



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 March 19, 2015 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. FOR DISCUSSION: Report on CURES, California's Prescription Drug Monitoring Program

Mike Small, DOJ Administrator II, is program administrator of DOJ's Law Enforcement Services Program which oversees CURES. Robert Sumner, Deputy Attorney General, is a Department of Justice legislative advocate. Both will present information on the new computer system for CURES and on CURES staffing. They will address the number of prescribers and dispensers enrolled in CURES and the number of patient queries the system has received. They will also report on the CURES budget and how additional funds from prescribers and pharmacists are being utilized.

2. FOR DISCUSSION: Report on a Pharmacist's Corresponding Responsibility in Regards to Dispensing Prescription Medications

The Board of Pharmacy has completed enforcement actions involving pharmacies and corresponding responsibility. Staff will highlight some of the completed enforcement actions.

Attachment 1 contains a copy of Health & Safety Code 11153 regarding a pharmacist's corresponding responsibility.

3. FOR DISCUSSION AND POSSIBLE ACTION: The Board Requiring Continuing Education on Pain Management

The committee will discuss ways to educate pharmacists on opioid dispensing, consultation and corresponding responsibility to prevent opioid abuse and overdose.

Attachment 2 contains a copy of Code of Regulations 1732.5 for requirements for continuing education for pharmacists.

4. FOR DISCUSSION: Report on Naloxone Emergency Regulations to Prevent Opioid Overdose Deaths

An update will be given on the status of the board's emergency regulation regarding pharmacists furnishing the opioid antagonist naloxone without a prescription.

A copy of the emergency regulation and naloxone fact sheet is included in **Attachment 3**.

5. FOR DISCUSSION: Presentation on University of California, San Diego Webinar and Other Activities Related to Prescription Drug Abuse

Nathan A. Painter, Pharm.D., CDE and Associate Clinical Professor at the University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Science will provide presentations on what is being done to educate students about prescription drug abuse. His presentation will include information from UC Student Health, the California Pharmacist Association and prescription drug abuse elective and other courses in the UCSD Skaggs School of Pharmacy curriculum addressing controlled substances.

Attachment 4 contains a copy of Dr. Painter's PowerPoint presentation.

6. FOR DISCUSSION AND POSSIBLE ACTION: Proposal to Prepare a Draft Report on the Subcommittee's Findings and Recommendations on the Opioid Epidemic

The committee will consider the creation of a report to summarize what the committee has heard on the severity of the opioid epidemic and the related rise in heroin abuse. The report would also focus on efforts by California State agencies to address the crises, including the work of CURES.

7. FOR INFORMATION: Activities to Promote Prescription Drug Abuse Awareness Month, ACR 26 (Levine)

Before the end of March, the board plans to alert pharmacists, consumers and the media about the availability of naloxone to treat opioid overdoses once the emergency regulation goes into effect. Press releases would include links to the board's prescription drug abuse prevention page. The board will be assisted in this effort by the state Prescription Opioid Misuse and Overdose Prevention Workgroup.

Attachment 5 contains a copy of ACR 26 (Levine) proclaiming March Prescription Drug Abuse Awareness Month.

8. FOR INFORMATION: Report on the Conversion of the Board of Pharmacy Website

Staff is working to convert the board website to the newer version that is provided for state agencies. A basic template is available, but everything must be customized for the Board of Pharmacy. It is estimated that the redesign will take a minimum of four to six months of IT staff time to complete. Currently, staff is working on the home page and five categories have been identified as top categories to organize the page. They are Licensees, Applicants, Consumers, Online Services, and About Us. There will also be a list of quick hits on the home page for the most popular items. Currently, the top places visited on the board website are the pharmacy law book, board meetings and publications.

Attachment 6 contains a screenshot of the draft home page of the redesigned website.

9. FOR INFORMATION: Articles Documenting the Issues of Prescription Drug Abuse

Attachment 7 contains articles of interest on the issue of prescription drug abuse.

10. FOR INFORMATION: Public Outreach to Address Prescription Drug Abuse

- December 2, 2014: Board staff participated in a Prescription Opioid Misuse and Overdose Prevention Workgroup meeting
- January 21, 2015: Board staff participated in a Prescription Opioid Misuse and Overdose Prevention Workgroup meeting
- February 12: Board Member Rosalyn Hackworth presentation
- February 12: Virginia Herold gave a presentation on corresponding responsibility to Keck pharmacy students
- February 19: Board staff attended an Interagency Prevention Advisory Council (IPAC) meeting on prescription drug abuse
- February 27: Board staff participated in an Interagency Data Meeting of the Opioid Safety and Overdose Prevention Workgroup

- March 10: Virginia Herold gave a presentation on corresponding responsibility to Touro University pharmacy students
- March 19: Presentation at Orange County Rx Coalition meeting for professionals who deal with prescription drug abuse.
- March 20: Board staff to participate in Prescription Opioid Misuse and Overdose Prevention Workgroup meeting
- April 1, 2015: Board staff to address California State University, Sacramento public health class on opioid abuse and pharmacy issues
- April 17: Virginia Herold to present at a DEA community program at Sac. State
- April 30, 2015: Board staff to address Downtown Los Angeles pharmacists on corresponding responsibility. Program will be conducted jointly with L.A. City Attorney office, L.A. Police Department and DEA. Two hours of CE will be given.

11. Public Comment For Items Not on the Agenda, Matters for Future Meetings*

**(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))*

ATTACHMENT

1

11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment in the state prison or in the county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both a fine and imprisonment.

(c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

ATTACHMENT

2

1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

ATTACHMENT

3

What is an opioid overdose?



Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone...

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit www.prescribetoprevent.org



SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
CALIFORNIA STATE BOARD OF PHARMACY

Opioid safety and how to use naloxone



A GUIDE FOR PATIENTS AND CAREGIVERS

DEVELOPED BY
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

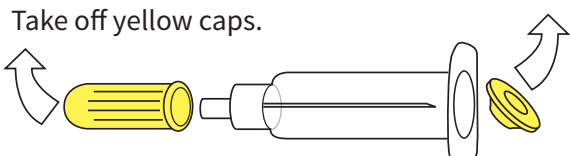
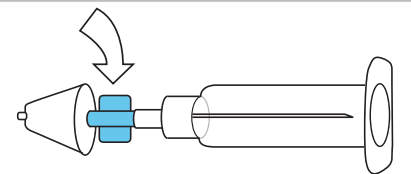
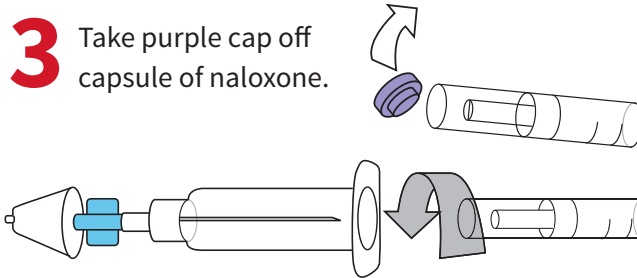
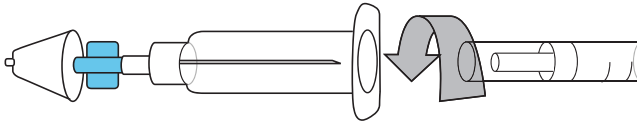
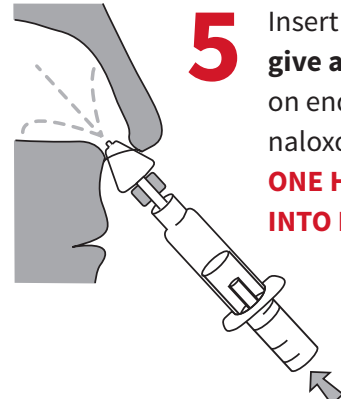
How to identify an opioid overdose:

In case of overdose:

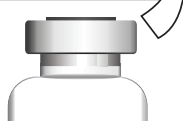
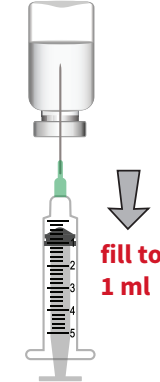
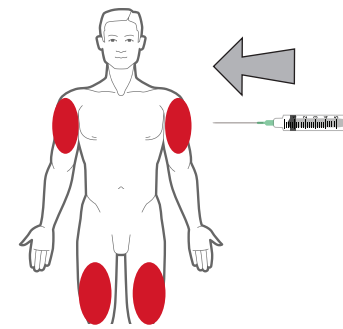
How to give naloxone:

There are 3 ways to give naloxone. Follow the instructions for the type you have.

Nasal spray naloxone

- 1** Take off yellow caps. 
- 2** Screw on white cone. 
- 3** Take purple cap off capsule of naloxone. 
- 4** Gently screw capsule of naloxone into barrel of syringe. 
- 5** Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**  Push to spray.
- 6** If no reaction in 3 minutes, give second dose.

Injectable naloxone

- 1** Remove cap from naloxone vial and uncover the needle. 
- 2** Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.  fill to 1 ml
- 3** Inject 1 ml of naloxone into an upper arm or thigh muscle. 
- 4** If no reaction in 3 minutes, give second dose.

Auto-injector

The naloxone auto-injector is FDA approved for use by anyone in the community. It contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed.

Title 16. Board of Pharmacy. Adopt §1746.3, which is new regulation text, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions Code authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide access to naloxone hydrochloride via standardized procedures so that pharmacists may educate about and furnish naloxone hydrochloride to decrease harm from opioid¹ overdose.

(3) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

(A) Screen for the following conditions:²

- (i.) Whether the potential recipient³ currently uses or has a history of using illicit or prescription opioids (If yes, skip question ii and continue with Procedure);
- (ii.) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (If yes, continue with Procedure);
- (iii.) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).

(B) Provide training in opioid overdose prevention, recognition, response, and administration of the antidote

naloxone.

(C) When naloxone hydrochloride is

furnished:

- (i.) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

¹ For purposes of this protocol, "opioid" is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

² These screening questions shall be made available in alternate languages for patients whose primary language is not English.

³ For purposes of this protocol, "recipient" means the person to whom naloxone hydrochloride is furnished.

- (ii.) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
- (iii.) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: Naloxone hydrochloride may be supplied as an intramuscular injection, intranasal spray, and auto-injector. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5) Suggested Kit Labeling:

Intramuscular	Intranasal	Auto-Injector
<p>Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 vials and 2 syringes.</p>	<p>Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 prefilled needleless syringes and 2 atomizers.</p>	<p>Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Kit is commercially available as a twin pack with directions for administration included.</p>

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be

made available in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(10) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

ATTACHMENT

4



California Board of Pharmacy Prescription Drug Abuse

Nathan A. Painter, PharmD, CDE

Associate Clinical Professor of Pharmacy

UC San Diego Skaggs School of Pharmacy and Pharmaceutical
Sciences

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

Prescription Drug Abuse in College Students

- Provide an overview of prescription drug abuse in the college population
- Identify drug-seeking behavior with case examples
 - Aberrant drug seeking behaviors
 - Red flags
- Explore tools to use with patients at risk of prescription drug abuse
 - Opioid risk tool, SOAPP
 - Stimulant/benzos
- Describe prescription drug monitoring programs (CURES) for identifying patients at risk
 - Setting limits
 - Seeing the frequently
 - Limited amount on rx
 - Referring to psych if needed or other campus resources to access for disability
 - San Diego safe prescribing <http://www.sandiegosafeprescribing.org/>
- Examine the role of naloxone in preventing drug overdose

Target Audience

- UC Student Health
 - Physicians
 - Physician assistants
 - Nurse practitioners
 - Pharmacists
 - Pharmacy technicians
 - Psychologists and therapists

Prescription Drug Abuse and the Pharmacists' Role

- Epidemiology of Rx abuse
- San Diego County initiatives/taskforce
- Legal issues relating to pharmacists
 - Red flags
 - Corresponding responsibility
 - DEA
- CURES: Past, present and future
 - How to use CURES/FAQs
 - Signing in
 - Updating password
 - Legal issues with CURES reports
 - An example of a CURES report

UC San Diego SSPPS Curriculum

- Law and Ethics
- Therapeutics
- Prescription Drug Abuse Elective

Continuing Education Programs

- Many available to pharmacists
- Most target physicians and other prescribers
- Not much on dispensing

San Diego Safe Prescribing

(www.safesandiegoprescribing.org)

- ED Prescribing Guidelines
 - San Diego county
 - Statewide
- One San Diego
 - One physician
 - One pharmacy

Questions?

ATTACHMENT

5

BILL NUMBER: ACR 26 INTRODUCED
BILL TEXT

INTRODUCED BY Assembly Member Levine
(Coauthor: Senator McGuire)

FEBRUARY 19, 2015

Relative to Prescription Drug Abuse Awareness Month.

LEGISLATIVE COUNSEL'S DIGEST

ACR 26, as introduced, Levine. Prescription Drug Abuse Awareness Month.

This measure would proclaim the month of March 2015 as Prescription Drug Abuse Awareness Month and encourage all citizens to actively participate in prevention programs and activities, and to safely store and dispose of their medications on a continual basis.

Fiscal committee: no.

WHEREAS, Drug overdose was the leading cause of injury and death in 2012, and among people 25 to 64 years of age, drug overdose caused more deaths than motor vehicle traffic crashes; and

WHEREAS, Every day in the United States, 120 people die as a result of drug overdose, and another 6,748 are treated in emergency departments for the misuse or abuse of drugs; and

WHEREAS, In 2013, drug overdoses in the United States caused 43,982 deaths and 22,767, or 52 percent, of those deaths were from prescription drugs; and

WHEREAS, In 2011, 2.5 million emergency department visits were related to the misuse or abuse of pharmaceuticals; and

WHEREAS, Nonmedical use of prescription painkillers costs health insurers up to \$72.5 billion annually in direct health care costs; and

WHEREAS, Overdose deaths involving opioid pain relievers now exceed the number of deaths from heroin and cocaine combined; and

WHEREAS, As many as 70 percent of people who abuse prescription drugs get them from a relative or friend instead of a doctor; and

WHEREAS, During the last National Prescription Drug Take-Back Day, the United States Drug Enforcement Administration (DEA) collected 617,150 pounds (309 tons) of unwanted medication on Saturday, September 27, 2014; and

WHEREAS, The 2014 National Drug Control Strategy listed four interventions to reduce prescription drug abuse, one of which was to provide safe drug disposal by increasing return and take-back programs. We support California acquiring a sustainably funded and well publicized statewide medication take-back system that is much more convenient to consumers than the current one-day events or disposal at hazardous waste facilities; and

WHEREAS, The National Coalition Against Prescription Drug Abuse, law enforcement, community-based organizations, alcohol and other drug service providers, and civic and business leaders coordinate

Prescription Drug Abuse Awareness Month activities in California to engage our citizens in demonstrating their commitment to prevention campaigns and education aimed at raising awareness about the abuse and misuse of prescription drugs, promoting prescription drug safe storage and disposal, and using medications only as prescribed; and

WHEREAS, Families, schools, businesses, faith-based communities, law enforcement, medical professionals, county and local governments, health care practitioners, and pharmacists in the state, and the general public will demonstrate their commitment to the prevention of prescription medication abuse by participating in activities intended to highlight local efforts during the month of March; and

WHEREAS, The Legislature supports National Prescription Drug Take-Back Day as declared by the DEA, and encourages residents to locate their local collection site and safely dispose of their accumulated unwanted and unused prescription drugs; now, therefore, be it

Resolved by the Assembly of the State of California, the Senate thereof concurring, That the Legislature hereby declares March 2015 as Prescription Drug Abuse Awareness Month and encourages all citizens to actively participate in prevention programs and activities, and to safely store and dispose of their medications on a continual basis; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the author for appropriate distribution.

ATTACHMENT

6



BE AWARE AND TAKE CARE:
Talk to your pharmacist!
 CALIFORNIA STATE BOARD OF PHARMACY


[About](#)
[Applicants](#)
[Licensees](#)
[Consumers](#)
[Online Services](#)

Container Style A

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ATTACHMENT

7

2013 Drug Overdose Mortality Data Announced

15/01/2015 07:44:00

<http://www.healthcanal.com/public-health-safety/59144-2013-drug-overdose-mortality-data-announced.html>

Prescription Opioid Deaths Level; Heroin-related Deaths Rise

Washington, D.C. – Today, the White House Office of National Drug Control Policy (ONDCP) is announcing the 2013 drug overdose mortality data from the Centers for Disease Control and Prevention (CDC). The data show that drug deaths related to prescription opioids have remained stable since 2012, but the mortality rate associated with heroin increased for the third year in a row.

The data show a 6% increase in all drug poisoning deaths from 2012, and a 1% increase in deaths involving opioid analgesics over 2012. Deaths involving heroin had the largest upsurge overall, with a 39% increase from 2012, while deaths involving cocaine increased 12%. These results demonstrate that while the Administration's efforts to curb the epidemic of the nonmedical use of prescription drugs is working, much more work is needed to improve the way we prevent and treat substance use disorders.

"The data announced today underscore that the nation's drug problem is evolving, and requires a comprehensive solution—including preventing drug use before it ever begins, reducing the supply coming from foreign nations, educating our nation's youth on the risks of substance use, and the work of our nation's Federal, state, local, and tribal law enforcement to continue reducing the amount of trafficking within the United States," **said Michael Botticelli, Acting Director of the White House Office of National Drug Control Policy.**

Substance use disorders are progressive diseases, and, in the case of opioid use disorders, the problem often begins with a prescription, or taking pills from a home medicine cabinet. Nearly 68% of people who begin using prescription drugs non-medically for the first time obtain those drugs from a family member or friend. But more frequent or chronic users (those who used pain relievers non-medically once a week or more on average in the past year) were more likely to obtain the drug from the illicit market than were less frequent users. In 2014, ONDCP joined the Drug Enforcement Administration (DEA) to announce the Final Rule for the Disposal of Controlled Substances, which outlines methods to transfer unneeded or expired medications to authorized collectors for disposal—a pillar of the Obama Administration's *2011 Prescription Drug Abuse Prevention Plan*.

Early intervention in a healthcare setting is an essential component of the comprehensive approach to reducing drug use. Healthcare providers are critical to identifying and intervening in a developing disorder. By intervening early and providing medication assisted treatment when appropriate, healthcare providers—including primary care physicians, ER doctors, dentists, nurses, and other healthcare workers—can dramatically reduce the possibility of a future overdose, and significantly improve the likelihood that a patient will enter treatment and sustain a life in long-term recovery.

"These troubling statistics illustrate a grim reality: that drug, and particularly opioid, abuse represents a growing public health crisis," **said Attorney General Eric Holder.** "In response, the Department of Justice has been marshaling a variety of resources -- and rallying a broad coalition of public health and public safety leaders -- to implement a comprehensive approach to fight back. By focusing on treatment and intervention, as well as interdiction and enforcement, we are committed to combating this scourge -- and helping to save and improve lives -- across America."

As part of its broad response to the opioid crisis, the Department of Justice recently released a [toolkit for law enforcement](#) on the use of naloxone, the life-saving opioid overdose reversal drug. When administered quickly

and effectively to a person experiencing overdose related to opioids—which includes prescription painkillers and heroin—naloxone can save a life. Law enforcement agencies across the nation have equipped and trained officers with naloxone, saving hundreds of lives since the first pilot program was launched in 2010 in Quincy, Massachusetts.

“Deaths from drug overdose are tragic, and we need to scale up both prevention and treatment of addiction,” said **CDC Director Tom Frieden, M.D., M.P.H.** “Most people who use heroin in the U.S. today used prescription opioids first. Reducing inappropriate prescribing will prevent overdose from prescription opioids and heroin.”

The Centers for Disease Control and Prevention provides resources and scientific expertise directly to states to address the key drivers of prescription drug overdose. With \$20 million in new funding in 2015, CDC will dramatically expand this work and provide more resources to states on the front lines of the epidemic.

The Office of National Drug Control Policy promotes a balanced approach to reducing drug use and its consequences by directing more funding in the federal drug control budget to treatment and prevention programs than to domestic law enforcement. In 2011, ONDCP established a *Prescription Drug Abuse Prevention Plan* with four pillars, focusing on educating prescribers and patients about the dangers of prescription drug abuse and misuse; increasing the number of prescription drug monitoring programs nationwide (there are now 49 across the country); promoting proper disposal of prescription drugs; and law enforcement efforts to decrease pill mills, drug trafficking, and doctor shopping.

The Obama Administration remains committed to fostering healthy individuals and safe communities, by effectively leading the nation’s effort to reduce drug use and its consequences in the United States.

For more information about the Office of National Drug Control Policy
visit: www.whitehouse.gov/DrugPolicyReform

For information on the High Intensity Drug Trafficking Area program visit: www.whitehouse.gov/ondcp/high-intensity-drug-trafficking-areas-program

View CDC’s 2013 mortality data, including drug-induced deaths, [here](#).

Crush-Proof OxyContin Pills Have Done Little To Curb America's Problem With Drug Abuse

<http://www.medicaldaily.com/crush-proof-oxycontin-pills-have-done-little-curb-americas-problem-drug-abuse-325262>

Mar 11, 2015 04:00 PM By Justin Caba

□@jcaba33

Abuse-deterrent OxyContin has not solved prescription drug abuse. Almond Butterscotch, CC by 2.0

Law enforcement's approach to curtailing drug abuse has been heavily focused on taking away the supply while the demand part of the equation works itself out. Many "experts," however, fail to understand that active drug addicts will do almost anything to get their "high." A recent study conducted at Washington University School of Medicine in St. Louis has revealed that drug users in the United States have not let crush-proof OxyContin get in the way of abusing their drug-of-choice.

"We found that the abuse-deterrent formulation was useful as a first line of defense," Dr. Theodore J. Cicero, a professor of neuropharmacology in psychiatry, said in a statement. "OxyContin abuse in people seeking treatment declined, but that decline slowed after a while. And during that same time period, heroin use increased dramatically."

Cicero and his colleagues surveyed nearly 11,000 drug users from 150 drug-treatment facilities across the U.S. OxyContin was originally designed to release small amounts of the pain-killing drug oxycodone over time. Drug abusers soon realized that they could get a more intense "high" just by crushing up the pills and snorting or dissolving the powder in liquid and then injecting themselves. Drug manufacturers sought to end this practice by designing a new OxyContin pill that cannot be crushed or dissolved.

Crush-proof OxyContin was introduced to the market in 2010. At that time, 45 percent of the study's participants said they had used OxyContin in the past 30 days. Although crush-proof OxyContin did successfully deter drug abuse among some users, the effect has not been widespread. In fact, approximately 25 percent of abusers and addicts entering a drug rehabilitation facility said they found a way around the prescription drug's abuse-deterrent formulation.

"Some people found ways to get around the abuse-deterrent formulation so that they could snort or inject it, and others simply swallowed the pills, but many people switched to heroin, and that's a major concern," Cicero explained. "The newer formulations are less attractive to abusers, but the reality is — and our data demonstrate this quite clearly — it's naïve to think that by making an abuse-deterrent pill we can eliminate drug abuse. There are people who will continue to use, no matter what the drug makers do, and until we focus more on why people use these drugs, we won't be able to solve this problem."

Among drug users who stopped using OxyContin but ended up switching to another drug, 70 percent started using heroin. The heroin trade in the U.S. has moved past the dark alleys of city streets and the

abandoned buildings in impoverished neighborhoods. Today, heroin can be purchased easily in both suburban and rural areas of the country. Around 50 percent of drug abusers surveyed in 2014 admitted to using heroin in the 30 days prior to entering treatment. The majority of users who switch from prescription drugs to heroin do so for economic reasons.

“A few years ago when we did interviews with people in treatment, many would tell us that although they were addicts, at least they weren’t using heroin, but now, many tell us that a prescription opioid might run \$20 to \$30 per tablet, while heroin might only cost about \$10,” Cicero added. “Some people have come to see it as a cost-effective method of getting high. If they can tolerate the intravenous injection and overcome their reluctance to give themselves a shot, many of the people in our study said it was a fairly simple decision and that heroin now represents a cheaper, more attractive alternative.”

Source: Ellis M, Cicero T. Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States Lessons Learned From OxyContin. *JAMA Psychiatry*. 2014.

Does Zohydro ER help people with long-term pain?

Consumer Reports commissioned a review of the research used to approve this opioid painkiller. The results may surprise you.

Published: March 08, 2015 06:00 AM

Prescription opioids claim the lives of more than 16,000 people each year in the U.S., and send nearly half a million people to the emergency room, according to the Centers for Disease Control and Prevention (CDC). In more than half of cases, people got their prescriptions from their regular doctor.

Zohydro ER (hydrocodone) is one of five narcotic pain drugs approved for sale by the Food and Drug Administration since late 2013. The other four are Embeda (morphine and naltrexone), Hysingla ER (hydrocodone), Targiniq ER (oxycodone and naloxone) and Xartemis XR (oxycodone and acetaminophen).

Those five drugs are long-acting opioids, meant to treat moderate-to-severe long-term pain in people who need round-the-clock relief. Narcotic pain drugs are essential to help treat severe, short-term pain from, say, surgery, and can also help with longer-lasting pain from cancer or a terminal illness. But [the drugs can also be addictive and pose other serious risks](#), including a risk of overdose and death.

That's why we commissioned Lisa M. Schwartz and Steven Woloshin, both physicians and professors at Dartmouth's Institute for Health Policy and Clinical Practice at the Geisel School of Medicine, to [review the evidence](#) that the FDA relied on when the agency [approved Zohydro ER](#) back in October 2013.

When drug companies apply for approval of a new drug, they must submit research showing that the drug is safe and effective. In some cases, the FDA asks an independent committee of experts to review the studies and vote their opinion. We took a closer look at Zohydro ER because this committee voted 11 to 2 *against* approval of the drug (you can [read the meeting transcripts](#)). For the other four drugs, no such committee meeting to review the study evidence was held, although a summary of the research is publicly available.

The FDA primarily used one study on how well Zohydro ER works to approve the drug and it was published in the medical journal Pain Medicine in 2014. It included about 300 adults with chronic back pain who were already taking opioid pain relievers.

Here's how the study worked: First, everyone took Zohydro ER for six weeks. Then researchers had some people continue to take the drug while other people were switched to a sugar pill (placebo) for three months. The people in the study didn't know if they were taking Zohydro ER or the sugar pill, and neither did their doctors. If someone in the study had pain that was particularly bad, they were allowed to take a different, short-term opioid pain drug whenever they needed.

In our analysis, Schwartz and Woloshin took that study and [summarized it in an-easy-to-understand Drugs Fact Box](#). It's similar to the Nutrition Facts on packaged foods. It shows that Zohydro ER did not help much to relieve pain or help people move around easier during their day-to-day activities.

How well did Zohydro ER work?

Every day, people in the study were asked to rate how severe their pain was. At the end of the study when those ratings were averaged together, they showed that people who took Zohydro ER felt only slightly better than those who took a sugar pill. People who took Zohydro ER also reported that the drug didn't help them function much better.

Surprisingly, if people took Zohydro ER, it did not reduce their need to take other pain relievers to treat flare-ups of pain. Both people who took Zohydro ER and those who took a placebo wound up taking additional pain medications about 7 out of every 10 days.

Also, the study found that about one-third of people who took a placebo pill instead of Zohydro ER experienced at least moderate pain relief.

Zohydro ER's side effects

Some people who took Zohydro ER said it caused them side effects, including constipation, nausea, vomiting, stomach pain, or headache, which are typical of all opioid drugs. Some people who took the sugar pills also experienced some of those side effects, although generally not as often.

Unfortunately, one person died during the study after taking an overdose of Zohydro ER and other opioid medications, which underscores the danger of misusing these powerful drugs.

Schwartz says because the drug is new and has only been studied in a small group of people, she worries that more serious side effects may surface when more people use it over a long period of time. "Unfortunately, at this point, the long-term safety and benefits are unknown," she says.

Weighing risks and benefits

Some medical experts say that the evidence the FDA reviewed wasn't strong enough to show that Zohydro ER is a safe and effective way to treat back pain, or other forms of long-term pain that is not caused by cancer or a terminal illness.

The FDA committee that reviewed the data on Zohydro ER also said it was concerned that people could abuse or misuse the drug. This was because it was not originally formulated to make it harder to abuse. (However, just recently, the FDA approved a new formulation of the drug that should discourage people from abusing it to get high.)

The FDA approved the original version of Zohydro ER anyway. And the agency highlighted new rules it created for the entire class of these opioid drugs as ways to reduce risk for people who took the drugs. The new rules require stronger warnings on labels and that drug manufacturers make education available to health care providers who prescribe the drugs.

The agency also [pointed out](#) that abuse-deterrent technology has not been perfected. The technology makes it harder for people who intentionally abuse opioids to tamper with the pills—by, for example, crushing or dissolving them so that they can snort or inject the entire extended-release dose all at once. Embeda, Hysingla ER, Targiniq ER, and Xartemis XR are formulated to be hard to tamper with.

Unfortunately, the hard truth is that growing evidence suggests *none* of the drugs in this class are safe or very effective when used long term against many forms of chronic pain.

One recent statement by the American Academy of Neurology this past September underscores this issue: The professional association officially warned its physicians about the use of opioids for non-cancer chronic pain such as back pain, frequent headaches, or fibromyalgia, stating that the risk of death, overdose, addiction or other serious side effects likely outweigh any potential benefit.

"The science on the treatment of chronic pain is evolving. Right now, we do not have evidence that people who take around-the-clock opioids for chronic non-cancer pain over the long-term function better or have better quality of life. It does not make sense to add more—and possibly more dangerous—opioids to the list until their long-term benefit and safety are proved," Woloshin says.

Proponents say that Zohydro ER as well as another newly approved narcotic, Hysingla ER, may be safer for some patients because they contain hydrocodone alone and are not combined with acetaminophen (the active ingredient in Tylenol) like Vicodin and other popular narcotic prescription painkillers. Acetaminophen, while safe for most people if used as directed, can damage your liver if you take too much.

But like the FDA advisory panel, our experts remain unconvinced that the absence of acetaminophen makes Zohydro ER a substantially safer opioid. While liver failure is an

important issue, about *20 times* more people die as a result of overdose from opioids than from acetaminophen according to the CDC.

Instead, one of the most important recent safety measures taken by the U.S. Drug Enforcement Agency was to [tighten the restrictions on prescribing Vicodin](#) and other hydrocodone-combination drugs, some of the most commonly prescribed drugs in the U.S. We also applaud the FDA's move to reduce the maximum dose of acetaminophen in prescription drugs to 325 milligrams per pill and hope they will act soon to do the same for over-the-counter products. Acetaminophen is a [significant culprit behind liver failure in the U.S.](#), and nonprescription products account for 80 percent of the drug taken in this country.

Bottom line: Few conditions are as frustrating as debilitating long-term pain. Unfortunately, for most sufferers, opioids don't provide much relief and subject them to potentially too much risk of harm.

"People who suffer from chronic pain should try to find a good team of people with expertise in dealing with the condition to make sure that other medications and nondrug options have been given a chance to work before resorting to round-the-clock narcotics," Schwartz advises.

Little Evidence Opioid Drugs Work for Chronic Pain

<http://psychcentral.com/news/2015/01/17/little-evidence-opioid-drugs-work-for-chronic-pain/80055.html>

By Traci Pedersen Associate News Editor

Reviewed by John M. Grohol, Psy.D. on January 17, 2015

New research has found little to no evidence that opioid drugs are effective for long-term chronic pain, despite explosive growth in their use, according to a new paper released by the National Institutes of Health (NIH).

The findings reveal that many of the studies used to justify the prescription of these drugs were either poorly conducted or of insufficient duration.

“The prolific use of these drugs is surprising,” said study author David Steffens, M.D., M.H.S., chair of the psychiatry department at University of Connecticut Health.

“When it comes to long-term pain,” he says, “there’s no research-based evidence that these medicines are helpful.”

In the U.S., prescriptions for opioid drugs have more than tripled in the past 20 years, with more than 219 million prescriptions written in 2011, according to the study. Abuse of these drugs has also skyrocketed, leading some to label it an epidemic.

More than 16,000 people died from prescription opioid overdoses in 2012, according to the Centers for Disease Control, and drug overdose now causes more deaths than motor vehicle accidents for people ages 25-64.

This level of opioid use and abuse is unprecedented in the world. The U.S., which is just 4.6 percent of the world’s population, consumes 80 percent of the world’s opioid drugs. That, said Steffens, makes this “a peculiarly American problem.”

Steffens, like the other members of the panel, was surprised by many of these findings, since he is not an expert in opioid drugs, in drug abuse, or in pain management; Steffens’ specialty is geriatric psychiatry.

In fact, all members of the panel were experienced clinicians from other fields. “The NIH intentionally invited people from other fields of medicine,” he said, “in order to avoid potential conflicts of interest, and to get a fresh perspective on the issue.”

Over two days, the panel listened to evidence presented by an independent agency, which had conducted an exhaustive search of all the available studies about the use of opioid drugs. The final report is published in the *Annals of Internal Medicine*.

One of the greatest challenges, noted Steffens, is the fact that opioid drugs clearly are an effective treatment for some people dealing with pain, but it is hard to predict where trouble will crop up. There is a strong need for better communication about best practices to physicians who are prescribing these drugs, he notes.

“There are certain syndromes, like fibromyalgia, where opioids are less likely to be effective and patients are more likely get into trouble with abuse,” he said.

Another pressing issue is that pills from the pharmacy don’t always end up with the person for which they were prescribed. The phenomenon of medicine being sold or given away (known as diversion) has long been known as a key driver in the rise of prescription drug abuse.

“I wish that doctors treating people for sports or workplace injuries would be cautious with the amount of pills they dispense,” says Steffens.

Source: University of Connecticut

**NABP, Stakeholders Release Consensus Document on the Challenges
and “Red Flag”
Warning Signs Related to Prescribing and Dispensing Controlled
Substances**

***Document Seeks to Help Prevent Diversion and Abuse While Maintaining
Legitimate Access to Medications***

A coalition of stakeholder organizations released a consensus document representing the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions. As detailed in the [consensus document](#), the goal is to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny. Overall, challenges faced by health care practitioners in regard to prescribing and dispensing controlled substances can be overcome through collaboration, communication, and broader efforts to prevent the diversion and misuse of controlled substances while ensuring access to the medications for patients who need them for legitimate reasons.

The stakeholders initially met on October 2, 2013, and subsequently met numerous times over the course of 2013 and 2014 to discuss the aforementioned challenges and red flag warning signs including categorizing the signs to indicate the likelihood that diversion, misuse, or abuse are occurring. In fostering the understanding of health care practitioners’ roles, the dialogue and resulting consensus document shed light on unappreciated challenges, such as the demands placed on physicians to provide direct patient care and the pharmacist’s corresponding responsibility under Drug Enforcement Administration regulations to ensure controlled substance prescriptions are legitimate. The red flag warning signs for both physicians and pharmacists were placed into two categories – those factors more indicative of substance abuse or diversion, and other aberrant medication-related behaviors and factors potentially indicative of substance abuse or diversion. Below is the coalition of stakeholders that, along with the National Association of Boards of Pharmacy[®] (NABP[®]), supports the consensus document:

- American Academy of Family Physicians
- American College of Emergency Physicians
- American Medical Association
- American Osteopathic Association
- American Pharmacists Association

- American Society of Anesthesiologists
- American Society of Health-System Pharmacists
- Cardinal Health
- CVS Health
- Healthcare Distribution Management Association
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Pharmaceutical Care Management Association
- Purdue Pharma L.P.
- Rite Aid
- Walgreen Co

The consensus document, "Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances," is available under Position Papers in the Members section of the NABP website, www.nabp.net.

NABP is the independent, international, and impartial Association that assists its state member boards and jurisdictions for the purpose of protecting the public health.

New Recommendations For Pain Management Among Active Military And Veterans

<http://www.forbes.com/sites/cjarlotta/2015/02/13/managing-chronic-pain-in-the-active-military-and-veteran-populations/>

Much of the conversation around managing chronic pain has been directed toward the general U.S. population. One specific group deserves a little more attention: active military and veterans.

The National Center for Complementary and Integrative Health (NCCIH), part of the National Institutes of Health (NIH), this week delivered its recommendations for assisting military veterans with pain management. A working group from the center's advisory council administered the report.

The group's findings were prepared after a series of five meetings. During these engagements, the council listened to presentations by experts in various backgrounds: pain research, study design, complementary and integrative approaches. The Department of Defense (DOD) and the Department of Veterans Affairs (VA) gave input on initiatives, practices and priorities. Leaders from several veterans organizations also addressed the group.

The working group recommended that large-scale collaborative research into pain management for U.S. veterans should do the following: assess the impact of pain on patient function and quality of life as primary outcome measures, with changes in the use of opioids and other drugs as a secondary outcome; evaluate an integrated package of non-drug treatments, an integrative model of care, or a holistic approach to care rather than focusing on individual complementary health approaches; focus on patients in the early stages of chronic pain; leverage natural experiments and existing resources whenever possible; and be pragmatic and embedded in the delivery of care.

"I think these recommendations are very important, and I sincerely hope the people who can bring them to fruition pay heed to them," said Bob Twillman, executive director of the American Academy of Pain Management, in an interview.

He believes the Interagency Pain Research Coordinating Council and the NIH Pain Consortium should use this research "as a cue to see if there are ways to apply these ideas in a civilian population, as well."

Dr. Josephine P. Briggs, director of the NCCIH, told Forbes in an interview that additional research on chronic pain treatment for both the general public and within the military population is needed. A 2011 report conducted by the Institute of Medicine revealed that more than 100 million Americans are suffering from chronic pain. According to a study published last year in JAMA Internal Medicine, a peer-reviewed medical journal published by the American Medical Association, 44 percent of U.S. military members have reported chronic pain after returning home from deployment.

"Many rely on opioids to manage pain," Briggs said. There were more than 16,235 deaths involving prescription opioids in 2013, an increase of 1% from 2012. These numbers are concerning to many, including President Obama. The president's drug control priorities for the 2016 fiscal year include reducing prescription drug abuse by allocating additional funding to states with prescription drug monitoring programs (PDMPs), expanding and improving treatment for addicts, and spearheading efforts to make naloxone — an opioid antagonist — more readily available to first responders.

"While these drugs are key to managing certain types of pain, such as acute pain following surgery, the use for chronic, long-term pain can become problematic," Briggs said. "Thus, our research collaborations are focusing on non-drug approaches for managing pain."

Twillman in a previous interview suggested the following alternatives to ingesting prescription opioids for pain management: acupuncture, chiropractic, psychotherapy and physical therapy. He believes expanding access and providing reimbursement for these alternative methods will bring down prescription opioid abuse. In order for this to happen, however, prescribers will need to become better educated on alternatives to prescription opioids for pain management.

Managing pain within the military population can be little more complex, Briggs noted. For example, many returning service members have co-existing conditions such as PTSD, traumatic brain injury, drug addiction and sleep disorders.

“The logical next step for NCCIH is to assess the feasibility of undertaking one or more large-scale studies in cooperation with the VA and the DOD to answer core policy and patient care questions about the use of integrative approaches in pain management,” she said. “NCCIH has a growing intramural research program and a robust extramural portfolio in pain research and we have experience in real-world research through our work with the NIH Healthcare Systems Research Collaboratory and our work with the Patient-Centered Outcomes Research Institute (PCORI).”

Opioid Abuse Drops, Then Levels Off: About a third of patients successfully defeated the abuse-deterrence mechanism.

<http://www.medpagetoday.com/Psychiatry/Addictions/50440>

Making an abuse-deterrent formulation of OxyContin (oxycodone) diminished abuse in the short term, but the reductions eventually hit a plateau, researchers found.

In a survey of patients being treated for opioid abuse, there was a significant reduction in past-month OxyContin abuse after the abuse-deterrent formulation came on the market (45% versus 26%, $P < 0.001$), according to Theodore Cicero, PhD, and Matthew Ellis, MPE, of Washington University in St. Louis, Mo.

But the decline eventually plateaued, remaining in the range of 25% to 30% a few years thereafter, they reported online in JAMA Psychiatry.

Cicero said the findings imply that while supply-side issues are important, addressing only these "will not solve the opioid abuse problem unless efforts are made to reduce the demand for these drugs."

When it was introduced in the mid-1990s, extended-release OxyContin was marketed as harder to abuse because of its timed-release technology. But those set on abusing the drug were able to foil that mechanism and release all of the opioid at once.

More than a decade later, in 2010, OxyContin maker Purdue Pharma replaced its original drug with an abuse-deterrent formulation that made it harder to crush or dissolve the drug, with the hope that it might reduce abuse.

Early work showed that the new formulation did reduce abuse in the short term. But to track longer-term trends, Cicero and colleagues looked at data from the Survey of Key Informants' Patients (SKIP) program, which is part of the RADARS surveillance system.

It included 10,784 patients who'd been diagnosed with opioid use disorder and subsequently admitted to a drug treatment program. These patients completed an anonymous survey of opioid abuse patterns from January 2009 to June 2014, and there was an 82% response rate.

The survey showed that the reformulation was associated with a significant reduction in past-month abuse (45% in January to June 2009 versus 26% in July to December 2012, $P < 0.001$), which was tied to a migration to other opioids, particularly heroin, Cicero said.

But the reduction eventually leveled off -- from 2012 to 2014, about 27% of patients reported past-month abuse of OxyContin.

In more in-depth interviews, the researchers found that the plateau reflects three trends. First, 43% of patients reported transitioning from non-oral routes of administration to oral use.

About a third of patients successfully defeated the abuse-deterrent mechanism and were able to continue inhaling or injecting the drug.

And 23% said they continued to abuse the drug orally, they reported.

The FDA has long been trying to address questions about the role of abuse-deterrent technologies with opioids. It released a draft guidance in January 2013 and held a 2-day meeting last fall on that guidance. It's still not clear when the final rules will be released.

The study implied that even though abuse-deterrent formulations curtail abuse to an extent "their effectiveness has clear limits, resulting in a significant level of residual abuse," he wrote. Thus, he called for efforts not only on the supply side of the issue, but on the demand side.

That includes better educational efforts to prevent abuse in the first place, along with better access to treatment programs, the authors wrote.

FDA Urges Continued Caution for Pain Meds in Pregnancy

Megan Brooks

January 09, 2015

In a drug safety communication issued today, the US Food and Drug Administration (FDA) says it is aware of recent reports "questioning" the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy, but that it lacks adequate studies to change current recommendations.

The benefits and risks of using prescription and OTC pain medicines during pregnancy need to be carefully weighed, the FDA reminds healthcare providers in the [communication](#).

The FDA evaluated published studies on the following:

- Prescription nonsteroidal anti-inflammatory drugs (eg, ibuprofen, naproxen, diclofenac, and celecoxib) and the risk for miscarriage in the first half of pregnancy.
- Opioids (eg, oxycodone, hydrocodone, hydromorphone, morphine, and codeine) and the risk for birth defects of the brain, spine, or spinal cord in infants born to women who took these products during the first trimester of pregnancy.
- Acetaminophen in both OTC and prescription products and the risk for attention-deficit/hyperactivity disorder in children born to women who took this medicine at any time during pregnancy.

According to the FDA, the studies contain too little information to make any recommendations based on these studies at this time. "Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. We urge pregnant women to always discuss all medicines with their health care professionals before using them," the agency notes.

All the studies have potential limitations in their designs, and some contain conflicting results that prevent drawing reliable conclusions, the FDA says. "As a result, our recommendations on how pain medicines are used during pregnancy will remain the same at this time."

The agency advises pregnant women to "always consult with their health care professional before taking any prescription or OTC medicine. Women taking pain medicines who are considering becoming pregnant should also consult with their health care professionals to discuss the risks and benefits of pain medicine use. Health care professionals should continue to follow the recommendations in the drug labels when prescribing pain medicines to pregnant patients."

More information on today's announcement is available on the [FDA website](#).

Report blames doctors for overprescribing painkillers

http://www.healthcentral.com/dailydose/cf/2015/02/5/report_blames_doctors_for_overprescribing_painkillers

The current wave of opioid and heroin addiction and overdoses is tied to the overprescribing of painkillers by doctors, according to a report of a team of researchers.

Based on analysis of data since 2002, scientists at Johns Hopkins University, Brandeis University and the University of North Florida, found that new cases of non-medical abuse has declined, yet painkiller overdose deaths are on the rise, and that, they say, suggests that recreational use of painkillers is not a key driver of the opioid crisis.

"I think we have overestimated the benefits of prescription opioids and underestimated their risks," said study co-author Dr. Caleb Alexander at the Johns Hopkins' Bloomberg School of Public Health.

To help solve this problem, the researchers suggest that some of the same public health strategies used for controlling disease outbreaks can be effective for bringing the opioid crisis under control, such as focusing on prevention and access to treatment. Prevention strategies outlined in the report include increased public education on the risks of prescription opioids and wider use of state prescription drug monitoring program data to alert doctors to possible doctor-shopping by patients looking for painkillers.

The study also recommends increasing access to the addiction medicine buprenorphine and ensuring that first responders, syringe exchange programs, and family members of high risk opioid users have access to the opioid overdose antidote, naloxone.

Washington Post

The legal drug epidemic

http://www.washingtonpost.com/opinions/the-legal-drug-epidemic/2015/03/11/0448b6be-c826-11e4-b2a1-bed1aeea2816_story.html

By Charles Lane Opinion writer March 11 at 8:23 PM à

When is this country going to wake up — really wake up — to the catastrophe that prescription opioid painkillers have caused since they came into widespread use in the early 1990s?

Before then, deaths related to prescription opioid overdose were practically unknown. In 2013, though, opioids killed 16,235 people; that's approximately half as many as died in traffic accidents that year, and about 2,000 more than were murdered. Both traffic accidents and murder have been declining for years, however, while painkiller-related deaths quadrupled between 1999 and 2013, according to the Centers for Disease Control and Prevention.

Charles Lane is a Post editorial writer, specializing in economic policy, federal fiscal issues and business, and a contributor to the PostPartisan blog. [View Archive](#)

The total toll from prescription opioid overdoses in that time exceeds 175,000, three times the U.S. body count in the Vietnam War.

In short, the United States' massive investment in reducing avoidable deaths from other causes has been undone to a large extent by avoidable deaths stemming from the abuse of opioids, whose trade names include OxyContin, Vicodin and Percocet.

The latest evidence of these drugs' destructive impact comes from the Urban Institute, where researchers investigated the odd fact that death rates from various causes for non-Hispanic white women ages 15 to 54 — a usually healthier-than-average cohort — appear to have spiked between 1999 and 2011. Indeed, this was the only group to have experienced a marked rise in death rates during that period.

It turns out that prescription opioid overdoses explain half of the phenomenon, according to the Urban Institute study, which was released last week.

This epidemic was brought to you not by Colombian drug cartels or some other nefarious outlaw force but by the American establishment — corporate, governmental and medical — which blessed the wider use of modern opioids in the belief that pain was vastly undertreated and that new, extended-release opioid formulations would not be addictive.

To question that judgment — to suggest that pain is inherently subjective and that encouraging doctors to pass out these powerful pills not just to patients with cancer but also to those with routine lower back problems, was a huge, deadly mistake, driven in significant part by the profit motive — is to risk being accused of insensitivity to suffering people.

As Stanford University psychiatrist Anna Lembke explained in a *New England Journal of Medicine* article (candidly titled “Why Doctors Prescribe Opioids to Known Opioid Abusers”), many doctors give drug-seeking patients what they want to avoid bad reviews on patient surveys and in social media.

Policies and attitudes toward opioids have become more realistic since Lembke’s article appeared in October 2012. Yet even after a recent federal-state “crackdown” on opioid over-prescription, the Food and Drug Administration last year approved a new compound, Zohydro, despite a recommendation from an advisory committee that feared it would be too easily abused.

Most U.S. doctors concede that opioids are overprescribed, and they have become more cautious about prescribing. But most also say they personally are not to blame for the problem, according to a Johns Hopkins Bloomberg School of Public Health study published last year. Pharmacies still filled 207 million prescriptions for opioids in 2013, the most recent year for which data exist, according to the National Institutes of Drug Abuse.

That’s nearly triple the number in 1991 — and a far, far higher rate of opioid prescription than any other country. The United States accounts for almost 100 percent of world consumption of hydrocodone and 81 percent of oxycodone, NIDA reports. Does this mean doctors in Europe and Asia are indifferent to their patients’ suffering?

The slight recent reduction in opioid prescription has contributed to a rise in heroin abuse, and heroin overdose deaths, as opioid addicts seek a chemical equivalent on the street. Some argue the heroin boom discredits attempts to rein in opioid over-prescription.

This is exactly backward. The real point is how hard it is to wean thousands and thousands of people off these powerfully addictive substances, and, therefore, how terribly mistaken it was to distribute them so extensively in the first place. The sad fact is that many of those dying from heroin overdoses now might have died of prescription opioid overdoses without the “crackdown.”

The United States is in the midst of a national debate about alleged excesses in the war on illegal drugs. It’s a vigorous and necessary discussion. It’s also ironic, given that the worst havoc in recent years was wrought not by illegal substances but by perfectly legal ones. Indeed, they were produced in factories, vetted by the FDA and distributed by licensed physicians.

It appears that reducing the country’s most troubling drug-related public health problem depends on more, and more intelligent, regulation, not less.

Whatever we do, we should remember that, like so many tragedies in the past, America’s deadly prescription opioid epidemic stemmed from a combination of greed, hubris and the best of intentions.