even cold medicine—as "snivel gear," and relentlessly mock those who bring it as pussies.*
>
> --Evan Wright, in *Generation Kill*

But macho attitudes toward pain that are normal, even healthy, in wartime, may be abnormal and distinctly *un*-healthy back home. In the middle of a firefight, if you sprain your ankle you don't stop to tape it up—you keep going. Do the same thing at home and you will likely multiply the damage, delay recovery, and increase your pain. In a war zone, a headache hardly even deserves your attention. But ignore a headache at home and you may be ignoring a sign of a serious problem such as high blood pressure, chronic stress, or a brain injury—and the pain itself may seriously disrupt your work or ability to be a good parent or spouse.

The point is that when veterans come home, they need to do some serious attitude adjustment when it comes to pain, especially if they are wounded. It is no longer smart or healthy to deny pain, delay seeking help, or continue on as if nothing has happened. Back home, not only is it normal to admit you are in pain, it's *healthy* to do so. *Pain is not a sign of weakness.* It may take some time for this to sink in, but it's essential that you leave that attitude behind on the battlefield.

I can run to Birmingham just like this
(repeat)
I can run to Miami just like this
(repeat)
All the way to Florida just like this
(repeat)
All the way
(repeat)
Everyday
(repeat)
Ho Ha
(repeat)
Suck it up
(repeat)
Blow it out
(repeat)
Suck it up
(repeat)
One, two three four
(repeat)
Run a little, run a little more

--Marine Corps cadence

Admitting to pain and seeking help is not just about reducing your immediate suffering—though that's certainly important. As you'll learn in more detail in the next chapter, pain can grow. Nerves carrying pain messages for long periods of time can become *more* sensitive to pain. Acknowledging that you are in pain and getting help quickly, therefore, can prevent pain from becoming "hardwired," chronic, and more difficult to treat. In addition, people who are in constant pain can be difficult to live with. If you try to "tough it out" with pain, you'll be adding stress to your relationships with those around you. Thus, getting help and finding ways to reduce or manage your pain is as much about looking out for others as it is helping yourself.

Self-medication

Alcohol is probably the world's most ancient pain medication. It is also the world's least effective and dangerous pain medication. But because it is relatively inexpensive and widely available, and because drinking is so deeply woven into the military culture, many returning veterans turn to booze to escape chronic pain. Unfortunately, although alcohol certainly can numb pain in the short term, it does nothing to solve whatever physical problem lies at the root

of the pain. Alcohol usually only makes the situation worse by eroding relationships, impairing your overall health, and increasing the risk of accidents, fights, and depression.

> *I shouldn't drink. I shouldn't. My headshrinkers at the VA tell me alcohol is not good for my recovery and, to be honest, I have been drinking way too much since I got back. Self medicating. Using it to cover the pain, to go to sleep, to forget, trying to fill the empty void where my heart used to be by crawling into a bottle. No, no, no... Not this time, damn it.*
>
> --Iraq veteran and blogger Red2Alpha

Despite these fairly well-known risks, many returning soldiers continue to drink—and they often drink more than they did before deployment. A recent report found that Reserve and National Guard soldiers who were deployed and had combat exposure were significantly more likely to begin heavy weekly drinking and binge drinking upon their return, compared to Reserve/National Guard members who did *not* deploy.

Cutting back on your drinking, or stopping altogether, can be extremely difficult, but it's certainly possible. If you think that you or someone you love is drinking to the point that they are harming their relationships, their health, or their ability to function at a job or in a family, seek help. There are many services in nearly every city and town that offer support, including organizations such as independent Veterans Centers, where you can talk confidentially with other vets or counselors. Check out the Resources section at the end of this book, or the *Exit Wounds* website for more information on this subject.

Wounds of the Mind

To this point, we have been using "pain" to describe *physical* pain. But, of course, military personnel commonly experience many types of *mental* pain as well. Depression, grief, anxiety, post-traumatic stress, guilt and many other types of mental states can all produce a suffering that can be just as insidious and difficult to treat as the pain from shrapnel or an IED. In fact, physical and emotional pain are intimately connected and can feed on each other. As Derek's story will vividly illustrate, the experience of unrelenting and unresolved pain can be deeply depressing. The depression, in turn, can exacerbate the pain, both directly via disturbances in brain chemistry, and

indirectly by making it less likely a person will seek help or stick to a schedule of pain-management treatments.

Post-traumatic Stress Disorder, depression, and anxiety are all extremely important topics, but they are not the primary focus of this book. We will touch on the emotional fallout from chronic pain as we take a holistic, wide-angle view of pain and pain treatment. But *Exit Wounds* is mostly concerned with physical pain, its causes and ways to relieve it. In the next chapter we will take a close look at the anatomy of pain, because understanding the different types of pain is essential for understanding why you or a loved one may be suffering and how that suffering can best be relieved.

Advice for Family Members

There are many ways family members can support returning veterans, and these are especially important if the veteran has been wounded or is in pain. Here are some ideas:

- Ask them how much they want to talk about their experiences—if they don't want to talk about it, don't push. But let them know you care about what happened, are willing to listen, won't judge them, and that you want to support them.
- Be patient—time really can heal and returning vets will need a period to re-adjust to civilian live.
- If pain is an issue, learn more about it…reading this book is a great start!
- Don't expect them to be exactly the same person they were before they left
- If they seem to be having a lot of trouble coping with the stress of being home or you see signs of stress or inappropriate behaviors, seek professional help.
- Encourage returnees to connect with other veterans through local meetings, support groups, or the Internet.
- Don't raise sensitive issues if you or a loved one is either tired, hungry, or intoxicated. Wait. Mornings are usually better than evenings, weekends better than weekdays.
- Use "I" statements, such as "I feel hurt when you…" or "I liked it when you…" Avoid all-or-nothing thinking and expressions such as "You always…" or "You never…"

Voices of Survival for Chapter 2

Robert Anthony, 23, found returning home from a in Iraq more difficult than he expected. Now studying business at Michigan State University, he says it's been difficult to make friends. "I value school and a lot of things in life that people our age usually take for granted," he says. "What people find important now doesn't seem very relevant; video games, or who's famous."

Even common situations like sleeping in a room verses a tent seems weird to Anthony.

"It was so different," he says. "I mean, when you're used to sleeping in a tent and going to the bathroom in a port-a-potty. It was crazy just being in a room with a door, it was like you were in another world."

"I feel really different in a good way and a bad way. I'm really motivated, disciplined, and I'm focused, but at the same time, it's also really hard because most people at school, they just value things differently; it's hard to explain."

Anthony returned home injured, but not from combat. He has six herniated disks in his back, caused from driving oil tankers from base to base, and also driving a gun truck. He also thinks he has some combat stress reactions. He says he's hyperaware of people and his surroundings and more jumpy than he was prior to deployment.

Still, he is forging on. He hopes to go into financing or marketing and invest in real estate, get a realtor's license, then a broker's license. "Something that lets me spend time with family," he says.

Chapter 3
The Anatomy of Pain

Chapter Recon:

This chapter will answer the following questions:

- How does pain work?
- What are the different types of pain?
- What's the difference between acute pain and chronic pain?
- How can the mind or emotions affect pain?
- How do conditions such as PTSD, traumatic brain injury, and substance abuse complicate the treatment of chronic pain?

Pain 101

In order to find the most effective relief for the pain you or a loved one may be feeling, and to *prevent* pain from getting worse, it helps to know how the body's pain system works. We're going to keep this short and sweet, but if you want a more detailed explanation of the anatomy and physiology of pain, check out the "Exit Wounds" website at www.exitwounds.org

The first thing to appreciate about pain is how subjective it is. You can't measure pain with a blood test, or a sensor, or a scan. Doctors are forced to rely on their observations of your behavior (for instance, if you wince when a sensitive spot is touched) and what you *tell* them you are experiencing. More and more doctors are accepting the maxim that *pain is what the patient says it is.* The assumption should be, in other words, that patients are being honest and are being as accurate as they can be in reporting what they are feeling. This has not always been the prevailing view, and, sadly, some doctors still have not embraced this stance.

Some doctors—and Derek had the misfortune to come across several—will dismiss a patient's report of pain if there is no obvious physical cause…if the x-ray is "clean" or if the surgery was "successful." Unfortunately, nerves are nearly impossible to see, so things can look perfectly normal on an x-ray or to the naked eye, even though, at the level of nerves, something is seriously wrong.

Of course, it is always possible that a patient is lying about their pain in an effort to obtain pain medication. But in the experience of many pain physicians, the opposite is more often the case: patients are more likely *not* to complain about pain, out of a desire not to look "weak" or because they don't want to bother the physician, or because they figure that "it's just old age," or any of a dozen reasons. The reality is that only a tiny minority of patients try to fake their pain, and it's not that difficult to ferret them out if a physician suspects deceit. It makes sense, therefore, for doctors to assume that pain is real unless there is reason to suspect otherwise.

Pain can be classified in many ways. One way is simply how it feels. Sharp? Burning? Shooting? Dull? Throbbing? Your doctor will ask you to describe the pain as best you can because this can provide clues to what's causing it. There are two basic types of nerves that carry pain signals. One type, called "C fibers" carry relatively slow-moving signals. These produce dull, achy pain that is hard to pinpoint. C fibers are primarily located below the skin in muscles, tendons, ligaments, and in the various internal organs. Signals carried by your C-fibers are responsible for the ache of a bruise, a sprain, or a stomach ache.

The other type of pain fibers carry fast-moving signals. These A-Delta fibers are mostly located just under the skin, and they are responsible for sharp, localized pain such as one feels from the prick of a thorn, a cut, or an abrasion. The pain caused from the firing of A-Delta fibers can be intense, but it normally does not last that long.

Which brings us to another way to classify pain: by how long it lasts.

Pain caused by an injury such as a cut, broken bone, or infection that lasts only hours or, at most, days, is called *acute* pain. Acute pain fades as an injury heals.

If pain remains even after an injury, infection, or surgery has healed, or if it continues for longer than expected, it is called *chronic* pain. About 70 million people suffer from chronic pain in the U.S. alone. Chronic pain can be frustrating and exhausting. It can become the focus of your life. Work, play, and relationships can suffer. Pain that suddenly erupts or emerges though

the "comfort state" induced by a treatment is called "breakthrough pain" or a "pain flare-up." This can be a feature of either acute or chronic pain.

This is one more way to think about, or diagnose, pain. This is particularly important for veterans and their family members to understand because so many vets have complicated or serious injuries, some of which involve amputation. Understanding this way to classify pain requires a bit of background about where pain comes from in the first place.

Think about things that cause pain. Accidents, combat wounds, an infected tooth, food poisoning…you might think the possibilities are endless. But there are really only three basic things can cause pain: extreme temperature (either hot or cold); mechanical damage; or harm from chemicals. Our bodies come equipped with three types of "alarm systems" to alert us to either potential harm, or harm that has already occurred. Our skin and most of our internal organs (except the brain) are covered with three distinct types of microscopic sensors. Called pain receptors, or nociceptors, these sensors are similar to other sensors that respond to non-hazardous levels of thermal, mechanical, or chemical stimulation. A light touch, for example, is detected by sensors that detect the movements of the fine hairs on the skin or the slight mechanical bending of the skin. But pain receptors require more vigorous stimulation—they have a higher threshold for firing. Only when enough heat, cold, stretch, movement, or chemical change is detected will a pain receptor fire.

Still with us? Good! We're almost there.

If you accidentally cut yourself, the receptors for mechanical damage generate signals that travel from your finger to your spinal cord. They then get relayed, through some complicated circuitry, to other nerves that lead up into the brain. Only when the signals reach the brain do you feel pain and say "Ouch!" This is a key point. If the pain signal is blocked *before* it gets to your brain, you feel nothing. That complicated relay station in the spinal cord that we just mentioned turns out to be vital to all sorts of pain issues…and we'll get to that in a minute.

The kind of pain you feel when pain receptors are stimulated is "normal" pain. It can be sharp or dull (depending on which type of nerve fibers are involved). It's the pain of a minor burn (thermal receptors); broken leg (mechanical receptors), or the sting on the tongue of a jalapeño pepper (chemical receptors). Because these types of pain arise from the stimulation of

pain receptors (nociceptors), it is called *nociceptive pain*. This is pain that arises from something that could, or already has, caused real harm.

Nociceptive pain is usually proportional to the amount of actual tissue damage or receptor stimulation—the more damage, the more pain. (Though some parts of the body, such as lips, nipples, and fingertips, are crammed with more pain receptors, so even small injuries to these regions can generate a lot of pain.) Nociceptive pain is also usually relatively short-lived…it begins to fade quickly and will disappear once healing has occurred.

The other major type of pain is *not* "natural." It arises even when there is *no* danger of harm. It is called *neuropathic pain* and it is produced not by stimulation of pain receptors, but by the abnormal ("pathological") firing of pain nerves themselves, in the absence of receptor stimulation. This most often happens if a nerve is cut, damaged, or has become hyper-sensitive for one reason or another. Unlike nociceptive pain, neuropathic pain may *not* fade—in fact, it may get worse with time. This is often the type of pain that can set in after very serious injury or amputation. It's important to appreciate the difference between nociceptive and neuropathic pain because the two types respond differently to pain treatments, such as medications or nerve blocks. (We'll be talking about these and all the other types of treatment options for pain later in the book).

There. That wasn't too bad, was it? Now you know the key ways that doctors assess pain:

- How it feels (sharp, dull, burning, etc.)
- How long it lasts (acute or chronic)
- Whether it is caused by actual bodily harm (nociceptive) or by damaged and mis-behaving nerves (neuropathic)

One last thing: regardless of its origin, duration, or qualitative feel, pain can vary in intensity. Even though pain intensity is subjective, it can still be assessed. Doctors often use either a pain scale from zero (no pain) to 10 (worst imaginable pain). Another scale uses cartoon-like faces that express varying pain intensities. A patient's answers, using either scale, can help a health care provider two ways: it conveys a sense of the patient's distress with their pain, and it allows the patient to set a "benchmark" that can be compared with later responses using the same scale (after, for example, a pain medication has been given).

The Phantom

In 1551, French military surgeon Ambroise Paré recorded the first documentation of a type of pain that is in a category all its own. He wrote that "Patients, long after the amputation is made, say that they still feel pain in the amputated part." More than 300 years later, another military surgeon coined the term "phantom limb" to describe this phenomenon. In 1871, Silas Weir Mitchell wrote that "thousands of spirit limbs were haunting as many good soldiers, every now and then tormenting them."

Today, the term "phantom limb pain" refers to painful perceptions of a limb or organ that is not physically part of the body. Such pain is usually the result of an amputation, but it can also be caused by spinal cord injury or nerve damage from surgery. They may also occur following the removal of a breast or an internal organ. The prevalence of phantom limb pain differs based on the location of the amputation. The prevalence of phantom pain in upper limb amputees is nearly 82%, while the prevalence of pain in lower limb amputees is only 54%.

Phantom limb pain is a type of neuropathic pain, but the exact causes remain a subject of debate and ongoing research. There appears to be a complex interaction between existing pain receptors on a stump, pain pathways in the spinal cord, and the parts of the brain that contain "maps" of the body. The fact that our brains contain quite detailed "models" of all parts of our body explains why amputees often have "phantom sensations"—that is, non-painful sensations of the missing limb or body part. Even though a limb is gone, the "brain model" of the limb remains and, if stimulated, will produce a vivid illusion that the limb is restored. Why and how phantom sensations become phantom pain is a more difficult question. Fortunately, although phantom limb pain is relatively common, there are a number of exciting new treatments which hold the promise for relief. (See Chapter 6 for details.)

The Mind's Role in Pain

Understanding the basics of pain "anatomy" not only helps you understand pain symptoms, it also helps explain how the mind plays a central role in our experience of pain. Our beliefs, expectations, emotions, and attitude call all drastically affect our pain levels. They can work in either direction: they can ease our pain or make it worse. Soldiers know this first-hand: many know that in the heat of battle, they may be quite seriously wounded and yet feel little or

no pain. Why? Many reasons. A soldier in a fight for his or her life is so intensely focused on survival they simply don't pay attention to pain signals. Also, the brain can generate its own pain medications, called endorphins, which dull pain. And a barrage of non-pain nerve signals can interfere with pain signals arriving at the "relay station" in the spine that we discussed earlier.

This "relay station" is at the heart of many ways to modify pain symptoms—not just the experience of pain by soldiers in combat. The intersection of nerve pathways in this area can act like a "gate," either allowing pain signals to pass, modifying them, or stopping them altogether. One way the "gate" can be closed is by non-pain signals arriving at the same intersection at the same time. Ever bump an elbow and instinctively rub it? The rubbing generates non-pain signals that compete or interfere with the pain signals in the "relay station" in the spine. This kind of interference may also explain how acupuncture can achieve such striking anesthetic effects—the signals produced by the needles arrives at the "relay station" and interrupts the pain signals.

The pain "gate" can also be closed by endorphins and other chemicals produced in the brain or elsewhere in the body. These chemicals can be release by many kinds of activities including hypnosis, meditation, and anything that induces a "relaxation response." The relaxation response is a reduction in muscle tension, blood pressure, pulse rate, breathing rate, and production of stress hormones such as cortisol. It can be achieved many different ways, which we will cover in Chapter 6. The point here is simply that this is not some kind of mystical belief system…it's rooted in the nuts and bolts of physiology. We have explained it here because you can't harness your body's own pain-killing abilities if you don't know they even exist! Knowing that these effects are real and believing they will help can also be a critical element in your overall recovery and pain management.

When Pain Grows

A theme we will be repeating in *Exit Wounds* is that anyone suffering from pain should seek help as soon as possible. First, of course, there's not point in prolonging your suffering. But just as important, uncontrolled pain can spiral up into more pain, and pain that is more difficult to treat. Here we'll explain how this works.

Recall that C fibers carry the relatively slow pain signals that we feel as dull, throbbing, or aching that is hard to pinpoint. If these nerve fibers are continuously firing they generate a number of chemicals, both on the receptor end of the fiber and in the spinal cord "relay station." This is called "wind up." The body doesn't have time to remove these pain-generated compounds and they build up. One result is called "peripheral sensitization." This means that the nociceptors change their threshold for firing. Instead of firing only when dangerous levels of temperature, mechanical distortion, or chemical irritation occur, they fire even at normal and safe levels of stimulation. The result is pain signals sent when they shouldn't be, a condition called hyperalgesia.

But sensitization can also occur at deeper levels—in the spinal cord and brain. This is called "central sensitization." Again, any kind of massive or sustained stimulation of C fibers releases compounds such as substance P, glutamate, and a variety of other compounds which induces "wind up" in the "relay station" of the spinal cord or in the brain itself. The "relay station" then acts like an amplifier for future pain signals. You can easily see how this can become a vicious circle: repeated pain produces amplification, which produces *more* pain, which produces more amplification, etc., etc.

Some studies have found that low doses of certain pain killing medications given before a painful stimulus can prevent wind-up and central sensitization. Research into the use of "pre-emptive analgesia" is ongoing. But the take-home point for veterans suffering pain is that getting help early can really reduce your risk of suffering from chronic pain.

Complications

Another theme that will crop up repeatedly in *Exit Wounds* is that pain affects all aspects of a person's body and mind. The greater the pain, the greater its effects on your body, your mood, your relationships—your life. And it's a two-way street. Pain can affect your mood and outlook, yes, but your mood and outlook can also affect the way you experience pain—for better or worse. Anything that affects how your brain works will affect your perception of pain. For returning veterans, the for biggest things with this potential are:

- Post traumatic Stress Disorder
- Traumatic brain injury

- Depression
- Substance abuse

Having any one of these conditions will complicate, and potentially worsen, any pain you may be suffering. Having more than one—which is fairly common—just ups the ante even more. These four conditions make recovery from chronic pain harder both directly and indirectly in the following ways:

- By physically changing the brain's sensitivity to pain, the sensitivity of pain receptors or the response of the "relay station" in the spine
- By making it harder for a person to remember to take medications, go to therapy, or follow instructions from a doctor
- By sapping the energy and motivation required for sticking with a treatment plan
- By making it harder to exercise—which can be a key component in therapy
- By eroding relationships and the ability to function at a job

The tight connection between pain and all the other aspects of one's life is why pain is best fought on many fronts. It's never enough to focus on pain relief. If there are other serious issues in your life, or the life of a loved-one, such as alcohol problems, depression, or PTSD, these must be addressed as well. In fact, sometimes progress must be made on these problems *before* direct treatment of pain can be pursued.

In this chapter we've given you a crash course in the nature of pain. You've learned why some types of pain feel different than others, and that some pain is "normal" (the result of stimulation of pain receptors) and some pain is "pathological" (the result of nerve damage). You saw that pain signals don't simply go straight to the brain, but pass through a "relay station" where they can be interrupted, modified, or amplified. This "relay station" is at the heart of the beneficial effects of many types of pain treatments, ranging from oral or injected anesthesia to acupuncture. Finally, you saw that untreated pain can create a domino-like chain of events that results in more pain—pain that is "hardwired" and more difficult to treat.

In the next chapter we'll pull back from a microscopic and anatomical view and look at whole human beings and the many ways they can be adversely affected by chronic pain.

Advice for Family Members

Here are some ways you can help a loved-one who is experiencing pain:

- Encourage them to seek help sooner rather than later to reduce the risk that their pain will get worse or become “hardwired”
- Go with them to visit the doctor, both for moral support and to act as a second pair of ears for information being given.
- Take notes during doctor visits
- If a doctor seems to be dismissing a loved-one’s pain or suggests that it’s “all in their head” urge your loved-one to find another doctor.
- Encourage your loved-on to find a pain specialist or other health care provider who can introduce ways to harness the power of the mind to help control pain

Voices of Survival for Chapter 3

Stephen's Story

It was February 1976. I was in Vietnam with Special Forces and we were jumping from a C-130. The man before me stepped off rather then jumping and his static line didn't rise far enough. It caught across my throat when I jumped and I got tangled in the static line. I was bouncing against the plane when someone in the plane cut the static line holding me. The people in the plane thought I was probably dead. My static line opened my chute. I came to when I was about 300 feet from the ground. I had just enough time to drop my pack before hitting the ground on top of my pack.

I hurt from the beating I took from bouncing against the aircraft. I also had burn across my throat from sliding down the static line. Other then feeling like I had been run over by a truck, I had got up, collapsed and stowed my chute in the bag, put my pack on, flipped the bag with my chute over my head and walked off the DZ. A little pain wasn't going to stop me.

Two days later I couldn't move. I was in so much pain I couldn't describe it. They put me in the hospital and gave me morphine. The Army then shipped me stateside. A year later I was discharged from the Army and that is when the VA started treating me.

I was in agonizing pain. The VA awarded me a 30% disability. I had a wife and two young kids. There was no question; I had to go back to work. Back strain was the official name of my injury until 2000 when I finally found out what the disease was. All I knew was that I was in intractable pain all of the time. I had sciatica down both legs, my hands hurt, and my hands and arms were numb from the elbow down.

I went back to neurosurgery and they ran more MRI's. The neurosurgeon told me I had arachnoiditis (inflammation of one of the membranes surrounding the brain and spinal cord)! Today my disability is rated at 100% service connected effective June 2001. The pain clinic has put me on the Duragesic patch, but before they gave me the patch they tried various opiates morphine, methadone, tramadol. None of them worked. I threw up a lot. I lost 40 pounds looking for a medication I could stand. The patch combined with other medications to treat pain has given me a great deal of relief from my pain.

My life was changed on that day in 1976, but I never gave into my pain. I work full time and always have. I own a real estate company and a mortgage company. I will never let my pain control me. It is too easy to submit to pain and allow it to control your life. I will never stop fighting.

Chapter 4
The Consequences of Untreated Chronic Pain

Chapter Recon:

This chapter will answer the following questions:

- How does chronic pain add to the sense of isolation felt by many veterans?
- How are family members, spouses, and children affected by a loved-one's pain?
- In what ways does pain interrupt ones work, career, or education?
- Does chronic pain increase ones risk for depression and suicide?

The Truth of Consequences

In the previous chapter we introduced the idea that pain affects everything it touches—and it touches everything in your life. Here we'll unpack this idea and explore the full scope of pain's consequences.

We can get a sense of the magnitude of the pain problem among veterans from an online survey conducted by the American Pain Foundation in October, 2006. A total of 753 veterans or members of the military replied to the online survey. Of these, 721 respondents (96%) indicated that they were in pain. And more than *half* of these veterans said their pain had persisted more than 10 years.

Astoundingly, 70% rated the intensity of their pain between 7 and 10 on a scale of zero to 10 (0=none, 10=worst pain imaginable) on a daily basis. This represents a truly staggering about of ongoing suffering among veterans.

Of the 721 veterans in pain, two-thirds (66%) also said that they suffer from depression and one-third (34%) said that they suffer from PTSD. Sadly, 29% indicated that they suffer from pain, depression *and* PTSD.

In terms of other consequences of chronic pain, almost three-fourths (73%) of the veteran respondents said that pain has "very much" interfered with their quality of life, 69% said pain interfered "very much" with their ability to work, and more than half (54%) said pain interfered "very much" with their relationships.

Some of the more serious consequences of chronic pain include:

- Isolation
- Alcohol abuse
- Physical deconditioning
- Disturbed sleep
- Reduced sexual activities
- Family stress
- Impaired ability to work
- Decreased self-esteem
- Irritability
- Depression

We're doing to take a closer look at these kinds of potential consequences below. Why? Not because we want to belabor the problems that are wrapped up with chronic pain, and certainly not to bum you out. *All of the challenges discussed below can be managed in one way or the other.* None of these consequences is a dead-end, and you'll learn ways to cope with these in later chapters.

Our motivation here is simply to emphasize the seriousness of this condition for those who might be tempted to try to "tough it out" or for those who are not aware of how drastically chronic pain can affect your life. Of course, many of you reading this may already know about these realities from first-hand experience. But many of you may be returning from Iraq or Afghanistan with pains or wounds that they might not think warrant medical attention and which do not, at the moment, greatly interfere with their lives. This chapter is really targeted at these readers. We hope that by going into some detail about these consequences—and quoting extensively from those who have suffered—readers will take their pain seriously, seek help sooner rather than later, and not be afraid to admit they are in pain. As is vividly illustrated below, the stakes are very high!

Isolation

> *There are days when I feel like a broken bottle, all the pieces hurt and I can't seem to bring them together to make an entire vessel. Sleepless nights, days where you don't want to see anyone, do anything or go anywhere.*
> --Anonymous post #6 on APF website

Pain is designed to be hard to ignore. It is Nature's siren—and it typically trumps all other aspects of your life. One of the things that can easily get shoved to the background as you try to respond to the wail of pain's siren is your social life. Bowling? Forget it. Dancing? No way. Even just going to a movie can hurt and, therefore, not be worth it.

Returning veterans, of course, can feel socially isolated even *without* pain in their lives, for all of the reasons we discussed in Chapter 2. Chronic pain makes the challenge of re-entry even tougher, makes it harder to connect with others, and sets the stage for un-healthy ways of coping with isolation, such as by drinking or using drugs.

Alcohol abuse

> *Most nights when Anthony Klecker, a former marine, finally slept, he found himself back on the battlefields of Iraq. He would awake in a panic, and struggle futilely to return to sleep. Desperate for relief, Mr. Klecker, 30, drank heavily. One morning, his parents found him in the driveway slumped over the wheel of his car, the door wide open, wipers scraping back and forth. Another time, they found him curled in a fetal position in his closet.*
>
> --New York Times, July 8, 2008 "After the Battle, Fighting the Bottle at Home" by Lizette Alvarez.

In classic Western movies, whisky is the all-purpose anesthesia. Need an arrow removed? No problem…give the guy a few slugs and yank. Sterilize a wound? Pour whisky on it! Want to forget that gal who ditched you back in Dodge City? Nothing a hip flask by the camp fire can't cure.

In real life many people in chronic pain still use alcohol to self-medicate—and the pull of alcohol for vets can be very strong because drinking is such an ingrained part of military culture.

And alcohol *can* reduce pain temporarily because it depresses the central nervous system, slows down the brain and nervous system, and, thus, provides a certain amount of relief.

But alcohol, of course, is also an extremely hazardous drug, especially for people who are returning from duty and who are in the midst of the stresses and strains of re-adjustment. We hardly need to list the ways alcohol can hurt you or your loved-ones. Most people who drink already know it will make them quicker to anger, more likely to get into fights, physical or verbal, and a danger on the road – and that they're likely to feel worse, not better, in the morning.

But it bears repeating here that, most often, using alcohol if you are in chronic pain is almost certain to make everything worse—your ability to cope, your relationships, your ability to work, your parenting skills—everything. This is particularly true if you are on some kind of pain medication—which, of course, is true for most people in chronic pain. Alcohol can powerfully enhance the sedative effects of some types of pain medications, making the combination potentially lethal. And even if a person "knows their limits" with alcohol from years of experience, the addition of pain medications makes that experience irrelevant and can lead to very risky behaviors, such as driving or operating dangerous machinery.

The last thing we want to sound like here is your mother. We're not trying to lecture or scold. But everything's different when you're in pain, and because humans have such a well-honed ability to deceive themselves about their own capabilities, you are likely to be at much higher risk for getting into serious trouble with alcohol or other drugs if you're in the midst of battling pain.

Physical deconditioning

> *Even just walking hurt. As someone who had run, played ball, biked, chain-sawed, or did something else strenuous every day of my adult life, it was troubling to find that a flight of steps wiped me out. Climbing steps took gripping both hands on the railing, hard, rising one stair at a time.*
>
> --Bob Nylen, Army veteran, from post on APF website

The service men and women who make it through the various boot camps of the U.S. military are at the peak of physical conditioning. In all branches of the military, PT is a central,

constant element of life. Being lean, buff, and strong is a source of pride and satisfaction for many military men and women. That's why it can be particularly cruel when chronic pain prevents them from maintaining their conditioning. Many will tolerate a huge amount of pain to keep running, keep training, keep pumping iron, keep doing reps. But chronic pain can conquer the strongest will. And, if it does, one inevitable result is physical deconditioning—a loss of muscle tone and mass and an increase in fat deposits. This can be a wrenching and depressing situation for many OIF/OEF veterans and it's often a strong motivation to seek professional help.

Disrupted sleep

Roughly 70% of veterans of OIF/OEF who say they have some kind of painful condition, also say they have poor or un-refreshing sleep. This isn't a minor issue. The value of sleep to people's overall mental and physical health is greatly under-appreciated in this country. Most people get less sleep than they should, and they compensate with caffeine or other stimulants, which usually just makes it harder to sleep the following evening.

But sleep is also one of the most potent components of healing. Because it disrupts sleep, chronic pain impairs one of the keys to its own resolution. Sometimes a person in pain is all too aware they're not getting enough sleep because they simply can't get comfortable and realize that they're tossing and turning. But sometimes the problem isn't so obvious. People normally cycle through stages of sleep, including times called "micro arousals" in which they rise naturally to a light, non-dreaming state of sleep which doesn't have the healing benefits of deep sleep. Pain can lead to many more of these micro arousals. The person in pain may not realize they have spent much less time in deep, healing sleep—they may simply say they awaken not feeling as refreshed or ready for the day as they used to.

The problem of sleep deprivation is complicated by the use of pain medications, which can profoundly alter sleep rhythms. Alcohol, too, can disrupt sleep. It can promote drowsiness early in the evening, but often produce a "rebound" state of wakefulness in the middle of the night as the sedative effects wear off.

Bottom line? Sleep disorders are a huge problem even for vets who are *not* physically wounded—and it's an even bigger problem when a returning service man or woman is battling chronic pain.

Reduced sexual activity

> *Your having the time of your lives, and from out of no-where, you're stopped with the most terrible pain you've ever felt, in your life. Your lower back is hurting so bad, you have no choice but to cry in pain ! It takes all you have to roll over. And your girlfriend/lover/wife (whichever applies), asks you, Are you ok ? And you want to get mad as a hornet. But you can't. You're finished.*
>
> --Posting by chronic pain sufferer

Sadly, one of the first things to disappear in the life of somebody in chronic pain is something that is fairly good at relieving pain: sex. The relaxation, emotional tenderness, comfort, and release of endorphins that can accompany sex all reduce pain. But if you're in pain -- especially if it's pain caused by moving parts of the body involved in sex, such as the back and pelvis -- making love is about the last thing you may be interested in.

Pain can impair your sex life many ways. Either you or your partner may be afraid of causing more pain by the physical activity of sex. The person in pain may simply not feel very attractive or sexy, or they may not have the energy or motivation to pursue sex. And, on top of these barriers, many pain medications can interfere with sex drive, the ability to get an erection, or the ability to have an orgasm.

Family stress

> *Before I deployed down range I was different about my wife and kids. Now that I'm back I can only let them get so close before I have to get away from them. I used to have fun letting my boys jump and crawl all over me. We would spend hours playing like that. Now I can only take a couple of minutes of it before I have to get out. I usually get in my truck and drive back to the base to be with my platoon.*
>
> --Paratrooper home from Iraq, quoted in *Down Range*

Living with somebody who is in chronic pain isn't as bad as being in pain yourself…but it's no picnic either. A spouse, children, parents, or other companions may have to pick up a lot of slack around the house because a loved-one cannot lift, move easily, drive, or do other jobs. Frustrations can build on both sides. The one in pain may feel guilty or simply sad that they can't help as they used to. The one supporting may feel unfairly burdened or irritated but also hesitate

to say anything because they know how much pain the other person is feeling. The result can be a real stew of complicated, sometimes contradictory emotions.

As we saw in the previous chapter, stress produces physical changes such as increased muscle tension, reduced blood flow, and increased production of stress hormones. All of these amplify pain. Fights, tension, and unresolved or unacknowledged hostility between spouses or partners can be a major contributor to the overall stress a person in chronic pain is feeling, with significant consequences.

Inability to work

> *I never got to enter that world of professionals because it's hard to work when you're hurting all of the time, and employers don't want to hear you telling them "I'm in to much pain to work today.*
>
> --Afi, posted on APF "voices of pain" site.

Whether you're a bricklayer or an accountant, chronic pain is likely to be disrupting. Certainly chronic pain can prevent you from doing physical tasks such as lifting, bending, or carrying heavy objects. But the gnawing irritation of chronic pain can make it difficult to concentrate on purely mental tasks such as writing, programming, computation, or analysis. And if the pain itself isn't disruptive, the medications used to treat it *can* be…which, as we'll discuss in Chapter 7, is one reason to be persistent and assertive in your search for a treatment that not only relieves your pain, but improves your ability to function at home and work.

Decreased self esteem

> *I cannot lift as much as a gallon of milk. Brush out my own hair and on high pain days I cannot properly dress myself. I am ashamed at how little I can do following this travesty. I am a very proud person who is humiliated by the life I am forced to lead.*
>
> --Cynthia, post on APF site

Cynthia's quote here pretty much says it all: being stripped of your ability to function normally by chronic pain can lead to a descending spiral of self-esteem. You can feel

humiliated by your helplessness, frustrated, and, then, humiliated and frustrated that you even feel that way because, of course, your head "knows" you can't help it and are doing the best you can.

Chronic pain can also lead to the loss of other sources of self-esteem, such as your job, your role as bread-winner, your athletic abilities, or your role as a leader in volunteer organizations. Many people with chronic pain can recover their function—and their self-esteem—with proper treatment. But this consequence of chronic pain can be just as serious as more high-profile consequences such as an increased risk for alcohol use.

Irritability

It was Thanksgiving. I was at my grandparents house, lots of aunts and uncles and cousins around. At the top of the hour CNN gave the highlights of another day in Iraq, in Baghdad. Tens and tens killed and hundreds wounded in Sader City by IEDs, hospitals packed with wounded, flooding into hallways awash in blood. I snapped.

"Can we please watch something else for fucks sake!"

I might as well have taken a shit on the living room floor. All conversation stopped and everyone looked at me as I stood there frozen. Not knowing what to do I stormed out of the room to the bedroom I was staying in.

--Red2Alpha, Iraqi vet

People naturally become more irritable, short-tempered, and grouchy when they're tense, tired, hungry or all of the above. No surprise, then, that chronic pain can lead to a quantum jump in a person's level of irritability. The simple fact of having pain that isn't being relieved is frustrating and irritating, but add to that the effects of interrupted sleep, the stress of not being able to do a job or enjoy recreational activities, and the mood-altering effects of pain medications and you have all the ingredients for a "perfect storm" of irritability!

Depression

> *After a stay in the hospital and a year of physical therapy, the doctors said they could do no more for me, that I would have to learn to live with the pain. It was such a blow, I thought that they could fix me and my life could go on. What a shattering blow to find out that you will never be the same again. That triggered my 1st suicide attempt.*
>
> --Anonymous post # 7 on APF website

Pain and depression are tightly linked: pain causes depression—depression causes (or enhances) pain. About 30% of patients with persistent pain conditions suffer from clinical depression related to that pain, and almost all persons will experience some mood changes. And 75% of patients with clinical depression come to their doctors complaining of physical symptoms, including pain. People in pain who are also depressed experience more impairment than those who aren't depressed.

Depression and pain go hand-in-hand for a lot of reasons. One is that both mood and pain signals are affected by the same kinds of brain chemicals—neurotransmitters—such as dopamine, serotonin, and norepinephrine. In addition, high levels of stress hormones, particularly cortisol, have been linked to depression. Chronic pain itself can raise cortisol levels, but simply being in combat situations does the same thing—even if you aren't physically wounded. Having your brain constantly bathed in stress hormones may predispose you to chronic pain symptoms later in life.

Interestingly—and encouragingly—some of the same medications used to treat depression also help reduce chronic pain. Again, this is because many similar brain regions and neurotransmitter systems are involved in the two disorders. This is why the same medications that are helpful in depression may also effectively treat pain, because they enhance the pain and mood regulating effects of these chemical systems in your brain.

We'll be returning to the issue of depression in later chapters, but here we want to emphasize the seriousness of depression because of its most tragic potential outcome: suicide. As we mentioned in the introduction, the rate of suicide among OIF/OEF service men and women was the highest since statistics began being kept in 1980. This is not simply due to high levels of chronic pain—the higher-than-normal levels of PTSD among these vets is also a very

significant cause. But certainly the complexity of the wounds suffered by OIF/OEF vets and the increased likelihood they'll face some kind of pain is also significant.

Moving Forward

We've talked about the most serious consequences of chronic pain as though they are separate from one another. But, of course, life is messy. In reality, many of these issues may be going on to one degree or another simultaneously in the life of an individual or within a family. For example, depression can lead to drinking, which can worsen the depression *and* the experience of pain…. which can result in the breakup of a relationship which can lead to more depression. And so on.

But that doesn't mean all is lost! In fact, the connections between the various issues going on in your life or the life of a loved-on can be a reason to hope. *Because if you can improve one area in a person's life, other areas can improve as well.* Yes, it's possible to get caught in a downward, self-perpetuating spiral. But it's equally possible to create an *upward* self-reinforcing spiral. The most obvious way to do this is to get good, professional, holistic help for your chronic pain condition. As you will learn in later chapters, the goal of treatment is to *improve your function* in all areas of your life. If that can be done—and it can almost always be done if you stick with it—then the upward spiral can begin. You might be able to return to work, for example, which can raise self-esteem, reduce family tension, and reduce depression—all of which will help to further reduce your pain.

The key is to begin. And beginning with the actual pain condition may not be the best approach. If somebody is suffering from serious alcoholism, they may need to enter rehabilitation and get sober before real progress can be made. Same goes for depression—a seriously depressed person will simply not have the energy or motivation they need to stick to a program of pain management. They may need to get prompt treatment for the depression before they can make progress on the pain front.

There simply is no one-size-fits-all answer here. You, with the help of your health care providers and, we hope, an experienced pain specialist, will create a roadmap for recovery that is tailored to your own specific needs and priorities. In the next section of this book, we'll begin to explain what this actually looks like and what your treatment options are.

Advice for Family Members

In the chapters to come we will be talking at length about ways to treat chronic pain and the kinds of negative consequences we've discussed here. The issues here are big…depression alone is an enormous topic about which entire books have been written. Here we'll focus on some concrete things you, as a family member, can do if you see that someone you love is suffering from one or more consequences of chronic pain.

- Seek treatment for the pain condition itself, since this is a root cause of other problems
- Try to keep the lines of communication open—talk about issues and concerns—remember that "revealing is healing."
- Be as patient as possible with a loved-one's limitations without becoming an "enabler" of helplessness
- Listen without trying to "fix" or "solve" an issue or problem
- Encourage some kind of physical activity every day, even if it is very small. Even people in severe pain can usually move to some extent, or move some part of their body. Doing even very small range-of-motion exercises can be helpful and can provide a way to measure progress
- Take care of yourself
- Look for support groups of others dealing with the same issues you are. Support groups for care providers, spouses of veterans, spouses of people dealing with substance abuse, and many others are available. (See the resources section at the back of this book for a short list and the "Exit Wounds" website for a complete list of places to find such groups.)
- Trust your instincts. If you sense there is a problem—with a relationship or with a person you love—there probably IS a problem.
- Learn more about the specific problem a loved-one might be having (i.e. sleep disorders, depression, or sexual problems) by reading, talking to others, or consulting with a family health care provider

Chapter 5
Your Mission: Improve Function

Chapter Recon

This chapter will answer the following questions:

- What's the goal in treating acute pain?
- Why is the goal different when treating or managing chronic pain?
- What does "improving function" really mean in the real world?
- If you can't measure pain, how can you tell if a treatment is working?
- How can you measure progress toward functional goals?
- What health professionals, aside from my doctor, am I likely to be working with in order to accomplish the mission of reducing pain and improving function?

Beyond Pain Relief

If you break a bone, have a tooth ache, or burn yourself, you're feeling acute pain and you want it to stop. Fair enough. Both you and your doctor will focus on dampening or eliminating the pain (and fixing whatever is wrong, of course). The treatment goal for acute pain, therefore, is straightforward: pain relief. And it's not too difficult to tell if the treatment is working; if you're still feeling pain, it's not working.

But it's a different story for chronic pain—which is the type of pain readers of this book are most likely to be grappling with. Although it might sound odd, the goal of treatment for chronic pain is *not* simply pain relief. This chapter is devoted to explaining this central fact,

because, as you know well from your military training, you have to know what your mission is before you can figure out how to achieve it. Same thing with pain. You need to be very clear about what your goals are before you and the team of healthcare professionals we hope you have with you can decide which treatment tools (i.e. medications, physical therapies, medical devices, etc) will best help you fulfill your mission. The next chapter is all about those tools—but before we get there, we need to explain why the mission isn't as simple as "stop the pain."

In the previous chapter we saw the many ways that chronic pain can erode your quality of life—how it can slowly contract your horizons, limit your activities, and reduce your functioning at work and home. Because chronic pain is, by definition, a long-term problem it is extremely likely that by the time a person with chronic pain seeks help, he or she will be living in a state of reduced functioning. They may not be sleeping well, they may not be exercising, or enjoying recreational activities, or having sex, or working to their full potential at their jobs. This is what we mean by "functioning." It really means living the life you desire, the life you had before you were injured or wounded. The ultimate goal of chronic pain treatment—the real mission—is to restore you to that life, to restore you to a healthy level of functioning. Relieving your pain is a necessary part of achieving that goal—but relieving your pain is not what the mission is really about. The mission is about function, and relieving your pain is simply one of the means to that end, it's not the end itself.

What's that look like in real life? Here's an example.

Mike returned from Afghanistan suffering from back pain due to a shrapnel wound that fractured two lumbar vertebrae and injured some of the spinal nerves in the area.[*] He underwent laminectomy and spine fusion surgery to repair and stabilize the vertebrae. Unfortunately, the expected bone re-growth didn't occur and the fusion surgery had to be repeated. This fusion appeared to work, but he continued to be in pain. Several nerve block procedures failed to bring relief.

Mike came to his doctor and asked for a long-acting opioid pain medication. His doctor asked him a simple question: "What do you want to do, by using this medication, that you can't do now?" At first Mike wasn't sure. "I don't know," he said. "I just want the pain to stop, that's all."

[*] This is a composite character based on several real stories.

His doctor explained that stopping the pain was just the first step. She asked Mike to think about what components of life he had lost because of his injury and subsequent pain and what components he hoped to regain by using the medication and engaging in other activities that would be part of his overall plan for managing his pain.

"Well, I guess I'd like to be able to walk without pain…or even hike with a pack," he said after a moment.

His doctor thought those were both reasonable goals, though she suggested a plan with some intermediary goals. She explained the need to start slow, set realistic goals, and set up ways to measure progress. They agreed to aim first for sleeping in his bed again, and attending a play at his son's elementary school in a month. He would also enroll in a pain education class, and begin a program of gentle but long-term physical therapy. He would bring records from his class and physical therapy sessions and his wife would confirm his progress in the other areas and would attend a follow-up meeting in a month.

Four weeks later Mike and his wife came in for a follow-up. He said that the opioid medication had allowed him to make progressive steps. He started by taking tentative steps around the house. Then worked up to walking around the block. And he was able to sleep comfortably in his bed again. His pain was not gone; he said it varied from about a 3 to a 5 (out of 10) from day to day. But he could live with that. Indeed, he *was* truly living for the first time since his initial surgeries. He was walking again and working up to a short climb. He was benefiting from the positive feedback loop we discussed at the end of the previous chapter: reducing pain can lead to improved function, which, in turn, can further reduce the pain, which further increases function and so on.

Mike's functional goal was to walk and then hike with a pack. Derek's goal had been to run again. The goal for someone who is brain-injured might be cognitive: the ability to read and remember what they read. For others the goal might be to return to work or reduce their use of pain medications so as to reduce their side effects. Your goals (or the goals of a loved-one) will reflect your own desires and life situation.

Here are some of the main benefits of a function-based, goal-oriented approach to treating chronic pain:

- Both patient and doctor have objective, verifiable treatment goals and outcomes, as opposed to un-testable and subjective ones such as the patient's report of "feeling better"
- Individual differences among patients, in terms of pain tolerance and functional goals, are easily accommodated
- A set of functional goals provides a solid basis for making decisions about whether or not to increase or decrease dosages, or switch to other forms of medication altogether
- A function-based treatment strategy is much more likely to improve the patient's quality of life

Setting functional goals isn't a one-time event. Managing chronic pain is a long-term process—a marathon, not a sprint. You will probably need to move the functional goalposts from time to time, in collaboration with your doctor. If you achieve a goal or set of goals, you may want to re-set the goals to reach the next level. For instance, if you've been able to return to swimming laps once a week, you might set a goal of swimming three times a week. Conversely, if you've set too ambitious a goal and you're getting discouraged, you can bring the goal down a notch.

Keep in mind that in the early phases, goals can be extremely modest. Simply being able to turn your head 90 degrees left or right might be a challenge! You might also think that there is *no* motion that doesn't hurt. This is unlikely. Some range of motion is almost always possible. It may be tiny. But it can be the toe-hold on which you can climb higher—slowly, and in collaboration with your doctor and pain management team.

Finding the movement that does not cause pain may not be easy but it is possible. Doing that exercise for a while, and doing it repeatedly, can begin the conditioning process and allow for gradual increases in activity over time. After a while, you will become slightly more conditioned and able to gently expand the intensity.

<u>How Much Pain Relief is Enough?</u>

If you're in pain, you may think that one of your first goals is to eliminate your pain. That's understandable, but usually neither realistic nor necessary. The traditional zero-to-10 pain scale used so often in clinics and hospitals inadvertently implies that the ideal condition is "zero

pain." In truth, hardly anybody lives with zero pain. In fact, certain very rare individuals are born with an inability to feel pain—and they typically die young from accidents, diseases, and an accumulation of un-attended injuries. It is normal to feel a little achy, or itchy, or to have mild pain from the ordinary bumps and bangs of daily life.

For patients in chronic pain, the goal, therefore, is not zero pain, but acceptable pain. And that, of course, is a highly individual matter. What comes as a surprise to many people in pain is that relatively modest reductions in pain—say, a 20 percent reduction in a pain score (i.e. two points on the standard pain scale) can produce significant benefits.

Most people in chronic pain certainly need to see some reduction in their pain, but it may not need to be as much as they think if, at the same time, they are making obvious progress toward their functional goals. The key is that pain relief—especially if it involves opioid medications—is always a trade-off. To take an extreme example, a person could feel almost no pain at all with a large enough dose of an opioid—but they would be a zombie incapable of much beyond sleeping or watching television. The dose of medication (or use of other, non-medication treatments) must be balanced with the amount of function they allow. You should use a medication or treatment as long as it is letting you reach your functional goals. If the treatment begins to get in the way of those goals, other treatments should be found.

Building a Team

Successfully treating chronic pain, as we've seen, is about more than pain relief. It's about regaining function. That means you will do best if you have a team of professionals who can help you achieve your functional goals. If you are fortunate, one member of the team will be a pain specialist. Pain specialists are physicians with extra training in pain medicine. They look for a balance of different treatments that are tailored for each person's needs. There are not enough pain specialists yet in either the military or civilian health care systems, so you may not be able to avail yourself of them. But it is worth pushing for because pain medicine is a large, complex medical specialty and primary care physicians simply don't have the time to keep abreast of the rapid changes in this field.

> *The good physician treats the disease; the great physician treats the patient who has the disease.*
> --William Osler, Physician 1849-1919

Because many OIF/OEF veterans, like Derek, sustain complex wounds that involve many body systems, many different specialists may be required for comprehensive care. This may include:

- Physical therapists
- Occupational therapists
- Neurologists
- Speech therapists
- Vision therapists
- Psychologists or counselors
- Prosthetists

In your effort to overcome chronic pain, you are like the commanding officer of a battalion. Your doctor and the other specialists you assemble are like military specialists in communication, artillery, logistics, and navigation. They have expertise and advice you need and must rely upon. But, at the end of the day, you're the one who calls the shots, and you are, ultimately, the one responsible for the success or failure of the mission. Now you're ready to learn more about the arsenal of treatment options for chronic pain—which is the subject of the next chapter.

Advice for Family Members

Family support can be a critical factor in the success of the "mission" to manage chronic pain. There are many ways family members can work with a loved-one to help them achieve the kinds of functional goals we have discussed in this chapter. In fact, family members are the ones on the front lines here, not the doctors, nurses, and other health care professionals. Many

functional goals involve things that family members are ideally positioned to observe: sleep habits, exercise levels, mood, energy, ability to participate socially, etc. And some functional goals are impossible to achieve without the participation of certain family members. Resumption of sexual activity is an obvious example, but others, such as resuming social activities that involve partners (i.e. dancing, bridge, bowling) can be equally important. Here are some other ways you can help a loved-one make steady progress toward their functional goals:

- If possible, go with your loved-one to meetings with doctors or whomever is setting up an overall treatment plan.
- If functional goals—or a functional approach to pain management—is *not* being used, look for a doctor or pain specialist who *will* use this approach (visit the *Exit Wounds* website for a complete list of resources to help you locate such a specialist in your area)
- Once a set of goals has been established, support your loved-one in achieving them with gentle reminders, encouragement, and words of praise. No need to nag…just let them know that you care about them and want to help them succeed any way you can.
- Encourage patience. Many veterans have a very "can-do" "gung-ho" "get-the-job-done" attitude that puts a premium on getting results *fast.* But achieving functional goals, especially if it involves the healing of major wounds, is simply a slow process. Going too fast, driving too hard, will hurt, rather than help, a veteran accomplish their mission.
- Remember: it's a marathon, not a sprint.
- Make an agreement with your loved-one that you are empowered to call the doctor directly if you feel there is a problem or if you see that your loved-one is not reaching their functional goals. Having this agreement in place *early* is key—if you wait until later, your loved-one may feel you are overstepping your role or usurping their control. Make it clear: this is a team effort, and you are a vital part of the "command and control" structure!

Chapter 6
Your Arsenal of Treatment Options

Chapter Recon

This chapter will answer the following questions:

- What are the different categories of pain relievers?
- What are opioids and how can they best be used to manage chronic pain?
- What's the difference between tolerance and addiction?
- Are there other types of medications, besides opioids, that are used to help fight pain?
- What rehabilitation techniques can help with chronic pain?
- What are injection and infusion therapies?
- What are implantable devices and when are they appropriate?
- What surgical interventions can help reduce chronic pain?
- How can I best use complementary and alternative medicine techniques?
- What are the latest treatments for phantom limb pain?

Treating the Whole Person

Before we take a look at the many ways chronic pain can be treated, remember that pain is complex and very individual. What works for one person may not work for you. You should collaborate with your doctor and pain management team to map out a treatment plan tailored to

your specific needs. Your overall goal is to improve your functioning and enhance your quality of life. Reducing your pain level is one piece of the puzzle toward accomplishing those goals.

Many times, a combination of treatments works better than just one treatment. This is called a "multi-modality" approach. For example, your healthcare provider may prescribe a medication along with activities to reduce stress (e.g., yoga, deep-breathing exercises). To improve daily functioning, specific therapies may be suggested to increase muscle strength and flexibility, enhance sleep and reduce fatigue.

This chapter will review the most common treatment options in 7 broad categories:

- Medications
- Psychosocial Treatments
- Physical Rehabilitation
- Complementary and Alternative Techniques
- Injection and Infusion Devices
- Implantable Devices
- Treatments for Phantom Limb Pain

We'll be giving you the big picture here. We want you to understand how broad the range of potential treatments really is, and see how they can fit together as part of your overall treatment plan. But there's certainly more to be said about each option! Additional information is available on the "Exit Wounds" website.

Medications

Anti-inflammatory Medications

Aspirin, which was introduced as a pain reliever in 1899, is the founding member of a class of medications called non-steroidal anti-inflammatory drugs, or NSAIDs. All NSAIDs relieve mild to moderate pain and reduce fever and inflammation. They decrease the formation of natural substances in the body called prostaglandins, which are produced at sites of injury or swelling and make nearby pain receptors more sensitive. By decreasing prostaglandins, NSAIDs reduce pain and inflammation. But prostaglandins also help protect a number of areas

in the body such as the stomach and kidneys. Because NSAIDs work all over the body, they can produce side effects such as stomach upset or kidney problems.

Aspirin, ibuprofen (for example Motrin®), (for example Aleve®) and ketoprofen (Orudis® and Oruvail®) are the only NSAIDs available over-the-counter (OTC) without a prescription. A different class of NSAIDs, the selective COX-2 inhibitors, were not marketed until quite recently and were developed to reduce the risk of ulcers caused by NSAIDs. Only one selective COX-2 inhibitor, celecoxib (Celebrex®), is still available at this time.

NSAIDs are effective against mild to moderate pain, and are important for the management of both acute and chronic pain. They are also commonly used in combination with other drugs such as opioids for treating more severe pain. But NSAIDs alone are *not* effective for reducing neuropathic pain or the pain of fibromyalgia.

There is no evidence that one NSAID is a better pain reliever than another; however, each individual may get better pain relief from one than from another. Finding the right NSAID to treat persistent pain is a matter of trial and error. It may take awhile for the drug to work, so you and your provider will need to allow an adequate trial of the drug before judging its benefit.

NSAIDs have an important limitation, called a dose *ceiling*. Taking doses above the ceiling dose will significantly increase the risk of serious side effects, such as kidney failure, which can be life threatening.

Common Side Effects of NISAIDS

- Stomach upset
- Stomach ulcers
- GI bleeding
- Delayed blood clotting
- Decreased kidney function
- Possible increased risk of stroke or heart attack with selective COX-2 inhibitors

Acetaminophen

Acetaminophen (marketed as Tylenol® and also available as a generic) can relieve mild to moderate pain and treat fever, but it is not an NSAID and does not reduce swelling. It produces few, if any, side effects at the doses that can relieve pain, but it can damage the liver when used

in large doses. The labeling specifies an upper limit of 4000 mg 24 hours (which is equivalent to just eight extra-strength tablets). If you've got liver disease or a history of alcohol abuse you should limit your use of acetaminophen and talk to your doctor about other types of pain relievers.

As with the NSAIDs, acetaminophen is often combined with an opioid medication—usually they are in the same pill or capsule—to treat moderate to severe pain. You may not be aware that opioid medications like Vicodin® or Percocet® contain significant levels of acetaminophen. Be sure to check the amount with your pharmacist. Don't decide to take extra acetaminophen on your own if a combination pain medicine is not controlling your pain because you may end up using too much acetaminophen and that could cause liver damage. You should also be aware that many OTC cough, cold and sinus remedies contain acetaminophen.

Possible side effects with acetaminophen:

- Few side effects when used appropriately
- If taken in large doses, liver damage is possible
- If taken frequently in combination with alcohol, risk of liver damage and stomach bleeding is raised

Opioids

Many veterans of Operation Enduring Freedom have probably seen first-hand the flowers of the opium poppy, since at least 500,000 acres of this plant are under cultivation in Afghanistan. The principle active drug in opium is morphine, which was synthesized in 1803. Morphine was the first in what is now a very large class of pain-relievers called "opioids." Many of these drugs are made synthetically, although some drug companies continue to grow and harvest vast expanses of opium poppies to acquire the raw materials for modern pain medications.

The pain-relieving properties of opioids continue to be unsurpassed. They remain the "gold standard" of pain medications and are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often under-used. For a number of

reasons, health care providers may be afraid to give them and patients may be afraid to take them.

At the core of many of these fears is the specter of addiction, so let's tackle this issue right now.

If you take an opioid medication your body will get used to the drug. This is called tolerance. Because your body adapts to the medication, you will experience withdrawal effects if you suddenly stop taking it. With opioids, withdrawal symptoms usually include sweating, nausea, rapid heart beat, diarrhea, or anxiety. Withdrawal can be a problem with many medications used on a long-term basis, such as antidepressants and medicines to control high blood pressure. Tolerance to a medication, or the experience of withdrawal if the medication is stopped, are *not* signs of addiction!

Opioid medications, of course, can be abused or used as recreational drugs. And some people who use opioids this way will become addicted. Addiction is a disease state in which a person can no longer control their use of a drug that is causing them harm. They continue to crave and use the drug *despite* the harm it may be doing to their health, their relationships, or their ability to function in other spheres of life.

Long experience with opioids shows that for people who are not predisposed to addition are very unlikely to become addicted to opioid pain medications. When used correctly, opioid pain medications *increase* your level of functioning. When a drug is used by somebody who is addicted, their function *decreases.*

Doctors will typically ask patients if they or any close relatives have a history of addiction. Answering "yes" does *not* disqualify a person from getting a prescription for opioids. It simply means that both the patient and the physician will need to pay close attention to the use of the medication and watch for any signs of addictive behaviors. The doctor may ask the patient to sign a written treatment plan that spells out exactly how the medication will be prescribed and how future decisions to continue or end use of the medication will be made. But we want to be clear: denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards.

Types of Opioids

There are many classes of opioid pain medications. Some are fast-acting, some last a long time, some are more apt to induce sleep, some are less likely to cause stomach upset. The range of medications and the many ways the medications can be delivered mean that your doctor can look for the medication that works best for you and your specific pain. This might require some experimentation—but the diversity of available medications makes it more likely you'll find one that works.

Here are some of the more common types of opioids and some representative brand names (in parentheses):

- Codeine (Emprine® or Tylenol® with codeine)
- Morphine (Avinza®)
- Methadone (Dolophine®)
- Hydrocodone (Vicodin®)
- Oxycodone (Oxycontin®)
- Hydromorphone (Palladone®)
- Meperidine (Demerol®)
- Propoxyphene (Darvon®)
- Fentanyl (Duragesic patch®)

As mentioned above, sometimes an opioid is combined with acetaminophen or a NSAID. Vicodin® is a mixture of acetaminophen and hydrocodone, and Percocet® is a mixture of acetaminophen and oxycodone. Combination medications have relatively low dose limitations because of the dangers of liver toxicity from the acetaminophen. For severe pain, pure opioids are used because their doses can be gradually increased over time if the pain increases.

One of the advantages of opioid drugs is that they can be given in so many different ways. For example, they can be given by mouth, rectal suppository, intravenous injection (IV), subcutaneously (under the skin), transdermally (through the skin, via a patch) or into a region around the spinal cord. Patches, IV injections and infusions are very important for patients who cannot swallow or whose GI tracts are not working normally.

Opioids also vary in their duration of effect. "Ordinary" opioid medications (i.e. ones not altered to extend their effects) provide just several hours of pain relief after a dose. But

extended-release formulations (also called "modified-release," "controlled-release," "sustained-release" and sometimes "long-acting") can provide pain relief from eight to as long as 24 hours. Medications, such as Fentanyl, can be delivered via a patch that can provide relief for as long as 72 hours.

Opioid Side Effects

Finding the medication, dose, and delivery route that works best for you is often a matter of balancing the benefits of the medication against the side effects it produces. You and your doctor will seek the most benefit with the least side effects—which, again, is a highly individual thing.

The most common side effects of opioids are:

- Constipation
- Nausea and vomiting
- Sleepiness
- Mental clouding
- Itching
- Dizziness
- Difficulty urinating

The good news is that, with the exception of constipation, most side effects go away after a few days for most (but not all) people. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, poor diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. If any of the other side effects don't go away, tell your doctor. Perhaps another type of opioid can be tried, or there may be ways to treat the side effects with another medication.

The bottom line with opioids is that these are very valuable pain-relievers when used correctly and responsibly and can really help improve your functioning in daily life. The key, as always, is good communication with your health care provider, persistence, and a positive attitude.

Medications for Neuropathic Pain

Recall that neuropathic pain is caused by damaged nerves rather than stimulation of pain receptors. For a variety of reasons, this makes neuropathic pain more difficult to treat than nociceptive pain. (Phantom limb pain, a special case of neuropathic pain, is discussed in a separate section later in this chapter.) Drugs from several different classes, including certain antidepressants, anticonvulsants, and corticosteroids have been found to help. Certain opioids, too, may be used. Often a combination of drugs will provide the best relief. For example, a recent study confirmed that combining gabapentin and morphine gives better relief for neuropathic pain than using either one alone.

Some of the medications commonly used for neuropathic pain:

- Opioid analgesics and tramadol (Ultram®)
- Lidocaine patch (Lidoderm®)
- Antidepressants, particularly tricyclic medications, venlafaxine (Effexor®), and duloxetine (Cymbalta®)
- Anticonvulsants, such as gabapentin (Neurontin®) and pregabalin (Lyrica®)
- Corticosteroids (if pain is due to inflammation)

Physical Rehabilitation

Physical methods have been used for pain relief for centuries. Today, there are a variety of skilled healthcare professionals with specialized training in the use of physical techniques that help reduce pain. Many work in the field of rehabilitative medicine, and include physiatrists (physicians who specialize in physical medicine), physical therapists, occupational therapists and exercise physiologists. Some forms of physical rehabilitation involve hands-on manipulations such as deep-tissue massage, while others use devices such as transcutaneous electrical stimulation.

Physiatry

Physiatrists provide a wide variety of treatments for the musculoskeletal system (the muscles and bones) and do not perform surgery. Because the back is the core of the

musculoskeletal system, many physiatrists are considered specialists in treating back pain. A number of physiatrists have additional training in special areas, like sports medicine, brain (e.g., stroke or trauma) or spinal cord injury, pain management or pediatric medicine.

Physical Therapy

Physical Therapists (PTs) help restore function, improve mobility, relieve pain and prevent or limit permanent physical disabilities of those suffering from injuries or disease. They restore, maintain and promote overall fitness and health. If you've suffered a serious wound during service, it is very likely that you'll work with a PT in the course of your recovery. You'll first be tested to assess your strength, range of motion, balance and coordination, posture, muscle performance, respiration and motor function. Then an individualized plan will be drawn up to maximize your independence and function.

Physical therapists use a variety of treatment methods to relieve pain and reduce swelling including electrical stimulation, hot packs, cold compresses, traction, deep tissue massage and ultrasound. They also teach patients to use assistive or adaptive devices, such as crutches, prostheses and wheelchairs. Exercise training is often provided, which can be performed at home to help advance recovery by reducing immobility and improving flexibility, strength and/or endurance. As treatment continues, physical therapists will document your progress, conduct periodic examinations and modify therapies when necessary.

Occupational Therapy

Occupational therapists (OTs) help people perform tasks required for daily living and in the work setting. They help you learn a wide range of activities, ranging from using a computer to mastering everyday needs such as dressing, cooking and eating. Physical exercises may be used to increase strength and skillfulness. Therapists instruct those with disabilities in the use of adaptive equipment, including wheelchairs, splints and aids for eating and dressing. They can design or make special equipment needed at home or at work.

Hydrotherapy

Hydrotherapy is the use of water to maintain health or promote healing. Also known as Aquatic or Pool Therapy, the use of therapeutically warm water and exercise may help ease

painful muscles and joints. Gentle movement may help build strength, relax stiff joints and sore muscles. Water buoyancy greatly reduces the pressure on joints, making it easier to perform range of motion exercises. Hydrotherapy is a part of the physical therapy department of virtually every hospital and medical center.

Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is a method of physical therapy that attempts to decrease pain without needles or surgery. The TENS unit is designed to block or prevent pain by providing opposing stimulation to compete with the unpleasant signals that cause pain. The TENS sensation(s) interrupt pain signals in the body, perhaps by blocking the pain "gate" in the spinal cord that we discussed in Chapter 4.

TENS can be used in the treatment of acute and chronic pain, including pain of the lower back, neck, pelvis, nerves, and muscles. Used properly, TENS units are very safe, and do not hurt.

Complementary and Alternative Techniques

Complementary and alternative techniques encompass many medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine. Some of these approaches, such as acupuncture, are widely used and accepted. They can be used alone or in combination with medications or more conventional approaches. Other therapies, such as homeopathy, are not widely accepted by the medical community, although some people claim benefits from using them. Here we'll describe techniques known to be helpful for alleviating pain.

Acupuncture

Acupuncture has a growing acceptance in the field of conventional medicine. Today, acupuncture describes a family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.

People experience acupuncture differently, but most feel no or minimal pain as the needles are inserted. Some people feel energized by treatment, while others feel relaxed. Improper needle placement, movement of the patient, or a defect in the needle can cause soreness and pain during treatment. This is why it is important to seek treatment from a qualified acupuncture practitioner (most states require a license to practice acupuncture, and the FDA regulates the manufacture and labeling of acupuncture needles).

A related technique is acupressure, which is based on the same Chinese system of thought that underlies acupuncture. With acupressure, pressure by the hands or fingers of a practitioner are used instead of needles. Acupressure relaxes muscular tension and balances what are thought to be the vital life forces of the body. The patient lies fully clothed on a soft massage table while the practitioner presses gently on points situated on various parts of the body. The session is non-invasive and gentle. An average session lasts for about one hour. However, most people require a number of sessions to complete a treatment.

Chiropractic Care

The chiropractic therapeutic approach focuses on the relationship between bodily structure (primarily that of the spine) and function, and how this relationship affects the protection and restoration of health. Chiropractors use spinal manipulative therapy as a basic treatment tool. The primary belief of the chiropractic profession supports a natural method of healthcare that includes a deep respect for the human body's ability to heal itself without the use of surgery or medication. Chiropractors give careful attention to the biomechanics, structure and function of the spine, its effects on the musculoskeletal and neurological systems, and the role played by the proper function of these systems in the preservation and restoration of health.

Chiropractors frequently treat individuals with a variety of pain disorders, such as headaches, joint pain, neck pain, low back pain and sciatica.

Massage

Massage therapists manipulate muscle and connective tissue to enhance function of those tissues and promote relaxation and well-being. Massage is an old healing art with many techniques and approaches. Massage acts directly on the nervous system, activating the opposite

of the "fight or flight syndrome" and promoting relaxation. It eases painful, tight muscles and reduces spasm by stretching and gently separating individual muscle fibers that may have become bound and knotted together.

Massage can help increase range of motion in joints, enhance blood circulation, and relieve pain. Massage may also promote a restful sleep by helping the body and mind relax.

Injection and Infusion Therapies

This class of pain treatment involves either an injection (one-time, rapid) or an infusion (slow delivery over longer time period) of pain medications or some other type of treatment such as electricity, heat, or cold. These methods may be used to prevent or control both acute and chronic pain.

Injection Therapies (Nerve Blocks)

Injection therapies may be used to treat painful conditions in many areas of the body. Also called "nerve blocks" these techniques involve placing a needle into a muscle, joint, spine, or around a specific group of nerves, followed by the injection of medication(s) or delivery of some other treatment such as electricity, heat or cold.

Nerve blocks can be used to help determine if your pain is coming from a specific nerve, muscle or joint. Certain kinds of nerve blocks are first done with a local anesthetic medication. If you have relief, a more permanent type of block may be recommended. Nerve blocks can also be used to prevent development of chronic pain syndromes (prophylactic nerve blocks). Therapeutic nerve blocks may reduce pain, either alone or as a complement to other pain treatment options.

Neuroablative therapies

Neuroablative therapies usually produce a longer lasting effect than nerve blocks. These therapies use thermal (heat or cold) or chemical agents (alcohol or phenol) to "destroy" certain nerves or nerve chain pain pathways, thereby providing you with prolonged pain relief. Your pain specialist might choose this option if your pain is severe, expected to persist, and cannot be lessened by other therapies.

Infusion therapies

Infusion therapies, especially intravenous (IV) drug delivery, are a convenient and effective way to control your pain. Giving pain medications through a small tube placed under the skin, in your vein or in your spine provides faster and more effective pain relief than medications taken by mouth. These methods are commonly used after surgery, injury, or trauma.

Delivery of a medication under the skin can be very helpful for people in chronic pain. A small needle is placed under your skin into your subcutaneous or "fatty" tissue. The needle is connected to a tube and infusion pump, which delivers the pain medication into the tissue. Subcutaneous infusion can successfully be used in the home setting if you are trained to do so.

Infusing pain medications and/or local anesthetics near or directly into the spinal fluid space within the spine (epidural analgesia) is sometimes used after surgery, painful injury or illness. This can help you get better pain relief and help you move better after surgery. It is also possible to use less pain medicine and have fewer side effects, which should help your recovery.

Chronic neuropathic pain may be alleviated with infusions of a local anesthetic such as lidocaine. The local anesthetic is given over a 30-60 minute period of time and is usually done in an outpatient or ambulatory care setting.

Implantable Devices

Advances in medical technology have allowed for the implantation of pain medication pumps or electrical stimulators, which can reduce the risk of infections and provide targeted pain relief to major nerves and the spinal cord. A wide range of devices and interventions are available, which can be tailored for particular types of pain or particular parts of the body.

Spinal Cord Stimulation (SCS)

SCS therapy may be used to treat chronic neuropathic pain in the neck or arms, chest, mid to low back or legs. Your doctor or pain specialist will perform a SCS "trial" to see if the therapy will help to relieve your pain. If the trial is successful, a SCS system will be surgically implanted.

SCS uses a small battery-powered device, called a pulse generator or receiver, to deliver

electrical impulses near nerves along the spinal cord. These impulses interfere with the transmission of pain signals to the brain. When successful, you feel a mild tingling sensation instead of pain. There are two types of SCS systems: Implantable Pulse Generator (IPG) or Radiofrequency (RF). See the "Exit Wounds" website for more information on these options.

Intraspinal Drug Delivery Systems

Intraspinal Drug Delivery is the continuous infusion of pain medications into your spinal fluid with an implanted infusion pump. Your doctor or pain specialist may choose this type of advanced pain treatment therapy if you have chronic pain that is not controlled in other ways.

There are many similarities to SCS therapy: a trial infusion of the opiate medication will determine if the method will work. If successful, the system is surgically implanted beneath the skin of your abdomen. A small flexible tube runs from the pump to a selected spot in your spine. A computerized program controls how much drug is delivered.

Treatments for Phantom Limb pain

As of late 2008, nearly 900 of the 33,000 total U.S. wounded in Iraq and Afghanistan have lost at least one limb, according to the Pentagon. Most of these amputees will experience the sensation that the limb is still there—called "phantom sensation," and roughly 90% will experience phantom pain as well. Because it is a type of neuropathic pain, and because the pain can be complicated and exacerbated by the fit and use of prostheses, phantom limb pain can be difficult to treat. Nonetheless, you should be hopeful that you will find relief and be able to use a prosthetic to regain lost functioning.

All of the techniques we have discussed above, particularly the medications for neuropathic pain and some of the implanted electrical stimulator devices, are used to help manage phantom limb pain. Again, because people vary so much in their responses to medications, and because the nature of the stumps remaining from combat wounds can be so unique, it will probably take some trial-and-error searching before a medication or medication combined with a medical device or complementary therapy is found that reduces phantom pain without exacting too high a price in terms of side effects.

Two newly-developed pain-relieving techniques are specific to phantom pain and deserve your attention. We will review them briefly here, and you can read much more about them on the "Exit Wounds" website.

Mirror Box Therapy

This innovative treatment fights one illusion (phantom pain) with another illusion—that the limb is restored. Many amputees experience pain as a result of a clenched phantom limb, and because phantom limbs are not under voluntary control, unclenching becomes impossible. The theory behind the mirror box treatment is that the brain has become accustomed to the fact that a phantom limb is paralyzed because there is no feedback from the phantom back to the brain to inform it otherwise. Doctors at Walter Reed Army Medical Center constructed a box that uses mirrors to create visual feedback of a restored limb.

The intact limb is placed on one side of the mirror, and in the patient's sight, while the amputated limb is placed on the other side, out of sight. The patient sees an intact second limb through the mirror and sends motor commands to both limbs to make symmetric movements. The movement gives the brain positive feedback that the phantom has moved, and it becomes un-paralyzed.

Several studies have found success rates for the treatment as high as 80% and it is being actively pursued by doctors in many medical hospitals. Treatment with a mirror box therapy can involve several weeks of therapy, once or twice a day.

Deep Brain Stimulation

Deep brain stimulation is a surgical technique that has been shown to reduce or eliminate phantom pain in some patients. In this technique, nerves or brain regions that are active during a phantom pain experience are identified. An electrode is then implanted in the identified area, which is connected to a pulse generator implanted under the skin of the upper chest. Only a few studies of this technique have yet been done, but initial results are encouraging. In one study of three amputees, overall phantom pain was cut in half, and the burning component of the pain was eliminated. The use of opioid medications in the two amputees who had been using them was reduced, and all three reported significant improvements in their quality of life.

Planning for Relapse

Let's assume, for the moment that you have used one or more of the treatments we've reviewed here, that your pain has been brought under control, and that you have regained lost functions. If this is the case, your health care team or pain specialist should talk to you about what to do if the pain comes back. This is not defeatist or pessimistic. It's just a realistic approach to a wily enemy. Pain is a moving target. Your pain level can be affected by many things that change in life: the amount and nature of physical activity; stress; mood; or accidents involving a sensitive spot. Sometimes an existing condition, such as arthritis, will worsen, increasing pain levels. Or nerves that had been "quiet" may—for known or unknown reasons—become sensitized.

Planning ahead for a recurrence of pain makes sense, and it can give you the peace of mind that comes with knowing you are prepared. Planning may mean having a supply of a pain medication on hand or the right types of heating and cooling pads to provide thermal treatments. The specifics of your "bad pain day" plan will be unique to you, your pain, and the nature of the wounds you may have suffered.

Here are some other things to keep in mind if you're having a recurrence of pain:

- Remind yourself that *you* will manage your pain rather than it managing you
- Reach out for the support of loved ones who can help with physical tasks or simply provide moral support
- Be as specific as possible in asking for help
- If pain persists for more than a day or doesn't seem to respond to treatment, seek medical help sooner rather than later
- Get outside, if possible. Sometimes it can help to take a walk, get some fresh air, and get your blood moving.
- Don't give in to despair—a recurrence does not mean a return to the frustrating days of prior suffering. If your pain was successfully treated at one point, it can be successfully treated again.

A Final Word

We hope you now see that your arsenal of potential pain treatments is formidable. Not all of these options are available everywhere, and not all physicians are aware of all of these

treatments, much less be expert in their use. But now you're aware that they exist and can advocate for yourself or a loved one. If a treatment isn't working, there are other options. You may need to push—hard—to get the attention and care you deserve from individual care givers or from the often enormous institutions in which they work. But keep pushing! Everyone deserves full and effective pain treatment —but especially those who have willingly put themselves in harms way on the country's behalf!

Advice for Family Members

The choice of treatments for managing chronic pain is, of course, the decision of the person in pain and his or her team of care givers. But family members can support pain treatment in many ways:

- Remind a loved-one to take medications according to the prescribed schedule. (This can be particularly important if the person is using opioid medications since these can cause mental clouding, forgetfulness, and a failure to pay attention to time.)
- Remain alert for signs of depression, anxiety, or post-combat stress reactions since these can make pain worse and erode motivation to "stick with the program."
- Help with scheduling and making appointments with health care providers.
- Keep track of how much medication is left and make sure refills are ordered and obtained before they run out.

Voices of Survival for Chapter 6

Melissa Stockwell was commissioned as an officer in the U.S. Army in May 2002, after which she received training as a transportation officer. She was deployed to Iraq in March 2004 and quickly found out that a transportation officer's job is as dangerous as any other soldier's.

Melissa was in the lead vehicle of a convoy heading toward Baghdad when it was hit by an IED. Her vehicle slammed into a guardrail and crashed into a house. Between the blast and the crash, Melissa lost he left leg above the knee.

She woke up in a Baghdad military hospital. Her husband, Dave, also serving in Iraq, was there. She says they made an immediate decision: "Let's get on with this, and on with life."

From Iraq, Melissa was flown to Landstuhl and then to Walter Reed, where she spent a year in recovery and rehabilitation. She underwent 15 surgeries in all and says the treatment she received at Walter Reed was the "best care in the world. The rehab was wonderful."

Melissa is now fully mobile. She has even re-learned to ski. "Skiing was absolutely the best experience I had after being hurt. I felt so free just to fly down the side of a mountain."

She is now earning a bachelor's degree in prosthetics from Century College in Minnesota. She says she felt "absolute joy" when she made a prosthetic leg for a ten-year-old girl, and watched the child put the leg on, then get up and jump around. In the future, she is hoping to help wounded soldiers coming back from Iraq and Afghanistan get their lives back through prosthetic care.

Chapter 7
Exercise: A Key to Pain Relief

Chapter Recon

This chapter will answer the following questions:

- Why is exercise so important for pain relief?
- What is the best approach to starting, or returning to, an exercise program for veterans in chronic pain?
- What's the best way to treat a sprain or strain to minimize pain and speed healing?
- How does exercise benefit amputees?

The Benefits of Regular PT

No matter what branch of the armed services you have served in, you were exposed to PT—that shorthand for all of the physical conditioning exercises you did in boot camp, on active duty, and while deployed. The goal of PT in those times was to prepare you for combat and maximize your chances of fulfilling your mission. Now, post-deployment, you can again use PT to help you reduce your pain and improve your total functioning.

As you have probably experienced for yourself, exercise and physical activity help not only your body, but also your mind, your spirit, and your soul. That's because when you exercise, you are doing more than moving your muscles. You're increasing your oxygen levels, increasing blood circulation to the brain, and you're generating those pain-reducing compounds called endorphins that we talked about in the previous chapter. If you maintain your physical shape, you're also simply going to feel better about yourself, which is part of the overall picture of improving your functioning.

Of course, it's one thing to do PT in boot camp when you have no choice. Quite another when you're back at home, in pain, and perhaps stressed out by children, a job, or other complications! It's hard enough for un-injured civilians to carve out time for regular exercise. It's even harder if you are in pain from your wounds, when even simple movements like walking and changing position hurts. But here's the thing: the folks for whom exercise is hardest are the ones who stand to benefit the most from doing it.

Exercise not only keeps you healthy, it will reduce your pain over time. Weight-bearing and cardiovascular exercise strengthens your heart, lungs, bones and muscles. Physical activity protects against falls and bone fractures—which is especially important if you are an amputee. Research also suggests that exercise may help control joint swelling and pain caused by arthritis.

You can "double your money" with exercise if you do it with others. Derek's closest friends are not his neighbors or colleagues at school—they are his buddies on the Semper Fi team who he trains with and races with. By incorporating friends or family members into your exercise routine, you can build the relationships that support your emotional health, which will, in turn, support your physical health.

Here's a summary of what exercise can do for you:

- **Release endorphins**, which block pain and help alleviate anxiety and depression
- **Build strength,** which reduces the load on your bones and cartilage and can reduce pain
- **Increase your flexibility**, which can also reduce pain
- **Improve your sleep quality**, by lowering stress hormones
- **Boost your energy level**
- **Help you maintain a healthy weight,** which can reduce stress on your joints — another way to improve chronic pain
- **Enhance your mood**
- **Protect your heart and blood vessels--**exercise decreases the risk of high blood pressure, diabetes, heart attack and stroke

You may find it helpful to work with an exercise physiologist (EP), especially in the early phase of a course of physical training. EPs work in wellness or fitness centers as well as certain clinical settings, such as rehabilitation centers or hospitals. They can help you assess your

functional abilities, such as your level of cardiovascular conditioning. They can also help tailor the types and intensities of exercise for your particular needs. Sometimes an exercise physiologist is a part of the pain management team and provides the team with regular reports on your progress.

Getting started

You've probably heard this already, but you shouldn't begin an exercise program without talking to your doctor. This is particularly important if you've been wounded in any serious way, or have a chronic condition such as diabetes or high blood pressure. Your doctor or physical therapist can guide you toward exercise that is appropriate for your level of conditioning, your range of motion, and your state of healing. If you are in pain, you may be worried that exercise will make the pain worse, or that you might injure yourself. While there's some truth to the saying "No pain, no gain," you shouldn't take that too literally. You *can't* exercise if you are in severe pain. So you need to gain some control over any severe pain you are having and *then* begin exercising. A better slogan to follow is "Start low, go slow." That means starting with low weights, low repetitions, low distances, and not pushing your limits too soon. Many servicemen and women are used to pushing their bodies hard. But if you've been seriously wounded, you will be de-conditioned to one extent or another. Your brain may remember what you used to be capable of, but your body will not be up to the task—and you can hurt yourself if you don't take it slow.

When you are considering what type of exercise to do, think about what you actually enjoy doing. Some people, for example, love gyms and the whole indoor workout culture that entails. Other people don't like gyms at all and prefer outdoor forms of exercise such as running, biking, walking, or climbing. The point is simply that you are much more likely to stick with an exercise program if it is pleasurable for you

Most exercise programs involve three components:

- **Aerobic exercise**, which raises your heart and breathing rate and sustains that level for at least 20-30 minutes.
- **Strength training**, using dumbbells, resistance bands, body weight, strength training machines or improvised weights.

- **Stretching**, either before or after exercise to increase flexibility and reduce the risk of strains, sprains, or other types of injury.

Aerobic exercise

During aerobic exercise, you repeatedly work large muscles in your arms, legs and hips. You'll breathe faster and more deeply. This maximizes the amount of oxygen in your blood. Your heart will beat faster, which increases blood flow to your muscles and back to your lungs. Your small blood vessels (capillaries) will widen to deliver more oxygen to your muscles and carry away waste products, such as carbon dioxide and lactic acid. Aerobic exercise is also the type of exercise that releases endorphins (strength training generally doesn't release endorphins).

Studies show that aerobic exercise reduces your risk of many conditions, including obesity, heart disease, high blood pressure, type 2 diabetes, stroke, and osteoporosis. And, interestingly, research shows that it's the *amount* of exercise you do, not the *intensity* that makes the difference. You don't need to sweat buckets and feel like you're about to pass out, in other words. Doing a moderate 30 minutes of exercise is much better for your body than 10 minutes of intense exercise.

Strength training

Many people find that combining some kind of strength training to a program of aerobic exercise improves their endurance and overall fitness level. A regular strength training program can reduce your body fat, increase your lean muscle mass, and help you burn calories more efficiently. Strength training can be done at home or in the gym using the following methods:

- **Body weight.** You can do many exercises with little or no equipment — use your body weight instead. Try push-ups, pull-ups, abdominal crunches, and leg squats.
- **Resistance bands.** Elastic bands of different strengths are an inexpensive and versatile way to do resistance exercises.
- **Free weights.** Barbells and dumbbells are classic strength training tools. You can also try homemade weights, such as plastic soft drink bottles filled with water or sand.

- **Weight machines.** Most fitness centers offer various resistance machines. You can also invest in weight machines for use at home.

Stretching

Most aerobic and strength training programs inherently cause your muscles to contract and flex. Stretching those muscles after your workout can help prevent and relieve pain and reduce your risk of injury. Stretching can also improve the range of motion in your joints, improve your posture, and help relieve stress.

There is ongoing debate about whether stretching before or after exercise is preferable. Scientific data support both camps, so the choice is up to you. But everyone agrees that stretching muscles when they're cold increases your risk of injury, including pulled muscles. So if you stretch before your workout, take it slow and easy. And, alternatively, if you plan to stretch only *after* your workout, begin the activity slowly, with high reps and low power to allow your muscles to warm up before you pick up the pace or intensity.

Here are some tips on stretching:

- **Feel the pull, not pain.** If a stretch hurts, you've gone too far. Back off until you feel no pain, then hold.
- **Hold each stretch for at least 30 seconds.** Muscle tissue takes time to relax and lengthen. 30 seconds can seem like a long time, so keep an eye on the clock or your watch.
- **Don't bounce.** If you bounce during a stretch you can create small rips in the muscle that can leave behind scar tissue, which just makes the muscle even less flexible.
- **Don't hold your breath while you're stretching**.

Sprains and strains

If you exercise regularly, even if you don't intentionally push yourself or engage in higher-risk activities such as skiing or rock climbing, you're likely, at some point, to overdo it. A "pulled muscle" is a strain, which is when a muscle or tendon is stretched or torn. A sprain is when you over-stretch or tear a ligament, which is the tough tissue that connects bone to bone.

Minor sprains and strains are usually treated at home—but the way you treat them can make a difference in how fast they heal and how quickly the pain will go away.

The recommended steps to deal with a minor strain or sprain can be remembered using the RICE acronym:

- Rest
- Ice
- Compression (only possible on certain joints, such as ankles and wrists)
- Elevation

Prompt use of an ice pack on the affected area has been shown to significantly decrease healing time. The cold causes blood vessels to constrict, which reduces swelling and possibly the release of pain-producing compounds from injured tissues. Apply ice or cold for 15-20 minutes, then let the area warm up naturally. Repeat every hour as needed to reduce swelling and pain. Don't put the ice pack directly on the skin—wrap it in a towel or cloth.

After two days, you can switch to heat because, by then, swelling should be controlled. Heat opens blood vessels, which can help flush the affected area with blood and oxygen, which can facilitate healing.

You can also, of course, use a NSAID pain medication such as ibuprofen to reduce the pain of a strain or sprain. NSAIDs may be preferable to acetaminophen because they have an anti-inflammatory effect, which may help reduce swelling.

Exercise after amputation

Exercising for amputees is a large and important field in and of itself. You'll find excellent, detailed information on the Exit Wounds website. Here we simply want to stress how important exercise is for amputees. You don't have to run races, like Derek, though that can be a great way to provide motivation. Doing any kind of regular exercise will provide all the usual benefits of exercise and, in addition, will improve your prosthetic performance and the health of the remaining portion of a limb.

If you have a lower-limb prosthesis, here are some key points to consider as you work up to aerobic exercise:

- Develop a good sense of balance over both your feet.
- Maintain equal weight bearing through both lower limbs.
- Learn to use your muscles in the socket, your knee and your hip quickly and efficiently because timing is everything.
- Continue to keep your body weight over your prosthetic limb long enough to fully deflect the prosthetic foot for maximum "energy release."
- Practice moving in multiple directions with your prosthesis and, therefore, using your muscles in a variety of situations.

It takes time to learn to use any prosthesis. But practice makes perfect! Learning how to let your prosthesis work for you instead of against you can make life much more rewarding.

The best drug

We hope this chapter has convinced you of the merits of exercising, particularly if you are in chronic pain. A good program, started slowly and carefully with the guidance of your doctor, exercise physiologist, physical therapist or other health care worker, can do more for your health, your mood, your recovery, and your pain control than any other single component of care -- including medication. Yes, medications can be invaluable…even indispensable. And, as we said, you need to bring your pain under at least some control before you can effectively begin to exercise regularly. But the benefits of exercise extend to *all* levels of your being—physical, emotional, mental, even spiritual. That's something no pill or device can do. You owe it to yourself to take full advantage of the healing powers of exercise!

Advice for family members

- Recognize that for veterans who were wounded or who are dealing with pain, exercise is not a luxury—it's a vital part of their recovery and on-going ability to function. You can help by giving them the time they need to exercise.
- Consider exercising with your loved-one, if possible—it can be a great way to bond and strengthen your relationship.

- If your loved-one wants to eat a healthy diet as part of an overall program of exercise, try to eat the same way. It's much easier to stick to a healthy diet if everyone in the house is eating the same way.
- Remind your loved-one that even if they don't feel like exercising at first, they will feel better once they start and *much* better after they've finished. Praise them for sticking with it!

Chapter 8
Treating the Inner Wounds

Chapter Recon

The chapter will answer the following questions:

- Why do some people resist getting help for mental or emotional difficulties?
- What is a "confiding relationship" and why is having one important for healing?
- What sorts of treatments exist for mental or emotional difficulties?
- What are some ways to rekindle and revive a sex life that has evaporated because of chronic pain?
- What role does spirituality play in reducing pain and healing mental and physical wounds?
- What is "resilience" and why is that a better overall goal than "strength"?

The First Step

If you or a loved-one is in pain, you know how it can affect your emotions, your behavior and how it can interfere with your ability to concentrate, manage everyday tasks and cope with stress. In short, you know that pain ripples through all parts of your life and the lives of those surrounding the affected individual. You also know that the mental/emotional sides of chronic pain, such as depression, anxiety, and combat stress responses, can make pain worse and interfere with your efforts to improve your level of functioning. We call these non-physical difficulties "invisible wounds" because even though you can't see them physically, they can be just as disabling as any mortar wound or lost limb.

Treating "invisible wounds" can be just as challenging as treating chronic pain. As tricky and complicated as pain can be, it at least involves somewhat tangible things like nerves, brains, limbs, and injuries. There also isn't much stigma associated with getting treatment—pain is seen as a medical problem requiring a medical response.

But emotional difficulties? Depression? Post-deployment stress reactions? For many reasons, these can be harder to treat than the pain that often lies at the root of the problems. But that just means it's even more important not to ignore these kinds of issues and to seek help for them sooner rather than later. Because, just like pain itself, untreated mental and emotional problems often get worse over time.

There are as many ways to treat, heal, and overcome non-physical pain and difficulties are there are to treat, heal, and overcome the pain itself. We'll review the major options in this chapter. But, first, you have to *seek* these options. You have to take the first step of asking for help and looking for answers. This isn't always easy, especially for veterans. In some quarters there remains a stubborn stigma about getting help for mental conditions such as a depressed mood, anxiety reactions, sexual problems, or relationship difficulties. Actually, there's a stigma about getting *any* kind of help. On duty or in combat, weakness is bad, strength and self-reliance are good. And asking for help, as rational and normal as that is, can be perceived as weakness. Add to that generic hesitancy to get help the lingering stigma of getting help for a mental or emotional problem and you've got a significant barrier that many vets have to overcome before they can take even the first steps toward getting help.

Fortunately, there is a growing awareness in the military that mental health issues are important, that mental health services must be provided, and that commanders need to convey the common-sense idea that everyone has problems now and then and that getting help is a sign of strength, not weakness. It's even more critical to get help if you're in chronic pain, because life difficulties can really get in the way of your progress. In addition, counseling of various sorts—which we'll be discussing in more detail in this chapter—is usually covered by TRICARE, the military's medical insurance program, as well as many private health insurance companies. The resources are there, in other words. You just have to ask for them.

Confiding Relationships

At the heart of almost all healing from the non-physical wounds of combat and difficulties such as depression, anxiety, or stress responses, is opening up to somebody about these issues. We've used this phrase before, but it bears repeating: "Revealing is healing." Like most bumper-sticker slogans, of course, the reality is more complicated than the slogan.

Who can you reveal your innermost fears or your most wrenching combat experiences? Who can take that kind of un-varnished candor? Who can you trust to keep things private? Who will understand you at that deep level of honesty?

We don't know who that person is. But we want to say as clearly and strongly as possible that you need to find that person in your life. At least one. If you're lucky, maybe you'll have more than one. And if you don't have one, you need to cultivate one. These people, to whom you can tell everything, with whom you can be utterly and completely honest, and who will understand and accept without judgment all you have to say, can be the keys to your healing, your recovery, and your development as a person. These are special relationships—called "confiding relationships" in the jargon of psychotherapy.

Some people automatically assume that their confiding relationship is with their spouse or partner. Turns out that's not often the case. Let's be honest: one of the more vexing things about life can be your relationship with your spouse or partner! It's often easier to have a confiding relationship with somebody you are *not* living with and *not* sleeping with.

What matters is that you can talk about anything, admit everything, and reveal all the sides of your personality—the good, the bad, and the ugly. Why is this so helpful? Why is utter candor so healing? Truth is, nobody really knows. Maybe it's something about release, about pent-up tension, or about the comfort that comes from dropping the masks and the facades that we all have to wear from time to time. Walt Whitman once famously said, "I am large. I contain multitudes." Talking about your life in the context of a confiding relationship can give voice to these "multitudes" and, from that, can come insight, new perspective, and healing.

Treatment Options for Non-Physical Difficulties

Just like physical pain, problems with mood, emotions, or relationships can be treated in many ways by many types of health care professionals. There are many kinds of "talk" therapy, for example. And we're not talking here about laying on a couch and talking about how your

mother treated you as a child. Modern talk therapy is much more akin to private tutoring—you are taking advantage of a "skilled consultant" in order to learn ways to cope, resolve, or get over some particular problem in your life. The emphasis is on solving current issues. Of course, some here-and-now problems have roots in the past, and it can be very helpful to better understand those roots, but that's not generally the focus. The goal is more usually insight. Insight about yourself, who you really are, why you respond the way you do to people and events around you, and how you can learn new, more effective ways to cope with challenging situations.

Problems of stress, anxiety, or depressed mood also involve your brain. Sometimes, particularly for veterans, there may be actual physical damage, such as the traumatic brain injury Derek suffered. But even in the absence of outright damage, who we are as individuals and how we respond to others has everything to do with how our brains are functioning. Being depressed, or anxious, or having combat-related stress reactions all can change the way your brain works—and not for the better. It can sometimes be helpful, therefore, to use medications that buffer stress, calm anxiety, or boost energy and outlook. The subject of medications for problems of the mind is much too large to cover here, but more information on this is available on the Exit Wounds website. Here we want to briefly cover some of the types of psychotherapies that others have found to be extremely helpful in helping them overcome chronic pain. In fact, some forms of psychotherapy have been shown in careful scientific studies to be just as effective as medications for helping people deal with problems of mood, anxiety, or stress.

The words counseling, therapy, and psychotherapy are often used to describe the same process. Whatever term you use, counseling is a process that involves a series of discussions with a trained professional who can help you identify your feelings or problems, talk about them, and find ways to cope with or solve them. Counseling and therapy can occur individually, with another person, with a family, in a group, or in a combination of these. Therapists working with couples often see the individuals separately as well as together. When working with families, they may see individuals, the parents, other combinations of family members, or the whole family together. Therapy need not be long-term—most of the time a great deal can be gained by short-term, goal-oriented therapy of between six and 12 sessions.

Counseling is a highly personal process, and the match between a counselor or therapist and a client is highly personal, too. As a potential client, the more information you have, the

easier it can be to make the right match. Some therapists may specialize in treating women, men, children, or couples. Others may focus on different issues, such as pain, grief, or substance abuse. There are many different kinds of counseling theories. Some focus on the relationships in your life, others on the thinking processes that underlay our behaviors, others on how behavior patterns we learned in youth can cause problems when we are adults. A good therapist should know when to select a particular approach to treat a specific problem. Even more important, however, is the way you feel about a therapist or counselor. You want to find someone who seems genuine, caring, and interested in helping you.

One type of therapy that has been shown to work well in many studies is cognitive-behavioral therapy (CBT). CBT involves a relatively short series of weekly meetings with a therapist with the goal of identifying and changing negative or irrational thought patterns that can lead to dysfunctional behaviors. (The actual number of sessions varies widely and is influenced as much by insurance or health-plan policies as actual patient needs.) For instance, you might not realize how powerfully your need for praise drives behaviors that ultimately undermine your ability to achieve your goals. During CBT, therapists help patients see these kinds of patterns and suggest ways to interrupt or replace negative or unhelpful thinking with more realistic, positive attitudes and expectations.

For difficulties with relationships, other types of therapy can be very helpful. Interpersonal therapy is a pragmatic, results-oriented process that typically involves 12 to 16 one-hour sessions focused on specific goals usually dealing with relationships. Family therapy can be extremely valuable when children, teens, or other family members have been affected by an anxiety disorder in another family member. Family therapy can provide a safe forum for everyone involved to speak and be heard, which can be difficult, but also tremendously rewarding.

Group therapy, as Derek discovered, can also be very helpful. Being with others who understand what you've been through or are currently dealing with can be comforting, supportive, and even fun at times.

Where can you go to find a group like that, or a counselor or therapist? Start by visiting your installation Family Support Center or Community Support Center. You could also make an appointment with your command or installation chaplain. These sources will be able to offer options for consultation with counselors who are attuned to military lifestyle issues and prepared

to offer confidential, professional assistance. Services are usually free of charge and confidential, unless what you share suggests a danger of harm to yourself or others. You can also look for counselors and therapists in your local community. Private services may be covered by your TRICARE benefits (see the resources section for contact information).

Rekindling Intimacy

Often, one of the first casualties of a chronic pain condition is sex, which can be a big deal for veterans who are typically in the prime of their sexual maturity. Pain itself is an anti-aphrodisiac, and many of the medications used to treat pain can reduce sex drive or sexual response. But one of the key "functions" many people seek to recover by successfully treating their pain is sexual functioning. This isn't always easy. But you owe it to yourself and your partner to look for ways to regain a level of intimacy that involves sexual pleasure. Not only is sex a natural and healthy part of life, it can actually reduce pain sensations by releasing endorphins and lowering stress.

How you and your partner go about restoring a sexual life will depend on the nature of the wounds suffered by the injured partner. Obviously, the more serious the wound, the more likely it is that one or both of you will have to adjust the way you make love. In fact, intercourse may not even be possible if, for example, the genitals were seriously injured. But, even in the most extreme cases, it may still be possible to give and receive pleasure—and that intimacy can be just as deep and satisfying as "normal" sex. If you focus on the intimacy first, not "penetration" or "intercourse," and if you broaden your idea of what "sex" is, you are more likely to find satisfaction.

The first step is to talk about it. Sex and intimacy aren't always easy to talk about, which can lead to subtle mis-understandings. You may think, for example, that your partner has stopped touching you because he or she has lost interest, or finds you unattractive when, in fact, your partner might be afraid of causing you more physical pain. If you can find a time to talk about sex with your clothes on and not in bed, you can open up feelings and build bonds that can later be the foundation of a renewed sexuality. Talking can also help you both adjust expectations about what you want in bed. It can be a relief if you agree to take it slow and not even worry about intercourse at first.

In bed, you might want to consider a process called "sensate focusing," which simply means that you caress, hold, and touch each other *without* touching the genitals. The goal is not orgasm. It's about learning what feels good to you and to your partner. You take turns touching your partner and, either with words or gestures, say what feels good or not. Later (and you and your partner can decide if that means "15 minutes later" or "several days later") you both can include the genitals in the touching. One technique that can work is called "hand riding." By placing one hand on top of the partner's hand while being touched, one can indicate if he or she would like more or less pressure, a faster or slower pace, or a change to a different spot.

When you and your partner are ready for more deliberate sex, keep in mind that there are many ways to satisfy one's needs for sexual stimulation and human closeness. If one or both of you believes that sex is only good if you both have orgasms at the same time during vaginal intercourse you are setting yourselves up for frustration! That goal isn't realistic even for perfectly healthy, un-injured young people. The truth is that it's fine for one person to have an orgasm before the other—it's fine if *only* one person has an orgasm if that's what they want. It's fine to have an orgasm without intercourse. It's fine for *neither* of you to have an orgasm. See? The fewer unconscious "rules" you have, the better. Flexibility, creativity, and openness to new ways of doing things are the way to go here. The only rule we suggest is simply that no partner be coerced into doing anything he or she doesn't feel comfortable with.

Here are some other ideas you might find helpful:

- If you think a pain medication is interfering with your sex life, talk to your doctor about it. Sometimes a different medication can be prescribed which doesn't have the same sexual side-effects.
- Masturbation is a normal and healthy way to fulfill your sexual needs. Self-stimulation, during love-making, in fact, is the only way many woman can orgasm during sex. But self-stimulation can be a perfectly good way for either partner to experience sexual pleasure. This can be especially important if one partner is unable to be very active.
- Oral sex can be an alternative or supplement to traditional intercourse.
- Experiment with different positions. Lie side by side, kneel or sit or use furniture. Do whatever works for both of you.

- Vibrators for either the man or the woman can add pleasure without physical exertion. The variety of available vibrators is nearly endless. With a little experimentation you may discover entirely new dimensions to sex.
- If lack of natural lubrication is a problem (or even if it's not) you might try using an over-the-counter lubricant (i.e. K-Y jelly) or one of the more specialized lubricants available online or from adult erotica stores.
- Remember that although a little alcohol can facilitate relaxation, a lot of alcohol is a sure-fire way to kill one's sexual response.
- Try to keep a sense of humor. Sex should be fun…it is, after all, just sex.

The Value of Spirituality

In addition to formal and informal counseling or therapy, you might consider joining a faith community that you feel comfortable with. Studies show that people involved in a spiritual group of some kind have a lower risk of death or illness than those not involved. The reasons for this benefit are not well understood. It could simply be that people who attend a spiritual group are less likely to have unhealthy habits such as smoking. Or perhaps the diets of some religious groups are healthier than is typical. It may also be that the fellowship, good will, and emotional support offered by spiritual groups promote healthy living. What matters are not the specifics of a religion or spiritual practice—they can be as orthodox or liberal as you like—but that you get involved in a community of like-minded people.

Many veterans have faced death and confronted their own mortality at an age when most civilians are still feeling young and immortal. Being in the line of fire or coming close to death yourself from grave wounds can be a life-changing experience. It can force you to re-assess your priorities and values and lead you to consider what gives you a sense of meaning, or purpose in life. A common response is: "making a contribution and helping others." Derek, for example, is working on his Masters Degree so that he can go back and work with wounded veterans. We're not making a value judgment here—Derek's not better than another vet who pursues a career or chooses to raise children. It's just that the experience of war can have this spiritual dimension, and acting on this charitable impulse can be deeply satisfying.

What's this got to do with chronic pain? Nothing, directly. But that's the point of this chapter—all of the *indirect* parts of your life can change your experience of pain for the better. Feeling a sense of mission in your life, or joining a community of faith can be part of the mix, part of your solution. They're not for everyone—we're just pointing out that, for some people, the spiritual side of life can support recovery.

Resilience: A Better Kind of Strength

We end this chapter about the non-physical sides of chronic pain by inviting you to consider a framework for viewing not just your struggle with pain, but your growth and development in general. Yes, if you are in pain, your goal is to overcome the pain and restore your "normal" level of functioning. But progress in both psychology and neuroscience suggests the possibility of a more ambitious goal: the development of psychological resilience and emotional fitness.

Resilience is the capacity to maintain, recover, and improve mental and physical health in the face of challenge. Recent studies have shown that resilience can be improved with intentional effort. People can learn to build their psychological reserves, toughen their physical responses to stress, and become less vulnerable to maladies such as anxiety or depression.

The central metaphor of resilience is flexibility, not rigidity. It's a different kind of strength. Resilience implies a capacity to absorb blows, not repel them with armor. Resilience means having the full spectrum of human emotion, from positive to negative, as appropriate for a given situation, so that one does not become stuck in an emotion or fixated on a problem or event. This idea is hardly new, of course. Lao Tzu, the great Chinese philosopher, wrote something similar some 2600 years ago:

Green plants are tender and filled with sap
At their death they are withered and dry
Therefore the stiff and unbending is the disciple of death
The gentle and yielding is the disciple of life

This may sound hopelessly naïve to a Marine, a Sailor, an Airman, or a soldier who has been trained to kill and survive the ravages of war. But neither we nor Lao Tzu are talking about combat or the qualities a person needs to fight and survive. You certainly *do* need "armor" in

battle, you *do* need a rigid kind of strength, and you cannot be gentle with an enemy intent on killing you. But you are not at war. You're home now. And switching to a resilient type of strength is going to be far more productive and rewarding than remaining, like a clenched fist, in a fighting stance.

Resilience has many roots—it emerges from strength at four levels: biological, psychological, social, and external. When these pillars are strong, a distinctive cluster of personality traits appears: good intellectual functioning; effective self-regulation of emotions; positive self concept; optimism; altruism; an active style of coping with stressful situations; and an ability to bond with a group around a common mission.

Resilience is not an all-or-nothing proposition, however. People are complicated, and so is their resiliency. Some people have extraordinary resilience in one type of situation (such as being in physical danger) but not in another (such as in dealing with the loss of a loved-one). But the four pillars of resiliency can be harnessed to maintain emotional fitness in the face of different types of challenges.

Physical health is the first pillar of resilience. This is where getting prompt, effective treatment for your pain comes in. You can't cope optimally with adversity, loss, or trauma if you're in pain—or sick or injured. Regardless of age or physical condition, people can improve their physical resilience by taking simple steps such as eating well, exercising, getting enough sleep, and avoiding excessive use of alcohol and other recreational drugs. Aerobic exercise, for instance, reduces cortisol, raises testosterone, improves insulin function, and alters a variety of brain chemicals in ways that improve mood.

The second pillar is psychological resilience. This is a broad area and has to do, in part, with how easily a person forms and maintains emotional connections with others. But there's another aspect of psychological resilience with particular relevance to veterans: how adverse events are viewed. In psychological terms, this is called "appraisal." Generally speaking, adverse events can be appraised as either threats or challenges.

If a situation is appraised as a threat, the body reacts immediately. A cascade of hormones including adrenalin and cortisol surge through the body preparing it for action. Meanwhile, on an emotional level, an appraisal of threat elicits fear, apprehension, anxiety, and defensiveness.

Situations viewed as challenges, however, have quite different hormonal and emotional qualities. Challenge implies the possibility for growth or gain and the emotions surrounding a challenge are often positive: eagerness, excitement, and determination, for example. The hormones released by an appraisal of challenge include growth factors, insulin, and other compounds that promote cell repair, trigger relaxation responses, and stimulate efficient energy use.

Both types of appraisal can be valid, and both types of hormonal response can be helpful. But people who habitually or unconsciously assess situations as threats will erode their resilience because they will be constantly engaging their more defensive and biologically taxing bodily responses.

As long as a balance exists between one's appraisals and the subsequent hormonal responses, and as long as the threat or stressor is not constant or chronic, exposure to threats can actually toughen our hormonal response system and confer greater future resilience. The trouble comes when a non-threatening event such as constructive criticism is appraised as a threat rather than a challenge, or when an actual threat is unrelenting, as in the case of child abuse or, of course, war. Exposure to constant threat greatly raises the risk for post-traumatic stress disorder.

The third pillar of resilience is the social network one lives in. Humans are innately social creatures with deep instinct to form groups, create social hierarchies, bond emotionally, and simply hang out together. Having a network of friends and family is a powerful safety net in times of trouble and a key factor in resilience. Particularly important are the confiding relationships we talked about earlier.

The last pillar of resilience are your external supports such as money, education, food, clothing, and shelter. In general, having such supports contributes only modestly to resilience while *lacking* them significantly erodes it. For example, many studies show that wealth beyond that needed for adequate shelter, food, and opportunity does little to increase happiness.[12] But having money can help in times of crisis by allowing one more freedom—giving one the opportunity, for example, of hiring others to do household work, or of flying to family members who can provide comfort and support. Similarly, having a college education, by itself, doesn't guarantee resilience, but it does confer some protection, perhaps because education develops "cognitive complexity," a variety of intellectual abilities and the capacity to view matters from

multiple perspectives. Still, in many ways, the external components of resilience are the least important of the factors we've just discussed.

The four pillars of resilience combine to form your level of resilience at any particular moment. They determine how easily you respond to the changing load of physical, emotional, and mental stressors in life. The hallmark of resilience is the ability to smoothly adjust to the demands of the outside world in order to maintain your physical and mental health.

How can you become more resilient? Many veterans have already had experiences that can promote resilience. The adage "what doesn't kill you makes you stronger" contains an important element of truth verified by researchers studying resilience. Many people emerge from a challenge such as the loss of a loved one or combat saying they have gained from their experience. The book *Posttraumatic Growth* reviews many stories of people who have endured serious hardships or trauma and not only survived, but went on to thrive. Research—and stories such as Derek's—suggests that adversity or trauma can sometimes produce greater resiliency.

> *In the midst of winter, I finally learned that there was in me an invincible summer.*
> -- Albert Camus

Another finding is that aerobic exercise can produce toughening effects that mirror those induced by moderate, intermittent stress. For example, physical training programs have been linked to lower base-line physiological arousal rates, quicker return to base-line after stress, improved use of blood sugar, reduction in muscle tension, and a reduction in various compounds that are associated with the fight-or-flight arousal of the nervous system.

The bottom line is that as you cope with chronic pain and recover your functioning, you can also improve your overall resilience. Of course, it won't be a smooth, uninterrupted process. Life events will happen that sometimes support and occasionally erode resiliency. But by attending to both your physical health and the kinds of non-physical issues we've discussed in this chapter, you can make steady progress and reach goals you might not think possible now.

Advice for Family Members

- Encourage a loved-one to seek help with any mental, emotional, or relationship issues they might be having and remind them that doing so is part of their overall treatment and recovery.
- Show your support of a loved-one with actions as well as words.
- Be willing to go with a loved-one to a counselor or therapist if that is requested or suggested.
- Go with a loved-one to religious services if they choose to do so.

Chapter 9
Getting The Help You Deserve

Chapter Recon

This chapter will answer the following questions:

- How can I get the best care from providers and health care systems?
- What are recovery coordinators and what do they do?
- What kinds of medical benefits are veterans entitled to?
- How does the military determine level of benefits for those who were severely wounded in combat?
- How does the Combat Related Special Compensation process work?

Working with health care providers

As was vividly illustrated by Derek's struggles with the medical system, finding the most effective pain relief often requires an assertive attitude of self-advocacy. This is true whether the system is military or civilian. Doctors, nurses, administrators—practically everyone is over-burdened, short on time, and over-worked. That means you sometimes have to be the "squeaky wheel" to get the attention and the care you deserve. In this chapter we'll explore the most effective ways to get the best possible medical care and pain treatment. We'll also give you an overview of the types of medical benefits for which you may be eligible—a complete list and more detailed information is available on the Exit Wounds website.

If you are dealing with chronic pain issues, you need a team of health care professionals, as we've discussed in previous chapters. If you're fortunate enough to have a pain specialist as part of that team, he or she may do some of the work of coordinating all of the team members and sharing information between them about your condition and progress. If you don't have a

pain specialist, or if he or she doesn't want that coordination role, you may need to do some of it yourself. This might mean sending email updates to team members or working out scheduling conflicts for appointments.

As you interact with the various medical providers on your team, keep the following questions in mind:

- Are your providers able to clearly communicate medical information?
- Do you get enough information to make informed choices about your treatment?
- Do you get referrals to specialists when you should have them?
- Are your own suggestions and inquiries treated respectfully?
- Are requests for second opinions granted quickly and without resistance?

If the answer to any of these questions is "no" then think about finding another provider. Yes, that is a hassle, and no, you shouldn't have to do it. But just like in the rest of life, some relationships are better than others, some people are a better "fit" for your particular needs, style, or personality, and sometimes everyone is better of with a separation. Make a good-faith effort to work with your providers, but if things aren't working out after a matter of weeks or months, it's time to look elsewhere.

You have responsibilities in these various health care relationships as well, of course. For example, you should come to office visits prepared with information or lists of questions you want answered. During appointments, ask questions about anything you don't understand, and find out what you need to do after you leave the office. Ask providers to write down any instructions you might forget, or bring a notebook and pencil with you to write them down yourself. Keeping one notebook for all medical appointment notes can help keep everything organized.

If you're having some kind of difficulty, whether it's with a medication side effect, an ability to stick to a treatment plan, a financial problem, or any other concern, speak up! Your health care provider may be able to make adjustments that will make things better. For example, you may be able to gradually reduce the dosage of a medicine with unpleasant side effects or get financial help through a veteran-related service organization. And if you're feeling discouraged or so frustrated that you can't remain calm when dealing with providers or administrators, call on

a trusted family member or friend for support. It's important to advocate for yourself—but it's also smart to know when you need to let somebody else step in and lobby on your behalf.

If you are using—or want to use—some type of non-traditional treatment or practitioner, it's important to share the information with everyone on your health team. They won't—or shouldn't—take offense if you want to seek care from an acupuncturist or chiropractor, and they can advise you about such things as interactions between certain herbal products and any existing medications you might be using.

Using a Recovery Coordinator

If you've been seriously wounded, you may be assigned a Recovery Coordinator at the military hospital where you received treatment. Coordinators are part of a new program designed to coordinate care in both the military and civilian health care systems. If you are assigned a Coordinator, he or she will work with the doctors, nurses, social workers and service-specific program staff to create a Recovery Plan. This Plan, in part will help guide you in identifying, applying for and receiving the right benefits and compensation. Depending on where you are being cared for, your Recovery Coordinator will be available in person or via phone and e-mail.

Types of Medical Benefits

There are many types of medical benefits available to veterans. Which ones you may be eligible for depends on such things as the seriousness of your disability, length of service, and the military branch in which you served. Here are the most common types of medical or health-related benefits (many other types of benefits, such as direct disability compensation, exist as well, of course).

Medical care

The Department of Veterans Affairs (VA) offers medical care in their nation-wide system of medical centers, clinics, rehabilitation centers, and nursing homes. Access to VA medical care is based on discharge status, length of service, disability rating, and income level. Vets with service-connected disabilities receive the highest priority at VA medical facilities.

The VA offers a host of special programs for veterans, including:

- Treatment for Gulf War Illness
- Treatment for post-traumatic stress disorder
- Services for blind veterans
- Readjustment counseling
- Dental care
- Home health care
- Hearing aids

Care-giver financial support

Family members often want to be with a loved-one while they are treated for an illness or injury. In the past, this meant some family members had to choose between employment and providing care for a service member. In 2008, however, Congress passed legislation that allows for payments to care-givers under certain conditions. The new rules mean family members may be eligible for up to 26 weeks of unpaid leave in a one-year period to care for a loved-one. For this benefit, you must have a serious injury or illness that occurred in the line of duty while on active duty. Not all family members are eligible. Spouses, children, parents, and/or a next of kin are usually covered if they meet the requirements in the law for time worked at the place of employment. Other family members may be eligible in some cases.

Home and car adaptation

Veterans and service members with specific service-connected disabilities may be eligible for grants to help them adapt their homes or cars to meet their disability requirements.

Community-based counseling

The VA operates a system of 232 community-based Vet Centers, which are staffed by small teams of dedicated providers, many of whom are combat veterans themselves. Vet Centers provide *free* individual, group, and family counseling to all veterans who served in any combat zone. Here are some of the areas in which you can get help at Vet Centers:

- Readjustment counseling
- Marriage and family counseling
- Grief counseling;

- Help with medical referrals and applying for VA benefits
- Employment guidance and referral
- Alcohol and drug abuse
- Counseling and referral for sexual trauma that happened in the military

Vocational rehabilitation

The VA offers rehabilitation and employment services to help service members and veterans transition out of the military. These programs provide such things as counseling services, education and training, job assistance, and financial aid. To be eligible, you must have a service-connected disability and require vocational rehabilitation in order to find a job. The program is also available to active-duty service members who are awaiting discharge because of a disability.

Service-Connected Disability Compensation

If you are seriously wounded, injured, or become ill as a member of the armed forces, a formal set of rules exists to determine which benefits you are eligible for and what level of services you will need. This process is called the Disability Evaluation System (DES). The process usually begins when your doctor determines that you have suffered a permanent or long-lasting effect from a wound, illness, or injury. Every patient is different, and in some cases a doctor will wait to write the narrative summary until he or she sees how you respond to treatment and rehabilitation therapy before referring you to the DES. The doctor will refer your case only after he or she is satisfied that everything medically possible has been done to improve your condition. The services generally also require doctors to initiate the DES process after a year of treatment for the same injury or illness.

Each service uses a slightly different method to enter a member into the DES, and there are different ways that the level of disability is determined. The Army, for instance, uses a physical profile system that measures soldiers' physical limitations in six areas with a level between 1 (fully healthy) to 4 (severely limited) in each. If a soldier receives a permanent level 3 or 4 in any area, the doctor is required to recommend that a Medical Evaluation Board (MEB) review the soldier's case. In the Navy and Marine Corps, the process begins with the doctor

writing the narrative summary and no prior requirements exist. You should talk with your chain of command and your doctors to find out how the DES process begins for your service.

Usually, a copy of your medical record is sent to the nearest designated military treatment facility commander, who assigns a Physical Evaluation Board Liaison Officer (PEBLO) to help guide you through the DES process. Once you have been assigned a PEBLO, an MEB will review your record to decide if you meet your service's medical retention standards. While each service has individual rules, generally the MEB is made up of medical professionals. The PEBLO will build a packet of information containing:

- Your medical records
- Results from tests and medical exams performed for the MEB related to your condition Letters from your chain of command related to how the injury or illness impacts your duty
- Copies of your performance evaluation reports
- Other personnel records that the MEB may require

When the MEB members review your case, they are responsible for answering the question "Do you meet the retention standards for your service?" In answering this question, there are several decisions they can make. They may determine that you meet medical retention standards and return you to full duty in your current job. They may determine that you meet medical retention standards in another job and recommend you retrain for that position. If they determine that you do not meet the medical retention standards, they will forward a recommendation to a Physical Evaluation Board (PEB). This is an important point that can be confusing: the MEB does *not* determine your fitness for duty or level of disability. That step is only taken by the PEB.

PEBs usually consist of three people, with a mix of military and civilian members. The boards usually include a line officer and a senior medical officer. The PEB will usually meet informally to review your case and will not require you to attend the informal meeting. Using the packet developed by the PEBLO during the MEB process, the board will review your medical record, the doctor's narrative summary, your personnel evaluations, and letters from your commander. The board will then make an initial decision on your case. The PEB

will determine if you are fit or unfit for continued service. The members will determine the severity of any disability you may have, with a rating between 0-100 percent. The members will then determine your disposition – return to duty, separation, or permanent or temporary retirement.

The PEBLO will notify you of the findings of the informal PEB. At this point, you have to choose between requesting a formal PEB or accepting the informal PEB findings. If you choose to have a formal PEB hearing, you will be allowed to appear before the PEB and discuss your case with the board members to ask them to reconsider their decision. You can also provide them additional information important to that reconsideration. Additionally, you have a right to be represented by legal counsel at the formal PEB. If you disagree with the determination of the formal PEB, you have the right to appeal the decision.

The methods used by both the Department of Defense and the VA to determine the level of disability are complicated. But if you're thinking of filing a claim for disability compensation, you'll need to dig in and learn as much as you can about this process. There is simply no substitute for knowledge! Consult the information on the Exit Wounds website; talk to other veterans who have been through the process; and talk to your doctor and others on your health care team. If you're confused about anything, keep asking questions until it's clear.

If all your conditions result in a combined disability rating of 30 percent or higher, and your condition is considered stable (meaning it is unlikely, in the doctor's opinion, that your disability rating will change within five years), you will be permanently retired for disability. You will be eligible for disability retirement pay, access to TRICARE for you and your dependent family members, you will have access to commissary and exchange shopping, and all other benefits of regular military retirement.

The Road Ahead

The readers of this book—or someone they love—will be at all stages in their struggle with pain. Perhaps they are still in the earliest phase of recovery—still in a hospital, still facing surgeries to repair their wounds. Perhaps they are in rehabilitation, re-learning former skills, or learning new ways to cope with the aftermath of a wound. Or perhaps they are home, "repaired" to the extent possible, but still in pain. We hope that no matter where you or a loved-one are in this process that you have gained insight, knowledge, and hope from the stories and information

we have provided thus far. With persistence and the right team of health care providers, we know you or a loved-one will emerge, as Derek has, from struggle, pain, and frustration into a life that doesn't revolve around pain, a life in which you have regained important functioning, a life in which you can appreciate, with perhaps a heightened degree of intensity, the ordinary pleasures that each day can offer.

Advice for Family Members

Dealing with complex medical and military systems can be frustrating and tiring! Family members can help in many ways as their loved-ones as they navigate these systems:

- Offer to help research medical care options by finding information online, at libraries, or on the phone. Summarize what you find in writing.
- Make a list of all health care providers working with your loved-one, including addresses, phone numbers, and (if available) email addresses.
- Go with a loved-one on appointments and be the "secretary" taking notes and making sure previously-written-down questions are answered fully.
- If possible, read about the various benefits and eligibility requirements for medical care—sometimes two heads are better than one!

Resources

American Pain Foundation
1-888-615-PAIN (7246)
www.painfoundation.org

Military-Related Organizations

Amputee Coalition of America
1-888/267-5669
www.amputee-coalition.org

Defense and Veterans Brain Injury Center
1-800-870-9244
www.dvbic.org

Disabled American Veterans (DAV)
1-877-426-2838
www.dav.org

U.S. Department of Veterans Affairs
1-877-222-8387
www.va.gov

Find a Pain Specialist

American Academy of Family Physicians
www.familydoctor.org

American Academy of Nurse Practitioners
www.aanp.org
202-966-6414

American Academy of Pain Management
www.aapainmanage.org
209-533-9744

American Academy of Pain

Medicine
www.painmed.org
847-375-4731

American Academy of Physician Assistants
www.aapa.org
703-836-2272

American Board of Pain Medicine
www.abpm.org
847-375-4726

American Medical Association
www.ama-assn.org
312-464-5000

Case Management Resource Guide
www.cmrg.com
800-784-2332

Commission on Accreditation of Rehabilitation Facilities
www.carf.org
520-325-1044

Mayo Clinic Pain Management Center
www.mayoclinic.com

National Hospice and Palliative Care Organization
www.nhpco.org
703-837-1500

National Pain Foundation
www.nationalpainfoundation.org

Pain.com
www.pain.com/painclinics/default.cfm

FIND A COMPLEMENTARY & ALTERNATIVE MEDICINE (CAM) SPECIALIST

American Academy of Medical Acupuncture
www.medicalacupuncture.org
323-937-5514

American Association for Naturopathic Physicians
www.naturopathic.org
866-538-2267

American Association of Oriental Medicine
www.aaom.org
866-455-7999

American Chiropractic Association
www.amerchiro.org
703-276-8800

American Holistic Health Association
www.ahha.org
714-779-6152

American Massage Therapy Association
www.amtamassage.org
877-905-2700

American Osteopathic Association
www.osteopathic.org
800-621-1773

American Physical Therapy Association
www.apta.org
703-684-APTA (2782)

Find a Support Group

American Chronic Pain Association
www.theacpa.org
800-533-3231

Caring Connections
www.caringinfo.org
800-658-8898

Family Caregiver Alliance
www.caregiver.org
800-445-8106

Friends' Health Connection
www.friendshealthconnection.org
800-48-FRIEND (483-7436)

National Chronic Pain Society
http://ncps-cpr.net
281-357-4673

National Family Caregivers Association
www.thefamilycaregiver.org
800-896-3650

PainAid
www.painfoundation.org

Pain Connection
www.pain-connection.org
301-309-2444

Well Spouse Association
www.wellspouse.org
800-838-0879

This is just a sampling of available resources. For more information, visit www.exitwounds.org.

PAIN

Finding Relief

Pain Management for Older Adults

DVD Inside

Featuring
KATHY BAKER

Complaints of pain are the #1 reason older adults go to the doctor!

PHYSICIANS DEDICATED TO RE I ING PAIN
the AMERICAN ACADEMY of PAIN MEDICINE
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PAIN

Finding Relief

Pain Management for Older Adults

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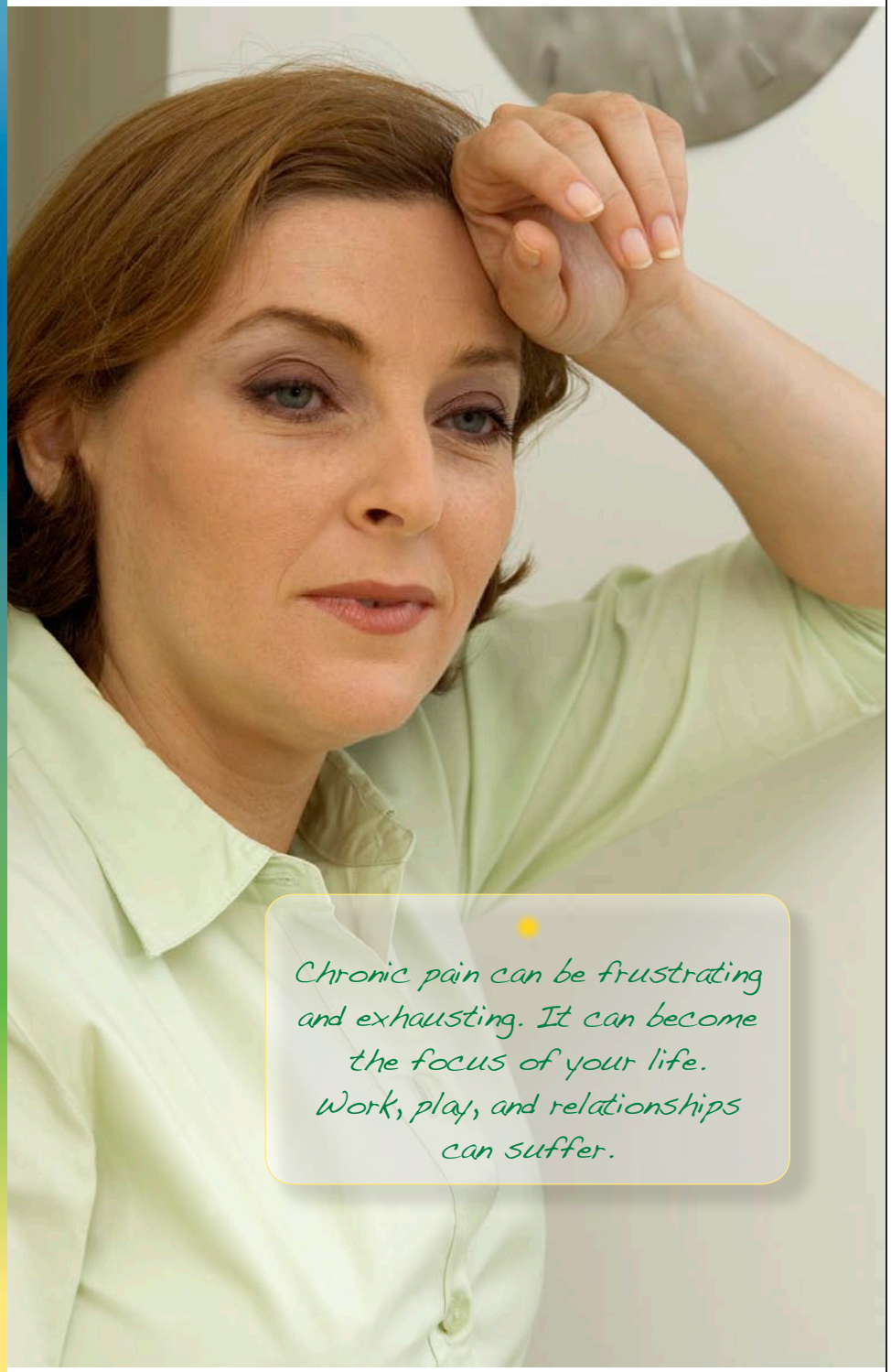
Introduction

Complaints of pain are the #1 reason people go to the doctor, and painful conditions, such as arthritis, tend to increase with age. Pain affects more Americans than diabetes, heart disease, and cancer combined.

These days, most pain can be very effectively treated. But, unfortunately, many older adults don't get the relief they deserve. Untreated pain not only causes needless suffering, but it can also lead to many other problems. If pain is not treated quickly, it may become worse or become more difficult to treat. And long-term pain can lead to loss of function at home and work, lost income, and personal-relationship problems.

This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.

You will learn about your options for pain management and how to find the treatment that's right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.



Pain Basics

Pain is the body's alarm system. It tells us when something is wrong. Pain caused by an injury such as a cut, broken bone, or infection can be intense, but it doesn't usually last very long. This is called *acute* pain.

If pain remains even after an injury has healed, or if it continues for longer than expected, it is called *chronic* pain. About 70 million people suffer from chronic pain in the U.S. alone. Chronic pain can be frustrating and exhausting. It can become the focus of your life. Work, play, and relationships can suffer.

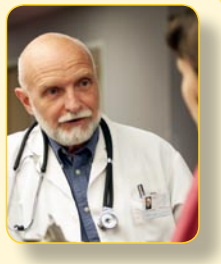
One difficult thing about pain is that it can't be measured. No test or device can measure how much you hurt. That's why most doctors say that "pain is what the patient says it is." In addition, sometimes a physical cause of pain cannot be found. Some people worry that a doctor will think their pain is "all in their head." Most doctors know better. They will take your pain seriously and work hard to find a solution.

This booklet focuses on treatments for the most common causes of acute and chronic pain. It does not address the special situations of pain caused by cancer or nerve damage, or pain occurring at the end of life.

Finding Out What's Wrong

When you visit your doctor, he or she will ask you questions about your pain.

The questions will help him or her understand the pain.

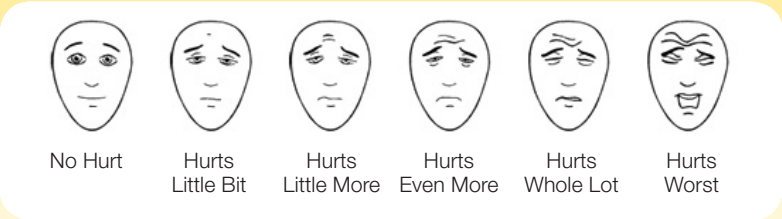


You may be asked:

- Where does it hurt?
- Does the pain move from place to place?
- Do you have pain in more than one place?
- When does the pain happen?
- How long does it last?
- Does the pain come and go?
- Have you had this pain before?
- Does the pain keep you from doing all you want to do?
- Does the pain disrupt your sleep?
- Has your mood changed because of the pain?
- Are your relationships being affected by the pain?
- What do you think is causing the pain?
- What makes the pain better?
- What makes it worse?

The answers to these questions will help your doctor find possible causes.

You may also be asked to rate your pain on a scale of some kind. Some scales use faces showing different expressions:



Other scales use numbers, from 0 to 10:

0	1	2	3	4	5	6	7	8	9	10
No pain					Moderate pain					Worst pain possible

In most cases, additional tests, such as x-rays, are not needed. A thorough patient history and physical exam are usually enough to guide effective pain treatment.

But even if a specific physical cause cannot be found, your pain is real! And even when the source is unknown, the pain can almost always be managed.

Pain-Medicine Specialists

Your doctor may suggest that you see a pain specialist. Pain specialists are physicians with extra training in pain medicine. They try to treat the whole person, not just the pain. They look for a balance of different treatments that are tailored to each person's needs.

Special centers for treating pain are in many parts of the country. (You can find a physician who is expert in treating pain by using the "Physician Finder" on the website of the American Academy of Pain Medicine, www.painmed.org, or by calling 847-375-4731.)

Many people with chronic pain rely on a team that may include:

- Their doctor
- A pain specialist
- A physical therapist
- A mental-health worker
- Specialists in other disorders , such as diabetes or heart disease

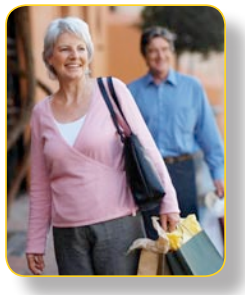
Pain relief is not the only goal in treating chronic pain. Full recovery means regaining functions lost to chronic pain.

Treatment Goals—It's Not Just About Pain Relief!

If you are in pain, you want it to stop. That's certainly understandable! But pain relief is not the *only* goal in treating chronic pain. Sometimes people stop doing things because of pain. They stop exercising, working, walking, or even just sleeping in their own bed. Full recovery means regaining functions lost to chronic pain. Reducing pain is often just the first step.

Your recovery will be measured by how well you reach functional goals, such as:

- Sleeping without waking from pain
- Sleeping in your own bed
- Returning to work
- Enjoying recreational activities
- Having sex
- Walking without help
- Climbing stairs



You and your doctor will work together to set goals that are right for you. The key to success is finding the right balance between your goals and the treatments needed to achieve those goals.

Treating chronic pain is a marathon, not a sprint!

Medications for Pain Relief

Medications that relieve pain are called *analgesics*. Analgesics are the mainstay of pain management. But many non-drug treatments, such as exercise or acupuncture, can also be used, either alone or with medications. Combining such treatments may reduce the intensity of your pain, boost your ability to cope, enhance your comfort and improve your quality of life.

There are many types of analgesics. You can buy some in stores; others require a prescription. This section describes the common types of analgesics.

Aspirin

Aspirin was discovered and first used more than a century ago. It remains one of the most widely used pain relievers in the world.

Advantages

- Relieves minor to moderate pain, fever, headaches, and swelling
- Inexpensive
- No prescription needed

Disadvantages

- Can cause stomach upset or bleeding in the stomach or intestines
- Can cause kidney damage if taken at high doses or for a long time

Acetaminophen

Acetaminophen is a non-aspirin pain reliever. It is used alone for mild to moderate pain. It is also combined with other types of pain medications to treat more serious pain.

Advantages

- Relieves minor to moderate pain, headaches, and fever
- Little or no stomach upset or bleeding
- Inexpensive
- No prescription needed

Disadvantages

- Does not reduce swelling
- Can cause liver and kidney damage if taken in excessive doses

Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are a large family of medicines that work in a similar way to aspirin by relieving both pain and swelling. This class includes drugs such as ibuprofen, naproxen, and celecoxib. Some are available without a prescription.

Advantages

- Relieve mild to moderate pain, fever, headaches, and swelling

Disadvantages

- Can cause stomach upset or bleeding in stomach or intestines
- Can cause kidney or liver damage if taken at high doses or for a long time
- May cause adverse reactions in people with asthma
- Can increase the risk of heart attack and stroke

Topical anesthetics

Topical anesthetics are used to numb the surface of a body part. They can be used to numb the front of the eye, the inside of the nose, the throat, the skin, the ear, the anus, and the genital area. Topical anesthetics are available in creams, ointments, aerosols, sprays, lotions, and jellies. They are used to relieve many types of pain and itching, such as that caused by sunburn, minor burns, insect bites or stings, nerve damage, or conditions such as hemorrhoids.

Opioid medications

Medicines containing opioids have been used for centuries. *Opioids* are strong pain medicines for moderate to severe pain. Today, opioids come in many forms and strengths. Some work very quickly but don't last very long. Some give long-lasting pain relief. And some are less likely to be addictive.

All opioids require a prescription. Talk to your doctor about what type of opioid would be best for you.

Opioids usually produce side effects. At first, the drugs can cause upset stomach or sleepiness. These side effects often go away as you get used to the drugs. Some other side effects, such as constipation, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis.

Used properly, opioid medications can make it possible for people with chronic pain to "return to normal"—get back to work, walk or run, play sports, and participate in other activities.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

Other types of medications

Many other types of drugs can relieve pain. Some have special effects that can be very helpful for some people. For example, some medicines can improve your mood and relieve pain. This can be good for people who are both depressed and in pain.

Here are three types of drugs your health care professional might suggest:

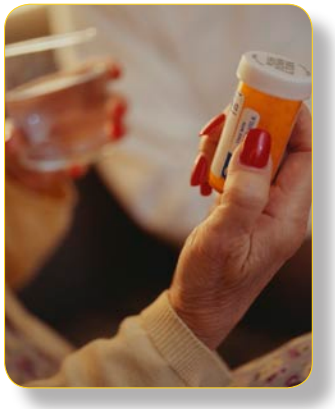
- Drugs that improve your mood (antidepressants)
- Drugs that give you more energy (stimulants)
- Drugs that relieve anxiety (anxiolytics)

These drugs may be combined with other pain medications. Sometimes a combination of drugs works better than a single drug.

Responsible Prescription Use

Some people today use prescription medicines to get "high" or to relieve stress. They may steal these medicines from parents, friends, or relatives. If you are taking an opioid medication for pain, you must be careful. Follow this advice:

- Store medications in a safe, secure place
- Take note if any pills appear to be missing
- Never share your medication with others
- Don't take your medication more often—or in a larger dose—than prescribed



Being responsible also means knowing yourself. Be aware of how you react to your medication. Are you having any unusual side effects? Is the medication working as well as you think it should? Your goal should always be to balance the benefits of a drug with the side effects the drug might cause. If you have any questions, call your doctor or other health care professional.

Physical therapists may use electrical stimulation, hot packs, cold compresses, traction, deep-tissue massage, and ultrasound.

Injection Therapies

Injection therapies (sometimes called "nerve blocks") may be used to treat painful conditions in many areas of the body. These procedures involve placing a needle into a muscle, joint, the spine, or around a specific group of nerves. Then medication is injected or some other treatment is used, such as electricity, heat or cold. Injection therapies can be used for both acute and chronic pain.

Physical Therapy

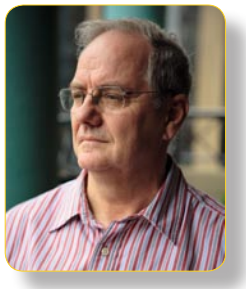
Physical therapy can help restore function, improve mobility, and relieve pain. In addition to teaching patients how to exercise, physical therapists may also use such treatments as electrical stimulation, hot packs, cold compresses, traction, deep-tissue massage, and ultrasound. Physical therapists may also teach patients to use assistive or adaptive devices, such as crutches, prostheses, and wheelchairs.

The most important part of physical therapy is exercise training. Once taught, exercises can be performed at home to help relieve pain flare-ups, improve flexibility, and increase strength and/or endurance. Physical therapy can help you function better even if your pain doesn't completely go away.

Mental health is important, too. If you're busy and active, and your mind is engaged, that helps in life in general – and in pain management.
–Kathy Baker

Counseling and Emotional Support

Living with pain often causes a ripple effect that touches many parts of your life. You may feel a range of emotions, such as fear, anger, hopelessness, confusion, and isolation. Those around you may have similar feelings. Individual counseling—and in some cases, counseling with your family—can help. Many people find great benefit from individual or group counseling specifically focused on pain and related worries. Trained professionals can teach useful skills and provide needed emotional support and guidance.



One form of therapy that can help people in chronic pain is *cognitive behavioral therapy* (CBT). This is a short-term, focused form of psychotherapy. You and the therapist identify goals and problem-solve to find ways of reaching them. With any type of therapy, it's important to take an active role in the process. Patients who are assertive and fully engaged in their own health care cope better than those who are more passive.

Alternative and Complementary Approaches

Many Americans have tried alternative methods of controlling their pain, such as acupuncture or hypnosis. Some of these methods have been shown to work for some patients. Most alternative treatments rely on the power of the mind to control pain. These methods can be used alone or combined with medications and other "traditional" treatments. The most important thing older adults with chronic pain can do is work with their doctor to create a treatment plan that is right for them.

Acupuncture

Acupuncture uses very fine needles inserted into the skin. Needles may be placed according to theories developed in China more than 2000 years ago or using techniques developed more recently. Some scientific studies show that acupuncture can relieve chronic pain. The evidence is strongest for relief of back, neck, and arthritis pain.

Hypnosis

Hypnosis is a range of techniques that can alter people's awareness of themselves or their surroundings. It was first used more than 100 years ago to help patients in pain. The scientific study of hypnosis as a treatment for pain is ongoing, but early research has shown promise. When a patient is hypnotized, his or her mind is focused and aware. For reasons that are not yet understood, this state can relieve many types of pain.

Meditation

Meditation is any method of focusing and calming the mind. It need not have a religious or spiritual component. Several medical centers now use meditation to help patients manage chronic pain. The techniques vary, but all involve calming the body, being aware of oneself, and focusing attention. Some scientific studies have shown that patients who meditate regularly may function better and have less pain.

Massage

There are many techniques and approaches to *massage*, but most can help relieve pain. Massage acts directly on the muscles and nerves to promote relaxation. It can ease tight, painful muscles and reduce spasms.

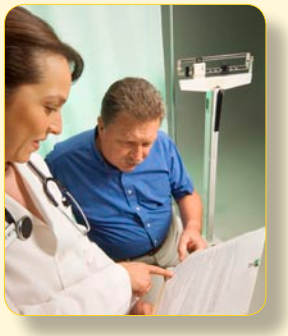
Tips for Managing Pain

Older adults in pain can almost always be helped these days. With the right treatments and a good health care team, most people can return to the activities they enjoy. There are many things you can do to secure your progress and manage your pain. The choices you make can make a big difference!

Keep the following tips in mind:

Exercise regularly. Keeping your muscles strong will help prevent future injury. Start slow and easy. Work up gradually to more distance, time, or weight. The type of exercise is not as important as exercising on a regular basis. Always talk to your doctor before trying a new exercise.

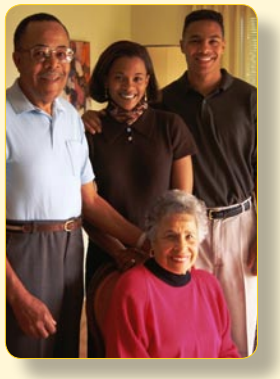
Stay flexible. Yoga or stretching exercises can be a great way to become more flexible. Just be careful to stretch gently. If it hurts, you're going too far!

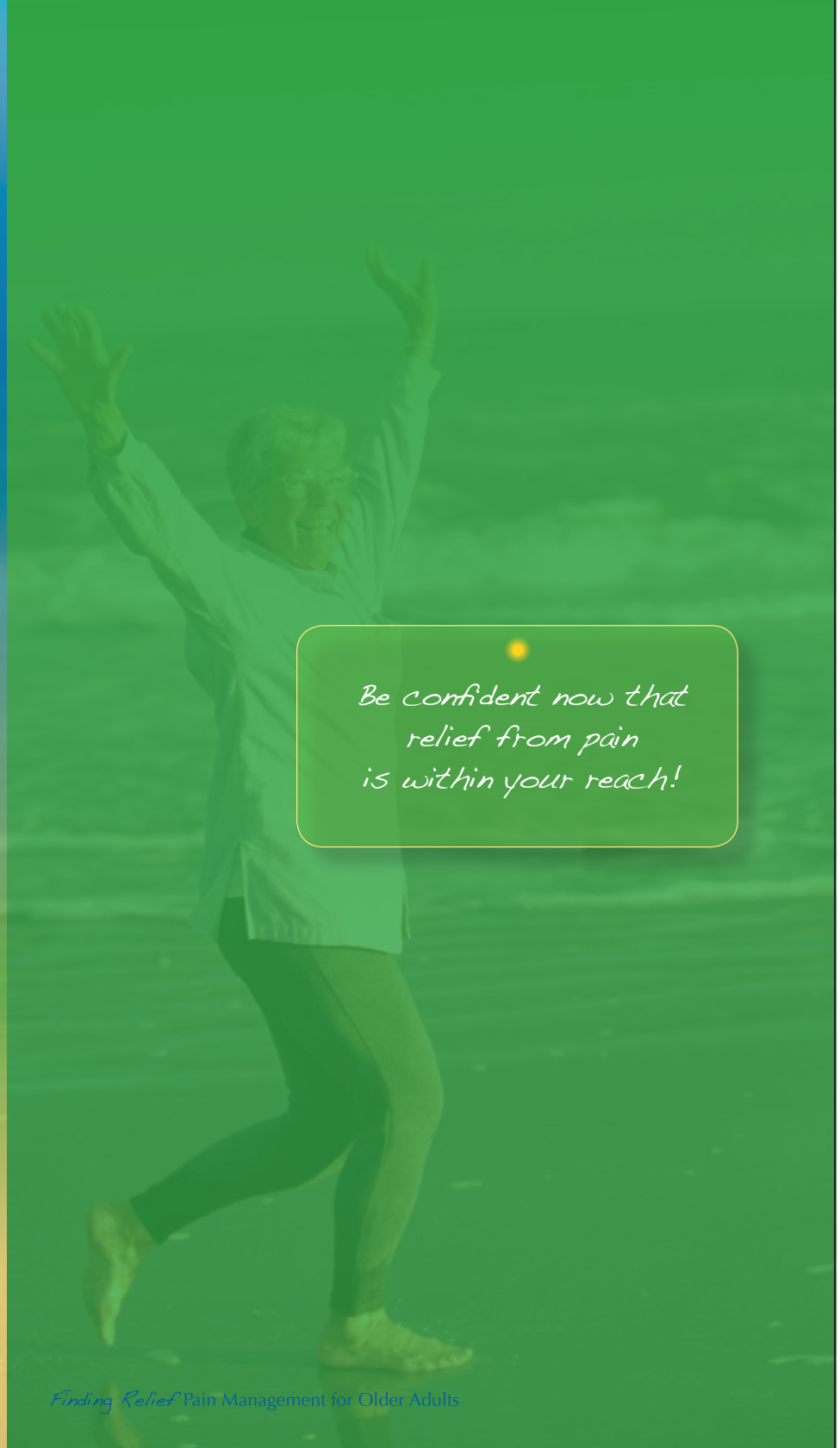


Lose weight if you need to. Extra body weight strains joints, muscles, and your back. Even losing just 10 pounds can make a difference!

Learn how to lift, sit, and stand. Keep your back straight when lifting. Use your legs, not your back! Keep your back straight when sitting and standing as well. If you use a computer, be sure to position your arms and hands so they are relaxed and well-supported.

Connect with others. It can be hard for others to understand what it feels like to be in chronic pain. That's why it can be so helpful to find people who can "share your pain." Chronic-pain support groups can be found in almost every city. You can also find online support groups. People can share their feelings and swap tips that have helped them manage their pain. (You can find support groups through the organizations listed at the back of this booklet.)





Reasons for Hope

The key messages of this booklet are; Be educated, be responsible, and be confident. Acute and chronic pain can almost always be managed! It may take some time to find the best balance between your goals and a treatment program. But if you stick with it, you can overcome your pain.

Remember that you have a right to adequate and effective pain relief. Nobody should suffer with needless pain today. Work closely with your doctor. Determine whether you should see a pain specialist. Use a team of health care professionals who can give you what you need. By reading this booklet, you have begun learning about your condition. You can be confident now that relief from pain is within your reach!

Resources

American Academy of Pain Medicine
The AAPM site provides educational materials and a search feature to help you find a board-certified pain physician in your region.
www.painmed.org

American Chronic Pain Association
Support for those suffering with chronic pain through education and self-help group activities.
www.theacpa.org
800-533-3231

American Geriatrics Society
A nonprofit organization devoted to improving the health, independence and quality of life of all older people.
www.americangeriatrics.org
212-308-1414

AGS Foundation for Health in Aging
www.healthinaging.org
800-563-4916

American Pain Foundation
www.painfoundation.org
888-615-7246

Arthritis Foundation
www.arthritis.org
800-283-7800

The National Pain Foundation
An online education and support community for pain patients and their families.
www.painconnection.org

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The American Academy of Pain Medicine is the medical specialty society representing physicians practicing in the field of pain medicine. The Academy is involved in education, training, advocacy, and research in the specialty of pain medicine. The practice of pain medicine is multidisciplinary in approach, incorporating modalities from various specialties to ensure the comprehensive evaluation and treatment of the pain patient. AAPM represents the diverse scope of the field through membership from a variety of origins, including such specialties as anesthesiology, internal medicine, neurology, neurological surgery, orthopedic surgery, physiatry, and psychiatry.

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the voice of pain medicine

American Geriatrics Society

The American Geriatrics Society is a not-for-profit organization of more than 6,700 health professionals devoted to improving the health, independence and quality of life of all older people. The Society provides leadership to health care professionals, policymakers and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy. Our mission is to improve the health, independence and quality of life of all older people.

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AGS Foundation for Health in Aging

The AGS Foundation for Health in Aging champions initiatives in public education, clinical research, and public policy that advance the principles and practice of geriatrics medicine; educate policymakers and the public on the health care needs and concerns of older adults; support research on aging that reduces disability and frailty, and improves quality of life and health outcomes; encourage older adults to be effective advocates for their own health care; and help family members and caregivers take better care of their older loved ones and themselves.

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American Academy of Pain Medicine

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American Geriatrics Society Foundation for Health in Aging

Contributors to the Video

Bruce Ferrell, MD
Professor of Medicine
Division of Geriatrics
David Geffen School of Medicine at UCLA
Los Angeles, CA

Rollin M. Gallagher, MD, MPH
President Elect, American Academy of Pain Medicine
Editor-in-Chief, Pain Medicine, Official Journal of the American Academy of Pain Medicine
Pain Management Service, Philadelphia Veterans Affairs Medical Center and Center for Pain Medicine, Research and Policy, University of Pennsylvania
Philadelphia, PA

Debra K. Weiner, MD
Associate Professor of Medicine, Psychiatry, & Anesthesiology
Director, Older Adult Pain Management Program
University of Pittsburgh, Pittsburgh, PA
Staff Physician, Geriatric Research, Education and Clinical Center
VA Pittsburgh Healthcare System

Special Thanks to:

KATHY BAKER

Photograph by Gregory Schwartz

Actress Kathy Baker has played critically acclaimed roles in more than two dozen movies and several television series since she entered the film business 1983. Her credits include *Edward Scissorhands*, *The Cider House Rules*, and *Cold Mountain*. Her performance in *Street Smart* earned her Best Supporting Actress awards from the Boston Society of Film Critics and the National Society of Film Critics.

Project Manager
Gina Conrad Black
Executive Producer
Conrad Productions, LLC

Guidebook Author
Stephen R. Braun
Medical Writer
Amherst, MA

Guidebook Design
Cinda Debbink
Design Partners
www.dgdesignpartners.com

Video Production
Tania Wilk
Executive Producer
Alan Weiss Productions
www.awptv.com

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PAIN

DVD Inside

Finding Relief

Pain Management for Older Adults

Older adults suffer pain more often than younger people. Complaints of pain are the #1 reason older people go to the doctor.

These days, most pain can be very effectively treated. But, unfortunately, many older adults don't get the relief they deserve. Untreated pain not only causes needless suffering, but it can also lead to many other problems. If pain is not treated quickly, it may become worse or become more difficult to treat. And long-term pain may lead to loss of function at home or work, lost income, or harm to personal relationships.

This program is focused specifically on older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief. You can return to doing the things you did before the pain began!

This guidebook and DVD will help you:

- ***Be educated about your pain and possible treatments***
- ***Be responsible about your use of prescription medications***
- ***Find ways to minimize the side effects of some treatments and maximize their effectiveness***
- ***Be confident that you can find relief and manage your pain***

Featuring
KATHY BAKER

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the AMERICAN ACADEMY of PAIN MEDICINE
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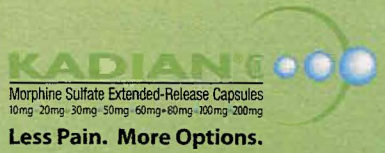

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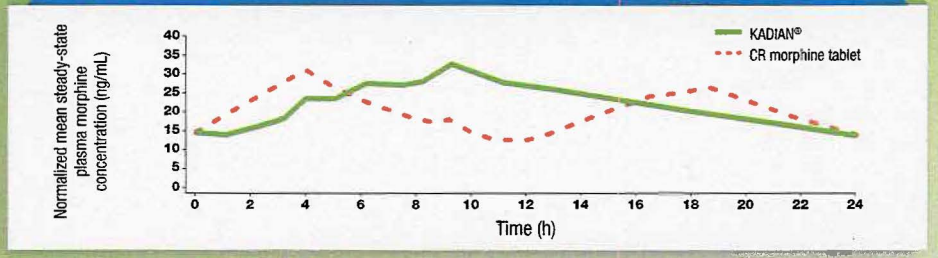
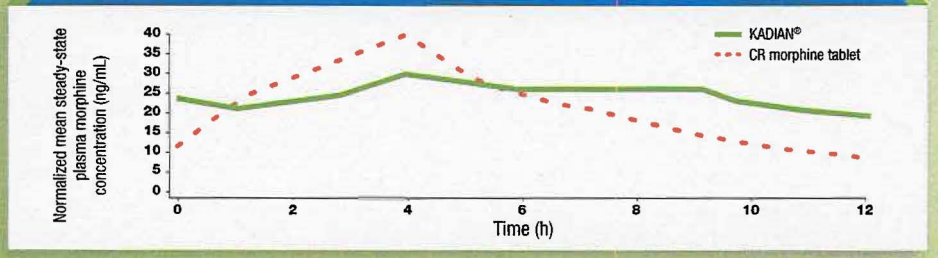
Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q12h and q24h[1]

Pharmacokinetics of **ONCE-DAILY KADIAN®** vs twice-daily CR morphine tablets over 24 hours[1,2]



Pharmacokinetics of **TWICE-DAILY KADIAN®** vs twice-daily CR morphine tablets over 12 hours[1,2]



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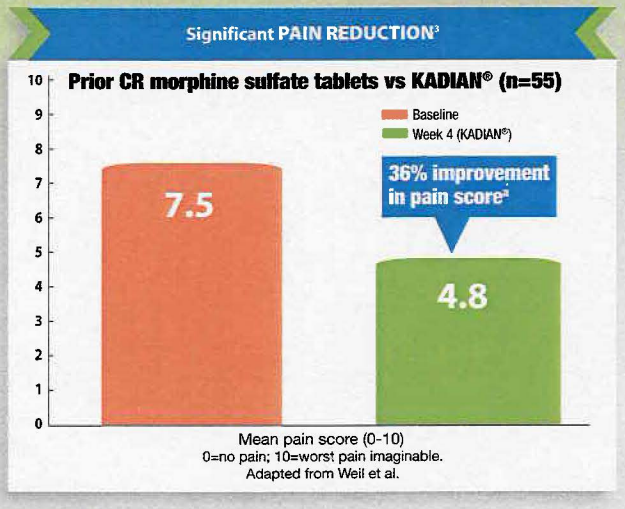
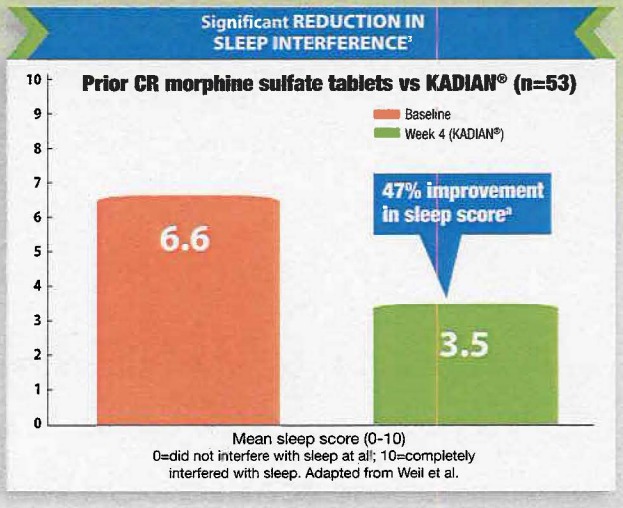
Better pain control and improved sleep scores

Improved pain control and sleep scores in patients treated with KADIAN® who were previously on CR morphine tablets[3*]





[a]*Both significant at P<0.001. Baseline vs week 4 per protocol population, post hoc analysis.*

Allow patients to live with less pain and get adequate rest with less medication[3]

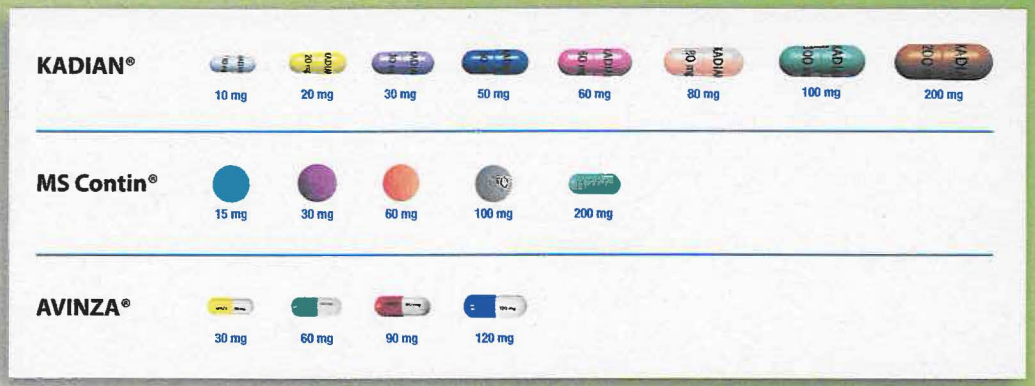
**In a subanalysis of a randomized, open-label, blinded endpoint study of patients previously taking CR morphine tablets and switched to KADIAN® capsules.*

Please see accompanying complete Prescribing Information.

KADIAN®
Morphine Sulfate Extended-Release Capsules
10mg · 20mg · 30mg · 50mg · 60mg · 80mg · 100mg · 200mg
Less Pain. More Options.

Fewer barriers to prescribing

The unique dosing flexibility of KADIAN® gives you more options with a morphine[1,4,5]



Capsules and tablets are not shown at actual size.

- No immediate-release (IR) component
- No ceiling dose—contains no acetaminophen, ibuprofen, or fumaric acid[1]
- Allows for titration in increments of 10 mg, with a low dose of 10 mg[1]

Allow individualization and customization of a patient's pain treatment

Please see accompanying complete Prescribing Information.

Prescribe KADIAN®—Less pain for your patients. More options for you.

WARNING:
KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. KADIAN® can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing KADIAN® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

KADIAN® capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

KADIAN® Capsules are NOT for use as a prn analgesic.

KADIAN® 100 mg and 200 mg Capsules ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. Ingestion of these capsules or of the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids. KADIAN® CAPSULES ARE TO BE SWALLOWED WHOLE OR THE CONTENTS OF THE CAPSULES SPRINKLED ON APPLE SAUCE. THE PELLETS IN THE CAPSULES ARE NOT TO BE CHEWED, CRUSHED, OR DISSOLVED DUE TO THE RISK OF RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

Safety considerations:
Serious adverse reactions that may be associated with KADIAN® therapy in clinical use are those observed with other oral opioid analgesics and include: respiratory depression, respiratory arrest, apnea, circulatory depression, cardiac arrest, hypotension, and/or shock.

References: 1. KADIAN® [current prescribing information]. Piscataway, NJ: Alpharma Pharmaceuticals LLC. **2.** Gourlay GK, Cherry DA, Onley MM, et al. Pharmacokinetics and pharmacodynamics of twenty-four-hourly Kapanol compared to twelve-hourly MS Contin in the treatment of severe cancer pain. *Pain.* 1997; 69(3):295-302. **3.** Weil A, Nicholson B, Ross E, Sasaki J. Patients with chronic, non-malignant, moderate/severe pain can be successfully switched from other sustained-release morphine or oxycodone compounds to KADIAN® (morphine sulfate sustained-release capsules): the KRONUS-MSP trial. Poster presented at: American Pain Society 23rd Annual Scientific Meeting; May 6-9, 2004; Vancouver, BC, Canada. **4.** AVINZA® [prescribing information]. Bristol, TN: King Pharmaceuticals Inc; October 2006. **5.** MS Contin® [prescribing information]. Stamford, CT: Purdue Pharma LP; August 2007.

For further information, please visit www.KADIAN.com or call 1-888-840-8884.
Please see accompanying complete Prescribing Information.

KADIAN® is a registered trademark of Alpharma Pharmaceuticals LLC.
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ALPHARMA.
Pharmaceuticals

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KADI8D0231 April 2008 Printed in USA

KADIAN®
Morphine Sulfate Extended-Release Capsules
10mg · 20mg · 30mg · 50mg · 60mg · 80mg · 100mg · 200mg
Less Pain. More Options.

save up to **$50** each month toward your KADIAN® prescription.

Please see accompanying complete Prescribing Information.

Expiration date: 12-31-09

KADIAN®
CO-PAY ASSISTANCE Program

Save up to $50
toward each prescription of KADIAN®
See details inside.

Good for up to $600 for 12 months

KADIAN®
Morphine Sulfate Extended-Release Capsules
30mg · 60mg · 90mg · 120mg · 150mg · 180mg · 200mg

For questions about this program, please call the Help Desk at 1-877-637-4629.
Pharmacists only: For claim-related questions, please call *Therapy First* at 1-800-422-5604.

KADIAN®
CO-PAY ASSISTANCE Program

save up to **$50** each month toward your KADIAN® prescription.

Please see accompanying complete Prescribing Information.

Expiration date: 12-31-09

KADIAN®
Morphine Sulfate Extended-Release Capsules

For further information about KADIAN®, please visit www.KADIAN.com or call 1-877-637-4629.

Bin #: 004682 RxPCN: CN
Group #: LCPML892 ID #: PML804766464

The KADIAN® (morphine sulfate extended-release) Capsules Co-pay Assistance Program

The KADIAN® Co-pay Assistance Program provides up to $50 toward your co-pay or out-of-pocket cost for your KADIAN® prescriptions. Please see your pharmacist to help you determine your monthly savings amount.

Present this card with your KADIAN® prescription and insurance card, if applicable. You can use the same card with every prescription of KADIAN® until the expiration date that's printed on the card.

Terms and Conditions: Valid only at participating retail pharmacies in the US and Puerto Rico. Not valid through mail-order pharmacies. This offer is limited up to one savings per prescription. Card is limited to 1 per patient for the life of the program and is not transferable. This coupon card is not valid for prescriptions purchased under Medicaid, Medicare, federal or state programs (including state prescription drug programs, private indemnity or HMO Insurance plans which reimburse you for the entire cost of your prescription drugs). This offer is not valid in Massachusetts, except for cash paying patients. Void where prohibited by law, taxed or restricted. Actavis reserves the right to rescind, revoke or amend this offer without notice at any time.

Please see accompanying complete Prescribing Information.

KADIAN® (morphine sulfate extended-release) Capsules $50 Multi-Use Coupon FAQ Sheet

Question: Do I have to call an 800 number or go onto the Internet to activate the card?

Answer: No. The card is already active. Simply present the card with a valid 30-day prescription for KADIAN® capsules to your pharmacist. You can request a card at www.kadian.com.

Question: Do I have to present the card every time?

Answer: Present this card to your pharmacist every time you fill your Kadian® prescription.

Question: What if I have an issue with redeeming the $50 multi-use coupon card at the pharmacy?

Answer: You must contact the Help Desk at 1-877-637-4629 to address this issue.

Question: How long do I have to wait before I can use the card for the next prescription?

Answer: You can re-use the card after 23 days of the last fill date.

Question: Can I use the card with mail order programs?

Answer: No. You can not use this card with participating mail order pharmacies. To find a local pharmacy that participates, please contact the Help Desk at 1-877-637-4629.

Question: Can I use the $50 multi-use coupon card after the expiration date?

Answer: No. The card cannot be used past the expiration date.

If you have any questions on how to use your Co-Pay Assistance Card, please call 1-877-637-4629.

Why is pain management important?

Pain management is a large part of your overall health care plan. Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life. If left untreated, pain can place stress on your body and your mental health. Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse.

What is chronic pain?

Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe. It can be inconvenient and can keep you from your daily tasks.

How can I treat my chronic pain?

To help manage your pain, your healthcare provider will determine what level of pain control you need. Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you.

Please see accompanying complete Prescribing Information.

KADIAN® capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

KADIAN® capsules are not for use as a prn analgesic.

Safety considerations:

KADIAN® (morphine sulfate extended-release) Capsules contain morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. KADIAN® can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing KADIAN® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

Serious adverse reactions that may be associated with KADIAN® therapy in clinical use are those observed with other oral opioid analgesics and include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and/or shock.

KADIAN® 100 mg and 200 mg capsules are for use in opioid-tolerant patients only. Ingestion of these capsules or of the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids.

KADIAN® capsules are to be swallowed whole or the contents of the capsules sprinkled on apple sauce. The pellets in the capsules are not to be chewed, crushed, or dissolved due to the risk of rapid release and absorption of a potentially fatal dose of morphine.

For further information about KADIAN®, please visit www.KADIAN.com or call 1-877-637-4629.

Please see accompanying complete Prescribing Information.

KADIAN® is a registered trademark of Actavis.

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creating value in pharmaceuticals
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KAD200901 January 2009
Printed in USA.

KADIAN® C
Morphine Sulfate Extended-Release Capsules
10mg • 20mg • 30mg • 50mg • 60mg • 80mg • 100mg • 200mg

save up to $50 each month toward your KADIAN® prescription.

Please see accompanying complete Prescribing Information.

Expiration date: 12-31-09

KADIAN®
CO-PAY ASSISTANCE Program

Save up to $50
toward each prescription of KADIAN®
See details inside.

Good for up to $600 for 12 months

KADIAN® C
Morphine Sulfate Extended-Release Capsules
10mg • 20mg • 30mg • 50mg • 60mg • 80mg • 100mg • 200mg

For questions about this program, please call the Help Desk at 1-877-637-4629.
Pharmacists only: For claim-related questions, please call *Therapy First* at 1-800-422-5604.

n over 25 years for the relief
atients 18 years of age or older

NTA® CII
dol

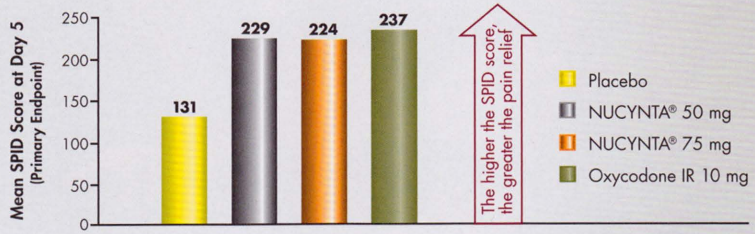
—Visit www.NUCYNTA.com

OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY

In patients with end-stage degenerative joint disease of the hip or knee...

Proven opioid efficacy

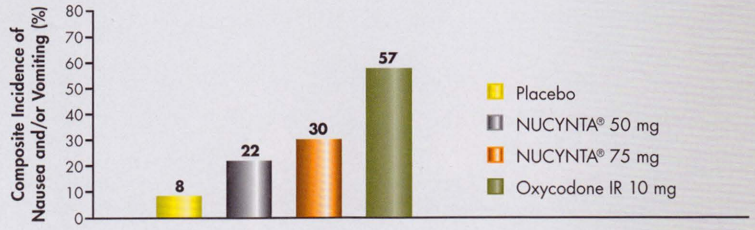
Change in pain intensity as measured by mean SPID* of NUCYNTA® 50 mg and 75 mg vs placebo (*P*<0.001) or 10 mg oxycodone IR† at Day 5[1]



Intent-to-treat population‡ (N=659) with a mean baseline pain intensity score of 6.7 was randomized to 50 mg or 75 mg of NUCYNTA®, 10 mg oxycodone IR, or placebo dosed every 4 to 6 hours while patients were awake. The primary efficacy analysis is based on the last observation carried forward (LOCF) imputation method. Adjusted *P*-values using Hochberg procedure (oxycodone group was not included). Higher value in SPID indicates greater pain relief.

GI tolerability profile demonstrated in a clinical trial

Composite incidence of nausea and/or vomiting with NUCYNTA® 50 mg and 75 mg, oxycodone IR† 10 mg, and placebo[1,2]



Safety population (N=666) with a mean baseline pain intensity score of 6.7 was randomized to 50 mg or 75 mg of NUCYNTA®, 10 mg oxycodone IR, or placebo dosed every 4 to 6 hours while patients were awake. Incidence is based on the number of subjects experiencing at least one adverse event, not the number of events.

*SPID is defined as the sum of pain intensity difference.

†Clinical trials were conducted with immediate-release oxycodone, which is the opioid ingredient in Percocet®, Percodan®, and OxyIR®.

‡Intent-to-treat population included all randomized subjects who received any amount of study drug (ie, at least one study drug intake following randomization) and had a valid baseline pain assessment.

Percocet and Percodan are registered trademarks of Endo Pharmaceuticals Inc.

OxyIR is a registered trademark of Purdue Pharma Inc.

References: 1. Data on file. Johnson & Johnson Pharmaceutical Research & Development, LLC. **2.** Hartrick C, Van Hove I, Stegmann JU, Oh C, Upmalis D. Efficacy and tolerability of tapentadol immediate release and oxycodone HCl immediate release in patients awaiting primary joint replacement surgery for end-stage joint disease: a 10-day, phase III, randomized, double-blind, active- and placebo-controlled study. *Clin Ther.* 2009;31(2):260-271.

NUCYNTA® CII
tapentadol

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for more information.

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access2wellness.com
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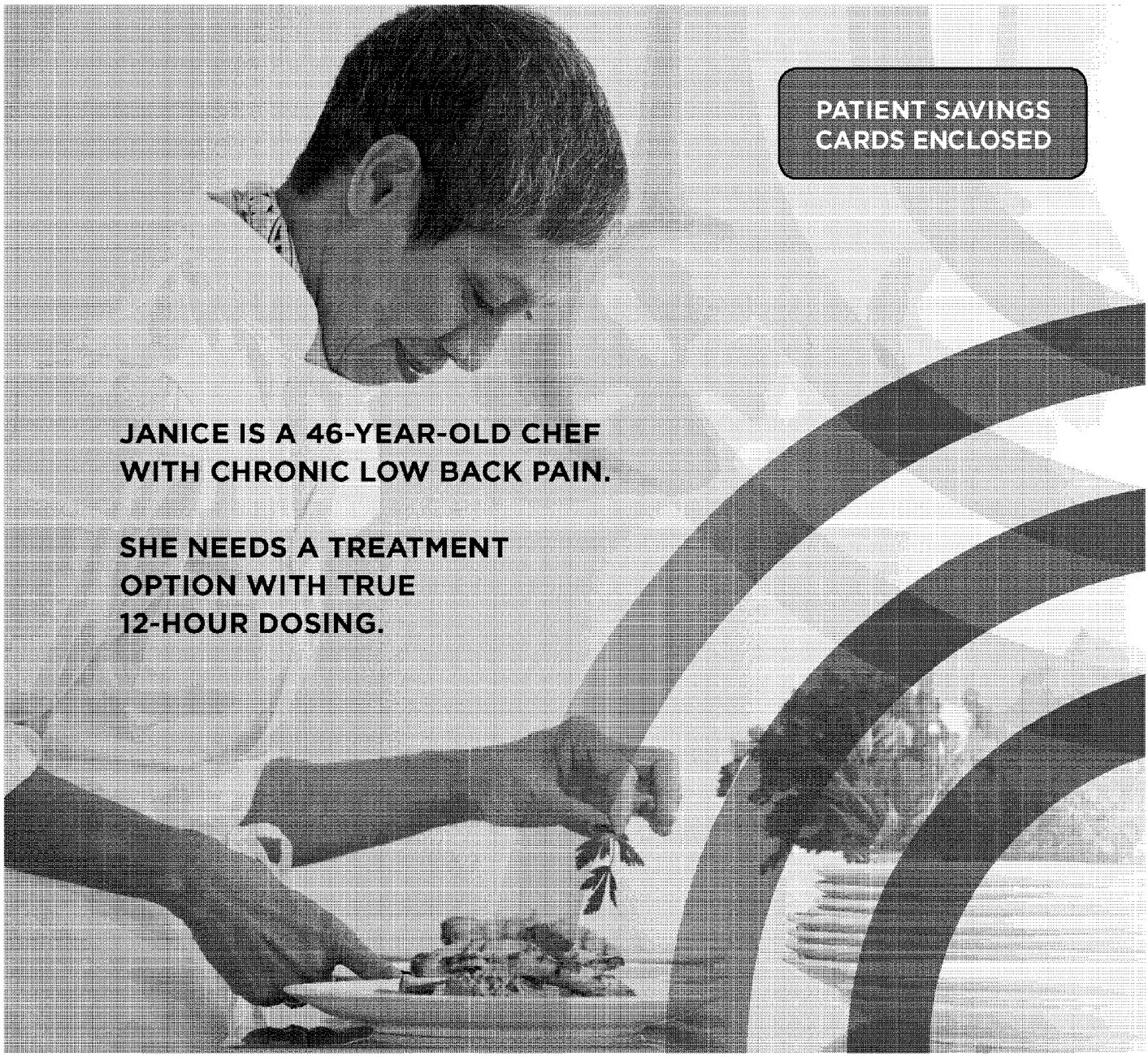
IMPORTANT SAFETY IN

- Like other drugs with mu-opioid agonist activity, NUCYN acute or severe bronchial asthma or hypercapnia in unm contraindicated in patients who have or are suspected t using or within 14 days of using monoamine oxidase in may result in adverse cardiovascular events.
- Respiratory depression is the primary risk of mu-opioid a patients and in those suffering from conditions accompa moderate therapeutic doses may significantly decrease p elderly, debilitated patients, and patients with conditions as: asthma, chronic obstructive pulmonary disease or co CNS depression, or coma. In such patients, even usual respiratory drive to the point of apnea. Alternative non-m employed only under careful medical supervision at the be treated as any mu-opioid agonist-induced respiratory
- Patients receiving other mu-opioid agonist analgesics, ge other CNS depressants (including alcohol) concomitantly resulting in respiratory depression, hypotension, profoun with NUCYNTA®. When such combined therapy is cont
- Opioid analgesics can raise cerebrospinal fluid pressure NUCYNTA® should not be used in patients susceptible t and increased intracranial pressure. Opioid analgesics pupillary response and consciousness. NUCYNTA® shou sources of preexisting increased intracranial pressure.
- NUCYNTA® is a mu-opioid agonist and is a Schedule II addiction disorders. Diversion of Schedule II products is similar to other mu-opioid agonists, legal or illicit. This sh where the physician or pharmacist is concerned about a agonists require careful monitoring for signs of abuse an injecting the product. These practices pose a significant
- Experience with NUCYNTA® overdose is very limited. M agonism. Primary attention should be given to reestablish when overdose of NUCYNTA® is suspected. Supportive management of circulatory shock and pulmonary edema require cardiac massage or defibrillation.
- Patients should be cautioned that NUCYNTA® may impa potentially hazardous tasks such as driving a car or oper at any change of dosage as well as in combination with
- NUCYNTA® has not been systematically evaluated in pa studies. NUCYNTA® should be prescribed with care in p patient at risk of seizures.
- The development of a potentially life-threatening serotoni particularly with concomitant use of serotonergic drugs su metabolism of serotonin (including MAOIs). Serotonin sy coma), autonomic instability (eg, tachycardia, labile bloo incoordination) and/or gastrointestinal symptoms (eg, na
- Withdrawal symptoms may occur if NUCYNTA® is disco rigors, pain, nausea, tremors, diarrhea, upper respiratory be reduced by tapering NUCYNTA®.
- Pregnancy Category C. There are no adequate and we be used during pregnancy ONLY if the potential benefit in women during and immediately prior to labor and del monitored for respiratory depression. NUCYNTA® should
- NUCYNTA® is not recommended in patients with severe patients with moderate hepatic impairment. Like other dru sphincter of Oddi and should be used with caution in pa
- The most common adverse events are nausea, dizziness,

Please see Brief Summary of Prescribing Informati



HIGHLY CONFIDENTIAL- OUTSIDE COUNSELS' EYES ONLY

OPANA® ER WITH INTAC® TECHNOLOGY[1] HAD NO SIGNIFICANT DIFFERENCE IN THE RATE AND EXTENT OF ABSORPTION COMPARED TO THE ORIGINAL FORMULATION OVER 12 HOURS[2]

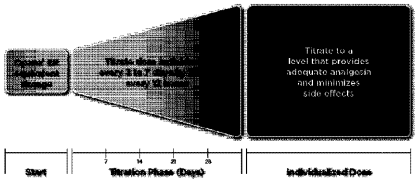
Symmetrical, every 12-hour dosing is appropriate for the majority of patients.[1]

Opana® ER with INTAC® technology offers the dosing flexibility to fit Janice's needs

Seven dosage strengths for individualized titration and dosing to help achieve adequate pain relief.[1]

Tablets shown are not actual size.

Titrate Opana® ER to a level that provides adequate analgesia and minimizes side effects



INDICATIONS

- OPANA® ER is an opioid agonist indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.
- Not intended for use as an as needed analgesic. Not indicated in the immediate post-operative period or if the pain is mild or not expected to persist for an extended period of time.

Please see additional Important Safety Information on following pages and accompanying full Prescribing Information, including boxed WARNING, for Opana® ER.

opana® ER (oxymorphone HCl) ℄

EXTENDED-RELEASE TABLETS

5mg • 7.5mg • 10mg • 15mg • 20mg • 30mg • 40mg

IMPORTANT SAFETY INFORMATION

OPANA® ER has a boxed warning as follows:

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, ACCIDENTAL EXPOSURE, and INTERACTION WITH ALCOHOL

Abuse Potential
OPANA ER contains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit. Assess each patient's risk for opioid abuse or addiction prior to prescribing OPANA ER. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OPANA ER for signs of misuse, abuse, and addiction during treatment.

Life-threatening Respiratory Depression
Respiratory depression, including fatal cases, may occur with use of OPANA ER, even when the drug has been used as recommended and not misused or abused. Proper dosing and titration are essential and OPANA ER should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OPANA ER or following a dose increase. Instruct patients to swallow OPANA ER tablets whole. Crushing, dissolving, or chewing OPANA ER can cause rapid release and absorption of a potentially fatal dose of oxymorphone.

Accidental Exposure
Accidental ingestion of OPANA ER, especially in children, can result in a fatal overdose of oxymorphone.

Interaction with Alcohol
The co-ingestion of alcohol with OPANA ER may result in an increase of plasma levels and potentially fatal overdose of oxymorphone. Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while on OPANA ER.

HIGHLY CONFIDENTIAL- OUTSIDE COUNSELS' EYES ONLY

ENDO_OP_ACT_0000189

OPANA® ER WITH INTAC® TECHNOLOGY[1] HAD NO SIGNIFICANT DIFFERENCE IN THE RATE AND EXTENT OF ABSORPTION COMPARED TO THE ORIGINAL FORMULATION OVER 12 HOURS[2]

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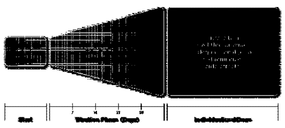
Seven dosage strengths for individualized titration and dosing to help achieve adequate pain relief.[1]

Tablets shown are not actual size.

Titrate Opana® ER to a level that provides adequate analgesia and minimizes side effects



INDICATIONS

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- Not intended for use as an as-needed analgesic. Not indicated in the immediate post-operative period or if the pain is mild or not expected to persist for an extended period of time.

Please see additional Important Safety Information on following pages and accompanying full Prescribing Information, including boxed WARNING, for Opana® ER.

opana® ER (oxymorphone HCl) CII

EXTENDED-RELEASE TABLETS
5mg • 7.5mg • 10mg • 15mg • 20mg • 30mg • 40mg

IMPORTANT SAFETY INFORMATION

OPANA® ER has a boxed warning as follows:

> **WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, ACCIDENTAL EXPOSURE, and INTERACTION WITH ALCOHOL**
>
> **Abuse Potential**
> OPANA ER contains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit. Assess each patient's risk for opioid abuse or addiction prior to prescribing OPANA ER. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OPANA ER for signs of misuse, abuse, and addiction during treatment.
>
> **Life-threatening Respiratory Depression**
> Respiratory depression, including fatal cases, may occur with use of OPANA ER, even when the drug has been used as recommended and not misused or abused. Proper dosing and titration are essential and OPANA ER should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OPANA ER or following a dose increase. Instruct patients to swallow OPANA ER tablets whole. Crushing, dissolving, or chewing OPANA ER can cause rapid release and absorption of a potentially fatal dose of oxymorphone.
>
> **Accidental Exposure**
> Accidental ingestion of OPANA ER, especially in children, can result in a fatal overdose of oxymorphone.
>
> **Interaction with Alcohol**
> The co-ingestion of alcohol with OPANA ER may result in an increase of plasma levels and potentially fatal overdose of oxymorphone. Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while on OPANA ER.

Help manage expectations for patients like Janice

- Inform your patients of potential adverse reactions they may experience during conversion and titration to a new long-acting opioid therapy. Adverse reactions reported at (≥2%) in placebo-controlled trials were: nausea, constipation, dizziness, somnolence, vomiting, pruritus, headache, sweating increased, dry mouth, sedation, diarrhea, insomnia, fatigue, appetite decreased, and abdominal pain.
- Continue active patient dialogue to ensure they're getting the relief they need.

Opana® ER is widely available on managed care plans (including Medicare Part D) for 8 out of 10 covered patients

Visit opana.com for more information

Please see additional Important Safety Information below and accompanying full Prescribing Information, including boxed WARNING, for Opana® ER.

IMPORTANT SAFETY INFORMATION

LIMITATIONS OF USAGE

OPANA ER is not intended for use as an as-needed (PRN) analgesic, for pain that is mild or not expected to persist for an extended period of time, for acute pain, for postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

CONTRAINDICATIONS

OPANA ER is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma or hypercarbia; known or suspected paralytic ileus; moderate and severe hepatic impairment; hypersensitivity (e.g., anaphylaxis) to oxymorphone, any other ingredients in OPANA ER, or to morphine analogs such as codeine; and conditions that increase the risk of life-threatening respiratory depression.

WARNINGS AND PRECAUTIONS

- Respiratory depression is the primary risk of OPANA ER. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status.
- While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of OPANA ER, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression when initiating therapy with OPANA ER, following dose increases, and when OPANA ER is given concomitantly with other drugs that depress respiration. Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics due to poor fat stores, muscle wasting, or altered clearance compared to younger, healthier patients.
- Monitor patients for respiratory depression who have significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression, particularly when initiating therapy and titrating with OPANA ER, as in these patients, even usual therapeutic doses of OPANA ER may decrease respiratory drive to the point of apnea. Consider the use of alternative non-opioid analgesics in these patients if possible.
- Hypotension, profound sedation, coma, or respiratory depression may result if OPANA ER is used concomitantly with other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). Additionally, consider the patient's use, if any, of alcohol or illicit drugs that cause CNS depression. If OPANA ER therapy is to be initiated in a patient taking a CNS depressant, start with a lower OPANA ER dose than usual and monitor patients for signs of hypotension, sedation and respiratory depression and consider using a lower dose of the concomitant CNS depressant.
- There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension after initiating or titrating the dose of OPANA ER.
- Monitor patients taking OPANA ER who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors) for signs of sedation and respiratory depression, particularly when initiating therapy with OPANA ER. Opioids may obscure the clinical course in a patient with a head injury.
- Avoid the use of OPANA ER in patients with circulatory shock, with impaired consciousness or coma, or with GI obstruction.
- The oxymorphone in OPANA ER may cause spasm of the sphincter of Oddi. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.
- The oxymorphone in OPANA ER may aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. Monitor patients with a history of seizure disorders for worsened seizure control during OPANA ER therapy.
- Do not abruptly discontinue OPANA ER. If OPANA ER is abruptly discontinued in a physically-dependent patient, an abstinence syndrome may occur. Use a gradual downward titration of the dose every two to four days to prevent signs and symptoms of withdrawal.
- Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal symptoms.
- Chronic maternal use of oxymorphone during pregnancy can affect the fetus with subsequent withdrawal signs. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts.

IMPORTANT SAFETY INFORMATION (continued)

- OPANA® ER is not recommended during labor and delivery, pregnancy, or nursing.
- OPANA ER may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of OPANA ER and know how they will react to the medication.
- Patients 65 years of age or older, patients with mild hepatic impairment and patients with moderate to severe renal impairment, have an increase in oxymorphone bioavailability. For these patients on prior opioid therapy, start at 50% of the starting dose for a younger patient or a patient with normal hepatic or renal function and titrate slowly and monitor closely for respiratory and central nervous system depression.
- In opioid-naïve patients initiate OPANA ER using the 5 mg dose and monitor closely for respiratory and central nervous system depression.
- OPANA ER can be abused and is subject to criminal diversion. The high drug content in extended release formulations adds to the risk of adverse outcomes from abuse and misuse. Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to reduce abuse of opioid drugs. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests as required by state law, is strongly advised.
- OPANA ER is administered at a frequency of twice daily (every 12 hours). Administer on an empty stomach, at least 1 hour prior to or 2 hours after eating.

Risks Specific to Abuse of OPANA ER

- OPANA ER is for oral use only. Abuse of OPANA ER poses a risk of overdose and death. This risk is increased with concurrent abuse of OPANA ER with alcohol and other substances. OPANA ER tablets must be taken whole, one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth. Taking cut, broken, chewed, crushed, or dissolved OPANA ER enhances drug release and increases the risk of overdose and death.

ADVERSE REACTIONS

- Adverse reactions reported at (≥2%) in placebo-controlled trials were: nausea, constipation, dizziness, somnolence, vomiting, pruritus, headache, sweating increased, dry mouth, sedation, diarrhea, insomnia, fatigue, appetite decreased, and abdominal pain.
- In clinical trials there were several adverse events that were more frequently observed in subjects 65 and over compared to younger subjects. These adverse events included dizziness, somnolence, confusion, and nausea.
- Post-marketing Experience – The following adverse reactions have been identified during post approval use of OPANA ER. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Nervous system disorders: amnesia, convulsion, memory impairment.

DRUG INTERACTIONS

- Concurrent use of OPANA ER and other CNS depressants including sedatives, hypnotics, tranquilizers, general anesthetics, phenothiazines, other opioids, and alcohol can increase the risk of respiratory depression, hypotension, profound sedation, or coma. Monitor patients receiving CNS depressants and OPANA ER for signs of respiratory depression and hypotension. When such combined therapy is contemplated, reduce the initial dose of one or both agents.
- Mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, butorphanol, or buprenorphine) may reduce the analgesic effect of OPANA ER or may precipitate withdrawal symptoms in these patients. Avoid the use of mixed agonist/antagonist analgesics in patients receiving OPANA ER.
- Cimetidine can potentiate opioid-induced respiratory depression. Monitor patients for respiratory depression when OPANA ER and cimetidine are used concurrently.
- Anticholinergics or other medications with anticholinergic activity when used concurrently with opioid analgesics may result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. Monitor patients for signs of respiratory and central nervous system depression when OPANA ER is used concurrently with anticholinergic drugs.

References: 1. Opana® ER [package insert]. Chadds Ford, PA: Endo Pharmaceuticals, Inc; 2012. 2. Benedek I, Jobes J, Xiang Q, Fiske WD. Bioequivalence of oxymorphone extended release and crush-resistant oxymorphone extended release. *Drug Des Devel Ther.* 2011;5:455-463. 3. Data on file. [illegible] Endo Pharmaceuticals: June [illegible], 2011.

Please see accompanying full Prescribing Information, including boxed WARNING, for Opana® ER.

opana® ER (oxymorphone HCl) CII

EXTENDED-RELEASE TABLETS
5mg • 7.5mg • 10mg • 15mg • 20mg • 30mg • 40mg

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[illegible] January 2013 www.opana.com 1-800-462-ENDO (3636)

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OPANA® ER Indication

- OPANA ER is indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time
- OPANA ER is not intended for use as an as needed analgesic
- OPANA ER is not indicated for pain in the immediate post-operative period (12–24 hours following surgery) for patients not previously taking opioids because of the risk of oversedation and respiratory depression requiring reversal with opioid antagonists
- OPANA ER is not indicated for pain in the post-operative period if the pain is mild or not expected to persist for an extended period of time

OPANA ER Important Safety Information

WARNING: OPANA ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

OPANA ER is NOT intended for use as an as needed analgesic.

OPANA ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, or prescription or nonprescription medications containing alcohol, while on OPANA ER therapy. The co-ingestion of alcohol with OPANA ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

- OPANA ER is **contraindicated** in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of OPANA ER; in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated such as: patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings), acute or severe bronchial asthma, hypercarbia, and in any patient who has or is suspected of having paralytic ileus
- OPANA ER is not indicated for pain in the immediate post-operative period (the first 12–24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OPANA ER is only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (see American Pain Society guidelines)
- Respiratory depression is the chief hazard of OPANA ER, particularly in elderly or debilitated patients. OPANA ER should be administered with extreme caution to patients with conditions accompanied by hypoxia, hypercapnia, or decreased respiratory reserve such as: asthma, chronic obstructive pulmonary disease or cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, central nervous system (CNS) depression, or coma
- Patients receiving other opioid analgesics, general anesthetics, phenothiazines or other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) may experience additive effects resulting in respiratory depression, hypotension, profound sedation, or coma
- OPANA ER should be used with caution in elderly and debilitated patients and in patients who are known to be sensitive to CNS depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease. OPANA ER should be used with caution in patients with mild hepatic impairment and in patients with moderate to severe renal impairment. These patients should be started cautiously with lower doses of OPANA ER while carefully monitoring for side effects
- OPANA ER is not indicated for preemptive analgesia (administration preoperatively for the management of post-operative pain)
- The most common adverse drug reactions (≥10%) in all clinical trials for OPANA ER were nausea, constipation, dizziness (excluding vertigo), vomiting, pruritus, somnolence, headache, increased sweating, and sedation
- Patients and their families should be instructed to flush any OPANA ER tablets that are no longer needed

Please see Brief Summary of Prescribing Information on back of adjacent page.

think™

OPANA
(oxymorphone H
Extended-release tablets
5 mg, 7.5 mg, 10 mg, 15 m

5 mg 7.5 mg 10 mg 15 mg

Tablets shown are not actual size.

For moderate to se

think™ No known CYP45

think™ True 12-hour dosi

think™ Widely available

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specific to your are

OPANA ER should be administered on a

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US CONCERNS

Opana® ER Indications and Important Safety Information

Indication

- **Opana® ER** is indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

Limitations of Usage

- **Opana® ER** is not intended for use as an as needed analgesic.
- **Opana® ER** is not indicated for pain in the immediate post-operative period or if the pain is mild or not expected to persist for an extended period of time.
- **Opana® ER** is only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (see American Pain Society guidelines).

Opana® ER has a boxed warning as follows:

WARNING: POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT SELECTION AND LIMITATIONS OF USE.

See full Prescribing Information for complete boxed warning.

- **Opana® ER contains oxymorphone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics.**
- **Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Opana® ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.**
- **Opana® ER is NOT intended for use as an as needed analgesic.**
- **Opana® ER tablets are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed as this leads to rapid release and absorption of a potentially fatal dose of oxymorphone.**
- **Patients must not consume alcoholic beverages, prescription or non-prescription medications containing alcohol. Co-ingestion of alcohol with Opana® ER may result in a potentially fatal overdose of oxymorphone.**

- Opana ER is **contraindicated** in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of Opana ER; in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated such as: patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings), acute or severe bronchial asthma, hypercarbia, and in any patient who has or is suspected of having paralytic ileus.
- Opana ER is not indicated for pain in the immediate post-operative period or if the pain is mild, or not expected to persist for an extended period of time. Opana ER is only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (see American Pain Society guidelines). Opana ER is not indicated for pre-emptive analgesia (administration pre-operatively for the management of post-operative pain).
- Respiratory depression is the chief hazard of Opana ER, particularly in elderly or debilitated patients. Opana ER should be administered with extreme caution to patients with conditions accompanied by hypoxia, hypercapnia, or decreased respiratory reserve.
- Patients receiving other opioid analgesics, general anesthetics, phenothiazines or other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) may experience additive effects resulting in respiratory depression, hypotension, profound sedation, coma or death.
- In the presence of head injury, the respiratory depressant effects of Opana ER and the potential to elevate cerebrospinal fluid pressure may be markedly exaggerated.
- Opana ER may cause severe hypotension in patients with compromised ability to maintain blood pressure. Administer with caution to patients in circulatory shock.
- Prolonged gastric obstruction may occur in patients with gastrointestinal obstruction, especially paralytic ileus.
- Use with caution in patients with biliary tract disease, as it may cause spasm of the sphincter of oddi.
- Opioid analgesics impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.
- Opana ER is not recommended during labor and delivery, pregnancy, or nursing.
- Opana ER should be used with caution in elderly and debilitated patients and in patients who are known to be sensitive to CNS depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease. Opana ER should be used with caution in patients with mild hepatic impairment and in patients with moderate to severe renal impairment. These patients should be started cautiously with lower doses of Opana ER while carefully monitoring for side effects.
- Adverse reactions reported at (≥2%) in placebo-controlled trials were: nausea, constipation, dizziness, somnolence, vomiting, pruritus, headache, sweating increased, dry mouth, sedation, diarrhea, insomnia, fatigue, appetite decreased, and abdominal pain. In clinical trials there were several adverse events that were more frequently observed in subjects 65 and over compared to younger subjects. These adverse events included dizziness, somnolence, confusion, and nausea.
- Drug Interactions—CNS depressants: Increased risk of respiratory depression, hypotension, profound sedation, coma or death. When combined therapy with CNS depressant is contemplated, the dose of one or both agents should be reduced. Mixed agonist/antagonist opioids (i.e., pentazocine, nalbuphine, and butorphanol): May reduce analgesic effect and/or precipitate withdrawal symptoms. Cimetidine: Combination use may precipitate confusion, disorientation, respiratory depression, apnea, seizures. Anticholinergics: May result in urinary retention and/or severe constipation, which may lead to paralytic ileus. Monoamine oxidase inhibitors (MAOIs): Potentiate the action of opioids. Opana ER should not be used in patients taking MAOIs or within 14 days of stopping such treatment.
- Patients and their families should be instructed to flush any Opana ER tablets that are no longer needed.

Please see Brief Summary of Prescribing Information on back of adjacent page.

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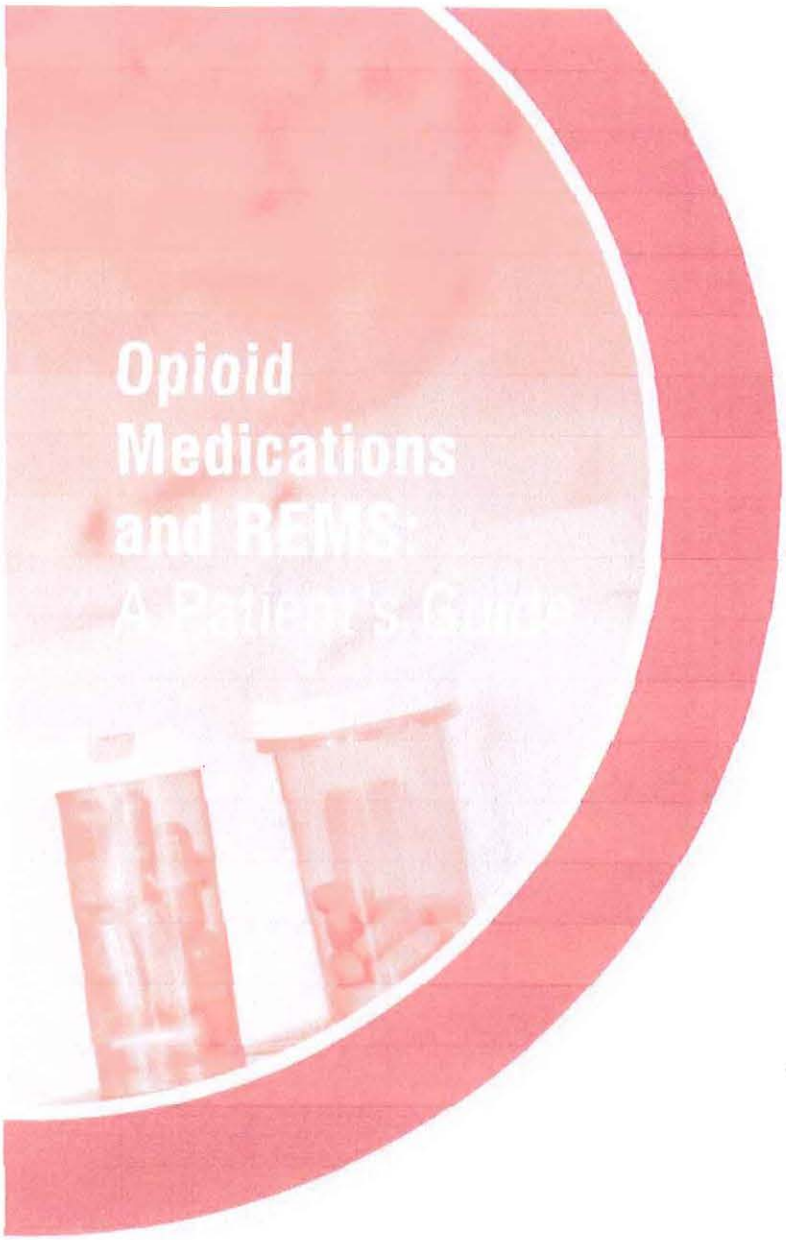
Opioid Medications and REMS: A Patient's Guide



READY FOR REMS™

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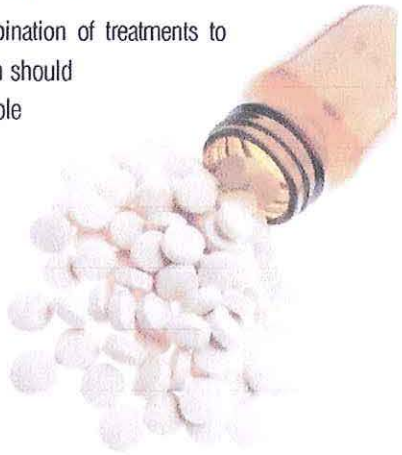
Things You Should Know About Your Opioid Medication

Opioid medications are an important part of pain treatment.



- Most people with long-term pain require a combination of treatments to properly relieve their pain. These treatments, which should only be given under the direction of a knowledgeable healthcare professional, may include medicines, physical and psychological therapy, devices, or surgery. Some patients find that non-traditional treatments, such as meditation, acupuncture, massage, and complementary medicines, can help too, but you should always check with your doctor before trying any of these. Psychological treatment approaches, such as cognitive behavioral therapy, involving modifying negative thoughts related to long-term pain, have also been found to be effective in helping to reduce pain, disability, and anxiety.

- Prescription medication is the most common treatment for long-term pain, and opioid medications are a useful option doctors may use to treat some people with severe, long-term pain. Your doctor may suggest that an opioid might be the best medicine for you, but patients on opioids need to be monitored to determine if opioids should be continued.

Opioid medications are associated with certain risks.

- When used as directed, opioid medications can be highly effective for controlling pain and improving functioning in many people.

- Opioid medications are strong painkillers and have certain risks, particularly if they are taken in a way that is not intended by your doctor. These risks include overdose, abuse, and addiction. Overdose, which may be due to abuse or addiction, can be fatal.

clinical trials demonstrate only modest pain relief (20-30%) @ 12 weeks.
Trials have not been able to demonstrate improved function.

Addiction risk is minimized.

Addiction is a common risk when treating patients with opioids long-term.

- Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids. If you find yourself taking your opioids more often than you should, or you feel a craving for them, then it is important to talk to your doctor. It is not a sign of addiction if you find that you need increasing amounts of an opioid to control your pain (which may be tolerance to pain relief), or if you experience unpleasant symptoms when your opioid is suddenly stopped (withdrawal due to physical dependence), or if, over time, some of the opioid side effects, like nausea, become less bothersome to you (tolerance to side effects).

- Certain opioid medications are so powerful that they can only be used in patients who have already built up a tolerance to opioids; such opioids may prove harmful or even lethal in people who have not first developed a tolerance.

Risk Evaluation and Mitigation Strategies, or REMS.

- Risk Evaluation and Mitigation Strategies, also called REMS, are programs required by the US Food and Drug Administration to promote the safe use and distribution of certain prescription medications, including opioids. They are intended to make sure that the benefits outweigh the risks, such as overdose.

- REMS may continually educate both healthcare providers and patients about safety with regard to opioids, and may create certain procedures for obtaining and dispensing such drugs.

- Your doctor will talk with you about safety and necessary precautions, confirming that you have understood what has been discussed. You will also be given a medication guide. This is a pamphlet outlining the nature and purpose of the opioid medication as well as the benefits and risks (see *Read your medication guide*).

- Once in place, REMS programs must be followed. Currently, some opioid medications have a REMS while others do not yet have one. In the meantime, we will give you some general information that you can use now to help keep you safe while taking your opioid medication. Your healthcare provider will talk to you about other responsibilities for specific opioid REMS as they are introduced.

PAIN | Opioid Therapy

SHORT- VS LONG-ACTING OPIOIDS: WHAT'S THE DIFFERENCE?

Short-acting opioids

- Work more quickly
- Treat pain for a short period
- Taken as needed when you first start to feel pain

Long-acting opioids

- Are released in the body over a longer period of time so pain relief lasts for several hours
- Treat persistent pain
- Taken on a regular schedule (every 8–12 hours) at the same time every day

EXPLAIN YOUR PAIN

ONLY YOU KNOW HOW MUCH PAIN YOU ARE IN.

Be sure to tell your healthcare provider the following information about your pain to help him best treat it:

- ✓ When it starts
- ✓ Where it occurs
- ✓ How long it lasts
- ✓ Any "triggers" that cause you pain

Remember, having pain is *not* a way of life—all types of pain can be treated, and be controlled or decreased as the result of treatment.

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The National Initiative on Pain Control® (NIPC®) is sponsored by Professional Postgraduate Services®, Secaucus, NJ.

The NIPC is supported by an educational grant from Endo Pharmaceuticals Inc.

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Opioids can be taken safely for pain relief. This handout will review some of the risks and benefits of opioid therapy, and what you can expect once you start taking an opioid medication.

Opioids are used to treat moderate-to-severe pain (pain that is greater than 4 on a pain scale where 0 is no pain and 10 is the worst possible pain). They work like natural substances found in the body (known as *endorphins*) that are produced to control pain. *Hydrocodone* (Vicodin), *morphine* (Avinza, Kadian, MS Contin, Oramorph), *codeine* (Tylenol with Codeine, Empirin with Codeine), *oxycodone* (OxyContin, Percocet), *methadone* (Dolophine, Methadose), *fentanyl* (Actiq, Fentora, Duragesic), and *oxymorphone* (Opana) are the names of commonly prescribed opioids.

Opioids are either *short-* or *long-acting* (*see "Short- vs Long-Acting Opioids" box*), and can be used to treat *chronic* and *acute* pain. *Chronic* (or *persistent*) pain is present over a long period of time. Some examples include pain that is associated with a long-term illness or condition, such as arthritis, low back pain, or cancer. *Acute* pain is short-term and may be severe, for example, pain that is caused by an injury.

It is important to talk with your healthcare provider about the type of pain that you are experiencing. See the checklist on the left (*Explain Your Pain*) for some tips about communicating your pain level to your healthcare provider.

What are some of the benefits of opioid therapy?

Opioids can be very beneficial for treatment of both acute and chronic pain. Opioid therapy can:

- Reduce pain
- Improve pain-related dysfunction (that is, when your pain stops you from doing your normal activities of daily living)
- Improve quality of life

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

Your healthcare provider will work with you to ensure that you are taking your opioids safely. As with all prescription medications, some risks are associated with opioid therapy. These include *tolerance, physical dependence, withdrawal,* and *addiction.*

When patients become *tolerant* to a medication, it means that they need increasing amounts of the medication to give the same effect that occurred when they first started taking it. Once you are on the right dose of medication for your pain, tolerance usually does not occur. Unless your pain worsens, you will most likely remain on the same opioid dose throughout your treatment. Just because you are tolerant and need more medication does not mean that you are addicted.

Physical dependence means that you may experience symptoms of *withdrawal* if you stop taking regular doses of your opioid too quickly. Common symptoms of withdrawal include restlessness, insomnia, sweating, or nausea/vomiting. These symptoms can be avoided by slowly decreasing the opioid dose. You should not change your dose on your own; speak with your healthcare provider if you feel that you need to have your medication adjusted. Just because you develop withdrawal symptoms if you miss a dose does not mean that you are addicted.

Addiction is excessive use of a medication or drug even though it may be harmful to the user. People who take opioids as prescribed usually do not become addicted. It is important to keep up an ongoing dialogue with your healthcare provider and let him know if you feel that you are using your medications for reasons other than pain control or if you feel unable to control how often and how much of your medication you are taking.

What can you expect in terms of pain relief and improvements in your quality of life?

After starting opioid therapy, you may see the following positive improvements:

- Your pain level may decrease
- Your level of function should improve: you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse
- Your sleep may improve

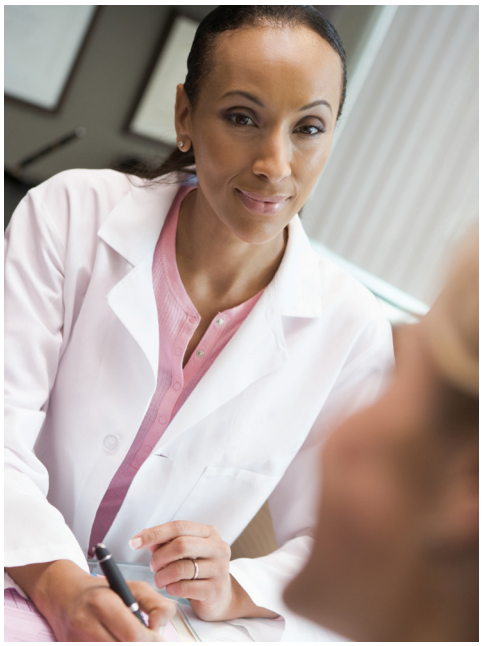
What if opioid treatment doesn't work?

If opioid treatment is not appropriate for you, or if you are experiencing side effects, talk with your healthcare provider. She can help to decide on the next best course of action, which may include switching to a different opioid or to a new pain medication. Do not stop taking your opioid medication on your own; make sure to discuss stopping medication with your healthcare provider first.

Opioids are just one part of your pain treatment. Your healthcare provider will partner with you to help reduce your pain, and may also recommend other medications, lifestyle changes, or non-drug treatments that can be used with opioid treatment to obtain the best results.

FOR MORE INFORMATION:

Talk to Your Healthcare Professional

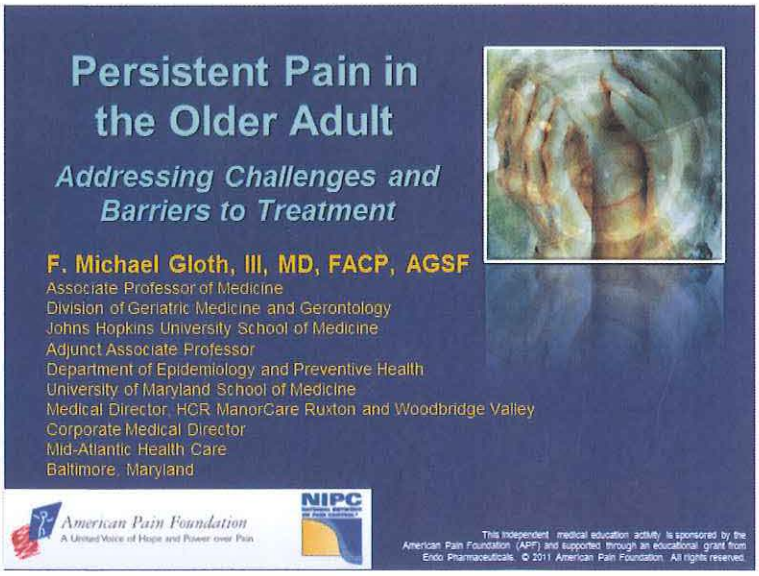


TIPS for Using Opioids to Treat Pain

- Take your medication *exactly* as it is prescribed.
- Discuss any concerns that you have regarding opioid therapy with your healthcare provider.
- Let your healthcare provider know if you are experiencing any side effects. She can modify your dose or change your medication.
- Tell your healthcare provider about any other medication(s) that you may be taking.
- Keep all of your appointments with your healthcare provider.
- Keep track of the time when you took your pain medication and the activity that you were doing when your pain occurred.

REFERENCES American Cancer Society. Pain control: a guide for people with cancer and their families. Available at: http://www.cancer.org/docroot/MIT/content/MIT_7_2x_Pain_Control_A_Guide_for_People_with_Cancer_and_Their_Families.asp. • Katz WA. Opioids for nonmalignant pain. *Rheum Dis Clin N Am.* 2008;34(2):387-413. • National Pain Foundation. Addiction and chronic pain. Available at: http://nationalpainfoundation.org/MyTreatment/MyTreatment_Addiction_and_Chronic_Pain.asp. All websites accessed January 15, 2009.

Slide 1



Slide 2

Learning Objectives

- Describe key clinical challenges related to pain management in older adults
- Summarize issues surrounding the use of therapeutic interventions in older adults
- Discuss use of rational multimodal pharmacotherapy in the pain treatment plan
- Engage in patient and caregiver communications that emphasize safe and appropriate use of multimodal persistent pain treatments

1

Slide 3

Which barrier do you find most prohibitive when treating persistent pain in older adults?

1. Communication
2. Assessing patients with dementia
3. Drug-drug interactions/adverse effects
4. Safe use
5. Fear of addiction

2

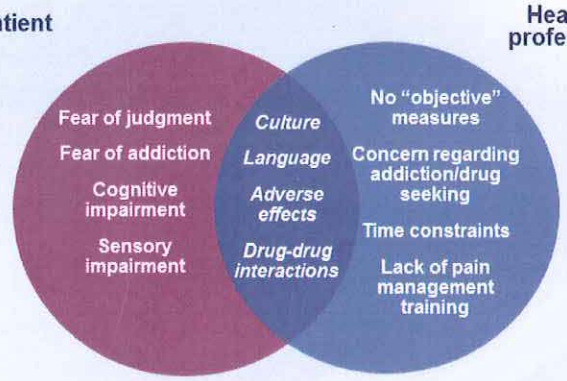
Slide 4

Which barrier do you find most prohibitive when treating persistent pain in older adults?

0%	1. Communication
8%	2. Assessing patients with dementia
58%	3. Drug-drug interactions/adverse effects
17%	4. Safe use
17%	5. Fear of addiction

Slide 5

Barriers to Managing Persistent Pain in Older Adults



Hadjistavropoulos T, et al. *Clin J Pain*. 2007;23(suppl 1):S1-S43.
McAuliffe L, et al. *J Adv Nurs*. 2009;65(1):2-10.

3

Slide 6

Persistent Pain in the Older Adult:
Addressing Challenges and Barriers to Treatment

This program will

- Focus on three barriers associated with managing persistent pain in older adults
- Discuss strategies for addressing these barriers

Before we begin, let's look at some information about persistent pain and its impact on older adults...

4

Slide 7

Prevalence of Persistent Pain in the United States

Type of Pain	Reported Sufferers
Recurrent (day long)	One in four[1]
Persistent (>24 h/month)	One-fifth of adults aged >65 years[1]
Persistent (≥1 year)	Three-fifths of adults aged >65 years[1]
Attributable to military service	Two-thirds of veterans[2]

1. National Center for Health Statistics Report: Health, United States, 2006, Special Feature on Pain. Available at: http://www.cdc.gov/nchs/pressroom/06facts/hus06.htm. Accessed April 22, 2011.
2. American Pain Foundation. Survey of veterans and pain. Available at: http://www.painfoundation.org. Accessed April 22, 2011.

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Slide 8

Pain Can Affect All Aspects of a Person's Life

Functional Status
- Physical functioning
- Ability to perform activities of daily living
- Work
- Recreation

Psychological Morbidity
- Depression
- Anxiety, anger
- Sleep disturbances
- Loss of self-esteem
- Posttraumatic stress disorder

Social Consequences
- Marital/family relations
- Intimacy/ sexual activity
- Social isolation

Socioeconomic Consequences
- Healthcare costs/utilization
- Disability
- Lost workdays

All diminish function and quality of life (QoL)

AGS Panel on Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2002;50(6 suppl):S205-S224.

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Slide 9

Pain Pentagon©

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Gloth FM III, ed. *Handbook of Pain Relief in Older Adults.* 2nd ed. New York, NY: Humana Press; 2011.

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Slide 10

A Closer Look: Communication

How can HCPs improve communication with patients and caregivers?

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Slide 11

A 92-year-old patient with metastatic cancer laughed when asked to rate her pain using your facility's assessment scale.

How do you respond?

1. Request that a mental status evaluation be obtained (eg, Mini-Mental State Examination [MMSE])
2. Order a neuropsychiatric evaluation
3. Ask which specific pain scale was utilized
4. 1 and 3
5. All of the above

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Slide 12

A 92-year-old patient with metastatic cancer laughed when asked to rate her pain using your facility's assessment scale.

How do you respond?

7% 1. Request that a mental status evaluation be obtained (eg, Mini-Mental State Examination [MMSE])

7% 2. Order a neuropsychiatric evaluation

21% 3. Ask which specific pain scale was utilized

21% 4. 1 and 3

43% 5. All of the above

Slide 13

Effective Pain Management in Older Adults

- Requires
  - Accurate assessment of pain
  - Appropriate therapeutic interventions
  - Methodical reassessment of pain
- Assessment methods include
  - Self report
  - Caregiver/family member report
  - Observations

Hadjistavropoulos T, Herr K, Turk D, Fine PG, et al. *Clin J Pain*. 2007; 23(suppl 1): S1-S43.

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Slide 14

Self-Report Assessment Tools to Consider for Older Adults

- Brief Pain Inventory
- Faces Scales
- Functional Pain Scale (FPS)[a]
- Iowa Pain Thermometer[a]
- Numeric Pain Intensity Scales
- Short Form–McGill Pain Questionnaire (SF-MPQ)
- Verbal Descriptor Scale
- Visual Analog Scale

Remember: **older adults with cognitive impairment may not be able to self-report pain.**

Consult with caregiver to gather information on the patient's pain:

- **Exacerbating and alleviating factors**
- **Duration**
- **Quality**
- **Impact on function**

[a]Available for download at PainKnowledge.org

Additional information available in:
Gloth FM III, ed. *Handbook of Pain Relief in Older Adults*. 2nd ed. New York, NY: Humana Press; 2011.
Hadjistavropoulos T, et al. *Clin J Pain*. 2007;23(suppl 1):S1-S43.

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Mini-Mental State Examination (MMSE)

- One of several tools that can be used
- Max total score=30[1,2]
  - Section 1: orientation, memory, attention (max score=21)
  - Section 2: ability to name, follow verbal and written commands, write sentences spontaneously, copy a complex figure (max score=9)
- Scoring may vary depending on age and education level[3]

Mild dementia	≥21
Moderate dementia	10-20
Severe dementia	≤9

1. Folstein MF, et al. *J Psychiatr Res*. 1975;12(3):189-198.
2. Cockrell JR, et al. *Psychopharmacol Bull*. 1988;24(4):689-92.
3. O'Bryant SE, et al. *Arch Neurol*. 2008;65(7):963-967.

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Slide 16

Assessing Analgesia in Patients With Cognitive Impairment

- Cognitively normal or slightly compromised[a] older adults are generally able to use assessment tools
- Patients with dementia[b] are more accurately assessed using a verbal rating scale
- Symbolic and visual representations of pain may be difficult to comprehend by older hospitalized or institutionalized adults

[a]Considered MMSE ≥17 in this study.
[b]Considered MMSE <17 in this study.

Pesonen A, et al. *Acta Anesthesiol Scand.* 2009;53(5):657-664.

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Slide 17

Assessing Analgesia in Patients With Limited Ability to Communicate

- Aphasic or poorly verbal patients (stroke, severe dementia, terminally ill) have difficulty using self-report assessments
- Behavioral observation is necessary to assess pain intensity
  - Facial expressions
  - Movement patterns (bracing, guarding, distorted postures, avoidance of activity)
  - Nonverbal sounds (moans, cries, respiratory pattern)
  - Reports from family members/caregivers

Hadjistavropoulos T, Herr K, Turk D, Fine PG, et al. *Clin J Pain.* 2007; 23(suppl 1): S1-S43.

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How can clinicians enhance caregivers' competencies in managing pain medications in older adults with persistent pain?

1. Set realistic goals for care
2. Draw on caregiver's life experience
3. Develop complex plans of care
4. 1 and 2
5. All of the above

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How can clinicians enhance caregivers' competencies in managing pain medications in older adults with persistent pain?

0% 1. Set realistic goals for care
0% 2. Draw on caregiver's life experience
0% 3. Develop complex plans of care
31% 4. 1 and 2
69% 5. All of the above

Slide 20

Caregivers' Assets and Limitations for Treating Older Adults With Persistent Pain

Assets

- Life experiences
- Self-confidence

Limitations

- Negative emotional state
- Cognitive/physical impairments
- Low literacy, poor language proficiency
- Competing responsibilities
- Patient-driven demands
- Poor ability to communicate with patient, providers

Lau DT, et al. *J Palliat Med.* 2010;13(9):1085-1090.

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Co-Management Strategies for Working With Caregivers

- Identify support networks
- Discuss ways to reduce competing caregiver responsibilities, if possible
- Understand the impact of negative emotional states on a caregiver's ability to manage medications
- Address the stigma attached to the use of opioid analgesia
- Educate and build consensus around treatment plans

Lau DT, et al. *J Palliat Med.* 2010;13(9):1085-1090.

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Medication Management: Caregiver Challenges

- Perceived stress, or hassle intensity, increases with medication regimen complexity
- Greater medication administration hassles[a] seen among
  - Whites and Hispanics vs other groups
  - Caregivers managing those with moderate levels of cognitive functioning vs those with care recipients having very high or very low cognitive functioning

[a]Based on Family Caregiver Medication Administration Hassles Scale.

Travis SS, et al. *Patient Educ Couns*. 2007;66(1):51-57.

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Medication Management and the Caregiver

- Requires going beyond knowledge and skill-building
- Social context
  - Good communication, positive relations help patients accept assistance
  - Patients' comfort needs should outweigh caregiver preferences
- Support networks
  - Provide respite for the primary caregiver
  - BUT: poor cohesion among family caregivers may result from deep-seated conflicts
  - AND: privately-hired, non-medically trained personal care assistants may not be on board with the plan of care

Lau DT, et al. *J Palliat Med*. 2010;13(9):1085-1090.

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Clinical Pearls

HCP Communication With Patients and Caregivers

- Assess—and reassess—pain on an ongoing basis
  - A pain diary completed by the patient or caregiver can be useful for assessing pain between visits[3]
- Use an assessment tool that corresponds with the patient's ability to communicate
- Maintain ongoing dialogue with caregiver to ensure treatment/management plan suits patient needs
- ***Resource in your meeting folder:*** APF patient tool that will help older adults and caregivers to navigate the pain treatment plan

[3] *Targeting Chronic Pain: Your Personal Notebook* is available at the American Pain Foundation website: http://www.painfoundation.org/.

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A Closer Look: Safe Use of Adjuvants

What are some strategies for safely using adjuvant pain medications in older adults with persistent pain?

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Which of the following will increase safety when prescribing adjuvant pain medications?

Select all that apply

1. Determine all OTC medications patient is using
2. Discuss potential interactions between prescribed and OTC medications
3. Remind patient to read all safety information provided by pharmacy
4. Provide patient with written materials/medication guide when medication is prescribed

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Which of the following will increase safety when prescribing adjuvant pain medications?

Select all that apply

24% 1. Determine all OTC medications patient is using

36% 2. Discuss potential interactions between prescribed and OTC medications

20% 3. Remind patient to read all safety information provided by pharmacy

20% 4. Provide patient with written materials/medication guide when medication is prescribed

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Use of Analgesics in Older Adults

- OTC analgesics may be well tolerated and appropriate for the short-term when used as recommended
- However, long-term use and use at higher doses than recommended may result in significant adverse events (AEs; eg, GI/CV/renal/hepatic events)[1]
- Components of OTC medications may be found in prescribed analgesics[1]
  - Patient knowledge of prescribed and OTC analgesic use is vital for optimal provider-patient education and ensuring safe use of all therapies
  - Caregiver is particularly important: older patients may not be aware of medication names, dosages

1. Roumie CL, et al. *Drugs Aging*. 2004;21(8):485-498.

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Slide 29

AGS Recommendations: Pharmacological Management of Persistent Pain in Older Persons (2009)

- Multidisciplinary panel of experts reviewed evidence-based literature published since the preceding AGS guidelines (2002) and drafted new recommendations
- Each recommendation graded by
  - Strength (strong, weak, or insufficient)
  - Quality of evidence (high, moderate, or low)

Full guideline available at:
http://www.americangeriatrics.org/health_care_professional/clinical_practice/clinical_guidelines_recommendations/2009/

AGS=American Geriatrics Society.

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc*. 2009;57(8):1331-1346.

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Slide 30

FDA Limitations on Acetaminophen

- January 2011: FDA asks manufacturers to make the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit 325 mg
  - No changes to total number of tablets or capsules that may be prescribed or time intervals at which they may be prescribed

Full listing of prescription products containing acetaminophen, and patient information, available at: http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm

US FDA. FDA Drug Safety Communication: Prescription acetaminophen products to be limited to 325 mg per dosage unit; boxed warning will highlight potential for severe liver failure. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm. Accessed March 3, 2011.

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Slide 31

FDA Limitations on Acetaminophen: Information for HCPs

- Maximum recommended total daily dose: 4 grams/day
- Adverse effects reported with acetaminophen use
  - Severe liver injury, including acute liver failure
  - Rare: anaphylaxis and hypersensitivity reactions
- Educate patients on importance of reading all prescription and OTC labels to ensure they are not taking multiple acetaminophen-containing products
- Advise patients about acetaminophen use
  - Do not drink alcohol
  - Seek medical help immediately if more acetaminophen than directed has been taken or swelling of the face, mouth, and throat, difficulty breathing, itching, and/or rash occur

US FDA. FDA Drug Safety Communication: Prescription acetaminophen products to be limited to 325 mg per dosage unit; boxed warning will highlight potential for severe liver failure. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm. Accessed March 3, 2011.

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FDA Safe Use Initiative

- Purpose: Experts in geriatrics, pain management, medication safety convened to identify areas of focus for safe use of pain medications in older adults
- Goal: develop, implement interventions to reduce potential harm from pain medication use
- First meeting held November 2010
  - *Will meet regularly to chart future steps, engage and recruit participants, and focus on specific interventions to improve safe use of NSAIDs in older adults*

US FDA. Safe Use Initiative: Expert roundtable on pain management in older adults. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm231647.htm. Accessed March 3, 2011.

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Encourage Active Participation

- Educate and empower patients and caregivers
  - Responsibility in minimizing risk
  - Improve access to quality pain care
- Coordination of care with patient and caregiver is critical
  - Multiple medications may be an issue
  - Knowing conditions patients are being treated for and medications being taken can help to ensure that all medications are used safely and effectively

For more information, see the APF PainSAFE™ website: http://www.painsafe.org

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In your experience, what is the most common reason for medication nonadherence?

1. Adverse effects
2. Concerns regarding becoming "addicted" to medication
3. Economic reasons
4. Belief that the medication should cure the problem, not just reduce its severity
5. Most of my patients are adherent

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In your experience, what is the most common reason for medication nonadherence?

31%	1. Adverse effects
23%	2. Concerns regarding becoming "addicted" to medication
23%	3. Economic reasons
23%	4. Belief that the medication should cure the problem, not just reduce its severity
0%	5. Most of my patients are adherent

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Pharmacologic Changes With Aging that May Affect Treatment (cont'd)

Pharmacologic Concern	Change With Normal Aging	Common Disease Effects
Liver metabolism	• Oxidation is variable and may decrease, resulting in prolonged drug half-life • Conjugation is usually preserved • First-pass effect usually unchanged • Genetic enzyme polymorphisms may affect some cytochrome enzymes	• Cirrhosis, hepatitis, tumors may disrupt oxidation but not usually conjugation
Renal excretion	• GFR decreases with advancing age, resulting in decreased excretion	• Chronic kidney disease may predispose further to renal toxicity
Transdermal absorption	• Few changes in absorption based on age; may be related to patch technology used	• Temperature and other specific patch characteristics may affect absorption

GFR=glomerular filtration rate.

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2009;57(8):1331-1346. Used with permission.

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Rational Multimodal Pharmacotherapy

- Several pathophysiologic mechanisms may be governing pain
  - Multiple agents may be needed to achieve pain relief
- Combining drugs with complementary mechanisms of action may afford greater relief with less toxicity than single agents
  - Consider delivery methods (eg, use of topical therapies, shorter-acting agents) to avoid potential toxicity issues
  - May be important for conditions in which no single agent can produce pain relief without adverse effects
- Multiple medications may require increased supervision, communication with family/caregiver

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2009;57(8):1331-1346.

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Avoiding Potential Drug-Drug Interactions

- Know the actions, adverse effects, and toxicity profiles of all prescribed and OTC medications
  - Select therapies with a low risk of drug or nutrient interactions
- Be mindful of agents that may
  - Induce or inhibit CYP isoenzymes
  - Prolong QTc interval
    - Tables available at: www.geriatricsatyourfingertips.org *(registration required)*
- Closely observe patients during the first few weeks of new therapy

Geriatrics At Your Fingertips. Appropriate prescribing, drug interactions, and adverse events. Available at: www.geriatricsatyourfingertips.org. Accessed March 30, 2011.

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Slide 41

Nonpharmacologic Therapies

- Pharmacologic therapy may be an important treatment component for some patients
- Nonpharmacologic therapies should also be considered
  - Integrate into the treatment plan where appropriate

Remember:
All treatments (including no treatment) have risks as well as benefits.

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Integrating Nonpharmacologic Therapies into the Treatment Plan

- Benefit of nonpharmacologic interventions (including complementary and alternative medicine) is usually enhanced when combined with pharmacologic strategies[1]
- Integrate systematically in a multimodal approach
  - May be effective alone for some types of pain or low-intensity pain (<4/10)
- Assessment is key
  - Have past treatments been successful? If not, why not?
  - What is he/she willing to try next?
- Some complementary therapies not covered by insurance
  - Is he/she able to pay out of pocket? Are pharmaceutical company programs available to subsidize cost?

Courtesy of American Pain Foundation.

1. AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2009;57(8):1331-1346.

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Clinical Pearls

Safe Use of Adjuvant Pain Medications

- Educate older adults and caregivers about all medications—prescribed and OTC—to ensure safe use
- Be aware of pharmacologic considerations specific to older adults
- Be mindful of using a single agent to cover multiple patient issues
- Integrate nonpharmacologic therapy into the treatment plan where appropriate

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A Closer Look: Safe Use of Opioids

How can opioid therapy be used safely in older adults?

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Slide 45

An 80-year-old woman with history of MI, HTN, and knee OA, taking 1 baby aspirin daily for CV prophylaxis, has associated moderate chronic musculoskeletal pain (pain intensity=3/10).

Which of the medications below would be a reasonable choice for her?

1. Ibuprofen
2. Duloxetine
3. Prednisone
4. Topical diclofenac 1% gel
5. Transdermal buprenorphine

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An 80-year-old woman with history of MI, HTN, and knee OA, taking 1 baby aspirin daily for CV prophylaxis, has associated moderate chronic musculoskeletal pain (pain intensity=3/10).

Which of the medications below would be a reasonable choice for her?

36%	1. Ibuprofen
29%	2. Duloxetine
0%	3. Prednisone
14%	4. Topical diclofenac 1% gel
21%	5. Transdermal buprenorphine

Slide 47

Speaker:
Ibuprofen - "I would steer away from this for an older adult."

Issues Related to Chronic Use of Opioids in Older Adults

Pros
- Potent
- Effective
- Less risk of systemic organ failure
- Possibly less potential for abuse than in younger patients

Cons
- Adverse effects
  - Constipation
  - Nausea
  - Sedation
  - Confusion
  - Dizziness
  - Falls
  - Itching
- Drug-drug interactions
- Endocrine disorders

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc* 2009;57(8):1331-1346.

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Slide 48

Speaker:

Opioids in Older Adult Pain Relief: Guideline Recommendations from AGS

- Opioid therapy for older adults with persistent pain
  - Based upon the potential efficacy and risks compared with other modalities
  - Balanced against the harms of unrelieved pain and potential adverse effects of opioid therapy

AGS=American Geriatrics Society.

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc* 2009;57(8):1331-1346.

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Opioids in Older Adult Pain Relief: Guideline Recommendations from AGS

Consider a trial of opioid therapy for older patients with moderate to severe persistent pain, guided by the following questions:

(I) Initial evaluation

1. What is the conventional practice for this type of pain or patient?
2. Is there an alternative therapy that may have an equivalent or better therapeutic index for pain control, functional restoration, improvement in QoL?
3. Does the patient have medical problems that may increase the risk of opioid-related adverse effects?
4. Is the patient likely to manage the opioid therapy responsibly (or relevant caregiver likely to responsibly co-manage?)

Cont'd on next slide

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc* 2009;57(8):1331-1346.

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Opioids in Older Adult Pain Relief: Guideline Recommendations from AGS (cont'd)

(II) Role of Consultant or Specialist

1. Am I able to treat this patient without help?
2. Do I need assistance from a pain specialist or other consultant to co-manage this patient?
3. Are appropriate specialists and resources available to help me co-manage this patient?
4. Do the patient's medical, behavioral, or social circumstances warrant referral to a pain medicine specialist for treatment?

AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2009;57(8):1331-1346.

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Opioid Dose Considerations in Older Adults

- Start with lowest dose possible (typically 25%–50% of adult dose); increase slowly
- Carefully titrate medications with long half lives
  - Eg, methadone, levorphanol, transdermal fentanyl
- Use morphine equivalents as a common denominator for all dose conversions to avoid errors; titrate to effectiveness
- When rotating from one opioid to another, decrease equivalent analgesic dose 25%–50% due to incomplete cross-tolerance

Cont'd on next slide

Geriatrics At Your Fingertips. Pain. Available at: www.geriatricsatyourfingertips.org. Accessed March 30, 2011.

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Opioid Dose Considerations in Older Adults (cont'd)

- Use methadone with extreme caution, and only if you are experienced in monitoring, because of highly variable half-life and risk of dose accumulation

Remember:
Selection of medications and dosages should be individualized to each patient and his/her circumstances.

- If opioid needs to be discontinued, taper gradually to avoid withdrawal symptoms (decrease daily dose by 10%–20% each day for 10 days)

Geriatrics At Your Fingertips. Pain. Available at: www.geriatricsatyourfingertips.org. Accessed March 30, 2011.

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Slide 53

Comparative Safety of Opioids in Older Adults

- Cohort analysis comparing safety of opioids used for nonmalignant pain
  - Hydrocodone, codeine, oxycodone, propoxyphene[a], tramadol
- N=6,275 Medicare beneficiaries
  - Mean age=79 years; new initiators of opioid therapy for nonmalignant pain
  - AEs examined: CV events, fracture, GI events, hospitalization (safety event or death), all-cause mortality
- Results showed that rates of AEs vary significantly by agent

Before initiating a trial of opioid therapy, thorough evaluation and assessment are crucial to determine the most appropriate treatment for each patient.

[a]Withdrawn from US market in 2010.

Solomon DH, et al. *Arch Intern Med.* 2010;170(22):1979-1986.

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Slide 54

A 72-year-old man with severe allodynia and dermatomal back pain (pain intensity=7-8/10) associated with PHN recently started tramadol 50 mg q 6 hours and pregabalin 150 mg BID.

After 1 week, he has modest pain relief and constipation.

What is your next step?

1. Advise him to remain on the current regimen
2. Decrease dosages of current medications
3. Rotate to a different opioid
4. Prescribe a different nonopioid (eg, duloxetine or lidocaine patch 5%) and consider a laxative regimen

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Slide 55

A 72-year-old man with severe allodynia and dermatomal back pain (pain intensity=7-8/10) associated with PHN recently started tramadol 50 mg q 6 hours and pregabalin 150 mg BID.

After 1 week, he has modest pain relief and constipation.
What is your next step?

0% 1. Advise him to remain on the current regimen

13% 2. Decrease dosages of current medications

13% 3. Rotate to a different opioid

75% 4. Prescribe a different nonopioid (eg, duloxetine or lidocaine patch 5%) and consider a laxative regimen

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Opioids in Pain Management

- Tolerance to many symptoms develops within days to weeks[1]
- Constipation still requires[2]
  - Activity
  - Hydration
  - Bulk fiber (only if hydration can be maintained)
  - Non-stimulant laxatives (eg, sorbitol)
  - Stimulant laxatives (eg, senna)

1. McNicol E, et al. *J Pain*. 2003;4(5):231-256.
2. Geriatrics At Your Fingertips. Management of chronic constipation. Available at: www.geriatricsatyourfingertips.org. Accessed April 22,2011.

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Management of Opioid Adverse Effects

Adverse Effect	Treatment
Nausea and vomiting	Antiemetics; switch opioids[a]
Constipation	Treat prophylactically with stool softeners, bowel stimulants; nonpharmacologic measures
Sedation	Lower dose (if possible); add nonsedating co-analgesic; add stimulant or attention enhancer
Itching	Antipruritic therapy (eg, antihistamines)
Endocrine dysfunction/ reduced libido/loss of menstrual period	Endocrine monitoring; testosterone replacement; endocrine consultation
Edema and sweating	Switch opioids[a]
Dizziness	Anti-vertigo agents
Confusion	Titrate dose

[a]Opioid switching is an option for any adverse effect.

Chou R, et al. *J Pain*. 2009;10(2):113-130.
Swegle JM, et al. *Am Fam Physician*. 2006;74(8):1347-1354.

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Rationale for Opioid Rotation

- Ineffectiveness or tolerance to current opioid
- Adverse effects/toxicity of current opioid
- Interpatient variability of response
  - Efficacy and adverse effects vary unpredictably
  - Demonstrated hyperalgesia or pseudoaddiction
  - Intricate pharmacokinetics and pharmacogenetics involved
  - Incomplete cross tolerance
  - Multiple mu-opioid receptor subtypes exist

Fine PG, et al. *J Pain Symptom Manage*. 2009;38(3):418-425.

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Six Opioid Safety Steps

1. Never take a prescription pain medication unless it is prescribed for you
2. Do not take pain medicine with alcohol
3. Do not take more doses than prescribed
4. Use with other sedative or anti-anxiety medications can be dangerous
5. Avoid using prescription pain medication to help you fall asleep
6. Lock up prescription pain medicines

For more information, see the PainSAFE educational initiative: www.painsafe.org

APF. PainSAFE™. Six Opioid Safety Steps. Available at: http://www.painfoundation.org/painsafe/safety-tools-resources/six-opioid-safety-steps.pdf.; Zero Unintentional Deaths. Six steps to zero. Available at: http://www.zerodeaths.org/. Accessed February 7, 2011.

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Slide 60

Safe Storage and Disposal of Opioids: Tips for Older Adults and Caregivers

Monitor and secure opioids

Always be in a position to know if any pills are missing

- Take note of how many pills are in each prescription bottle or pill packet
- Keep track of refills
- Make friends and relatives aware of the risks
- Store in a secure, safe place

Do not flush prescription drugs down the toilet unless instructed to do so

- Remove prescription drugs from original containers and mix drugs with an undesirable substance (eg, cat litter; used coffee grounds) before disposing of them
- Conceal or remove personal info and Rx number on empty containers
  - Cover with black permanent marker or duct tape; scratch off

APF. PainSAFE™. Problems with opioids can be prevented. Available at: http://www.painfoundation.org/painsafe/healthcareprofessionals/pharmacotherapy/opioids/preventing-problems.html. Accessed January 19, 2011.

Office of National Drug Control Policy. Proper disposal of prescription drugs. Available at: http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf. Accessed January 19, 2011.

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Clinical Pearls

Safe Use of Opioid Therapy

- Consider opioid therapy for older adults with persistent pain based upon potential efficacy and risks/benefits vs other modalities
- Individualize therapy
  - Mode of delivery may help to address concerns related to opioid use in older adults
- Treatment should never be "prn" (pain relief negligible)
- Establish a regular schedule for dosing (patient may refuse medications)
- Empower patients and caregivers to take an active role in controlling analgesia

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Key Messages
Persistent Pain in Older Adults

- Determine patient's pain management priorities
  - How can functional status, psychological morbidity, social factors, socioeconomic issues be addressed through treatment?
- Use assessment tools that have been standardized in similar populations
- Monitor both pain scores and function, and treat to function
  - Function is affected by inadequate pain treatment

Cont'd on next slide.

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Key Messages
Persistent Pain in Older Adults *(cont'd)*

- Maintain ongoing dialogue with patient and caregiver
  - Work with caregiver to monitor pain status, response to treatment
- Be mindful of pharmacologic considerations specific to older adults
  - Mode of delivery, dose considerations, AEs
- Educate patients, caregivers about OTC, prescription medications to optimize safe use
- Employ rational pharmacotherapy and nonpharmacologic treatments where appropriate as part of multimodal treatment plan

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Slide 64

PROVIDING RELIEF PREVENTING ABUSE

2nd Edition

A reference guide to controlled substance prescribing practices

This quick reference guide features a brief history of opioid use, Drug Enforcement Administration (DEA) schedules of controlled substances, and meaningful definitions related to the use of opioids in the treatment of pain. It also provides information on how to identify patients with potential abuse or diversion problems, so you can help them seek appropriate treatment. This is intended to serve as a general guide, and should not be used as a sole resource or in lieu of clinical experience, legal advice or professional judgment.

AT PURDUE PHARMA, WE ARE COMMITTED TO:

- Ensuring that people with legitimate medical need have access to appropriate analgesic therapy
- Providing educational resources to both the medical and law enforcement communities to help ensure proper use and availability of these medications
- Helping to prevent the abuse and diversion of these medications

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THE HISTORY OF OPIOIDS

Opium and its derivatives have been around for thousands of years. Use of opioids dates as far back as 3400 BC.[1] It is important to note that almost all opioids available today, both legally and illicitly, share a common lineage beginning with the opium poppy.

OPIOID CLASSIFICATION[2]

Opioids can be classified into three groups depending on how they are derived. The naturally occurring opioids are alkaloids derived directly from opium.[2] Most semisynthetic opioids are derived from relatively simple modifications of morphine or thebaine. Synthetic opioids are produced using no naturally-occurring opium alkaloids and are derived purely from chemical synthesis.

Naturally Occurring Opioids[2]	Semisynthetic Opioids[2]	Synthetic Opioids[2]
Morphine Codeine Thebaine	Hydrocodone Hydromorphone Oxycodone Oxymorphone Heroin Buprenorphine	Meperidine Methadone Fentanyl Pentazocine

The word **opioid** is a broad term that refers to all compounds related to opium.[2] The term **narcotic**, once used to refer to any drug that induced sleep, is today usually used in a legal context to refer to a variety of substances, not restricted to opioids, with abuse or addiction potential.[2]

Opioid Timeline (selected events of historical importance)[1,3-5]

- ~3400 BC — Opium poppies cultivated in lower Mesopotamia in the Tigris and Euphrates river systems.
- 1552 BC — The *Therapeutic Papyrus of Thebes (Papyrus of Ebers)* mentions opium as a component of 700 remedies.
- ~1000 BC — Knowledge of opium present in Europe and Northern Africa.
- ~400 BC — Hippocrates recommends medicinal use of poppy juice – sparingly and controlled.
- 973 — Opium recommended for dysentery in the Chinese medical herbarium, *K'ai pao pên tsäo.*
- 1806 — F.W.A. Sertürner publishes experiments in which he isolated the *principum somniferum* from opium; later named **morphine**, after the Greek god of sleep and dreams.
- 1853 — Dr. Alexander Wood in Edinburgh injects morphine via an improved syringe, noting rapid onset and thinking that by avoiding the enteral route, addiction would be avoided.
- 1874 — C.R. Alder Wright synthesizes diacetylmorphine (heroin) from morphine.
- 1875 — *San Francisco Evening Post* estimated 120,000 opium addicts in US, excluding Chinese immigrant laborers, who introduced smoking opium to the US.
- 1898 — Bayer Chemical Company introduces diacetylmorphine as an antitussive, naming it Heroin.
- 1906 — The Food and Drugs Act prohibits interstate commerce in misbranded drugs. Many patent medicines containing opioids are no longer marketed.
- 1914 — Harrison Narcotic Tax Act mandates registration of physicians and pharmacists who dispense "narcotic drugs" (opium and cocaine).[1]
- 1919 — US Supreme Court upholds Harrison Act in Webb, et al. v. US; physicians can no longer maintain addiction by dispensing narcotics.
- 1961 — UN adopts the Single Convention on Narcotic Drugs; endorses the Principle of Balance between control of abuse and legitimate medical use.
- 1970 — Controlled Substances Act conforms US laws to the Single Convention and establishes scheduling of controlled substances.
- 1973 — President Nixon creates the Drug Enforcement Administration by Executive Order to establish a unified command to combat "the drug menace."
- 1974 — Narcotic Addict Treatment Act establishes methadone maintenance treatment for addiction to opioids.
- 2000 — Drug Addiction Treatment Act allows physicians to prescribe specific opioids for treatment of addiction to opioids.

DEA SCHEDULES OF CONTROLLED SUBSTANCES

IMPORTANT INFORMATION FROM THE CONTROLLED SUBSTANCES ACT OF 1970, AS AMENDED[3,5]

For more information about prescribing requirements in your state, including prescription requirements for controlled substances, please contact your State Medical Board or Board of Pharmacy. Also visit: www.deadiversion.usdoj.gov/21cfr/index.html

Type	Examples[2,6,7]	Prescription notes**	Refill notes**
Schedule I*	Marijuana, heroin, LSD	No prescribing permitted	N/A
Schedule II	Morphine, codeine, hydrocodone,† hydromorphone, oxycodone, oxycodone with acetaminophen, oxycodone with aspirin, oxymorphone, fentanyl, meperidine, methadone, tapentadol	Written only,††† partial filling permitted in certain circumstances (may be transmitted via fax in certain circumstances)	No refills permitted. Some states allow an individual practitioner to issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided certain conditions are met.**
Schedule III	Codeine with acetaminophen, hydrocodone with acetaminophen,†† hydrocodone with ibuprofen,†† hydrocodone-containing elixirs,†† buprenorphine/ buprenorphine combinations	Written, oral (promptly reduced to writing by pharmacist), partial filling permitted (may be transmitted via fax)	No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which the prescription was issued. A maximum of five prescriptions are allowed.
Schedule IV	Propoxyphene, propoxyphene with acetaminophen, phenobarbital, benzodiazepines	Written, oral (promptly reduced to writing by pharmacist), partial filling permitted (may be transmitted via fax)	
Schedule V	Diphenoxylate combination products, codeine-containing elixirs	Written, oral (promptly reduced to writing by pharmacist), partial filling permitted (may be transmitted via fax)	No restrictions listed

- The Controlled Substances Act, and its implementing regulations, can be accessed at **http://www.deadiversion.usdoj.gov/21cfr/index.html** on the Drug Enforcement Administration Web site.
- If there is a difference between federal and state law or regulation, the more restrictive applies. Please consult your state's controlled substance authority for more information

*Schedule I substances have no currently accepted medical use in the United States.

**For more information about prescribing requirements in your state, including prescription requirements for controlled substances, please contact your State Medical Board or Board of Pharmacy. Also visit: www.deadiversion.usdoj.gov/21cfr/index.html

†Single-entity hydrocodone not available in the U.S. at this time.

††Hydrocodone combination products containing <15 mg hydrocodone per dosage unit

†††Oral is allowed, but only in emergency situations, as defined by the Code of Federal Regulations. Some states are more restrictive than federal regulations (e.g., emergency oral prescription of Schedule II opioids is not allowed under any circumstances in Kentucky).

MEANINGFUL DEFINITIONS

IMPORTANT DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN[8]

Addiction*: a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[8]

Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse. The kind of drug, the person's environment, genetic factors, including their psychological makeup, and social factors can contribute to the risk of addiction.[9]

Physical dependence*: a state of adaptation manifested by a specific drug class withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or the administration of an antagonist.[8]

Physical dependence is a known effect of certain medications. Confusing physical dependence with addiction is a common error, caused by the fact that most people that health care or law enforcement professionals encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction. The number of people who are physically dependent (i.e., at risk for withdrawal syndrome, if the medicines are abruptly stopped) on some type of medication (e.g., antihypertensives, decongestants) far exceeds the number who are addicted to drugs that induce physical dependence. Discussion of the topic is also muddled because for many years addiction was called "psychological dependence" (not to be confused with physical dependence) and thus an addict was often said to be simply "dependent" on the drug.

Tolerance*: a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[8]

Tolerance may develop to some opioid side effects, such as respiratory depression.[9]

Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis. Exceeding tolerance, by taking larger than usual doses or abusing a number of drugs simultaneously, can be fatal.[9]

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate.[9] The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated.[9,10] Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.[9] Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[9]

*** As recommended by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.**

Proposed Algorithm for Consideration of Setting of Opioid Analgesic Therapy[9]			
Some factors helpful in determining the best treatment setting of care			
← **Towards generalist or solo care**		— **Towards specialist or more coordinated care** → [Pain, addiction, psychiatric, or other specialist as appropriate]	
Pain etiology	Clear, straightforward etiology of pain	Uncertain etiology, but some physiologic clues or a suggested pattern of pain	Etiology unknown, no physiologic clues, no familiar pattern, or complex treatment needs
Psychiatric	No history of psychiatric disorder	Stable, well-compensated psychiatric disorder	Psychiatric instability
Addiction	No history of substance misuse or addiction	In recovery from or history of substance abuse disorder	Active addiction, current illicit use
Social Support	Good social support	Some social discord or challenging social network	Isolated, major social distress, destructive relationships
Activity Engagement	Rich work or avocational life	Some engagement with meaningful activities	No satisfying work, recreation, other activities

Proposed algorithm for consideration of setting of opioid therapy. Adapted from: Savage SR, Horvath R. Opioid therapy of pain. In: Ries R, Fiellin D, Miller S, Saitz R, eds. American Society of Addiction Medicine, *Principles of Addiction Medicine.* 4th Ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2009:1347.

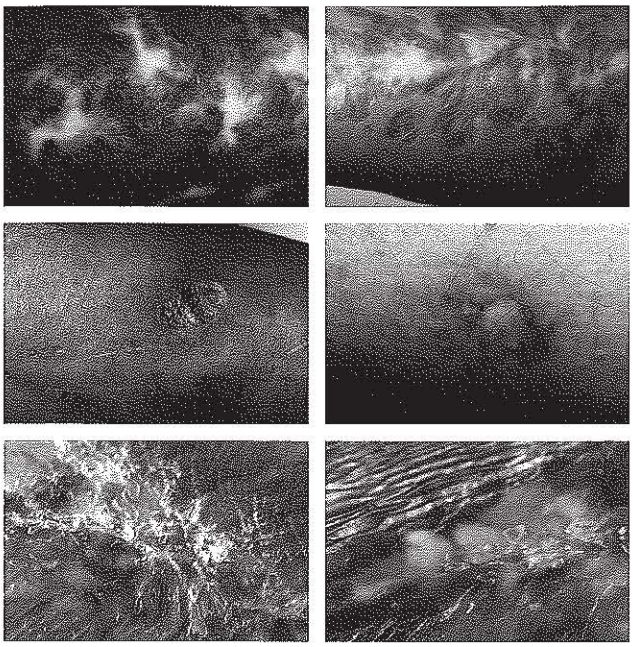
INDICATIONS OF POSSIBLE DRUG ABUSE

POTENTIAL SIGNS CONSISTENT WITH DRUG ABUSE[11]*

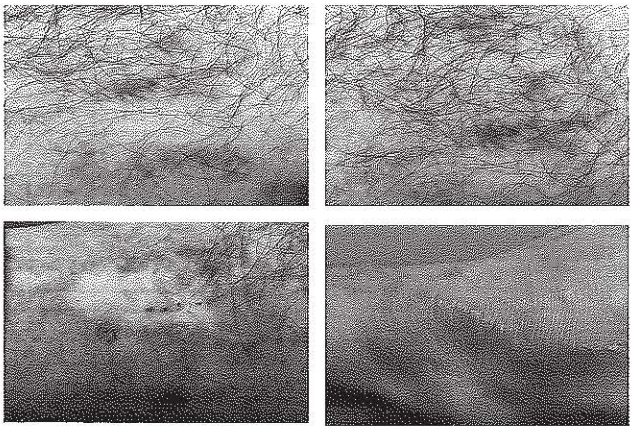
Some diverters are also abusers and are diverting to support their untreated abuse or addiction. Look for signs of drug abuse:

- Marks caused by injections

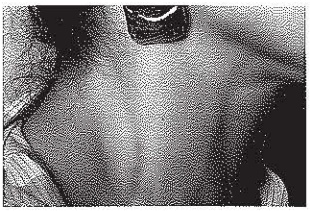
Skin popping (caused by injecting drugs under the skin)



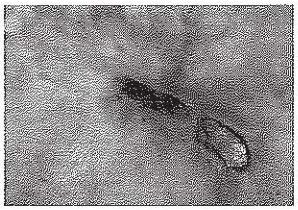
Track marks (arm) (rows of scars from repeated injections)



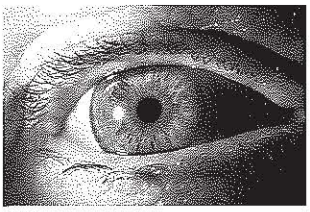
Track marks – jugular vein (neck)

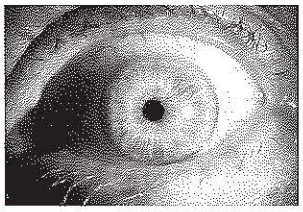


Healing ulcer (leg)

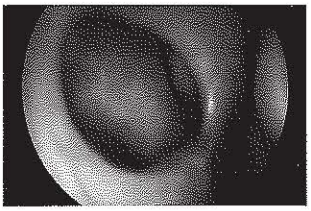


- Constricted pupils

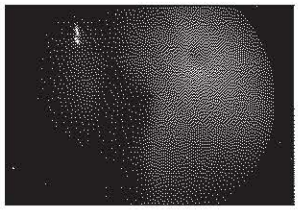




- Perforated nasal septum



(Healthy nasal septum)



Perforated Nasal Septum: In this patient, the photograph is taken through a speculum placed in the left nares. One of the left turbinates is visible in the far-right side of the photograph (where the light reflex is). The structure in the middle is in the septum, which allows the examiner to also view the right turbinates through the septal perforation.

also:

- Loss of appetite
- Sniffles, watery eyes, cough, nausea
- Lethargy, drowsiness, nodding
- Possession of paraphernalia: syringes, bent spoons, needles

***While these signs usually suggest abuse, some of them may be associated with legitimate opioid use (e.g., pupillary constriction) or other medical therapy (e.g., track marks following an extended stay in a hospital). They should not be the only criteria for determining whether opioid abuse has occurred.**

INDICATIONS OF POSSIBLE DRUG ABUSE (CONT'D)

BEHAVIORS OFTEN SEEN IN DRUG DIVERTERS/ABUSERS

- Strange stories surrounding why they need medication[12]
- Reluctance to cooperate with a treatment plan[11]
- Unusually high or low understanding of medications[12]
- Repeated episodes of lost or stolen prescriptions[13]
- Exaggerating or feigning symptoms[12]
- Specific drug requests[12]
- Use of multiple physicians or pharmacies[13]
- Wanting appointments toward the end of office hours[14]
- Calling or arriving after hours or when their primary physician is not available[14]
- Insistence on being seen immediately because they are late for another appointment[14]
- Not interested in having a physical examination, giving permission to obtain past records, or undergoing diagnostic tests[12]
- Unwilling/unable to give name of regular physician; often claim to have no health insurance[12]
- Reciting textbook symptoms or giving vague medical history[12]

LAB SIGNS THAT MAY SUGGEST SUBSTANCE ABUSE

- Elevated MCV[15]
- Abnormal liver enzymes[15]

- Unexpected results in urine drug testing (The use of this technology requires understanding of specificity and sensitivity of the particular analytic method employed. Some point-of-care urine tests for "opioids" or "opiates" do not, for example, detect semisynthetic or synthetic opioid analgesics. See page 18).

PROTECTING PRESCRIPTIONS

Whether you are a healthcare professional who prescribes or dispenses controlled substances or a law enforcement officer in the position to advise prescribers, these steps may be useful in protecting prescriptions and curbing diversion:

- **Keep prescription pads locked away and secure.** This will reduce opportunities for theft.
- **Never sign an incomplete prescription.** Diverters are notorious for altering prescriptions or adding information that you do not intend
- **Write quantities and strengths in both numbers and letters.** This will prevent most attempts at altering the intended dose, quantity or strength.
- **Use tamper-resistant prescription pads.**
- Write on the prescription the name of the pharmacy where the patient wants to have it filled
- Consider faxing the prescription to the pharmacy for later comparison and authentication by the pharmacist
- Do not have medical license number or DEA registration number pre-printed on prescriptions. Write them each time they are required. This will make it harder for prescription pad thieves to successfully forge or counterfeit prescriptions.

STRATEGIES FOR IDENTIFYING ABUSERS

ASK THE RIGHT QUESTIONS

These questions can be asked during the patient history

Method 1: The CAGE-AID Questions[16]

One or more positive answers may indicate a problem with substance abuse.

1. Have you ever tried to **C**ut down on your alcohol or drug use?
2. Do you get **A**nnoyed when people comment about your drinking/drug use?
3. Do you feel **G**uilty about things you've done while drinking/using drugs?
4. Do you need a drink or a drug as an "**E**ye-opener"?

Method 2: The Trauma Test[17]

Two or more positive answers (or 2 or more accidents) may indicate a problem with substance abuse.

Since your 18th birthday, have you...

1. Had any fractures/dislocations of bones or joints (excluding sports injuries)?
2. Been injured in a traffic accident?
3. Injured your head (excluding sports injuries)?
4. Been in a fight or assaulted while intoxicated?
5. Been injured while intoxicated?

ADDITIONAL SCREENING TOOLS

The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)[18]
World Health Organization (WHO) ASSIST Working Group. Available at: http://www.who.int/substance_abuse/activities/assist_v3_english.pdf

The Drug Abuse Screening Test (DAST-20)[19]
Developed by Dr. Harvey A. Skinner. Available at: http://www.camh.net/Publications/CAMH_Publications/drug_abuse_screening_test.html

Car, Relax, Alone, Forget, Friends, Trouble (CRAFFT)[20]
Developed by Dr. J.R. Knight. Available at: http://www.ceasar-boston.org/clinicians/crafft.php

BE ON THE LOOKOUT

Warning indicators of a possible problem with drug abuse

- Atrophied or perforated nasal septum[17]
- Sexually or needle-transmitted diseases[17]
  — Endocarditis
  — Hepatitis
  — HIV/AIDS
- Complaints of sexual dysfunction with no other cause found[17]

Note: Appearance of these indicators serve to alert you to potential problems. They do not mean you should withhold appropriate care.

WHAT TO DO

How to handle a patient whom you suspect of addiction or drug abuse[17]

- Remember, a person abusing drugs or addicted is in need of treatment
- Refer the patient to an addiction specialist or treatment center if warranted
- If you are not the primary care physician, always consult a patient's regular physician before initiating treatment with an opioid analgesic.
- Contact authorities if you are threatened in any way

Identifying patients with drug abuse problems will help you direct them to appropriate care. It also helps ensure that those with legitimate medical need for opioid medications will be able to obtain them.

DRUG TESTING

Urine is currently the most widely used and extensively validated biologic specimen for drug testing.[14] This information should serve as an overview of things you should look for or ask for with urine drug testing (UDT)

TWO MAIN TYPES[14]:

1. Immunoassays (laboratory-based or at point-of-care [POC])

- Generally detect classes of drugs
- Some are designed to detect a certain substance
- Classify substances as present or absent
- False-positive and -negative results can occur
  - — Cross-reaction can occur with structurally-similar or some unrelated drugs
  - — Opiate immunoassays may not reliably detect synthetic or semisynthetic opioid analgesics (such as methadone or oxycodone). The appropriate use of these assays requires an understanding of the sensitivity and specificity of the test with regard to a specific drug.

2. Laboratory-based specific drug identification (e.g., gas chromatography/mass spectrometry [GC/MS], high-performance liquid chromatography [HPLC])

- Identifies individual drugs and drug metabolites
  - — No cross-reaction
- A drug level may fall below a test's cutoff concentration
  - — Do not assume a negative result means no drug is present
  - — Consider asking for "no threshold" testing
- There is no consistent relationship between dose and urine concentration of a drug or its metabolites.

BEFORE ORDERING A TEST[14]

- Ask the patient:
  - — Are you taking any prescription, OTC, or herbal medications or products?
    - When was the last dose/use?
  - — Drug abuse history
- Let the laboratory know:
  - — Medications that the patient is taking
  - — What you are looking for:
    - Illicit substance
    - Prescription drug use or misuse

PRACTICAL STRATEGIES[14]

- Select testing laboratory or POC device supplier
- Select routine UDT panel for commonly abused drugs:
  - — Recommended immunoassay screens[14] are:
    - Cocaine
    - Amphetamines (including ecstasy)
    - Opiates
    - Methadone
    - Marijuana
    - Benzodiazepines
  - — Additional drug tests, as needed
    - Drug identification:
  - — GC/MS or HPLC for all the patients prescribed opioids
    - Specify "no threshold" to increase likelihood of detecting prescribed medications
- Specimen collection:
  - — Random collection preferred
  - — Unobserved specimen collection usually acceptable
  - — Temperature testing should be routine, regardless of method of assay. Creatinine concentration and specific gravity should be routinely determined when specimens are sent to a laboratory.

DRUG TESTING (CONT'D)

- UDT results:
  - — Anticipate what you will do with results
  - — A positive UDT result reflects recent drug use
  - — Use a negative result for prescribed medication to initiate a dialogue with patient to preserve therapeutic alliance
    - Schedule appointment to discuss abnormal or unexpected results with patient
    - Use results to strengthen doctor-patient relationship and support positive behavior change
  - — Document results and interpretation
  - — Understand what you are looking for
    - UDT may detect other opioids that were not prescribed. These may have been taken by the patient or may be metabolites of the drug(s) prescribed (e.g., codeine is partially metabolized to morphine; hydrocodone may be partially metabolized to hydromorphone; morphine may be partially metabolized to hydromorphone; oxycodone is partially metabolized to oxymorphone).

ADDITIONAL TESTING METHODS[14]

Factors influencing the type of drug test to choose are ease of specimen collection, analytical/testing considerations, and interpretation of results. These tests are new, and there are limitations (eg, false-positive/false-negative results, interferences, and cross-reactivity).

Method	Pros	Cons
Saliva	Ease of sample collection Minimal personal invasiveness Limited preanalytical manipulation	Drugs and metabolites generally retained for shorter period and at lower concentrations than in urine
Hair	Retrospective, long-term measure of drug use directly related to hair length	Dark hair has greater capacity to bind drug than fair/gray hair (bias) Irregular growth Labor-intensive sample preparation
Sweat	Noninvasive, cumulative measure of drug use over days/weeks Most appropriate in monitoring drug use in chemical dependency or probation programs	Varying sweat production Risk of accidentally removing or contaminating collection device
Blood	More accurate determination of drug concentrations provided by quantitative analysis	Not amenable to rapid screening Not recommended for routine testing

- More complete information on urine drug testing can be downloaded from the California Academy of Family Physicians public Web site:

http://www.familydocs.org/files/UDTmonograph.pdf

RESOURCES

The following resources can provide important information on prescription pain medications, their identification, their appropriate use, and drug abuse and diversion.

- The American Pain Society (APS): www.ampainsoc.org
- American Academy of Pain Medicine (AAPM): www.painmed.org
- The American Society of Addiction Medicine (ASAM): www.asam.org
- Pain and Policy Studies Group of the University of Wisconsin Carbone Cancer Center: www.painpolicy.wisc.edu
- Drug Enforcement Administration (DEA): www.deadiversion.usdoj.gov
- Food and Drug Administration (FDA): www.fda.gov
- Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov
- National Association of Drug Diversion Investigators (NADDI): www.NADDI.org
- Local law enforcement
- Local addiction treatment specialists/centers

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Responsible Opioid Prescribing

A PHYSICIAN'S GUIDE

Scott M. Fishman, MD

Federation of STATE MEDICAL BOARDS

Responsible Opioid Prescribing

A PHYSICIAN'S GUIDE

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A PHYSICIAN'S GUIDE

Scott M. Fishman, MD

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Federation of State Medical Boards

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by James N. Thompson, MD
President and CEO, Federation of State Medical Boards

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Author:
Scott M. Fishman, MD
Professor of Anesthesiology
Chief, Division of Pain Medicine
Department of Anesthesiology and Pain Medicine
University of California, Davis
Vice Chairman, American Pain Foundation
Past President, American Academy of Pain Medicine

Medical Writer: Stephen Braun

Associate Editors:
Perry G. Fine, MD
Professor of Anesthesiology
School of Medicine, Pain Research Center
University of Utah, Salt Lake City, UT
Vice President for Medical Affairs
National Hospice and Palliative Care Organization
Alexandria, VA

Rollin M. Gallagher, MD MPH
Clinical Professor of Psychiatry and Anesthesiology
Director, Center for Pain Medicine, Research and Policy
University of Pennsylvania School of Medicine
Director of Pain Management
Philadelphia VA Medical Center
Philadelphia, PA
Editor in Chief: PAIN MEDICINE, Journal of the
Am. Academy of Pain Medicine.

Aaron Gilson, Ph.D.
Co-Director
U.S. Policy Research Pain & Policy Studies Group/
World Health Organization Collaborating Center
University of Wisconsin-Madison
Madison, WI

Michael Moskowitz, MD, MPH
Assistant Professor of Anesthesiology and Pain Medicine
School of Medicine
University of California, Davis
Director, Bay Area Pain Medical Associates
Mill Valley, CA

Foreword

By James N. Thompson, MD
President and CEO, Federation of State Medical Boards

Hippocrates' seemingly straightforward directive to "First, do no harm" is anything but simple in today's medical practice. Nowhere is its complexity more evident, and vexing, than in pain management with controlled substances—particularly with opioids.

Patients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication; to deprive them of optimal pain-relief certainly does them harm. Yet these same life-restoring medications carry the potential to do grave harm to patients who may be at risk for addiction and abuse. Significant quantities of prescription opioids are diverted into an illegal black market that puts millions of non-medical "recreational" users at risk of addiction and death—many of them young adults and teenagers. Very few physicians are complicit in this criminal diversion, and there are no proven methods for preventing patients from deceptively acquiring prescriptions—pain, after all, is a subjective symptom for which there are no foolproof diagnostic tests. But the fact that some patients will deceive a physician in order to obtain prescription opioids for non-medical use requires us to be vigilant when prescribing these potent and potentially abusable medications.

Physicians cannot single-handedly eliminate the diversion and abuse of prescription opioids. *But we have a solemn responsibility—to our patients and to society—to be vigilant in reducing these risks.* Too few physicians have educated themselves about the simple steps they can take to become more responsible opioid prescribers.

Sadly, many physicians have sought to reduce the risks of opioid prescribing—including the tangible risk to a physician's own licensure if he or she prescribes outside the standards of medical care—by simply not treating patients in pain, or by not treating them with controlled substances. But as pain treatment becomes increasingly intertwined in the larger medical mission of patient care, it's increasingly important for physicians to become sophisticated about the risks and benefits of opioid therapy—the risks of diversion, abuse, and addiction as well as the benefits in managing acute and chronic pain.

Physicians who prescribe opioids are obliged to comply with both state regulations and the federal Controlled Substances Act. In 2005, there were approximately 720,290 Medical Doctors (MDs) and Doctors of Osteopathic Medicine (DOs) registered with the Drug Enforcement Administration (DEA). All physicians should be familiar with the clinical practices that will help them comply with state and federal statutes.

The Federation of State Medical Boards (FSMB) has commissioned this book and is distributing it to physicians to offer clear and concise guidance in managing the risks of pain management with opioids. Incorporating these strategies into your practice will help you fulfill your dual responsibilities to your patients and to your state and federal licensing authorities.

This book grows out an initiative launched a decade ago by the FSMB to create its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* These consensus guidelines were formulated with input from the major stakeholders on all sides of the issue, including leading pain and addiction specialists, medical societies, state medical boards, and federal law enforcement agencies including the DEA. These guidelines, which were subsequently updated to a *Model Policy* in 2004, have been praised as "well balanced" by such groups as the Pain and Policy Study Group of the University of Wisconsin.* Twenty-eight state medical boards have adopted the Guidelines or *Model Policy* verbatim as their state guidelines, and ten other states have adopted guidelines with similar language.

The FSMB's *Model Policy* distills safe opioid prescribing into seven concise principles:

1. Evaluation of the Patient
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Consultation
6. Medical Records
7. Compliance With Controlled Substances Laws and Regulations

Although the *Model Policy* represents the most concise consensus guidelines for safe opioid prescribing, until now this document has not been translated into practical terms for clinical practice. Consequently, few physicians are

** For more information see www.medsch.wisc.edu/painpolicy.*

familiar with these guidelines, and even fewer utilize them in their practice.

This book answers that unmet physician need by explaining how to incorporate the *Model Policy* into your real-life practice. Its author, Scott M. Fishman, MD, is Past President of the American Academy of Pain Medicine and a true thought leader in academic medicine, clinical practice, and public health policy. Dr. Fishman has worked closely with the FSMB on establishing the current *Model Policy* and has been a champion for safe and effective prescribing for pain management.

After reading this book, you'll understand simple steps you can take to comply with state and federal regulations regarding controlled substance prescribing for pain. FSMB's website (www.fsmb.org/pain) will keep this book updated and offers valuable links to state-by-state regulations and other useful websites to help facilitate pharmacovigilant opioid prescribing in your practice.

The term "pharmacovigilance" is one Hippocrates would surely have grasped. It derives from the Greek *pharmakon*, "drug;" and the Latin *vigilare*, "to keep awake and alert, to keep watch." In modern parlance, it refers to watchfully monitoring and managing the risks of adverse events and side effects of any medication, regardless of the class of drug. Becoming a pharmacovigilant opioid prescriber requires that we understand the risks specific to opioid analgesics and take simple steps to manage them.

Armed with the information in this essential handbook, we can each reaffirm our commitment to "First, do no harm."

Introduction: Pharmacovigilance and Good Medicine

Over the past decade, two important public health trends have become entwined like the twin serpents in the caduceus: (1) increasing clinical attention across all medical specialties to the undertreatment of pain, and (2) shifting patterns of drug abuse from illicit to prescription drugs—most notably a dramatic rise in diversion and non-medical use of opioid pain medications within the United States. The collision between the War on Pain and the War on Drugs has created a "perfect storm" of controversy. And, for better or worse, physicians are being enlisted to fight on both fronts: combating pain while simultaneously reducing the risk of diversion and abuse of, as well as addiction to, pain medications.

Many of us bristle at adding "pharmacovigilance" and "risk management" to our already lengthy task list. But the combination of potential therapeutic benefit and high risk associated with opioid* analgesics leave us no alternative but to become more sophisticated risk managers. Millions

** The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl among others. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids, it is not the mechanism that produces pain relief.*

of legitimate patients rely on these medications for pain relief and functional improvement, so we must include them in our repertoire of potential medication therapies. However, we cannot ignore the potential risks associated with the use of controlled substances, including addiction.

Managing risk is what we physicians do every day with every patient, whether we're considering procedures, medications, or non-medication interventions. Every treatment plan carries potential risks, as does the decision not to treat. Managing risks associated with opioids is fundamentally the same as pharmacovigilance concerning adverse reactions to any class of drugs: essentially following sound principles of medical practice and prescribing and achieving transparency in treatment decisions. The difference with opioids is that these drugs are increasingly diverted or otherwise abused.

Scope of the Problem

A statistical snapshot of prescription drug abuse and diversion in the United States reveals the scope of this alarming public health crisis:

- In 2005 (the latest year for which data are available), more than 10 million Americans were abusing prescription drugs—which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants.
- The Centers for Disease Control and Prevention report that prescription opioids are now associated with more drug overdose deaths than cocaine and heroin combined: between 1999 and 2002, there was a 91.2 percent increase in the reporting of opioid analgesics on death certificates.[1]

- Continuing a decade's long trend, in 2005 more new drug users began abusing pain relievers (2.2 million) than marijuana (2.1 million) or cocaine (872,000). By comparison, in 1990 only an estimated 628,000 people initiated illicit use of pain killers.[2]
- Data from a set of selected states show that almost 13,000 incidents of prescription controlled substances were diverted by theft from 2000 to 2003. In 2003 alone, 2 million dosages of six opioid analgesics were reported stolen from the supply chain, mainly from retail pharmacies.[3]

Behind these figures lie millions of individual stories of personal tragedy: untimely death, fractured families, shattered dreams, and wasted lives. Certainly the same spectrum of ills can be found in the wake of any abused drug, but the magnitude of the current problem makes it imperative that physicians become vigilant risk managers who demonstrate transparency in the decisions behind the care they deliver.

Much remains to be learned about the nature of prescription drug abuse in the United States. For example, the exact contribution of prescribers to prescription drug diversion and abuse is not presently known. Because the rise of prescription drug abuse has occurred alongside increased use of opioids in legitimate pain relief, it is tempting to assume cause and effect. However, preliminary evidence does not support this conclusion and more information about how prescription drugs are diverted is crucially needed. If we are to have responsible and effective responses to prescription drug abuse, the problem must be

considered in its full context. To avoid penalizing those with legitimate needs, solutions must factor in the full complexity of drug abuse, addiction and all of the related social and medical disorders. In particular, we must be careful with implications that prescription drug abuse is mostly related to prescribers and their patients, and be careful with implying that limiting medically appropriate use may have significant effects on reversing this disturbing trend.

A Countervailing Need

Concurrent with the epidemic of prescription drug abuse, patients and patient advocates have been pushing to address the equally legitimate cause of undertreated pain. Although these efforts began in the relatively circumscribed spheres of end-of-life care and cancer-related pain, medicine has appropriately widened its perspective to include all debilitating pain that has lost its purpose as an adaptive alarm signal, regardless of the source.

Significant effort has been made to reduce the incidence of untreated or undertreated pain in children, older patients, and in all other vulnerable patient populations. And at least at the level of clinical guidelines, policy statements, and organizational goals, the following general principles are widely accepted:

- Pain management is integral to good medical practice for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;

- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient;
- The use of opioids for other than legitimate medical purposes poses a threat to the individual and society; and
- Physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances.

If opioids had no medically redeeming value, the issue of their abuse would be tragic but physicians would have no role to play in minimizing abuse by changing their behaviors or monitoring their actions. The current need for guidance on opioid prescribing arises from the fact that, as addictive and life-destroying as opioids can be for some, they are life-enhancing and non-addictive for others.

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. Misunderstanding of addiction and dependence; and
4. Lack of understanding of regulatory policies and processes.

To these factors might be added a fifth: the lack of clearly written government regulations and professional guidelines for prescribing, or assistance with how to easily and efficiently incorporate these approaches into the hectic daily practice of physicians.

Filling an Unmet Need

This book is intended to help the responsible clinician understand and implement practices that support rational and transparent opioid prescribing. The following chapters examine each of the seven steps in the FSMB's *Model Policy*:

1. Patient Evaluation
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Referral and Patient Management
6. Documentation
7. Compliance With Controlled Substance Laws and Regulations

Each of these steps, which are only briefly described in the *Model Policy*, are here given an expanded discussion from the perspective of real-world clinical practice. Most physicians already perform many of the key steps recommended in the *Model Policy*. This book focuses on explanations and techniques that specifically address the issues that arise when prescribing opioids. Sometimes this simply means adhering to existing standards of care. At other times—such as in the creation of function-based treatment plans—a significant paradigm shift in perspective will be presented that translates into novel models for creating, monitoring, and modifying treatment goals for your patients in pain.

Prescription drug abuse and undertreated pain are both serious public health crises, but the solution to one need not undermine the other. The least we clinicians can do is make sure that the casualties of this clash are not suffering

patients who legitimately deserve relief. Informed clinicians can take simple steps to ensure that opioids are prescribed safely and transparently—and in the process, those prescribers can justify their decisions should they encounter the scrutiny of regulators.

Regulators and law enforcement agencies, such as the Drug Enforcement Administration, have urged prescribers to be vigilant when prescribing abusable drugs, particularly for patients with known or suspected risk of abuse. Clearly, effective solutions must address the current state of inadequate education that most clinicians receive on safe and effective prescribing of controlled substances. This book is intended as a much-needed step in that direction. Unfortunately, simply knowing the tenets of the FSMB *Model Policy* will not be of value without a basic knowledge of pain, substance abuse, and their treatment. Although this book will not serve this role, other resources are available, many of which are recommended in Appendix A. Moreover, this book will not substitute for maintaining the desire to relieve suffering or the recognition that an important part of mitigating pain is simply being present with your patients and showing them that you care. Although the elements of care described here are critically important for maintaining appropriate delivery of controlled substances, unless you also incorporate the personal part of care, your patients will continue to feel alone and uncared for—and may even resist treatment.

As a physician who specializes in Pain Medicine, I'm optimistic about the future of pain treatment. The confusions and frustrations that currently characterize pain management may simply be the growing pains of a wiser, saner,

and more uniformly effective patient care approach. Appropriate concerns about the potentially harmful or addictive aspects of opioid medications can be balanced with the equally valid needs of optimal pain relief with adequate risk management. Medicine is all about managing risk while improving health and easing suffering; the safe and effective use of opioids is no different. Opioids are ancient drugs that have been both glorified and demonized in past centuries. It is time we found ways to harness their very real gifts while curbing their very real dangers.

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Chapter 1: Effective Patient Evaluation

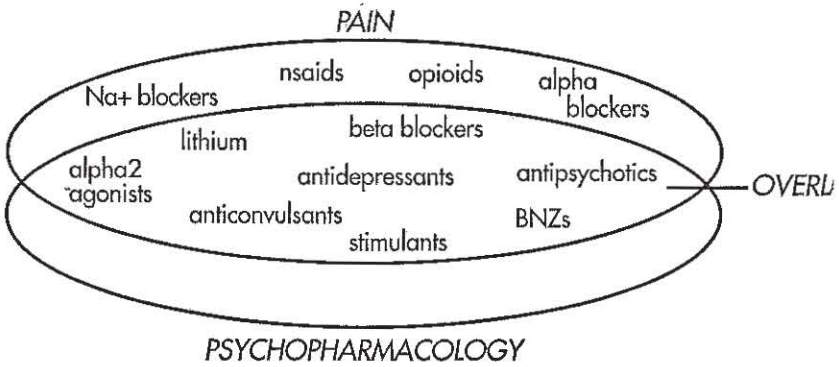
"A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance."
—*FSMB Model Policy*

At the core of the requirement to evaluate patients thoroughly is a paradox: although a physician can take a history, do a physical examination, list past treatments, probe for a history of substance abuse, and note coexisting diseases, he or she cannot measure or even confirm the pain that a patient is experiencing. Despite modern diagnostic and evaluative tools, such as MRI, ultrasonography, and electromyography, pain remains an untestable hypothesis. Perhaps one reason that physicians are reluctant to aggressively treat pain has to do with the often frustrating fact that we can't prove that someone is or is not in pain, just as we can't prove the presence or absence of pain relief. However real pain is to a patient, it remains subjective to

the physician. As Elaine Scarry notes in her book *The Body in Pain*: "To hear about pain is to have doubt; to experience pain is to have certainty." In the end, physicians must accept the maxim "Pain is what a patient says it is." Anyone complaining of pain is suffering from something; the physician's job is to try to figure out the cause of the suffering and to formulate a plan for reducing it.

Today it is widely recognized that pain is never simply "physical" or "psychological." The mind is *always* involved in a patient's experience of pain, and it can magnify or diminish pain perception. The almost complete overlap between the medication groups used by both psychiatrists and pain specialists attests to the inextricable links between mind and body that make meaningless the cliché phrase "the pain is all in your head." (See the graphic below.)

The Overlap of Major Drug Groups Used in Pain Medicine and Psychiatry



Pain measurement scales, such as the familiar 0 to 10 numerical pain scale or the "faces" pain rating scale, can provide some degree of guidance about a patient's experience of pain intensity, but all are open to wide variations among subjects experiencing similar problems, and within a subject at different times. Multidimensional instruments, such as the McGill Pain Questionnaire or the Brief Pain Inventory, provide a broader picture of a patient's experience, but are usually more cumbersome to administer in a busy clinic setting and, in the end, suffer the same limitations as all other attempts to measure pain.

The best way to begin assessing a patient's pain is to ask about it and listen. This may sound trivial, but, in the hurly-burly of daily clinical life, it is essential. All too often physicians become overly focused on quantifying, categorizing, and deciding how best to treat pain as a single symptom. In the process, they may not ask pertinent questions that relate to their patients' global experience of suffering, and they ultimately distance themselves from their patients. In focusing narrowly on a disease or symptom, physicians can lose the "big picture" of the whole person and thus miss important diagnostic clues that could lead to more effective interventions.

Three relatively simple steps can vastly improve taking a history from a patient in pain:

- Take control of time;
- Focus on the patient, not the pain; and
- Use reflective listening skills.

These steps can reconnect the clinician with the patient, improve the efficacy of analgesic treatments, and increase personal satisfaction.

Step 1: Take Control of Time

In some ways, this suggestion may be largely outside our control. Physicians are increasingly pressured to see more and more patients. The average patient in pain, particularly those in chronic pain, typically has a complex presentation and histories. Clinicians must be relentlessly thorough, looking under every "rock" for clues. And being a clinical professional means we withhold judgment until we have ample evidence. This is an unavoidably time-consuming process. Thus, a patient in pain is almost automatically a "difficult case."

Unfortunately, these challenges can lead clinicians in exactly the wrong direction. Instead of allotting increased time and patience to the diagnostic task, physicians confronted with "difficult" patients may *speed up* and, either consciously or unconsciously, rush to judgment in an effort to minimize time spent with an emotionally sensitive, demanding, or frustrated patient. Full adherence to the Evaluation component of the FSMB *Model Policy*, in other words, requires a commitment to spending enough time and attention to what the patient is saying both verbally and through behaviors.

Step 2: Focus on the Patient, Not the Pain

In taking a history about pain, physicians should ask questions not only about the pain itself (its location, intensity, duration, etc.), but also about the pain's collateral damage to the patient's life. To use a musical metaphor, you need to listen not just to the lyrics (the self-evident parts of what the patient says), but to the music as well (the less obvious verbal and nonverbal messages about their feelings, fears, expectations, goals, etc.). Clinicians need to be alert to subtle warning signs of trouble and take the time to ask follow-up questions.

Pain is usually interwoven with unpleasant experiences, such as fatigue, nausea, depression, and anxiety, among others. These are absolutely vital connections for a diagnostician—if you miss them, you'll miss understanding the true dimensions of a patient's pain and possibly some of the most useful avenues for alleviating his or her suffering. For example, depression can dramatically alter pain perception—almost always for the worse. Patients may not offer unprompted information about their depression out of fear that the physician will think their pain is "all in their head." If you don't ask direct questions related to mood, or pick up on the subtle signs from the patient's answers that suggest psychosocial deterioration, you may not recognize this significant factor in the experience of pain. Similarly, many other aspects of a person's life can affect his or her pain, such as the use or abuse of licit or illicit drugs, high stress levels at work or home, or physical deconditioning because of a lack of activity.

Step 3: Use Reflective Listening Skills

Patients in chronic pain are frequently more emotional than they might be otherwise. Pain undermines our ability to cope with the ups and downs of normal life. Pain can make any of us defensive, short-tempered, or even hostile. Not only are these patients experiencing pain but, by the time they see you, they may have undergone previous treatments that either were ineffective or exacerbated their symptoms. In some cases, the tension may be

palpable and, in others, it may simply be suppressed. It must be emphasized that above all, the patient in pain wants and needs to be believed and validated. In a sense, then, treatment actually begins during the process of assessment.

An effective strategy for collecting a comprehensive history and building a successful patient-physician relationship is *reflective listening*. This means listening carefully and non-judgmentally to what your patient is saying, then reflecting it back in a slightly modified or reframed manner. Aside from allowing the clinician to confirm the accuracy of their beliefs, this gives the patients both the indication that they are being heard and a chance to correct mistaken beliefs or perceptions that could affect their care.

Using a reflective listening strategy may be easier said than done. If a patient says something at odds with the evidence, or uses threatening or hostile language, one's natural reaction is to immediately defend oneself, rebut the charges, or deny the underlying assumptions. This can quickly create confrontation or a power struggle that can be difficult to overcome. It is much more effective to take a moment before responding, and then to consciously try to simply restate what the patient just said. For example, a patient may angrily say "Doctor, those pills you gave me don't work—I told you before that I need something stronger." Even in cases where you suspect the patient may be angling for stronger and possibly riskier medications for spurious reasons, a directly confrontational approach would probably be ineffective. A better response might be something like "You seem to be irritated with me because you don't think the medications I

prescribed are working for you." Reflective listening responses such as this provide several advantages:

- They are less likely to evoke or exacerbate patient defensiveness;
- They encourage the patient to keep talking and reveal more about his or her true motives;
- They communicate respect, caring, and compassion, and encourage a therapeutic alliance; and
- They open an opportunity for the patient to correct misunderstandings or clarify exactly what he or she means.

Although reflective listening can be particularly helpful when a patient is emotional, it is a useful approach for following up on or probing answers to questions that you ask during any patient encounter.

Elements of a Comprehensive History

Comprehensive evaluation of a patient in pain usually requires moving beyond the typical list of questions asked during a general history. In most cases where pain is the chief complaint, it is certainly appropriate to begin a conversation by asking about the pain, but then it is usually advantageous to move on to the broader context and impact of that pain. Here are some points that may be useful to cover in an initial evaluation:

- Location of pain
- Character of pain (i.e., shooting or stinging, continuous or intermittent, worse at night or in the morning)
- Lowest and highest pain on 0 to 10 scale in a typical day
- Usual pain on 0 to 10 scale on a typical day (anchored by verbal descriptors)
- How and when pain started

- Exacerbating and relieving factors (i.e., stress, alcohol, other medical concerns)
- Effect of pain on sleep
- Effect of pain on mood
- Effect of pain on functioning at work
- Effect of pain on quality of personal life, such as relationships, sex, or recreation
- Is the patient involved in a legal or protracted insurance process connected to his or her chronic pain, such as a motor vehicle accident or disability case?
- What does the patient expect from medications or other treatments in terms of analgesia or recovered function?

In the course of your conversations with patients, be alert to signs that they are minimizing their pain. Although it may seem counterintuitive, some patients fail to convey the true nature and severity of their pain, which can, albeit unintentionally, undermine the effectiveness of their treatment. They may not want to disappoint their physicians or offer a distraction from treating their primary disease; they may think they should just "suck it up" and endure their pain; they may think pain is inevitable with their illness; or they may want to avoid acknowledging that their disease is progressing. Some may worry that if they mention their pain, their doctor will see them as complainers or even as drug-seekers or addicts. Many people also under-report pain because they fear that pain medications will dull their cognitive abilities, lead to addiction, or result in unmanageable side effects. And last, some patients may believe that there is value in suffering, it is their due, or that in some way they deserve to be in pain to expiate some form of "wrong-doing" or "sinfulness."

If you suspect a patient is minimizing his or her pain, reflective listening can help the patient see what you see and allow you to probe for the reasons underlying the minimizing. At some point, you might scratch your head and say "I wonder if you are the silent sufferer type?" Very few are offended by being described as "stoic," which is usually considered something of a compliment to many patients. Being seen as someone who is doing his or her part to bear the suffering is usually consoling. Regardless of the reasons for minimizing, this approach can help you take a history by allowing patients to feel that they will not be judged negatively and can speak freely and candidly about their pain.

Screening Patients for the Possibility of Addiction or Drug Abuse

All patients complaining of pain are suffering from something and deserve a physician's empathy and compassion. But a small minority of people seeking treatment may not be reliable or trustworthy. The problem for the clinician at the front line of medicine is not that such patients are bad people who are committing sins; it is that the help that such patients are asking for will not remedy their problem and may be harmful to themselves and others. This approach evokes the professional responsibility to first do no harm. It is based solely on risk management that requires you to maintain constant vigilance without impulsively rushing to judgment. This is not unusual for physicians. For instance, there is an old adage that if you don't suspect a pulmonary embolism, you'll never catch one. The same level of suspicion (without judgment)

applies to the assessment of the patient in pain. If you do not suspect the pain may be caused by a nerve injury, you may never catch neuropathic pain. If you don't suspect the possibility that someone who asks for an opioid by its brand name might have a problem with drug abuse, you may miss a valuable opportunity to help the patient.

On the other hand, allowing suspicions to foster judgmental conclusions may be equally harmful to the patient and society. A physician must, therefore, maintain a discreet but keen vigilance for potential harm from any treatment. In the case of treatments that include controlled substances, this must include the potential for deception and abuse.

Although it may sound contradictory to exhort physicians to be empathic and supportive while simultaneously probing aggressively in search of the truth (including information that the patient may not want to reveal), this is not such a difficult balance to achieve in daily practice. You can maintain a tolerant, nonjudgmental, and concerned posture yet remain persistent in your quest for the valid information required for prudent decision making.

Whenever a clinician considers treating pain with a controlled substance, such as an opioid, risk of abuse or diversion is always a possibility, no matter how remote, and must be assessed. Exactly who to suspect and when to be proactive in investigating risk factors is an area of great debate. To date, no convincing data exist to support the strategy of focusing on any one specific population or setting—which means that physicians must be vigilant with all their patients. The term "universal precautions" has been applied to this approach and, in pain care, assumes

that any patient in pain could have a drug abuse problem—just as any patient requiring a blood draw for a simple lab test could have HIV. Gourlay and Heit (2006) argue that "since there is no one behavior that is [diagnostic] of a substance use disorder, and since the prevalence of addiction in the general population is not insignificant, it is prudent to thoroughly inquire into substance use in all patients, not only those who are being treated with the opioid class of drugs. Failure to do so may leave a potentially treatable condition, such as addiction, undiagnosed and untreated."[1]

Treating everyone with the same screens, diagnostic tests, and administrative procedures can be viewed from one angle as an attempt to remove bias and essentially level the playing field so everyone is treated equally and screened thoroughly. It also could be perceived as undermining the patient-physician relationship. Despite defensible efforts to be as consistent as possible to all, as well as to cast the broadest possible surveillance, some patients or clinicians may see the universal precautions approach as a sign of distrust or evidence that the patient is being presumed guilty until proven innocent. Dealing with this may require clear education for patients as to why such procedures and practices are necessary and in their best interest.

For the actual assessment of a patient's risk of having a substance abuse problem, several tools have been developed but, to date, no single tool has been widely endorsed or thoroughly validated. CAGE is a classic rapid screen developed for alcohol abuse that can easily be modified for any abusable drug. This brief questionnaire (which can be

incorporated into a self-administered written assessment form) asks whether a patient has ever:

C: Wanted or needed to Cut down on drinking or drug use?

A: Been Annoyed or Angered by others complaining about the patient's drinking or drug use?

G: Felt Guilty about the consequences of the patient's drinking or drug use?

E: Taken a drink in the morning as an "Eye opener" to decrease hangover or withdrawal?

A single positive response suggests that the clinical decision to prescribe opioids to the patient must be considered in relation to a potential for abuse and addiction. It does not mean that opioid use will become problematic or that opioids are contraindicated, just that you should carefully determine if the therapeutic benefits of prescribing an abusable drug is in the patient's best interest. If you deem a controlled substance is appropriate, you must exercise particular care in crafting your patient-physician agreement (whether verbal or written) and your risk management plan for monitoring and follow-up.

Many other tools exist to help screen for addiction or abuse and are listed in Appendix A. However, no one tool will be entirely reliable and the astute clinician will recognize that the signs of abuse or addiction may not be readily or immediately apparent in the typical clinical setting. If suspicion is raised for a given patient, information about previous problems with substance abuse may be obtained from a collateral source, such as a family member, friend, or other health care professional. Treatment is not required to commence until the physician is comfortable with the integrity of the situation. Understanding the signs and

symptoms of abuse or addiction will help guide questions. Feeling rushed to make a prescribing decision may in itself reflect a clinical problem (not related to the issue of abuse or addiction) that is worthy of review and discussion with the patient.

Necessity of a Comprehensive Physical Examination

Although Medicare and other institutions have defined what constitutes a physical examination for purposes of coding and reimbursement, exactly what comprises an appropriate or acceptable physical examination for pain is not well-defined, largely because it will differ from case to case. Regulators who expect to see a physical examination as part of the evaluation that leads to appropriate pain care involving controlled substances assume that a basic, if not focused, examination is warranted. The exact components of the examination are left to the judgment of the clinician who is expected to have performed an examination proportionate to the diagnosis that justifies a treatment.

For instance, it might be expected that a patient treated with opioids for chronic low back pain will have at least received a basic examination of the lumbar spine. Such an examination might reveal pathology that could be amenable to other treatments, perhaps some with less risk. Even if the physical exam does not offer clues in the case of some pain disorders, this cannot be confirmed until an examination is completed. Unless due diligence is evident with a documented physical examination, a physician's decision to begin a treatment that carries risk may be questioned.

Exceptions

It's not always possible to obtain a thorough history or evaluation for a patient. In the emergency department, the operating room, at night or on weekends, a physician or surgeon may not always be able to verify the patient's history and past medical treatment. In such circumstances, physicians must balance the need for vigilance about potential addiction or diversion with the need to treat the patient's pain. As with most treatment decisions, an approach based on risk versus benefit must determine the appropriate response. Physicians are commonly faced with risks associated with treating as well as with withholding treatment. Too often, it is impossible to know which risks are more likely and the clinician must choose to either avoid suffering and treat, accepting the potential risk for abuse or choose to prevent potential abuse and not treat, accepting the risk that the patient might suffer unnecessarily. Such decisions must be based on the long-term impact of the treatment, its duration, and the potential for diagnosing an adverse outcome were it to occur. For example, it would be acceptable practice in the case of a complaint of pain in the ER to prescribe small amounts of an opioid analgesic that would get the patient through to the following day until a clinician with a longitudinal relationship with the patient is available to follow up. The potential harm from undertreated pain, weighed against the limited potential harm of a few opioid pills, may support this determination.

Assessing Risk and Benefit

Physicians must routinely balance the potential risks and benefits of any treatment plan. But in the face of the complexity of pain, as well as the specter of scrutiny from healthcare regulators and law enforcement, it's easy to become paralyzed and decide that the least risky course is to not treat the pain aggressively or at all. But doing nothing can be the riskiest decision of all. For example, consider the case of a 76-year-old woman who comes into an emergency room with rib fractures. Adequately treating her pain is not just a matter of relieving her immediate physical problem: inadequate lung inflation and efforts to suppress coughing because of pain increase her risk of pneumonia and death. While most cases aren't this clear or dramatic, ongoing pain erodes quality of life and slowly deconditions a person's physical, emotional, and spiritual well-being. Both directly (via inappropriate activation of stress-related hormones) and indirectly (by inducing inactivity, insomnia, anxiety, or depression), pain compromises the body's defenses and leaves sufferers vulnerable. Uncontrolled chronic pain also undermines the management of any pre-existing chronic condition, such as diabetes, cardiovascular disease, and psychiatric conditions such as anxiety or depressive disorders. Chronic pain in combination with depression increases the risk of suicide.

Looking at the complete landscape of pain and its collateral damage, it is clear that the decision whether or not to treat pain offers physicians no risk-free option. If the risk to the patient associated with a given treatment outweighs the risk of withholding that treatment, then other less risky treatments must be considered. Although physicians should not feel compelled to use any treatment modality (including opioid analgesics), the risk of non-treatment must always be factored into any pain management

decision; not treating pain is often not a "safe" option. This may seem obvious, but physicians face patients in pain each day and choose what they perceive as the lesser of evils: less treatment as a means to avoid "risk."

Another risk posed by nontreatment or undertreatment of pain affects the physician, but not the patient directly. Physicians have been successfully sued for not treating pain aggressively. For example, the 2001 *Bergman vs. Eden Medical Center* case involved a physician who was found guilty of "elder abuse" arising from alleged under-prescribing of pain medication. This jury brought a $1.5 million verdict against this physician, and the jury was a single vote away from levying fines for much higher damages. This case led the California legislature to pass a law requiring the Medical Board to publicly declare its policies on how it investigates physicians in pain cases and requiring all California physicians to have mandatory continuing medical education on pain and end-of-life care. A more recent California case, in which a physician was accused of elder abuse for under-treating pain, was settled just prior to the start of the trial for an undisclosed sum. In this case, the Medical Board formally and publicly sanctioned the physician for undertreatment of pain. Even though such cases represent rather extreme situations, these legal precedents sound a warning that there are risks associated with under-treating.

This does not imply, however, that all patients must be treated aggressively with opioids or any specific treatment. It simply means that all patients complaining of pain deserve adequate assessment and treatment based on consideration of risks and benefits to the patient. When transparent documentation provides the rationale for treatment decisions, physicians should feel comfortable that they have done their best to provide appropriate patient care while meeting their fiduciary obligations as "officers of the public health."

Summary

This chapter has reviewed the key elements of effective patient evaluation. Despite modern diagnostic and evaluative tools, pain remains an untestable hypothesis. Nonetheless, the evaluation and history taking of patients in pain can be improved by: taking control of your time; focusing on the patient, not the pain; and using reflective listening skills. Be alert to any signs that a patient may be minimizing his or her pain. And when considering use of a controlled substance in pain treatment, take a substance abuse history, and as in any therapeutic intervention, pay close attention to the risk management plan. In doing so, the risks involved in not treating must always be factored into any pain management decision; not treating pain is often not a "safe" option.

References

1. Gourlay, D., and H. Heit. Universal precautions: a matter of mutual trust and responsibility. *Pain Medicine*, Mar.-Apr. 2006, 7(2):210-211, author reply 212.

Chapter 2: Creating a Treatment Plan

"The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment."
—*FSMB Model Policy*

Because measuring pain is fundamentally an untestable hypothesis, the use of subjective reports of pain relief as the sole outcome of treatment will be difficult to measure objectively. Indeed, the very notion and practice of "pain relief" often contains a hidden assumption: that it's possible and desirable to "relieve" pain completely. Everyone lives at certain times with varying degrees of physical and/or emotional pain or discomfort. People also differ significantly in their pain tolerance and have individual thresholds at which pain impairs function. The rare cases of people with a congenital inability to feel pain demonstrates (usually tragically) the profound disadvantages of a life with "zero pain."

Ironically, the traditional 0 to 10 pain scale used so often in clinical care perpetuates this misconception: that the ideal or attainable condition is "zero pain." It's a small step from this subtle assumption for doctors (and their patients) to assume that the goal of pain treatment is the *elimination* of pain. This chapter will review some of the pitfalls of this approach. Even the primary goal of pain *reduction* may miss an essential point: the direct sensation associated with pain is not the only important variable associated with a patients complaint of pain and may not be the most important feature of the overall presentation. A critically important part of understanding pain, as a means of formulating an effective treatment plan, is to look beyond the pain sensations themselves to how those sensations are affecting and possibly eroding a patient's quality of life. Specifically, how is pain affecting the patient's functioning in daily life?

From Analgesia to Functioning: A Necessary Paradigm Shift

Since pain impacts all domains of a patients' life, complete evaluation of pain involves looking into the *effects* that these noxious signals are having on physical and psychosocial functioning. This knowledge is critically important for creating the solid treatment decisions and management plan envisioned in the *Model Policy*. Shifting from analgesia alone (or uni-dimensional pain intensity scores) to a function-based paradigm offers the following tangible advantages:

- Treatment goals become more objective and verifiable (not relying on subjective reports alone);
- Individual differences among patients, both in terms of pain tolerance and functional goals, are respected;
- An individualized evidence base is created for making appropriate risk/benefit decisions on pain treatment options; and
- Prescribing decisions (including decisions to wean a patient from a drug regimen) are tied to multidimensional outcomes, many of which may be objectively demonstrable to the clinicians and the patient.

Most important, a function-based treatment strategy offers the promise of increasing your patients' quality of life and subsequently decreasing the burden of their pain. Under normal circumstances, pain is an alarm that warns us of impending or actual harm. It is designed to grab our attention, and when pain is severe enough, to make it impossible to attend to anything else. Thus, when the alarm itself is injured or malfunctioning, pain does not turn off normally and the constant drain on attention undermines the affected individual's ability to attend to the other aspects of his or her life—often aspects that make life worth living. Chronic pain intrinsically diminishes one's capacity to function and subsequently erodes the basic elements of daily life, such as physical activity, concentration, emotional stability, interpersonal relationships, and sleep. This can, in turn, degrade role function, such as at work or home, leading to depression, anxiety, and insomnia, among other comorbidities. While significant pain worsens function, relieving pain should reverse that effect and improve function. Simply "feeling better," without improving functioning in some aspect of an individual's life, may reflect an inadequate outcome. The most successful chronic pain management includes regaining collateral losses associated with that pain.

This is a paradigm shift for many physicians, most of whom have been trained to focus almost exclusively on pain sensation and intensity—believing that the sole outcome is to reduce or eliminate a patient's intensity rating. But reducing a patient's pain score from, say, 9 to 3 is only one piece of a much larger puzzle. Particularly when treating chronic conditions for indefinite periods, it is not enough that patients say they "feel better." Depending only on such a purely subjective outcome can easily lead a physician to overlook evidence that a medication is ineffective or is producing side effects that may be reducing the patient's quality of life. In some cases, pain relief may occur without significant functional gains but on more thorough assessment, function may be found to have deteriorated. The possible reasons for this are many, including side effects, use of analgesic medications for secondary purposes such as sleep or anxiety rather than pain, or even frank abuse or addiction. Even if a medication is effective for a certain symptom, its side effects may present risks that outweigh benefits. A broad perspective and a comprehensive history are required in order to assimilate the salient facts that inform more carefully reasoned treatment decisions. Reliance solely on patient self-reporting also, of course, makes it easier for patients to deceive clinicians and themselves about their treatment outcomes, including when problems relate to drug abuse.

Setting Functional Goals

Evaluating treatment effectiveness by linking pain relief to functional gain makes many physicians uneasy. It is understandably difficult to subjugate a patient's positive subjective report of improvements in pain intensity to objective evidence that functional gains have or have not been achieved—or, worse, that actual harm is taking place. But analogous situations are frequently encountered in other realms of medicine. For example, if a diabetic also has problems with chronic vasculitis, corticosteroids may effectively ease some of his or her symptoms. But corticosteroids, amongst other risks, worsen glucose control with serious consequences in a diabetic. Diabetic patients who would argue that they should be chronically maintained on corticosteroids because it is the only way they feel well challenges the physician who must make a rational clinical decision in the context of the severe toxicity of chronic corticosteroids in diabetes. No reputable physician would normally accommodate such a request except under highly select circumstances (e.g., end-of-life care where comfort is the principle goal of treatment). Most would clearly recognize that the risks outweigh the benefits. The physician is forced to say, "I'm sorry, but I can't give you this medication even though it makes you feel better because it's going to harm you in the long run." A patient who continues using an opioid medication, but whose quality of life is either unchanged or actually worsens, may well be in the same boat—and our response as physicians must be the same: "This treatment is not working well because . . . We can do better so let's find a more effective way to both control your pain and improve the quality of your day-to-day life (or help you become more functional)."

As illustrated by the case example below, some patients may report large changes in their pain score even as their quality of life erodes.

Contrast this case with the patient who reports that her pain dropped from 8 to 6 but is no longer bed bound, is

Case Study

Mike was a 38-year-old construction worker with lumbar disc injury. After laminectomy and fusion surgery, the expected bone regrowth didn't occur and the fusion surgery was repeated. This fusion appeared to work, but his pain continued. Several nerve block procedures failed to bring relief.

After several housebound months, Mike sought help at a nearby pain center. He lacked energy, slept through each night in his reclining lounge chair, and was often irritable and short-tempered with his wife and children. He complained that the hydrocodone he was prescribed wasn't working anymore. His wife reported that Mike had used various drugs in the past and currently used both alcohol and cannabis.

His physician negotiated a realistic function-based treatment plan for Mike. His initial goals were to sleep in his bed again, attend a function at his son's elementary school, enroll in a pain education class, and begin a program of gentle but long term physical therapy. Four weeks later Mike had titrated up his opioid dose as prescribed. "The medication is really working doc," Mike said. "My pain's gone from an 8 to a 2 most of the time."

But under questioning it became clear that Mike had not actually made progress. He was still sleeping in the lounge chair. He missed the school science fair. He had only seen the physical therapist once. He also wasn't sleeping well . . . even though he felt sleepy most of the time.

The physician realized that the sedation he was experiencing was interfering with his progress toward functional goals.

After considerable patient education and negotiation, Mike agreed to taper off the opioid and try a new regimen of a non-amphetamine stimulant in the morning and a sedating medication for the evening. This normalized his sleep/wake cycles and left him with more energy during the day. He used non-opioid analgesics for his pain.

Four weeks later, Mike had attended five meetings of a chronic pain support group, and several sessions with a pain psychologist who taught him skills for coping, distraction, and relaxation. His wife reported that he had been regularly attending physical therapy. Twelve weeks later Mike looked relaxed and alert. His pain was not gone; he said it varied from about a 3 to a 5 (out of 10) from day to day. But he said he could live with that. He was moving around, making slow but steady progress in physical therapy, and becoming socially active. He was benefiting from a positive feedback loop: a relatively minor reduction in his pain led to improvements in function. This, in turn, further reduced the importance of pain in his life, which further increased his function.

able to bathe herself again, and is starting to engage in small amounts of exercise. Clearly this is an example where the patient with the greater reduction in pain score should be viewed as a treatment failure and the patient with the more modest pain score reduction is a treatment success. A 20-percent reduction in a pain score (i.e., two points on the standard pain scale) may not seem significant, but it is a perfectly acceptable goal when it produces significant benefits for a patient, as illustrated in the chart below.

Activities Impaired by *Increasing* Pain Severity*

					Relate
				Walk	Walk
			Sleep	Sleep	Sleep
		Active	Active	Active	Active
		Mood	Mood	Mood	Mood
	Work	Work	Work	Work	Work
Enjoy	Enjoy	Enjoy	Enjoy	Enjoy	Enjoy
3	4	5	6	7	8

>>>>>>>>>>>> **Worst Pain Rating** >>>>>>>>>>>>

* Assessed in cancer pain patients

Source: Cleeland, C.S., and K.M. Ryan, *Ann. Acad. Med. Singapore*, 1994,23:129-138.

The illustration reflects the typical 0 to 10 pain scale as it impacts function at scores ranging from 3 to 8. It clearly shows how function is progressively impaired as the pain rating increases, and conversely, how seemingly modest reductions in pain can translate into dramatic functional improvements as pain ratings are reduced. A patient told that a specific treatment will reduce his or her pain by 20

percent may be unimpressed by this goal. In some cases of chronic pain, the spiraling loss of function may be a paramount concern, and halting a pattern of progressive loss of function and other losses related to pain may become a functional goal in itself.

A single pain score may be important to patients as they may have learned through other medical experiences that it is important to their clinicians as a quantitative yardstick with which to effectively communicate with their health care providers. But pain is so subjective that a single value on a single visit may have much less utility than pain scores used to help monitor changes over time. If the treatment outcome is framed, instead, in terms of the reclaimed function through a few-point reduction on the pain scale, they may be much more likely to see this as a major positive outcome and commit to this treatment goal. Reductions in pain scores are nonetheless important and must be honored and incorporated. Subjective pain relief is valuable and desirable. However it is a potential problem when subjective pain relief is used in isolation and as a sole determinant of treatment outcomes for a chronic condition. In chronic pain management, it is often best used as part of the primary treatment outcome with the overarching goal of functional improvement.

Function and Controlled Substances

Switching to a function-based paradigm for creating treatment plans has particular value in the area of controlled substances, because function offers a useful way to differentiate a patient who is truly addicted from one who has a similar appearance but is not. This differentiation is

grounded on the fact that addiction (as well as pain) leads to dysfunction while pain relief should improve function. When given adequate pain relief, persons in chronic pain can gain or maintain function in their lives. Addiction, on the other hand, involves drug use that causes dysfunction in one or more spheres of a person's life. Addicts have a disease that impairs their ability to control or modulate their use of a drug despite the dysfunction and harm that it incurs. In the setting of active addiction, function does *not* improve with exposure to the drug. Although many cases where analgesic trials do not lead to functional improvement are caused by something other than addiction or abuse, the lack of functional improvement always indicates a problem with the treatment or some other facet of the patient's life that deserves attention. At the very least, in cases where analgesic trials do not lead to functional improvement, re-evaluation should occur, utilizing a differential diagnosis that considers substance misuse, diversion, abuse, or addiction.

A lack of function or dysfunction that is manifest in a treatment program may turn out to have its roots in function-limiting side effects, such as sedation, or may be caused by untreated affective disorders that are commonly associated with chronic pain. However, sometimes the manifestation of dysfunction will represent addiction, diversion, or abuse, a distinction that may be difficult to make without objective measures. Putting functional goals at the heart of a treatment plan, in other words, can shed valuable light on the sometimes confusing presentations of patients in pain. (The subject of addiction versus pseudoaddiction is covered in more detail in Chapter 4.)

As mentioned in the previous chapter, the phrase "universal precautions" has been borrowed from the field of infectious diseases. The term refers to a standardized approach to the assessment and ongoing management of *all* patients with pain. Just as it is impossible to predict if patients (or their body fluids) will harbor an infectious agent, it's impossible to predict with any degree of certainty which patients in pain will abuse prescription medications. Using standardized assessments and approaches for *all* patients, such as written agreements, random drug screening, or screening instruments for risk of abuse, makes it possible to offer a broader safety net that avoids potential disparities in care, helps meet requirements for informed consent, improves patient education and participation, and minimizes overall risk. If logistical or financial constraints limit the ability to pursue this broad strategy, an alternative is to apply randomized screening only on high risk patients or patients exhibiting aberrant behavior. However, since we are not adept at determining who is and is not at risk for opioid abuse, such approaches have risk for stigmatizing patients and potentially creating disparities in care.

Getting Started

You don't need expensive interventions or high-tech diagnostics to embark on a function-based treatment plan. All you need is a pen, paper, and the information you've gleaned from a basic conversation with your patient. The functional goals of a treatment plan must be achievable and realistic. Progress is usually slow and gains are made one step at a time. In the case of chronic illness marked by

longstanding deconditioning, recovery requires reconditioning that may take weeks or months. Patients should be educated about this need for reconditioning and it must be stressed that the process is a marathon, not a sprint. Experience shows that if a patient can achieve one goal, his or her motivation and attitude improve, making the next goal that much easier to achieve. As with other life pursuits, "The key to success is success."

Here, for example, is how a set of functional goals could be set up for "Mike," the construction worker featured in the case study earlier in this chapter. Although Mike was focused exclusively on his pain and need for relief, the larger goal for any physician (after sufficient medical evaluation for a treatable lesion) should be to find a strategy that would improve his activity level, restore his self-esteem, and rebuild his quality of life. Often the best place to start is with a simple yet important question: "What is it that you're going to do on this medicine (or treatment) that you can't do now?" Sometimes patients won't know how to answer at first because they are unused to thinking in terms of functional goals. They might say, "I don't know . . . I just want to feel better, that's all."

As just explained, this is an understandable response, but it does not help to develop a set of realistic functional goals and some "hard" measures by which to evaluate outcomes. For example, upon further questioning Mike might want to sleep in his bed again instead of the reclining chair, attend a function at his son's elementary school, attend a pain education class, and begin a program of gentle but long-term physical therapy. He might agree to bring records from his class and physical therapy sessions and

have his wife confirm his progress in the other areas. Both physician and patient would now have the start of a road map by which to measure progress, and the physician would have evidence on which to base treatment decisions.

This approach also lays the foundation for making decisions about changing the course of, or even terminating treatment in cases where goals are not met, adverse effects outweigh benefits, or in rare cases where a person is knowingly deceiving a physician to procure opioids for illicit purposes. For persons who intend to abuse drugs that are being prescribed to them, participating in a program with expectations for objective functional outcomes will present a sizeable barrier. Many such individuals may seek care elsewhere rather than undertake the effort of participating in a functional outcomes charade.

Components of an Effective Treatment Plan

A function-based treatment paradigm offers both the clinician and patient many benefits that can liberate a treatment course from the often murky terrain of chronic pain management. As you integrate this approach into your practice, keep these principles in mind:

- Elimination of all pain (i.e., "zero" pain) is usually neither possible nor desirable;
- A patient's pain score is just one of many variables related to overall status and potential for recovery;
- Treatment goals should not be set *primarily* in the form of changes in pain scores;
- Seemingly insignificant pain-score reductions may actually be extremely significant in terms of reclaimed function;

- Functional goals must be set collaboratively between patient and doctor, be realistic and achievable, be meaningful to the patient, and be verifiable;
- Functional goals must be revisited and recalibrated at regular intervals by both doctor and patient; and
- Because patient values and the functions they desire in life vary, each patient will have a unique set of functional treatment endpoints.

Although using functional outcomes may add some work to the start of a treatment plan, it will pay dividends over time. As noted above, a functional plan need not be onerous, complex, or elusive. On the contrary, a commonsense and individualized approach should result from asking simple questions, respecting the patient's values, and targeting goals of importance to the patient, starting with the most attainable and progressing over time to greater challenges. Goals must be periodically followed up and outcomes assessed, using the results to determine the direction of future care. At some point, patients may plateau at a certain level of function and each clinician, in consultation with the patient, will have to use their clinical judgment to determine whether this is acceptable or changes are needed. Even after a plateau has been reached in which stable medications are offset by stable function at an acceptable level, ongoing periodic review with follow-up functional assessments are necessary to be able to detect any decline or improvements that may occur over time.

Summary

Chapter 2 explored how to create effective treatment plans for patients in pain. In formulating a plan, targeting direct

sensations associated with pain are not the only important feature to focus on. Complete evaluation and planning means looking beyond the pain signals to the effects that those signals have on physical and psychosocial functioning. Optimal outcomes include "feeling better," but are best objectified with improved functioning in some or multiple aspects of an individual's life. Switching to a function-based paradigm offers a useful way to differentiate a patient who is succeeding with an analgesic treatment from someone who is not and may even be abusing, diverting, or addicted. Attention should be paid to even small reductions in the pain score, since they may be extremely significant in terms of reclaimed function. Sustained success will require that functional goals are revisited and recalibrated at regular intervals by both doctor and patient.

Chapter 3: Informed Consent and Agreements

"The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including: urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement)."
—*FSMB Model Policy*

Like all treatments, effectively treating pain requires a plan that will often hinge on a careful bilateral negotiation with the patient. In medicine, any treatment plan should constitute an implied agreement between a physician and a patient. Formalizing a treatment plan by putting it in writing can serve many helpful purposes, not least of which is obtaining and documenting informed consent. (The general subject of documentation will be covered more thoroughly in Chapter 6.) A written patient-physician

agreement can serve to achieve a complete and uniform process, as well as help deal with any potential curves or bumps that may occur along the road. Such an agreement, often termed a patient care contract, can cover many different facets of care ranging from risk/benefit assessment and informed consent to administrative policies or any other educational issues that the clinician believes should be emphasized. Written agreements can also improve the coordination of care among a team of healthcare providers when they all are required to sign the agreement. (The articles in the suggested reading at the end of this chapter provide more details about these approaches.)

Any written agreement should document all the major points you have covered and agreed upon with the patient. Some pain-management centers use an agreement or contract with all patients as part of their standard practice, because selective use of these tools can be perceived as potentially reflecting prejudicial bias. Some programs apply these agreements or contracts with all patients who chronically receive any opioid-containing medication, and some have even proposed generalizing the practice to include a written agreement with all analgesic treatments. A clearly-written understanding of the agreed-upon treatment regimen helps to enlist patient adherence, even in regimens that do not include opioids. Although opioid prescribing may include more risk-management and monitoring obligations than non-opioid analgesic regimens, any treatment regimen carries varying degrees of benefit versus risk. Regardless of whether or not a physician is prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent agreement process.

It is worth noting that the term "agreement" is perceived by some to be more acceptable to patients than "contract"—though from a legal standpoint, any written or oral agreement between a doctor and a patient may be considered a "contract" and both parties should treat them as such. Be sure that the terms in any agreements you use are understood by your patients, acceptable, attainable, and consistent with your practice.

Components of an Effective Agreement

Crafting these agreements may add some up-front time to patient care but provides a number of advantages that will benefit any patient and any treatment regimen. Written agreements:

- Engage the patient in a collaborative decision-making process;
- Assist in framing expected outcomes with specific functional goals and clarify the patient's role and responsibility in attaining these goals;
- Serve as motivational reminders to the patient (and his or her caregivers) of the specific goals agreed upon with the physician;
- Serve as informed consent forms for a variety of treatment approaches. (Be sure to obtain expert advice as to what constitutes informed consent, and adequate documentation thereof, in the jurisdiction(s) in which you practice.);
- Help avoid misunderstandings or distortions of understanding over time;
- Provide a foundation for later decision-making about changes in medications if functional goals are not

achieved, or even termination of treatment if problems arise (such as aberrant behaviors that cannot be otherwise managed—see pages 61-64); and

- Potentially enhance the therapeutic relationship between patient and doctor by enabling clear communication and expectations.

Although examples of standard informed consent agreements for opioid treatment are available at professional society websites such as the American Academy of Pain Medicine (www.painmed.org), many variations of treatment agreements are possible and they can be tailored for specific types of treatment. (Some sample agreements are available through links provided at www.fsmb.org/pain.) They can offer fixed language or include "open" areas to be filled in with specific and unique aspects of the patient's treatment plan. For example, a list of functional goals can be generated within an agreement (written in by hand or typed into a computer-based form and printed out for signing). Clinicians may want to consider adding any of the following common elements to their treatment agreements:

- Education about the risks and benefits of the agreed-upon treatment;
- Clarification of goals for treatment decisions;
- Statements relating to expectations around individualized goals and agreed-upon processes for documenting progress;
- Need for the patient to inform the treating physician of relevant information (i.e., side effects, use of other medications, changes in condition);
- Statement of time frame for which the agreement is in effect;

- Requirements for including or communicating with additional healthcare providers involved (e.g., primary care physician, pharmacist, psychologist, physical therapist, etc.);
- Who receives the agreement, where the agreement is kept, etc.;
- Statement of patient privacy rights;
- Administrative policies and expectations (e.g., missed appointment, follow-up, appearing without appointment, single pharmacy requirements, expectations of how emergencies will be handled, etc.); and
- Specific terms for administrative or other termination (e.g., abusing medication, missed appointments, violating agreement, inappropriate behavior, no improvement, pregnancy, tolerance, toxicity, etc.).

Treatments involving controlled substances may be well served by including the following additional elements:

- Patient responsibilities on improper use of controlled substances (e.g., overdosing, seeking medication elsewhere, selling medication, stopping medication abruptly);
- Limits on replacing lost medication or changing prescriptions;
- Limits on drug refills (e.g., phone allowances, mailing or faxing policy, normal office hours, etc.);
- Agreement to comply with random drug screens;
- Education on side effects (including tolerance and withdrawal);
- Education on addiction risks and behaviors;
- Pharmacy issues (e.g., one pharmacy, in-state pharmacy);

- Additional risks (e.g., interactions with other drugs, masking conditions, driving safety, misusing, pregnancy);
- Legal considerations (if applicable because of state laws);
- Need for single prescriber for all opioid prescriptions; and
- Terms regarding specific medication (e.g., type prescribed: long-acting, generic brands, etc.).

Effective Communication

In addition to including all relevant aspects of a proposed treatment in a written agreement, physicians should discuss the risks and benefits of the use of any controlled substances with the patient (or with the patient's surrogate or guardian if the patient is without medical decision-making capacity). Patients must be given the opportunity to ask questions, and physicians should "check in" with patients to ensure they understand what they are being told. A treatment that is simply handed to a patient without his or her input, or which is hastily explained with the potential to be misunderstood by a patient, will not suffice. Reviewing the consent form and not treating it as a mere formality to be buried in the chart transforms this from a perfunctory document with the sole purpose of protecting the physician's practice to a living cornerstone of understanding about the agreed upon course of care that may assist in treatment success.

Since any beneficial treatment always carries some risk, and more aggressive treatments usually carry greater risk, sharing these concerns and decisions about risk is critically important. The patients, after all, will ultimately take on the work of treatment adherence, tolerating possible side

effects and the challenges of achieving functional improvement. Moreover, they will bear the consequences of any adverse outcomes. A paternalistic approach, where the physician is the sole decision-maker, may result in half-hearted patient acceptance without investment or full commitment to the treatment. If expected outcomes are not achieved, the head of this treatment regimen—the physician—will then be responsible. Although it may be considered noble for the clinician to shoulder the responsibility, it is usually not in the best interest of the patient. The incentive for success must be with a patient who clearly understands that treatment success or failure necessitates his or her participation and investment. Although the physician has ultimate responsibility for the treatment plan, he or she may be well served to take the position of the expert advisor and consultant. The patient is best served by being put in the role of chief executive officer of his or her treatment regimen.

Effective communication and patient education are integral parts of "best practices" from both an ethical and legal standpoint. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly "informed" as required by both law and the ethical guidelines for medical practice. Inadequate communication on the part of a physician and the failure to educate the patient about the treatment regimen, in other words, can have serious consequences.

Summary

Key elements of informed consent and agreements were reviewed in this chapter.

In medicine, almost any treatment plan constitutes an implied agreement between a physician and a patient. Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent written agreement. Be sure that the terms in any agreements you use are completely acceptable, attainable, and consistent with your practice. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly "informed" as required by both law and the ethical guidelines of medical practice. You can create treatment agreements that help meet informed consent requirements using templates that are available online or by tailoring one from the specifics of your practice.

Suggested Readings

1. Fishman, S.M., T. Bandman, A. Edwards, and D. Borsook. The Opioid Contract in the Management of Patients on Chronic Opioid Therapies. *J. Pain and Symptom Management*, 1999, 18(1):27-37.

2. Fishman, S.M., G. Mahajan, S.W. Jung, and B. Wilsey. Bridging the Pain Clinic and the Primary Care Physician through the Opioid Contract. *J. Pain and Symptom Management*, 2002, 24(3):254-262.

Chapter 4: Periodic Review

"The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities."
—*FSMB Model Policy*

Periodic review refers to follow-up after initiating a treatment plan. The tests performed, questions asked, and evaluations made are tailored to the patient and guided by the physician's clinical judgment. For example, a physical examination may or may not be required at each follow-up visit. (Check with your medical licensing board—some states may require a physical examination at each visit).

When controlled substances are involved, physicians must attend to predetermined treatment outcomes and be alert to a wide range of potential adverse effects. These include the common physical adverse effects of opioids such as sedation, constipation, urinary hesitancy, dry mouth, nausea/vomiting, itching, sweating, and hypogonadism, as well as more subtle behavioral effects such as mood changes, signs of drug craving or seeking, or impaired function in spheres of daily living.

Monitoring a patient's progress toward a set of functional goals (as opposed to simply asking if he or she "feels better") requires a means of measuring the progress (or lack thereof). This neither means that physicians have to become private investigators, nor that significantly more work is required as long as the goals and means of verification are clearly set up from the beginning. The key is to work with patients to create a set of realistic treatment goals and a means of charting progress towards these goals. The major responsibility of attaining those goals and presenting the evidence lies with the *patient.*

As discussed in previous chapters, patients in chronic pain suffer collateral losses that are manifested through lost function and decreased quality of life. Reviewing a patient's functional losses and desired gains is an essential part of determining an initial treatment plan and is critical to establishing useful measures for progress on return visits. Functional goals should not be extravagant or difficult to detect, but they should span as many domains of a person's life as possible: personal and social relationships, work, physical activities, hobbies, and spiritual activities. On the next page are examples of some simple functional

Functional Goal	Evidence
Begin physical therapy	Letter from physical therapist
Sleeping in bed as opposed to lounge chair	Report by family member or friend (either in-person or in writing)
Participation in pain support group	Letter from group leader
Increased activities of daily living	Report by family member or friend
Walk around the block	Pedometer recordings or written log of activity
Increased social activities	Report by family member or friend
Resumed sexual relations	Report by partner
Returned to work	Pay stubs from employer or letter confirming the patient is off of disability leave
Daily exercise	Gym attendance records or report from family member or friend

goals and ways they might be verified during periodic review.

When validation requires a report from a spouse, partner, family member, or friend, it may be useful, if the patient is willing, to have that person accompany the patient to follow-up visits. Of course, no validation scheme is 100-percent foolproof—if somebody really wants to fool a physician, he or she will find a way. But experience suggests that dysfunctional or even deceptive patients reveal themselves at some point—and repeated

requests for the kind of evidence just mentioned forces this unmasking earlier in the course of treatment. Such patients rarely are able to keep up a charade of documenting functional improvement, particularly if their general level of function is decreasing. If patients are looking for easy access to an abusable prescription drug, they may well simply go elsewhere when they see a function-based approach or when asked for evidence of progress.

But the purpose of validating treatment goals is not simply to detect abuse of prescription drugs—though it can certainly help. The real purpose of putting "teeth" into a functional goal agreement is to motivate patients to achieve their goals and to provide the physician with the information needed to determine if a given course of treatment is working or not.

The evidence you request will vary with the patient, and your clinical judgment will dictate what evidence will be necessary, for how long, and to what degree it will be needed. Remember that the patient is largely responsible for his or her therapeutic outcomes, and part of this responsibility is to provide you with evidence of his or her progress. Meeting this part of the "deal" is a functional outcome in and of itself. If a patient is unable to document or achieve the progress outlined in an agreement, this suggests a need to reassess and possibly make adjustments.

Reviewing Functional Goals

Although functional goal-setting is critically important at the outset of a treatment plan, it isn't a one-time event. Goal-setting is a process that evolves across the span of a long-term therapeutic treatment course. As is the case in

the treatment of so many other medical conditions, periodic review may mean that you and your patient collaboratively agree to continually move the functional goalposts. In these circumstances, the physician is akin to a sports coach. If a patient has achieved a goal or set of goals, you should recalibrate the goals to motivate the patient to reach the next level. For instance, if a patient, after three months of incremental improvement, has been able to return to swimming laps once a week, you might set a new goal of swimming three times a week. Conversely, if you've set an initial goal that is too ambitious, and the patient is becoming discouraged by the lack of progress, you can revise the goal downward or change it all together.

A common dilemma for physicians is a patient who resists engaging in physical activity toward functional goals because they report that any activity hurts too much. In such cases, rather than feeling forced to increase the dose of an opioid medication, physicians may wish to take a step back and re-evaluate the functional goals. All patients—even those with end-stage disease—can do some kind of physical motion at least some time during the day. It may appear to be so minimal that it doesn't "count" as an "activity," but it may nonetheless be a starting point for a functional goal—it all depends on how you define function. Patients with a chronic pain condition may initially need an exceedingly gentle but persistent exercise plan. This plan may need to specifically isolate and avoid using the most painful areas until some degree of physical conditioning has been established. Patients in chronic pain are not in a sprint—they are running a marathon that requires careful pacing and controlled, graduating exertion over sustained periods of time.

The patient who says that he or she can't exercise because of pain may simply be signaling that their exercise is starting at too intense a level or they are fearful of injury, increased pain, or even losing their identity as being "disabled." These myriad psychological barriers to initiating an upward cycle of improvement are beyond the therapeutic reach of prescription drugs or nerve blocks, reinforcing the importance of a team approach to integrated behavioral and rehabilitative pain management.

Almost all patients, however, can find some movement that does not cause pain. Finding that movement may not be easy, but it usually is possible. Doing that exercise for a while, and doing it repeatedly, can begin the conditioning process and allow for gradual increases in activity over time. Trying to do too much too soon will lead to failure, but this should never be an excuse for doing nothing.

Monitoring Adherence

Monitoring adherence to medication regimens is an imperfect science, but it remains an essential part of the overall process of periodic review. There are, at present, multiple ways to assess adherence but no single best approach exists. The simplest way is to just ask patients if they have been taking their medications as prescribed. Other methods include diaries, written agreements, tablet counts, and laboratory testing. Effective adherence monitoring usually involves combining several of these techniques.

Traditional methods of measuring adherence to medical therapies include tablet counts, diaries, and patient interviews. Such methods have a number of advantages as well

as drawbacks. Gross tablet counts are often unreliable because tablets may be discarded or possibly, in the case of opioids, hoarded, diverted, or sold, and offer no information about the pattern of medication use. In addition, containers can be lost or intentionally withheld. Patient diaries are questionable representations of reality, particularly when reflecting use of opioids or any other potentially abusable or psychoactive drug. They also may have the undesirable effect of keeping patients "tuned in" to their pain, rather than allowing them to "get on with their lives." Patient interviews are subject to favorable recall bias on the part of the patient, as well as forgetfulness, especially when the interval between drug use and interview exceeds two weeks.

Laboratory testing remains a popular part of assessing adherence to a treatment regimen involving controlled substances. However, such tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies, and interpreting laboratory data. Effective use of laboratory methodologies requires understanding many details of physiology, pharmacology, and toxicology, which are topics beyond the scope of this discussion. Laboratories vary in their testing thresholds and standards. Physicians must, therefore, understand these details before using the lab data with confidence.

Some labs, for example, only report values that are found to be above a certain preset threshold. Thus, a patient might have a measurable level of a drug, but since it does not exceed the given threshold, it is reported as a "negative" finding. This might lead the clinician to suspect that a prescribed drug, which should be present at the time of drug screening,

is absent because of diversion when, in fact, the drug is possibly being taken properly by the patient. A problem on the other end of the spectrum is when a patient wants to demonstrate compliance with a given medication by taking it only prior to a scheduled screen—a practice known as "white coat compliance."

The presence and level of drugs can be detected in serum, urine, hair, and saliva. For routine drug surveillance, urine screening is most commonly used even though such screens are seldom quantitative (i.e., they usually simply confirm the presence or absence of a drug). Serum determination offers quantitative data but may not be necessary in most clinical situations. Use of serum levels of opioid analgesics in clinical practice is rarely justified, based on the wide interpatient variation in minimum effective analgesic concentration, the possible development of tolerance to analgesic or other opioid effects, and the considerable intrapatient variability in relating pharmacokinetic data to pharmacodynamic effects. Many comprehensive laboratories are expanding their urine toxicology services and limiting serum analysis to special needs.

Urine is the standard and often exclusive specimen used in laboratory screening for routine drug surveillance of opioids or other controlled substances. Advantages of urine testing include relative ease of sample acquisition, availability of rapid, inexpensive, simple testing methods, and longer duration of a positive result compared to serum. Unfortunately, urine screening is not perfect. Testing of opioids in urine is generally of two types: a screening method and a confirmatory test. Specimens found to be negative by the screening method usually

require no further analysis. It is imperative to know the sensitivity and specificity of screening tests for controlled substances, as many point-of-care screens for "opiates" do not reliably detect any opioid other than codeine and morphine, or may not report if levels are below a certain threshold. Therefore, they may give false-negative results for semi-synthetic and synthetic opioid analgesics. Positive samples may be further studied by a confirmatory test.

Confirmatory studies are necessary when the consequences of a false-positive result are significant, or when identification of specific opioid agents is required, such as morphine and codeine, rather than a class-specific opiate-positive finding. In such cases, it is advisable to use a laboratory that complies with the Substance Abuse and Mental Health Services Administration (SAMHSA) standards and to use accepted chain of custody procedures for obtaining and handling specimens. (The SAMHSA standards are available at: www.workplace.samhsa.gov/)

Managing Non-Adherent Patients

Suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, *not* a summary rush to judgment. We all must acknowledge that in managing challenging cases and difficult patient-physician relationships, the problem is not always just with the patient. The way we interact with these patients will impact the relationship and influence treatment outcome. The difficult patient may raise a host of reactions in the clinician and recognizing these reactions is critically important to delivering the best possible care.

Be aware of the distinction between *pseudoaddiction* and addiction. Patients who are receiving an inadequate dose of opioid medication often "seek" more pain medications to obtain pain relief. This is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction. (Recall that addiction is when a person loses control over the use of a substance, uses it compulsively, and continues to use it despite harm and dysfunction.) Some common signs of pseudoaddiction resulting from inadequate analgesia are:

- Requesting analgesics by name,
- Demanding or manipulative behavior,
- Clock watching,
- Taking opioid drugs for an extended period,
- Obtaining opioid drugs from more than one physician, and
- Hoarding opioids.

Note that these same behavioral signs can indicate addiction. One way to discriminate between the two is to observe as closely as possible the functional consequences of opioid use. Whereas pseudoaddiction resolves when the patient obtains adequate analgesia, addictive behavior does not. Consultation with an addiction medicine specialist or psychiatrist may be necessary at the point when addiction becomes a concern. As always, high vigilance and tempered judgment are required with certain signs that may or may not indicate an abuse problem. (See the chart on the next page.)

It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence, such as those discussed above, should be considered before a judgment is

(Behaviors LESS indicative of addiction)	(Behaviors MORE indicative of addiction)
Express anxiety or desperation over recurrent symptoms	Bought pain medications from a street dealer
Hoard medications	Stole money to obtain drugs
Taken someone else's pain medications	Tried to get opioids from more than one source
Aggressively complained to doctor for more drugs	Performed sex for drugs
Requested a specific drug or medication	Seen two doctors at once without them knowing
Used more opioids than recommended	Performed sex for money to buy drugs
Drink more alcohol when in pain	Stole drugs from others
Express worry over changing to a new drug even if it offers potentially fewer side effects	Prostituted others for money to obtain drugs
Expressed concern to physician or family members that pain might lead to use of street drugs	Prostituted others for drugs
Asked for second opinion about pain medications	Prescription forgery
Smoke cigarettes to relieve pain	Sold prescription drugs
Ever used opioids to treat other symptoms	

Source: Passik, S.D., K.L. Kirsh, K.B. Donaghy, and R. Portenoy. Pain and Aberrant Drug-Related Behaviors in Medically Ill Patients With and Without Histories of Substance Abuse. *Clinical J. Pain*, 2006, 22(issue):173-181. (see p. 65, no. 1)

made. If for any reason a physician's suspicions are aroused, he or she has a duty and obligation to increase his or her vigilance through closer observation, increased testing, and greater involvement of consultants or other supportive clinicians. This approach is no different than for the management of any patient in whom you suspect toxicity from a drug therapy. Use of the type of patient–physician agreement detailed previously can guide such a process and may make implementation less confrontational or controversial.

Components of Effective Follow-Up

Progress toward treatment goals is seldom smooth. Reversals and patient frustration are common. Your goal is to help patients see the long view, support their efforts, and troubleshoot problems. Here are some tips for effective periodic review:

- Careful and compassionate listening;
- Attention to the entire patients, not just to their pain;
- Referral to related health professionals as needed to support a treatment plan (e.g., other medical specialists, mental health professionals, physical therapists, social workers, support group, etc.);
- Adjustments to pain medications if indicated and reasonable in the larger context of the patient's situation—linking continuation of these medications to evidence of reasonably improved function or stabilization at an acceptable level;
- Modifications, if needed, of functional goals. Goals can be scaled back if progress is lacking, or can be made more aggressive if progress is rapid;

- Revising the patient-physician agreement as needed to reflect changes in treatment regimen, functional goals, or other aspects of the patient's condition; and
- Complete documentation that offers transparent descriptions of the risks involved in the ongoing treatment plan, the risks of not taking such actions, and the ongoing risk management strategy.

Summary

This chapter examined the need for periodic review of treatment outcomes for patients in pain, particularly when controlled substances are involved. Physicians must closely attend to expected treatment outcomes and be alert to a wide range of potential adverse effects. Monitoring a patient's progress toward a set of functional goals requires a means of measuring the progress (or lack thereof). But the responsibility of attaining those goals and presenting the "hard data" may be best held with the patient. The purpose of validating treatment goals is not simply to detect abuse of prescription drugs, it is to motivate patients and help you determine if treatment is working or is problematic for any variety of reasons. Sometimes functional goalposts must be moved in order to maintain a patient's motivation. In the course of periodic review, suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, not a summary rush to judgment. It is easy to mistake pseudoaddiction for the real thing. One way to discriminate between pseudoaddiction and addiction is that pseudoaddiction resolves when the patient obtains adequate analgesia; addictive behavior does not.

Suggested Readings

1. Michna, E., R.N. Jamison, E.D. Pham, F.L. Ross, D. Janfaza, S.S. Nedeljkovic, S. Narang, D. Palombi, and A.D. Wasan. Urine toxicology screening among chronic pain patients on opioid therapy: frequency and predictability of abnormal findings. Clinical J. Pain, 2007, 23(2):173-179.

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4. Fishman, S.M., B. Wilsey, J. Yang, G.M. Reisfield, T.B. Bandman, and D. Borsook. Adherence monitoring and drug surveillance in chronic opioid therapy. J. Pain and Symptom Management, 2000, 20(4):293-307.

Chapter 5: Referral and Patient Management

"The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients."
–FSMB Model Policy

Patients in chronic pain can present an extremely complicated picture. As we've seen, the subjective nature of pain is difficult in and of itself, but the collateral impact of patients' pain may disrupt their work and personal lives. In addition, patients in pain may have comorbid physical or emotional conditions for which they may be taking multiple medications. This complexity can challenge even the most broadly trained physicians, and can lead them into diagnostic and treatment areas that lie outside their expertise and professional comfort.

The tradition of medical referral exists to address this reality. In caring for patients in pain, referral to specialists or sub-specialists is common—and, indeed, often

necessary—for the typical clinician. Very few of us can practice effectively without help on a regular basis from colleagues who offer more specialized skills, perspectives, and capabilities in certain areas than we possess. Recognizing our own clinical limitations is a vitally important facet of medical professionalism. Because chronic pain affects every sphere of a patient's life, physicians should expect that they will need to request help from colleagues with expertise in diverse disciplines, such as mental health, addiction, physical rehabilitation, or any other medical or surgical subspecialty.

Here are a few basic requirements for facilitating the referral process:

1. Don't delay.

Almost all medical conditions or problems are easier to tackle early in their development rather than later. This applies with particular gravity to the case of chronic pain treatment with controlled substances. Valuable time can be wasted if a physician stubbornly tries to solve all problems by him or her self.

2. Invest in the pre-referral process.

Try to obtain the basic information that a consultant will need to efficiently evaluate your patient. This may seem obvious, but sometimes obtaining the required medical records, prescription records, or lab results can be logistically complicated.

3. Be as specific as possible in your request.

The more vague the referral, the less useful the consultation. Tell your consultant exactly how he or she can help you and your patient, and then be transparent in your documentation about the reason for consultation

and how it may affect treatment decisions and patient management. In particular, always state directly what you hope to achieve by your referral.

4. Know your consultants.

Survey your most knowledgeable colleagues to develop (and keep updated) a list of potential consultants. Think "out of the box" about consultants (i.e., those outside your institution, at a university, or in private practice). Cultivate professional relationships with such consultants to facilitate input by phone, email, or in-person meetings.

5. Plan in advance.

When treating patients with opioids it is ideal to have both a "go-to" pain specialist and an addiction specialist available if consultation becomes necessary. Unfortunately, these two types of specialists are often in short supply, and many physicians struggle to find specialists to accept their referrals. An optimal level of care, when possible, would include consultants who can assist you with your patients and continue to give you guidance after most of the patients have been returned to you for chronic treatment. If it evolves that a patient is to receive ongoing care from a consultant, this understanding should be worked out between you and the consultant, so that the patient receives clear messages and clear treatment.

6. Expect your consultant to communicate with you.

This may seem fundamental to any consultation, but problems can arise when the consultant treats your patient without communicating the treatment plan with you or fails to keep you informed as treatment progresses. This is a two-way street, of course. You must be

available to discuss the plan and progress with the consultant, as well. Often this can be done with an exchange of notes, but more immediate contact by phone and email may be most expedient and preferable.

Referral for Patient Behavior Issues

One of the more common reasons a physician may need to seek help by referral is with patients who are difficult because of their behaviors. Primary care clinicians or specialists must both maintain an alliance with their patients and set boundaries within which good healthcare can proceed and harm can be avoided. When the relationship becomes strained by constant demands or other difficulties, it can be helpful to bring in a second party, such as a pain consultant, who can offer an objective perspective and who has not yet been influenced by the patient's mixed messages or inconsistent behavior. (Effective pain management consultants should offer strategies that preserve the self-esteem of both the patient and any staff involved. They should assiduously avoid pointing blame or embarrassing the patient, physician, or staff.)

Patients dealing with chronic pain can exhibit a range of behaviors that can challenge the most poised and professional clinician. Patients in pain may have many reasons to be angry, argumentative, mistrustful, anxious, and depressed. (Depression and anxiety disorders are two-to-three times more prevalent among patients in chronic pain than in the general population.) These patients may strongly disagree with the physician's assessment or treatment and can have idiosyncratic reactions to procedures, such as a severe provocation of pain in the absence of any procedural

complication. Even the most mild-mannered and polite person can become demanding and even obnoxious under the lash of constant pain, sleep deprivation, hassles associated with working through the maze of healthcare bureaucracy, and frustration with physical limitations that make even the simplest activities, such as tying one's shoes, a struggle. They can also display destructive behaviors, such as threats of suicide, self-mutilation, extreme noncompliance with treatment, and opioid misuse.

Aberrant patient behaviors do not exist in a vacuum, of course. Sometimes the physician can weaken the relationship as well. In the pressure-cooker of daily practice, it is all too easy to lose patience, compassion, warmth, and one's sense of humor. As a result, physicians can be perceived as arrogant, uncaring, unintelligible, or rushed. In any situation involving a patient's aberrant behavior, the source of the difficulty lies either with the patient, the physician, or (most often) in a combination of personality attributes embedded in a complex set of stressful circumstances.

Managing Difficult Patient-Physician Relationships

Although referral for difficult patient behaviors is legitimate and often desirable, it is also true that physicians can work to improve their own practices and learn ways to deal early with potentially difficult situations. Ideally, we try to act well before the patient-physician relationship has degenerated to the point where referral is a means to avoid the patient. Indeed, although aberrant patient behavior is certainly challenging, successfully dealing with such behaviors can be rewarding. Most difficult behaviors will be found, upon compassionate reflection, to be rooted in

patient fear, frustration, bias, anxiety, past trauma, or simply the corrosive effects of pain, fatigue, and stress. In many ways, the patients displaying the most severe behaviors are the ones most in need of a physician's help. Disliking a patient is never comfortable, but it's important that you not deny or avoid recognizing those feelings. Self-awareness can allow you to effectively isolate the potentially harmful reactions that accompany such personal dislike. Moreover, awareness can be the tool that allows you to retain the elements of care that make your practice viable and worthwhile.

Aberrant patient behaviors, such as manipulation, verbal abuse, or hostility, may promote clinical mistakes that would never be made in typical non-threatening interactions. The most classic mistake is for a physician faced with a difficult patient to rush an examination or treatment decision in a desire to get to the next case or to prompt the patient to move on to somebody else who will take responsibility for his or her care. This is like driving in a rain storm with slippery roads and, instead of slowing down, you speed up—thinking that the faster you go, the sooner you'll be out of the storm. This is obviously a formula for disaster, either in a car or in the clinic with a challenging patient.

The only universal rule in difficult situations is to SLOW DOWN! Listen and watch more purposefully than usual. Take your own pulse—ask yourself what you are feeling and why. Check your assumptions about the case and ask whether you are being pressured to do something without justification. Perhaps you need to add a follow-up visit or a consultation with another physician before jumping into therapeutic action. A common-sense solution is usually available if you take the time to find it.

Here are some practical rules of thumb for dealing with aberrant patient behaviors:

1. **Listen reflectively.** Listen to the patient in order to determine his or her understanding of the problem, disease, or expectations from treatment, including any religious or cultural factors that might be influencing his or her beliefs. Ask questions that confirm or correct your understanding or assumptions about the case.
2. **Assume a non-confrontational stance.** Dealing with a difficult patient can easily spiral into a battle of wills or wits that will solve nothing. Try to approach patients with the assumption that you are both on the same side. If a patient says or does things you disagree with or feel are groundless, pause and then reflect back what he or she just said rather than automatically rejecting, denying, dismissing, or contradicting. This takes practice and patience. If sometimes you "lose it" and find yourself stuck in a thicket of heated emotions, step back (literally, if necessary) and collect yourself. (Don't worry, this happens to everyone sooner or later.)
3. **Avoid paternalistic interactions.** Remember that patients are in charge of their own health decisions. Rather than assuming the role as key decision-maker or all-knowing sage, physicians can help themselves and their patients by framing their role as a partner or "medical consultant." This means that the patient can choose to accept or reject physician recommendations, stay with a physician, or see someone else. This shifts responsibility and the direction of information flow from the perceived

"omnipotent" physician dictator, who is telling the patient what to do, to the "strong advisor" physician who offers realistic solutions for the client to adopt.

4. **Include the patient in planning the treatment regimen.** The largest single determinant of the success of a treatment regimen may be a patient's ability and willingness to carry it out. Patients who participate in creating their treatment plan and who understand its underlying rationale may be much more likely to adhere to it than those who are merely told what to do.
5. **Focus on the big picture.** Patients understandably focus narrowly on their pain, illness, or incapacitation and their words or actions arise from that tunnel vision. Physicians can "pull back" to see not only the present situation, but the larger life context of the patient, antecedents that might be contributing to the problem, and the path from the present pain to a future function-based goal or outcome.
6. **Set limits for acceptable behavior.** No patients, regardless of the pain they may be in, have the right to insult, verbally abuse, threaten, or physically harm a healthcare worker. At the first instance of such behavior, you can set or reinforce clear limits. In such cases, firmly and clearly establish (1) that the behavior is unacceptable, and if repeated, you will remove yourself from their care until acceptable behavior is possible; and (2) that you will have to evaluate whether ongoing care within your practice is possible. You could also turn care over to another physician in such instances, since sometimes a different personality type may work better with certain patients. But such a transfer must always be based on the patient's best interest, with adequate transfer of records and information to assist in optimal care in the future.
7. **Maintain safety.** Keep firmly in mind that immediate safety is the first priority, and if patients threaten to harm themselves or others (including you), they may need to be physically restrained and assisted by either the police or psychiatric professionals. Maintain procedures within your office that promote easy exit from a room in which you might feel physically unsafe or develop strategies through which help can be immediately called for and received. Safety for patients, your staff, and yourself must be your highest priority. Determine in advance what rules and policies govern your institution or practice setting, and strictly adhere to any institutional policies or state laws in such cases. Educate all staff on policies and procedures, and practice your response to potential scenarios before they occur.

A specific type of difficult patient behavior that is more likely to crop up in the context of prescribing controlled substances is deception and distrust. Some patients lie, but only sometimes does a lie represent a real threat to the therapeutic relationship and the effectiveness of a treatment regimen. If you suspect a patient is lying and you feel the issue is important, you may want to deal with the issue directly. In doing this, it is again helpful to frame your role as that of a professional consultant, with the patient in charge of ultimate decision-making. Your role is not to judge or punish but to present facts and find solutions.

It can be difficult, but it is helpful to try to see lies as revealing important information about the patient. Many of us react to being lied to with offense and hurt feelings.

However, every clinician will probably be lied to from time to time. It's a "yellow light" signaling caution, and in and of itself, does not require rejection or termination. Your task is to try to find the truth without stigmatizing or harming the patient and without making yourself feel better at the expense of the patient.

Treatment Termination

Aberrant patient behaviors will occasionally require that the patient be dismissed from a practice. Physicians can, and should, have a "zero tolerance" policy for illegal behaviors (e.g., selling prescription medications, threatening violence, or forging physician signatures) or dangerous situations. Other circumstances can make "administrative termination" necessary, such as an opioid-addicted patient who refuses treatment for his or her addiction.

In such cases, abandonment must be avoided and the patient should be informed of the reasons he or she can no longer be treated by you. Such messages may occur during a face-to-face visit and followed up with a formal letter, and it may be advisable to include a witness, such as a nurse or medical assistant. In the absence of such a meeting, since face-to-face opportunities may simply be impossible, a certified letter can be used. You can specify the terms of separation (e.g., 30 days after receiving the letter, the patient will no longer be admitted to your practice). Exactly how to achieve the best result for the patient and yourself, however, will require individualization and possibly, consultation with a bioethics committee, a risk-management specialist, or an attorney.

All physicians are bound ethically not to abandon a patient in their care. Exactly how you fulfill this responsibility may also require professional consultation. In some states, there may be legal or regulatory requirements for termination of a patient-physician relationship. In many situations, you may give the patient names of other providers in his or her community or contact information for the local medical society, from which the patient can obtain a list of providers. Last, at discharge, you must consider how the patient will tolerate treatment discontinuation without harm, and, in cases involving such drugs as opioids, benzodiazepines, anticonvulsants, and antidepressants, and others, safe discontinuation may require a tapering schedule.

Summary

This chapter has discussed the common need to seek consultation from allied health professionals when dealing with patients in chronic pain. It has explored the related issue of managing the patient whose behavior has become difficult. We have seen that, although aberrant patient behavior can be difficult, it also can be potentially rewarding. Challenging behaviors usually arise from fear, frustration, poor pain control, or the corrosive effects of fatigue and stress. As such, the patients behaving "worst" are often the ones most in need of a physician's help. Working to expand self-awareness and cultivating a network of other professionals whom you can call for help can enable you to remain in control and retain the elements of care that make your practice effective for your patients and gratifying for you—even when confronted by the most difficult patients.

Chapter 6: Documentation

"The physician should keep accurate and complete records to include: the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review."
–*FSMB Model Policy*

Documentation is important in the management of any patient, and particularly so when opioids or other controlled substances are used as part of pain management. Not only is clear, consistent, and detailed documentation part of "best practices," it also is a necessity for reliable and legitimate assessment of the effectiveness of a longitudinal treatment regimen. Although documentation is valuable as a record of one's rationale for a particular treatment regimen and offers obvious benefits and protection for the treating clinician, the focus here is on creating and maintaining a solid record because it is in the patient's best interest.

Given the impossibility of remembering the details of all your patients, a written record may be the only way to keep track and to spot trends over time, whether they be

progress toward functional goals, severity of side effects, or subtle changes in patient demeanor or affect. In the event of a need to refer a patient to a specialist, careful documentation will enable optimal continuity of care.

Everybody wins when clinical behavior and decision making are as transparent as possible.

Transparent documentation is the part of the process where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient. This means that, not only has the basic care plan been documented, but the decision-making process and the rationale behind specific courses of treatment also have been adequately considered. Remember that both treating and not treating involve risks. Physicians cannot avoid managing risks. Considering the risks and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Everybody benefits when clinical behavior and decision making are as transparent as possible.

This means that not only has the basic care plan been documented, the decision-making process and the rationale behind specific courses of treatment also have been adequately communicated. Remaining focused on the risks being considered and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Remember that both treating and not treating involve risks—physicians cannot avoid being risk managers. Transparent documentation is the part of risk management where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient.

Many computerized systems are now available for the acquisition, storage, integration, and presentation of medical information. Most offer advantages that will benefit both patients and physicians, because, among many other advantages, records are kept up to date and information relevant to prescribing or treatment is instantly available. In the future, even more sophisticated information systems may become available that include customized and automated patient-education and patient-assessment tools. Such systems offer the promise of greatly improving practice efficiency and patient satisfaction.

Clear documentation, however, is not dependent on computerization or electronic record-keeping; it's dependent on a commitment to achieving clear and enduring communication in a systematic fashion. Paper and pen or the dictated word still can be sufficient.

Elements of Effective Documentation

As a broad guide, six basic elements of a patient's care should be documented in writing: (1) Assessment, (2) Treatment Agreements, (3) Education, (4) Action Plans, (5) Outcomes, and (6) Monitoring.

Each clinician has to use clinical judgment to determine how often each element of documentation is required to be repeated. Each of these should at least be part of initial evaluations and considered for updating on periodic review of the case. Regardless of the system used to document clinical decisions, detailed, readily available, and transparent documentation in the patient medical record must cover a broad range of areas, including the following: (However, assessing all areas is not required at every visit and depends on patient and treatment variables.)

- Medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;
- Records of periodic reviews of patient behaviors, side effects, and functional outcomes.
- Medications (including date, type, dosage, strength, and quantity prescribed);
- Pain intensity levels;
- Levels of functioning, and quality of life;
- Subjective complaints of the patient;
- Objective findings by the physician;
- Diagnostic impressions, and potential treatment options;
- Treatment objectives
- Other specific aspects of the treatment or treatment program;
- Discussion of risks and benefits;
- Informed consent;
- Instructions and agreements; and
- Plans for periodic review of patient behaviors, side effects, and functional outcomes.

Specifics of Documenting Controlled Substance Prescriptions

Each state has laws that govern the appropriate prescribing of controlled substances and prescribers are required to know and abide by these regulations. Each state's board of medicine (titled differently by each state) oversees the professional conduct of physicians, or more precisely, the conduct of physicians who are practicing within the bounds of medicine. As such, a medical board review of a physician's practice will focus on whether or not care is delivered within or outside the

standards of care. Demonstrating whether a practice is within the standard of care usually relies to a large degree on a physician's self-generated documentation of his or her work. It will be through this documentation that reviewers assess the level of awareness of risks involved in the delivery of care and the rationale for the choices that were made. In medical practice, there are often no absolutes on the exact treatment for every patient, and physician judgment is often the mitigating variable. Therefore, understanding the elements of the physician's judgment, which is best supported through transparent documentation, may be all that a medical board investigation has to go on to judge a physician's practice. Moreover, most medical boards will consider maintenance of adequate records of patient care as a requirement in and of itself.

Federal law also governs the appropriate prescribing of controlled substances and prescribers are also required to know and abide by these regulations. The authority to prescribe Schedule II-V drugs is granted by the Federal Government through the Drug Enforcement Administration (DEA.) The DEA, which resides within the Federal Department of Justice, describes a number of specific steps that practitioners must follow to document the use of controlled substances. These procedures may, or may not, correspond with state-specific standards. Each practitioner, therefore, must fully understand his or her state rules as well as follow the DEA requirements.

A revised DEA practitioner's manual was introduced in September 2006 and is available online at www.deadiversion.usdoj.gov. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA) and

the Code of Federal Regulations. Although all prescribers of controlled substances must know these federal requirements, a complete review is beyond the scope of this book. The Appendix includes links to relevant DEA websites, including the 2006 DEA Practitioner's Manual. Excerpts from that manual that relate to general aspects of prescribing controlled substances, including requirements for appropriate documentation, are posted on FSMB's website: www.fsmb.org/pain.

Accurate Coding

Nowhere are information systems more detailed and often idiosyncratic than in the area of communicating with payers for authorization and billing. Although learning the details of these requirements can be formidable, physicians who fail to adequately conform to a documentation system can compromise both the overall efficiency of the system and the care their patients receive. Documentation requirements and procedures may vary considerably across institutions, and across administrative or reimbursement systems within a single institution or practice.

Documentation for coding purposes is often compromised by providing inadequate specific information to accompany a code or assuming that the person reading the document (often a non-medically trained "coder") understands the implications of examination results or other details of the history or treatment plan. It has become an all-too-apparent reality that coders are limited in what they can code, and physicians must understand basic documentation requirements for coding. Coders are not allowed to "interpret" and must depend on the quality of the documentation in the medical record. For instance, if a physi-

cian writes that the patient has a hemoglobin of 5.0 in the medical record, the coder cannot interpret this as anemia, even if he or she knows enough to suspect this finding. In order to code it, the physician must specifically document anemia in the record—in this case example, there might also be a need for additional information such as other specifics around the type of anemia and its relationship to other comorbid diagnoses that may impact the accuracy of coding assignment. In general, physicians should document their suspicions to the highest degree known, yet another example of the benefits of transparency.

Proportionate Prescribing

At times, prescribers may feel inclined to assist their patients by prescribing more doses of a scheduled drug than the patient may need to manage an acute pain condition. This is particularly the case for schedule III medications such as hydrocodone or schedule II drugs such as oxycodone.

For example, a patient with an acute backache might be anticipated to need hydrocodone with acetaminophen several times over several days. In some cases, this might amount to a maximum of eight tablets per day over two to three days, perhaps for a maximum of five days. Pain lasting beyond this period might suggest that the patient should be re-evaluated. Although the total anticipated need would add up to a maximum of 40 tablets, physicians too commonly write a prescription for 90 to 150 tablets, perhaps with a few refills, innocently believing it is in the patient's interest to have more on hand if pain persists.

However, in the current environment where prescription opioids are increasingly diverted or abused—sometimes

from households where medicine cabinets with leftover medication are accessible to children, teenagers, and others—vigilance is required more than ever. This includes tailoring the amount of a scheduled drug to a reasonable assessment of how much you think your patient will need.

Some physicians may consider a schedule III drug such as hydrocodone to be relatively safe, unaware that hydrocodone is the most prescribed medication in the United States[1] and is widely sought after and diverted for nonmedical purposes. Regulators recognize that medical judgment is not a science but is nonetheless required for optimal clinical efficacy and overall safety—and this includes prescribing appropriate amounts and refills that are proportionate to expected clinical outcomes.

Summary

Although it comes near the end of the list of guidelines in the FSMB *Model Policy*, documentation is an essential component at every step of the process of delivering appropriate pain care. Effective documentation is vital to supporting all of the other elements of the FSMB *Model Policy*. Moreover, complete documentation is essential to indicate compliance with state and federal laws that govern prescribing controlled substances. Last, documentation is required for supporting coding, billing, and reimbursements.

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Chapter 7: Compliance With Relevant Law

"To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations."
–*FSMB Model Policy*

As useful as they may be, opioid medications are scheduled as controlled substances because they also have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated by a complex series of federal and state policies on controlled substances, as well as other state laws and regulations that govern healthcare practice. Such policies are intended to prevent drug abuse and substandard prescribing practice. But in some cases, they can have impact that goes beyond their intended purpose in ways that can hamper legitimate medical practices and create barriers for caregivers and patients.[1]

Although considerable progress has been made in the past decade to amend state laws in hopes of striking balanced regulatory policies, significant state-to-state inconsistencies remain. Some state policies may create particular

practice standards that differ from national conventions. Growing attention to the separate public health crises of undertreated pain and prescription drug abuse are leading to calls for more circumspect and specific regulations. Some state laws have been recently revised or are in the process of revision. In some states, however, there still may be legal language in the professional and business codes that could raise concerns by:

- Limiting the amounts of opioids that can be prescribed and dispensed;
- Requiring special government-issued prescription forms;
- Restricting access to patients in pain who have a history of substance abuse or addictive disease;
- Using antiquated and ambiguous language that can confuse patients in pain with people who have addictive disease; or
- Requiring opioids to be only a treatment of last resort.

Language that can enhance pain management is now frequently being added to state policies and laws. However, there remain some states in which the need for appropriate pain care is not well articulated. For example, some states do not recognize that controlled substances are necessary in some cases, or that pain management is an integral part of the practice of medicine.

It is imperative that physicians are thoroughly familiar with their own state's laws and regulatory practice standards. (Access to these laws, or summaries of the laws, is available through the Federation of State Medical Boards website: www.fsmb.org/pain.) Unfortunately, evidence suggests that many physicians remain ignorant of the state regulations under which they practice. This may have divergent consequences: On the one hand, some physicians may limit their use of controlled substances in the mistaken belief that their state laws are restrictive or overly punitive; on the other hand, some physicians may be practicing in a manner inconsistent with accepted standards and this might be viewed as potentially suspicious by their state's regulatory agencies that oversee medical practice.

Physicians also must have a firm grasp of the federal laws relating to controlled substances. These laws are articulated in the federal Controlled Substances Act (CSA), which attempts to balance the competing demands of both control and availability. Under this act, licensed professionals can prescribe, dispense, and administer controlled substances for legitimate medical purposes in the course of professional practice. (Note that most opioid analgesics are Schedule II drugs although a few, which happen to be the most prescribed, are schedule III drugs—Schedule I drugs such as heroin and LSD are considered to have no legitimate medical uses.) The "control" portion of the CSA attempts to prevent diversion, establishes a system of secure manufacture and distribution, requires record-keeping procedures, and sets up penalties (including criminal prosecution) for violating its provisions.

Prescription Monitoring Programs

In response to the problems of drug diversion and abuse of prescription medications, the Federal Government and many states have promoted prescription monitoring programs (PMPs). Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct reviews and analyses of the

data, and disseminate the data to appropriate regulatory and law enforcement agencies. Some have begun to make these data available to clinicians and a few have even made the data readily available at the point of care. It seems certain that more states will be moving in this direction in the future.

Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use state-issued multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacies return one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state law enforcement agency and some states charged a fee for the forms or limited the amount that could be ordered at any time.

Only one multiple copy prescription program still exists because of the barriers to care that most caused, as well as the advent of technological solutions that use computerized information systems to take the burden of prescription monitoring away from the front lines of clinical care. Most states are now moving to computerized PMPs. In such systems, pharmacies transmit data to the state on controlled substances prescriptions. Although there is currently a federal program that supports individual states in their efforts to implement a PMP (National All Schedules Prescription Electronic Reporting Act of 2005), in practice, PMPs take different forms because each state government is charged with determining the goals, structure, and organization of its

program. Variation between states is still common, even in states that border each other and must deal with patients crossing state lines for care.

Certain characteristics of PMPs can have a deterrent effect on potential criminal activities. For example, some state authorities report that use of tamper-resistant prescription forms significantly reduces or eliminates prescription forgery. Thus, while government-issued serialized prescriptions have largely been abandoned as useful tools for prescription monitoring, the use of security paper that is tamper-resistant is increasing. These security-paper prescription forms employ the same technology that has long been used on personal bank checks or on paper money—these include a watermark that may be viewed at a certain angle, photochromic features that produce an image such as the word "void" if the paper is copied or scanned by a light source, or even thermochromic features in which the paper changes color when touched by warm fingers or a heat source. In addition, PMPs that make prescribing information available to clinicians at the point of clinical care may be useful for identifying "doctor shopping." An individual who is identified as doctor shopping should have his or her treatment plan re-evaluated, may need additional guidance and education, may be directed into treatment for chemical dependency, or may be prosecuted, depending on the circumstances of the case.

To date, not all PMPs have been created equal, however, and some may have inadvertently erected barriers, either overt or implicit, to the appropriate prescribing of opioids for legitimate medical purposes.[4] Some programs may have sent unintended and subtle messages to physicians that

encourage them to be stingy with or paranoid about prescribing strong pain medicines. Data show that physicians recognize such messages and alter their practices accordingly, often with detrimental results. For instance, California had the oldest PMP system in the United States, which used serialized triplicate prescriptions solely for Schedule II drugs. On several occasions, pain-care advocates tried to convince the California legislature to rescind the triplicate program as it was widely believed to be a barrier to adequate pain management. On each occasion, arguments were made that if California removed its triplicate-based PMP, it would see markedly increased Schedule II prescribing, which often provides optimal treatment for patients with severe chronic pain, but also increases abuse of these medications. The assumption was that maintaining low levels of Schedule II drug prescribing was protecting citizens from drug abuse. The triplicate PMP was ultimately removed when the legislature was able to see that while the triplicate PMP clearly resulted in low Schedule II prescribing, including low prescribing rates of sustained release oxycodone, California had a disproportionately high rate of Schedule III opioid prescribing and abuse, particularly hydrocodone (found in products compounded with acetaminophen such as Vicodin, Norco, Lortab, etc.) Ironically, hydrocodone is the most prescribed drug in the United States, prescribed in far greater numbers than any other opioid.

The California experience was predictable. It is well-established that when physicians are faced with barriers to prescribing a certain type of medication, they will often prescribe around that barrier, turning instead to drugs that are perceived to be less scrutinized, even if they are less efficacious and/or potentially harmful. This pattern is known as the substitution effect.[5] The problem of the substitution effect is one example of how we may view a set of data relating to the drug abuse problem and draw conclusions that neither factors in all of the relevant variables nor anticipates the full collateral impact on the drug-abusing population or on patients with a legitimate need for controlled substances.

Contemporary PMPs are not intended to interfere with medical practice, and attempts are increasingly being designed to reduce potential barriers to care. Unlike PMP programs of the past that were intrusive at the point of clinical care, newer electronic-based PMPs collect data behind the scenes of clinical care. Likewise, contemporary PMPs typically do not require physicians to obtain prior approval to issue prescriptions and they do not impose limits on the quantity that may be prescribed. Limitations on prescribing controlled substances do exist, but are governed by laws that are separate from those related to PMPs. For instance, federal law prohibits prescribing refills on Schedule II drugs, and recently the DEA has made adjustments to exactly what constitutes a refill. Likewise, some state laws may limit quantities that can be prescribed in one prescription, but such limitations are completely distinct from the individual state's PMP.

More states are likely to institute PMPs in the future because of the 2005 congressional approval of the National All Schedules Prescription Electronic Reporting Act (NASPER). This law instituted a program that offers individual states funding for establishing PMPs. Although NASPER was hailed as a major tool for clinicians, it did not mandate that the collected information would be directly available to physicians at the time that they treat

their patients. However, PMP data should and likely will be more available to clinicians at the point of care. Using these data may prove to be increasingly important in the management of patients who use controlled substances.

Federal Guidelines for Prescribing Controlled Substances

As noted in Chapter 6, the DEA released an updated Practitioner's Manual in September 2006. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the CSA. The complete manual is available online (www.deadiversion.usdoj.gov) and physicians are urged to read it carefully. This internet website is also of value for any updates that may occur. Moreover, the DEA also issued a clarification of its policies relating to the use of controlled substances for pain that appeared in the September 6, 2006 Federal Register (Vol. 71, No. #52716- 52723, 172, 21 CFR Part 1306.) This document is titled Dispensing Controlled Substances for the Treatment of Pain. Select passages that are posted on www.fsmb.org/pain offer DEA clarification on the following topics:

- Purposes and Structure of This Document
- The Statutory Role of DEA in Regulating the Prescribing of Controlled Substances
- The Meaning of the "Legitimate Medical Purpose" Requirement
- Other Recurring Questions
  - ☐ What are the potential signs to a physician that a patient might be seeking drugs for the purpose of abuse or diversion?

  - ☐ What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?
  - ☐ What additional precaution should be taken when a patient has a history of drug abuse?

In the fall of 2007, the DEA also issued a final ruling [Issuance of Multiple Prescriptions for Schedule II Controlled Substances in the Federal Register: November 19, 2007 (Volume 72, Number 222,Page 64921-64930)] that amends its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance. These multiple prescriptions allow a physician to write, and a patient to receive, sequential prescriptions for up to a 90-day supply of that controlled substance. Thus practitioners may write multiple prescriptions, each dated the day the prescriptions are written, but only one would be for immediate filling while the others would have sequential and non-overlapping fill dates. The intervals are up to the prescriber so that it might be days, weeks or months. For instance, a prescriber might state "do not fill until 30 days from prescription date" or "do not fill until 60 days from prescription date", etc.

Summary

Current federal regulations, emerging state laws, and in particular, the FSMB *Model Policy* seek a rational balance that supports society's need to be protected from drug abuse and to receive effective treatment for pain. Physicians who find such balance in their practice will likely find themselves congruent with the goals of regulators and, most important, with

the needs of their patients. New or revised regulations, and the reality of changing or inconsistent existing regulations at both federal and state levels, reinforce the fundamental message of this chapter and the FSMB *Model Policy*: physicians must take the time to educate themselves about the realities of the legal environment in which they practice and remain up to date on any changes to those policies. Doing so will facilitate best clinical practices in terms of pain management and will reduce the chances for practice disruption through inadvertent intrusion by the legal system.

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Overview: A Capsule Summary of Steps You Can Take Today

This book and the updated resources on the FSMB's website offer a pragmatic framework for treating pain with compassion and vigilance. I hope it adds to your confidence to practice medicine by seeking to cure when possible, but to always treat suffering.

The steps that are stressed in these chapters should not impose new burdens, because the approaches, procedures, and mindset advocated in the *Model Policy* articulate the standards that are essential components of sound medical care that physicians strive to achieve every day. Putting the *Model Policy* to work, therefore, is more a matter of reframing one's approach than adopting an entirely new way of practice. However, many of these steps will be difficult to attain on a daily basis in a busy general practice without increasing your knowledge base about pain management and developing simple, skills, tools, and procedures that will expedite the process.

This will not be an onerous addition to your work if you prepare in advance for the education and monitoring needs of your patients who require controlled substances and refine your general knowledge base and skills around assessment and documentation. And once accomplished, the principles and practices discussed in this book will enhance your clinical operation well beyond prescribing controlled substances.

Below is a capsule summary of the steps you can take right now to integrate the tenets of the *Model Policy* into your day-to-day practice:

1. Patient Evaluation

- Make time to listen carefully to patients in pain.
- Use a reflective listening approach.
- Remain mindful of the need for suspicion without a rush to judgment.
- Look for signs of abuse, but recognize the complexities of presentation and the possibilities of pseudoaddiction.
- Remember that not treating pain is often not a "safe" option.

2. Treatment Plan

- Use a function-based paradigm at diagnosis and follow through with a function-based treatment plan.
- Develop a list of functional losses and gains that will be impacted by care, then track and modify them throughout care.
- Simply "feeling better," without improving functioning in some aspect of an individual's life, may not reflect improvement in quality of life.
- Modest reductions in pain score may actually be extremely significant in terms of reclaimed function.

3. Informed Consent and Agreement for Treatment

- Patients must fully understand the potential risks and benefits of any procedure or treatment to be truly "informed" as required by both law and medical ethics.
- Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent process.
- Prepare the educational materials and other documents that you will need in advance and develop in advance an efficient process for implementing these steps for all of your patients—much of which can take place outside of your exam room. (See Appendix A for online educational resources you can download and use in your practice.)
- A written agreement/informed consent process can help addresses the key points of the *Model Policy* (Go to www.fsmb.org/pain for more information about agreements and sample agreements that you can adapt to the needs of your patients and practice.)

4. Periodic Review

- As in all treatments, including those involving controlled substances, physicians must closely attend to treatment outcomes and be alert to a wide range of potential adverse effects.
- Monitoring progress toward a set of functional goals requires a means of measuring progress (or lack thereof), which must be clearly documented from the start of treatment.
- The responsibility of attaining treatment goals and presenting supporting evidence lies with the patient.
- Assess functional goals and move the "goalposts" as needed.

5. Referral and Patient Management

- Build a network of clinical experts to whom you can turn for specialized needs.

- Be clear with yourself about the breadth and depth of your expertise, and don't hesitate to refer patients at the earliest signs they may need help.
- Remember that patients in pain can appear "difficult," but that the most "difficult" patients are often the ones who most desperately need your help.

6. Documentation

- Documentation is an essential component at every step of the process of delivering pain care.
- Document assessments, treatment agreements, education; action plans, and patient monitoring activities.
- Be clear about why you are taking risks and your plan for risk management. Transparency as to your reasoning about risk management decision-making is a critical component of documentation.
- Include enough specific information that a person reading the document understands the implications of exam results or other details of the history or treatment plan.

7. Compliance With Controlled Substance Laws and Regulations

- Know your state regulations on controlled substances and adhere strictly to them.
- Be familiar with and adhere to all relevant Federal regulations.
- Access to relevant state and federal laws is available through the Federation of State Medical Boards website: www.fsmb.org/pain.

Conclusion: Balancing Vigilance and Compassion

As the preceding chapters demonstrate, the FSMB *Model Policy* focuses on process-oriented aspects of patient care, leaving selection of drug, dose, duration, etc. well within the bounds of each physician's clinical judgment. These principles are presented as a basic framework for an organized, systematic medical practice. They offer substantial latitude and flexibility, allowing practitioners to deviate from these steps if, in their reasoned judgment, it's in the best medical interest of a patient.

By incorporating this framework, you can take comfort in knowing that, although heightened concern about controlled substances may remain among clinicians and regulators, practicing in accord with the FSMB *Model Policy* squarely aligns you with adherence to basic tenants of well-established medical practices. Perhaps more important, adhering to the tenants of the *Model Policy* not only facilitates appropriate treatment of pain with controlled substances, but also supports a healthy overall practice.

That is the backdrop against which this book and the *Model Policy* were conceived: Delivering optimal care to patients in pain. The patient is the ultimate beneficiary of therapeutic pharmacovigilance. As we treat patients in pain, it is all too easy to lose sight of these goals, particularly in an atmosphere of legitimate concerns over abuse

and diversion. It is vitally important that the best interest of the patient and society always remain in the foreground.

As the FSMB *Model Policy* emphasizes, opioid analgesics are legitimate and effective agents for pain control. Nonetheless, they are not always indicated or appropriate. As always, clinicians must base their decisions to use or withhold opioids on a case-by-case risk/benefit analysis, keeping in mind that there are substantial risks associated with ignoring pain. As described in its introduction, the FSMB *Model Policy* is a tool that medical boards and other regulators use to assess whether your practice is within the standard of care. Thus, a practice consistent with the tenets of the *Model Policy* should be positively viewed by regulators. This may reduce the hesitation—or even paralysis—that some practitioners now feel about prescribing controlled substances.

The fundamental tenets of responsible opioid prescribing for pain—complete evaluation, balanced risk-management, and transparent documentation—are the pillars of any functional medical practice, particularly in pain management. In the often murky realm of pain assessment and treatment, trust and transparency are paramount within the therapeutic relationship. Therefore, I cleave to the Russian proverb that Ronald Reagan liked to quote: "Trust, but verify." Maintaining clinical vigilance is critically important in all domains of medical practice and is particularly important for patients in pain who are at increased risk of a host of complex collateral consequences. These include an array of manifestations of physical as well as psychological deconditioning, such as fatigue, insomnia, depression, anxiety, and even suicide. Some patients may also be at risk for

addiction. By establishing a clear framework for assessing, treating, and tracking patients, we improve our odds of achieving an optimal therapeutic outcome.

The FSMB *Model Policy* does not set a standard of medical practice. These details of care require medical knowledge and information about a patient that can only be determined through the deliberate and individualized clinical judgment of the treating physician. Since few generalizable treatment algorithms exist, regulators should recognize—as I believe they do—that society is best served by prudent risk-conscious practitioners who apply their best judgment, based on individual characteristics that vary greatly from patient to patient.

Physicians are given great latitude in judgment when risks are managed with rational and systematic care. This involves treatment choices that are made with circumspect consideration of past and ongoing case details, a reasonable breadth of diagnostic expertise and treatment options, and vigilant attention to treatment goals and outcomes—all of which are clearly and transparently documented. With no single accepted method for comprehensive assessment and monitoring, physicians must use their knowledge and judgment to determine a best plan for each individual patient. This may include global policies and procedures applied to all patients in your practice, or used on a case-by-case basis. Just as in managing risk in any other treatment setting, the foundation for success rests on knowledge, concern, awareness, and proactive initiative. And as with all aspects of medical care, whenever risk is decreased, barriers to initiating interventions are lowered and chances for beneficial outcomes rise. Managing risks and benefits is

at the core of what we physicians do with all our patients; vigilance in pain management is nothing more or less than effective risk management.

Obviously, physicians must remain current not only with new developments in medicine, but also with related changes in state and federal laws. To this end, the Federation of State Medical Boards is posting updated information relevant to opioid prescribers on its website at www.fsmb.org/pain. Amongst many valuable resources, this site includes:

- Updated prescribing standards for each state;
- Links to updated information about the DEA's requirements for prescribing controlled substances; and
- Links to SAMHSA, FDA, and other government websites where you can find updated information and warnings about prescription medications.

In addition to providing resources for pharmacovigilant practice, the FSMB site also offers links to useful online pain management resources. Though most of us are called upon to treat patients in pain, few physicians have been given a full set of resources to respond to these patients' special needs. I believe that the reason many doctors resist treating pain is not that they lack compassion, are unwilling to engage with difficult cases, or that they shy away from potential legal and regulatory hassles. It is because, in the past, medicine has not made pain care a priority, and consequently most physicians are not well-trained or well-equipped to manage pain.

Pain Medicine is a young discipline that is still barely represented in medical school curricula or residency programs. Continuing medical education in pain management is largely sponsored by industry, and its quality and practicality often is hit-or-miss. We are unlikely to succeed in reversing the problem of undertreated pain without increasing education and support for physicians at all levels of training—not just in pain management, but also in drug abuse, addiction, and rational approaches to a functional practice that balances compassionate care with appropriate pharmacovigilance.

Meanwhile, the science and technology of pain medicine is expanding at a rapid rate, encompassing pain physiology, medications, procedures, devices, and other therapies. Each of us has a responsibility to attain a basic working understanding of pain management, and if one chooses to prescribe opioids or other controlled substances, a clear understanding of safe and effective prescribing practices.

Obviously, the content of this book cannot substitute for the commitment to relieve suffering. The tenets of the FSMB *Model Policy*, or any consensus practice guidelines, are only useful in service to conscientious pain management. There is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades. The cost of undertreated pain in dollars is astronomical, but the cost in human suffering is immeasurable. Turning away from patients in pain simply is not an option.

Appendix A: Resources for Pharmacovigilance and Pain Management

The FSMB's wesite at www.fsmb.org/pain can serve as a first stop destination for up-to-date resources for pharmacoviglance in pain management. On this site you'll find:

- The FSMB *Model Policy* for the Use of Controlled Substances for the Treatment of Pain
- Updated state-by-state prescribing guidelines for the use of controlled substances, as well as other relevant state-based regulations
- Links to websites at the Substance Abuse and Mental health Services Administration, Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) where you'll find updated information about drug safety and pharmacovigilance

In addition to staying current with state and federal regulations governing controlled substance prescribing, it's also important to stay abreast of safe and effective pain management. As with any job, effectively treating patients in chronic pain is easier when you use the right tools. I'm talking here about assessment instruments, scales for quantifying pain, intake questionnaires, patient education handouts, and well-crafted doctor/patient agreements. Many versions of these kinds of tools are available for downloading from the

Internet. Below I've listed the sites I can recommend to you—and I've marked my most highly recommended sites with a ✪. I've also listed some books about pain and pain management that you or your patients might find helpful.

1. **Federal Government Resources**
2. **Medical Specialty Society Sites**
3. **Nonprofit Pain Organizations (and other sites of interest to medical professionals)**
4. **Treatment Guidelines**
5. **Pain and Function Assessment Tools**
6. **Commercially Sponsored Sites Offering Useful Clinical Tools**
7. **Medical Journals Focusing on Pain**
8. **Sites with Educational Information for Consumers**
9. **Professional and Patient Sites by Disorder**
10. **Pain-Related Books**

1. FEDERAL GOVERNMENT RESOURCES

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov/

- National Survey on Drug Use and Health: Nonmedical Users of Pain Relievers, Characteristics of Recent Initiates: www.oas.samhsa.gov/2k6/pain/pain.cfm
- NonMedical Use of Pain Relievers: www.oas.samhsa.gov/subState2k6/agePain.htm
- Directory of drug and alcohol abuse treatment programs: http://findtreatment.samhsa.gov

Drug Enforcement Administration (DEA): www.usdoj.gov/dea/index.htm

- Drug Scheduling: www.usdoj.gov/dea/pubs/scheduling.html
- Drug Information: www.usdoj.gov/dea/concern/concern.htm
- Diversion Control: www.deadiversion.usdoj.gov/
- DEA Practioners Manual: www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html
- Survey of State Prescription Monitoring Programs: www.deadiversion.usdoj.gov/pubs/program/ijis_pmix_survey20070204.pdf

The U.S. Food and Drug Administration (FDA): www.fda.gov

The National Institute on Drug Abuse (NIDA): www.drugabuse.gov

- Prescription Drug Abuse Chart: www.drugabuse.gov/DrugPages/PrescripDrugsChart.html

The Office of National Drug Control Policy: www.whitehousedrugpolicy.gov

- The President's National Drug Control Strategy: www.whitehousedrugpolicy.gov/publications/policy/ndcs07/

2. MEDICAL SPECIALTY SOCIETY SITES

American Academy of Orofacial Pain
www.aaop.org
19 Mantua Road
Mount Royal, NJ 08061
856-423-3629
Fax: 856-423-3420

The American Academy of Pain Medicine
www.painmed.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4731
Fax: 847-375-4777

American Medical Association
www.ama-assn.org
515 N. State Street
Chicago, IL 60610
800-621-8335

American Pain Society (APS)
www.ampainsoc.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4715
Fax: 877-734-8758
A multidisciplinary organization of basic and clinical scientists, practicing clinicians, policy analysts, and others. The mission of the APS is to advance pain-related research, education, treatment, and professional practice.

American Psychological Association
www.apa.org
750 First Street, NE
Washington, DC 20002
800-374-2721
Offers referrals, assistance, and resources for coping with the psychological aspects of trauma and terrorism.

American Society of Addiction Medicine
www.asam.org
Email@asam.org
4601 North Park Ave, Arcade Suite 101
Chevy Chase, MD 20815
301-656-3920
Fax: 301-656-3815

American Society for Pain Management Nursing
www.aspmn.org
P.O. Box 15473
Lenexa, KS 66285-5473
888-34-ASPMN (342-7766) or 913-895-4606
Fax: 913-895-4652
ASPMN advances optimal nursing care for people affected by pain by promoting best nursing practice through educational resources, such as its peer-reviewed journal, *Pain Management Nursing*, at www.painmanagementnursing.org.

3. NONPROFIT PAIN ORGANIZATIONS (and other sites of interest to medical professionals)

Alliance of State Pain Initiatives
www.aspi.wisc.edu
1300 University Avenue, Room 4720
Madison, WI 53706
608-265-4013
Fax: 608-265-4014

American Council for Headache Education
www.achenet.org
19 Mantua Road
Mt. Royal, NJ 08061
856-423-0258, or 800-255-ACHE (255-2243)
Fax: 856-423-0082

AMA Pain Management: The Online Series
www.ama-cmeonline.com
Web-based Continuing Medical Education program on pain management from the American Medical Association

Arthritis Foundation
www.arthritis.org
help@arthritis.org
1330 West Peachtree Street
Suite 100
Atlanta, GA 30309
800-568-4045, or 404-872-7100, or 404-965-7888
Fax: 404-872-0457

City of Hope Pain/Palliative Care Resource Center
www.cityofhope.org/prc/
City of Hope Pain/Palliative Care Resource Center
1500 East Duarte Road
Duarte, CA 91010
A clearinghouse of resources to enable individuals and institutions to improve the quality of pain management delivery.

The Cochrane Collaboration
www.cochrane.org
A wide-ranging collection of evidence-based reviews including topic in pain management.

Fibromyalgia Network
www.fmnetnews.com
Educational materials on fibromyalgia syndrome (FMS) and chronic fatigue syndrome (CFS).

International Association for the Study of Pain
www.iasp-pain.org
The leading international society of multidisciplinary pain professionals; its website offers many valuable resources for professionals.

National Consensus Project for Quality Palliative Care
www.nationalconsensusproject.org
A collaborative project of the American Academy of Hospice and Palliative Medicine, Hospice and Palliative Nurses Association, and the National Hospice and Palliative Care Organization to promote the implementation of Clinical Practice Guidelines for new and existing palliative care services.

National Institute of Dental and Craniofacial Research (NIDCR)
www.nidcr.nih.gov
nidcrinfo@mail.nih.gov
National Institutes of Health, DHHS
31 Center Drive, Room 5B-55
Bethesda, MD 20892

National Headache Foundation
www.headaches.org
info@headaches.org
312-274-2650, or 888-NHF-5552 (643-5552)
Fax: 312-640-9049
820 N. Orleans
Suite 217
Chicago, IL 60610-3132

UCLA History of Pain Project: The John C. Liebskind History of Pain Collection
www.library.ucla.edu/libraries/biomed/his/pain.html
The most exstensive resource on the history of Pain Medicine.

✪ **Pain and Policy Studies Group**
www.medsch.wisc.edu/painpolicy/
The leading resource for pain-related public policy and legislative issues.

4. TREATMENT CONSENSUS STATEMENTS, GUIDES, AND GUIDELINES

✪ **Model Policy for the Use of Controlled Substances for the Treatment of Pain**
www.fsmb.org/grpol_policydocs.html
Federation of State Medical Boards
Offers clear guidance on standards for controlled substance prescribing.

The Use of Opioids for the Treatment of Chronic Pain
www.asam.org
www.painmed.org
Consensus statement by American Pain Society, American Academy of Pain Medicine, American Society of Addiction Medicine.

JCAHO Pain Management Standards
www.jcrinc.com

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction
www.kap.samhsa.gov/products/tools/keys/pdfs/KK_40.pdf
Substance Abuse and Mental Health Services Administration (SAMHSA)

World Health Organization Cancer Pain Relief: Guide to Opioid Availability
www.who.int/cancer/publications/en/
World Health Organization

Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain
www.ampainsoc.org
American Pain Society

Definitions Related to the Use of Opioids for the Treatment of Pain
www.asam.org/pain/definitions2.pdf
American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine

5. PAIN AND FUNCTION ASSESSMENT TOOLS

The assessment tools below are widely available online for downloading in various formats, including at several of the commercially sponsored sites described in the following section.

Initial Pain Assessment Tool
www3.mdanderson.org/depts/prg/bpi.htm
A charting form that can be used on the patient's initial admission to document location, intensity, quality of pain, and relief

Brief Pain Inventory (BPI)
www.cityofhope.org/prc/pdf/BPI%20Short%20Version.pdf
A brief, simple, and easy to use tool for the assessment of pain in both clinical and research settings. The BPI uses simple numeric rating scales from 0 to 10 that are easy to understand and easy to translate into other languages. It is a well-validated instrument to measure pain intensity, functionality, and the impact of pain on one's life in the past 24 hours and within the past week.

McGill Pain Questionnaire
www.cityofhope.org/prc/pdf/McGill%20Pain%20Questionnaire.pdf
A 20-item scale that allows patients to articulate ranges of pain sensation, both internal and external.

Visual Analog Scale
www.ndhcri.org/pain/Tools/Visual_Analog_Pain_Scale.pdf
A linear scale from Worst Imaginable Pain to No Pain. Patients place a mark along the line to indicate their current pain level.

Wong-Baker FACES Pain Rating Scale
www3.us.elsevierhealth.com/WOW/
A scale that employs pictures of faces, ranging from happy to sad to assess pain in children; while designed to assess pain in children; it is also used to assess pain in adults.

6. COMMERCIALLY SPONSORED SITES OFFERING USEFUL CLINICAL TOOLS

Many of the clinical tools described in this book are available at one or more of these commercially sponsored pain management sites.

Emerging Solutions in Pain Management
www.emergingsolutionsinpain.com
A diverse collection of practical tools and resources for clinical pain management.
Sponsored by Cephalon.

National Pain Education Council™ (NPEC)
www.npecweb.org
A compendium of online CME, clinical tools, and other pain management reference sources.
Supported by Ortho-McNeil.

Pain.com
www.pain.com
Clearinghouse for chronic pain management resources, including breakthrough pain and cancer pain.
Sponsored by Purdue Pharma L.P. and Cephalon.

PainBalance.org
www.PainBalance.org
An educational site featuring physician and patient resources that emphasize the balance between safe and effective pain management and opioid abuse.
Sponsored by Alpharma Pharmaceuticals LLC.

PainEDU.org
www.painedu.org
An online resource for clinically relevant information about pain assessment and management.
Supported by Endo.

Partners Against Pain
www.partnersagainstpain.com
An informational site for patients, health professionals, and physicians.
Supported by Purdue Pharma L.P.

Legal Side of Pain
www.legalsideofpain.com
Free and subscription based information on legal issues related to pain.

7. MEDICAL JOURNALS FOCUSING ON PAIN

Headache: The Journal of Head and Face Pain
American Headache Society
www.blackwellpublishing.com/journal.asp?ref=0017-8748

Journal of Pain
American Pain Society
http://journals.elsevierhealth.com/periodicals/yjpai

Journal of Pain and Symptom Management Pain
www.elsevier.com/homepage/sah/pain/menu.html

Journal of Pain & Palliative Care Pharmacotherapy
www.haworthpress.com/store/product.asp?sku=J354

Pain
International Association for the Study of Pain
www.sciencedirect.com/pain

Pain Medicine
American Academy of Pain Medicine
www.blackwellpublishing.com/journal.asp?ref=1526-2375&site=1

8. SITES WITH EDUCATIONAL INFORMATION FOR CONSUMERS

✪ **American Pain Foundation**
www.painfoundation.org
info@painfoundation.org
201 North Charles Street, Suite 710
Baltimore, MD 21201-4111
888-615-PAIN (7246)
Fax: 410-385-1832
An excellent source for patient information and advocacy with extensive links to further information as well as monitored chat rooms for consumers.

✪ **National Pain Foundation (NPF)**
www.nationalpainfoundation.org
aardrup@nationalpainfoundation.org
300 E Hampden Avenue, Suite 100
Englewood, CO 80113
A comprehensive online education and support community for pain patients and their families.

9. PROFESSIONAL AND PATIENT SITES BY DISORDER

ADDICTION

American Society of Addiction Medicine (ASAM)
www.asam.org/

National Institute on Drug Abuse
www.nida.nih.gov

ARTHRITIS

Arthritis Foundation
www.arthritis.org

Medical College of Wisconsin/Arthritis
healthlink.mcw.edu/arthritis/

Mayo Clinic Arthritis Center
www.mayoclinic.com/health/arthritis/AR99999

BACK AND SPINE PAIN

Spine Health
www.spine-health.com

Spine Universe
www.spineuniverse.com

CANCER PAIN

American Cancer Society
www.cancer.org

Cancer Pain Control:
www.WHOcancerpain.wisc.edu

The Cancer Pain Education Resource (CAPER)
www.caper.tufts.edu

City of Hope Pain/Palliative Care Resource Center
www.cityofhope.org/prc

FIBROMYALGIA PAIN

The American Fibromyalgia Syndrome Association
www.afsafund.org

Fibromyalgia Network
www.fmnetnews.com

National Fibromyalgia Association
http://fmaware.org

HEADACHE PAIN

National Headache Foundation
www.headaches.org

American Council for Headache Education
www.achenet.org

TMJ Tutorial
www.rad.washington.edu/anatomy/modules/TMJ/TMJ.html

COMPLEX REGIONAL PAIN SYNDROME (CRPS) PAIN INTERNET RESOURCES

Reflex Sympathetic Dystrophy Syndrome Association of America
www.rsds.org

American RSDHope Group
www.rsdhope.org

NINDS Complex Regional Pain Syndrome Information Page
from the National Institute of Neurological Disorders and Stroke
www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/reflex_sympathetic_dystrophy.htm

PEDIATRIC PAIN

American Academy of Pediatrics
www.aap.org

KidsHealth
www.kidsheath.org

Pediatric Pain—Science Helping Children
www.dal.ca/~pedpain/pedpain.html

10. PAIN-RELATED BOOKS

(available at amazon.com and other online bookstores)

The Body in Pain: The Making and Unmaking of the World
Elaine Scarry (Oxford University Press 1985).

Cancer Pain Relief
International Association for the Study of Pain; World Health Organization, (World Health Organization 1986).

Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee, WHO Technical Report Series 804
World Health Organization (World Health Organization 1990).

Core Curriculum for Professional Education in Pain
International Association for the Study of Pain, Task Force on Professional Education, (IASP Publications 1991).

The Culture of Pain
David B. Morris (University of California Press 1993).

Dying Well: Peace and Possibilities at the End of Life
Ira Byock (Riverhead 1998).

Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness
Jon Kabat-Zinn (Delta 1990).

Handbook of Cancer Pain Management 3rd Edition
Weissman, et al. (Wisconsin Pain Initiative 1992).

How We Die: Reflections on Life's Final Chapter
Sherwin B. Nuland (Vintage 1995).

The Illness Narratives: Suffering, Healing, and the Human Condition
A. Kleinman (Basic Books 1988).

Managing Pain Before It Manages You
Margaret A. Caudill (Guilford Press 2001).

Mastering Pain: A Twelve-Step Program for Coping With Chronic Pain
Richard A. Sternbach (Putnam 1987).

Natural Pain Relief: A Practical Handbook for Self-Help
Jan Sadler, Patrick Wall (C.W. Daniel Company 2004).

Nature of Suffering and the Goals of Medicine
Eric J. Cassell (Oxford University Press, USA 2004).

On Death and Dying
Elisabeth Kubler-Ross (Scribner 1997).

Pain and Suffering
William K. Livingston, Howard L. Fields (IASP Press 1998).

Phantoms in the Brain: Probing the Mysteries of the Human Mind
V.S. Ramachandran, Sandra Blakeslee (Harper Perennial 1999).

Principles & Practice of Pain Management
Carol A Warfield, Zahid H. Bajwa (McGraw-Hill Professional Publishing; 2nd edition 2003).

Suffering
Betty Ferrell, Editor (Jones & Bartlett Publishers 1996).

The War on Pain
Scott Fishman (Harper Paperbacks 2001).

When Bad Things Happen to Good People
Harold S. Kushner (Anchor 2004).

Wherever You Go, There You Are: Mindfulness Meditation in Everyday Life
Jon Kabat-Zinn (Hyperion 2004).

Appendix B: Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory

agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of

[1] As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.

[2] SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.

[3] A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised *Model Policy* is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be an important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. In addition, this policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing

the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain and update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing

patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The

Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that

some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. *Evaluation of the Patient*—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
2. *Treatment Plan*—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
3. *Informed Consent and Agreement for Treatment*—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should

receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

a. urine/serum medication levels screening when requested;
b. number and frequency of all prescription refills; and
c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. *Periodic Review*—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
5. *Consultation*—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. *Medical Records*—The physician should keep accurate and complete records to include
   a. the medical history and physical examination,
   b. diagnostic, therapeutic and laboratory results,
   c. evaluations and consultations,
   d. treatment objectives,
   e. discussion of risks and benefits,
   f. informed consent,
   g. treatments,
   h. medications (including date, type, dosage and quantity prescribed),
   i. instructions and agreements and
   j. periodic reviews.

   Records should remain current and be maintained in an accessible manner and readily available for review.
7. *Compliance With Controlled Substances Laws and Regulations*—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors

influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

About the Author

Scott M. Fishman, M.D., is a nationally recognized author and advocate for patients in pain. He is Chief of the Division of Pain Medicine and Professor of Anesthesiology and Pain Medicine at the University of California, Davis. He was formerly Medical Director of the Massachusetts General Hospital Pain Center at Harvard Medical School. Dr. Fishman is trained and board certified in Internal Medicine, Psychiatry, Pain Medicine, and Hospice and Palliative Care.

Dr. Fishman is the author of *The War on Pain* and *Listening to Pain*. He is the co-author of *The Massachusetts General Hospital Handbook of Pain Management 2nd Edition*; and *Essentials of Pain Medicine and Regional Anesthesia*. He serves as Senior Editor for the journal *Pain Medicine* and sits on the editorial board of numerous other medical journals.

Dr. Fishman is past president of the American Academy of Pain Medicine, is Vice Chairman of the board of directors for the American Pain Foundation, and has served on the board of directors for the American Pain Society. He has helped national and state legislatures with pain-related laws and consults to numerous government agencies and organizations, such as the Federation of State Medical Boards (FSMB), The Drug Enforcement Administration (DEA), and various state medical boards.

$12.95

Responsible Opioid Prescribing offers physicians effective strategies for reducing the risk of addiction, abuse, and diversion of opioids that they prescribe for their patients in pain. Written by pain medicine specialist Scott M. Fishman, M.D., this concise handbook translates the Federation of State Medical Board's *Model Policy for the Use of Controlled Substances for the Treatment of Pain* into pragmatic steps for risk reduction and improved patient care, including:

- Patient evaluation, including risk assessment
- Treatment plans that incorporate functional goals
- Informed consent and prescribing agreements
- Periodic review and monitoring of patients
- Referral and patient management
- Documentation
- Compliance with state and federal law

Scott M. Fishman, M.D., is a leading pain medicine clinician, researcher, teacher, lecturer, and writer. He is Chief of the Division of Pain Medicine and Professor of Anesthesiology at the University of California, Davis. Board certified in Internal Medicine, Psychiatry, Hospice and Palliative Medicine, and Pain Medicine, Dr. Fishman is Past President of the American Academy of Pain Medicine, author of *The War on Pain* and *Listening to Pain*, and coauthor of *The Massachusetts General Hospital Handbook of Pain Management* and *Essentials of Pain Medicine*.

WATERFORD
LIFE SCIENCES

Attachment 4

Agenda Item 16

Guidelines for Prescribing Controlled Substances for Pain

Medical Board of California

October 2014
(DRAFT)

Edmund G. Brown Jr., Governor
David Serrano Sewell, J.D., President, Medical Board of California
Kimberly Kirchmeyer, Executive Director, Medical Board of California

Guidelines for Prescribing Controlled Substances for Pain

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PREAMBLE

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality medical practice and California law dictate that the people of California have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." This was used to provide guidance to physicians prescribing controlled substances. Several legislative changes since 1994 necessitated revising these guidelines; most recently in 2007.

In November 2011, the Centers for Disease Control and Prevention declared prescription drug abuse to be a nationwide epidemic. Drug overdose is now the leading cause of accidental deaths, exceeding deaths due to motor vehicle accidents. A majority of those overdose deaths involved prescription drugs. The diversion of opioid medications to non-medical uses has also contributed to the increased number of deaths, although the problem is not limited to the aberrant, drug-seeking patient. Injuries are occurring among general patient populations, with some groups at high risk, (e.g., those with depression). Consequently, the Board called for revision of the guidelines to provide additional direction to physicians who prescribe controlled substances for pain.

These guidelines are intended to help physicians improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain. Opioid analgesics are widely accepted as appropriate and effective for alleviating moderate-to-severe acute pain, pain associated with cancer and persistent end-of-life pain [1] Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal. These guidelines underscore the extraordinary complexity in treating pain and how long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured. Since opioids are only one of many options to mitigate pain, and because prescribing opioids carries a substantial level of risk, these guidelines offer several non-opioid treatment alternatives. These guidelines are not intended to mandate the standard of care. The Board recognizes that deviations from these guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. Physicians are encouraged to document their rationale for each

[1] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

prescribing decision. Physicians should understand that if one is ever the object of a quality of care complaint, peer expert review will be sought by the Board. The expert reviewer must consider the totality of circumstances surrounding the physician's prescribing practice (e.g., issues relating to access of care, paucity of referral sources, etc.) Specifically, experts are instructed to define the standard of care in terms of the level of skill, knowledge and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question."

In an effort to provide physicians with as many sources of information as possible, these guidelines link to numerous references relating to prescribing. Additionally, numerous appendices are attached. The Board recognizes that some of the links/appendices may not be consistent with either each other or the main text of the guidelines. The intent for including as many sources of information as practicable is so that physicians can consider varying perspectives to arrive at the best patient-appropriate treatment decision. The Board does not endorse one treatment option over another and encourages physicians to undertake independent research on this continuously evolving subject matter.

UNDERSTANDING PAIN

The diagnosis and treatment of pain is integral to the practice of medicine. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives long-term opioid therapy.

The California Medical Association[2] has defined and clarified key concepts relating to pain excerpted below:

Pain: The definition of pain proposed by the International Association for the Study of Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." It has also been said that "Pain is what the patient says it is." Both definitions acknowledge the subjective nature of pain and are reminders that, with the rare exception of patients who intentionally deceive, a patient's self-report and pain behavior are likely the most reliable indicators of pain and pain severity. As a guide for clinical decision-making, however, both of these definitions are inadequate. In addition, it is important to remember that the subjectivity of pain, particularly when the cause is not apparent, can lead to the stigmatization of those with pain.

[2] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Acute and Chronic Pain: Traditionally, pain has been classified by its duration. In this perspective, "acute" pain is relatively short-duration, arises from obvious tissue injury, and usually fades with healing. "Chronic" pain, in contrast, has been variously defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as 3 or 6 months. Temporal pain labels, however, provide no information about the biological nature of the pain itself, which is often of critical importance.

Nociceptive and Neuropathic Pain: A more useful nomenclature classifies pain on the basis of its patho-physiological process. Nociceptive pain is caused by the activation of nociceptors, and is generally, though not always, short-lived and is associated with the presence of an underlying medical condition. It is a "normal" process; a physiological response to an injurious stimulus. Nociceptive pain is a symptom. Neuropathic pain, on the other hand, results either from an injury to the nervous system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus; a pathological process. It is a neuro-biological disease. Neuropathic pain is caused by abnormal neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

A key aspect of both nociceptive and neuropathic pain is the phenomenon of sensitization, which is a state of hyper excitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgia or allodynia. Sensitization may arise from intense, repeated or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation. Importantly, many patients – particularly those with persistent pain --- present with "compound" pain that has both nociceptive and neuropathic components, a situation which complicates assessment and treatment.

Differentiating between nociceptive and neuropathic pain is critical because the two respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory (NSAID) agents. Other classes of medications, such as anti-epileptics, antidepressants or local anesthetics, may provide more effective relief for neuropathic pain.

Cancer and Non-Cancer Pain: Pain associated with cancer is sometimes given a separate classification, although it is not distinct from a patho-physiological perspective. Cancer-related pain includes pain caused by the disease itself and/or painful diagnostic or therapeutic procedures [and the sequelae of those processes]. The treatment of cancer-related pain may be influenced by the life expectancy of the patient, by co-morbidities and by the fact that such pain may be of exceptional severity and duration. A focus of recent attention by the public, regulators, legislators, and physicians has been chronic pain that is not associated with cancer. A key feature of such pain, which may be caused by conditions such as musculoskeletal injury, lower back trauma and dysfunctional wound healing, is that the severity of pain may not correspond well to identifiable levels of tissue damage.

Tolerance, Dependence and Addiction: Related to the nomenclature of pain itself is continuing confusion not only among the public, but also in the medical community, about terms used to describe the effects of drugs on the brain and on behavior. To help clarify and standardize understanding, the American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) have recommended the following definitions:

> *Tolerance:* A State of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time.
>
> *Physical Dependence:* A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist.
>
> *Addiction:* A primary, chronic, neurobiological disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.

Pain as an Illness: Finally, it may be helpful to point out that pain can be regarded as an illness as well as a symptom or a disease. "Illness" defines the impact a disease has on an organism and is characterized by epiphenomena or co-morbidities with bio-psycho-social dimensions. Effective care of any illness, therefore, requires attention to all of these dimensions. Neuropathic pain, end-of-life pain and chronic pain should all be viewed as illnesses.

SPECIAL PATIENT POPULATIONS

All patients may experience pain. Below are treatment considerations for differing patient populations or scenarios. As previously addressed, these guidelines are intended to particularly address the use of opioids in the long-term treatment of chronic, non-cancer pain. However, since many of the recommendations cited in these guidelines might be appropriate for other types of pain, other scenarios are listed below to provide additional guidance in prescribing opioids, when appropriate.

Acute Pain[3]

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies likely will not provide adequate pain relief. When opioid medications are prescribed for treatment of acute pain, the number dispensed should

[3] Utah Department of Health (Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, 2009).

be for a short duration and no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

Long (and intermediate) duration-of-action opioids or extended release/long acting opioids (ER/LA) should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely, if ever, indicated for treatment of acute pain. The use of opioids should be re-evaluated carefully, including the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

It is important to emphasize that numerous (but not all) recommendations cited in these guidelines may not be relevant for the physician treating a patient for acute pain. For example, a physician treating a patient who presents to an Emergency Department or primary care physician with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a psychological assessment, utilize a pain management agreement, confer with the Prescription Drug Monitoring Program database, order a drug toxicology screen, etc.

Emergency Departments
Treating patients in an emergency department (ED) or urgent care clinic presents unique challenges in that, oftentimes there is limited ability to procure adequate patient history and the primary physician is not available. Drug seeking patients may take advantage of this in order to secure controlled substances.

The American College of Emergency Physicians (ACEP) Clinical Policy - Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department (Appendix 1) - identifies acute low back pain as a common presenting complaint in the ED. Opioids are frequently prescribed, expected or requested for such presentations. Consequently, ACEP clinical policy recommends:

(1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether non-opioid analgesics and non-pharmacologic therapies will be adequate for initial pain management.
(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or non-opioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.
(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (e.g.,<1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

For patients presenting to the ED with an acute exacerbation of non-cancer chronic pain, ACEP recommends the following:

(1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED.

(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., < 1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.
(3) The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.

ACEP recommends that the use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

End-of-Life Pain[4]
Pain management at the end of life seeks to improve or maintain a patient's overall quality of life in addition to relieving suffering. This focus is important because sometimes a patient may have priorities that compete with, or supersede, the relief of pain. For some patients, mental alertness sufficient to allow lucid interactions with loved ones may be more important than physical comfort. Optimal pain management, in such cases, may mean lower doses of an analgesic and the experience, by the patient, of higher levels of pain.

Fear of inducing severe or even fatal respiratory depression may lead to clinician[5] under-prescribing and reluctance by patients to take an opioid medication. Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration and time of death in patients using opioids in the context of terminal illness. A consult with a specialist in palliative medicine in these situations may be advisable.

Cancer Pain
The California Medical Association writes that pain is one of the most common symptoms of cancer, as well as being one of the most-feared cancer symptoms. Opioid pain medications are the mainstay of cancer pain management and a trial of opioid therapy should be administered to all cancer patients with moderate or severe pain, regardless of the known or suspected pain mechanism. The American Academy of Pain Management advised the Board that some cancer survivors with moderate-to-severe pain benefit greatly from the use of non-opioid medications, and when these are effectively administered, opioids are unnecessary. Similarly, other treatments such as surgeries, radiation therapy, and other procedures may provide sufficient pain relief that opioids are not necessary.

Extended-release/long-acting (ER/LA) opioid formulations may lessen the inconvenience associated with the use of short-acting opioids. Patient-controlled analgesia using an ambulatory infusion device may provide optimal patient control and effective analgesia. The full range of adjuvant medications should be considered for patients with cancer pain, with the caveat that such patients are often on already

[4] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).
[5] The term "clinician" throughout the document means "physician."

complicated pharmacological regimens, which raises the risk of adverse reactions associated with polypharmacy.[6]

Older Adults
With appropriate precautions opioid therapy for elderly patients can be efficacious. It is important to begin with lower starting doses, slower titration, longer dosing intervals, and more frequent monitoring. Tapering of benzodiazepines is important to reduce the potential for respiratory depression.

For additional information, see Appendix 2.

Pediatric Patients
Extreme caution should be used in prescribing opioids for pediatric patients. A trial of opioid therapy may be considered with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed or are unlikely to be effective for acute pain. Additionally, close monitoring and consultation should be undertaken.

For additional information, see Appendix 3.

Pregnant Women
Clinicians should encourage minimal or no use of opioids during pregnancy unless the potential benefits clearly outweigh risks. Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible.

Additional information on the appropriate use of opioids for pregnant patients is available: American Congress of Obstetricians and Gynecologists (ACOG) committee opinion titled *Opioid Abuse, Dependence, and Addiction in Pregnancy*.

Patients Covered by Workers' Compensation[7]
This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work. Conflicts of motivation may also exist in patients on workers' compensation, such as when a person may not want to return to an unsatisfying, difficult or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers' compensation

[6] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).
[7] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

For additional information on treating patients covered by Workers' Compensation please see *State of California Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries*.

Patients with History of Substance Use Disorder[8]

Use of opioids for patients with a history of substance use disorder is challenging because such patients are more vulnerable to drug misuse, abuse and addiction. In patients who are actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by potential risks, and such therapy should not be prescribed outside of highly controlled settings (such as an opioid treatment program with directly observed therapy). In other patients, the potential benefits of opioid therapy may outweigh potential risks. Although evidence is lacking on best methods for managing such patients, potential risks may be minimized by more frequent and intense monitoring compared with lower risk patients, authorization of limited prescription quantities and consultation or co-management with a specialist in addiction medicine. Clinicians should use the [Controlled Substance Utilization Review and Evaluation System (CURES) Prescription Drug Monitoring Program (PDMP)] CURES PDMP to identify patients who obtain drugs from multiple sources.

If either the patient's medical history, self-report or scores on screening assessment tools such as the Opioid Risk Tool suggest an above-average risk of substance abuse, clinicians should consider the following steps in proceeding with a pain management strategy:

- Exhaust all non-opioid pain management methodologies prior to considering opioid therapy;
- Consult with a specialist in addiction medicine;
- Create a written treatment plan and patient agreement and review carefully with the patient, obtaining their signed informed consent;
- Closely monitor and assess pain, functioning and aberrant behaviors;
- Regularly check with a PDMP for compliance with prescribed amounts of opioids (using cross-state PDMP systems whenever they are available);
- While the patient is on long-term opioid therapy, implement urine drug testing, if possible;
- If misuse or abuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, present options for referral, opioid taper/discontinuation or switching to non-opioid treatments, and avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

[8] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Psychiatric Patients
A higher risk for deleterious side effects exists for patients with psychiatric diagnoses who are receiving opioid treatment. Opioids should only be prescribed for well-defined somatic or neuropathic pain conditions. Physicians should titrate slowly, closely monitor the patient and seek consultation from the appropriate specialist.

Patients Prescribed Benzodiazepines
Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression, particularly elderly patients. Physicians should consider a trial of benzodiazepine tapering in patients concomitantly using opioids or other respiratory depressant medications. If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. For additional information, see Benzodiazepines: How They Work and How to Withdraw.

Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder
Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief of acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see *Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy*.

PATIENT EVALUATION AND RISK STRATIFICATION

When considering long-term use of opioids for chronic, non-cancer pain, given the potential risks of opioid analgesics, careful and thorough patient assessment is critical. Risk stratification is one of the most important things a physician can do to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. This includes but is not limited to:

- Completing a medical history, and physical examination (Appendix 4).
- Performing a psychological evaluation.
    - Psychological assessment should include risk of addictive disorders. Screening tools that can be considered for use include:
        - CAGE-AID (Appendix 5);
        - PHQ-9 (Appendix 6);
        - Opioid Risk Tool (ORT) (Appendix 7); and
        - SOAPP®-R (Appendix 8)
        - Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians must be aware that seasoned diverters know the right answers to these tools so they look "normal."
- Establishing a diagnosis and medical necessity (review past medical records, laboratory studies, imaging studies, etc. and order new ones, if necessary or if

previous studies are outdated). Screening tools that can be considered for use include:
  - Pain Intensity and Interference (pain scale) (Appendix 9)
  - Sheehan Disability Scale (Appendix 10; permission for use pending)
- Exploring non-opioid therapeutic options.
  Opioid medications may not be the appropriate first line of treatment for a patient with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDS), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Resources that can be consulted include:
  - Therapeutic Options for Pain Management (Appendix 11)
  - Non-Opioid Pain Management Tool (Appendix 12; permission for use pending)
- Evaluating both potential benefits and potential risks of opioid therapy.
- Being cognizant of aberrant or drug seeking behaviors.
- As a universal precaution, undertaking urine drug testing.
- Reviewing the Prescription Drug Monitoring Program (PDMP) report for the patient [Controlled Substance Utilization Review and Evaluation System (CURES)]. This allows a physician to check to see if a patient is receiving controlled substances from other prescribers in California (assuming the prescription is being filled at a California pharmacy).

CONSULTATION

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, or an addiction or mental health specialist as needed. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available.

Physicians who prescribe long-term opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed.

TREATMENT PLAN AND OBJECTIVES

When considering long-term use of opioids, for chronic, non-cancer pain, the physician and the patient should develop treatment goals together. The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important, but it is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. Effective pain relief improves functioning,

whereas addiction decreases functionality. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and non-pharmacologic. It also should specify measurable goals and objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function.

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. The treatment plan should also include an "exit strategy" for discontinuing opioid therapy in the event the tapering or termination of opioid therapy becomes necessary.

PATIENT CONSENT

When considering long-term or chronic use of opioids, or in other medically appropriate situations, the physician should discuss the risks and benefits of the treatment plan with the patient, with persons designated by the patient, or with the patient's conservator if the patient is without medical decision-making capacity. If opioids are prescribed, the patient (and possibly family members, if appropriate) should be counseled on safe ways to store and dispose of medications. For convenience, patient consent and a pain management contract can be combined into one document.

Patient consent typically addresses:

- The potential risks and anticipated benefits of long-term opioid therapy.
- Potential side effects (both short-and long-term) of the medication, such as nausea, opioid-induced constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Gegmann et al., 2008) and cognitive impairment.
- The likelihood that some medications will cause tolerance and physical dependence to develop.
- The risk of drug interactions and over-sedation.
- The risk of respiratory depression.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.

PAIN MANAGEMENT AGREEMENT

Use of a pain management agreement is recommended for patients:

- On short-acting opioids at the time of third visit within two months;

- On long-acting opioids; or
- Expected to require more than three months of opioids.

Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:

- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication to prevent misuse by other household members).
- The patient's agreement to share information with family members and other close contacts on how to recognize and respond to an opiate overdose, including administering an opioid antagonist, such as naloxone, if necessary. (Appendix 13)
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice and one pharmacy.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Samples of pain management agreements:

- Patient Pain Medication Agreement and Consent (Appendix 14)
- Treatment Plan Using Prescription Opioids (Appendix 15)

COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE

Empirical evidence has shown that lay persons can be trained to recognize the signs of an opiate overdose and to safely administer naloxone, an opiate antagonist. Programs that have trained lay persons in naloxone administration have reported more than 10,000 overdose reversals.[9]

It is important to educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

[9] Centers for Disease Control and Prevention. Community-based opioid overdose prevention programs providing naloxone-United States, 2010. Morbidity and mortality weekly report, February 17, 2012 / 61(06);101-105

- Snoring heavily and cannot be awakened.
- Periods of ataxic (irregular) or other sleep-disordered breathing.
- Having trouble breathing.
- Exhibiting extreme drowsiness and slow breathing.
- Having slow, shallow breathing with little chest movement or no breathing.
- Having an increased or decreased heartbeat.
- Feeling faint, very dizzy, confused or has heart palpitations.
- Blue skin/lips
- Non-responsiveness to painful stimulation.

Effective January 1, 2015, California pharmacists will be able to furnish an opioid overdose reversal drug, naloxone to family members of patients at risk for overdose, those who might be in contact with an individual at risk for overdose, or anyone who requests the drug without a prescription.

SAMHSA's Opiate Overdose Toolkit and Prescribe to Prevent contain numerous documents relating to overdose prevention and management.

INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 45 days) and with specific evaluation points. The *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*[10] reveals that "[o]ver half of persons receiving 90 days of continuous opioid therapy remain on opioids years later. Factors most strongly associated with continuation were intermittent prior opioid exposure, daily opioid dose≥120 mg MED, and possible opioid misuse. Since high dose and opioid misuse have been shown to increase the risk of adverse outcomes, special caution is warranted when prescribing more than 90 days of opioid therapy in these patients."

The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety.

According to the California Medical Association[11]:

> Oral administration, especially for the treatment of chronic pain, is generally preferred because it is convenient, flexible and associated with stable drug levels. Intravenous administration provides rapid pain relief and, along with rectal, sublingual and subcutaneous administration, may be useful in patients who cannot take medications by mouth. Continuous infusions produce consistent drug blood

[10] Journal of General Internal Medicine article (December 2011, Volume 26, Issue 12, pp 1450-1457).
[11] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

levels but are expensive, require frequent professional monitoring and may limit patient mobility.

Transdermal administration is a convenient alternate means of continuous drug delivery that does not involve needles or pumps. Patient-controlled analgesia (PCA) allows patients to self-administer pain medications and may be useful if analgesia is required for 12 hours or more and mobility is not required. Intrathecal delivery of opioids is a viable option for patients with chronic pain who have not responded to other treatment options, or for whom the required doses result in unacceptable side-effects. Patients with intrathecal delivery systems typically require ongoing ambulatory monitoring and supportive care.

Patients on a steady dose of an opioid medication may experience pain that breaks through the analgesic effects of the steady-state drug. Paper or electronic pain diaries may help patients track these breakthrough episodes and spot correlations between the episodes and variables in their lives. A short-acting opioid is typically prescribed for treatment by patients with breakthrough pain.

Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse, abuse, or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as frail older persons or those with comorbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to “start low and go slow.”

Since opioids are known in some circumstances to worsen pain (hyperalgesia), instances of ongoing pain may suggest opioid insensitivity (or an inadequate dose). Careful assessment must be undertaken. If hyperalgesia is suspected, a dose reduction, opioid rotation or tapering to cessation could be considered.

Dosing Recommendations For Opioid Naïve Patients

There is a plethora of data available regarding recommended dosages for various analgesics. Because this is continuously evolving, physicians are encouraged to review the Food and Drug Administration’s website and other relevant information sources.

Morphine Equivalent Dose (MED)

There are differing opinions among reputable experts and organizations as to what MED should trigger a consultation. The Board recommends that physicians proceed cautiously (yellow flag warning) once the MED reaches 80 mg/day. Referral to an appropriate specialist should be considered when higher doses are contemplated.

There is no absolute safe ceiling dose of opioids, however, and caution and monitoring are appropriate for applications of these medications.

The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

ONGOING PATIENT ASSESSMENT

When a trial of an opioid medication is successful and the physician and patient decide to continue opioid therapy, regular review and monitoring should be undertaken for the duration of treatment.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale or other validated assessment tools, may be helpful and time effective.

Consider the 5-As method for chronic pain management assessment:

Analgesia:	the patient is experiencing a reduction in pain.
Activity:	the patient is demonstrating an improvement in level of function.
Adverse:	the patient is not experiencing side effects.
Aberrance:	the patient is complying with the pain management agreement and there are no signs of medication abuse or diversion.
Affect:	the patient's behavior and mood are appropriate.

"Opioid rotation," the switching from one opioid to another in order to better balance analgesia and side effects, may be used if pain relief is inadequate, if side effects are bothersome or unacceptable, or if an alternative route of administration is suggested. Opioid rotation must be done with great care, particularly when converting from an immediate-release formulation to an Extended Release (ER)/Long Acting (LA) product. Equianalgesic charts, conversion tables and calculators must be used cautiously with titration and appropriate monitoring. Patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind, hence physicians may want to use initially lower-than-calculated doses of the switched-to opioid.

COMPLIANCE MONITORING

Physicians who prescribe opioids or other controlled substances for pain should ensure the provisions of a pain management agreement are being heeded. Strategies for monitoring compliance may include:

- *CURES Report*
  The CURES report can be useful in establishing whether or not an individual is receiving controlled substances from multiple prescribers. The CURES report should be requested frequently for patients who are being treated for pain as well as addiction.

- *Drug Testing*
  A patient's report of medication use is not always reliable; therefore, drug testing can be an important monitoring tool.

  Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist. Urine toxicology tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies and interpreting laboratory data. Laboratories vary in their testing methodologies, thresholds and standards. Results from drug screens may involve diverse drug classes and interpreting them requires clinical understanding well beyond opioids.

  "Variability may result from differences between laboratories. Some labs, for example, only report values above a certain preset threshold. So, a patient might have a measureable level of drug, but since it does not exceed the given threshold, it is reported as "negative" finding. This might lead the physician to suspect that a prescribed drug, which should be present at the time of testing, is absent."[12]

  "Limitations to Urine Drug Testing (UDT): There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug. A recent systematic review of the use of drug treatment agreements and urine drug testing to discourage misuse when opioids are prescribed for chronic non-cancer pain, found weak, heterogeneous evidence that these strategies were associated with less misuse. Limited research did find that UDT was a valuable tool to detect use of non-prescribed drugs and confirm adherence to prescribed medications beyond that identified by

[12] Responsible Opioid Prescribing, A Clinician's Guide, Second Edition, 2012, Scott Fishman, M.D.; Federation of State Medical Boards (FSMB), FSMB Foundation, and University of Nebraska Medical Center.

patient self-report or impression of the treating physician."[13] "Consequently, additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, may be deemed necessary to monitor and treat patients receiving chronic opioid treatment and is considered part of a medically necessary treatment and monitoring program."[14]

It is important to be aware of cost barriers related to a patient's ability to pay for the testing. There are numerous CLIA-waived office drug testing kits which are inexpensive and which physicians may wish to consider for use for initial drug testing, however unexpected results from office-based testing should be confirmed by the more-sensitive laboratory testing before the patient's plan of care is changed.

- *Pill Counting*
  Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing or giving away medications).

The physician must decide whether or not to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory.
If it is suspected that a patient may be abusing or diverting prescribed medications, or using "street" drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of abuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, a language barrier or economic concerns. A physician should arrange for an in-person meeting in order to have a non-judgmental conversation to clarify his or her concerns. If abuse is confirmed, minimally, consultation with an addiction medicine specialist or mental health specialist trained in substance abuse disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be immediately facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient

[13] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part D: Comparison Of Recommendations From Existing Opioid Guidelines.
[14] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part B Recommendations.

relationship. In situations where the patient has engaged in criminal behavior (e.g., prescription forgery or assaultive behaviors), the physician is strongly encouraged to contact the police/ Drug Enforcement Agency (DEA). Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death.

DISCONTINUING OPIOID THERAPY

Discontinuation or tapering of opioid therapy may be required for many reasons and ideally, an "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment.[15] Reasons may include:

- Resolution or healing of the painful condition;
- Intolerable side effects;
- Failure to achieve anticipated pain relief or functional improvement (although ensure that this failure is not the result of inadequate treatment);
- Evidence of non-medical or inappropriate use;
- Failure to comply with monitoring, such as urine drug screening (although ensure that this failure is not the result of a cost issue);
- Failure to comply with pain management contract;
- Exhibition of drug-seeking behaviors (although ensure this behavior is not the result of inadequate treatment) or diversion, such as:
    - Selling prescription drugs;
    - Forging prescriptions;
    - Stealing or borrowing drugs;
    - Aggressive demand for opioids;
    - Injecting oral/topical opioids;
    - Unsanctioned use of opioids;
    - Unsanctioned dose escalation;
    - Concurrent use of illicit drugs;
    - Getting opioids from multiple prescribers and/or multiple pharmacies;
    - Recurring Emergency department visits for chronic pain management.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely-structured tapering regimen. Opioid withdrawal symptoms are uncomfortable, but are generally not life threatening. Opioids can be stopped abruptly when the risks outweigh the benefits. This is not true for benzodiazepine withdrawals, which can be life threatening. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist. "Approaches to weaning range from a slow 10% reduction per week to a more aggressive 25 to 50% reduction every few days. In general, a slower taper will produce fewer unpleasant symptoms of withdrawal."[16] For strategies on tapering and weaning, see Appendix 16. The termination of opioid therapy should not mark the end

[15] Responsible Opioid Prescribing, A Clinician's Guide, Second Edition, 2012, Scott Fishman, M.D.; Federation of State Medical Boards (FSMB), FSMB Foundation, and University of Nebraska Medical Center.
[16] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If complete termination of care is necessary (as opposed to termination of a specific treatment modality), physicians should treat the patient until the patient has had a reasonable time to find an alternative source of care, and ensure that the patient has adequate medications, if appropriate, to avoid unnecessary risk from withdrawal symptoms. Physicians can be held accountable for patient abandonment if medical care is discontinued without justification or adequate provision for subsequent care. If a patient is known to be abusing a medication, initiating a detoxification protocol may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Physicians may want to also consult health plan contracts to ensure compliance. The Board provides guidance on how to terminate/sever the patient relationship.

If a patient is dismissed for not honoring treatment agreements, consider referral to addiction resources. This can also include a 12-step program.

MEDICAL RECORDS

Every physician must maintain adequate and accurate medical records. The content of a patient's medical record may vary considerably, depending on numerous factors. For a physician treating a patient with opioids for chronic, non-cancer pain, an adequate medical record includes, but is not limited to, the documentation of:

- the patient's medical history;
- results of the physical examination and all laboratory tests ordered by the physician;
- patient consent;
- pain management agreement;
- results of the risk assessment, including results of any screening instruments used;
- description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity);
- instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement;
- notes on evaluations by and consultations with specialists;
- any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors (these may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers);
- authorization for release of information to other treatment providers as appropriate and/or legally required; and
- results of CURES data searches.

The medical record should include all prescription orders for opioid analgesics and other controlled substances, whether written, telephoned or electronic. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed, if the pharmacy that the patient will use is known. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review.

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.

SUPERVISING ALLIED HEALTH PROFESSIONALS

Physicians who supervise physician assistants or nurse practitioners who prescribe opioids should be aware of the specific regulations and requirements.

COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS

California laws:

- California laws regarding controlled substances
- Guide to the Laws Governing the Practice of Medicine

Federal laws:

- Title 21 United States Code (USC) Controlled Substances Act

Other information:

- Pharmacist corresponding responsibilities

Appendix 1 - Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the ED

Please see pages BRD 16-59 to BRD 16-85.

Appendix 2 - Older Adults

Older Adults[17]

The prevalence of pain among older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution and clinicians should "start low, go slow" with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended.

The various challenges of pain management in older adults, only sketched here, suggest that early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

[17] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 3 - Pediatric Patients

Pediatric Patients[18]

Children of all ages deserve compassionate and effective pain treatment. In fact, due to their more robust inflammatory response and immature central inhibitory influences, infants and young children actually may experience greater pain sensations and pain-related distress than adults. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a place in the treatment armamentarium. Developmental differences, however, can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn's life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance. For older children, dosing must be adjusted for body weight.

Although a thorough discussion of this topic is not possible in this document, the following are summary recommendations for pain management in children and teens from the American Pain Society and the American Academy of Pediatrics:

- Provide a calm environment for procedures that reduce distress-producing stimulation;
- Use age-appropriate pain assessment tools and techniques;
- Anticipate predictable painful experiences, intervene and monitor accordingly;
- Use a multimodal approach (pharmacologic, cognitive, behavioral and physical) to pain management and use a multidisciplinary approach when possible;
- Involve families and tailor interventions to the individual child; and
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain.

[18] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 4 - Patient Evaluation and Risk Stratification

Patient Evaluation and Risk Stratification[19]

The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing?.

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

[19] Federation of State Medical Boards - Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers.

If possible, the patient evaluation should include information from family members and/or significant others. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community.

Appendix 5 - CAGE-AID

CAGE-AID Questionnaire

CAGE-AID Questionnaire

Patient Name _____ Date of Visit _____

When thinking about drug use, include illegal drug use and the use of prescription drug other than prescribed.

Questions:	YES	NO
1. Have you ever felt that you ought to cut down on your drinking or drug use?	☐	☐
2. Have people annoyed you by criticizing your drinking or drug use?	☐	☐
3. Have you ever felt bad or guilty about your drinking or drug use?	☐	☐
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	☐	☐

Scoring
Regard one or more positive responses to the CAGE-AID as a positive screen.

Psychometric Properties

The CAGE-AID exhibited:	Sensitivity	Specificity
One or more Yes responses	0.79	0.77
Two or more Yes responses	0.70	0.85

(Brown 1995)

Appendix 6 - PHQ-9 Nine Symptom Checklist

PHQ-9 — Nine Symptom Checklist

Patient Name _____ **Date** _____

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.

   a. Little interest or pleasure in doing things
   Not at all **Several days** **More than half the days** **Nearly every day**

   b. Feeling down, depressed, or hopeless
   Not at all **Several days** **More than half the days** **Nearly every day**

   c. Trouble falling asleep, staying asleep, or sleeping too much
   Not at all **Several days** **More than half the days** **Nearly every day**

   d. Feeling tired or having little energy
   Not at all **Several days** **More than half the days** **Nearly every day**

   e. Poor appetite or overeating
   Not at all **Several days** **More than half the days** **Nearly every day**

   f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down
   Not at all **Several days** **More than half the days** **Nearly every day**

   g. Trouble concentrating on things such as reading the newspaper or watching television
   Not at all **Several days** **More than half the days** **Nearly every day**

   h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual
   Not at all **Several days** **More than half the days** **Nearly every day**

   i. Thinking that you would be better off dead or that you want to hurt yourself in some way
   Not at all **Several days** **More than half the days** **Nearly every day**

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

   Not Difficult at All **Somewhat Difficult** **Very Difficult** **Extremely Difficult**

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PHQ-9 — Scoring Tally Sheet

Patient Name _____ **Date** _____

1. **Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.**

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling asleep, staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down				
g. Trouble concentrating on things such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual				
i. Thinking that you would be better off dead or that you want to hurt yourself in some way				
Totals				

2. **If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**

Not Difficult At All	Somewhat Difficult	Very Difficult	Extremely Difficult
0	1	2	3

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How to Score PHQ-9

Scoring Method For Diagnosis

Major Depressive Syndrome is suggested if:

- Of the 9 items, 5 or more are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Minor Depressive Syndrome is suggested if:

- Of the 9 items, b, c, or d are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Scoring Method For Planning And Monitoring Treatment

Question One

- To score the first question, tally each response by the number value of each response:

  Not at all = 0

  Several days = 1

  More than half the days = 2

  Nearly every day = 3
- Add the numbers together to total the score.
- Interpret the score by using the guide listed below:

Score	Action
≤4	The score suggests the patient may not need depression treatment.
> 5-14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment.
≥15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment

Question Two

In question two the patient responses can be one of four: not difficult at all, somewhat difficult, very difficult, extremely difficult. The last two responses suggest that the patient's functionality is impaired. After treatment begins, the functional status is again measured to see if the patient is improving.

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Appendix 7 - Opioid Risk Tool (ORT)

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		[ ]		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8

Appendix 8 - SOAPP®-R

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is NOT intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

SAMPLE

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SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

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Scoring Instructions for the SOAPP®-R

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is 2.5 times (2.53 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	2.53	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician' care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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Appendix 9 - Pain Intensity and Interference (pain scale)

Pain Intensity and Interference (pain scale)[20]

Pain intensity and interference

In the last month, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? [*That is, your usual pain at times you were in pain.*]

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

In the last month, how much has pain interfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

Interpretation of the Two Item Graded Chronic Pain Scale – This two item version of the Graded Chronic Pain Scale is intended for brief and simple assessment of pain severity in primary care settings. Based on prior research, the interpretation of scores on these items is as follows:

Pain Rating Item	Mild	Moderate	Severe
Average/Usual Pain Intensity	1–4	5–6	7–10
Pain-related interference with activities	1–3	4–6	7–10

Although pain intensity and pain-related interference with activities are highly correlated and tend to change together, it is recommended that change over time be tracked for pain intensity and pain-related interference with activities separately when using these two items.

For an individual patient, a reduction in pain intensity and improvement in pain-related interference with activities of two points is considered moderate but clinically significant improvement.

Similar pain ratings have been widely used in the Brief Pain Inventory, the Multidimensional Pain Inventory, and the Pain Severity Scale of the SF-12.

There is extensive research on the reliability, validity and responsiveness to change of these pain severity ratings, which is summarized in the following reference:

Von Korff M. Chronic Pain Assessment in Epidemiologic and Health Services Research: Empirical Bases and New Directions. Handbook of Pain Assessment: Third Edition. Dennis C. Turk and Ronald Melzack, Editors. Guilford Press, New York., In press

[20] Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy (Washington State Agency Medical Directors' Group)

Appendix 10 - Sheehan Disability Scale

Sheehan Disability Scale - permission for use pending

Appendix 11 - Therapeutic Options for Pain Management

Therapeutic Options for Pain Management[21]

In treating pain, clinicians can avail themselves of five basic modalities of pain-management tools:

1. Cognitive-behavioral approaches
2. Rehabilitative approaches
3. Complementary and alternative therapies
4. Interventional approaches
5. Pharmacotherapy

Not all of these options are necessary or appropriate for every patient, but clinical guidelines suggest that all options should be considered every time a health care provider decides to treat a patient with chronic pain. These options can be used alone or in combinations to maximize pain control and functional gains. Only one of these options involves medications and opioids are only one of many types of medications with potential analgesic utility. Which options are used in a given patient depends on factors such as the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost and the local availability of the treatment option.

Cognitive-behavioral Approaches

The brain plays a vitally important role in pain perception and in recovery from injury, illness or other conditions involving pain. Psychological therapies of all kinds, therefore, may be a key element in pain management. At the most basic level, such therapy involves patient education about disease states, treatment options or interventions, and methods of assessing and managing pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called “catastrophizing” or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to “fix” their pain with little or no work or responsibility on their part. Another way to frame this is to assess whether a patient has an internal or external “locus of control” relative to their pain. Someone with an external locus of control attributes the cause/relief of pain to external causes and they expect that the relief comes from someone else. Someone with an internal locus of control believes that they are responsible for their own well being; they own the experience of pain and recognize they have the ability and obligation to undertake remediation, with the help of others.

Some chronic pain patients have a strong external locus of control, and successful management of their pain hinges, in part, on the use of cognitive or other types of

[21] California Medical Association (Prescribing Opioids: Care amid Controversy March 2014)

therapy to shift the locus from external to internal. Individual, group or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient.

In general, psychological interventions may be best suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, or whose personal relationships are suffering as a result of chronic or recurrent pain. Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive provider reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall function.

Rehabilitative Approaches

In addition to relieving pain, a range of rehabilitative therapies can improve physical function, alter physiological responses to pain and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility; gait and posture training; stretching; and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga or core-training may also be useful. Other noninvasive physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

Complementary and Alternative Therapies

Complementary and alternative therapies (CAT) of various types are used by many patients in pain, both at home and in comprehensive pain clinics, hospitals or other facilities.27 These therapies seek to reduce pain, induce relaxation and enhance a sense of control over the pain or the underlying disease. Meditation, acupuncture, relaxation, imagery, biofeedback and hypnosis are some of the therapies shown to be potentially helpful to some patients. CAT therapies can be combined with other pain treatment modalities and generally have few, if any, risks or attendant adverse effects. Such therapies can be an important and effective component of an integrated program of pain management.

Interventional Approaches

Although beyond the scope of this paper, a wide range of surgical and other interventional approaches to pain management exist, including trigger point injections, epidural injections, facet blocks, spinal cord stimulators, laminectomy, spinal fusion, deep brain implants and neuro-augmentative or neuroablative surgeries. Many of these approaches involve some significant risks, which must be weighed carefully against the potential benefits of the therapy.

Pharmacotherapy

Many types of medications can be used to alleviate pain, some that act directly on pain signals or receptors, and others that contribute indirectly to either reduce pain or improve function. For patients with persistent pain, medications may be used concurrently in an effort to target various aspects of the pain experience.

NSAIDs and Acetaminophen

Non-steroidal anti-inflammatory drugs (NSAIDs), which include aspirin and other salicylic acid derivatives, and acetaminophen, are categorized as non-opioid pain relievers. They are used in the management of both acute and chronic pain such as that arising from injury, arthritis, dental procedures, swelling or surgical procedures. Although they are weaker analgesics than opioids, acetaminophen and NSAIDs do not produce tolerance, physical dependence or addiction. Acetaminophen and NSAIDs are also frequently added to an opioid regimen for their opioid-sparing effect. Since non-opioids and opioids relieve pain via different mechanisms, combination therapy can provide improved relief with fewer side effects.

These agents are not without risk, however. Adverse effects of NSAIDs as a class include gastrointestinal problems (e.g., stomach upset, ulcers, perforation, bleeding, liver dysfunction), bleeding (i.e., antiplatelet effects), kidney dysfunction, hypersensitivity reactions and cardiovascular concerns, particularly in the elderly. The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4,000 mg in patients without liver disease (although the ceiling may be lower for older adults).

In 2009, the FDA required manufacturers of products containing acetaminophen to revise their product labeling to include warnings of the risk of severe liver damage associated with its use. In 2014, new FDA rules went into effect that set a maximum limit of 325 mg of acetaminophen in prescription combination products (e.g. Vicodin and Percocet) in an attempt to limit liver damage and other ill effects from the use of these products. Of note, aspirin (> 325 mg/d), ibuprofen, ketoprofen, naproxen and other non-cyclooxygenase-selective NSAIDs, are listed as “potentially inappropriate medications” for use in older adults in the American Geriatrics Society 2012 Beers Criteria because of the range of adverse effects they can have at higher doses.

Nonetheless, with careful monitoring, and in selected patients, NSAIDs and acetaminophen can be safe and effective for long-term management of persistent pain.

Opioids

Opioids can be effective pain relievers because, at a molecular level, they resemble compounds, such as endorphins, which are produced naturally in the human central nervous system. Opioid analgesics work by binding to one or more of the three major

types of opioid receptors in the brain and body: mu, kappa and delta receptors. The most common opioid pain medications are called “mu agonists” because they bind to and activate mu opioid receptors. The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation).

Physical tolerance develops for some effects of opioids, but not others. For example, tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects is unlikely to occur. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition remains stable.

Opioids, as a class, comprise many specific agents available in a wide range of formulations and routes of administration. Short-acting, orally-administered opioids typically have rapid onset of action (10-60 minutes) and a relatively short duration of action (2-4 hours). They are typically used for acute or intermittent pain, or breakthrough pain that occurs against a background of persistent low-level pain. Extended-release/long-acting (ER/LA) opioids have a relatively slow onset of action (typically between 30 and 90 minutes) and a relatively long duration of action (4 to 72 hours). The FDA states that such drugs are “indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

These agents achieve their extended activity in various ways. Some have intrinsic pharmacokinetic properties that make their effects more enduring than short-acting opioids, while others are modified to slow their absorption or to slow the release of the active ingredient. A given patient might be appropriate for ER/LA therapy only, short-acting only or a combination of an ER/LA opioid with a short-acting opioid. Note that patients may respond in very different ways to any given medication or combination of medications. One size does not fit all, and treatment is best optimized by titrating a given regimen on an individual basis. Combination products that join an opioid with a non-opioid analgesic entail the risk of increasing adverse effects from the non-opioid co-analgesic as doses are escalated, even if an increase of the opioid dose is appropriate.

In response to concerns about opioid misuse and abuse, abuse-deterrent and tamper-resistant opioid formulations have been developed. One class of deterrent formulation incorporates an opioid antagonist into a separate compartment within a capsule; crushing the capsule releases the antagonist and neutralizes the opioid effect. Another strategy is to modify the physical structure of
tablets or incorporate compounds that make it difficult or impossible to liquefy, concentrate, or otherwise transform the tablets. Although abuse-deterrent opioid formulations do not prevent users from simply consuming too much of a medication, they may help reduce the public health burden of prescription opioid abuse.

Patients who receive opioids on a long-term basis to treat pain are considered to be receiving long-term opioid analgesic therapy, which is differentiated from opioid use by patients who have an established opioid use disorder who use an opioid (e.g. methadone) as part of their treatment program.

Potential Adverse Effects of Opioids

Although opioid analgesics (of all formulations) may provide effective relief from moderate-to-severe pain, they also entail the following significant risks:

• Overdose
• Misuse and diversion
• Addiction
• Physical dependence and tolerance
• Potentially grave interactions with other medications or substances
• Death

At the heart of much of the current controversy over the use of opioid analgesics for chronic pain are beliefs about the degree to which these pain medications are potentially addicting. Unfortunately, it is difficult to quantify the degree of addictive risk associated with opioid analgesics, either for an individual patient or the population of pain patients in general.

In this context, it is critical to differentiate addiction from tolerance and physical dependence which are common physiological responses to a wide range of medications and even to widely-consumed non-prescription drugs (e.g. caffeine). Physical dependence and tolerance alone are not synonymous with addiction. Addiction is a complex disease state that severely impairs health and overall functioning. Opioid analgesics may, indeed, be addicting, but they share this potential with a wide range of other drugs such as sedatives, alcohol, tobacco, stimulants and anti-anxiety medications.

Rigorous, long-term studies of both the potential effectiveness and potential addictive risks of opioid analgesics for patients who do not have co-existing substance-use disorders have not been conducted. The few surveys conducted in community practice settings estimate rates of prescription opioid abuse of between 4% to 26%. A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of opioid-use disorder of 35%.41 The variability in results reflect differences in opioid treatment duration, the short-term nature of most studies and disparate study populations and measures used to assess abuse or addiction. Although precise quantification of the risks of abuse and addiction among patients prescribed opioids is not currently possible, the risks are large enough to underscore the importance of stratifying patients by risk and providing proper monitoring and screening when using opioid analgesic therapy.

Particular caution should be exercised when prescribing opioids to patients with conditions that may be complicated by adverse effects from opioids, including chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current or past alcohol or substance misuse, mental illness, advanced age or patients with a history of kidney or liver dysfunction.

In addition, opioids generally should not be combined with other respiratory depressants, such as alcohol or sedative-hypnotics (benzodiazepines or barbiturates) unless these agents have been demonstrated to provide important clinical benefits, since unexpected opioid fatalities can occur in these combination situations at relatively low opioid doses.

In addition to the potential risks just described, opioids may induce a wide range of side effects including respiratory depression, sedation, mental clouding or confusion, hypogonadism, nausea, vomiting, constipation, itching and urinary retention. With the exception of constipation and hypogonadism, many of these side effects tend to diminish with time. Constipation requires prophylaxis that is prescribed at the time of treatment initiation and modified as needed in response to frequent monitoring. With the exception of constipation, uncomfortable or unpleasant side effects may potentially be reduced by switching to another opioid or route of administration (such side effects may also be alleviated with adjunctive medications). Although constipation is rarely a limiting side effect, other side effects may be intolerable. Because it is impossible to predict which side effects a patient may experience, it is appropriate to inquire about them on a regular basis.

Patients should be fully informed about the risk of respiratory depression with opioids, signs of respiratory depression and about steps to take in an emergency. Patients and their caregivers should be counseled to immediately call 911 or an emergency service if they observe any of these warning signs.

As of January 2014, a California physician may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. A physician may also issue a standing order for the administration of an opioid antagonist to a person at risk of an opioid-related overdose to a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

The potential of adverse effects and the lack of data about the addictive risks posed by opioids do not mean these medications should not be used. Common clinical experience and extensive literature document that some patients benefit from the use of opioids on a short or long term basis. Existing guidelines from many sources, including physician specialty societies (American Academy of Pain Medicine, The American Pain Society), various states (Washington, Colorado, Utah), other countries (Canada) and federal agencies (Department of Defense, Veterans Administration), reflect this potential clinical utility.

Recommendations from authoritative consensus documents have been summarized in concise, user-friendly formats such as: Responsible Opiate Prescribing: A Clinician's Guide for the Federation of State Medical Boards; the 2013 Washington State Labor and Industries Guideline for Prescribing Opioids to Treat Pain in Injured Workers; and the Agency Medical Directors' Group 2010 Opioid Dosing Guideline for Chronic Non-Cancer Pain.

Methadone

Particular care must be taken when prescribing methadone. Although known primarily as a drug used to help patients recovering from heroin addiction, methadone can be an effective opioid treatment for some pain conditions. Methadone is a focus of current debate because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used to treat chronic pain.

Methadone must be prescribed even more cautiously than other opioids and with full knowledge of its highly variable pharmacokinetics and pharmacodynamics. Of critical importance is the fact that methadone's analgesic half-life is much shorter than its elimination half-life. This can lead to an accumulation of the drug in the body. In addition, methadone is metabolized by a different group of liver enzymes than most other opioids, which can lead to unexpected drug interactions.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. Consensus recommendations suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances, especially alcohol and other sedatives, with their medication. This should be explicitly stated in any controlled substance agreement that the patient receives, reads and signs before the initiation of treatment […].

Although uncommon, potentially lethal cardiac arrhythmias can be induced by methadone. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to a history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. In addition, it is important that an ECG be repeated periodically, because QT interval prolongation has been demonstrated to be a function of methadone blood levels and/or in response to a variety of other medications.

Adjuvant Pain Medications

Although opioid medications are powerful pain relievers, in the treatment of neuropathic pain and some other centralized pain disorders such as fibromyalgia, they are of limited effectiveness and are not preferred. Other
classes of medications, however, may provide relief for pain types or conditions that do not respond well to opioids. Some of these adjuvant medications exert a direct analgesic effect mediated by non-opioid receptors centrally or peripherally. Others have no direct analgesic qualities but may provide pain relief indirectly via central or peripheral affects.

Commonly-used non-opioid adjuvant analgesics include antiepileptic drugs (AEDs), tricyclic antidepressants (TCAs) and local anesthetics (LAs). AEDs, such as gabapentin and pregabalin, are used to treat neuropathic pain, especially shooting, stabbing or knife-like pain from peripheral nerve syndromes.TCAs and some newer types of antidepressants may be valuable in treating a variety of types of chronic and neuropathic pain, including post-herpetic neuralgia and diabetic neuropathy. LAs are used to manage both acute and chronic pain. Topical application provides localized analgesia for painful procedures or conditions with minimal systemic absorption or side effects. Topical Las are also used to treat neuropathic pain. Epidural blocks with LAs, with or without opioids, play an important role in managing postoperative and obstetrical pain.

Appendix 12 - Non-Opioid Pain Management Tool

Non-Opioid Pain Management Tool - permission for use pending

Appendix 13 – Suggested Language on Naloxone for Pain Management Agreement

- I understand that "overdose" is a risk of opioid therapy which can lead to death. I understand and can recognize the signs and symptoms of overdose including respiratory depression.

- I understand that I will be prescribed naloxone because overdose is a risk of opioid therapy. I understand that naloxone is a drug that can reverse opioid overdose. I understand when and how to use naloxone.
  - I understand it is strongly encouraged to share information about naloxone with my family and friends.
  - I understand it is strongly encouraged to teach family and friends how to respond to an overdose.

Appendix 14 – Suggested Patient Pain Medication Agreement and Consent

PATIENT PAIN MEDICATION AGREEMENT AND CONSENT

This agreement is important for you:

- *You will have a safe and controlled pain treatment plan.*
- *Your medicines have a high potential for abuse. They can be dangerous if used in the wrong way. You need to understand the risks that come from use of pain medicines.*

Please read and make sure you understand each statement here. Here are rules about refills and health risks. Here are also reasons for stopping your pain control treatment.

I WILL:

- ☐ I will only get my pain medicine from this clinic during scheduled appointments.
- ☐ I will take my pain medicine the way that my healthcare provider has ordered.
- ☐ I will be honest with all my healthcare providers if I am using street drugs.
- ☐ I will be honest about all the medicine I use. This includes medicine from stores and herbal medicines.
- ☐ I will be honest about my full health history.
- ☐ I will tell my healthcare provider if I go to an emergency room for any reasons.
- ☐ If I get pain medicine from an emergency room, I will tell my healthcare provider.
- ☐ I will call this office if I am prescribed any new medicine.
- ☐ I will call this office if I have a reaction to any medicine.
- ☐ I will tell all other healthcare providers that I have a pain medication agreement.
- ☐ I will tell the emergency room people that I have a pain medication agreement.
- ☐ I will take drug tests and other tests when I am told to do so.
- ☐ I will go to office visits when I am told to do so.
- ☐ I will go to physical therapy when I am told to do so.
- ☐ I will go to counseling when I am told to do so.
- ☐ I will follow directions for all treatment.
- ☐ I will show up on time for all appointments.
- ☐ I will make an appointment for refills before I run out of medicine.
- ☐ I will tell my health provider if I will be out of town so that I can get my refills.
- ☐ I will get past health records from other offices when needed.
- ☐ I will deliver these records by hand if needed. I will do this within one month of being asked. I will pay for these records if needed.
- ☐ I will give permission to this clinic to talk about my treatment with pharmacies, doctors, nurses, and others who are helping me.
- ☐ I will give permission to any healthcare provider to get information from this clinic about my health and my pain treatment.
- ☐ I will take responsibility if I overdose myself accidentally or on purpose.
- ☐ I will tell my healthcare provider if I plan to become pregnant.
- ☐ I will tell my healthcare provider if I am pregnant while I am taking pain medicine.
- ☐ I will only take this medicine the way I was told to take it.

CONTINUED ON NEXT PAGE

I WILL NOT:

- ☐ I will not share or sell, or trade any of my medicine.
- ☐ I will not drink alcohol or take street drugs while I am taking pain medicine.
- ☐ I know that I cannot call the office to have my medicine refilled over the phone.
- ☐ I will not go to the emergency room or other doctors for more pain medicine or other drugs.
- ☐ I know that when I drive a car, I must be fully alert. I know that when I use machines, I must also be fully alert. Pain medicines can make me less alert. When I am taking pain medicines, I need to be sure that I am alert. I need to be sure that it is safe for me to drive a car or use a machine.
- ☐ I will not stand in high places or do anything to hurt others after I have taken pain medicine.
- ☐ I will not leave my medicine where it can be stolen or where others can take it.
- ☐ I will not leave my medicine where children can find it.
- ☐ I will not suddenly stop taking my medicine. I know that if I do this, I can have withdrawals.

WHEN USING A PHARMACY, I WILL:

- ☐ I will use the same pharmacy for all my medicines. This is the pharmacy that I have picked: _____
- ☐ I will not ask for early refills or more pain medicine, even if I lose my medicine.

I KNOW THAT

- ☐ Pain management may include other treatment. Some treatment may not include medicine.
- ☐ Pain medicine will probably not get rid of all of my pain. Pain medicine can reduce my pain so that I can do more and have a better life.
- ☐ Part of my treatment is to reduce my need for pain medicine.
- ☐ If the pain medicines work, I will continue to use them. If the pain medicine does not help me, it will be stopped.
- ☐ My medicines will not be replaced if any of these things happen: Medicine is lost. Medicine gets wet. Medicine is destroyed
- ☐ If my medicine is stolen, I might be able to get more medicine if I get a report from the police about the medicine being stolen.
- ☐ Any of my healthcare providers can find out from the California Prescription Drug Monitoring Program about any other medicines I get from any other pharmacy in California. This is called a CURES report.
- ☐ My healthcare provider may contact the drug enforcement agency, if I try to get other doctors to give me pain medicine.
- ☐ Healthcare providers may contact the drug enforcement agency if I am not honest about how I take pain medicine.
- ☐ My doctor and my clinic will help with any investigation if I am suspected of prescription drug abuse.
- ☐ I may be sent somewhere else for drug abuse or addiction help if I need it.
- ☐ Pain medicine can be addictive. This means that my body may need more and more pain medicine or that it can be hard for me to stop taking this medicine.
- ☐ If I suddenly stop using the medicine, I can get withdrawals.
- ☐ If I use too much pain medicine, I can end up with health problems. I could die.
- ☐ If I mix medicines, I could also end up with health problems. I could die.
- ☐ Here are some things that could go wrong if I use too much medicine or mix medicines:

Overdose	Addiction	Constipation	Vomiting	Sleepiness
Slower reflexes	Nausea	Difficulty with urination	Confusion	Itching
Problems with sex	Dry mouth	Depression	Trouble breathing	Death

CAUSE FOR DISMISSAL FROM THIS CLINIC

- ☐ I know that the pain medicines may be stopped if I break any part of this contract.

My signature below means that I have read this contract. I am signing this to say that I understand all of this contract.

Patient Name _____ Doctor Name _____

Patient Signature _____ Doctor Signature_____

Date: _____

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Appendix 15 – Suggested Treatment Plan Using Prescription Opioids

Treatment Plan Using Prescription Opioids

Patient name: _____

Prescriber name: _____

THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.

I (patient) understand the following (initial each):

_____ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: _____

_____ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: _____

_____ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

_____ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

_____ There is a small risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

I agree to the following (initial each):

_____ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

_____ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

_____ I agree not to share, sell, or in any way provide my medication to any other person.

_____ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

_____ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

_____ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

_____ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

_____ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

_____ _____

Patient Signature Date

_____ _____

Prescriber Signature Date

Appendix 16 – Suggested Strategies for Tapering and Weaning

Strategies for Tapering & Weaning

Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation ("You are indifferent to my suffering")
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

TOOLS

Washington State Agency Medical Directors' Group, 2007

Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

From the American College of Emergency Physicians Opioid Guideline Writing Panel
Stephen V. Cantrill, MD (Chair)
Michael D. Brown, MD, MSc (Methodologist)
Russell J. Carlisle, MD
Kathleen A. Delaney, MD
Daniel P. Hays, PharmD, BCPS
Lewis S. Nelson, MD
Robert E. O'Connor, MD, MPH (ACEP Board Liaison)
AnnMarie Papa, DNP, RN, CEN, NE-BC (ENA Representative)
Karl A. Sporer, MD
Knox H. Todd, MD, MPH
Rhonda R. Whitson, RHIA (Clinical Practice Manager, ACEP)

Providing Technical Assistance:

Leonard J. Paulozzi, MD, MPH, Medical Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention
Chet Pogostin, DVM, MPA, Deputy Director, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention
Bob A. Rappaport, MD, Director, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, Food and Drug Administration
Jacqueline Spaulding, MD, Medical Officer, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, Food and Drug Administration

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ABSTRACT

This clinical policy deals with critical issues in prescribing of opioids for adult patients treated in the emergency department (ED). This guideline is the result of the efforts of the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, and the Food and Drug Administration. The critical questions addressed in this clinical policy are: (1) In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse? (2) In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? (3) In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids? (4) In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

INTRODUCTION

Pain is a major symptom of many patients presenting to the emergency department (ED), with up to 42% of ED visits being related to painful conditions.[1] Pain management has received increased emphasis in the past decade, including The Joint Commission's focus on patient analgesia[2] and increasing institutional emphasis placed on patient satisfaction surveys covering pain management. Much literature, including the most recent Institute of Medicine report on this topic, has stressed that health care providers have not done as well as possible in the area of pain management.[3] A possible unintended consequence of these efforts is the increase in prescription drug abuse, especially opioid abuse, the fastest-growing drug abuse problem in the United States.[4]

As part of this issue, there has been a startling increase in unintentional drug overdoses and related deaths since the late 1990s.[5,6] Reported overdose deaths involving opioid analgesics increased from 4,030 in 1999 to 14,800 in 2008.[7,8] Data from 2008 reveal that drug overdoses were the second leading cause of injury death in the United States, after motor vehicle crashes.[9] Currently, deaths from opioid analgesics are significantly greater in number than those from cocaine and heroin combined.[8]

The efforts of clinicians to improve their treatment of pain, along with pharmaceutical industry marketing, have been factors in contributing to a significant increase in the sale and distribution of opioids in the United States. For example, the sales of opioid analgesics to hospitals, pharmacies, and practitioners quadrupled between 1999 and 2010.[8] Drug sales and distribution data of opioids show an increase from 180 mg morphine equivalents per person in the United States in 1997 to 710 mg per person in 2010.[8,10] This is the equivalent of 7.1 kg of opioid medication per 10,000 population, or enough to supply every American adult with 5 mg of hydrocodone every 4 hours for a month.[8]

The dilemma of treating pain appropriately while avoiding adverse events is further complicated by insufficient data supporting the long-term use of opioids in the treatment of chronic noncancer pain. Although selective use of opioids in the treatment of acute pain is traditionally accepted, the treatment of chronic noncancer pain is more complex. Many authors have begun to question the routine long-term use of opioids for the treatment of chronic noncancer pain.[11-13] Multiple practice guidelines have been developed to address this issue.[14-19] However, most recommendations in this area are of a consensus nature, being based on experiential or low-quality evidence.

Data from 2009 show that there were more than 201.9 million opioid prescriptions dispensed in the United States during that year.[20] It is difficult to obtain reliable data concerning the degree to which this is an emergency medicine issue, but during 2009, in the 10- to 19-year-old and 20- to 29-year-old patient groups, emergency medicine ranked third among all specialties in terms of number of opioid prescriptions, writing approximately 12% of the total prescriptions in each age group. In the 30- to 39-year-old group, emergency medicine ranked fourth.[20] Although these data do not deal with total doses dispensed by specialty, it is commonly postulated that the population served in EDs as a whole is at high risk for opioid abuse.[21]

The significant increase in opioid-related deaths has raised the concern of many.[5,6,8] This problem has also been observed in the pediatric population.[22-24] Action at the national level includes the recent proposal from the Food and Drug Administration for the establishment of physician education programs for the prescribing of long-acting and extended-release opioids as part of their national opioid risk evaluation and mitigation strategy (the REMS program).[25] State efforts to address this issue have included the development of statewide opioid prescribing guidelines, such as those developed by the Utah Department of Health[17] and statewide ED opioid prescribing guidelines, such as those developed in Washington State by the Washington chapter of the American College of Emergency Physicians (ACEP) working with other state organizations.[16] Some individual EDs and emergency physician groups have also promulgated opioid prescribing guidelines. Some of these policies also deal with the necessity of patient education about the safe use and proper disposal of opioid medications. Early data indicate that, in some cases, these guidelines may decrease prescription opioid overdose.[26] Anecdotal experience suggests that public policies such as these may change patient perceptions of appropriate prescribing and mitigate complaints arising from more stringent prescribing practices. ACEP has approved related policy statements about optimizing the treatment of pain in patients with acute presentations and the implementation of electronic prescription drug monitoring programs.[27,28]

This clinical policy addresses several issues believed to be important in the prescribing of opioids by emergency physicians for adult patients treated and released from the ED for whom opioids may be an appropriate treatment modality. Although relieving pain and reducing suffering are primary emergency physician responsibilities, there is a concurrent duty to limit the personal and societal harm that can result from prescription drug misuse and abuse. Because long-acting or extended-release opioids are not indicated for the treatment of acute pain, the aim of this clinical policy is to provide evidence-based recommendations for prescribing short-acting opioids for adult ED patients with painful acute or chronic conditions while attempting to address the increasing frequency of adverse events, abuse, and overdose of prescribed opioid analgesics.

METHODOLOGY

This clinical policy was created after careful review and critical analysis of the medical literature. The critical questions were formulated in the PICO (patient, intervention, comparison, outcome)[29] format to strengthen the clarity and scientific rigor of the questions. Searches of MEDLINE, MEDLINE InProcess, and the Cochrane Library were performed. All searches were limited to English-language sources, human studies, adults, and years 2000 to 2011. Specific key words/phrases and years used in the searches are identified under each critical question. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members were included.

This policy is a product of the ACEP clinical policy development process, including expert review, and is based on the literature; when literature was not available, consensus of panel members was used. Expert review comments were received from emergency physicians, toxicologists, pain and addiction medicine specialists, pharmacologists, occupational medicine specialists, and individual members of the American Academy of Clinical Toxicology, American Academy of Family Physicians, American Academy of Pain Medicine, American Chronic Pain Association, American College of Occupational and Environmental Medicine, American College of Osteopathic Emergency Physicians, American College of Physicians, American Pain Society, American Society of Health-System Pharmacists, American Society of Interventional Pain Physicians, Emergency Medicine Resident's Association, and Emergency Nurses Association. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy. Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly. The Centers for Disease Control and Prevention was the funding source for this clinical policy.

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for quality and strength of evidence. The articles were classified into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic studies, respectively (Appendix A). Articles were then graded on dimensions related to the study's methodological features: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (eg, selection, detection, transfer), external validity (ie, generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula, taking into account the design and study quality (Appendix B). Articles with fatal flaws or that were not relevant to the critical question were given an "X" grade and were not used in formulating recommendations for this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may have varied according to the question, and it is possible for a single article to receive different levels of grading as different critical questions were answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of this policy. Evidence grading sheets may be viewed at http://www.acep.org/clinicalpolicies/?pg=1.

Clinical findings and strength of recommendations about patient management were then made according to the following criteria:

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (ie, based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

Level C recommendations. Other strategies for patient management that are based on Class III studies, or in the absence of any adequate published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

This policy is not intended to be a complete manual on the evaluation and management of adult ED patients with painful conditions where prescriptions for opioids are being considered, but rather is a focused examination of critical issues that have

particular relevance to the current practice of emergency medicine.

The goal of the ACEP Opioid Guideline Panel is to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain enough quality information to answer a critical question, the members of the ACEP Opioid Guideline Panel believe that it is equally important to alert emergency physicians to this fact.

Recommendations offered in this policy are not intended to represent the only management options that the emergency physician should consider. ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

Scope of Application. This guideline is intended for physicians working in hospital-based EDs.

Inclusion Criteria. This guideline is intended for adult patients presenting to the ED with acute noncancer pain or an acute exacerbation of chronic noncancer pain.

Exclusion Criteria. This guideline is not intended to address the long-term care of patients with cancer or chronic noncancer pain.

CRITICAL QUESTIONS

1. In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. The use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

Key words/phrases for literature searches: opioid, drug prescriptions, drug monitoring, drug utilization review, substance abuse detection, drug-seeking behavior, drug and narcotic control, substance-related disorders, physician's practice patterns, program evaluation, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Emergency physicians must balance oligoanalgesia (undertreatment or ineffectual treatment of pain) with concerns about drug diversion* and doctor shopping.[†30-33] Therefore, the development of mechanisms to address these issues is justified. The expanded use of prescription drug monitoring programs to curb prescription opioid misuse was recommended in the 2011 Prescription Drug Abuse Prevention Plan released by the White House Office of National Drug Control Policy.[34] Prescription drug monitoring programs are state-based monitoring programs for certain controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies. Although existing in various forms for more than 3 decades, the first effort to standardize prescription drug monitoring practice was the passage in 2005 of the National All Schedules Prescription Electronic Reporting Act (NASPER). Unfortunately, this federal legislative mandate that intended to harmonize prescription drug monitoring programs across the various states has yet to be fully funded.

Prescription drug monitoring programs ideally serve multiple functions, including identifying patients who engage in doctor shopping, and patients, providers, or pharmacies who engage in diversion of controlled substances and providing information about prescribing trends for surveillance and evaluation purposes. Such information may serve to benefit the patients, the health care system, epidemiologists, policymakers, regulatory agencies, and law enforcement.[35] Certain large health care systems, particularly closed prescribing systems such as the Veterans Administration and health maintenance organizations, maintain databases that allow prescribers to view recent prescriptions of enrolled clients or patients. Forty-one states have operational prescription drug monitoring programs of various complexity and capability, with an additional 7 states having prescription drug monitoring program legislation in place but with programs that are not yet operational. [36] Most states allow health care providers and pharmacists to access the programs for patients under their care. Other groups such as law enforcement and regulatory boards may also have access. One program tracks only schedule II drug prescriptions, whereas most track drug prescriptions of schedule II to IV or II to V drugs.

Despite prescription drug monitoring programs providing an intuitive perception of benefit for the medical community, there are limited data to indicate any benefit of these programs for improving patient outcomes or reducing the misuse of prescription drugs.[37] In part, this relates to the limited optimization of and standardization between the programs and the lack of a mechanism to allow interstate communication.[35]

*Drug diversion: The diversion of drugs for nonmedical use through routes that do not involve the direct prescription of the drug by a provider. Diverted drugs might be provided by family or friends, purchased on the street market, or obtained through fraudulent prescription. Epidemiologic data suggest that most opioids used nonmedically are obtained through these means.

†Doctor shopping: The practice of obtaining prescriptions for controlled substances from multiple providers, which is regarded as a possible indication of abuse or diversion. There is no rigorous definition, and various authors have defined it in different ways, from 2 or more prescribers within 30 days, greater than 4 during 1 year, and greater than 5 during 1 year.[30-32] It has also been defined as the amount of drug obtained through doctor shopping compared with the amount intended to be prescribed.[33] The use of "pill mills," in which a prescriber provides ready access to prescriptions or pills, can be considered a form of doctor shopping.

One study has demonstrated that compared with states without a prescription monitoring program, those with such a program had a slower rate of increase in opioid misuse.[38]

In an attempt to quantify the effect of a prescription drug monitoring program, Baehren et al[39] conducted a prospective study (Class III) of 18 providers who cared for a convenience sample of adult patients with pain in a single Ohio ED. After the clinical assessment of a patient, the researchers queried the providers about 3 patient-specific issues: (1) the likelihood of querying the state's prescription drug monitoring program, called Ohio Automated Rx Reporting System; (2) the likelihood of providing an opioid prescription at discharge; and (3) if yes, which opioid and what quantity. They were then provided with a printout of the patient data from the prescription drug monitoring program and asked to reassess the same questions. Of the 179 patients with complete data, information from the Ohio Automated Rx Reporting System altered prescribing practice in 74 of 179 (41%). The majority (61%) of these patients received fewer or no opioids, whereas 39% received more. The change in management was attributed to the number of previous prescriptions, 30 of 74 (41%); number of previous prescribers, 23 of 74 (31%); number of pharmacies used, 19 of 74 (26%); and number of addresses listed, 12 of 74 (16%). A limitation of this study was that 4 prescribers accounted for almost two thirds of the total patient encounters. In this study, knowledge of the information provided by a prescription drug monitoring program had an important impact on the prescription practices for controlled substances in an ED, although the actual effect of prescription drug monitoring program data on patient outcomes in this study is unknown.

Although not specifically evaluating the benefit of prescription drug monitoring programs on identifying high-risk patients, Hall et al,[32] in a Class III study, reviewed characteristics of decedents who died of prescription drugs in West Virginia and reported that opioid analgesics accounted for 93% of deaths. Cross-referencing the medical examiner's detailed analysis of the cause of death with the West Virginia prescription monitoring program, the authors determined the prescription history of the drug associated with each fatality. Patients who had received controlled drugs from 5 or more prescribers in the year before death were defined as engaging in "doctor shopping," whereas those whose death was not associated with a valid prescription were considered to have obtained their drugs through "diversion." Of the 295 deaths that were reviewed, the mean age of patients who died was 39 years, and 92% were between ages 18 and 54 years. Diversion was associated with 186 (63%) of the fatalities, and doctor shopping was associated with 63 (21%) of the fatalities. Of the 295 total decedents, 279 (95%) had at least 1 indicator of substance abuse, and these differed according to whether the drug was obtained through diversion or doctor shopping. Deaths involving diversion were associated with a history of substance abuse (82.3% versus 71.6%; odds ratio [OR] 1.8; 95% confidence interval [CI] 1.0 to 3.4), nonmedical route of pharmaceutical administration (26.3% versus 15.6%; OR 1.9; 95% CI 1.0 to 3.8), and a contributory illicit drug (19.4% versus 10.1%; OR 2.1; 95% CI 1.0 to 4.9). Patients with evidence of doctor shopping were significantly more likely to have had a previous overdose (30.2% versus 13.4%; OR 2.8; 95% CI 1.4 to 5.6) and significantly less likely to have used contributory alcohol (7.9% versus 19.8%; OR 0.3; 95% CI 0.1 to 0.9). Few patients (8.1%) were involved in both doctor shopping and diversion. The study suggests that the information provided by a prescription drug monitoring program, with correct interpretation and action based on that knowledge, might have prevented some inappropriate prescribing and poor outcomes in this patient population.

In another Class III study, Pradel et al[33] monitored prescribing trends for buprenorphine in a select area of France, using a prescription drug database during a multiple-year period. During this time, a prescription drug monitoring program was implemented, allowing a before-after comparison of the buprenorphine prescribing pattern for more than 2,600 patients. The doctor shopping drug quantity, which was defined as the total drug quantity received by the patient minus the quantity prescribed by an individual provider, increased from 631 g in the first 6 months of 2000 to a peak of 1,151 g in the first 6 months of 2004, equivalent to 143,750 days of treatment at 8 mg/day. The doctor shopping ratio, determined as the ratio of the quantity delivered to the quantity prescribed, increased steadily from early 2000 (14.9% of the grams of drug prescribed) to a peak value in the first 6 months of 2004 (21.7%). After implementation of the prescription drug monitoring program in early 2004, this value decreased rapidly, in fewer than 2 years reaching the value observed in 2000. The points of inflection of the doctor shopping curves (quantity and ratio) coincided with the implementation of the prescription drug monitoring program, suggesting an immediate benefit of this program. The prescribed quantity did not change after the implementation, indicating that access to treatment may not have changed. Eighty percent of the total doctor shopping quantity of buprenorphine was obtained by approximately 200 (8%) of the total patients. However, it is difficult to make any inferences about the effect of a decrease in doctor shopping, given the fractional amount of total prescribing accounted for by this practice.[33] The authors suggested that the doubling in the street price of buprenorphine after the prescription drug monitoring program implementation was an indicator of success.

An observational study of opioid-related deaths by Paulozzi et al[37] highlights some important considerations in the assessment of the effectiveness of prescription drug monitoring programs. The authors assessed the mortality rate from 1999 to 2005 from schedule II and III prescription opioids in the United States and compared states that had prescription drug monitoring programs with those that did not. They further divided states with prescription drug monitoring programs into those that proactively informed prescribers, generally by mail, of potential

misuse and those that did not. This study found no difference in the mortality rates over time for states with and without a prescription drug monitoring program, nor did states with proactive prescription drug monitoring programs perform better than those with programs that were not proactive. There was a nonsignificantly lower rate of consumption of schedule II opioids and a significantly higher rate of consumption of hydrocodone (schedule III) in states that had a prescription drug monitoring program. A major limitation of this study is that the variability in the prescription drug monitoring program structure, including the ability of health care providers to access the database, was not considered. Current applicability is somewhat limited by substantial changes in the manner in which prescription drug monitoring programs function since the study was conducted, including the extent of physician access and the definition of patient inclusion criteria. Because of the practical limitation of the delay in informing the prescriber of a patient's potential drug misuse, the proactive notification aspect of these programs would have minimal effect on emergency medical practice in states that cannot provide prescription drug monitoring program data in real time.

In conclusion, there are no studies that directly evaluate the effect of real-time, voluntary access to a prescription drug monitoring program on prescribing practices of emergency physicians. In addition, the broader effect of such access on diversion, abuse, doctor shopping, mortality, and the possibility of pain undertreatment remains undefined. Prescription drug monitoring programs have many limitations in their current format, including complex access issues, limitations on access permission, thresholds for patient listing, timeliness, interstate communication, and whether the data are presented to the physician automatically or require physician effort to retrieve. Furthermore, the recent addition of prescription drug monitoring programs in several states and continuing changes in the structure or function of existing programs limit the direct application of even recently published research. Legislation designed to improve prescription drug monitoring program operation (eg, NASPER) has stalled or remained underfunded, and concerns over patient confidentiality have often trumped public health concerns. Until an interstate, frequently updated, multiple-drug-schedule, easily accessible, widely used prescription drug monitoring system is implemented, the likelihood of success is limited.[35]

2. In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management.

(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.

(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

Key words/phrases for literature searches: acute low back pain, opioid, and variations and combinations of the key words/phrases.

Acute low back pain is a common ED presenting complaint. Opioids are frequently prescribed, expected, or requested for such presentations.[40,41] In a recent study, it was estimated that low back pain–related disorders result in approximately 2.6 million annual ED visits in the United States. Of medications either administered in the ED or prescribed at discharge, the most frequently used classes were opioids (61.7%; 95% CI 59.2% to 64.2%), nonsteroidal anti-inflammatory drugs (NSAIDs) (49.6%; 95% CI 46.7% to 52.3%), and muscle relaxants (42.8%; 95% CI 40.2% to 45.4%).[41] The opioid analgesics most commonly prescribed for low back pain, hydrocodone and oxycodone products, are also those most prevalent in a Government Accountability Office study of frequently abused drugs.[42] Low back pain as a presenting complaint was also observed in a recent study to be associated with patients at higher risk for opioid abuse.[43] Low back pain, although a common acute presentation, is also often persistent and recurrent, with 33% of patients continuing to complain of moderate-intensity pain and 15% of severe pain at 1 year from initial presentation. Symptoms recur in 50% to 80% of people within the first year.[44] In one study, 19% reported opioid use at a 3-month follow-up.[40] Emergency physicians, as a specialty, are among the higher prescribers of opioid pain relievers for patients aged 10 to 40 years.[20] Recent data show simultaneous increases in overall opioid sales rates and prescription opioid–related deaths and addiction rates and suggest that widespread use of opioids has adverse consequences for patients and communities.[8]

There is a paucity of literature that addresses the use of opioids after ED discharge for acute low back pain versus the use of NSAIDs or the combination of NSAIDs and muscle relaxants. Two meta-analyses published in the last 5 years identified relatively few valid studies that address the use of opioids for low back pain.[45,46]

In a Class III 2008 Cochrane review, NSAIDs were compared with opioids and muscle relaxants for the treatment of low back pain.[46] Three studies were reviewed that compared opioids (2 of which are no longer in use) with NSAIDs for treatment of acute low back pain, including 1 study considered by the Cochrane reviewers to be of higher quality.[47] None of

the individual studies found statistically significant differences in pain relief. A Class III review by McIntosh and Hall[45] of clinical evidence for treatment of acute low back pain similarly found no evidence for superiority of opioids over other therapies and no direct information to demonstrate that opioids were better than no active therapy; however, the authors concluded that the opioid-related studies were too small to detect any clinically important differences.

A Class III Cochrane review of NSAID treatment for acute low back pain evaluated 65 studies (including more than 11,000 patients) of mixed methodological quality that compared various NSAIDs with placebo, other drugs, other therapies, and other NSAIDs.[46] The review authors concluded that NSAIDs are slightly effective for short-term symptomatic relief in patients with acute and chronic low back pain without sciatica (pain and tingling radiating down the leg). In patients with acute sciatica, no difference in effect between NSAIDs and placebo was found but moderate efficacy was found for opioids. The systematic review also reported that NSAIDs are no more effective than other drugs (acetaminophen, opioids, and muscle relaxants). Placebo and acetaminophen had fewer adverse effects than NSAIDs, and NSAIDS had fewer adverse effects than muscle relaxants or opioids.

A 2003 Cochrane review of muscle relaxants for low back pain (Class X because it did not address the role of opioids) found that muscle relaxants were effective for short-term symptomatic relief in patients with acute and chronic low back pain.[48] However, muscle relaxants were associated with a high incidence of adverse effects. This study cited strong evidence in 4 trials involving a total of 294 people that oral nonbenzodiazepine muscle relaxants are more effective than placebo in patients with acute low back pain for short-term pain relief, global efficacy, and improvement of physical outcomes.

Although no superiority has been demonstrated for opioids over other therapies for treatment of acute low back pain, groups have recommended against use of opioids as first-line therapy for treatment of this problem.[49,50] A guideline for diagnosis and treatment of low back pain endorsed by the American College of Physicians and the American Pain Society recommends opioids only for severe, disabling pain that is not controlled or not likely to be controlled with acetaminophen or NSAIDs.[49] In their 2007 guidelines, the American College of Occupational and Environmental Medicine stated that routine use of opioids for acute, subacute, or chronic low back pain is not recommended.[50]

Several observational non-ED studies also suggest caution with regard to opioid prescribing for back pain. Franklin et al,[51] in a retrospective study (Class X because of the non-ED patient population), found that workers with acute low back injury and worker's compensation claims who were treated with prescription opioids within 6 weeks of acute injury for more than 7 days had a significantly higher risk for long-term disability. In a subsequent Class III population-based prospective study of opioid use among injured Washington State workers with low back pain, Franklin et al[52] observed a strong association between the amount of prescribed opioids received early after injury and long-term use of prescription opioids. A retrospective study of 98 workers with acute low back pain and subsequent disability claims by Mahmud et al[53] found that patients whose treatment of new work-related low back pain involved opioid use for 7 days or more were more likely to have long-term disability (relative risk 2.58; 95% CI 1.22 to 5.47); however, the direct applicability of this study (Class X) was limited because most patients were not seen in the ED. In another study that addressed associations of long-term outcome with opioid therapy for nonspecific low back pain, Volinn et al[54] found that the odds of chronic work loss were 11 to 14 times greater for claimants treated with schedule II ("strong") opioids compared with those not treated with opioids at all. They further observed that the strong associations between schedule II use and long-term disability suggest that for most workers, opioid therapy did not arrest the cycle of work loss and pain. Although this study was also graded as Class X because of the population selected and failure to directly address acute or immediate benefit, the results highlight potential problems of treating acute low back pain with opioids.[54] Unfortunately, causation cannot be directly inferred from these studies because of possible confounding.

In summary, although opioids currently offer the most potent form of pain relief, there is essentially no published evidence that the prescription of opioid analgesics for acute low back pain provides benefit over other available medications or vice versa. Several observational studies suggest associations of both prescription of "strong" opioids or longer prescription duration (greater than 7 days) and early opioid prescribing with worsened functional outcomes. Additionally, as noted, the overall increased rate of opioid sales has been strongly associated with adverse effects in the community (overdose, addiction, aberrant use, and death).[8] Therefore, it can be recommended that opioids not be routinely prescribed for acute low back pain but reserved for select ED patients with more severe pain (eg, sciatica) or pain refractory to other drug and treatment modalities. Prescriptions for opioids should always be provided for limited amounts and for a limited period. Extra caution (such as use of prescription drug monitoring programs and seeking of collateral patient information such as patient visit history) may be indicated for patients identified as possibly having an increased risk for substance dependence or abuse.

3. In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids?

Recommendations

Level A recommendations. None specified.

Level B recommendations. For the short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone

products while considering the benefits and risks for the individual patient.

Level C recommendations. Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate.

Key words/phrases for literature searches: opioids, schedule II narcotics, schedule III narcotics, acute pain, acute disease, emergency service, and variations and combinations of the key words/phrases.

Schedules II and III are classifications established by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and determined by the Drug Enforcement Administration. Among other criteria, classification decisions for specific drugs are based on judgments about the potential for their abuse. Schedule II opioids include morphine (eg, MS Contin), oxymorphone (eg, Opana), oxycodone (eg, Roxicodone) and oxycodone combination products (eg, Percocet, Percodan), as well as hydromorphone (eg, Dilaudid) and fentanyl (eg, Duragesic patch, Actiq). Schedule III opioids include combination products, such as hydrocodone (15 mg or less) combined with acetaminophen (eg, Vicodin, Lortab) or ibuprofen (eg, Vicoprofen), as well as some of the codeine combination products.[55] Schedule classifications for opioids may change over time in response to a number of factors, including their perceived risk of abuse. Calls to reclassify hydrocodone combination products (eg, Vicodin, Lortab) from schedule III to schedule II have increased in recent years in response to increasing levels of abuse of these substances.

These recommendations address only new-onset acute pain. Long-acting or extended-released schedule II products such as oxycodone ER (OxyContin), methadone, fentanyl patches, or morphine extended-release (MS Contin) are indicated for chronic pain and should not be used for acute pain.[56] Long-acting and extended-release opioids are for use in opioid-tolerant patients only and are not intended for use as an "as-needed" analgesic. In addition, the immediate-release oral transmucosal formulations of fentanyl are indicated only for breakthrough pain relief in cancer patients who are already taking sustained-release medications and are opioid tolerant. These formulations should not be used for acute new-onset pain.

As part of the decision to prescribe opioids for new onset of acute pain, the care provider can select between short-acting schedule II or III agents (Table). In general, equianalgesic doses of opioids are equally efficacious in relieving pain. Therefore, *a priori*, there is no reason to consider an equianalgesic dose of a short-acting schedule II opioid more effective in providing pain relief than a short-acting schedule III opioid. However, some studies have compared schedule II and III opioids combined with nonopioid analgesics with one another. Two prospective randomized controlled trials have compared the efficacy of short-acting oxycodone, a schedule II drug, with hydrocodone combination products (schedule III) and found them to be equal.[57,58] In 2005, Marco et al[57] compared single doses of oxycodone 5 mg with hydrocodone 5 mg (both combined with 325 mg acetaminophen). In this single-site Class II study of 67 adolescent and adult subjects with acute fractures, no differences in analgesic efficacy were observed at 30 or 60 minutes. Constipation rates were higher for hydrocodone. In a 2002 Class I study, Palangio et al[58] compared oxycodone 5 mg combined with acetaminophen 325 mg (schedule II) with hydrocodone 7.5 mg combined with ibuprofen 200 mg (schedule III) in a prospective, multicenter, multidose, randomized controlled trial of 147 adults with acute or recurrent low back pain. During an 8-day study period, no differences were found in pain relief, doses taken, global evaluations of efficacy, health status, or pain interference with work. As noted above, equianalgesic doses of opioids have similar efficacy in the treatment of acute pain, no matter their Drug Enforcement Administration classification. Given this understanding, it was not unexpected that 2 randomized controlled trials comparing schedule II with III agents found no differences in analgesic efficacy.

Table. Short-acting oral opioid formulations. Dose and interval are recommended starting dosing ranges.

Medication	Initial Dose/Interval	Schedule
Codeine/APAP	30-60 mg* PO Q4-6h PRN	III
Codeine	30-60 mg PO Q4-6h PRN	II
Hydrocodone/APAP	5-15 mg* PO Q4-6h PRN	III
Hydromorphone	2-4 mg PO Q4-6h PRN	II
Morphine	15-30 mg PO Q4-6h PRN	II
Oxycodone/APAP	5-15 mg* PO Q4-6h PRN	II
Oxycodone	5-15 mg PO Q4-6h PRN	II
Oxymorphone	10-20 mg PO Q4-6h PRN	II

APAP, acetaminophen; *h*, hour; *mg*, milligram; *PO*, by mouth; *PRN*, as needed; *Q*, every.
*Listed dose is of the opioid component. Note that the acetaminophen component is now limited to 325 mg or less per pill.

4. In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic noncancer pain seen in the ED.

(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The clinician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and

consider past prescription patterns from information sources such as prescription drug monitoring programs.

Key words/phrases for literature searches: opioid, patient discharge, pain, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Patients with chronic noncancer pain, either already taking opioids or not, commonly present to the ED for treatment of acute exacerbation of their pain. There have been no studies that evaluate the efficacy or potential harms of prescribing opioids specifically for these patients on discharge from the ED. Thus, given the paucity of evidence, this critical question cannot be definitively answered. Despite the biological plausibility that treating any acute exacerbation of pain with parenteral or oral opioids should decrease pain intensity, no studies were found to support this hypothesis.

Only 2 randomized controlled trials were identified that addressed the use of short-acting opioids for the treatment of breakthrough pain in patients taking opioids for chronic noncancer pain; transmucosal fentanyl was the intervention for both trials.[59,60] Because of methodological problems, valid estimates for efficacy of the intervention could not be determined, but adverse event rates among both treated populations were common and similar (range 63% to 65%) (Class III).

A systematic review of nonrandomized studies by Devulder et al[61] examined the effect of rescue medications on overall analgesic efficacy and adverse events. They examined 48 studies of patients treated with long-acting opioids for chronic noncancer pain and compared the analgesic efficacy and adverse events among those that allowed short-acting opioid rescue medications for breakthrough pain with those that did not allow such rescue medications. Although graded Class X because of lack of randomized studies and the limitation of harms studied to adverse effects only, no significant difference in the analgesic efficacy between the rescue and nonrescue studies was found. There was also no difference between these 2 groups in the incidence of nausea, constipation, or somnolence. Kalso et al,[62] in a Class III systematic review, found that 80% of patients receiving opioids for chronic noncancer pain had at least 1 adverse event, including nausea (32%), constipation (41%), and somnolence (29%).

Studies of the use of opioids for chronic pain indicate that adverse effects of these drugs are common. Several studies assessed the adverse effects with the use of tramadol with acetaminophen in the treatment of patients with chronic low back pain.[63-65] All of the studies had high dropout rates and reported adverse event rates of nausea, dizziness, and somnolence between 8% and 17%. Allan et al,[66] in a nonblinded Class III study comparing transdermal fentanyl versus oral morphine, found a constipation rate of 48% in the morphine-treated patients compared with a rate of 31% in the fentanyl-treated patients. Constipation was also the major adverse effect in a Class III study by Hale et al[67] comparing oxymorphone extended release, oxycodone controlled release, and placebo. Furlan et al,[68] in a Class II meta-analysis of 41 randomized studies of opioid use in the treatment of chronic noncancer pain, found that constipation and nausea were the only significant adverse effects. Holmes et al,[69] however, in a Class III study, assessed an opioid screening instrument, the Pain Medication Questionnaire, in chronic noncancer pain patients and found that those patients with a higher score were more likely to have a substance abuse problem or request early refills of their opioid prescription. In a retrospective Class III cohort study, Jensen et al[70] conducted a 10-year follow-up on patients discharged from a pain clinic and found that chronic opioid treatment may put patients at risk for chronic depression. Unfortunately, near-universal shortcomings of these studies include the exclusion of patients with a history of substance abuse, other significant medical problems, or psychiatric disease, and lack of follow-up to detect long-term effects such as aberrant drug-related behaviors, addiction, or overdose. Therefore, studies such as these can be confounded, making the ability to draw conclusions about causality difficult.

Questions of opioid effectiveness involve the assessment of reduction in pain and improvement in function for the patient, potential patient adverse effects, and the potential harm to the community (eg, opioid diversion and abuse) from the drugs prescribed. Hall et al,[32] in a Class III retrospective analysis of 295 unintentional prescription overdose deaths, found that 93% were due to opioids, 63% represented pharmaceutical drug diversion, 21% of the patients had engaged in doctor shopping, and 95% of the patients had a history of substance abuse. Although no studies have addressed the effects related to dose and duration of prescribed opioids in this specific patient population, 2 general studies have shown a correlation between high daily opioid dose and overdose death.[71,72]

Patient assessment tools such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), Opioid Risk Tool (ORT), Diagnosis, Intractability, Risk, and Efficacy (DIRE), and others to assess the risk of prescription opioid misuse and abuse have yet to be fully validated in the ED in terms of sensitivity, specificity, and utility.[73] Many, however, believe that use of these tools, as imperfect as they are, represents a beginning in the ability to better quantify potential risks related to opioid prescribing for outpatients.

Many patients undergoing treatment for chronic noncancer pain have pain contracts/treatment agreements with their primary care providers. These should be honored if possible in treating any acute exacerbation of their pain.[74,75] As discussed in critical question 1, use of prescription drug monitoring programs may also assist the emergency physician in making appropriate clinical decisions about the use of outpatient opioid prescriptions for these patients.

FUTURE RESEARCH

Provider pain management practices related to opioids are highly variable. In part, this variability reflects the lack of evidence to guide many of these therapeutic decisions.[76]

Although there is high-quality research assessing the treatment of acute pain with opioid analgesics during the ED encounter, there is a paucity of studies assessing the benefits of prescribing opioids for discharged ED patients with acute pain and chronic noncancer pain, especially in comparison to other analgesic drugs and pain treatment modalities. Therefore, clinical decisions and practice recommendations must rely on practice experience and consensus rather than research evidence.

ED populations typically include patients with unmet substance abuse treatment needs and psychiatric comorbidities, and many of these patients present with acute pain.[77] In almost all pain studies, these patients are excluded, leaving clinicians with little evidence-based guidance for their pain management. There are also significant research gaps in clearly understanding the long-term harms of opioids, including drug abuse and addiction, aberrant drug-related behaviors, and diversion. As mentioned above, further research and validation is needed on ED patient abuse and addiction-related assessment tools. Additional studies to characterize individual patient-related risks for opioid abuse are also greatly needed.

Although there has been recent widespread adoption of prescription monitoring programs, there remains a dearth of evidence about the effectiveness of these programs in altering physician prescribing patterns or diminishing the adverse effects of opioids in the community. For research in this area to advance, further refinement of prescribing metrics (quantity, duration, and frequency) and public health measures is required. Comparison of the functionality and effectiveness of the various state prescription drug monitoring program models may provide additional insight into developing best practices that could be adopted nationally, including the sharing of data between states. Important distinctions among the states, such as immediate online prescriber access to the prescription monitoring program, should be examined for their relative contributions. However, this type of analysis must consider baseline variability among states for prescription opioid misuse (versus heroin or methadone, for example) and other state-specific issues (such as prescription-writing regulations).

With respect to the treatment of acute low back pain in the ED, there is a need for quality studies comparing the effectiveness of the more commonly prescribed opioids (hydrocodone and oxycodone congeners and other semisynthetic opioids) and nonopioid therapies, with attention to confounding variables such as depression or other psychopathology. Further study is needed to validate or refute the reported associations of early or potent opioid prescribing with increased rates of disability.[51] Given the frequency of acute low back pain as an ED presentation and its association with perceived drug-seeking behavior,[78] and with apparent higher risk for misuse,[43] more attention needs to be paid to discriminatory historical or physical factors that may be predictive of drug-seeking or abuse to allow better matching of treatment modality for individual patients.

Future studies should include additional multiple-dose analgesic protocols to better understand the postdischarge experience of patients with acute pain and what would constitute optimum patient follow-up provisions. Investigators should include clinically relevant study periods (days to weeks), which vary by diagnosis; thus, trials should be stratified by specific presenting complaints, pain site, discharge diagnosis, and classification of pain type, ie, nociceptive, neuropathic, and visceral pain. In addition to measuring pain and adverse effects, functional outcomes, such as return to work or pain-related quality-of-life measures, should be included.[79] Straightforward observational studies are needed to determine the relative duration of different acute pain presentations, thus informing decisions to prescribe an appropriate number of opioid doses per prescription. Current prescribing practice often involves a "one size fits all" pattern that is encouraged by electronic prescribing software. Prescribing practices that ignore variable durations of acute pain syndromes will predictably result in undertreatment for some patients and overtreatment for others. The latter increases the likelihood that unused opioids will be diverted into nonmedical use in communities at risk.

Additional research should include evaluation of the appropriateness of patient satisfaction as a quality metric as related to patient expectations of opioids and the prevalence of providers reporting pressure through low patient satisfaction scores or administrative complaints to provide opioids when the providers believe these drugs are not medically indicated. This issue may gain increased importance with the institution of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which may tie some reimbursement to patient satisfaction scores. Additional work is needed to investigate what constitutes an appropriate educational curriculum in both medical school and residency for physician education concerning safe, appropriate, and judicious use of opioids.

Research addressing the treatment of chronic noncancer pain would be enhanced by the use of accepted case definitions, standardized definitions of adverse events, and validated pain measurements. Case definitions should use a similar definition of chronic, nociceptive (musculoskeletal or visceral) versus neuropathic pain, or pain by disease type (headache, low back pain, etc). Research reporting also requires more refined descriptions of opioid potency and routes of administration.

Although opioids represent a treatment modality that has long been used in patient care, it is clear by the paucity of definitive answers to the questions posed in this document and the significant number of future research issues that much work remains to be done to clarify the best use of opioids in the care of patients.

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American Chronic Pain Association and has previously been a consultant to the pharmaceutical industry.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical questions.

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Evidentiary Table.

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hall et al[32]	2008	Retrospective, population based, observational study	Comparison of West Virginia medical examiner data with patient data from the state prescription monitoring program and opioid abuse treatment program records	Behaviors of those who died of a pharmaceutical overdose; diversion; doctor shopping; substance abuse history; type of drug	295 deaths; 67% male; 92% aged 18-54 y; 63% pharmaceutical diversion; 21% doctor shopping; 95% substance abuse history; 93% opioids	Actual source of opioids involved in death not known; single state; not validated definitions; retrospective	III
Pradel et al[33]	2009	Database	Review of prescription drug database (not prescription monitoring program) to identify amount of buprenorphine delivered, prescribed, and obtained by doctor shopping; extension of 2004 study, used multiple time period comparisons; evaluation of trends in doctor shopping over time	Determined prescribed quantity of buprenorphine, delivered quantity, and the doctor shopping quantity	Although there was some variation over time, the trend for prescribing stayed constant overall and doctor shopping decreased after 2004, associated with the change in the mechanism by which prescriptions are monitored	Reasons for multiple providers or overlapping or interrupted prescriptions unclear; did not examine risk factors for abuse	III
Baehren et al[39]	2010	Prospective, uncontrolled	Physicians prescribing analgesics for nonacute pain were asked details about the patient's prescription and then again after being informed of the prescription monitoring program search result for that patient	Change in prescription for the specific patient	179 enrolled; management changed in 41%; 61% received fewer opioids, 39% received more	Convenience sample; majority of data from 4 prescribers	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
McIntosh and Hall[45]	2011	Review of randomized controlled trials, systematic reviews, and observational studies found searching MEDLINE 1966-12/2009, EMBASE 1980 to 12/2009, and Cochrane database up to 12/2009; 49 studies met inclusion criteria	Multiple treatment modalities for acute low back pain, including oral drugs, local injections, and nondrug treatment	Clinical improvement of low back pain	NSAIDs shown to effectively improve symptoms compared with placebo, but use associated with gastrointestinal adverse effects; muscle relaxants may reduce pain and improve clinical assessment but are associated with adverse effects including drowsiness, dizziness, nausea	The studies examining the effects of analgesics such as acetaminophen or opioids were generally too small to detect any clinically important differences	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Roelofs et al[46]	2008	Cochrane review: search of MEDLINE, EMBASE, and Cochrane central registry of controlled trials up to 7/2007; 65 trials qualified for review	NSAIDs and COX-2 inhibitors administered to treat low back pain	Clinical improvement of low back pain	Review authors found NSAIDs are not more effective than other drugs (acetaminophen, opioids, and muscle relaxants); placebo and acetaminophen had fewer adverse effects than NSAIDs, although the latter had fewer adverse effects than muscle relaxants and opioids; the new COX-2 NSAIDs do not seem to be more effective than traditional NSAIDs but are associated with fewer adverse effects, particularly stomach ulcers, although other literature has shown that some COX-2 NSAIDs are associated with increased cardiovascular risk	7 studies reported on acute low back pain, 5 of which, including 1 higher-quality study, did not find any statistical differences between NSAIDs and opioids or muscle relaxants; there is moderate evidence that NSAIDs are not more effective than other drugs for acute low back pain	III
Videman et al[47]	1984	Double-blind parallel study	70 patients; comparative trial of meptazinol vs diflunisal for up to 3 wk	Patients examined at 1-wk intervals for task capability, range of motion, and subjective pain self-assessment	Both regimens produced marked improvement in most parameters, similar adverse effect profiles	No mention of patient randomization	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Franklin et al[52]	2009	Prospective cohort; Washington State workers with back injury; n=1,883	Prospective cohort of workers with back injuries interviewed at 18 days (medial) and 1 y after injury; pharmacy data obtained from computerized records; analyzed for demographic and covariates	Injury severity, pain, function, and quantities of opioids used	For long-term users total number of medications increased significantly (*P*=.01) from the first to the fourth quarter; after adjustment for baseline pain, function, and injury severity, the strongest predictor of longer-term opioid prescriptions was total number of medications in the first quarter; receipt of ≥10 mg/day medicine in first quarter more than tripled the odds of receiving opioids long term, and receipt of ≥40 mg/day medicine in first quarter had 6-fold odds of receiving long-term opioids; amount of prescribed opioid received early after injury predicts long-term use	Addressed progression to long-term use according to initial treatment and continuation of same	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Marco et al[57]	2005	Single site; prospective; double blind; randomized controlled trial; concealment method described; ED patients with fractures	Single dose of oxycodone 5 mg/acetaminophen 325 mg schedule II vs hydrocodone 5 mg/acetaminophen 325 mg schedule III	Primary outcomes were numeric pain scores (0-10) at 30 and 60 min	88 subjects evaluated, 73 enrolled, 67 completed ED study period, 35 to oxycodone, 32 to hydrocodone; no baseline differences, no differences in outcomes at 30 min: -0.6 (95% CI -1.8 to 0.5); 60 min -0.5 (95% CI -2.0 to 1.0); adverse effects higher for constipation with hydrocodone (21% vs 0%; (95% CI 3% to 39%)	Small sample size powered to address acute pain during the first 30 to 60 min in the ED; study also assessed adverse effects during a longer period of time; excluded history of alcohol or opioid or other substance abuse; limited time period	II
Palangio et al[58]	2002	Prospective multicenter (18 sites), randomized controlled trial, sequential assignment by computer-generated randomization schedule	Hydrocodone 7.5 mg/ibuprofen 200 mg (schedule III) vs oxycodone 5 mg/acetaminophen 325 mg (schedule II)	Primary outcome was mean daily pain relief score at endpoint (day 8 or day of discontinuation), study period up to 8 days, intention-to-treat analysis	147 subjects enrolled (75 hydrocodone/ibuprofen, 72 oxycodone/acetaminophen), adults with acute or recurrent low back pain requiring opioids, 85% completed study in both groups, mean days to endpoint 6.5 vs 6.9 days, no baseline differences, no differences in pain relief, number of pills, global evaluations, SF-36, pain interference with work, adverse events	Excluded drug or alcohol abuse, concealment methods described	I

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Portenoy et al[59]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic low back pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain in chronic low back pain; adverse effects in 65%; 34% during double-blind phase	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Simpson et al[60]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain; adverse effects in 63%; 22% dropout	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Kalso et al[62]	2004	Systematic review	Randomized trials in chronic noncancer pain comparing potent opioids with placebo	Pain intensity outcomes	15 randomized trials were included; 11 studies compared oral opioids for 4 wk; pain intensity decrease was 30% compared with placebo; only 44% were taking opioids by mo 7 to 24; 80% of patients experienced at least 1 adverse event: constipation (41%), nausea (32%), somnolence (29%)	4-wk duration on average; differing causes of pain; open label in many of the studies; limited power calculations; concealment not maintained in some studies	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Peloso et al[63]	2004	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; 3-mo trial	336 patients randomized; improved mean final pain scores (47 vs 63; *P*<.001), adverse effects: nausea 12%, dizziness 11%, constipation 10%, somnolence 9%	35%-40% dropout rate; pharmaceutical-sponsored research	II
Ruoff et al[64]	2003	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; Roland Disability Questionnaire	318 patients randomized; tramadol improved pain VAS (*P*=.15) and final Pain Relief Rating Scale (*P*<.001); adverse effects: nausea 13%, somnolence 12%, constipation 11%, dizziness 8%	153 of 318 dropped out; pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Schnitzer et al[65]	2000	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Time to discontinuation because of inadequate pain relief; Short Form Magill Pain Questionnaire; Roland Disability Questionnaire	380 patients in open-label phase; 254 entered into blinded phase; time to therapeutic failure was greater in the placebo group ($P<.0001$); other parameters showed improvement; adverse effects: nausea 17%, dizziness 15%, somnolence 14%, headache 12%	The dropout rate was the primary outcome; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Allan et al[66]	2005	Nonblinded, randomized comparison of 2 treatments in patients with chronic low back pain	Transdermal fentanyl vs sustained-release oral morphine; 680 total patients; dose titrated to effect; followed for 13 mo; outpatient setting; not applicable to ED	Pain relief (VAS scale); bowel function (validated questionnaire); quality of life (SF-36); disease, progression (3-point scale), days not working, adverse events all during 13 mo	Comparable pain relief, noninferior, VAS score for fentanyl (56) vs morphine (55); fentanyl had lower constipation rate: fentanyl (31%) vs morphine (48%)	Both groups had half of the participants drop out; vague definition of chronic low back pain; not blinded	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hale et al[67]	2005	Randomized trial, blinded	Comparison of oxymorphone extended-release vs oxycodone controlled release vs placebo in patients with chronic low back pain who were taking a stable dose of opioids	VAS of pain score 4 h after morning dose; use of breakthrough pain medications; categorical pain intensity, pain intensity, global assessment, adverse events	Opioids were superior to placebo at reducing VAS for pain compared with placebo, oxymorphone (-27), oxycodone (-36); oxymorphone was comparable to oxycodone in pain efficacy and adverse effects; sedation and constipation were more common with opioids (35% vs 29% vs 11%)	Only 22 of 75 patients in the placebo group completed the study; included only patients receiving stable opioids and then randomized to opioids or placebo; baseline characteristics between groups not specified; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/ Comments	Class
Furlan et al[68]	2006	Meta-analysis	Study included randomized trials of any opioid for chronic noncancer pain (defined as pain for longer than 6 mo) vs placebo or some other nonopioid treatment	41 randomized studies with 6,019 patients evaluated for effectiveness and adverse effects; most (80%) had nociceptive pain	81% of the studies were believed to be of high quality; dropout rates were 33% in the opioid group and 38% in the placebo group; opioids improved pain and functional outcomes compared with placebo in nociceptive and neuropathic pain; strong opioids were superior to naproxen and nortriptyline for pain relief; weak opioids were not superior; constipation and nausea were the only significant adverse effects observed	Average duration of the study was 5 wk (range 1-16 wk); adequate random patient assignment in only 17 of 41 trials; 90% of trials were pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Holmes et al[69]	2006	Prospective cohort	Convenience sample of patients who were new at a pain clinic; Pain Medication Questionnaire was administered; patients were treated with interdisciplinary treatment and/or medications alone, depending on the results of an initial evaluation	Beck Depression Inventory; Confidential Pain questionnaire; SF-36; Million VAS; Oswestry Disability Questionnaire; Physician Risk Assessment; VAS	271 patients, divided into low-, medium-, and high-score pain medication questionnaire; high-score group was more likely to have a known substance use problem (OR 2.6), request early refills (OR 3.2), or drop out of treatment (OR 2.3)	Only 26% of patients completed the full treatment program; heterogeneous types of pain diagnosis; differing treatment plans	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Jensen et al[70]	2006	Retrospective review of cohort	Patients who were treated and discharged from a pain clinic 10 y ago; medical records were abstracted and questionnaires were sent to willing participants	Demographics, health care utilization, SF-36; Hospital Anxiety and Depression Scale; Coping Strategy Questionnaire; CAGE* test	160 patients; 60% of patients were still taking long-acting opioids; dose escalation was unusual; chronic users had lower health-related quality of life and higher occurrence of depression	160 of 279 possible patients participated; no control group	III

COX-2, cyclooxygenase-2; *ED*, emergency department; *h*, hour; *mg*, milligram; *min*, minute; *mo*, month; *NSAID*, nonsteroidal anti-inflammatory drug; *OR*, odds ratio; *SF-36*, Short-Form Health Survey; *VAS*, visual analog scale; *vs*, versus; *wk*, week; *y*, year.

*CAGE (Cutting down, Annoyed, Guilty, Eye-opener) test is a method of screening for alcoholism.

Appendix A. Literature classification schema.*

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)

*Some designs (eg, surveys) will not fit this schema and should be assessed individually.
†Objective is to measure therapeutic efficacy comparing interventions.
‡Objective is to determine the sensitivity and specificity of diagnostic tests.
§Objective is to predict outcome, including mortality and morbidity.

Appendix B. Approach to downgrading strength of evidence.

	Design/Class		
Downgrading	**1**	**2**	**3**
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

Attachment 5

Prescription Drug Abuse Prevention

PRESCRIPTION DRUG ABUSE PREVENTION PUBLIC SERVICE ANNOUNCEMENT

- 60-second video
- 30-second video
- Medical Board Prescription Drug Abuse PSA Video

MATERIALS

Teens

- TEEN Poster *PDF*
- TEENS Drug abuse prevention *PDF*
- TEENS RX abuse prevention *PDF*

College Students

- COLLEGE RX abuse *PDF*
- COLLEGE STUDENTS Nonmedical use of prescription drugs *PDF*

Parents

- PARENT Talk Kit *PDF*
- PARENTING Practices to reduce child drug or alcohol problems *PDF*
- PARENTS Talking to your kids *PDF*
- PARENTS Abuse of prescription and OTC drugs is dangerous *PDF*
- PARENTS How teens abuse medicine *PDF*
- PARENT GUIDE Family drug and alcohol testing *PDF*
- PARENTS Synthetic Bath Salts K2 Spice *PDF*
- PARENTS Drug Chart *PDF*
- PARENTS Fact Sheet Preventing Teen Abuse of Prescription Drugs *PDF*
- PARENTS Overdose Prevention Toolkit *PDF*
- PARENTS Internet Pharmacies *PDF*

Teachers

- TEACHERS RX abuse education *PDF*

CONTACT US
1625 N Market Blvd, N219
Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

Pharmacists

- Corresponding Responsibility Brochure *PDF*
- PHARMACISTS CDC - Prescription Painkiller Overdoses Policy Impact Brief *PDF*
- PHARMACISTS 2014 White House National Drug Strategy *PDF*
- Red Flags Video

Treatment

- TREATMENT How to Find Help For Your Child *PDF*

WEBSITES

Teens

NIDA For Teens – the science behind drug abuse
http://teens.drugabuse.gov/
The National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), created this website to educate adolescents, ages 1
addresses appropriate questions and timely concerns.

Above The Influence
www.abovetheinfluence.com
This campaign is inspired by what teens say about their lives and how they deal with the influences that shape their decisions about not using drugs or a

Just Think Twice
http://www.justthinktwice.com/
Website for teens

Drugs: What you should know
http://kidshealth.org/teen/drug_alcohol/drugs/know_about_drugs.html
Also available in Spanish. TeensHealth is part of the KidsHealth family of websites. These sites, run by the nonprofit Nemours Center for Children's Heal

Parents

Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses
http://www.cdc.gov/injury/about/focus-rx.html
Centers For Disease Control

The Partnership at Drugfree.org
http://www.drugfree.org/
Working toward a vision where all young people will be able to live their lives free of drug or alcohol abuse.

Get Smart About Drugs
http://www.getsmartaboutdrugs.com/
DEA sponsored website to educate parents

Teens and Parents

AwareRx Get informed. Prescription drug safety.
http://www.awarerx.org/
National Association of Boards of Pharmacy offers authoritative resources about medication safety, prescription drug abuse, medication disposal, and sa

Wake up now. "In Your Face" Information
http://www.wakeupnow.org/
Educational campaign established by The Pain Truth, a Florida 501(c)(3), to combat the increase in prescription drug abuse among teenagers.

Educators

Free information kit for educators
http://www.drugfreeworld.org/freeinfo.html
The Foundation for a Drug-Free World is a nonprofit public benefit corporation that empowers youth and adults with factual information about drugs so tl

Free prescription drug abuse education materials for middle school and high school students
http://www.neahin.org/rxforunderstanding/
National Education Association Health Information Network. Shipping costs apply.

Free School Tool Kit for middle and high school students
http://www.nasn.org/

Pharmacists

White House Office of National Drug Control Policy
http://www.whitehouse.gov/ondcp/prescription-drug-abuse
Overview of the prescription drug abuse problem by the White House.

National Institute on Drug Abuse
http://www.drugabuse.gov/drugs-abuse/prescription-drugs-cold-medicines

Prescription Medication Overdose
http://www.cdc.gov/homeandrecreationalsafety/rxbrief/
Centers For Disease Control and Prevention policies overview

Treatment

Seeking Drug Abuse Treatment: Know What To Ask
http://www.drugabuse.gov/publications/seeking-drug-abuse-treatment-know-what-to-ask/introduction
The National Institute on Drug Abuse (NIDA)

Time to get help: Support for parents of a child struggling with drugs and alcohol
http://www.drugfree.org/
By bringing together renowned scientists, parent experts and communications professionals, The Partnership at Drugfree.org translates the science of teen drug use and addictior teens and young adults.

Treatment facilities
http://www.dhcs.ca.gov/provgovpart/Pages/SUD-Directories.aspx
California Department of Healthcare Services

This web site contains PDF documents that require the most current version of Adobe Reader to view. To

Get Adobe Reader

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Attachment 6

FOR IMMEDIATE RELEASE

Contact: DEA Public Affairs

(202) 307-7977

Press Release

DEA and Partners Collect 309 Tons of Pills on Ninth Prescription Drug Take-Back Day

Take-back initiative removes from circulation 2,411 tons of unused prescription drugs in four years

New disposal rules now in effect provide for convenient, ongoing disposal opportunities for patients' unwanted pharmaceuticals; law enforcement agencies may continue to hold take-back events

NOV 05 (WASHINGTON) —On its ninth National Prescription Drug Take-Back Day on September 27, the Drug Enforcement Administration (DEA) and 4,076 of its national, tribal, and community law enforcement partners collected 617,150 pounds (309 tons) of unwanted prescription drugs at 5,495 sites. This brought the total amount of drugs collected in four years to 4,823,251 pounds, or 2,411 tons. (A breakdown of this ninth Take-Back Day's results by state can be seen here.)

Unused prescription medications in homes create a public health and safety concern, because they can be accidentally ingested, stolen, misused, and abused. While the number of Americans who currently abuse prescription drugs dropped in 2013 to 6.5 million from 6.8 million in 2012, that is still more than double the number of those using heroin, cocaine, and hallucinogens like LSD and Ecstasy combined, according to the 2013 National Survey on Drug Use and Health. In addition, 22,134 Americans died in 2011 from overdoses of prescription medications, including 16,651 from narcotic painkillers, says the Centers for Disease Control and Prevention.

The survey of users cited above also found that the majority of abused prescription drugs are obtained from family and friends, including from the home medicine cabinet.

DEA began hosting National Prescription Drug Take-Back events four years ago, because at that time the Controlled Substances Act made no legal provision for patients and their caregivers to rid themselves of unwanted controlled substance prescription drugs except to give them to law enforcement; it banned pharmacies and hospitals from accepting them. Most people flushed their unused prescription drugs down the toilet, threw them in the trash, or kept them in the household medicine cabinet, resulting in contamination of the water supply and the theft and abuse of the prescription drugs.

The week after DEA's first Take-Back Day, Congress enacted the Secure and Responsible Drug Disposal Act of 2010. The Act authorized DEA to develop and implement regulations that outline methods the public and long-term care facilities can use to transfer pharmaceutical controlled substances and other prescription drugs to authorized collectors for the purpose of disposal. While those regulations were being developed and approved, the DEA continued to hold twice-yearly Take-Back events.

DEA's new disposal regulations were published in the Federal Register on September 9 and are intended to expand the options available to safely and securely dispose of potentially dangerous prescription medications on a routine basis. They can be viewed at www.deadiversion.usdoj.gov or at www.regulations.gov.

The new regulations authorize certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All authorized collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Anyone (not just authorized collectors) can hand out the pre-printed, pre-addressed mail-back packages in which patients and their caregivers can send their unused drugs to the mail-back program operators. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

The public may find authorized collectors in their communities by calling the DEA Office of Diversion Control's Registration Call Center at 1-800-882-9539.

Law enforcement continues to have autonomy with respect to how they collect controlled substance prescription drugs from patients or their caregivers, including holding Take-Back events. Any person or entity—DEA registrant or non-registrant—may partner with law enforcement to conduct Take-Back events. Patients also may continue to utilize the guidelines for the disposal of pharmaceutical controlled substances listed by the Food and Drug Administration and the Environmental Protection Agency. Any method of patient disposal that was valid prior to these new regulations being implemented continues to be valid.

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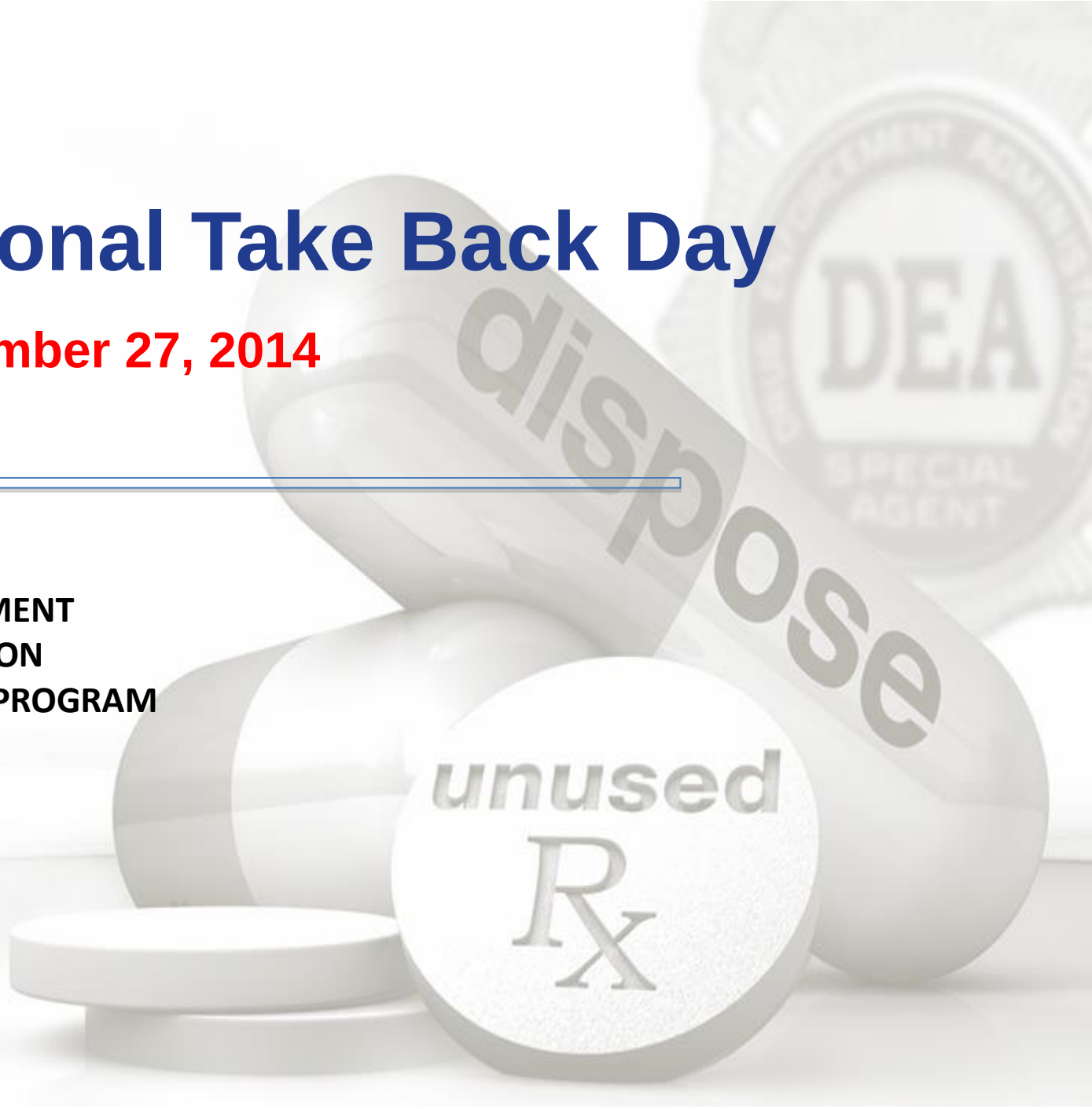
National Take Back Day

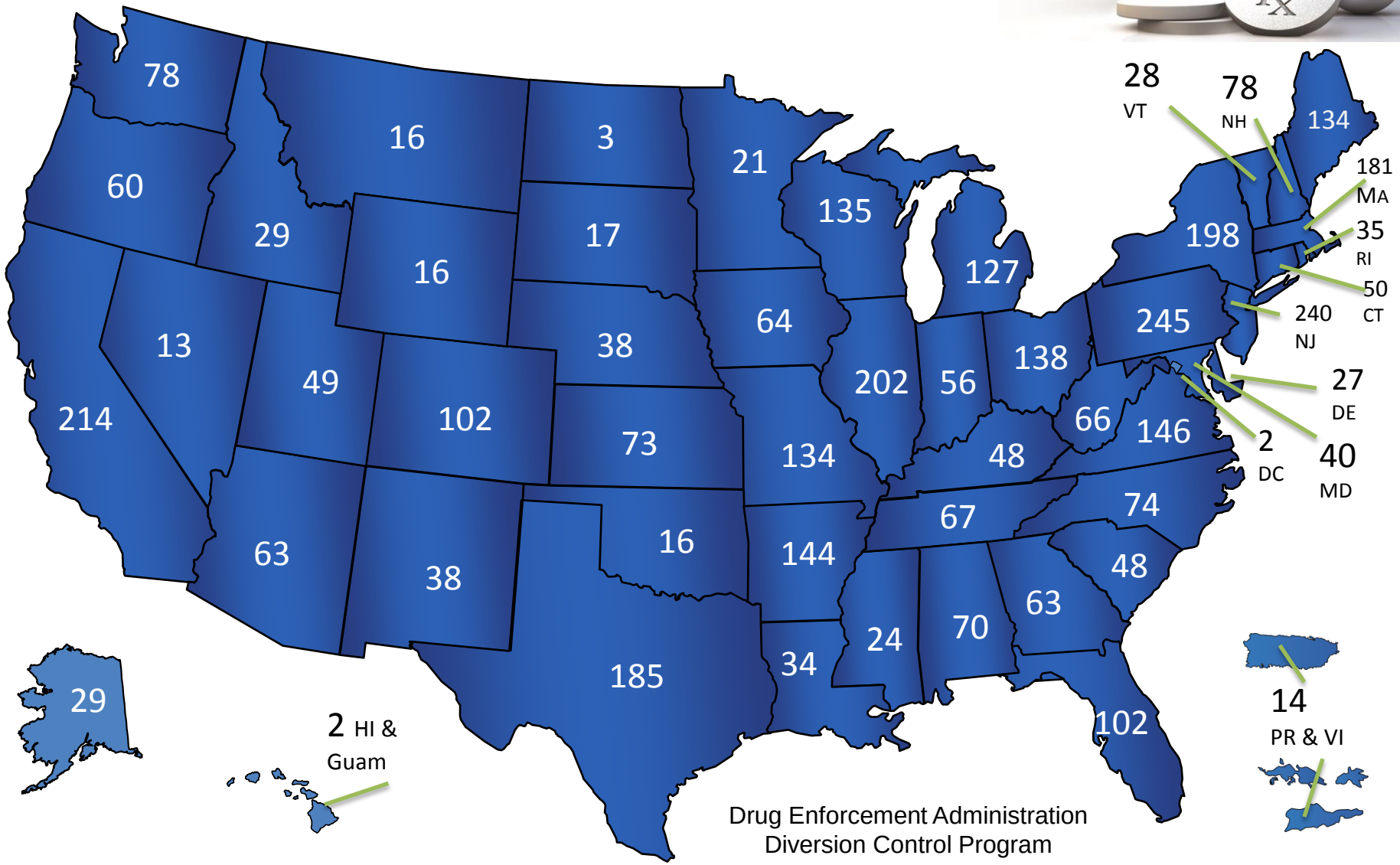
September 27, 2014

DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL PROGRAM



National Take Back Day: September 27, 2014

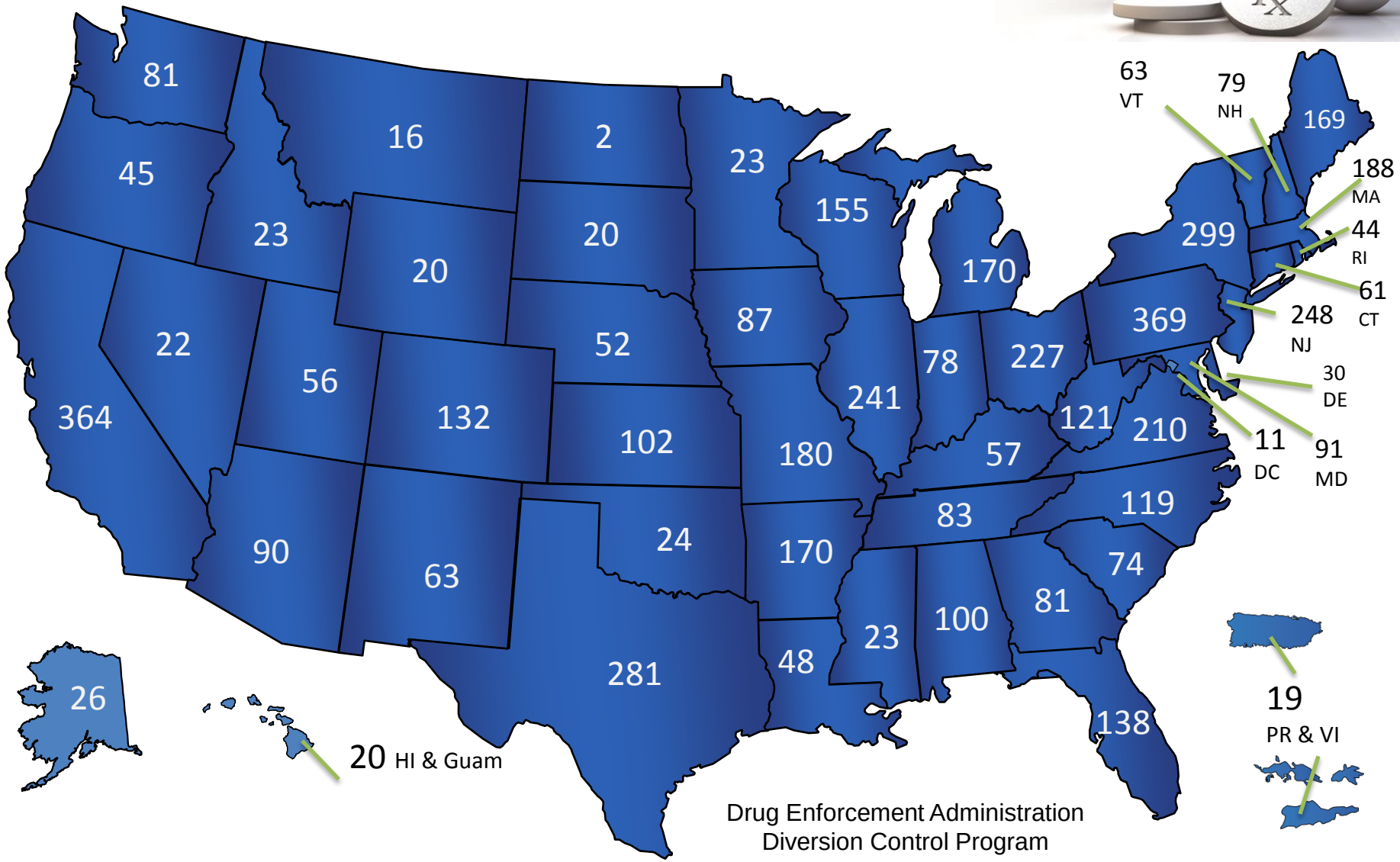
Total Law Enforcement Participation: 4,076



Drug Enforcement Administration
Diversion Control Program

National Take Back Day: September 27, 2014

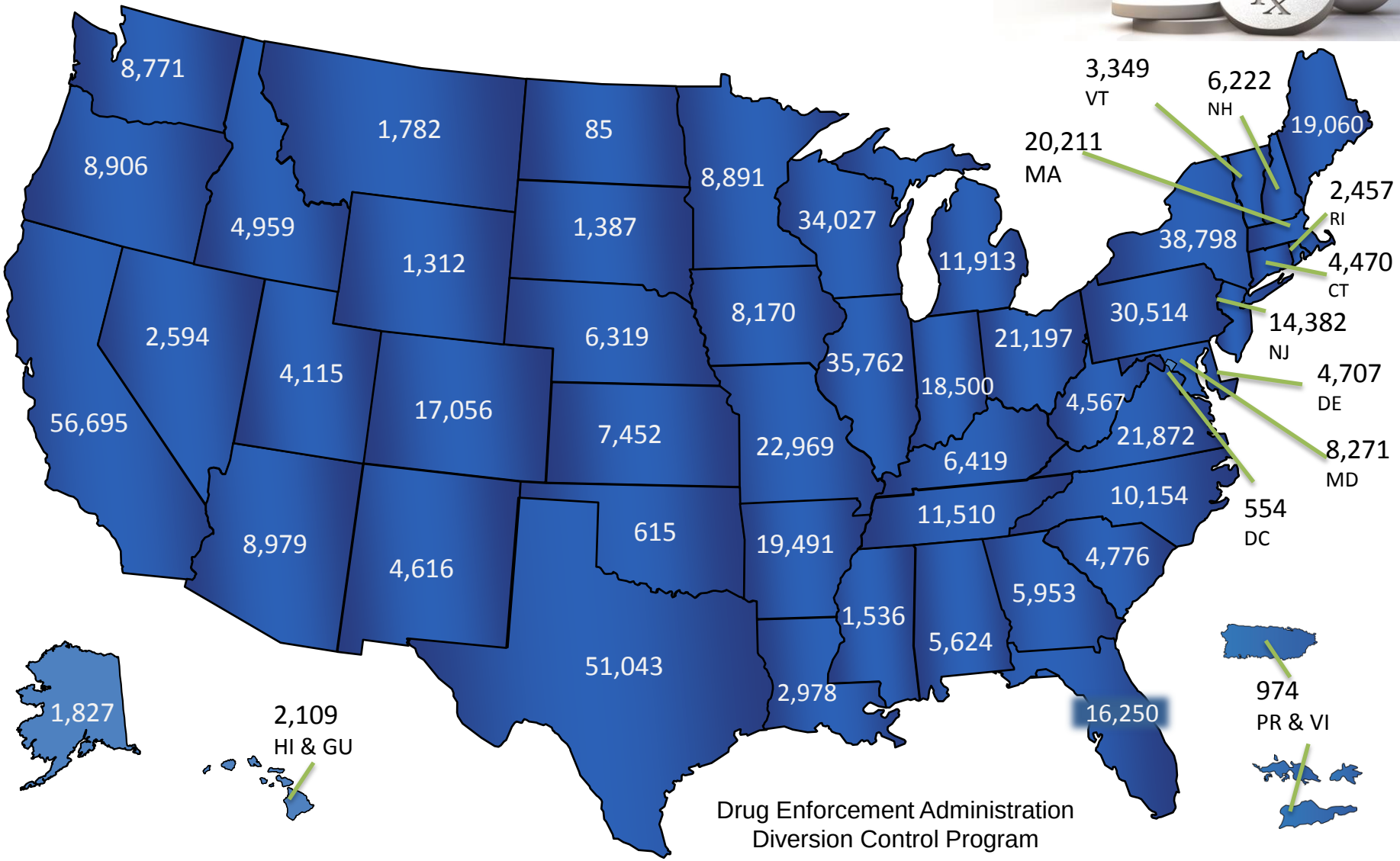
Total Collection Sites: 5,495



Drug Enforcement Administration
Diversion Control Program

National Take Back Day: September 27, 2014

Total Weight Collected (pounds): 617,150 (309 Tons)



Drug Enforcement Administration
Diversion Control Program

As Rx deaths dip, heroin overdoses surge

http://www.latimes.com/local/lanow/la-me-ln-drug-deaths-20141015-story.html

Prescription drug deaths declined in 2012 for the first time in more than a decade, but a surge in fatal heroin overdoses wiped out the modest improvement, according to U.S. government statistics released Wednesday.

Fatal heroin overdoses rose 35% to 5,927, while deaths involving chemically similar prescription painkillers such as OxyContin and Vicodin dropped 5% to 16,007, for an overall increase, according to figures released by the Office of National Drug Control Policy.

The statistics reflect, at least in part, the switch among addicts from prescription painkillers to heroin, which is cheaper and can be easier to get.

"Overall, we are not winning," said Andrew Kolodny, chief medical officer for Phoenix House, a national chain of addiction treatment centers.

Botticelli, acting director of the Office of National Drug Control Policy, said the prescription death figures were a "promising sign" that initiatives in education, treatment and enforcement launched by President Obama in 2011 were taking hold. But, he said, there was still work to do to turn around the "devastating impact" of the drug crisis.

Painkiller deaths quadrupled between 1999 and 2011, mirroring a sharp rise in the number of prescriptions for such drugs dispensed by pharmacies. In 2009, overdoses involving painkillers pushed drug fatalities past traffic accidents as a cause of death. And in 2011, the U.S. Centers for Disease Control and Prevention declared an epidemic.

The crisis had long been blamed on pharmacy robberies, teenage pill poppers and the "black market." But a 2012 Los Angeles Times study showed that physicians played an important role in prescription drug overdoses. The Times analysis of 3,733 fatalities found that drugs prescribed by physicians to patients caused or contributed to nearly half the deaths.

In response to overdoses and deaths, almost every state has created a prescription drug monitoring program so physicians can log into a computer to check whether a patient is getting a dangerous narcotic from another physician. And doctors have begun writing fewer prescriptions for some of the most popular painkillers, according to data compiled by IMS Health.

This year, CDC researchers reported the first sign that such efforts may be gaining ground. In Florida, they said, deaths involving narcotic painkillers dropped by 26% in the wake of a statewide crackdown on so-called pill mills that catered to addicts and dealers.

The latest rise in heroin deaths may be a sign that efforts to tighten up the supply of prescription painkillers is pushing addicts to use the illegal narcotic, said Amy Bohnert, a leading researcher in the field.

That, she said, presents a new policy challenge.

"The solutions so far have focused on how to change prescriber behavior, but the next step -- what to do with the patients affected by those changes -- hasn't occurred," said Bohnert, an assistant professor at the University of Michigan.

April Rovero, who founded the National Coalition Against Prescription Drug Abuse after her son Joey fatally overdosed on pills from a doctor, said she was pleased at the decline in painkiller deaths.

But, she said, "are we out of the woods? Absolutely not."

CALIFORNIA DRUG CONTROL UPDATE

This report reflects significant trends, data, and major issues relating to drugs in the State of California.

California At-a-Glance:

- Data from the Treatment Episode Data Set (TEDS) indicate 25% of voluntary California primary drug treatment admissions were for marijuana, while 36% were for stimulants (including methamphetamine).
- Approximately 9 percent of California residents reported past-month use of illicit drugs; the national average was 8 percent.
- The rate of drug-induced deaths in California is lower than the national average.

Drug Use Trends in California

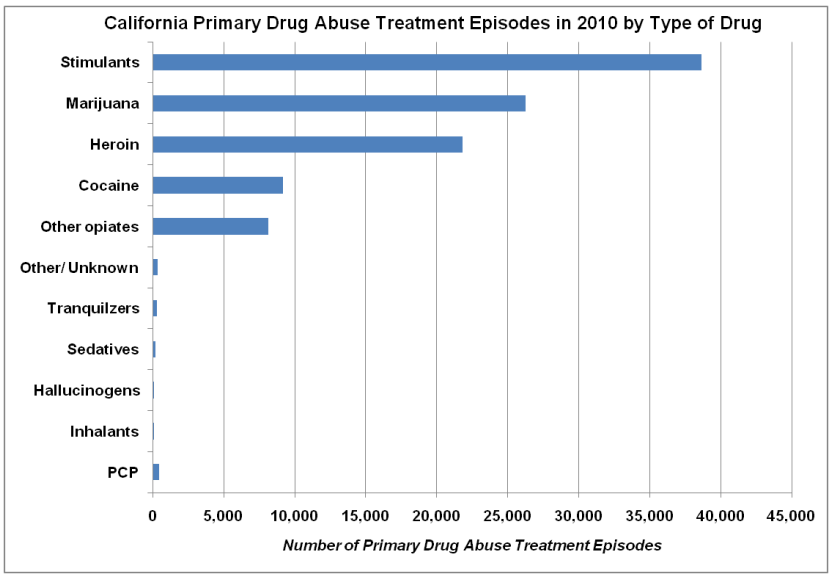
Drug Use in California: The National Survey on Drug Use and Health (NSDUH) provides national and state-level data on the use of tobacco, alcohol, illicit drugs (including non-medical use of prescription drugs) and mental health in the United States. In the most recent Survey, 9.07 percent of California residents reported using illicit drugs in the past month. The national average was 8.02 percent. Additionally, 3.94 percent of California residents reported using an illicit drug other than marijuana in the past month. The national average was 3.58 percent.
Source: Substance Abuse and Mental Health Services Administration - State Estimates of Substance Use from the 2007–2008 National Survey on Drug Use and Health: http://oas.samhsa.gov/2k8state/Cover.pdf

Drug-Induced Deaths: As a direct consequence of drug use, 4,178 persons died in California in 2007. This is compared to the number of persons in California who died from motor vehicle accidents (4,306) and firearms (3,268) in the same year. California drug-induced deaths (11.4 per 100,000 population) were lower than the national rate (12.7 per 100,000).
Source: Centers for Disease Control and Prevention - National Vital Statistics Reports Volume 58, Number 19 for 2007: http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf

Substance Abuse Treatment Admissions Data

California Primary Treatment Admissions

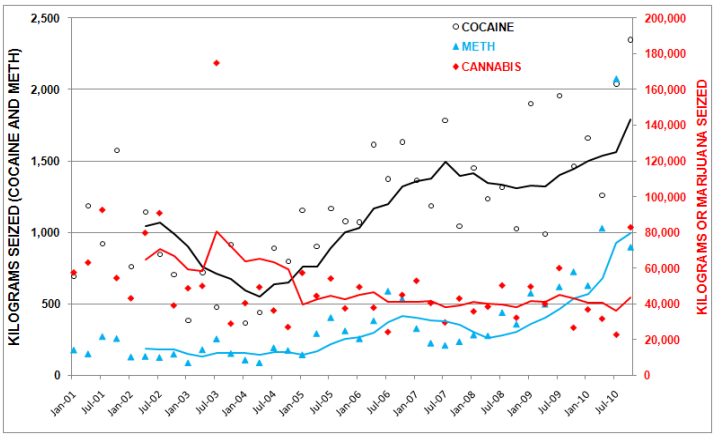
The graph at right depicts substance abuse primary treatment admissions in California in 2009. The data show stimulants, including methamphetamine, are the most commonly cited drugs among primary drug treatment admissions in California.
Source: Treatment Episode Data Set, Substance Abuse and Mental Health Services Administration: http://oas.samhsa.gov/dasis.htm



Southwest Border Drug Seizure Data

California Border Drug Seizure Data: The amount of cocaine seized along the California portion of the Southwest Border has steadily increased over the period 2001 to 2010. While the amount of marijuana seized over time has declined, methamphetamine seizures continue to increase.

Source: National Seizure System (NSS), EPIC, extracted 1/14/11

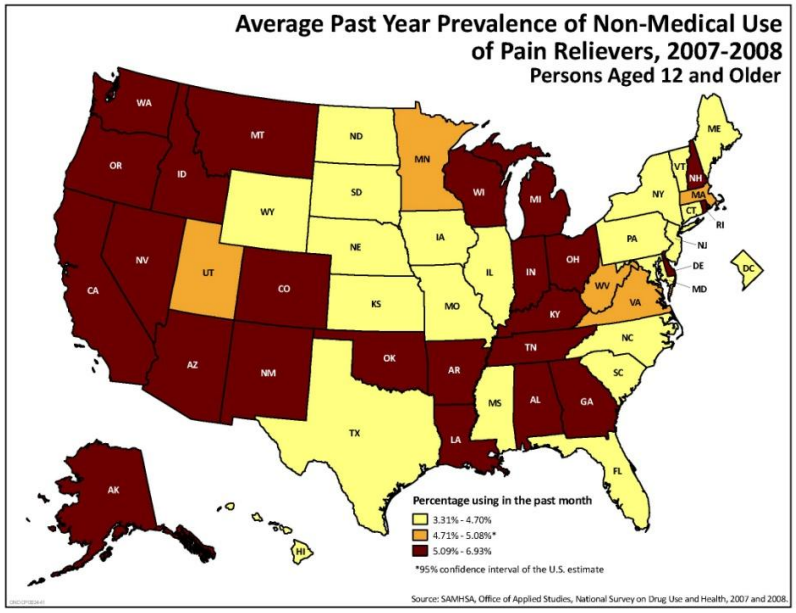


Quarterly Southwest Border drug seizures in California 2001-2010

Prescription Drug Abuse

ONDCP's Efforts to Combat Prescription Drug Abuse

Prescription drug abuse is the fastest-growing drug problem in the Nation. The Administration's Prescription Drug Abuse Prevention Plan, entitled, **"Epidemic: Responding to America's Prescription Drug Abuse Crisis,"** provides a national framework for reducing prescription drug diversion and abuse by supporting the expansion of state-based prescription drug monitoring programs; recommending secure, more convenient, and environmentally responsible disposal methods to remove expired, unused, or unneeded medications from the home; supporting education for patients and healthcare providers; and reducing the prevalence of pill mills and doctor shopping through enforcement efforts.



***State-Level Action:* Prescription Drug Monitoring Programs (PDMPs)**

PDMPs track controlled substances prescribed by authorized practitioners and dispensed by pharmacies. PDMPs serve a number of functions, including assisting in patient care, providing early warning signs of drug epidemics, and detecting drug diversion and insurance fraud. Thirty-five states have operational PDMP programs established by state legislation and funded by a combination of state and Federal funds. An additional 13 states have a prescription drug monitoring program authorized, but not yet operational. Adequate resourcing, increasing the number of states with operational PDMPs, and development of state-to-state information-sharing systems would

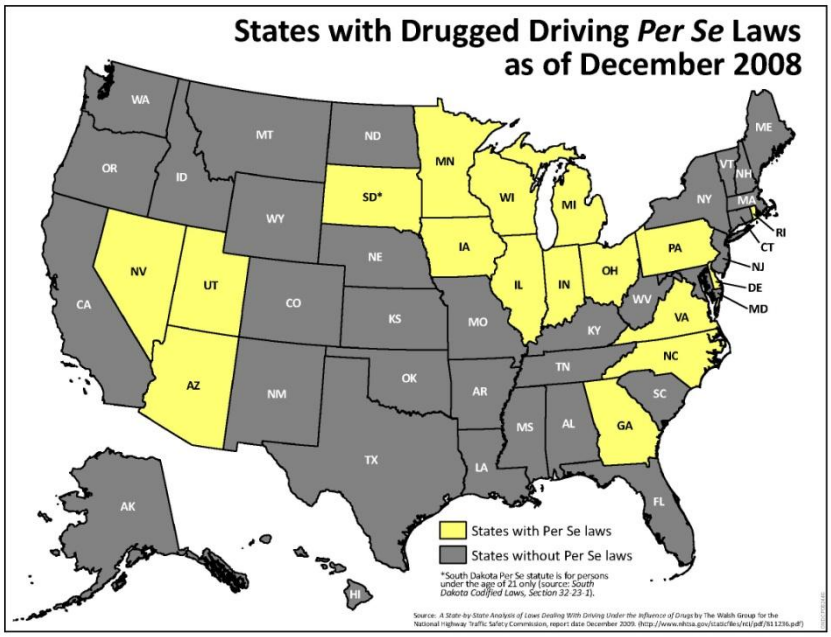
California's operational PDMP, the **Controlled Substance Utilization Review and Evaluation System (CURES),** contains over 100 million entries of controlled substances dispensed in California and responds to

more than 60,000 requests from practitioners and pharmacists each year. The system allows licensed healthcare prescribers, law enforcement, and regulatory boards to access real-time information on patients' controlled substance history.
Source: Office of the Attorney General, State of California. http://ag.ca.gov/bne/cures.php

***State-Level Action:* Drug Take-Back Programs**
A comprehensive plan to address prescription drug abuse must include proper disposal of unused, unneeded, or expired medications. Providing individuals with a secure and convenient way to dispose of controlled substances will help prevent diversion and abuse of these substances and demonstrate sound environmental stewardship. Federal rulemaking is underway and will further enhance the viability and scope of state and community take back programs. In the meantime, states are encouraged to work with the DEA to conduct additional take back events and educate the public about safe and effective drug return and disposal.

Prescription Drug Abuse

ONDCP Action on Drugged Driving
In 2007, the National Highway Traffic Safety Administration (NHTSA) found that one in eight weekend, nighttime drivers tested positive for illicit drugs. According to recent Fatal Accident Reporting System (FARS) data, one in three motor vehicle fatalities (33 percent) with known drug test results tested positive for drugs in 2009. Recognizing this growing problem, ONDCP is working to raise awareness of the dangers of drugged driving, provide increased training to law enforcement in identifying drugged drivers, and encourage states to consider *Per Se* laws to facilitate effective enforcement and prosecution of those who drive with drugs in their systems.



***State-Level Action:* Enacting *Per Se* Standards for Impairment**
Although all 50 states have laws against drugged driving, law enforcement often lacks adequate tools to enforce and prosecute drugged driving. ONDCP encourages states to develop and implement *Per Se* standards for impairment that make it illegal to drive a vehicle after taking illegal drugs. This is the same standard used successfully for 12 million commercial drivers in the United States over the past two decades. *Per Se* standards have been adopted in 17 states.

California does not have a *Per Se* standard. However, according to the California Vehicle Code (Section 23152 VC), it is unlawful for any person who is under the influence of any drug, or under the combined influence of any alcoholic beverage and drug, to drive a vehicle. It is also unlawful for any person who is addicted to the use of any drug to drive a vehicle.
Source: *A State-by-State Analysis of Laws Dealing With Driving Under the Influence of Drugs*, by the Walsh Group for the National Highway Traffic Safety Administration.

ONDCP Support for Community Based Prevention

National Anti-Drug Media Campaign

ONDCP's National Youth Anti-Drug Media Campaign provides consistent and credible messages to young people (including those in Native American and Alaska Native communities) about drug use and its consequences. *Above the Influence*, a major component of the Campaign, informs and inspires youth to reject illicit drugs and drinking via a mix of national and local advertising vehicles. The Campaign, in close partnership with local community-based, youth-serving organizations, also conducts teen-targeted *Above the Influence* activities to assist local groups with youth drug prevention work in their respective communities.

The Drug Free Communities (DFC) Program

Recognizing that local problems require local solutions, Drug Free Communities (DFC) organizations mobilize communities to prevent youth drug use by creating local data-driven strategies to reduce drug use in the community. ONDCP works to foster the growth of new coalitions and support existing coalitions through the DFC grants. In FY 2011, the following California coalitions received grants from ONDCP:

- A Sobering Choice
- Alcohol and Drug Prevention Coalition
- Alcohol, Tobacco and Other Drug Prevention Coalition
- Anderson Valley Community Action Coalition
- Ashland/ Cherryland Violence Prevention Collaboration (ACVPC)
- Boyle Heights Coalition for a Safe and Drug-Free Community
- California for Drug Free Youth
- Castro Valley Community Action Network
- CATALYST Coalition
- Cinco De Mayo Con Orgullo (With Pride) Coalition
- Coalition for a Drug-Free Nevada County
- Coalition for Gang Awareness and Prevention
- Coalition for Placer Youth
- Community-Supporting Alcohol and Drug Free Environment
- Crescenta Valley Drug and Alcohol Prevention Coalition
- Hemet Community Action Network (Hemet CAN)
- Julian Backcountry Collaborative
- Laytonville Healthy Start
- Mountain Communities Coalition to Address Substance Abuse
- NATHA
- Novato Blue Ribbon Coalition for Youth
- One East Palo Alto Community-Based Partnership for the Prevention of Alco, Tobac, and Other Drugs
- Preventing Alcohol Related Trauma in Salinas (P.A.R.T.S)
- Rancho Cordova Children, Youth and Families Collaborative
- Safety Wellness Advocacy Community Coalition
- San Dieguito for Drug Free Youth
- San Luis Obispo County Friday Night Live Partnership
- Santa Cruz County Community Prevention Partners
- Santa Ynez Valey Coalition
- Santee Solutions Coalition
- Saving Lives Camarillo
- Saving Lives San Fernando Valley California
- Siskiyou Substance Abuse Coalition
- Solano County Alcohol, Tobacco and Other Drugs (ATOD) Reducing Rates Coalition
- Sonoma County Prevention Partnership
- South County Collaborative
- South Orange County Coalition
- South Sacramento Coalition for Future Leaders
- Tahoe Truckee Future Without Drug Dependence (TT-FWDD)
- The Faith and Institutions Together for Health Coalition
- The Petaluma Coalition to Prevent Alcohol, Tobacco and Other Drug Problems
- Vision Coalition of Eldorado Hills
- We Stand United! Coalition of the Gridleyans United Against Drugs is a Necessary (GUARDIAN) Collaboration
- West End Gangs and Drugs Task Force
- YES Partnership

Source: Office of National Drug Control Policy
http://www.ondcp.gov/dfc/grantee_map.html

ONDCP High Intensity Drug Trafficking Area (HIDTA) County Info

The High Intensity Drug Trafficking Areas (HIDTA) program enhances and coordinates drug control efforts among Federal, State, and local law enforcement agencies. In designated HIDTA counties, the program provides agencies with coordination, equipment, technology, and additional resources to combat drug trafficking and its harmful consequences in critical regions of the United States.

HIDTA Counties in California

Central Valley HIDTA: Kern, Kings, Madera, Merced, Shasta, Stanislaus, San Joaquin, Fresno, Tulare, and Sacramento counties.
Los Angeles HIDTA: Los Angeles, Orange, Riverside, and San Bernardino counties.
Northern California HIDTA: Alameda, Contra Costa, Lake, Marin, Mendocino, Monterey, San Francisco, San Mateo, Santa Clara, Santa Cruz, and Sonoma counties.
Southwest Border HIDTA/California Region: Imperial and San Diego counties.

- The HIDTA program has been integral in targeting the major production and distribution threats of methamphetamine and marijuana in California.
- In addition to interdiction and eradication efforts, the four California HIDTAs participate in a state-wide, community-oriented demand reduction program.

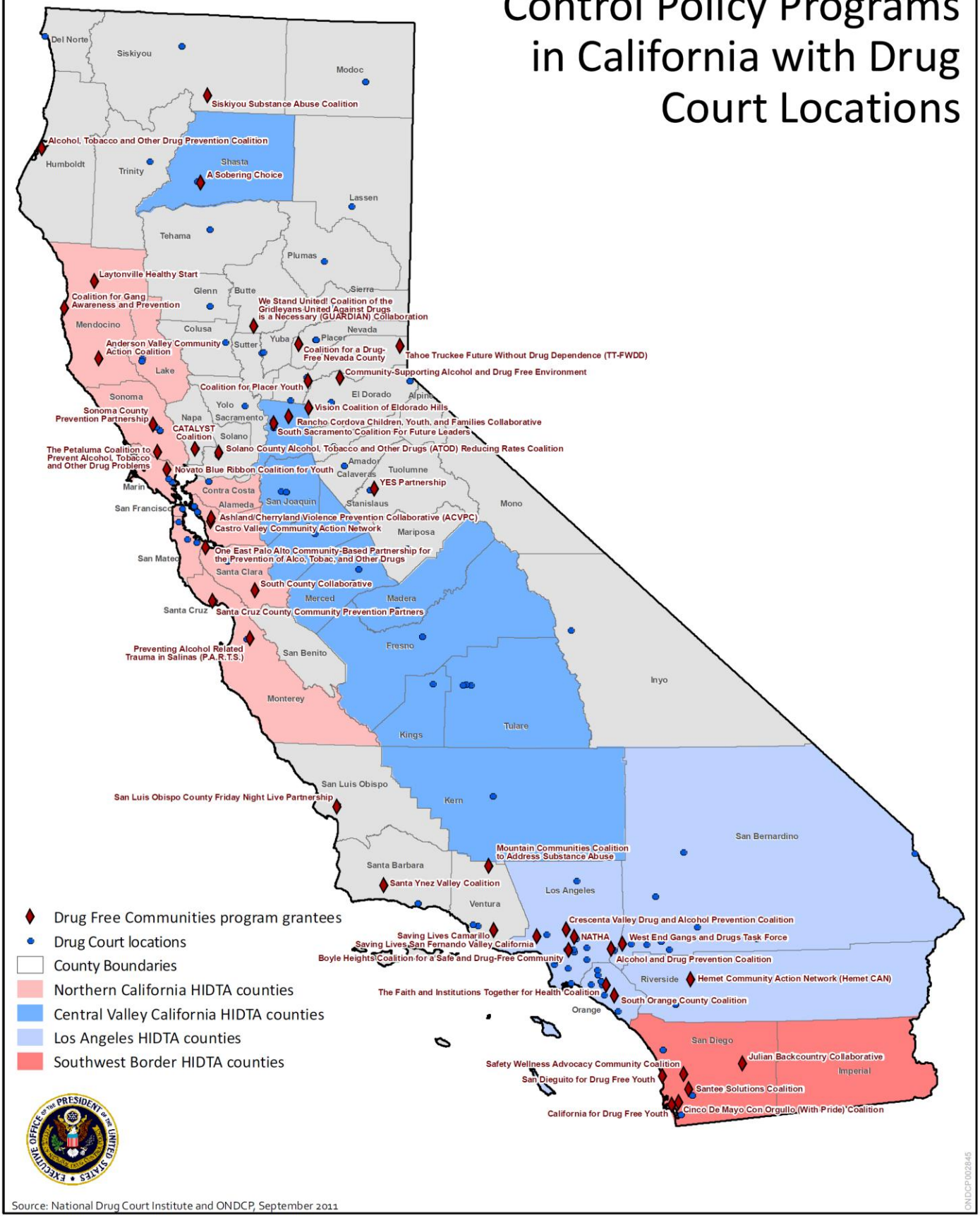
Federal Grant Awards Available to Reduce Drug Use in the State of California

The Federal Government awards competitive grants to help states in their efforts to reduce drug use and its harmful consequences. In FY 2010, direct support was provided to state and local governments, schools, and law enforcement organizations in your state for this purpose. Some Federal grant programs are dedicated to reducing drug use and its harmful consequences while others can be used for reducing drug use or for other purposes. In FY 2010, your State received support under the grant programs shown below.

Building State And Local Leadership Capacity for Preventing Youth Substance Use and Violence	249,554
Competition To Prevent High-Risk Drinking & Violent Behavior Among College Students	294,139
Grants For Coalitions To Prevent And Reduce Alcohol Abuse At Institutions Of Higher Education	-
Grants For School-Based Student Drug-Testing Programs	314,080
Improving The Climate For Learning	2,715,331
Safe Schools/Healthy Students Grants	23,518,353
Department of Health and Human Services	
Administration for Children and Families	**43,571,881**
Enhance the Safety of Children Affected by Parental Methamphetamine or Other Substance Abuse	3,834,000
Mentoring Children of Prisoners	3,519,692
Promoting Healthy and Stable Families	36,218,189
Centers for Disease Control and Prevention	**13,758,199**
HIV Prevention Activities_Non-Governmental Organization Based	13,758,199
Health Resources and Services Administration	**4,395,374**
Healthy Start Initiative	4,395,374
Immediate Office of the Secretary of Health and Human Services	**1,095,741**
Family and Community Violence Prevention Program	1,095,741
Indian Health Service	**2,070,038**
Urban Indian Health Services	2,070,038
National Institutes of Health	**154,324,327**
Discovery and Applied Research for Technological Innovations to Improve Human Health	45,701,848
Drug Abuse and Addiction Research Programs	108,622,479
Substance Abuse and Mental Health Services Administration	**332,075,296**
Block Grants for Prevention and Treatment of Substance Abuse	251,659,105
National All Schedules Prescription Electronic Reporting Grant	437,858
Projects for Assistance in Transition from Homelessness (PATH)	9,073,000
Substance Abuse and Mental Health Services_Projects of Regional and National Significance	64,201,333
Substance Abuse and Mental Health Services-Access to Recovery	6,704,000
Department of Housing and Urban Development	
Assistant Secretary for Community Planning and Development	**58,678,850**
Shelter Plus Care	58,678,850
Assistant Secretary for Housing--Federal Housing Commissioner	**26,804,793**
Shelter Plus Care	26,804,793
Department of Justice	
Office of Justice Programs	**124,362,138**
Community Capacity Development Office	1,410,940
Congressionally Recommended Awards	15,740,000
Criminal and Juvenile Justice and Mental Health Collaboration Program	549,322
Drug Court Discretionary Grant Program	2,243,377
Edward Byrne Memorial Justice Assistance Grant Program	57,966,279
Enforcing Underage Drinking Laws Program	356,400
Gang Resistance Education and Training	262,048
Harold Rogers Prescription Drug Monitoring Program	400,000
Indian Country Alcohol and Drug Prevention	1,195,590
Juvenile Accountability Block Grants	4,442,000
Juvenile Mentoring Program	1,178,161
National Institute of Justice Research Evaluation and Development Project Grants	17,983,739
Recovery Act - Eward Byrne Memorial Justice Assistance Grant (JAG) Program	54,835
Regional Information Sharing Systems	6,187,390
Residential Substance Abuse Treatment for State Prisoners	2,780,460
Second Chance Act Prisoner Reentry Initiative	8,568,563
Tribal Youth Program	2,068,865
Youth Gang Prevention	974,169
Department of Labor	
Employment and Training Administration	**1,000,000**
Reintegration of Ex-Offenders	1,000,000
Executive Office of the President	
Office of National Drug Control Policy	**29,942,125**
High Intensity Drug Trafficking Area Program	29,942,125
Substance Abuse and Mental Health Services Administration	**5,062,792**
Drug-Free Communities Support Program Grants	5,062,792
Grand Total	**832,107,905**

Note: Report as of 11/30/2010. FY 2009 includes additional grant awards under the Recovery Act. The Federal, State and Local Shares of Medicaid and the Federal Medicare Programs are not included above. File updated 3/10/2011.

Office of National Drug Control Policy Programs in California with Drug Court Locations



Source: National Drug Court Institute and ONDCP, September 2011

Heroin overdose deaths increased in many states through 2012

Still twice as many people died from prescription opioid overdoses

http://www.cdc.gov/media/releases/2014/p1002-heroin-overdose.html

Heroin deaths increased sharply in many states, according to a report of death certificate data from 28 states published by the Centers for Disease Control and Prevention in this week's *Morbidity and Mortality Weekly Report*. Despite these findings, still more than twice as many people died from prescription opioid overdoses as died from heroin in these states in 2012.

Though not directly addressed by this study, two things appear to be driving the increase in heroin overdoses: (1) widespread prescription opioid exposure and increasing rates of opioid addiction; and (2) increased heroin supply. While the majority of prescription opioid users do not become heroin users, previous research found that approximately 3 out of 4 new heroin users report having abused prescription opioids prior to using heroin. This relationship between prescription opioid abuse and heroin is not surprising; heroin is an opioid, and both drugs act on the same receptors in the brain to produce similar effects. Heroin often costs less than prescription opioids and is increasingly available.

"Reducing inappropriate opioid prescribing remains a crucial public health strategy to address both prescription opioid and heroin overdoses," said CDC Director Tom Frieden, M.D., M.P.H. "Addressing prescription opioid abuse by changing prescribing is likely to prevent heroin use in the long term."

Key Findings:

- This new study examined changes in heroin and prescription opioid death rates in 28 states [1] between 2010 and 2012. The 28 states represented 56 percent of the U.S. population.
- From 2010-2012, the overall heroin death rate across the 28 states doubled.
- The sharp heroin overdose increase extends the trend observed in the 2011 national mortality data.
- Five states had increases in prescription opioid death rates, seven states had decreases, and sixteen states had no change.
- Of the 18 states with reliable heroin overdose death rates examined individually in this study, 15 had statistically significant increases in heroin death rates. No state had a decrease in the heroin death rate.
- The increases in state heroin death rates from 2010-2012 were associated with increases in prescription opioid death rates.

"This study is another reminder of the seriousness of the prescription opioid overdose epidemic and the connection to heroin overdoses," said **Grant Baldwin, Ph.D, M.P.H**, Director, Division of Unintentional Injury Prevention. CDC and other federal agencies are working to promote a smart, coordinated approach to reduce inappropriate prescribing and help people addicted to these drugs."

While addressing prescribing is necessary to prevent opioid and heroin overdoses, it is important to help those already addicted to prescription opioids and heroin. Improving access to medication-assisted treatment is important. Increased use of naloxone, a prescription drug that can reverse an opioid or heroin overdose if administered in time, might also help save lives.

CDC's Injury Center works to protect the safety of everyone, every day. For more information about prescription drug overdoses, please visit www.cdc.gov/homeandrecreationalsafety/overdose.

Overdose Toolkit: http://store.samhsa.gov/shin/content//SMA14-4742/Overdose_Toolkit.pdf
Treatment Locator: http://findtreatment.samhsa.gov/

1 Alabama, Arizona, Colorado, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Utah, Virginia, and Washington.

###

ORIGINAL RESEARCH

Changes in Opioid Prescribing for Chronic Pain in Washington State

Gary M. Franklin, MD, MPH, Deborah Fulton-Kehoe, PhD, Judith A. Turner, PhD, Mark D. Sullivan, MD, PhD, and Thomas M. Wickizer, PhD

Purpose: **To conduct a survey of primary care physicians and advanced registered nurse practitioners (ARNPs) in Washington State (WA) focused on changes in practice patterns and use of support tools in the prescription of opioids for the treatment of chronic noncancer pain (CNCP).**

Methods: **A convenience sample of primary care providers in WA was obtained from diverse geographic regions and health care organizations. The web-based anonymous survey was conducted in March-August 2011.**

Results: **Among 856 provider respondents, 623 reported treating patients with CNCP and served as the analysis sample. Most providers (72%) reported concern about opioid overdose, addiction, dependence, or diversion. Only 25% indicated concern about regulatory scrutiny. Only a small proportion of providers overall (3.3%) reported that they had stopped prescribing opioids for CNCP, but twice as many ARNPs (5.8%) as physicians (MDs and osteopaths) (2.1%) reported this. A greater proportion of physicians (70.9%) than ARNPs (40.1%) reported familiarity with the Washington State opioid dosing guidelines. Physicians in a large health plan with substantial infrastructure support reported less concern about opioids compared with providers in other settings. Of providers in Spokane (the largest city in Eastern Washington), 45% reported very low capacity to access pain specialty consultation. The vast majority of providers reported a need to access more efficient, innovative means of support and education related to treating patients with CNCP, such as telemedicine consultation.**

Conclusions: **Overall, prescribing providers in WA reported ongoing concerns regarding opioid use for CNCP, but those affiliated with a health care organization with opioid prescribing guidelines and access to pain consultation were less likely to report being concerned about opioid-related problems or to have discontinued prescribing opioids. (J Am Board Fam Med 2013;26:394–400.)**

Keywords: **Chronic Pain, Nurse Practitioners, Opioids, Physicians, Primary Health Care**

A public health epidemic of morbidity and mortality related to prescribed opioids has engulfed the United States over the past decade, leaving in its wake approximately 15,000 deaths per year.[1] More citizens in the United States have died since 1999 from unintentional overdoses of prescription opioids than died in the Vietnam War.[2] Morbidity and mortality are increased in patients prescribed high daily doses of opioids (ie, >100 to 120 mg/day morphine-equivalent dose [MED]).[3–5] Although the vast majority of opioid use is short term, recent data suggest that the majority of patients receiving at least 3 months of continuous opioids continue to take opioids at least 2 years later.[6] Patients taking high doses and showing signs of opioid misuse are the most likely to proceed to years of use.[6] These

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From the Departments of Environmental and Occupational Health Sciences (GMF, DF-K) and Health Services (GMF), University of Washington School of Public Health and Community Medicine, Seattle; the Washington State Department of Labor and Industries, Olympia (GMF); the Departments of Neurology (GMF), Psychiatry and Behavioral Sciences (JAT), and Rehabilitation Medicine (JAT), University of Washington School of Medicine, Seattle; and the Division of Health Services Management and Policy, College of Public Health, Ohio State University, Columbus, OH (TMW).

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Corresponding author: Gary M. Franklin, MD, MPH, 130 Nickerson, Suite 212, Seattle, WA 98109 (E-mail: meddir@uw.edu)

data suggest that long-term opioid therapy may be a self-perpetuating or even lifelong therapy that may have a significant adverse financial effect on state Medicaid and workers' compensation systems.[7] In response to these serious problems, public agencies in the state of Washington (WA) implemented in 2007 the first opioid dosing guideline in the United States,[8]; in 2010 the state passed the first new laws repealing earlier permissive laws,[9] and implemented regulations[10] reflective of widely agreed upon best practices for the safe and effective prescription of opioids for chronic noncancer pain (CNCP).

The principal prescribers of opioids for adults with CNCP are primary care providers. These providers—prominently MDs, osteopaths, and, in some states, advanced practice nurses—are in a particularly difficult position, often facing patients with complex pain-related problems and demands. In a survey of WA primary care physicians in early 2009, the majority of providers reported serious concerns about the development of dependence, addiction, or diversion in their patients with CNCP who were treated with opioids.[11] Moreover, up to a third of primary care physicians report having experienced severe adverse events, including death, among their patients with CNCP who were treated with opioids.[12,13] At the same time, one third of WA primary care physicians report difficulty accessing pain consultation to assist in caring for these patients.[11] These converging circumstances may contribute to the reluctance of primary care providers to initiate opioid therapy in patients with CNCP or to accept new patients into their practices who are already receiving chronic opioid therapy.[12] Medical students report that treating complex patients with CNCP and opioids is a reason for them not to enter a primary care field.[14]

To better understand current practice patterns related to opioid prescribing for patients with CNCP in the rapidly changing policy and regulatory landscape in WA, we conducted a survey of primary care prescribers in the state, including nurse practitioners. In particular, we sought to examine (1) changes in physician practice patterns regarding opioid use for CNCP compared with an earlier survey, 2) differences in practice patterns between advanced registered nurse practitioners (ARNPs) and physicians, and 3) differences between prescribers across regions and health systems likely to have disparities in resource support. In our survey, we paid particular attention not just to identifying recognized problems, but also to identifying potential solutions to the current crisis.

Methods

Study Design and Survey Development

The current survey was adapted from a prior survey[11] of primary care physicians (N = 655) conducted in WA from October through December 2009. We revised the 21 items used in the prior survey[11] and added questions assessing other areas. The final survey consisted of 39 items and took 15 minutes on average to complete. In this survey, we focused largely on how practice patterns may have changed since implementation of the WA Opioid Dosing Guideline in 2007.[8] As an example of question format, we asked, "Has the frequency of your opioid prescribing for chronic, noncancer pain changed over the past 3 years?" Response choices were (1) "Yes, I prescribe opioids to more of my chronic pain patients now"; (2) "Yes, I prescribe opioids to fewer of my chronic pain patients now"; (3) "Yes, I stopped prescribing opioids"; (4) "I have not prescribed opioids in the past 3 years"; and (5) "There has been no change in the number of chronic pain patients for whom I prescribe opioids."

We approached numerous organizations and asked either clinical pain specialists/leaders or administrative personnel in those organizations to assist in disseminating the survey. Organizations that agreed to participate included the Washington State Medical Association (by sending out a link in their monthly newsletter); Group Health (GH), a large integrated health plan serving more than 400,000 members in WA (via listserv E-mail distribution by a pain specialist/leader); the Everett Clinic, a large multispecialty clinic in an urban area north of Seattle (via listserv E-mail distribution by a pain specialist/leader); the Washington Academy of Family Practice (via listserv E-mail distribution by administrative personnel); and the Spokane County Medical Society (via direct mail, E-mail, and web/newsletter notification by administrative personnel). The Spokane County Medical Society was added at their request because of perceived concerns regarding opioid use in the county. In addition, a current mailing list of actively practicing

ARNPs was accessed through the WA Department of Health, and invitations were mailed from our research office to ARNPs regarding potential participation. Once distributed in each organization or group, the survey was available for up to 120 days. Like the earlier survey, our adapted survey was anonymous and web-based, using Survey Monkey (http://www.surveymonkey.com/). The current survey was conducted from March through August 2011. The project was approved by the University of Washington Human Subjects Review Committee.

Statistical Analysis

The analysis sample consisted of survey respondents who said that they treated patients with CNCP. We used descriptive statistics to characterize the sample and survey responses. We used χ^2 tests to compare responses of different types of providers and providers in different settings. In particular, we compared responses of physicians and ARNPs. We also compared responses of providers in Spokane, the largest city in Eastern WA (county population of 451,000) with those of providers in other regions of the state. Finally, we compared responses of providers affiliated with GH, a nonprofit health care system in WA that in 2010 implemented a multifaceted risk mitigation initiative and guideline targeting management of patients receiving long-term opioid therapy.[15] Statistics were analyzed using 2-tail tests, and we considered statistical significance to be $P < .05$. SPSS version 15.0 (SPSS, Inc., Chicago, IL) was used to conduct the analyses.

Results

A total of 856 providers completed the survey. Response rates varied somewhat across the organizations: Group Health, 10.8% (63 of 584 providers on the E-mail distribution list); Washington Academy of Family Practice, 6.3% (169 of 2700 providers on the E-mail distribution list); and ARNPs, 8.5% (425 of 5000 who were mailed invitations to participate). Of these respondents, 623 said that they treated patients with CNCP; the respondents are the focus of this report. Among these respondents, 253 self-identified as an MD (40.6%), 243 as an ARNP (39%), 32 as an osteopath (5.1%), and 16 as a physician assistant (2.6%). Respondents with missing data for provider type (n = 79) were excluded from analyses by provider type. For analyses related to physicians, MDs and osteopaths are combined.

Overall, physician responses were similar to the responses in the prior survey,[11] with the exception that 71% of physicians in the current survey reported that they had read and/or applied the WA Opioid Dosing Guideline[8] compared with 62% in 2009 ($P = .01$). Compared with the 2009 survey, the current survey sample included a greater proportion of female providers (62.5% vs. 40%) and a smaller proportion of MDs (41% vs. 88%).

Table 1 summarizes the providers' reported opioid prescribing practices. Physicians were more likely than ARNPs to report prescribing opioids to ≥50% of their patients with CNCP (39.8% of physicians vs. 21.7% of ARNPs; $P < .01$). Fewer GH providers (18.8%) than non-GH providers (42.7%) reported prescribing opioids to ≥50% of their patients with CNCP ($P = .008$). Although 44.4% of respondents overall reported prescribing opioids to fewer patients with CNCP than in the past, the majority of both GH (60.4%) and Spokane providers (63%) reported this. More than twice as many ARNPs (5.8%) as physicians (2.1%) reported having stopped prescribing opioids altogether ($P = .03$). No GH providers reported that they stopped prescribing opioids. A majority of both GH (57.4%) and Spokane (58.9%) providers reported prescribing higher doses of opioids less often. A majority of providers (72.3% overall; 73.1% of physicians) reported being very concerned about overdose, addiction, dependence, or diversion. In the 2009 survey, 54% of physicians reported those concerns. In the current survey, a somewhat smaller proportion of GH providers (61.7%) reported being very concerned about those opioid-related problems compared with non-GH providers (73.2%; $P = .09$). A minority of all survey respondents who saw patients with CNCP (25.3%) indicated that they were very concerned about regulatory scrutiny. Only 12.8% of GH providers were so concerned, compared with 26.4% of non-GH providers ($P = .07$).

Table 2 provides information about the use of the WA Opioid Dosing Guideline and other resources. Compared with physicians, fewer ARNPs had read and/or applied the guideline (40.1% of ARNPs vs. 70.9% of physicians; $P < .01$). The majority of providers (87%) felt that the 120 mg/day MED yellow

Table 1. Opioid Prescribing Practices of 623 Primary Care Physician and Advanced Registered Nurse Practitioner (ARNP) Survey Respondents, Overall and by Physician, ARNPs, and Two Large Practice Site Subgroups*

	Overall (623)	Physicians	ARNPs	Spokane	Group Health
Prescribes opioids to ≥50% of patients with CNCP	186/610 (30.5)	113/284 (39.8)	52/240 (21.7)	25/75 (33.3)	9/48 (18.8)
Now prescribes opioids to:					
More CNCP patients	63/601 (10.5)	29/284 (10.2)	27/240 (11.3)	3/73 (4.1)	2/48 (4.2)
Fewer CNCP patients	267/601 (44.4)	129/284 (45.4)	103/240 (42.9)	46/73 (63.0)	29/48 (60.4)
Stopped prescribing	20/601 (3.3)	6/284 (2.1)	14/240 (5.8)	2/73 (2.7)	0/48 (0)
Now prescribes:					
Higher doses more often	34/594 (5.7)	17/282 (6.0)	12/238 (5.0)	1/73 (1.4)	1/47 (2.1)
Higher doses less often	277/594 (46.6)	142/282 (50.4)	97/238 (40.8)	43/73 (58.9)	27/47 (57.4)
No Change	262/594 (44.1)	117/282 (41.5)	116/238 (48.7)	26/73 (35.6)	18/47 (38.3)
When prescribing opioids, how concerned are you about (% very concerned):					
Overdose or addiction or dependence or diversion	425/588 (72.3)	207/283 (73.1)	169/236 (71.6)	56/73 (76.7)	29/47 (61.7)
Regulatory scrutiny	149/588 (25.3)	79/283 (27.9)	54/235 (23.0)	21/72 (29.2)	6/47(12.8)

Values are n/N (%).
*There were 623 respondents who said that they treated patients with chronic noncancer pain (CNCP), but the sample size for each question differed because of missing data and skip patterns. The physician, ARNP, Spokane, and Group Health categories are subgroups of the overall group and may overlap.

flag dose in the guideline was reasonable (71%) or too high (16%). More physicians compared with ARNPs reported having access to opioid prescribing policies and tools in their clinics (68.1% vs. 48.5%; $P < .01$) and electronic prescription records linked to electronic health records (84.1% vs. 62.5%; $P < .01$) that could assist in supporting appropriate opioid use. Spokane providers were the most likely to report "never or almost never" successfully obtaining a pain consultation compared with non-Spokane providers (42.5% vs. 12.8%; $P < .01$). Only 3.3% of GH providers reported such difficulty compared with 16.7% of non-GH providers ($P < .01$).

The great majority of all groups thought that specific innovative methods of consultation or assistance, such as telephone or video consultation with experts, would be helpful. Nearly 90% reported that web-based continuing medical education training would be useful. Only a minority of providers overall (17.6%) reported participating in collaborative therapy arrangements with pharmacists, but 47.7% of GH providers reported this capacity versus 14.9% of non-GH providers ($P < .01$).

Discussion

Primary care providers in the United States find themselves at an important crossroads concerning opioid therapy for CNCP. For more than a decade, pain experts and organized medicine called for more adequate treatment of pain with opioids, which increased prescribing by physicians and other providers who treated patients with CNCP.[16] Rates of use and daily doses of the most powerful schedule II opioids then rose dramatically.[17] These increased rates of use—especially increased rates of high-dose use—have contributed to the public health epidemic of overdose morbidity and mortality that has occurred over the past decade.[3–5]

In 2007, WA was the first state or jurisdiction to implement specific dosing guidance for opioids in the treatment of CNCP.[8] It was also the first state to repeal the "Intractable Pain" laws that had legalized long-term opioid therapy without a dosing ceiling and to implement new laws and regulations reflecting generally agreed upon best practices.[9,10] In a 2009 survey primary care physicians in WA reported that they rarely used most of these best practices and that they thought that more guidance and community resources, including dosing guidance, was needed.[11] WA agencies and our collaborating clinical and academic advisors responded with an updated Opioid Dosing Guideline in June 2010, which contained tools needed to implement most of the best practices.[8]

Table 2. Availability/Use of Guidelines, Tools, and Consultation, by Group*

	Overall (n = 623)	Physicians	ARNPs	Spokane	Group Health
Read and/or applied guideline	309/562 (55)	200/282 (70.9)	95/237 (40.1)	33/65 (50.8)	27/45 (60.0)
Yellow flag dose (120 mg/day morphine equivalents) reasonable or too high	489/561 (87.2)	241/283 (85.2)	211/237 (89.0)	58/65 (89.2)	42/46 (91.3)
Tools available in clinic					
Policy, guideline, or algorithm for prescribing opioids for CNCP	344/592 (58.1)	194/285 (68.1)	116/239 (48.5)	39/72 (54.2)	42/47 (89.4)
Electronic prescription record linked to EMR	440/590 (74.6)	238/283 (84.1)	150/240 (62.5)	57/71 (80.3)	45/46 (97.8)
Of those who tried to obtain a pain management consultation, percentage never or almost never successful	64/408 (15.7)	34/219 (15.5)	29/175 (16.6)	17/40 (42.5)	1/30 (3.3)
How helpful would you find each of the following in managing your patients with CNCP? (% somewhat or very helpful)					
Telephone consultation with experts	445/532 (83.6)	219/282 (77.7)	212/234 (90.6)	49/61 (80.3)	39/44 (88.6)
Telemedicine or web-based tool	360/532 (67.7)	169/281 (60.1)	178/235 (75.7)	44/61 (72.1)	28/43 (65.1)
Web-based CME training	466/531 (87.8)	234/279 (83.9)	218/235 (92.8)	49/61 (80.3)	40/43 (93.0)
Patient decision aids	468/533 (87.8)	240/280 (85.7)	213/237 (89.9)	54/60 (90.0)	37/43 (86.0)
Advanced training that would provide a certificate of special competence in treatment of CNCP	420/531 (79.1)	195/278 (70.1)	209/236 (88.6)	41/60 (68.3)	34/43 (79.1)
Prescription monitoring program	479/534 (89.7)	255/280 (91.1)	207/237 (87.3)	57/61 (93.4)	42/44 (95.5)
Collaborative drug therapy agreement with pharmacists to prescribe or manage patients taking opioids (% yes)	95/539 (17.6)	96/284 (33.8)	37/238 (15.5)	8/62 (12.9)	21/44 (47.7)

Values are n/N (%).
*There were 623 respondents who said that they treated patients with chronic noncancer pain (CNCP), but the sample size for each question differed because of missing data and skip patterns. The physician, advanced registered nurse practitioner (ARNP), Spokane, and Group Health categories are subgroups of the overall group and may overlap.
CME, continuing medical education; EMR, electronic medical record; Q24f.

When the WA Opioid Dosing Guideline was first published online in April 2007, it received strong negative feedback from professional pain organizations and patient advocacy groups and a lawsuit was filed but was subsequently overturned. However, in the 2009 survey of WA primary care physicians, 86% reported that a yellow flag dose of 120 mg/day MED was reasonable (75%) or too high (11%), which is similar to the results of the current survey (71% and 16%, respectively).[11] Of primary care prescribers who responded to the 2009 survey, 54% were concerned about dependence, addiction, and diversion. In the current survey, an even larger proportion of providers (72%) reported similar concerns. These concerns are consistent with survey data collected from primary care physicians in low-income clinics in the United States,[12] Canada,[13] and Veterans Affairs medical clinics.[18] Thus, while primary care physicians generally express confidence in their ability to use opioids to treat CNCP,[12,13] potential risks of dependence and addiction and lack of community and system resources are significant concerns.

In the current survey, providers in a large WA integrated health plan (GH) that has a long tradition of innovation in chronic care reported fewer concerns regarding opioid prescribing for CNCP. This is likely because of strong institutional support throughout the organization for adoption of best practices regarding opioid prescribing, including a risk mitigation initiative and prescribing guideline targeting patients receiving chronic opioid therapy that was implemented in October 2010.[15] Although 3.3% of all providers statewide reported they had stopped prescribing opioids for CNCP, no GH provider in our survey reported doing so. While 16.7% of non-GH providers and 42.5% of Spokane providers reported that they "never or almost never" can access a pain consultation, only one GH physician reported such difficulty. When WA passed new opioid laws early in 2010,[9] concern was expressed regarding regulatory

scrutiny and potential overreach by the government. However, in the current survey, conducted about 1 year after passage of the law, only a minority of WA providers overall (25.3%) reported being very concerned about regulatory scrutiny. Among providers at GH, only 12.8% reported such concern. In Spokane, a community with less support for opioid prescribing and chronic pain management best practices, 29.2% expressed concern.

Although ARNPs may prescribe controlled substances in WA and in most states,[19] this is the first report of opioid prescribing practices specific to ARNPs. Of the respondents in this survey, 39% were ARNPs. Overall, in our survey, ARNPs, as compared with physicians, were less likely to report prescribing opioids to the majority of their patients with CNCP, to have read/applied the WA Opioid Dosing Guideline, or to have available opioid policy tools or electronic health records in their clinical setting. Compared with WA physicians, ARNPs were more than twice as likely to have stopped prescribing opioids altogether to their patients with CNCP. The reasons for these differences are not clear.

Limitations of this study include the use of a convenience sample and a low response rate. The 2009 survey focused on acceptance and diffusion of the 2007 Opioid Dosing Guideline, whereas the current survey was expanded to include a focus on changing practices and needed resources. The addition of ARNPs to the survey sample and different methods of accessing respondents resulted in differences between the 2009 survey and the current survey that precluded ability to directly compare results.

Although questions remain concerning the long-term effectiveness of opioid therapy in people with CNCP, there is little question that more community-based resources will be necessary to effectively treat patients with CNCP. In this survey, the great majority of all prescribers reported enthusiasm for the diffusion of tools to help them manage patients with CNCP, including phone consultations with experts, web-based tools, web-based continuing medical education, and other advanced training, patient decision aids, and computerized programs to monitor prescription drugs. The current results also suggest a pressing need to increase capacity in the majority of communities that do not have the substantial resources required to effectively address chronic pain.[16]

We have begun to develop such capacity through payment incentives for best practices and improved care coordination among injured workers in WA[20] and by offering more efficient means of consultation, such as the use of video-linked consultations with panels of university-based experts.[21] The prevention and adequate treatment of chronic pain should be considered in the same conceptual framework offered by leaders of integrated care management for other chronic diseases.[22] As such, a medical home model to address chronic pain as a community-wide health delivery innovation should be considered. Insurers will be critical in developing incentives for best practices that could be effective alternatives to opioids in preventing and treating chronic pain, such as reducing patient avoidance of fear and promoting patient participation in customary activities, graded exercise, cognitive-behavioral therapy, and multidisciplinary intensive rehabilitation.[23] In addition, incentivizing balanced, evidence-based provider education on these best practices will be necessary to help ensure their dissemination.

Conclusion

Opioids have not turned out to be the effective and "not as addicting as we used to believe" treatment that some pain champions and pharmaceutical companies promised, based on no good scientific evidence, in the late 1990s.[24] We were told that there is no ceiling on dose and that the best way to treat tolerance is to keep increasing dose. We have now learned that dose is highly related to morbidity and mortality[3–5]; implementation of more clear-cut dosing guidance and other best practice tools are needed at this point.[8,15] Practitioners are clamoring for more guidance and community resources to deal with the multitude of patients now receiving long-term opioid therapy and the many other patients with chronic pain who are not taking opioids. There is a particularly urgent and critical need for research that will generate the information necessary to prevent the next cohort of patients from getting potentially lethal but ineffective doses of opioids and to shed light on effective ways to improve the suffering and function of those who already are dependent on or addicted to opioids and are still in pain.

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Prescription drug abuse: There is help

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NEWSROOM

By **Ashley N. Vaughan**, CNN
updated 4:32 PM EDT, Fri August 15, 2014

STORY HIGHLIGHTS

- Millions of people are nonmedical users of pain relievers, agency says
- Those affected by prescription drug abuse can call 1-800-662-HELP (4357)
- Treatment options should be tailored to fit an individual's needs, experts say

(CNN) -- Facing the reality that "I need help" and knowing where to actually get it are crucial initial steps for anyone battling prescription drug addiction. The process to recovery can be one ridden with pain, denial and shame.

If you search on the Internet for "Where to get help for prescription drug abuse?" search results are in the millions. Trying to find the best treatment options for yourself or a loved one can be overwhelming. But it is not impossible.

The Substance Abuse and Mental Health Services Administration, known as SAMHSA, estimates that in 2012, 4.9 million people in the United States older than 11 were nonmedical users of pain relievers. On SAMHSA's website, it offers an online Behavioral Health Treatment Services locator where individuals can type in their ZIP code and get directions to treatment centers in their community.

SAMSHA also offers a 24-hour free hot line for treatment referrals and support: 1-800-662-HELP (4357). Calls are confidential and offered in English and Spanish.

For treatment options tailored to the needs of veterans, the Veterans Crisis Line directs vets and their loved ones to "qualified, caring Department of Veterans Affairs responders through a confidential toll-free hot line": 1-800-273-8255, option 1.

The department's website says veterans of all "ages and circumstances" can also chat online and text 838255 for support options. All contact points are accessible 24 hours a days, seven days a week, 365 days a year. The organization says since its inception it has answered more than 1 million calls and has made 37,000 lifesaving rescues.

We need to approach substance abuse disorder from a whole person perspective.
-Jack Stein, NIDA

Once referred to a treatment center, knowing what to look for is key. Treatment options are not created equal or one-size-fits-all. When considering a program, the National Institute on Drug Abuse, or NIDA, recommends choosing a treatment method that is backed by solid scientific evidence. The organization also recommends asking if a program customizes treatment to the individual needs of each patient, taking into account a patient's background and particular history with drug abuse.

"Without attending to the social issues (of an individual) we will not see as great of an effect as potentially possible," says Jack Stein, director of the office of science policy and communication at NIDA. "We need to approach substance abuse disorder from a whole person perspective."

Stein also recommends selecting a treatment program that uses a combination therapy approach: one that addresses both detoxifying and the continuing needs of the individual.

NIDA offers advice about questions to ask upon starting a treatment program, such as whether the duration of treatment is sufficient for the need. On its website, NIDA says research suggests most addicted people need a minimum of three months in treatment. However, the best treatment strategies track one's progress and develop plans that will maintain a long-term recovery.

One way to guarantee continued support during and after a treatment program is to find a local chapter of Alcoholics Anonymous or Narcotics Anonymous. You can do so online.

Unfortunately, when it comes to prescription drug abuse, relapse can happen. It's important to realize, says NIDA, that even if relapse occurs, it doesn't automatically equal failure.

The organization encourages families to view substance abuse similarly to a chronic disorder such as heart disease or asthma, which will require "support and vigilance on the part of the individual."

Staying connected to a community like a local support group is key. So is recognizing there maybe setbacks.

"If someone returns to (drug) use, the key is there is an opportunity for the individual to return to treatment and continue on the path to recovery," Stein said. "We try to encourage families to understand that relapse can occur but the individual can recover."

Drug Topics
Voice of the Pharmacist
Published on *Drug Topics* (http://drugtopics.modernmedicine.com)

Coalition targets abuse of ADHD meds

Mark Lowery, Content Editor
Publish Date: AUG 29,2014

A new coalition has formed to help prevent the misuse, abuse, and diversion of medications for the treatment of attention-deficit/hyperactivity disorder (ADHD), particularly among college students.

Coalition to Prevent ADHD Medication Misuse (CPAMM) members include the American Academy of Family Physicians, Children and Adults with Attention-Deficit Hyperactivity Disorder (CHADD), the Jed Foundation, NASPA – Student Affairs Administrators in Higher Education, the BACCHUS Initiatives of NASPA, and Shire.

More U.S. adults relying on ADHD meds

CPAMM's focus will be research and educational programs. It plans to study the perceptions and attitudes of college students regarding ADHD prescription stimulant misuse and abuse. That research will be used to design educational campaigns to prevent nonmedical use.

"Shire opposes the misuse, abuse, and diversion of ADHD prescription stimulant medication and is committed to being a part of a solution to help prevent nonmedical use while preserving access to these important medications for those with a legitimate medical need," said Gwen Fisher, Shire's senior director of corporate communications. "Shire recognizes that to create change we need collaborative solutions, which is why we've brought together this team of diverse and experienced experts and advocates."

Misuse of ADHD medications is prevalent at many colleges and universities. A 2013 study at one large public university found that 9.3% of college students admitted nonmedical use of prescription stimulant medications.

"The misuse, abuse, and diversion of prescription drugs is a concern of student affairs administrators across the country. Often, students who inappropriately use ADHD prescription medications don't realize the consequences it may have on their academic career and future livelihood," said Kevin Kruger, PhD, president of NASPA – Student Affairs Administrators in Higher Education. "As an association that represents more than 14,000 professionals, it is imperative that we increase awareness of the serious impact of ADHD prescription misuse, abuse, and diversion."

For most chronic pain, neurologists declare opioids a bad choice

http://www.latimes.com/science/sciencenow/la-sci-sn-for-chronic-pain-opioids-20141001-story.html

But even for patients who do appear to benefit from opioid narcotics, the neurology group warned, physicians who prescribe these drugs should be diligent in tracking a patient's dose increases, screening for a history of depression or substance abuse, looking for signs of misuse and insisting as a condition of continued use that opioids are improving a patient's function.

In disseminating a new position paper on opioid painkillers for chronic non-cancer pain, the American Academy of Neurology is hardly the first physicians group to sound the alarm on these medications and call for greater restraint in prescribing them.

But it appears to be the first to lay out a comprehensive set of research-based guidelines that outline which patients are most (and least) likely to benefit from the ongoing use of opioids -- and what practices a physician should follow in prescribing the medications for pain conditions.

The statement would govern the prescribing of morphine, codeine, oxycodone, methadone, fentanyl, hydrocodone or a combination of those drugs with acetaminophen. It was published Wednesday in the journal Neurology.

The American Academy of Neurology's position statement also urges physicians to work with officials to reverse state laws and policies enacted in the late 1990s that made the prescribing of opioid pain medication vastly more commonplace.

The position paper notes that despite a national epidemic of painkiller addiction that has claimed more than 100,000 lives in just over a decade, many of the laws and practices adopted in the late 1990s remain unchanged. It adds that prescription drug monitoring programs -- online databases that would allow physicians to quickly check on all controlled substances dispensed to a patient -- "are currently underfunded, underutilized and not interoperable across state lines or healthcare systems."

The result is that patients' tendency to develop a tolerance for opioid drugs -- and to require ever-higher doses to achieve pain relief -- often go unnoticed. The result is not only addiction and misuse, but an escalating risk of accidental overdose, since opioid narcotics depress breathing and, especially when mixed with alcohol or other sedative drugs, can prove deadly.

In the age group at highest risk for overdose -- those between 35 and 54 -- opioid use has vaulted ahead of firearms and motor vehicle crashes as a cause of death.

The American Academy of Neurology statement cites studies showing that roughly half of patients taking opioids for at least three months are still on opioids five years later. Research shows that in many cases, those patients' doses have increased and their level of function has not improved.

In addition to screening patients for depression or past or present drug abuse, physicians prescribing a long-term course of opioids to patients with pain should draw up an "opioid treatment agreement" which sets out the responsibilities of patients and physicians. Physicians should track dose increases and assess changes in a patient's level of function, and if a specific daily dose is reached (a "morphine equivalent dose" of 80-120 mg) and a patient's pain is not under control, doctors should seek the help of a pain specialist.

The statement also recommends against prescribing any benzodiazepines or other sedating drugs to patients who take opioid painkillers. And it recommends the "prudent use" by physicians of random urine testing for patients taking opioids to detect misuse of the drugs or abuse of other, non-prescribed drugs. When a physician takes on the care of a patient who has taken opioid painkillers for more than three months and has aberrant behavior or a history of overdose, he or she should consider a trial aimed at weaning the patient off such medication.

Heroin overdose deaths increased in many states through 2012

http://www.cdc.gov/media/releases/2014/p1002-heroin-overdose.html

Still twice as many people died from prescription opioid overdoses

Heroin deaths increased sharply in many states, according to a report of death certificate data from 28 states published by the Centers for Disease Control and Prevention in this week's *Morbidity and Mortality Weekly Report*. Despite these findings, still more than twice as many people died from prescription opioid overdoses as died from heroin in these states in 2012.

Though not directly addressed by this study, two things appear to be driving the increase in heroin overdoses: (1) widespread prescription opioid exposure and increasing rates of opioid addiction; and (2) increased heroin supply. While the majority of prescription opioid users do not become heroin users, previous research found that approximately 3 out of 4 new heroin users report having abused prescription opioids prior to using heroin. This relationship between prescription opioid abuse and heroin is not surprising; heroin is an opioid, and both drugs act on the same receptors in the brain to produce similar effects. Heroin often costs less than prescription opioids and is increasingly available.

"Reducing inappropriate opioid prescribing remains a crucial public health strategy to address both prescription opioid and heroin overdoses," said CDC Director Tom Frieden, M.D., M.P.H. "Addressing prescription opioid abuse by changing prescribing is likely to prevent heroin use in the long term."

Key Findings:

- This new study examined changes in heroin and prescription opioid death rates in 28 states [1] between 2010 and 2012. The 28 states represented 56 percent of the U.S. population.
- From 2010-2012, the overall heroin death rate across the 28 states doubled.
- The sharp heroin overdose increase extends the trend observed in the 2011 national mortality data.
- Five states had increases in prescription opioid death rates, seven states had decreases, and sixteen states had no change.
- Of the 18 states with reliable heroin overdose death rates examined individually in this study, 15 had statistically significant increases in heroin death rates. No state had a decrease in the heroin death rate.
- The increases in state heroin death rates from 2010-2012 were associated with increases in prescription opioid death rates.

"This study is another reminder of the seriousness of the prescription opioid overdose epidemic and the connection to heroin overdoses," said **Grant Baldwin, Ph.D, M.P.H**, Director, Division of Unintentional Injury Prevention. CDC and other federal agencies are working to promote a smart, coordinated approach to reduce inappropriate prescribing and help people addicted to these drugs."

While addressing prescribing is necessary to prevent opioid and heroin overdoses, it is important to help those already addicted to prescription opioids and heroin. Improving access to medication-assisted treatment is important. Increased use of naloxone, a prescription drug that can reverse an opioid or heroin overdose if administered in time, might also help save lives.

CDC's Injury Center works to protect the safety of everyone, every day. For more information about prescription drug overdoses, please visit www.cdc.gov/homeandrecreationalsafety/overdose.

Overdose Toolkit: http://store.samhsa.gov/shin/content//SMA14-4742/Overdose_Toolkit.pdf

Treatment Locator: http://findtreatment.samhsa.gov/

1 Alabama, Arizona, Colorado, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Utah, Virginia, and Washington.

Opioids prescribed by doctors led to 92,000 overdoses in ERs in one year

http://www.latimes.com/science/sciencenow/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html

Prescription drug overdoses, a dangerous side effect of the nation's embrace of narcotic painkillers, are a "substantial" burden on hospitals and the economy, according to a new study of emergency room visits.

Overdoses involving prescription painkillers have become a leading cause of injury deaths in the U.S. and a closely watched barometer of an evolving healthcare crisis. Little was known, however, about the nature of overdoses treated in the nation's emergency rooms.

A new analysis of 2010 data from hospitals nationwide found that prescription painkillers, known as opioids, were involved in 68% of opioid-related overdoses treated in emergency rooms. Hospital care for those overdose victims cost an estimated $1.4 billion.

Prescription overdoses kill more people than heroin and cocaine. An L.A. Times review of coroners' records finds that drugs prescribed by a small number of doctors caused or contributed to a disproportionate number of deaths.

The estimated 92,200 hospital visits were more than five times the number of deaths involving opioid painkillers that year.

"What this study shows us is opioid overdose deaths are just the tip of an iceberg," said Andrew Kolodny, an addiction doctor who helped found Physicians for Responsible Opioid Prescribing.

In a report published online Monday in JAMA Internal Medicine, researchers from Stanford University, the University of Pennsylvania, Brown University and Rush Medical College analyzed data from the Nationwide Emergency Department Sample and adjusted the raw figures to generate national estimates.

Researchers found that fewer than 2% of the overdoses treated in emergency rooms were fatal. But in more than half the cases, victims had to be admitted to the hospital.

“Further efforts to stem the prescription opioid overdose epidemic are urgently needed,” the researchers concluded.

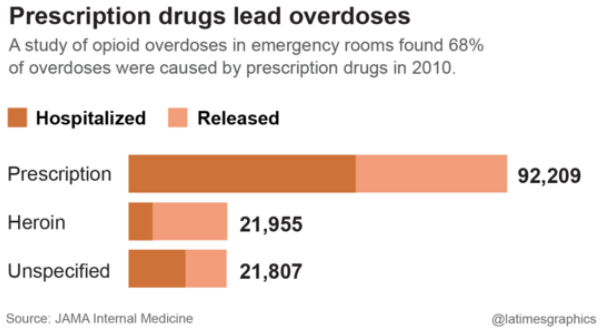
SCIENCE NOW

For most chronic pain, neurologists declare opioids a bad choice

U.S. Atty. Gen. Eric H. Holder Jr. made the same point in a speech to the nation’s police chiefs Monday. He unveiled a Justice Department “tool kit” to guide law enforcement agencies responding to drug overdose calls and encouraged police departments to provide officers with naloxone, a fast-acting antidote that can reverse overdoses and prevent death.

“It’s absolutely critical that we equip them to respond appropriately,” Holder said.

Opioid drugs — including forms of morphine, methadone, oxycodone and hydrocodone, such as OxyContin and Vicodin — are prescribed for patients who need powerful painkillers. But if patients take them for an extended period, they can develop a tolerance and require higher and higher doses of the drugs, making an overdose more likely. Patients who have too much of these drugs in their systems may lose consciousness and stop breathing.



Painkiller deaths quadrupled between 1999 and 2011, mirroring a sharp rise in the number of prescriptions for such drugs. In 2009, overdoses involving painkillers pushed drug fatalities past traffic accidents as a cause of death. And in 2011, the U.S. Centers for Disease Control and Prevention declared an epidemic.

The crisis had long been blamed on pharmacy robberies, teenage pill poppers and the black market. But a 2012 Los Angeles Times study showed that physicians played an important role in

prescription drug overdoses. The Times analysis of 3,733 fatalities found that drugs prescribed by physicians to patients caused or contributed to nearly half the deaths.

In response to the epidemic, almost every state has created a prescription drug monitoring program so physicians can log into a computer to check whether a patient is getting a dangerous narcotic from another physician.

Proposition 46 on the November ballot would require physicians to check California's prescription drug monitoring program, known as CURES, before prescribing certain drugs. The Medical Board of California is preparing to adopt new guidelines for prescribing opioid painkillers. And Gov. Jerry Brown recently signed into law a bill that allows people to buy the naloxone overdose antidote injector pens and nasal sprays without a prescription.

Opioid drug overdoses, the cause of some 16,000 fatalities and half a million emergency-department visits yearly, may have met their match: The Food and Drug Administration on Thursday approved the sale, by prescription, of a hand-held auto-injector of the opioid-reversal drug naloxone, a... (Melissa Healy)

The new study tallies some of the costs of overdoses. About 41% of the patients who went to a hospital after taking prescription opioids were treated in the emergency room and released; 55% were admitted to the hospital. And 4% were transferred to an acute care hospital. Among those who became hospital inpatients, the average stay was 3.8 days, and their average charges came to $29,497. For patients who were released without being admitted, the average charges were $3,640. Altogether, the cost of treating both groups of patients was nearly $1.4 billion in 2010.

The study found that patients who needed emergency care for an overdose of prescription opioids were most likely to be from the South (40%); to be between the ages of 18 and 54 (66%); and to live in a ZIP Code where the median income was below $67,000 (79%).

People with breathing, heart and mental health problems were at higher risk for drug overdoses, the study showed.

"That suggests that when a clinician writes a prescription for opioid painkillers for someone with one of these conditions, they need to do so with care," said Michael Yokell, a Stanford University medical student and one of the researchers.

"They need to think about alternatives," he said. "And if they choose opioids, they need to have a conversation ... about the risk of overdose."

Emergency room physicians said the findings reflected their experiences.

Dr. Cesar Aristeiguieta, who runs an emergency room in Houston, said physicians prescribed more narcotic painkillers out of a desire to relieve their patients' suffering and in response to pressure from medical boards and other health policymakers.

"Now we are seeing people can obtain narcotics easier than street drugs — and for free or low cost with insurance," Aristeiguieta said. "It's no wonder we're in the situation we're in."

Parents are first line of defense in war on opiate abuse

http://www.toacorn.com/news/2014-10-23/Front_Page/Parents_the_first_line_of_defense_in_war_on_opiate.html

By Becca Whitnall
becca@theacorn.com

Three years after the death of Thousand Oaks High School football player Griffen Kramer put heroin use in the Conejo Valley under the microscope, area teens continue to abuse the deadly drug and other opioids at an alarming rate.

Kramer's father, former NFL quarterback Erik Kramer, joined a panel of speakers last week at the Hillcrest Center in Thousand Oaks calling for parents to get more involved in the lives'of their children in hopes of detecting the problem before it's too late, even when it's difficult to broach the subject.

"As a parent, we would love to know the answers: What do we do? What do we talk about? How do we put it?" said Kramer, whose son died of a heroin overdose Oct. 30, 2011, at a friend's home in Agoura Hills.

" Somewhere along the way, the conversation has to be 'How do you talk to kids and how do you get them to start participating in the conversation?'"

Hosted by the Ventura County Sheriff's Office, the Oct. 15 Conejo Valley Community Drug Forum gave parents the opportunity to hear firsthand from addicts and the families of addicts. The most powerful moment came when a Westlake High School student performed a song he wrote in memory of his cousin who died two years ago of a heroin overdose.

The 24-year-old was one of 29 young adults in the county to lose their lives to the drug since 2012.

The crowd sat transfixed as Jack Cassidy, 16, played piano and sang the words: "If I could tell you that I love you one last time, if I could tell you, then I could save you from this world, from these lies, from this false sense of paradise."

Not even the yells of a man forcibly being removed from the meeting could break the spell. The unidentified man had demanded earlier in the day to speak at the meeting, and when he sat himself at the panelists' table, he was escorted out.

Prescription drug link

Heroin use is growing in the Conejo Valley and, in a large number of cases, its use can be traced back to prescription pill abuse, said Cmdr. Tim Hagel, Thousand Oaks' chief of police.

"I get asked all the time, 'What are the inherent issues around the Conejo Valley?' . . . I mention prescription drugs and heroin as one of our single greatest problems," Hagel said.

“The minute I mention heroin, what do you think I normally hear? Denial.”

According to Assistant Sheriff Gary Pentis, the most abused prescription drug in the county currently is Xanax, a benzodiazepine used to treat anxiety and panic disorders. Pentis also spoke at the meeting. He has been leading the fight against prescription pill abuse in the county.

But Xanax is far from the only drug being abused, he said.

“Right now, we’re having a hell of a time with Roxies,” Pentis said, referring to Roxicodone, which is pure, immediate-release oxycodone (unlike OxyContin, which is slow-release).

In a 2010 Healthy Kids Survey, 13 percent of ninth-graders and 20 percent of 11th-graders in the county said they’d misused prescription painkillers, said panelist Dan Hicks of the Ventura County Department of Behavioral Health.

“One in five high school juniors in Ventura County says they’ve used a prescription painkiller to get high,” Hicks said.

Pentis chimed in: “And this crosses every racial, economic, education boundary there is, and the parents are saying, ‘Well my kid’s a good kid, that kid’s a bad kid.’ Well dude, you’re stupid. Wake up.”

Both Roxicodone and OxyContin, members of the opioid family, can be prescribed legally for pain.

Because they’re prescribed, children sometimes get the wrong impression about the pills, Pentis said.

“It’s always been, for the kids, ‘Well, it’s not made in a lab in Colombia. It’s legal. My parents take it because the doctor gives it to them so it can’t really hurt you.’ But . . . opiates are highly addictive.”

Personal stories

Actor Patrick Cassidy, Jack’s father, said prescription painkillers are what led his niece to heroin.

The reason is simple: Once addicts can no longer afford expensive pills, they turn to tar heroin, which provides a stronger and cheaper high.

That was the case for the panel’s two young adults, identified only by their first names, Shane and Alli.

The young speakers told their story of addiction and recovery; both have now been sober for a few years.

Shane started smoking marijuana in sixth grade and drinking heavily in seventh. The first prescription drug he tried was Xanax, he said, but he didn't like it and started trying other drugs.

"I experimented with everything until I found OxyContin. That's kind of where I found my niche," Shane said.

When heroin was first offered to him, he refused it.

"I was like, 'No, no. I'm not going to do that. That's drug addict (stuff).' But within a week or two, I decided to do it because I was broke and I needed it," he said.

Eventually he went from smoking heroin to injecting it, and he realized he couldn't stop.

"I knew in the back of my head I'd become something I'd told myself I'd never become," Shane said.

In high school, when his family moved to California from New York, he said he was "deposited" in Westlake High School. He didn't make friends but did make connections.

"The only thing it took was asking around, and within a couple weeks I was getting exactly what I needed for exactly the price I wanted it," he said.

"I do think it's a really big issue in the Conejo Valley right now. . . . When we're talking about a place like this, it should not be that easy to get," Shane said.

Alli's journey to hard street drugs, including cocaine, also began with prescription pain medication. In her sophomore year of high school, she found her stepmother's drawer of prescription pills, she said.

She was able to keep her drug use under wraps for a long while.

"I fooled everybody. I was fooling myself as well. . . . (By that time) I was 18, I was in college and I was lost," she said.

Though her parents were loving and supportive, she said, they weren't as involved and aware as she thinks parents need to be, and she felt they wouldn't be open to discussing her problems.

Prevention

While law enforcement works to stem the supply side of the problem—busting bad doctors who overprescribe and arresting heroin dealers—parents need to step up as well, Pentis said.

An obvious step is to make sure you don't have unused medication sitting around the house. Every police station in the county has a drop box where residents can leave unused pills to be disposed of properly.

Since the drop boxes have been placed in the police departments, the county has destroyed more than 8 tons of prescription medication.

Experts say parents need to look for warning signs—like noticeable changes in behavior, slurred speech, an unusually hard time getting up in the morning and rapid speech.

And they need to talk to their children about drug use.

That's not always easy, especially when there are power struggles, Erik Kramer said.

"The power (teens) have is, 'Stay the (expletive) away from me.'"

Still, it's the parents' job to take charge, Pentis said. He recommended checking kids'phones, text messages and Instagram accounts if you're worried your child might be involved in drugs.

"If you're a parent, if you have a doubt, make your kid take a drug test . . . because they want to tell you the truth," he said.

"Drug test them. Get over this trust bull(crap). You're their parent, you're not their friend."

Pharmacy Shopping for ADHD Medications Similar to Opioids

Rachel Lutz
Published Online: Sunday, September 28, 2014
http://www.pharmacytimes.com/news/Pharmacy-Shopping-for-ADHD-Medications-Similar-to-Opioids

Medications for attention-deficit hyperactivity disorder (ADHD) are prone to the same abuse, misuse, and diversion as opioids, research published in *Drugs in R&D* suggests.

Using a pharmacy database encompassing 65% of US retail dispensing across all types of pharmacies, researchers from Janssen Research & Development, LLC, studied nearly 4.5 million ADHD patients who were dispensed ADHD medications between February 1, 2011, and January 31, 2012, and just over 6 million asthma patients who were dispensed asthma medications in that same time period.

The researchers included all FDA-approved medications for ADHD, comprised of the stimulants amphetamine, dexmethylphenidate, dextroamphetamine, lisdexamfetamine, methamphetamine, and methylphenidate, as well as the non-stimulants atomoxetine, clonidine, and guanfacine.

The investigators used asthma medications as a comparator "because they are frequently used by a population with roughly similar demographic characteristics as the population using ADHD medications, including a large representation of children and young adults, and are not believed to be widely abused or diverted."

The researchers then tracked the ADHD and asthma patients for 18 months to determine how many received potentially overlapping medications from different prescribers, as well as to calculate the number of prescribers and pharmacies involved in those transactions.

According to the study authors, an overlap occurred when 2 or more dispensings of medications from different prescribers were active on the same day, indicating a dispensed medication was used during the days' supply of another filled prescription. When patients exhibited more than 1 overlap, the incident with the greatest amount of multiple dispensings was further examined.

The researchers discovered that overlapping medications from 2 or more prescribers dispensed by 3 or more pharmacies was 4 times more frequent in the ADHD study group than the asthma counterpart. Based on that finding, the investigators extrapolated that ADHD medication shopping was more prevalent among those who were dispensed drugs during the 4 months prior to the study period.

"The fact that the criteria that serve to identify subjects who engage in ADHD medication shopping behavior and opioid shopping behavior are similar seems to suggest that overlapping prescriptions written by different prescribers and filled at 3 or more pharmacies can be used as an

operational definition to assess shopping behavior for medications that are prone to abuse and diversion in general," the authors concluded. "It is worth noting that subjects abusing a specific drug are likely to abuse other drugs or have a higher risk of developing abuse when exposed to other medications with abuse potential."

Unlike opioid shopping, in which only 0.5% of shoppers are aged 18 years or younger, shopping episodes for ADHD drugs most commonly occurred among those aged 10-39 years, 13% of whom were aged 10 years or younger.

Similar to opioids, however, a small proportion of ADHD medication shoppers were to blame for the majority of shopping behavior, as the 9.2% of subjects who shopped 6 times or more accounted for 42% of all shopping episodes.

The researchers said they hope to use their data to understand why ADHD patients need to visit multiple pharmacies and prescribers, though they cited a survey of undergraduate students that found the leading source of ADHD drugs for nonmedical use was friends and peers.
- See more at: http://www.pharmacytimes.com/news/Pharmacy-Shopping-for-ADHD-Medications-Similar-to-Opioids#sthash.tONbUJxG.dpuf

SAMHSA Uses Recovery Event to Report Rise in Substance Abuse

Vabren Watts

http://psychnews.psychiatryonline.org/newsarticle.aspx?articleid=1910445

The Substance Abuse and Mental Health Services Administration observes National Recovery Month and releases data that officials find troubling on the prevalence of substance abuse.

Last month, the Substance Abuse and Mental Health Services Administration (SAMHSA) celebrated the 25th anniversary of National Recovery Month, an observance emphasizing that mental health services can enable those with a mental illness, including substance use disorders (SUDs), to live healthy and rewarding lives.

SAMHSA Administrator Pamela Hyde, J.D., announces data from the 2013 National Survey on Drug Use and Health at a press conference celebrating the 25th anniversary of National Recovery Month and expresses concern about attitudes on marijuana use.

"[For] a quarter of a century we have been illuminating, defining, validating, and shaping a concept into a fact that people do recover from addiction and mental illness," said SAMHSA Administrator Pamela Hyde, J.D., at a press conference at the National Press Club in Washington, D.C. "Understanding that treatment works . . . is a critical component. [Today] we acknowledge and celebrate that reality."

As part of the event, SAMHSA released some of the data from its 2013 National Survey on Drug Use and Health (NSDUH). "An estimated 24.6 million Americans 12 years and older were current drug users," Hyde reported, emphasizing that means more than 9 percent of the U.S. population of

adolescents and adults acknowledged drug use at the time of the survey. Marijuana was the most commonly used illicit drug, with 19.8 million individuals saying they used it in the month prior to the survey. The next most common example of illicit drug use was nonmedical use of prescription pain relievers, used by 4.5 million individuals.

Alcohol use was estimated to be prevalent in about half (52.2 percent) of the U.S. population aged 12 and older, with 60.1 million individuals acknowledging that they engaged in binge drinking. SAMHSA reported that of the people who needed treatment for a substance use disorder or alcohol use disorder, only 11 percent received help for the problem.

Michael Botticelli, acting director of the White House Office of National Drug Control Policy, describes his personal story of recovering from alcohol abuse and the importance of National Recovery Month.

"This proves that substance use in our country still poses a significant public-health risk," said Michael Botticelli, acting director of the White House Office of National Drug Control Policy, who was a panel speaker. "We should keep in mind that the work to reduce substance use in America is not in vain . . . [and that] we have made significant progress."

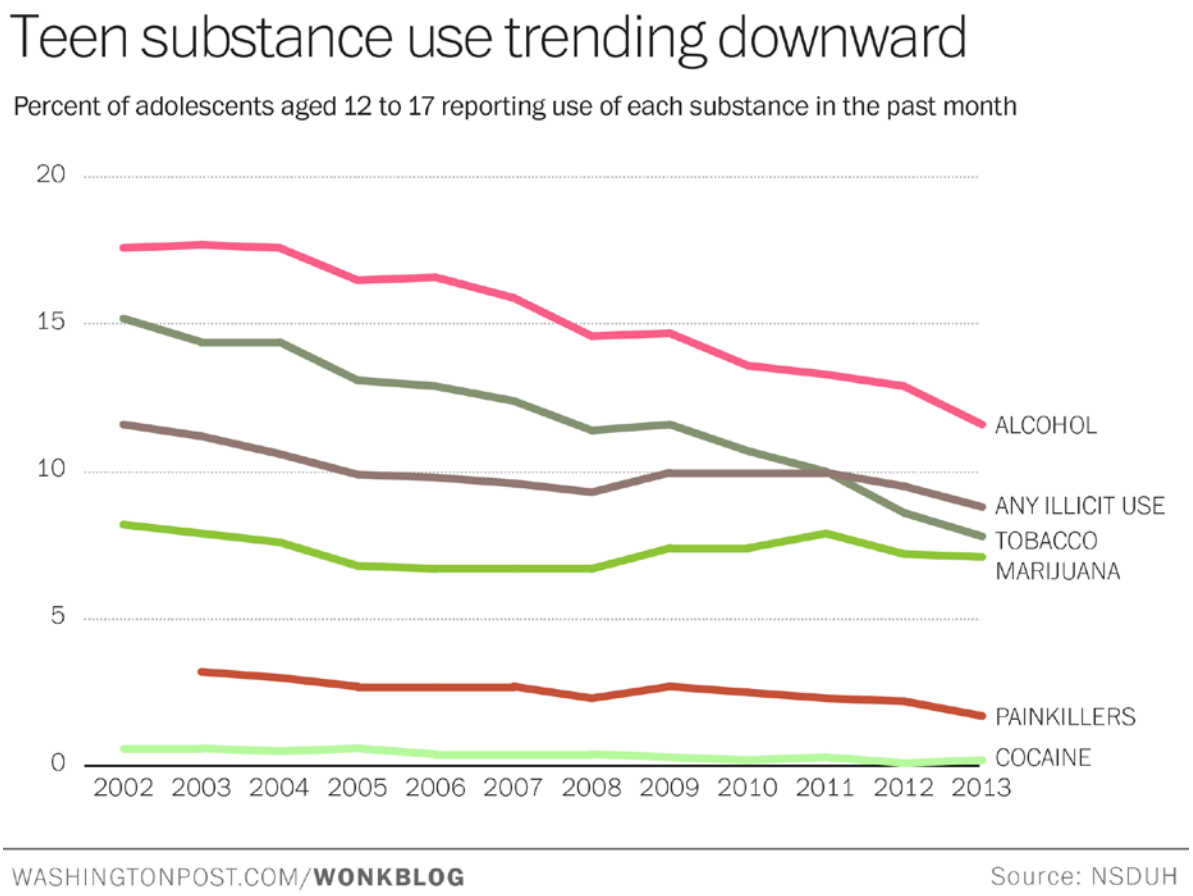
During an interview with *Psychiatric News*, Botticelli, who openly discusses his recovery from alcohol abuse over the past 25 years, said that by intensifying efforts to reduce stigma associated with mental health and substance use disorders, more people will be encouraged to access mental health care services. He told conference attendees that the time has come to rally for more community-based recovery support services and ensure that laws, policies, and practices do not continue to perpetuate barriers to recovery. "We need all your help to engage broader community stakeholders and policymakers at every level."

According to the 2013 NSDUH report, drug use is up slightly from 2012. Hyde stated that the alarming rates of drug use in adolescents and adults, particularly marijuana use, may be a result of a growing perception that one particular drug may be less harmful than others, a finding reported by prior NSDUH studies. "Social norms have to change, or else we are going to keep meeting here every fall and sharing the same problem. Understanding that treatment works and prevention works are critical components. We will be watching [trends in drug and alcohol use] closely over the next few years."

A full report of the 2013 NSDUH findings is scheduled to be released by the end of year, according to Hyde. ■

Teen drug and alcohol use continues to fall, new federal data show

http://www.washingtonpost.com/blogs/wonkblog/wp/2014/09/16/teen-drug-and-alcohol-use-continues-to-fall-new-federal-data-show/



Drug and alcohol use among America's teens continues to trend downward, according to new numbers released today by the Department of Health and Human Services. From 2002 to 2013, the average American teenager's odds of regular (at least monthly) tobacco use nearly halved. Recreational use of prescription painkillers saw a similar decline.

The rate of regular alcohol use among teens aged 12 to 17 declined from from 17.6 percent to 11.6 percent over the same period. Teen marijuana use, a

contentious topic now that several states have legalized marijuana sales, is also on the decline.

These findings come from the 2013 National Survey on Drug Use and Health (NSDUH), an annual, nationally-representative survey of roughly 70,000 Americans aged 12 and older. Because of its large sample size the survey is considered an authoritative account of the nature and scope of drug, alcohol and tobacco use in the United States.

"We're seeing really exciting numbers in terms of the 12 to 17 year-olds across the country," according to Peter Delany, the director of the Center for Behavioral Health Statistics and Quality (CBHSQ) at the Substance Abuse and Mental Health Services Administration. "We see illicit drug use down significantly from 2009. We see marijuana starting to trend downward. Hallucinogens and inhalants are also down slightly."

"The 2013 NSDUH results suggest that the Administration's efforts to reduce drug and alcohol use among young people is working," the White House Office of National Drug Control Policy (ONDCP) said in a press release.

The Changing Face of Heroin Use in the United StatesA Retrospective Analysis of the Past 50 Years

Theodore J. Cicero, PhD[1]; Matthew S. Ellis, MPE[1]; Hilary L. Surratt, PhD[2]; Steven P. Kurtz, PhD[2]

[+] Author Affiliations
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ABSTRACT

ABSTRACT | METHODS | RESULTS | DISCUSSION | CONCLUSIONS | ARTICLE INFORMATION | REFERENCES

Importance Over the past several years, there have been a number of mainstream media reports that the abuse of heroin has migrated from low-income urban areas with large minority populations to more affluent suburban and rural areas with primarily white populations.

Objective To examine the veracity of these anecdotal reports and define the relationship between the abuse of prescription opioids and the abuse of heroin.

Design, Setting, and Participants Using a mixed-methods approach, we analyzed (1) data from an ongoing study that uses structured, self-administered surveys to gather retrospective data on past drug use patterns among patients entering substance abuse treatment programs across the country who received a primary (*DSM-IV*) diagnosis of heroin use/dependence (n = 2797) and (2) data from unstructured qualitative interviews with a subset of patients (n = 54) who completed the structured interview.

Main Outcomes and Measures In addition to data on population demographics and current residential location, we used cross-tabulations to assess prevalence rates as a function of the decade of the initiation of abuse for (1) first opioid used (prescription opioid or heroin), (2) sex, (3) race/ethnicity, and (4) age at first use. Respondents indicated in an open-ended format why they chose heroin as their primary drug and the interrelationship between their use of heroin and their use of prescription opioids.

Results Approximately 85% of treatment-seeking patients approached to complete the Survey of Key Informants' Patients Program did so. Respondents who began using heroin in the 1960s were predominantly young men (82.8%; mean age, 16.5 years) whose first opioid of abuse was heroin (80%). However, more recent users were older (mean age, 22.9 years) men and women living in less urban areas (75.2%) who were introduced to opioids through prescription drugs (75.0%). Whites and nonwhites were equally represented in those initiating use prior to the 1980s, but nearly 90% of respondents who began use in the last decade were white. Although the "high" produced by heroin was described as a significant factor in its selection, it was often used because it was more readily accessible and much less expensive than prescription opioids.

Conclusion and Relevance Our data show that the demographic composition of heroin users entering treatment has shifted over the last 50 years such that heroin use has changed from an inner-city, minority-centered problem to one that has a more widespread geographical distribution, involving primarily white men and women in their late 20s living outside of large urban areas.

The New Heroin Epidemic

Ten years ago, prescription painkiller dependence swept rural America. As the government cracked down on doctors and drug companies, people went searching for a cheaper, more accessible high. Now, many areas are struggling with an unprecedented heroin crisis.

Olga Khazan
Illustrations by Lauren Giordano
October 30, 2014
http://www.theatlantic.com/features/archive/2014/10/the-new-heroin-epidemic/382020/

In a beige conference room in Morgantown, West Virginia, Katie Chiasson-Downs, a slight, blond woman with a dimpled smile, read out the good news first. “Sarah is getting married next month, so I expect her to be a little stressed,” she said to the room. “Rebecca is moving along with her pregnancy. This is Betty’s last group with us.”

“Felicia is having difficulties with doctors following up with her care for what she thinks is MRSA,” Chiasson-Downs continued. “Charlie wasn’t here last time, he cancelled. Hank ...”

“Hank needs a sponsor, bad,” said Carl Sullivan, a middle-aged man with auburn hair and a deep drawl. “It kind of bothers me that he never gets one.”

“This was Tom’s first time back in the group, he seemed happy to be there,” Chiasson-Downs went on, reading from her list.

“He had to work all the way back up,” Sullivan added.

Chiasson-Downs and the other therapists with the Chestnut Ridge Center’s opiate-addiction program had gathered to update each other on the status of their patients before launching into the day’s psychotherapy sessions. Here in West Virginia, where prescription painkillers have long “flowed like water,” as Sullivan said, the team works to keep recovering addicts sober through a combination of therapy and buprenorphine, a drug used to treat painkiller and heroin addiction.

Chiasson-Downs’ patients are in the “advanced” group—so called because they’re well into their recoveries. She relayed a few success stories—a new baby here, a relapse averted there—but even years after they’ve found sobriety, her charges’ lives are still precariously balanced.

What Tom (not his real name) was attempting to work his way back up from was the weekly “beginner” group, where advanced patients are sent if they relapse and cannot stay clean. It happens fairly frequently, Sullivan, the director of the treatment program, said.

For patients in the less advanced groups, the therapists’ updates are gloomier.

“Trent called in crisis last week, and he didn’t come,” said Laura Lander, another therapist. An acquaintance who was supposed to give Trent a ride to the clinic instead stole his money and medication and then left him by the side of the road.

“He went without his meds,” Doug Harvey, the case manager, added.

“He will have used this week,” Sullivan concluded.

“Jessica, she’s still living with her boyfriend, who is actively using.” Lander said.

“So she’s craving every day,” Sullivan noted.

“She’s financially dependent on him,” Lander said. “Three kids and nowhere to go. He’s a jerk to her.”

“She lives out in the middle of nowhere,” Sullivan added. “She talked about her neighborhood being full of people who use. Her family all uses. I’d be surprised if she’s clean today.”

The therapists’ stories go on, sketching a picture of a region that’s understaffed and under-resourced, and that found itself unprepared for an epidemic it has disproportionately been affected by. One woman has been skipping meetings and “doing weird things with her meds.” Another patient filled his prescription with a new doctor, raising the possibility he was “doctor-shopping,” or getting multiple prescriptions from different physicians simultaneously. A woman who lives more than two hours away wasn’t going to make it in—the Medicaid van that normally brings her fell through this week.

The meeting is brief and matter-of-fact. There’s some lighthearted banter between updates—one patient, apparently trying to curry favor with Lander, repeatedly called her “sweetie” over the phone. When the final chart is read, the group breaks, and the therapists head into their separate sessions.

In the newest front in the war on drugs, people from all walks of life are battling addictions to pills that are perfectly legal and distributed by medical professionals. Since prescription painkillers became cheap and plentiful in the mid-90s, drug overdose death rates in the U.S. have more than tripled. West Virginia was slammed especially severely, and for the past several years it’s had the highest drug overdose death rate in the nation.

More recently, heroin has taken root here after authorities cracked down on unscrupulous doctors who were overprescribing pain meds, sending addicts searching elsewhere for a similar high. In West Virginia, heroin-overdose deaths have tripled over the past five years, while prescription-painkiller deaths have dipped slightly. There were many contributing factors, not the least of which were personal decisions by the addicts themselves, but it’s clear that pharmaceutical companies, negligent doctors, and even the law-enforcement backlash have all played a role.

Now, the state’s few addiction treatment specialists—Sullivan is one—are drowning under their caseloads.

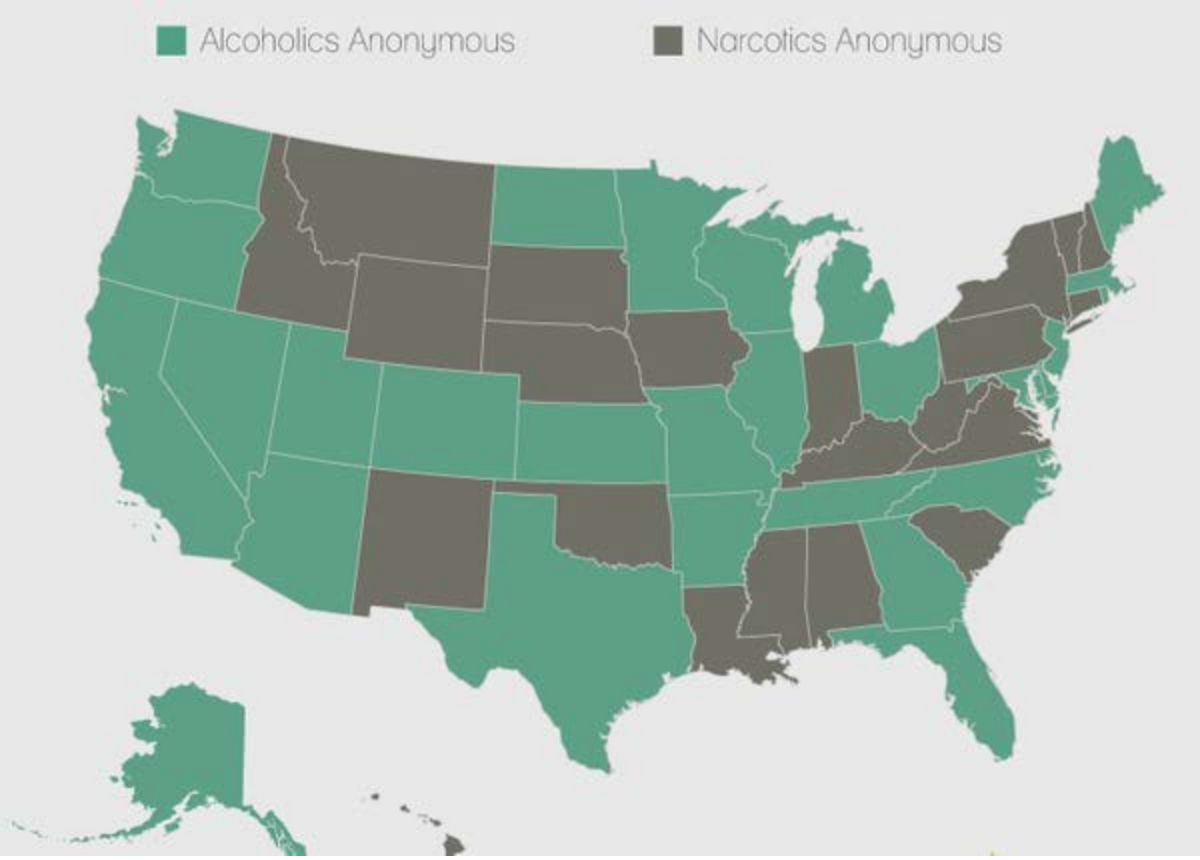
The goal at Chestnut Ridge, Sullivan explained, “is to treat effectively and treat as many we can. We’re exhausted and overwhelmed with how many opioid addicts there are in this area.”

(*The Atlantic* was granted access to Sullivan’s clinic, but some patients preferred to remain anonymous. In this article, these patients are identified by pseudonymous first names only.)

There’s a waiting list to get into the center’s program, and the only applicants prioritized are pregnant women. Sullivan isn’t above telling the sons of local tycoons to get in line. By the time they secure a spot, the average patient has been waiting for weeks or months.

Over the years, Sullivan has tried giving patients methadone, buprenorphine, and now naltrexone. He thinks buprenorphine—given out here in dissolving strips called Suboxone—is the best option, but he argues that the medicine isn’t the most important part. Here, all patients receive talk therapy as part of their treatment, and they can’t get their medication without attending psychoeducational group sessions. Those who are furthest into their recoveries attend once a month, but the others come weekly or biweekly. Moving from the weekly to the biweekly group takes 90 straight days of abstinence, a feat most patients can only accomplish within five or six months because of relapses. They’re also required to attend four 12-step Alcoholics Anonymous or Narcotics Anonymous meetings each week in their home communities.

Most Popular 12-Step Meeting by State



Recovery.org

The clinic tries to strike at “all parts of their addiction,” Sullivan explains. “The biological, legal, and psychological problems.”

Jeff Kesner, a janitor at a chicken plant, makes a five-hour round trip to Sullivan’s beginner group every Wednesday. This is the nearest addiction clinic to his home that accepts Medicaid, the health insurance program for the poor. He realized he needed help when he had what he describes as a nervous breakdown five months ago. He was using opiates, meth, “benzos”—anti-anxiety drugs—really anything he could find. One day he overdosed in public, and when the police arrived, he “flipped out,” he said. First he ran, yelling at the cops that they’d have to shoot him if they wanted to arrest him, and then he hit one of the officers.

“I’ve destroyed my life,” Kesner said. “I’m 41 years old, and I have nothing because of drugs.”

After 28 days in jail, he checked himself into Sullivan’s clinic. He and his sponsor have since started a Bible-based group, Celebrate Recovery, back in his hometown of Moorefield. He said he still knows lots of addicts, but he tries to avoid them.

“Back where I’m from, there is nothing for people to do,” he said. “There are no jobs. No drive-ins. No youth centers. There is no economy. People are going to doctors, getting scripts, and selling them on the street to survive.”

To explain why opioid addiction is such a hard condition to treat, Sullivan contrasts it with diabetes, which, while “a terrible disease,” is treated basically the same way whether the patient is in Denver or Dubai. But there’s no one way to cure a heroin or painkiller addict. With addicts, Sullivan said, “their whole lives are organized around them getting opioids.”

An invisible affliction, pain is one of the hardest ailments for doctors to treat. There’s no blood test, and there are no visible symptoms. It can be difficult to tell whether a patient is exaggerating, or whether their state of mind might be exacerbating their condition.

With the cause of their pain unclear, some chronic-pain patients have felt misunderstood and doubted as they’re passed off from specialist to specialist.

“Is it too much to ask that we, the patients, no longer be bound to a system ... of unbelievable referrals with unscientific, unproven treatments (and hope) sold to the patient by each referring physician?” one such patient told his pain-management advocacy group. “In many cases, patients end up worse and more and more destitute, yet they grasp for hope with each referral.”

Huge numbers of people suffer this way. A study out this month from Washington State University Spokane found that nearly one in five American adults report being in pain almost every day for spells of three months or longer.

Opioids are chemicals that change the way the brain perceives pain. Some chronic-pain patients, experiencing relief for the first time in years, describe them as “a miracle.” A pulled tooth might be agonizing, but with a little Vicodin, the brain thinks the mouth is in tip-top shape.

Narcotics such as morphine, based on the chemical compounds found in poppies, have been available since the early 1800s, but soon after these substances' medicinal properties were discovered, so too, were their addictive natures. In the early 20th century, scientists figured out how to synthesize new kinds of opioids—hydrocodone and oxycodone—with the hope that these new molecules would be less habit-forming. Percocet and Vicodin, which melded semi-synthetic opioids with acetaminophen (Tylenol), came along in the 1970s.

For decades, the medical establishment considered only the suffering of cancer and postoperative patients severe enough to be dosed with heavy-duty opioids. But in the 1980s, doctors began arguing in medical journals that all forms of chronic pain should be treated more aggressively. Congress declared the 2000s to be the "Decade of Pain Control and Research."

Makers of narcotic painkillers downplayed the risk of addiction and devised slick promotional campaigns for the drugs. Of this, the pain medication OxyContin was one of the most dramatic examples.

"The distribution to health care professionals of branded promotional items such as OxyContin fishing hats, stuffed plush toys, and music compact discs was unprecedented."

Shortly after Purdue Pharma introduced OxyContin, an oxycodone opioid, in 1996, the company sent thousands of physicians and pharmacists on all-expenses-paid junkets to resorts across the southwestern United States to learn about the drug. Purdue bolstered its sales force and compiled databases of doctors who were likely to prescribe OxyContin. Its sales representatives received millions in bonuses for persuading doctors to write scripts. The company argued that, because of its time-release formula, the drug was far less addictive than Percocet or Vicodin.

"The distribution to health care professionals of branded promotional items such as OxyContin fishing hats, stuffed plush toys, and music compact discs ... was unprecedented for a schedule II opioid," Virginia primary care doctor Art Van Zee wrote in an article in the *American Journal of Public Health*. Among the swag was a CD titled "Swing in the right direction with OxyContin" and a pedometer that reads, "OxyContin ... A step in the right direction." By 2002, doctors were prescribing 10 times more OxyContin than they had in 1997, and the drug's sales made up 80 to 90 percent of Purdue's revenues.

In 2007, Purdue pled guilty to misleading the public about the risk of addiction to the drug in a lawsuit brought by the U.S. Department of Justice, and it paid $634.5 million in fines. Three of its executives also pleaded guilty to criminal charges. In a statement to *The Atlantic*, a Purdue representative said the company "accepted full responsibility for the actions some of its colleagues took during a period that ended in 2001."

One of the consequences of the marketing blitz was a fundamental change in the way pain was perceived, both by doctors and by patients. Pain was no longer understood as something that had to be endured—it could be easily and quickly treated with pills.

“By the 1990s, it became unacceptable for patients to be in pain,” Sullivan said.

Even for a conscientious doctor, it can be hard to tell the difference between a desperate patient who is genuinely suffering and a manipulative patient who’s seeking out drugs. In one study of 2,486 visits made to a hospital emergency room, 15 percent of patients asked for a specific pain medication by name, and 30 percent said their pain level was a “10 out of 10.”

Worse yet, some hospital doctors’ pay and promotions are tied to “patient-satisfaction scores,” which can be sunk by bitter patients who feel their providers don’t dispense painkillers readily enough.

The delicate balance between over- and under-prescription is even trickier to strike in West Virginia, where some 20,000 people work in coal-mining jobs that gradually grind away at the body.

In the end, the doctors overshot. Painkillers were doled out for minor or nonexistent complaints. In the early 2000s, Vicodin was bought and sold through online pharmacies. Pain treatment centers would occasionally advertise like car dealerships: In 2006, one Florida clinic placed an ad reading "Need painkillers?" in a local newspaper alongside a discount coupon for new patients. Well-meaning general practitioners, who lacked the time or training to analyze their patients' vague symptoms of discomfort, blanketed the Ohio Valley with painkiller prescriptions instead.

Though painkillers are mostly safe if taken exactly as instructed, patients' chances of overdosing spike if they take a higher-than-recommended dose, if they combine the pills with other medications, or if they are predisposed to drug dependence. People without prescriptions would get their hands on the pills from family and friends—one 2006 study of people who died of painkiller overdoses in West Virginia found that 63 percent did not hold prescriptions in their own name. Some discovered that snorting or injecting a crushed OxyContin tablet could produce a powerful, heroin-like high. (In recent years, Purdue has developed new formulations of OxyContin that are encased in plastic, so that they can't be crushed or chewed.) By 2004, OxyContin was by some measures the most commonly abused prescription painkiller.

Several physicians in the area took advantage of the booming painkiller demand in order to get cash, sex, or both. One of Sullivan's patients had to stop seeing his physician when the doctor was charged for exchanging pills for sex. In 2012, a western Pennsylvania doctor named Michael Vogini was sentenced to six to 12 years in prison for prescribing Vicodin and Xanax to at least six female patients in exchange for sexual favors. One of the patients had died of an overdose in 2006, with the cause determined to be "acute combined drug toxicity of phentermine, diphenhydramine, dextromethorphan, carisoprodol, meprobamate, prochlorperazine, ropiramate, alprazolam, diazepam, hydrocodone, and hydromorphone."

Other cases devolved into inscrutable tangles in which the doctors were accused of sexual impropriety and the patients of lurid scheming. In 2006, the Maryland Board of Physicians suspended the license of the Baltimore-area pain specialist Nelson H. Hendler, saying, among other things, that he had allegedly demanded oral sex from female patients before he would give them medication. Among other allegations, one patient accused him, in 2002, of "pressuring her for sexual favors, telling her that her health insurance was insufficient to compensate him for his services," according to the suspension order.

After a patient of his died of a painkiller overdose, Hendler was charged with possession with intent to distribute narcotics. His medical license was revoked after he pled an Alford plea, in which the defendant maintains innocence but admits that there was sufficient evidence to convict.

In an interview with *The Atlantic*, Hendler claimed the charge resulted from the fact that, whenever he suspected patients were asking him for too many prescriptions, he would demand they turn in their unfinished pill bottles before prescribing them more painkillers. When the DEA raided his office, he said it was these unfinished pill bottles that he was accused of intending to distribute.

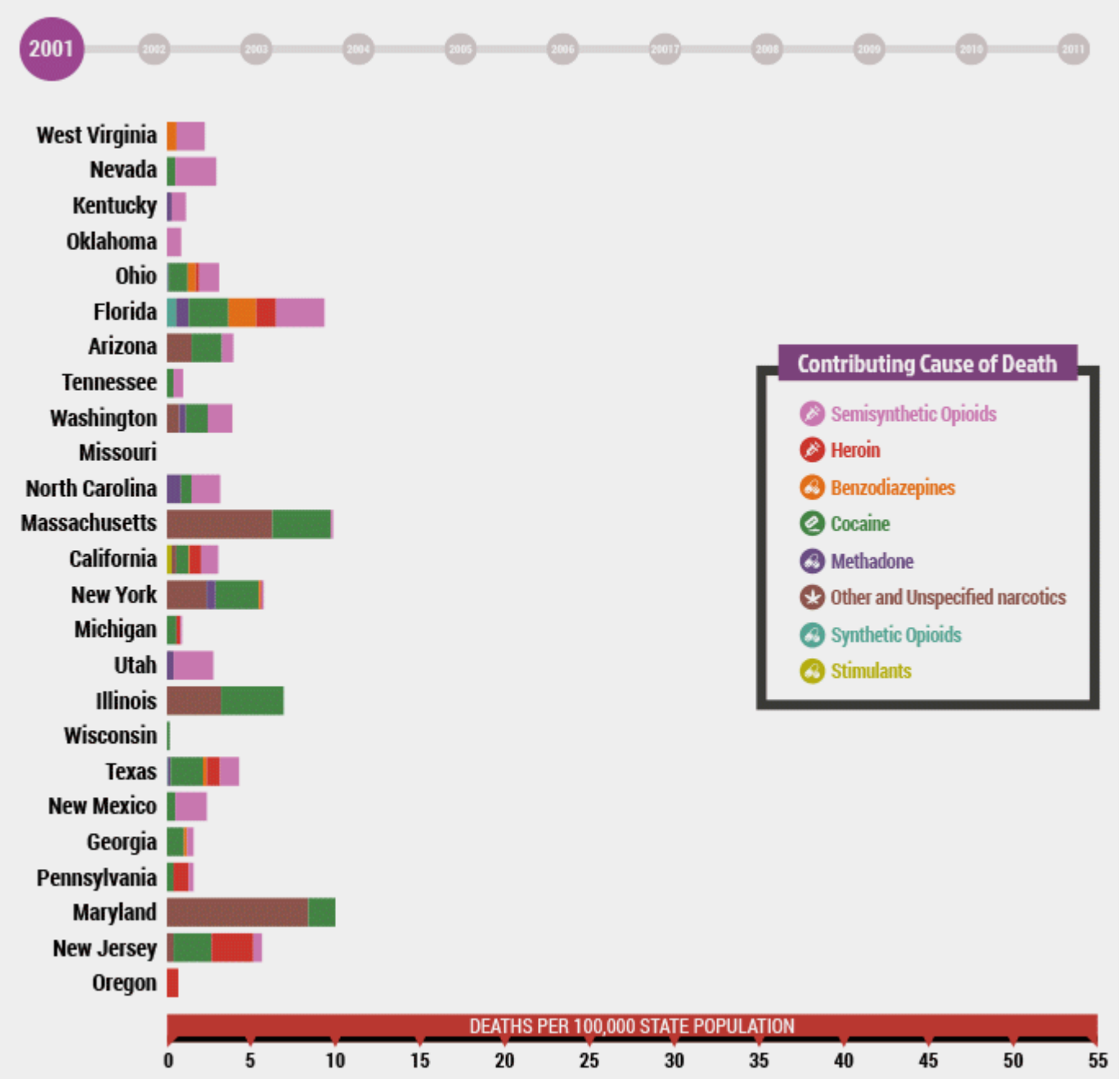
Later, several of Hendler's female patients sued him for allegedly forcing them to sexually pleasure him in exchange for painkillers. "Now, wasn't that worth it?" Hendler allegedly asked one such patient, according to the woman's attorney.

Hendler claims the women had substantial outstanding medical bills and, spurred by an angry ex-girlfriend, concocted a plot to get out of their debts by suing him. Two of the cases were dismissed, and two settled.

"Even if I could get my medical license reinstated, I wouldn't go back into the clinical practice of medicine," said Hendler, who now leads a quiet life in retirement. "While most of my patients were wonderful, decent people, the small percentage of them who are just out to get narcotics and money would still constitute a danger to me."

Sullivan said he knows of some doctors who continue to prescribe patients extra Suboxone, knowing that they'll sell it, in an attempt to "whet people's appetite" for the drug.

Drug Overdose Deaths Per 100,000 People



CDC Wonder Database/Drugabuse.com

West Virginia's first methadone clinic opened in 2000, and by 2003, six more had popped up to help treat the growing influx of painkiller addicts. According to an analysis by the *Charleston Gazette*, between 1999 and 2009, per capita consumption of oxycodone, hydrocodone, and fentanyl tripled in the state. By 2009, West Virginians were annually filling an average of 19 prescriptions per person, the highest rate in the nation.

Across the country, overdose deaths from prescription painkillers quadrupled between 1999 and 2011. That year, West Virginia led the nation in per-capita deaths attributed to semisynthetic

opioids. Like heroin, the drugs slow breathing down, sometimes until it stops altogether. Mix them with alcohol or other pills, and the chances of accidental death soar. For those who live, one perverse side effect of long-term opioid abuse is hyperalgesia—an increased sensitivity to pain.

Over the past couple of years, though, the prescription frenzy seems to have subsided slightly, partly thanks to a slow realization by physicians and lawmakers that the pills were ending up on the streets. Like that of many other states, West Virginia's pharmacy monitoring board now requires doctors to ensure patients aren't collecting painkiller prescriptions from multiple providers. West Virginia and several other states have linked their painkiller prescription databases in order to prevent out-of-state "painkiller tourism." In 2012, West Virginia officials sued 14 drug distributors for allegedly shipping painkillers to careless pharmacies.

Other doctors have been spooked away from handling chronic pain patients at all, fearing they could wind up in jail if a patient misuses the drugs. In 2004, a prominent Virginia pain doctor named William E. Hurwitz was sentenced to 25 years in prison for prescribing what prosecutors said was a dangerous amount of opioids to addicts, some of whom later re-sold their prescriptions. But at his trial, one patient who suffered from debilitating migraines said she was largely bedridden until Hurwitz began treating her. In 2007, Hurwitz' prison term was cut to five years, with the judge concluding that he helped more patients than he hurt.

This month, the Drug Enforcement Administration reclassified hydrocodone-based drugs such as Vicodin as schedule II drugs, just one level below outlawed substances like ecstasy and LSD. (OxyContin was already a schedule II drug.) Under the stricter classification, doctors will now only be able to prescribe the medications for a month at a time, and for no longer than three months total for any given patient.

"I've destroyed my life. I'm 41 years old, and I have nothing because of drugs."

In West Virginia, law-enforcement officials have been busting unscrupulous doctors. William Ihlenfeld, the U.S. Attorney for the Northern District of West Virginia, said the state is currently prosecuting a number of doctors accused of flagrant abuse of the system. One allegedly signed blank prescriptions and left them with her office staff, who weren't trained physicians, to give out as they saw fit. The staff of another doctor, this one in Harrison County just south of Morgantown, were allegedly selling painkillers on the side. Douglas Broderick, a New Jersey gynecologist who federal prosecutors said was feeding the painkiller addiction in West Virginia, was indicted but died before his trial. Ihlenfeld said Broderick was making $200,000 in cash each month from people who had no medical need for opioids. Fearful that he would be robbed, Broderick allegedly hired armed guards to protect him and his practice.

"We've come to realize the impact that even … one corrupt medical professional can have on a community," Ihlenfeld said. "If we identify someone like that and they aren't playing by the rules, it has the same effect as taking out 10 street-level drug dealers."

West Virginia still has one of the highest painkiller prescription rates in the nation—as well as one of the highest painkiller-overdose death rates—but the death rate from pills here is slowly declining. Between 2011 and 2012, oxycodone-related deaths in the state decreased from 223 to 182, and those from hydrocodone declined from 171 to 142. Two years ago, the DEA set up a tactical diversion squad in Charleston, West Virginia to fight illegal pill distribution.

The crackdown on doctors might have stanched the flow of prescription pills, but it did so with a deadly externality: West Virginians have turned to heroin—a cheaper and, frequently, more accessible high. Law enforcement officials here told me that heroin is now their "number-one problem."

Suzan Williamson, the DEA resident agent for West Virginia, said that she used to arrest stereotypical "junkies" when she worked in Manhattan decades ago—largely impoverished, deprived inner-city residents. These days in Appalachia, she said, "you have a broad span of addicts. Here you have somebody who might have had legitimate pain, [but] could no longer afford pills, so to keep the high they switched over to heroin."

Efforts to disrupt the heroin incursion are complicated by the fact that West Virginians seem to be equally susceptible to the drug, regardless of wealth or education level.

"It's affecting all segments of society," Ihlenfeld said. "All levels of income. All neighborhoods. It's [affecting] everybody."

What's more, West Virginia is in some ways the perfect market for heroin dealers—Morgantown is close to Pittsburgh, to the north, and Baltimore, to the east. Heroin costs just $20 per bag,

about half the price of a single OxyContin pill, but the cost adds up. One patient of Sullivan's is now spending $100 a day on Pittsburgh dope.

For Kevin, a 38-year-old "beginner" patient of Sullivan's, the transition to heroin was precipitated by a decades-long relationship with Vicodin and Percocet. His ex-wife had a Percocet prescription for her back pain, but she hardly ever took the pills. Instead, Kevin would take five or six each day.

"The only time I touched heroin was whenever I couldn't find pills," he said. "There were times where I did it for a couple days at a time until I found pills, then I would just do the pills." Still, the harder stuff took over eventually.

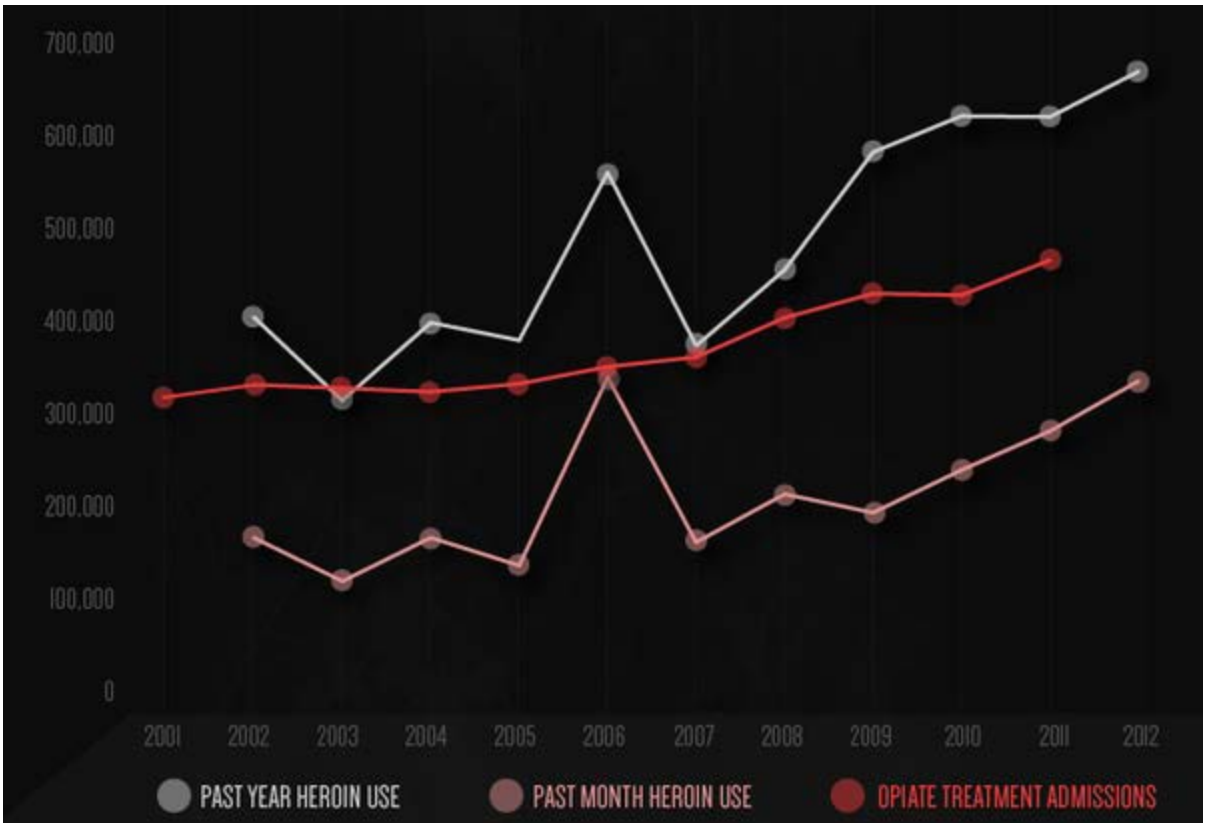
"If you were doing painkillers, you'd never be thinking, 'I'm going to be shoving a needle in my arm,'" he said.

Kevin moved to Morgantown from Florida, but within a few years he had broken up with his girlfriend and started living on the street. Eventually, he showed up at an emergency room.

"I just said, 'I'm depressed, I'm sick as a dog, I want to try to get into the clinic, I don't know what to do, I don't have a place to live, I don't have a job. I don't have any money, I don't have any insurance. If you send me out of here I'm going to go to a bridge and jump off.'"

West Virginia is a microcosm of the national drug-abuse picture. Recently, the prescription painkiller epidemic has finally begun to wane, but it's dragged heroin addiction along in its wake. In 2012, the most recent year for which data are available, nationwide deaths from prescription painkillers dropped 5 percent from 2011, but heroin overdose deaths surged by 35 percent.

Heroin Use and Opiate Treatment Admissions Over Time



National Survey on Drug Use and Health/Heroin.net

Heroin isn't necessarily more addictive than OxyContin, but it's more unpredictable, said Asokumar Buvanendran, an anesthesiology professor at Rush University Medical Center in Chicago. "Ten milligrams of Oxy is always 10 milligrams of Oxy," he said. With heroin, impurities and contamination can make an already dangerous drug even more deadly.

The CDC has found that three out of every four new heroin users report having abused prescription painkillers prior to taking up the drug. In a high-profile recent example, the actor Philip Seymour Hoffman died after his prescription painkiller addiction led him to heroin.

Sullivan, who has been working in addiction treatment in the region since 1985, said he rarely saw a heroin addict in his early years. "Even 10 years ago, we saw no heroin," he said.

Now, he sees it every day. One 19-year-old patient has been on heroin for four years. Of the four new patients Sullivan saw the morning we met, one heroin addict had Hepatitis C, Hepatitis B, and HIV. She came from a huge family, Sullivan said, most of whom are now dead from overdoses.

Alicia Frum, a patient in Sullivan's advanced group, had been smoking pot and dropping acid for about 10 years before she was introduced to heroin. It wasn't something she had set out to do, and yet, "the first time I did it, my brain and body said, *this is what you've been missing your whole life*."

She had a daughter at 16 with a fellow addict, and for a time, she thought her life was simply fated to be that way. “I thought, I haven’t died, and I haven’t overdosed,” she said. “Maybe this is what I’m supposed to be—some drug-addict mom.”

Two years ago, she got pregnant with her son, Cain, and decided she was tired of blowing through money and spending her days searching for her next fix. She talked to the intake staff of Chestnut Ridge on a Friday, bought enough heroin to last through the weekend, and had her first appointment on Monday.

Heroin is one of the most addictive drugs, more habit-forming than cocaine, alcohol, and other common substances. Buprenorphine alleviates the withdrawal symptoms of heroin without giving patients the same euphoric high of heroin, and without slowing respiration. It works better than quitting cold turkey, but it’s even more effective when it’s monitored properly and paired with therapy.

Unlike some opioid-stricken areas of the country, West Virginia lacks many of the resources necessary to treat the epidemic. On Staten Island, police carry naloxone, a nasal spray that helps revive people who are in the middle of an opioid overdose. This spring the West Virginia legislature killed a bill that would have let its emergency personnel do the same.

Though Suboxone and similar drugs are readily available at clinics throughout the state, group therapy is harder to find. West Virginia has 83 mental-health shortage areas, and only about two-thirds of West Virginians are able to access mental-health treatment.

Melinda Campopiano, medical officer for the Substance Abuse Mental Health Services Administration, said that there are only a few places in the country with an adequate supply of providers who can offer buprenorphine alongside therapy.

“The people in more rural states that have fewer doctors to start with have even fewer people who can treat opiate addiction with buprenorphine,” she said. “The hardship is magnified.”

Doctors who want to offer group therapy alongside medication may need to spend hours on the phone with insurance companies in order to hash out the correct billing codes. “So many doctors are just busy running from patient to patient,” Campopiano said.

Sarah, one of Sullivan’s patients, said the clinic her husband, also a former addict, attends takes a far more lax approach. “They never drug test him there,” she said. “He never sees the doctor. They say, ‘You don’t have to go to meetings.’ They’ve offered him a higher dose.’” There’s another addiction clinic in Parkersburg, closer to her home, but she said the treatment process there feels like “cattle-moving”: Patients wait in line for Suboxone, then leave.

Kesner, the man in the beginner group, said that when he was first calling around for help, all of the programs closer to his home had months-long waiting lists. The only reason he got into Chestnut Ridge, he said, is because he checked into the hospital’s emergency room first.

One reason for the scarcity of good treatment is that Medicaid payment rates for psychologists are extremely low. Sullivan said he gets just $22 per patient for an hour of therapy from Medicaid. On top of that, federal restrictions limit opioid-addiction doctors to 100 patients each, and all of the Chestnut Ridge doctors are maxed out.

Even his privately insured patients struggle with reimbursement. One man in Sullivan's advanced group has been paying the $500 for his treatment out-of-pocket for the past few months because of an insurance mix-up.

"I'm always approached by someone who says, 'I've got a daughter or a brother, or a son or a sister, and we just can't find a place for them to get treatment,'" William Ihlenfeld said.

It took Kevin, the formerly homeless man, several weeks to get into Sullivan's clinic after his ER visit. He now takes Suboxone, works at Burger King, and lives in a shared house in Morgantown. He's relapsed several times, but he said his life is dramatically better overall.

"[Suboxone] kind of gives you a buzz when you first start taking it, but after it's been in your system for a while, that goes away, and, like, I feel good every day when I wake up," he said. "I don't crave for drugs and pills and stuff like that anymore. I just feel normal, and I've been on it for almost a year and a half now. And honestly I think if I hadn't come here, I probably would have been dead."

For the first part of their therapy sessions, Sullivan's patients see him *en masse* for a half-hour. Sitting in a quiet circle, the dozen or so people discuss their 12-step meetings, personal issues, and medication refills. The group therapy model is based on the effectiveness of AA, in which alcoholics gather to share stories and offer support to one another.

"I'm in the process of going through a divorce," said Jennifer Gayda.

"Is he going to fight you?" Sullivan said.

"Oh hell yeah," she replied.

"Even losing a husband may not be the worst thing," Sullivan offered.

"Actually, it's pretty good. I'm doing the 10th step every night," she said, referring to the portion of the AA sequence in which addicts "take personal inventory" and admit their wrongdoings.

"This is nobody's first choice," Sullivan told me later. "Everyone tries multiple times on their own to quit unsuccessfully. They finally come here because they don't believe anything they do is going to work."

"They're in this kind of pain," he added, pointing to his head.

Sarah, who has been sober for four years and comes from a middle-class family, started using Vicodin and Percocet when she was in college. Soon, heroin arrived from Detroit, and she switched drugs in order to save money.

“At first I wasn’t shooting it, but it progressed to being an IV drug user, and that is something that takes everything away rather quickly,” she said. “Within the first six months I was using it, I ended up losing just about everything.”

Today, seeing her sitting in Sullivan’s group in a neat brown blouse and makeup, you’d never guess she had ever been an addict.

The group’s confessional style erodes denial and builds camaraderie. It gives patients sober friends and a place to go during the day. Most importantly, it’s an accountability mechanism: The only way to get kicked out of the clinic is to lie about having used.

After Sullivan leaves the room, Chiasson-Downs leads a longer talk-therapy session.

That day, it was Betty Cumberledge’s last session—she had been sober for three years and was no longer required to attend group therapy. To commemorate the event, she composed a goodbye letter. “I don’t know if I can live without you guys,” she said, tearing up.

Chiasson-Downs pulled out a bucket of Play-Doh and asked each person to sculpt two figurines: One depicting their lives while they were addicted, and one representing what it’s like to be in recovery.

An older man in a backward baseball cap rolled some yellow dough into a long snake. He tangled it and held it up: “I was a twisted pretzel,” he said. He pulled on the ends. “Now my life’s an untwisted pretzel.”

Cumberledge made, first, a coffee table covered in drugs, and then, a shining sun. “I feel like my life has come together,” she said.

Felicia Corley, a quiet blond in a gray sweatshirt, held up a purple jagged structure, saying her addiction had made her “rigid.” “Now,” she said, showing off a perfectly smooth ball, “I feel more solid.”

One boyish-looking man depicted his addiction as a jackass, complete with tiny yellow droppings. A pale, melancholy woman next to me made a startling realistic marijuana pipe filled with Play-Doh pot, along with a handful of small blue pills.

Gayda, the woman going through the divorce, made a round “no” sign, to represent the fact that while she was addicted, she had no time for friends, family, or her kids. “They were bothering me, they interrupted me getting high,” she said. Her “after” was a three-part triangle—the symbol for Alcoholics Anonymous.

Sarah made an orange tube—a bottomless pit.

“I was hating life, but it was never-ending,” she said.

Then she laid four clay letters, H-O-P-E, on the chair next to her. “Because I have that today.”

11 Tips for Better Opioid Prescribing

Roger Chou, MD, Charles E. Argoff, MD

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Editor's Note: *As part of its effort to facilitate responsible opioid prescribing, the American Academy of Addiction Psychiatry (AAAP) hosts a listserv where clinicians can submit clinical questions and receive responses from a rotating panel of pain experts. In conjunction with the AAAP, Medscape has selected 10 of the most common questions or topics related to opioid use that have been submitted, and asked Charles E. Argoff, MD, Director of the Comprehensive Pain Management Center at Albany Medical Center, and Roger Chou, MD, Professor of Medicine and Medical Informatics & Clinical Epidemiology at Oregon Health & Science University in Portland, to provide responses. For additional resources on appropriate opioid prescribing and opioid addiction treatment, please see the AAAP's PCSS-O and PCSS-MAT programs, which provide guidance on the safe and effective use of opioid medications and on the treatment of opioid addiction.*

The Genetic Risk for Substance Abuse

What is known about the genetic risk for substance abuse, and is there a statistical risk calculator for abuse that is based on a patient's family history?

Dr. Chou: Unfortunately, there is no simple estimate for risk for substance abuse based on genetics or family history. Twin studies suggest that the degree of heritability of addictive disorders ranges somewhere between 40% and 70%, depending on the substance being evaluated. The risk appears to be higher with first-degree relative than more distant relatives, but I am not aware of consistent or reliable estimates of the degree of risk with more distant relatives.

In addition, there is no simple mendelian inheritance pattern with addiction, and it is likely that the genetic relationships are complex. The risk for substance abuse is also dependent on environmental (eg, exposure) and other factors.

The bottom line is that in a patient being considered for opioids, a personal history of substance abuse is the strongest risk factor for future abuse, and a family history is also an important risk factor, though to a lesser degree.

Dr. Argoff: Although there is no simple answer to this question, at least one of the tools currently available to screen for risk for opioid misuse and abuse, the Opioid Risk Tool, incorporates family as well as personal history of substance abuse into risk stratification.

Risk Factors and Impact on Driving

What patient and treatment factors contribute to opioid use disorders?

Dr. Chou: The strongest risk factor for opioid use is a personal history of opioid use or other substance abuse. A family history of substance abuse is another important risk factor. Depression and other psychological comorbidities are another risk factor, as are age between 20 and 40 years in some studies and a history of preadolescent sexual abuse in women. Somatization is a risk factor in some studies.

In terms of treatment factors, there is no clear association between risk for abuse and use of short- vs long-acting opioids, specific opioid, or dose -- though there does appear to be a dose-dependent association with risk for accidental overdose.

What is the impact of opioids on cognition and driving?

Dr. Chou: Opioids can slow cognition and decrease reflexes and concentration, particularly when first started and when changing doses. However, some studies of simulated driving tests indicate no impaired driving ability in persons who have been on stable doses of opioids. Similarly, studies suggest no clear increased risk for motor vehicle accidents in patients on chronic, stable doses of opioids. Patients should be counseled about the potential effects of opioids on cognition and driving or work safety, the importance of not driving when feeling impaired, the need to avoid other substances and drugs that can affect cognition and driving safety, and to avoid driving when starting opioids or changing doses.

Short- or Long-Acting Opioids?

Should short-acting or long-acting opioids be used chronically for chronic pain?

Dr. Chou: Although long-acting, round-the-clock opioids have often been suggested for treatment of chronic pain, there is no evidence that they are superior to short-acting or as-needed dosing. Potential benefits of long-acting, round-the-clock opioids are fewer peaks and troughs that in theory might increase the risk for addiction or withdrawal, and more sustained pain control. However, long-acting, round-the-clock opioids also are likely to induce tolerance and probably have contributed to the trends toward use of higher doses. No study has shown that long-acting opioids are safer than short-acting opioids or more effective for pain relief.

The bottom line is that it's probably OK to use either; if a patient is doing fine on a short-acting opioid, there is no compelling reason to switch him or her to a long-acting opioid, and vice versa.

Dr. Argoff: Despite their use and claims of the benefits of long-acting opioids, not a single published study has demonstrated that patients with chronic pain experience greater relief with long-acting opioids compared with short-acting. In fact, at least one head-to-head study demonstrated the opposite conclusion. Each of these broad types of opioid therapies may play a role in the successful management of a specific person's specific chronic painful condition. We need to work with a patient to understand what regimen may be optimal for that person.

The Efficacy of Long-term Opioids

Is there evidence to support the efficacy of long-term opioids for chronic pain?

Dr. Chou: Evidence to support the efficacy of long-term opioids for chronic pain is extremely limited. No randomized trial of opioids vs placebo has treated patients for more than six months, and most treated patients for fewer than six weeks. In a Cochrane review,[1] there were very limited data from uncontrolled studies (eg, studies of patients originally randomly assigned to receive opioids in a clinical trial and then followed after the trial ended) that some proportion of patients do continue opioids long-term and report continued pain relief, although significant proportions also discontinued owing to adverse effects or lack of efficacy. Clearly, more long-term controlled studies are needed to understand efficacy of long-term opioids vs alternative therapies (placebo, no opioid, and nonopioid alternatives).

Dr. Argoff: I disagree to some extent with Dr. Chou. Population-based controlled studies, by their design, ignore an individual's response. This is an important omission if we want to know how often an individual does well on opioid therapy for one, two, or more years and how often an individual does not. We need to design a more clinically relevant approach to studying this important matter.

The Evidence for Multimodal Therapy

What is the evidence to support multimodal treatment of pain?

Dr. Chou: For functionally disabling chronic pain, interdisciplinary rehabilitation -- a type of multimodal treatment that typically incorporates supervised physical therapy and psychological therapies (eg, cognitive-behavioral therapy) as well as other modalities in an integrated fashion -- has been shown in randomized trials to be more effective than single-modality therapies for chronic pain. For low back pain, interdisciplinary rehabilitation has been shown to be as effective as fusion surgery for patients with nonradicular low back pain.

At the same time, there isn't great evidence that piling on lots of interventions is a more effective or efficient strategy in most patients than using one or a few interventions, particularly in patients with acute pain. Patients more likely to benefit from multimodal therapies are those who have chronic disabling pain that has not responded to single intervention, and those who have risk factors for developing chronic disabling pain.

Dr. Argoff: Unfortunately, given all that is recommended about the multimodal treatment of pain, there is little in the way of large prospective studies regarding such an approach to report. On the other hand, there are many studies to support the observation that a single intervention for chronic pain infrequently results in complete pain relief or even significant pain relief for *most* of the patients exposed to that intervention.

Upping the Dose vs Combination Therapy

Physicians in my hospital often seem to add a second opioid for treating pain rather than increasing the dose of the initial opioid. Do you have any suggestions for changing this practice that makes nursing care confusing and does not seem to promote patient comfort?

Dr. Chou: This seems to be the kind of thing that could be fairly easily flagged through electronic prescription records and brought to the attention of the physicians, so that they stick with one opioid rather than more. In some cases, there may be a reason to use two opioids (eg, one long-acting and one short-acting for titration or breakthrough pain), but there aren't too many reasons to prescribe more than one short-acting or more than one long-acting opioid.

Dr. Argoff: This is not a simple question to answer. The first step is to understand *why* the prescriber is adding another opioid. Whereas some patients sufficiently benefit from a single opioid, others experience optimal benefit when one particular opioid is used as a long-acting agent (eg, a fentanyl patch) and a different opioid compound is used for pain that breaks through this regimen (eg, short-acting oxycodone or oxymorphone).

There has been recent interest in the formal clinical development of a new medication that combines morphine and oxycodone in one preparation, because studies have shown that such a combination may enhance outcome; however, this preparation is not currently approved by the US Food and Drug Administration.

Buprenorphine While Breastfeeding?

I have a pregnant woman on buprenorphine who very much wants to breastfeed after delivery. Is buprenorphine safe in this scenario?

Dr. Chou: The decision to use medications while breastfeeding is an important one that women should always discuss with their physician. However, continuation of buprenorphine during breastfeeding is considered an accepted practice, owing to the low levels in breastmilk that result in low levels in the infant. Many infants born to mothers on methadone or buprenorphine will have neonatal abstinence syndrome, which may be somewhat attenuated by the small amount of buprenorphine in the breastmilk, though I am not aware of data showing that they can go home from the hospital earlier.

Avoiding Opioid-Induced Hyperalgesia

How does one avoid opioid-induced hyperalgesia (increased sensitivity to pain)?

Dr. Chou: Data to estimate the prevalence and clinical impact of hyperalgesia in humans, or how to avoid it, are quite limited. In clinical practice, it can be very difficult to distinguish hyperalgesia from tolerance. Some evidence suggests that hyperalgesia occurs at relatively high doses of opioids, and should be relatively uncommon at doses below 120 mg morphine equivalents per day. Some research suggests that blocking NMDA receptors (with such agents as dextromethorphan, ketamine, or methadone) may help prevent hyperalgesia, but a lot more research would be needed before using such drugs for these purposes could be recommended, because these come with their own potential harms.

Dr. Argoff: There are truly no good data to support or refute this entity. The quality of currently available studies regarding this matter is generally poor.

The Role of Nonphysicians

How can nonphysicians (eg, psychologists, physical therapists, pharmacists, nurses) who provide pain care to patients in the community best collaborate with physicians?

Dr. Chou: I think it's important for nonphysicians to provide the same messages regarding the importance of self-care and activity and not to reinforce negative coping behaviors, such as fear avoidance and catastrophizing. Similarly, it's important that physical and occupational therapists don't overemphasize findings on imaging (eg, degenerative changes in the back) that are very common and only weakly correlated with pain -- but rather stress with patients the importance of movement, and that exercise won't further damage the back. Consistent messages will help patients move and hopefully improve in function.

It is also important for nonphysicians to communicate to physicians when they are concerned about opioid use patterns (eg, if they see that a patient has gotten refills from different providers) or if patients are not effectively engaging in care; this can help the physician in terms of shaping future care plans.

Dr. Argoff: Communication and respecting each other's disciplines and approach to patient management are key. We (patients and providers) need to be reminded that no single treatment works for all or is likely to cure a person, and how important it is to personalize the approach to care. This last point is too often lost in today's algorithmic approach to medical care. This gets back to communicating well with each other to help the patient move forward in his or her specific treatment plan -- these can't be "rubber-stamped" for treatment to be successful.

Finally, it helps all of us to have an understanding of what each of us is doing for the patient -- how each of our interventions are likely to help the patient. For example, what is the role of opioid therapy in a multimodal approach to chronic pain management? What is the role of physical and occupational therapies, invasive pain management approaches, or cognitive-behavioral approaches? Most of us know that no one treatment usually

cures a person, and it's extremely valuable to integrate these various options seamlessly into a patient's treatment regimen.

Dealing With Doctor-Shoppers

I am not trying to stigmatize here, but the vast majority of addicts who show up in pain clinics are not interested in recovery. They are looking for a new source of drug. These folks are easy to spot if you are seasoned; however, even tactful observations about their doctor-shopping, historical addiction, story inconsistencies, and so on are typically met with the kind of anger that comes when your cover is blown. What are your recommendations for dealing with these patients?

Dr. Argoff: This is admittedly a tough group of patients to work with. I think that it is important to keep in mind that opioids represent only one class of pharmacologic therapy for chronic pain. Not only may other nonopioid pharmacologic approaches be medically appropriate to consider for the patient with chronic pain whose other behaviors are described above, nonmedical approaches may also be considered. It important to both treat this patient humanely as suggested above, and to treat that person safely.

References

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