



California State Board of Pharmacy

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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

Amy Gutierrez, PharmD, Board Member

Darlene Fujimoto, PharmD

Materials for the December 4, 2013 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: Development of Proposed Mission Statement for the Subcommittee**

Background:

At the last meeting, the subcommittee worked on ideas for a mission statement for the subcommittee.

As a reminder: this subcommittee was specifically formed to continue to explore ways to address the misuse and abuse of prescription medication, particularly of controlled substances.

The subcommittee has various issue areas:

- Educate the public and licensees about the dangers of prescription drug abuse
- Collaborate with prescribing boards to promote strengthen the sharing of information among practitioners (prescribers and dispensers)
- Promote the use of CURES by practitioners
- Continue to work with the Medical Board and other prescribing boards on topics in this area

The board has one mission:

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacists care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.

Each of the five strategic committees have general goals:

- Enforcement: Exercise oversight on all pharmacy and drug distribution activities
- Licensing: Ensure the qualifications of applicants and licensees
- Communication and Public Education: Provide relevant information to consumers and licensees
- Legislation and Regulation Committee: Advocate legislation and promulgate regulations that advance the mission and vision of the board
- Organizational Development: Achieve regulatory efficiency, customer service and consumer protection

At the last subcommittee meeting, members discussed components for a mission statement and directed staff to wordsmith it.

At this meeting:

The following is the proposed mission statement for the subcommittee:

Promote the prevention and treatment of prescription drug abuse, particularly the abuse of controlled substances. Provide education to practitioners and the public regarding prescription drug misuse, and optimize the widespread use of tools such as CURES.

The subcommittee should complete its work on the development of the mission statement.

2. Review and Discussion of Statistics Documenting the Issues of Prescription Medication Abuse in California

Attachment 1

At the initial meeting of the subcommittee, members reviewed national statistics on the prevalence of prescription drug abuse. Staff was directed to research California statistics on prescription drug abuse. Some statistics and additional background can be found in **Attachment 1**.

These statistics gathered from CURES about the number of controlled drugs dispensed to patients in California indicate that:

From the CURES System: 7/1/12 – 6/30/13

	Number of Prescriptions Filled	Total Quantity	Pills Prescribed Per Prescription	Pills Per Californian
Oxycodone & Combinations	3,164,677	286,706,709	90.6	8.2
Hydrocodone & Combinations	15,950,799	1,061,658,195	66.5	30.36
Alprazolam	3,646,130	205,983,740	56.5	5.89
Codeine Cough syrups	385,269	80,576,572	209 mL Per Rx	2.4 mL Per RX

3. Review and Discussion of the Medical Board of California's Guidelines for Prescribing Controlled Substances for Pain

Attachment 2

The Medical Board of California has *Guidelines for Prescribing Controlled Substances for Pain*. This document was developed in 1994 and revised in 2007.

According to Interim Executive Officer Kimberly Kirchmeyer, the Medical Board plans on another modification to these guidelines later in 2014, and will begin this process in late February at its next Prescription Drug Task Force Meeting.

The current guidelines are provided as **Attachment 2**. An excerpt of their current guidelines is provided below:

Preamble

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult this policy statement and the guidelines below.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines from intractable pain patients to all patients with pain.

Under past law, both Business and Professions Code section 2241 and Health and Safety Code section 11156 made it unprofessional conduct for a practitioner to prescribe to an addict. However, the standard of care has evolved over the past several years such that a practitioner may, under certain circumstances, appropriately prescribe to an addict. AB 2198, which became law on January 1, 2007, sought to align existing law with the current standard of care. Accordingly, a physician is permitted to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances. The law, Business and Professions Code section 2241, also set forth the conditions under which such prescribing may occur. Further, Business and Professions Code 2241.5 now permits a physician to prescribe for or dispense or administer to a person under his or her treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board

recognized that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

We have invited representatives from the Medical Board to attend this meeting to join in this discussion.

4. Discussion on the Implementation Schedule for the New CURES System and Impediments of the Current System

Background:

In California, the Controlled Substance Utilization Review and Evaluation System (CURES) is an electronic tracking program that tracks all pharmacy (and specified types of prescriber) dispensing of controlled drugs in Schedules II, III, and IV by drug name, quantity, prescriber, patient, and pharmacy. There is also a second component, a prescription drug monitoring program that is accessible by preapproved prescribers and dispensers to review the controlled substances dispensed to a specific patient.

Data from CURES aids this board in efforts to identify, prosecute and reduce prescription drug diversion. CURES provides invaluable information that offers the ability to identify if a person is "doctor shopping" (when a prescription drug addict visits multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs). Information tracked in the system contains the patient name, prescriber name, pharmacy name, drug name, amount and dosage, and is available to law enforcement agencies, regulatory bodies and qualified researchers. The system can also report on the top drugs prescribed for a specific time period, drugs prescribed in a particular county, doctor prescribing data, pharmacy dispensing data and is a critical tool for assessing whether multiple prescriptions for the same patient may exist.

Today and Scheduled for the Future:

In 2013, the CURES Program received additional funding to rebuild and replace its aging computer system and provide minimal but essential staffing to support the program in the future. This support was needed because CURES had been housed in the DOJ's Bureau of Narcotic Enforcement, a unit that was totally defunded several years ago in response to General Fund budget cuts made by Governor Brown in response to the state's fiscal crisis.

The new CURES funding source is now the regulatory boards in the Department of Consumer Affairs that license prescribers and dispensers. Beginning in April 2014, every practitioner eligible to prescribe (e.g., physicians, nurse practitioners, optometrists, veterinarians, dentists) or dispense (pharmacists, pharmacies), wholesalers and clinics will pay an ongoing fee of \$6 per year fee as part of their renewal. Additionally before January 1, 2016, every pharmacist (and each of the prescriber

classifications) will be required to submit an application to obtain approval to access CURES data. This process is intended to ensure widespread eligibility for prescribers and pharmacists to access CURES data on an individual patient -- when the practitioners so choose -- at the time of prescribing or dispensing.

Additionally, due to a trailer bill to the 2013/14 California State Budget, the board is funding for two years (2013/14 and 2014/15) an additional \$215,000 (in addition to ongoing annual funding of \$92,000 that we have been providing for approximately 10 years) that will be used to replace the aging CURES computer and replace it with a more robust system, capable of providing better access to the state's prescribers and dispensers who are checking the controlled substances dispensed to specific patients as part of the prescription drug monitoring program (PDMP). The dispenser boards are also contributing sizeable amounts to secure a new computer system.

Specifically, SB 809 provides the following goals for this computer system:

- (1) Upgrading the CURES PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.
- (2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.
- (3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.
- (4) Upgrading the CURES PDMP so that it is capable of accepting the reporting of electronic prescription data, thereby enabling more reliable, complete, and timely prescription monitoring.

Currently the DCA health care boards are working with the DOJ to develop the parameters for the new system. At this time there is nothing more that is available to be reported with respect to the implementation.

There is one additional item in SB 809: Section 2196.8 of the Business and Professions Code was amended to direct the Medical Board to “. . . periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Public Health, the boards and committees . . .”

5. Presentation by the National Association of Boards of Pharmacy (NABP) regarding the Parameters of the National Prescription Drug Monitoring Program Currently in Use

Attachment 3

At this meeting, the subcommittee will hear a presentation by Scotti Russell from the National Association of Boards of Pharmacy regarding its prescription monitoring program for controlled across state lines called InterConnect. This program provides another piece of the monitoring program for state regulators, prescribers and dispensers about what controlled substances patients may be receiving across state states.

Information from the NABP's website is provided in **Attachment 3**. Below is an excerpt of this information:

The NABP PMP's InterConnect facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users. It allows participating state PMPs across the United States to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.

PMPs are Connecting

The NABP InterConnect is now fully operational and allows users of PMPs in Arizona, Arkansas, Colorado, Connecticut, Delaware, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Virginia, and Wisconsin to securely exchange prescription data between the 21 participating states.

NABP continues to work with other state PMPs to facilitate their participation in the NABP InterConnect. It is anticipated that approximately 30 states will be sharing data or in an MOU to share data using NABP InterConnect in 2013.

6. Discussion and Identification of Effective Ways to Educate Pharmacists About Prescription Drug Abuse and Corresponding Responsibility

Corresponding Responsibility:

At the July Board Meeting, the board voted to make its decision in Pacifica Pharmacy a precedential decision regarding a pharmacist's corresponding responsibility. This decision is now posted on the board's website as a precedential decision, has been the subject of a subscriber alert, and was discussed recently at the October Board Meeting.

The board will highlight this decision in its next newsletter, *The Script*. A PowerPoint presentation has been specifically developed on corresponding responsibility to educate pharmacists about this concept. This program runs 1.5 -2 hours, for which continuing education credit is available.

Staff will also add this decision as a topic in prescription drug abuse presentations made to the public, and specifically call it to the attention of prosecuting DAGs when seeking discipline for a licensee's failure to adhere to corresponding responsibility.

Continuing Education Credit Awarded for Courses in this Subject Area:

Another approach to educate pharmacists about prescription drug abuse is to foster the development of continuing education courses in this area. The board currently provides training, jointly with the DEA, in this area periodically (this is in addition to the corresponding responsibility materials discussed above). The next scheduled joint presentation with the DEA is set for January 22 in Orange County. Staff is also working on a similar program in Sacramento for January 28. These joint presentations provide 6 units of CE to pharmacists.

The board also is proposing changes in its continuing education requirements in regulation to mandate CE in specific topics. The text of this approved modification is provided below:

**Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations
§ 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) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:
1. Emergency/Disaster Response
 2. Patient Consultation
 3. Maintaining Control of a Pharmacy's Drug Inventory
 4. Ethics
 5. Substance Abuse
- Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the requirements of this subdivision.
- ~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

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

Health Notes on Pain Management

In the mid 1990s and ending in the early 2000s, this board published a series of eight monographs for pharmacists whereby the board could ensure the consistency of education being available on specific topics, and for which a pharmacist could earn continuing education credit by completing and passing an exam on the materials' content. The board generally subcontracted with pharmacist experts in the field, and relied on academic editors to develop the articles. Each issue was attractive, but development of each issue was expensive and time consuming.

The first issue was on treating pain, including appropriate pain management, and other topics. This was developed following the then Administration's work in addressing under-treatment of pain. The policies advanced in this issue are now longer current with the board's thinking, and this issue has been removed from the board's website.

7. Presentations by the San Diego Task Force to Educate Parents, Teens Educators, Law Enforcement, Medical and Pharmacy Professionals About Prescription Drug Abuse

Attachment 4

At the last meeting of this subcommittee, Subcommittee Member Dr. Fujimoto commented

there are multiple educational groups who are looking for venues to put on workshops about prescription drug abuse, and suggested that the board consider reviewing and perhaps partnering with some of them.

Dr. Fujimoto also stated that she serves on a multidisciplinary task force whose goal is to educate parents, teens, educators and others about prescription drug abuse. This task force has been operating in San Diego for a while. Chairperson Castellblanch asked that this group be asked to provide information at a future subcommittee meeting.

At this meeting, we have at least the following individuals appearing from the San Diego task force to provide presentations and demonstrations of their work in this area:

- Tom Lenox Supervisory Special Agent, Tactical Diversion Squad, DEA San Diego Field Division
- Nathan Painter, PharmD, CDE, Health Sciences Associate Clinical Professor, UCSD , Skaggs School of Pharmacy and Pharmaceutical Science

A brochure developed to promote a recent project of this task force is provided as **Attachment 4**.

8. Presentation by the County of Orange Health Care Agency on Its Public Education Program about Prescription Drug Abuse

Attachment 5

At the October Board Meeting, a brief presentation was made by a representative of the County of Orange Health Care Agency on their public education campaign for prescription drug abuse. This group was invited to provide more information at a future subcommittee meeting. At this meeting, the agency will provide a fuller description of their program.

Attachment 5 contains the materials distributed at the October Board Meeting.

9. Discussion on the DEA's Proposed Rule to Add Tramadol to Schedule IV of the Federal Controlled Substances Schedules

Attachment 6

Prescription drugs that have a high potential for abuse and misuse are scheduled into the controlled substances schedules so they can be more closely tracked and monitored. Controlled drugs have restrictions on how they can be prescribed, dispensed and refilled. Prescribing and dispensing such drugs requires federal DEA registration. For the California Board of Pharmacy, there are actually two controlled substances schedules, one at the federal level and the other is in state law. While the two schedules are generally consistent, the federal schedule is a bit broader and is amended more frequently than the California schedule. To amend the California schedules, which are in the California Health and Safety Code, legislation is needed. The federal schedules can be amended by rulemaking action of the DEA.

Regulators, law enforcement and health care providers periodically observe that certain nonscheduled drugs are susceptible to the abuse typically associated with scheduled drugs. In such cases sometimes there is action to schedule such drugs into one of the controlled substances schedules.

For a number of years, Tramadol, which is a medication prescribed for pain, has been linked to drug abuse and misuse. As one example, in 2010, the federal Ryan Haight Act substantially eliminated the number of Internet drug operators offering controlled substance pain medications online because of the law's sanctions. Instead these operators shifted to selling Tramadol. The board observed this in its investigations of pharmacies filling prescriptions illegally generated via the Internet.

At least 10 states have already scheduled Tramadol as a controlled substance, and at least four citizen petitions to reschedule Tramadol have been pending at DEA since approximately 2005.

In early November, after discussions for a number of years, the DEA initiated action to reclassify Tramadol into Schedule IV of the federal schedule of controlled drugs. The Federal Notice to solicit these comments is provided in **Attachment 6**. Comments are due January 3, 2014.

Below is an excerpt from a related law blog regarding this proposed reclassification:

November 04, 2013

DEA Publishes Long-Anticipated Proposed Rulemaking Proposing to Place Tramadol in Schedule IV

By [Karla L. Palmer](#) –

On Monday, November 4, 2013, the Drug Enforcement Administration (“DEA”) published a [notice of proposed rulemaking](#) (“NPR”), proposing to place the substance 2 –((diethylamino)methyl)-1-(3-methoxyphenyl) cyclohexanol), and its salts, isomers, salts of isomers, and all isometric configurations of possible forms, **including Tramadol**, in Schedule IV of the Controlled Substances Act (“CSA”). Although not entirely unexpected given DEA’s published concerns about the abuse potential, it comes at time almost eighteen years after the drug was first marketed in the United States.

Trade names of the substance include Ultram® and Ultracet®. Schedule IV controlled substances are those substances that have a low potential for abuse relative to drugs in Schedule III, have a currently accepted medical use in the United States, and the abuse of the drug could lead to limited physical dependence relative to the drugs in Schedule III. Tramadol was approved for marketing in 1995 as a non-controlled analgesic. The drug was not scheduled based on information related to its low potential for abuse and very weak narcotic effect. DEA now reports that data demonstrates, because of inadequate product labeling (which has undergone several revisions) and lack of established abuse potential, it has become known to narcotics abusers. As a result, DEA received numerous reports of its abuse and dependence (see [here](#)). At least 10 states have already scheduled Tramadol as a controlled substance, and at least four citizen petitions to reschedule Tramadol have been pending at DEA since approximately 2005.

The CSA provides that scheduling of any drug may be initiated by the Attorney General: (1) by his own motion; (2) at the request of the Secretary of HHS; or (3) on the petition of an interested party. The NPR states that this particular rulemaking is

based on the recommendation from HHS and an evaluation of all other relevant data provided by DEA. The scheduling of Tramadol has been under review for over seven years. In 2007, DEA submitted to HHS its request for a scientific and medical evaluation (which findings are binding on DEA), and for HHS's recommendation on scheduling of Tramadol. In 2010, the HHS provided to DEA its scientific and medical evaluation, recommending, after completing the eight-factor analysis required in 21 U.S.C. s 811(b), placement of Tramadol in Schedule IV. DEA completed its own eight-factor review pursuant to 21 U.S.C. s 811(c) in 2011. Those analyses are attached [here](#) and [here](#), and are briefly summarized below:

(1) Drug's Actual and Relative Potential for Abuse: HHS and DEA found that since initial marketing of Tramadol in 1995, the drug has been, and currently is, abused for its opioid effects. DEA also found that individuals are taking Tramadol in sufficient amounts to create a public health threat, and there is "significant" diversion of Tramadol from legitimate channels. Individuals are also taking Tramadol on their own initiative, and not on the advice of medical practitioners. Tramadol also shares several pharmacological effects similar to other scheduled opioids.

(2) Scientific Evidence of the Drug's Pharmacological Effects, if Known: DEA and FDA recognized Tramadol as an opioid analgesic that produced effects, including adverse, analgesic, and other effects, similar to opioids in Schedules III and IV.

(3) The State of Current Scientific Knowledge Regarding the Drug or Other Substance: The NPR sets forth a chemical description of the substance that DEA seeks to schedule.

(4) Its History and Current Pattern of Abuse: Data reviewed by both FDA and DEA reveals that Tramadol has been abused since 1995 "by a wide spectrum of individuals of different ages, alone and in combination with other psychoactive substances." From 2009-2011, more prescriptions were written for Tramadol than for any other opioid other than hydrocodone and oxycodone. Collected data from several national databases demonstrate the misuse, abuse, and diversion of Tramadol in the United States. Data concerning Tramadol most closely resembles that of propoxyphene (Darvon®), another Schedule IV narcotic.

(5) Scope, Duration and Significance of Abuse: Similar to factor four, HHS considered 15 years of various sources of data detailing the medical and non-medical use and abuse of Tramadol. Data shows that Tramadol has less abuse potential than several narcotics currently controlled in Schedule II. As evaluated by both HHS and DEA, data shows, however, that Tramadol most closely compares to propoxyphene (Schedule IV) and codeine (Schedules II, III, and V). Thus, Tramadol's similarity to other controlled opioids and clear evidence of significant non-medical use and abuse, accompanied by serious adverse events, indicates that Tramadol has sufficient abuse potential and incidence of drug dependence and addiction to warrant control as a Schedule IV controlled substance.

(6) What, if any, Risk There is to the Public Health: DEA's analysis reveals that there are "numerous risks" to the public health that may result from Tramadol abuse, which adverse effects on the public health are consistent with other opioids. The incidence

of adverse events is similar to that of codeine-containing products, and emergency room visits due to non-medical use of Tramadol is similar to that of propoxyphene (Schedule IV), yet lower than that of Schedule II and III opioids. Reported exposure and death cases quadrupled from 2004 to 2011, ranking third behind oxycodone and hydrocodone combination products. The collected data from a number of sources indicates that Tramadol “presents risks to the public health,” which supports scheduling, but the data also suggest a lower schedule than Schedule III.

(7) Its *Psychic or Physiological Dependence Liability*: HHS reviewed information from clinical and pre-clinical studies, and found that repeated dosing of Tramadol resulted in dependence development, and withdrawal symptoms occurred upon discontinuation of treatment. HHS states that Tramadol may produce a “modest level of physical dependence;” studies suggested a degree of dependence development consistent with other opioids in Schedule IV.

(8) *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA*: Both HHS and DEA conclude that it is not an immediate precursor of other controlled substances.

Requirements for Handling Tramadol as a Schedule IV Controlled Substance

The NPR sets forth the requirements under the CSA and its implementing regulations for handling of a Schedule IV controlled substance. If Tramadol is placed in schedule IV, those entities that handle Tramadol will be, by the effective date of the final rule, subject to registration, security, labeling and packaging, inventory, recordkeeping, reporting (including ARCOS reporting), prescription, and import and export requirements required for substances placed in Schedule IV. Any activity involving Tramadol occurring after the effective date of the final rule that is in violation of the CSA or its regulations could result in civil, criminal or administrative sanctions.

10. Public Outreach to Address Prescription Drug Abuse

During the April Board Meeting there was discussion on the success of the February 2013 Joint Forum on Appropriate Prescribing and Dispensing with the Medical Board. The need for greater public activity with respect to prescription drug abuse led the board to form this subcommittee.

The Medical Board of California has expressed interest in cohosting another forum with this board on appropriate prescribing and dispensing practices. Such an event is tentatively focused at the late spring or summer 2014. Planning has not yet begun on this subsequent event by the staff of the two boards.

Meanwhile, the US Department of Justice is interested in duplicating and hosting its own version of the Pharmacy Board/Medical Board Forum perhaps in March 2014 in the Bay Area. We have no other information about this conference.

Some of the items suggested following the February forum include creation of a brochure for pharmacists on corresponding responsibility, sharing information on improving opioid use in

hospitals, and possible curriculum development for use in schools to advise students and parents of the dangers of prescription drug abuse and the attraction such drugs hold for youth.

The DEA has developed such a curriculum and we hope to secure a presentation on this at the January 2014 Board Meeting.

Over the last two years, the board has hosted several highly popular one-day seminars for pharmacists and other interested parties on drug diversion, prescription drug abuse and corresponding responsibility for pharmacists. The board's partner in this has been the Los Angeles Office of the Drug Enforcement Administration. Six hours of CE is awarded for this training, which is well attended and receives high evaluation scores. Two such sessions were provided in June and July 2013. As stated earlier we plan to host another such training in Orange County on January 22, 2014.

Also in mid August 2013, this board joined with the Washington, DC headquarters office of the DEA to co-host with them four, one-day seminars for pharmacists in California on controlled substances issues, prescription drug abuse, corresponding responsibility and other matters related to curtail drug diversion. Two were held in San Diego, and two held in San Jose. At least 300 pharmacists have attended each of these presentations. We hope to convene such training on January 29, 2014.

11. Discussion on Senate Bill 493 (Hernandez, Statutes of 2013) and Potential Changes of Pharmacists' Roles in Preventing Prescription Drug Abuse

Governor Brown signed legislation in October to authorize the creation of a specialty class of pharmacists, who once licensed may offer expanded patient care services. The board is initiating creation of the specific requirements for qualification as an advanced practice pharmacist.

Qualifications: possess 2 of the 3 below:

1. Earn certification in relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)
2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management, or health system

Chairperson Castellblanch will lead a discussion on the role of pharmacists in preventing prescription drug abuse in light of the new duties authorized by SB 493 during this segment of the meeting.

Attachment 1

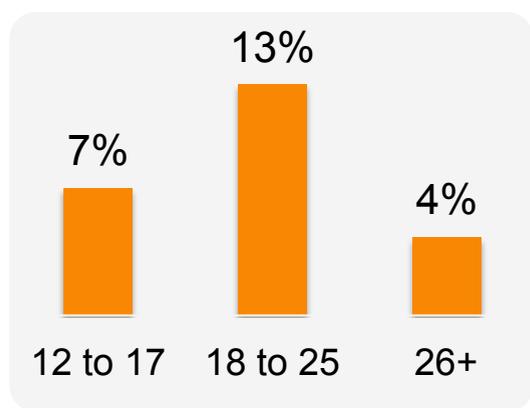
Abuse of Prescription (Rx) Drugs

Affects Young Adults Most

Young adults (age 18 to 25) are the biggest abusers of prescription (Rx) opioid pain relievers, ADHD stimulants, and anti-anxiety drugs. They do it for all kinds of reasons, including to get high, or because they think Rx stimulants will help them study better. But Rx abuse is dangerous: In 2010, almost 3,000 young adults died from prescription drug (mainly opioid) overdoses—more than died from overdoses of any other drug, including heroin and cocaine combined—and many more needed emergency treatment.



PAST YEAR USE



The nonmedical use of prescription drugs is highest among young adults.¹

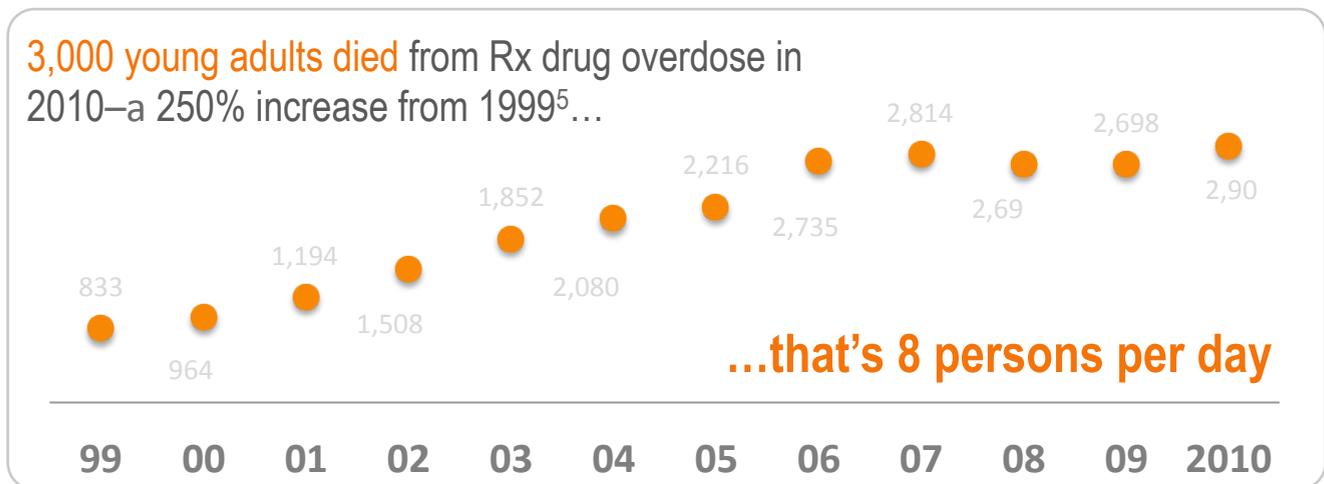
MOTIVATIONS FOR USE

Most young adults say they use Rx drugs to^{2,3,4}

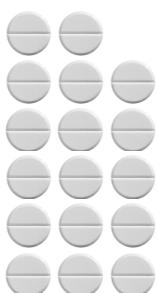


CONSEQUENCES

3,000 young adults died from Rx drug overdose in 2010—a 250% increase from 1999⁵...

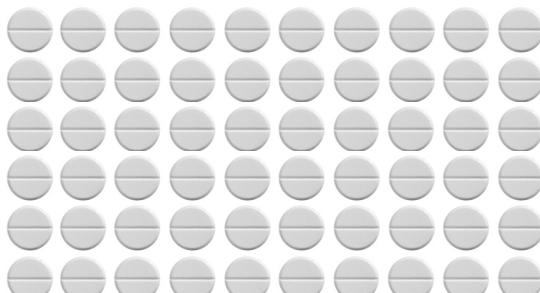


Among young adults, for every death due to Rx drug overdose, there were



17

Treatment Admissions⁶



66

Emergency Room Visits

¹ SAMHSA, NSDUH; ² Rabiner et al 2009; ³ McCabe et al 2007; ⁴ Lord et al 2011; ⁵ CDC Wonder; ⁶ SAMHSA, TEDS; ⁷ SAMHSA, DAWN

[← Back to Original Article](#)

Fatal drug overdoses in U.S. increase for 11th consecutive year

February 19, 2013 | By Joseph Serna

Fatal drug overdoses have increased for the 11th consecutive year in the United States, new data show.

According to a research letter published Tuesday from the National Center for Health Statistics, 38,329 people died of drug overdoses in the United States in 2010, an uptick from the previous year and the latest sign of a deadly trend involving prescription painkillers.

In 2010, 57% of overdoses, or more than 22,000, involved known prescription drugs. Three-quarters of those involved painkillers like Oxycontin and Percocet while another 9,400 involved some unidentified drug cocktail.

More than 74% of all prescription drug deaths were accidental, statistics show. Only 17% of overdoses were suicides. The numbers show how drugs in the opioid family, like Oxycontin, methadone and codeine, were often implicated in fatal drug cocktails.

An opioid was found in 77% of overdoses that involved benzodiazepine, a central nervous system depressant like Valium, Xanax or Ativan. The addictive narcotic was also involved in 65% of overdoses with antiepileptic or anti-Parkinsonian drugs; 57% of overdoses with antidepressants; and 56% of overdoses with anti-inflammatory and fever-reducing drugs.

The paper buttresses a Times investigation last year that showed a surge in painkiller prescriptions in California and across the nation has had fatal consequences.

Fatal prescription drug overdoses over the last decade have outnumbered deaths from heroin and cocaine combined, The Times reported. In nearly half of all accidental prescription drug deaths in Southern California, the deceased had a prescription for at least one of the drugs involved in the overdose.

The study was published in the American Medical Assn. journal and was written by scientists from the Centers for Disease Control and Prevention, which funded the study.

[Return to Booster Shots blog.](#)

ALCOHOL AND DRUG PROGRAMS ADP EN ESPAÑOL

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Prescription Drugs

In the 147 narcotic treatment programs licensed by ADP, the number of people admitted for addiction to pain relievers increased by more than 80 percent from 2006 to 2009. The misuse and abuse of prescription drugs is the fastest growing drug problem in California. You can help prevent prescription drugs from being diverted to misuse by others by disposing of them properly.

Last September, for the first Prescription Drug Take-Back Day, more than 242,000 pounds —121 tons — of prescription drugs were collected at nearly 4,100 sites across the country.

If someone in your house is prescribed a prescription painkiller, keep it locked up and dispose of any extra pills when you no longer need them. The effort could prevent a tragedy in your own family. For more information on prescription drug abuse prevention and how you can help prevent prescription drug diversion and abuse in your community, visit the website for the [Office of National Drug Control Policy](#).

WHAT ARE THEY?

Prescription drugs are medicines that are prescribed to a patient by a doctor to manage pain, treat or cure a health condition such as pain, mental disease, diabetes, cancer, or common infections. These drugs are regulated by the Food and Drug Administration (FDA) and are shown to have medical benefits when prescribed and taken exactly as directed by a health provider. For people who are suffering, these drugs allow them to control their symptoms, cure or treat their diseases, control pain, or fight an infection. **However, these medicines are only safe when taken exactly as directed by a doctor, healthcare provider, or as indicated on the packaging. This includes following directions on dosages, how often to take these drugs, and never taking any drug that is not prescribed for you.**

Taking prescription drugs that are not prescribed to you - or taking them in any way other than directed by a doctor — is considered non-medical use or abuse and can be as dangerous as taking an illegal drug, such as cocaine or heroin. "Misuse" of a prescription drug is taking it to treat a medical condition but not as directed by a doctor or packaging; "abuse" is taking prescription drugs with the sole intention of getting high. **When misused or abused, many prescription drugs can be as dangerous and as addictive as "street" drugs.** In recent years, there has been a dramatic increase in the number of poisonings and even deaths associated with the abuse and misuse of prescription drugs, including prescription painkillers and anti-depressants.⁶¹

In other words, **even if a medication is prescribed to you, taking larger doses than prescribed, taking it more often than directed, or using it in a way that it is not intended, is abuse** and can also lead to severe health consequences and addiction. Between 1995 and 2005, treatment admissions for dependence on prescription pain relievers such as oxycodone (OxyContin) and hydrocodone/acetaminophen (Vicodin) grew more than 300 percent.⁶²

Taking prescription drugs without a prescription, not taking them as directed, or mixing them with alcohol are all unsafe and potentially deadly. A 2008 study based on 224,355 U.S. death certificates for which people died from medication errors showed that there was a 3,196 percent increase between 1983 and 2004 in deaths at home from combining prescription drugs with alcohol and/or street drugs.⁶³

It's Illegal

Additionally, getting prescription drugs without a prescription, called "diversion" is illegal and may put you at risk for arrest and prosecution. Regardless of how you acquire a prescription medication, using these types of drugs without a valid prescription — written for you — is unsafe and illegal.

WHAT'S THE PROBLEM?

Teens are abusing some prescription and over-the-counter (OTC) drugs to get high. This includes **painkillers**, such as those drugs prescribed after surgery; **depressants**, such as sleeping pills or anti-anxiety drugs; and **stimulants**, such as those drugs prescribed for attention deficit hyperactivity disorder (ADHD). Teens are also abusing OTC drugs, such as cough and cold remedies.

Every day 2,500 youth age 12 to 17 abuse a pain reliever for the very first time. More teens abuse prescription drugs than any illicit drug except marijuana. In 2006, more than 2.1 million teens ages 12 to 17 reported abusing prescription drugs.¹ Among 12- and 13-year-olds, prescription drugs are the drug of choice.²

Because these drugs are so readily available, and many teens believe they are a safe way to get high, teens who wouldn't otherwise touch illicit drugs might abuse prescription drugs.

WHAT ARE THE DANGERS?

There are serious health risks related to abuse of prescription drugs. A single large dose of prescription or OTC painkillers or depressants can cause breathing difficulty that can lead to death. Stimulant abuse can lead to hostility or paranoia, or the potential for heart system failure or fatal seizures. Even in small doses, depressants and painkillers have subtle effects on motor skills, judgment, and ability to learn.

The abuse of OTC cough and cold remedies can cause blurred vision, nausea, vomiting, dizziness, coma, and even death. Many teens report mixing prescription drugs, OTC drugs, and alcohol. Using these drugs in combination can cause respiratory failure and death.

Prescription and OTC drug abuse is addictive. Between 1995 and 2005, treatment admissions for prescription painkillers increased more than 300 percent.⁴

1. Substance Abuse and Mental Health Services Administration [SAMHSA]. (2007). National Survey on Drug Use and Health, 2006, Table 1.5A. 2. Substance Abuse and Mental Health Services Administration [SAMHSA]. (2007). National Survey on Drug Use and Health, 2006. Office of Applied Studies 4. Treatment Episode Data Set [TEDS]. (2006). Substance abuse treatment admissions by primary substance of abuse according to sex, age group, race and ethnicity, 2004. Substance Abuse and Mental Health Services Administration.

OTHER RELATED DRUGS

[Painkillers](#) | [Depressants](#) | [Stimulants](#) | [Ritalin](#)



January 8, 2013

State Estimates of Nonmedical Use of Prescription Pain Relievers

In Brief

- Combined 2010 and 2011 data indicate that the rate of past year nonmedical use of prescription pain relievers among those aged 12 or older was 4.6 percent nationally and ranged from 3.6 percent in Iowa to 6.4 percent in Oregon
- Of the 10 States with the highest rates of past year nonmedical use of prescription pain relievers in 2010 and 2011, 7 were in the West region; of the 10 States with the lowest rates, 4 were in the Midwest region, and 4 were in the Southern region
- Comparisons of combined 2009 and 2010 data with combined 2010 and 2011 data showed that past year nonmedical use of prescription pain relievers among persons aged 12 or older decreased in 10 States (Kentucky, Louisiana, Massachusetts, Mississippi, New Hampshire, New York, Ohio, Oklahoma, Rhode Island, and West Virginia), and did not increase in any State

Misuse of prescription drugs is second only to marijuana as the Nation's most prevalent illicit drug problem¹ and is a public health concern, with approximately 22 million persons initiating nonmedical pain reliever use since 2002.² Data on geographic variation in the nonmedical use of pain relievers (as well as other drugs) are important for developing targeted prevention and treatment programs. This issue of *The NSDUH Report* highlights State estimates of the nonmedical use (i.e., misuse) of prescription pain relievers.

The National Survey on Drug Use and Health (NSDUH) asks persons aged 12 or older questions related to their nonmedical use of prescription pain relievers during the past year. Nonmedical use of prescription pain relievers is defined as use of these drugs without a prescription or use that occurred simply for the experience or feeling the drug caused; over-the-counter (OTC) use and legitimate use of prescription pain relievers are not included.³ Estimates of past year nonmedical use of pain relievers among persons aged 12 or older in each of the 50 States and the District of Columbia are included in this issue of *The NSDUH Report*. Model-based State estimates using the combined 2010 and 2011 NSDUHs are presented.⁴ This small area estimation methodology provides more precise estimates at the State level than standard direct estimation methods.

The results for pain relievers were extracted from a set of tables covering a variety of measures of substance use and mental disorders.⁵ Estimates are displayed in two tables. The first table shows estimates for persons aged 12 or older and lists States in rank order from highest to lowest and divided into quintiles (fifths).⁶ In the second table, estimates for three age groups are included along with estimates for persons aged 12 or older; States are listed alphabetically for easy reference.

State Estimates of Nonmedical Use of Prescription Pain Relievers

Combined 2010 and 2011 (hereafter "2010-2011") data indicate that about 1 in 22 (4.6 percent) persons aged 12 or older nationwide reported having used pain relievers nonmedically in the past year, which was lower than the rate using combined 2009 and 2010 (hereafter "2009-2010") data (4.9 percent). The 2010-2011 rates of nonmedical pain reliever use ranged from 3.6 percent in Iowa to 6.4 percent in Oregon (Table 1). Arkansas, Colorado, Oregon, and Washington were ranked in the top fifth of States for this measure in age groups 12 to 17, 18 to 25, and 26 or older, as well as for the total population aged 12 or older. Georgia was ranked in the lowest fifth in each of these age groups (Table 2).

Table 1. Nonmedical Use of Prescription Pain Relievers in the Past Year among Persons Aged 12 or Older, by Quintile and State: 2010-2011

Quintile and State	Percent	95% Confidence Interval
States with Rates between 5.33 and 6.37		
Oregon	6.37%	5.25-7.71
Colorado	6.00%	4.96-7.24
Washington	5.75%	4.76-6.92
Idaho	5.73%	4.74-6.91

Indiana	5.68%	4.68-6.89
Arizona	5.66%	4.60-6.94
Nevada	5.62%	4.57-6.89
Delaware	5.61%	4.61-6.82
Arkansas	5.55%	4.60-6.68
New Mexico	5.45%	4.47-6.64
States with Rates between 4.80 and 5.32		
Alaska	5.32%	4.41-6.42
Oklahoma	5.19%	4.26-6.30
Rhode Island	5.18%	4.26-6.27
Vermont	5.13%	4.24-6.19
Michigan	5.11%	4.57-5.72
Ohio	5.00%	4.49-5.56
Tennessee	5.00%	4.14-6.02
Louisiana	4.87%	4.09-5.80
Montana	4.84%	4.02-5.80
Missouri	4.83%	4.03-5.78
States with Rates between 4.46 and 4.79		
West Virginia	4.79%	3.97-5.75
California	4.68%	4.13-5.30
District of Columbia	4.68%	3.79-5.76
Wyoming	4.68%	3.85-5.68
South Carolina	4.62%	3.81-5.59
Virginia	4.60%	3.79-5.58
Minnesota	4.57%	3.79-5.49
New Hampshire	4.57%	3.77-5.53
Kansas	4.56%	3.77-5.50
Wisconsin	4.51%	3.68-5.52
Kentucky	4.48%	3.70-5.41
States with Rates between 4.08 and 4.45		
Mississippi	4.45%	3.67-5.39
Alabama	4.43%	3.64-5.39
Connecticut	4.38%	3.52-5.45
Texas	4.33%	3.84-4.89
Utah	4.33%	3.55-5.27
Massachusetts	4.27%	3.51-5.19
Pennsylvania	4.20%	3.72-4.74
Nebraska	4.18%	3.42-5.10
Maine	4.15%	3.37-5.11
New Jersey	4.14%	3.39-5.06
States with Rates between 3.62 and 4.07		
Illinois	4.07%	3.58-4.62
Florida	4.05%	3.57-4.59
North Carolina	4.00%	3.23-4.93
New York	3.98%	3.48-4.56
Hawaii	3.90%	3.09-4.90
Maryland	3.89%	3.14-4.81
North Dakota	3.84%	3.11-4.73
Georgia	3.79%	3.10-4.64
South Dakota	3.69%	2.92-4.65
Iowa	3.62%	2.92-4.49

NOTE: Estimates are shown in rank order so that the distribution and range of estimates can be more easily seen both within and across quintiles. Caution is advised against making statements such as "Oregon's rate is higher than Colorado's rate" or other similar statements as the difference between the rates may not be statistically significant. No significance tests were conducted between any two States.
Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2010 (Revised March 2012) and 2011.

Table 2. Nonmedical Use of Prescription Pain Relievers in the Past Year among Persons Aged 12 or Older, by Age Group and State: 2009-2010 and 2010-2011

	12 or Older	12 to 17	18 to 25	26 or Older
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State	2009-2010	2010-2011	2009-2010	2010-2011	2009-2010	2010-2011	2009-2010	2010-2011
Total United States	4.89^a	4.57	6.43^a	6.09	11.54^a	10.43	3.53	3.37
Alabama	4.62	4.43	7.29	6.56	11.08	10.09	3.18	3.18
Alaska	5.41	5.32	6.71	6.89	11.36	10.69	4.05	4.06
Arizona	6.31 ^b	5.66	7.58	8.04	12.68	11.49	5.07	4.36
Arkansas	5.51	5.55	7.48	7.81	12.39	12.89	4.13	4.02
California	4.95	4.68	6.61	6.06	9.68	9.35	3.82	3.62
Colorado	6.23	6.00	7.23	7.40	13.51	14.01	4.86	4.44
Connecticut	4.12	4.38	5.00	4.70	11.08	10.73	2.88	3.32
Delaware	5.56	5.61	6.19	5.95	13.70	14.26	4.14	4.13
District of Columbia	4.29	4.68	4.67	4.23	8.23	8.35	3.39	3.88
Florida	4.37	4.05	6.00	5.50	9.76 ^a	8.59	3.38	3.21
Georgia	4.27 ^b	3.79	6.04	5.37	10.47 ^b	8.76	2.95	2.70
Hawaii	4.22	3.90	5.35	5.69	9.25	8.19	3.30	3.04
Idaho	6.09	5.73	7.52	7.15	13.20	11.98	4.59	4.37
Illinois	3.94	4.07	5.47	5.16	10.04	10.19	2.64	2.86
Indiana	5.73	5.68	7.57	6.97	14.75	14.41	3.93	3.97
Iowa	3.69	3.62	6.41	5.81	9.10	9.12	2.39	2.37
Kansas	4.71	4.56	6.81	6.23	11.15	10.25	3.20	3.26
Kentucky	5.36 ^a	4.48	7.54	6.67	13.67 ^a	10.82	3.78 ^b	3.17
Louisiana	5.67 ^a	4.87	6.39	6.46	13.93 ^a	11.60	4.00	3.40
Maine	4.51	4.15	6.01	5.72	13.81 ^a	11.29	3.03	2.96
Maryland	4.23	3.89	5.80 ^a	4.63	10.17	9.13	3.03	2.93
Massachusetts	5.07 ^a	4.27	5.61	4.94	13.12 ^a	10.65	3.58	3.07
Michigan	5.53 ^b	5.11	6.40	6.35	13.41 ^a	11.74	4.06	3.81
Minnesota	4.09	4.57	5.73	6.20	10.79	11.34	2.74	3.23
Mississippi	5.10 ^a	4.45	8.52 ^a	6.86	11.06	9.59	3.51	3.16
Missouri	5.13	4.83	6.77	6.77	13.22	11.74	3.57	3.41
Montana	5.07	4.84	7.09	7.62	12.31 ^b	10.68	3.58	3.51
Nebraska	3.91	4.18	5.61	5.11	9.38	9.24	2.64	3.12
Nevada	5.96	5.62	7.74	7.79	13.22	11.94	4.62	4.34
New Hampshire	5.38 ^a	4.57	6.20	6.11	14.90 ^a	12.31	3.78	3.16
New Jersey	4.15	4.14	4.95	5.14	11.97	11.00	2.85	2.98
New Mexico	5.78	5.45	8.29	8.60	11.17	11.22	4.47	4.02
New York	4.45 ^a	3.98	5.26	4.70	11.55 ^a	8.90	3.09	3.04
North Carolina	4.54 ^b	4.00	6.89	6.28	10.58 ^b	8.96	3.25	2.89
North Dakota	4.11	3.84	6.66 ^b	5.54	9.05	7.84	2.66	2.74
Ohio	5.48 ^a	5.00	7.62	7.12	13.59 ^a	11.84	3.89	3.61
Oklahoma	7.01 ^a	5.19	7.94	7.04	15.65 ^a	11.11	5.30 ^a	3.86
Oregon	6.68	6.37	7.86	7.36	14.71	15.00	5.26	4.86
Pennsylvania	4.40	4.20	5.75	6.00	11.55	10.80	3.07	2.90
Rhode Island	5.93 ^a	5.18	6.29	5.33	14.64 ^a	12.30	4.24	3.80
South Carolina	5.06	4.62	6.06	5.94	12.30 ^b	10.67	3.74	3.44
South Dakota	3.64	3.69	6.08	5.55	8.48	7.78	2.45	2.72
Tennessee	4.44 ^b	5.00	6.19	6.94	11.90	13.07	3.05	3.46
Texas	4.62	4.33	6.10	6.03	10.60 ^a	9.21	3.26	3.16
Utah	4.92 ^b	4.33	6.57	5.62	10.31 ^a	8.23	3.31	3.18
Vermont	4.85	5.13	6.00	6.47	13.34	13.00	3.26	3.59
Virginia	5.13 ^b	4.60	6.97	5.95	12.48	11.39	3.62	3.25
Washington	6.20	5.75	7.48	7.44	14.44	13.40	4.70	4.28
West Virginia	5.61 ^a	4.79	7.25	7.21	14.39 ^a	12.35	4.11 ^b	3.38
Wisconsin	4.56	4.51	7.12	6.09	11.64	10.55	3.01	3.27
Wyoming	4.56	4.68	7.05	6.60	10.61	9.89	3.15	3.51

^a Difference between the 2009-2010 estimate and the 2010-2011 estimate is statistically significant at the .05 level.
^b Difference between the 2009-2010 estimate and the 2010-2011 estimate is statistically significant at the .10 level.
 Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2009, 2010 (Revised March 2012), and 2011.

Of the 10 States with the highest rates of past year nonmedical pain reliever use within the total population aged 12 or older, 7 were in the West region (Arizona, Colorado, Idaho, Nevada, New Mexico, Oregon, and Washington), 2 were in the South (Arkansas and Delaware), and 1 was in the Midwest (Indiana).² Of the States with the lowest rates of past year nonmedical pain reliever, 4 were in the Midwest region (Illinois, Iowa, North

Dakota, and South Dakota), 1 was in the Northeast (New York), 4 were in the South (Florida, Georgia, Maryland, and North Carolina), and 1 was in the West (Hawaii).

Changes over Time

The national rate for the total population declined between 2009-2010 and 2010-2011 (from 4.9 to 4.6 percent).⁸ This rate also decreased nationally among persons aged 12 to 17 (from 6.4 to 6.1 percent), and among those 18 to 25 (from 11.5 to 10.4 percent); however, the rate remained unchanged for persons aged 26 or older. Between 2009-2010 and 2010-2011, past year nonmedical use of pain relievers among persons aged 12 or older decreased in Kentucky, Louisiana, Massachusetts, Mississippi, New Hampshire, New York, Ohio, Oklahoma, Rhode Island, and West Virginia. Among 12 to 17 year olds, Maryland's and Mississippi's rates decreased between these time periods (from 5.8 to 4.6 percent and from 8.5 to 6.9 percent, respectively). Among persons aged 18 to 25, the rates of past year nonmedical use of pain relievers declined in 14 States (Florida, Kentucky, Louisiana, Maine, Massachusetts, Michigan, New Hampshire, New York, Ohio, Oklahoma, Rhode Island, Texas, Utah, and West Virginia). Among persons aged 26 or older, Oklahoma's rate decreased from 5.3 to 3.9 percent. There were no other changes at the State level in any of the age groups.

Availability of Additional Tables and Information

Complete 2010-2011 NSDUH State results will be available online at <http://www.samhsa.gov/data/NSDUH/2k11State/NSDUHsae2011/Index.aspx>. In addition to nonmedical use of pain relievers included in this short report, estimates for 24 other measures of substance use and mental health problems will be available, including use of illicit drugs, alcohol, and tobacco; substance dependence or abuse; serious mental illness; depression; and suicidal thoughts. National maps for all 25 measures and detailed tables including percentages for each State, census region, and the Nation by age will also be provided. In 2013, additional detailed tables for the 25 measures will be released, including comparisons of the 2009-2010 and the 2002-2003 State estimates to the 2010-2011 estimates by age for each State, census region, and the Nation.

Discussion

Nonmedical use of prescription pain relievers is a health concern for the citizens of every State and the District of Columbia. Data in this issue of *The NSDUH Report* highlight that use of these substances varies between States. These findings suggest that efforts to reduce the nonmedical use of pain relievers have resulted in some progress, although this progress has not been uniform across all States. Highlighting the prevalence of the nonmedical use of pain relievers in each State, as well as monitoring changes, will help State and Federal policymakers to refine and focus substance abuse prevention and treatment strategies designed to reduce the burden of pain reliever misuse on the Nation's health and health care system.

End Notes

¹ National Drug Intelligence Center. (2011, August). *National drug threat assessment 2011* (Product No. 2011-Q0317-001). Johnstown, PA: Author. Retrieved from <http://www.justice.gov/archive/ndic/>

² Center for Behavioral Health Statistics and Quality. (2012). *Results from the 2011 National Survey on Drug Use and Health: Summary of national findings* (NSDUH Series H-44, HHS Publication No. SMA 12-4713). Rockville, MD: Substance Abuse and Mental Health Services Administration. The approximate number of persons (22 million) initiating nonmedical pain reliever use since 2002 can be determined directly from the Table 7.36A in the detailed tables supporting the 2011 summary of national findings (<http://www.samhsa.gov/data/NSDUH/2011SummNatFindDetTables/NSDUH-DetTabsPDFWHTML2011/2k11DetailedTabs/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2011.htm#Tab7.36A>).

³ Respondents were shown a "pill card" displaying the names and color photographs of specific pain relievers and asked to indicate which, if any, they had ever used without a doctor's prescription or simply for the feeling of experience the drug caused. The following drugs were listed on the pain relievers pill card: (1) Darvocet-N®, Darvon®, or Tyleno® with codeine; (2) Percocet®, Percodan®, or Tylox®; and (3) Vicodin®, Lortab®, or Lorcet®/Lorcet Plus®. Additional drugs were (4) codeine; (5) Demerol®; (6) Dilaudid®; (7) Fioricet®; (8) Fiorinal®; (9) hydrocodone; (10) methadone; (11) morphine; (12) OxyContin®; (13) Phenaphen® with codeine; (14) propoxyphene; (15) SK-65®; (16) Stadol® (no picture); (17) Talacen®; (18) Talwin®; (19) Talwin® NX; (20) tramadol; and (21) Ultram®. The "pill card" used is at <http://www.samhsa.gov/data/2k12/NSDUH2009MRB/Volume%201/2k9Pillcards.pdf>. Respondents also were asked about their nonmedical use of any other pain relievers not included in this list and were asked to specify the names of the drugs that they used nonmedically.

⁴ All estimates in this report are based on a small area estimation (SAE) methodology in which State-level NSDUH data are combined with local-area county and census block group/tract-level data from the State. This model-based methodology provides more precise estimates of substance use and mental disorders at the State level than those based solely on the sample, particularly for smaller States. The precision of the SAE estimates, particularly for States with smaller sample sizes, can be improved significantly by combining data across 2 years (i.e., 2010 to 2011).

⁵ The data for this report along with other measures of substance use and mental disorders will be available at <http://www.samhsa.gov/data/NSDUH/2k11State/NSDUHsae2011/Index.aspx>. Additional tables, including those comparing 2009-2010 with 2010-2011 estimates, will be posted to this Web page in early 2013.

⁶ Estimates were divided into quintiles for ease of presentation and discussion, but differences between States and quintiles were not tested for statistical significance. In some instances, more than 10 or fewer than 10 States were assigned to each quintile because of ties in the estimated prevalence rates.

⁷ The West has 13 States: AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, and WY. The South has 16 States plus the District of Columbia: AL, AR, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, and WV. The Northeast has 9 States: CT, MA, ME, NH, NJ, NY, PA, RI, and VT. The Midwest has 12 States: IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, and WI.

⁸ All changes discussed in this report are statistically significant at the .05 level. Table 2 also show changes that are statistically significant at the .10 level (defined here as a level greater than .05 but less than or equal to .10) to highlight other possible changes that may be of interest despite not quite reaching statistical significance.

Suggested Citation

Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 8, 2013). *The NSDUH Report: State Estimates of Nonmedical Use of Prescription Pain Relievers*. Rockville, MD.

The National Survey on Drug Use and Health (NSDUH) is an annual survey sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). The survey collects data by administering questionnaires to a representative sample of the population through face-to-face interviews at their place of residence.

The NSDUH Report is prepared by the Center for Behavioral Health Statistics and Quality (CBHSQ), SAMHSA, and by RTI International in Research Triangle Park, North Carolina. (RTI International is a trade name of Research Triangle Institute.)

Information on the most recent NSDUH is available in the following publication:

Center for Behavioral Health Statistics and Quality. (2012). *Results from the 2011 National Survey on Drug Use and Health: Summary of national findings* (HHS Publication No. SMA 12-4713, NSDUH Series H-44). Rockville, MD: Substance Abuse and Mental Health Services Administration.

Also available online: <http://www.samhsa.gov/data/NSDUH.aspx>.

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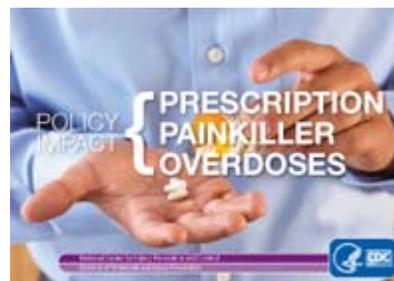
This page was last updated on October 1, 2012.

Policy Impact: Prescription Painkiller Overdoses

What's the Issue?

In a period of nine months, a tiny Kentucky county of fewer than 12,000 people sees a 53-year-old mother, her 35-year-old son, and seven others die by overdosing on pain medications obtained from pain clinics in Florida.¹ In Utah, a 13-year-old fatally overdoses on oxycodone pills taken from a friend's grandmother.² A 20-year-old Boston man dies from an overdose of methadone, only a year after his friend also died from a prescription drug overdose.³

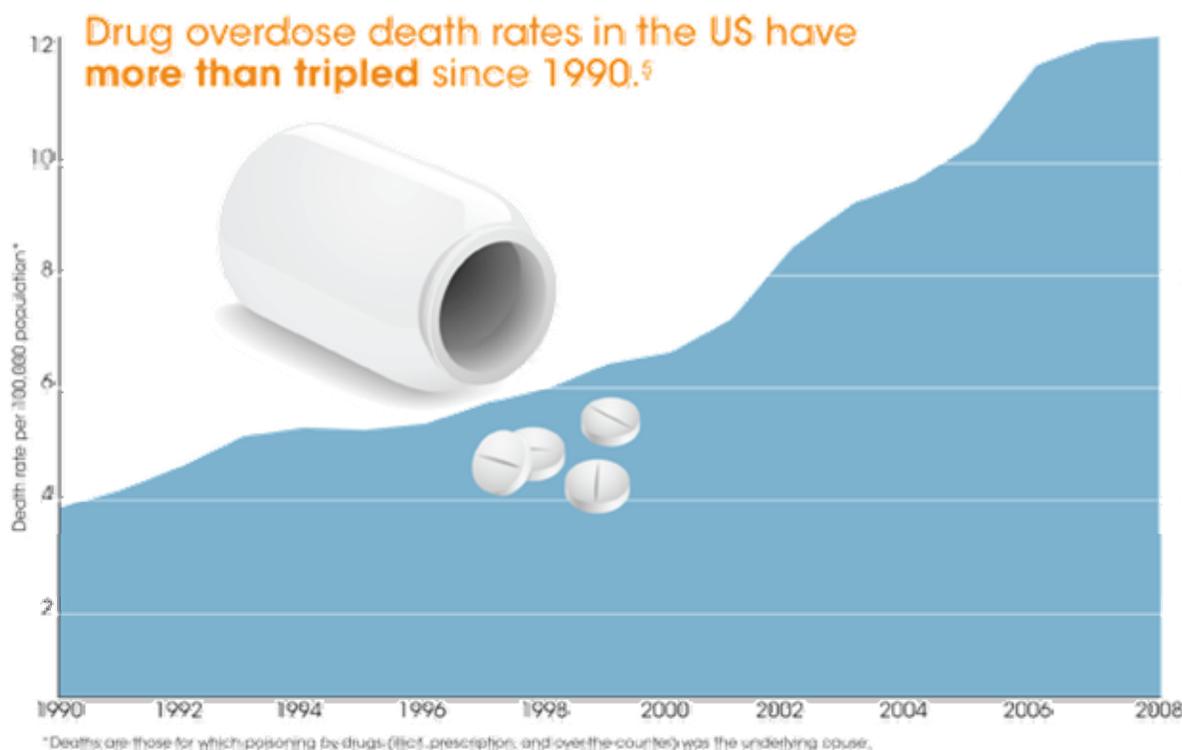
These are not isolated events. Drug overdose death rates in the United States have more than tripled since 1990 and have never been higher. In 2008, more than 36,000 people died from drug overdoses, and most of these deaths were caused by prescription drugs.⁴



Policy Impact:
Prescription Painkiller Overdoses 
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100 people die from drug overdoses every day in the United States.⁴



Attachment 2

Adopted Unanimously by the Board in 1994 and revised in 2007

"No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain."

Business and Professions Code section 2241.5(c)

Preamble

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult this policy statement and the guidelines below.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines from intractable pain patients to all patients with pain.

Under past law, both Business and Professions Code section 2241 and Health and Safety Code section 11156 made it unprofessional conduct for a practitioner to prescribe to an addict. However, the standard of care has evolved over the past several years such that a practitioner may, under certain circumstances, appropriately prescribe to an addict. AB 2198, which became law on January 1, 2007, sought to align existing law with the current standard of care. Accordingly, a physician is permitted to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances. The law, Business and Professions Code section 2241, also set forth the conditions under which such prescribing may occur. Further, Business and Professions Code 2241.5 now permits a physician to prescribe for or dispense or administer to a person under his or her treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognized that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

A High Priority

The board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of [medical organizations](#) have developed guidelines for acute and chronic pain management.

The prescribing of opioid analgesics for patients with pain may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Business and Professions Code section 2241.5 provides in part: "(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. (b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."

However, this section does not affect the power of the board to discipline a physician and surgeon for any act that violates the law, including gross negligence, repeated negligent acts, or incompetence; violation of section 2241 regarding treatment of an addict; violation of section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs; violation of section 2242.1 regarding prescribing on the Internet; failure to keep complete and accurate records of purchases and disposals of controlled substances; writing false or fictitious prescriptions for controlled substances; or prescribing, administering, or dispensing in violation of the pertinent sections of the Health and Safety Code.

The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

Guidelines

History/Physical Examination

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

- *Annotation One:* The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

- *Annotation Two:* The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

Treatment Plan, Objectives

The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

- *Annotation One:* Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.
- *Annotation Two:* When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors to physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

Informed Consent

The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

- *Annotation:* A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

Periodic Review

The physician and surgeon should periodically review the course of pain treatment of the patient 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. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

- *Annotation One:* Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.
- *Annotation Two:* Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family

members or other caregivers should be considered in determining the patient's response to treatment.

Consultation

The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.

- *Annotation One:* Coordination of care in prescribing chronic analgesics is of paramount importance.
- *Annotation Two:* In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code sections 2241 and 2241.5.

Records

The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

- *Annotation One:* Documentation of the periodic reviews should be done at least annually or more frequently as warranted.
- *Annotation Two:* Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

Compliance with Controlled Substances Laws and Regulations

To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

- *Annotation One:* There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.
- *Annotation Two:* Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.pac.ca.gov.

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for Schedule II through V controlled substances with the advanced approval by a supervising physician for a specific patient unless a physician assistant completes an approved education course in controlled substances and if delegated by the supervising physician. To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of Title 16, California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

Postscript

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain - including intractable pain - there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). In summary, a physician and surgeon must follow the same standard of care when prescribing and/or administering a narcotic controlled substance to a "known addict" patient as he or she would for any other patient.

The physician and surgeon must:

- perform an appropriate prior medical examination;
- identify a medical indication;
- keep accurate and complete medical records, including treatments, medications, periodic reviews of treatment plans, etc;
- provide ongoing and follow-up medical care as appropriate and necessary.

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.

Source: The Medical Board of California: http://www.mbc.ca.gov/pain_guidelines.html

Attachment 3

NABP'S INTERCONNECT

The NABP PMP InterConnect facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users. It allows participating state PMPs across the United States to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.

PMPs are Connecting

The NABP InterConnect is now fully operational and allows users of PMPs in Arizona, Arkansas, Colorado, Connecticut, Delaware, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Virginia, and Wisconsin to securely exchange prescription data between the 21 participating states.

NABP continues to work with other state PMPs to facilitate their participation in the NABP InterConnect. It is anticipated that approximately 30 states will be sharing data or in an MOU to share data using NABP InterConnect in 2013.

Which states have signed on? See the [NABP PMP InterConnect map](#) (PDF).

Protecting Public Health via Nationwide Platform for Tracking Drug Diversion

The NABP InterConnect enhances the benefits of state PMPs by providing the means for physicians and pharmacists to more easily identify patients with prescription drug abuse and misuse problems, especially if those patients are crossing state lines to obtain drugs. The lack of interoperability between current systems and difficulty of data sharing among states makes it easier for doctor shoppers to avoid detection. The program's connected web of information allows appropriate intervention and aid in the prevention of substance abuse and diversion of controlled substances.

Secure System to Enable Data Sharing Across State Lines

The NABP InterConnect is a highly secure communications exchange platform that facilitates the transmission of PMP data across state lines to authorized requestors, while ensuring that each state's data-access rules are enforced. The NABP InterConnect does not house any data and the system will not inhibit the legitimate prescribing or dispensing of prescription drugs.

Learn More

For additional information on the NABP PMP InterConnect, please contact NABP Government Affairs staff at governmentaffairs@nabp.net.

The [Fact Sheet](#) (PDF) provides an overview of the InterConnect's development, function, partners, security, and funding

Attachment 4



Save The Date!

You are invited to the West Coast Screening of

OUT OF REACH

a film for parents

(This film is **NOT** suggested for young adults)

(Invitation to follow)

A short-film documentary about a rising high school senior who sets out to uncover the growing problem of teens abusing prescription medicine in his hometown.

The documentary will be followed by a panel discussion

Hosted by US Attorney Laura Duffy

and

The Partnership at Drugfree.org

OLD MEDICINE IS NOT FORGOTTEN

OUT OF REACH

DATE: Wednesday, November 20, 2013 TIME: 5:30 - 6:30 PM

LOCATION: Junipero Serra High School- 5156 Santo Road San Diego 92124

1 IN 4 TEENS report having misused or abused a prescription drug at least once in their life time - a 33% increase over a five year period - that translates to

5 MILLION TEENS!

Attachment 5



How to

Monitor, Secure, and Destroy

your medications

MONITOR

Take inventory. Count your medications from the pharmacist. Count them as you use them. Take note of missing and quickly used medications.

SECURE

Lock medications to reduce access. Don't leave them in a bathroom. Keep them away from children and youth.

DESTROY

Don't throw unused or expired medications down the drain or toilet.

Follow these steps to properly destroy medications!

Preventing prescription drug and over-the-counter abuse starts in your home.

According to the latest National Survey on Drug Use and Health (2010), over 70 percent of people who abused prescription pain relievers got them from friends or relatives. Safeguard your medications by following all three important steps outlined here.

Monitor, secure, and destroy your medications.

How to Properly Destroy your Expired and Unwanted Medications at Home



You Will Need:

- Expired and unwanted medications
- Zip baggie
- Hot water (over 110° F)
- Kitty litter

Steps to Follow:

- 1) Pour unwanted or expired medications out of their original containers into a zip baggie.
- 2) Pour hot water (over 110° F — about as hot as a cup of coffee) into the baggie.
- 3) Insert kitty litter into the baggie. Seal baggie. Place in trash bin.

Be sure your medications are safeguarded. Shred prescription labels or use a black marker to cross out label information.

These steps are intended for Orange County, CA residents.

WOULD YOU NOTICE IF PILLS WERE MISSING?



MORE YOUNG PEOPLE DIE IN ORANGE COUNTY FROM ABUSING MEDICATION THAN FROM COCAINE, METH AND ECSTASY COMBINED.

 **MONITOR**  **SECURE**  **DESTROY**

    CSPINC.ORG/RX



Find us on Facebook
GOODMEDSBADBEHAVIOR



CSPINC.ORG/RX

Community Service Programs, Inc.—Project PATH (714) 441-0807

Project funded by the County of Orange Health Care Agency, Alcohol and Drug Education and Prevention Team



Cómo

Controlar, Asegurar y Destruir

sus medicamentos

CONTROLE

Haga un inventario. Cunte la cantidad de medicamentos que le dio el farmacéutico. Cuéntelos mientras los vaya usando. Tome nota de los medicamentos que faltan o que fueron consumidos rápido.

ASEGURE

Guarde los medicamentos bajo llave para reducir el acceso. No los deje en el baño. Manténgalos lejos del alcance de niños y jóvenes.

DESTRUYA

No tire los medicamentos vencidos o no deseados en la taza del baño o en el drenaje.

WOULD YOU NOTICE IF PILLS WERE MISSING?



MORE YOUNG PEOPLE DIE IN ORANGE COUNTY FROM ABUSING MEDICATION THAN FROM COCAINE, METH AND ECSTASY COMBINED.

 MONITOR  SECURE  DESTROY

  CSPINC.ORG/RX 

Prevención del abuso de medicamentos con o sin receta comienza en el hogar.

De acuerdo con la Encuesta Nacional Sobre el Uso de Drogas y la Salud (2010), más de 70% de las personas que abusaron de medicamentos con receta los obtuvieron por parte de amigos y familia. Proteja sus medicamentos por medio de seguir los tres pasos importantes descritos aquí.

Controle, asegure y destruya sus medicamentos.

Cómo Desechar Adecuadamente Los Medicamentos Vencidos o No Deseados en el Hogar



Lo Que Se Necesita:

- Medicamentos vencidos o no deseados
- Bolsita de plástico zip
- Agua caliente (más de 110° F)
- Arena de gato (kitty litter)

Siga Estos Pasos:

- 1) Vacíe los medicamentos no deseados o vencidos en una bolsita de plástico zip.
- 2) Eche agua caliente (más de 110° F — similar a la temperatura de una taza de café) dentro de la bolsita.
- 3) Agregue arena para gato dentro de la bolsita. Selle la bolsita. **Tírelo en la basura.**

Asegúrese de que sus medicamentos estén bien guardados. Corte en pedazos las etiquetas de los medicamentos o use un marcador negro para borrar información de la etiqueta.

Estas medidas están destinados a los residentes de Orange County, CA.

 Encuéntrenos en Facebook
GOODMEDSBADBEHAVIOR



CSPINC.ORG/RX

Community Service Programs, Inc.—Project PATH (714) 441-0807

Proyecto financiado por el Condado de Orange Agencia del Cuidado de Salud - Equipo de Educación y Prevención de Alcohol y Drogas

WOULD YOU NOTICE IF PILLS WERE MISSING?



MORE YOUNG PEOPLE DIE IN ORANGE COUNTY FROM **ABUSING MEDICATION** THAN FROM COCAINE, METH AND ECSTASY COMBINED.

 **MONITOR**

 **SECURE**

 **DESTROY**



CSPINC.ORG/RX



Project funded by the Orange County Health Care Agency, Alcohol & Drug Education and Prevention Team

Source: Coroner Division of the Orange County Sheriff's Department (2012)

**70% of people who abuse prescription pain relievers
get them from family or friends.**

Break the cycle by safeguarding medications in your own home.

MONITOR

Take inventory.

Count your medications from the pharmacist. Count them as you use them. Take note of missing and quickly used medications.

SECURE

Lock medications to reduce access.

Don't leave them in a bathroom.
Keep them away from children and youth.

DESTROY

Don't throw unwanted or expired medications down the drain or toilet.

Follow these steps instead:

- 1) Pour unwanted or expired medications out of their original containers into a zip baggie.
- 2) Pour hot water (over 110° F — about as hot as a cup of coffee) into the baggie.
- 3) Insert kitty litter into the baggie. Seal baggie.
Place in trash bin.

Source: National Survey on Drug Use and Health [2010]

Attachment 6

essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Significant disruption means a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Dated: October 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-25956 Filed 10-31-13; 11:15 am]

BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-351]

Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to place the substance 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol (the term “isomers” includes the optical and geometric isomers) into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant

Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.

DATES: Interested persons may file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before January 3, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),” 21 CFR 1300.01, may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 4, 2013.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-351” on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the on-line instructions at that site for submitting comments. An electronic copy of this document and supplemental information to this proposed rule are also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate electronic submissions are not necessary. All comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests

for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT:

Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 598-6812.

SUPPLEMENTARY INFORMATION: *Posting of*

Public Comments: Please note that comments received in response to this NPRM are considered part of the public record and will be made available for public inspection and posted at <http://www.regulations.gov> and in the DEA’s public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made public, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available.

Comments containing personal identifying information and confidential business information identified and located as set forth above will be made available in redacted form. The Freedom of Information Act (FOIA) applies to all comments received. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph, above.

Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

Pursuant to the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA) (5 U.S.C. 551–559). 21 CFR 1308.41–1308.45, and 21 CFR part 1316 subpart D. In accordance with 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).” 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing is restricted to “(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed. * * *” Requests for hearing, notices of appearance at the hearing, and waivers of an opportunity for the hearing or to participate in the hearing should be submitted to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, but they are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of scheduled substances is published at 21 CFR part 1308. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.” Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA, who has further delegated this authority to the Deputy Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the HHS; or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is based on a recommendation from the Assistant Secretary for Health of the HHS and on an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.¹

Background

Tramadol is an opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the “M1” metabolite (O-desmethyltramadol). Since March 1995, tramadol has been available as a non-

controlled and centrally acting opioid analgesic under the trade name ULTRAM® approved by the Food and Drug Administration (FDA) in the United States. Subsequently, the FDA approved generic, combination, and extended release products of tramadol.

Because of its chemical structure, 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol can exist as different isomeric forms. Thus, various prefixes can be associated with the name. Some examples of these prefixes include dextro, levo, d, l, R, S, cis, trans, erythro, threo, (+), (–), racemic, and may include combinations of these prefixes sometimes with numerical designations. Any such isomer is, in fact, 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol. Tramadol is typically formulated as a racemic mixture identified as (±)-cis-2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol hydrochloride.²

Proposed Determination To Schedule Tramadol

The DEA received four petitions between October and November 2005 requesting that tramadol be controlled as a scheduled substance under the CSA. Three of these petitions specifically requested the placement of tramadol into Schedule III; the remaining petition did not specify a schedule for control. One of the petitioners stated that “tramadol has significant abuse potential, consistent with its pharmacology. This abuse has significant public health policy implications.”

Pursuant to 21 U.S.C. 811(b) of the CSA, the DEA gathered the necessary data on tramadol and, on April 25, 2007 submitted it to the Assistant Secretary of the HHS with a request for a scientific and medical evaluation and the Secretary’s recommendation as to whether or not tramadol should be added as a controlled substance, and, if so, in which schedule. On September 16, 2010, the HHS provided to the DEA a written scientific and medical evaluation and scheduling recommendation entitled “Basis for the Recommendation to Schedule Tramadol in Schedule IV of the Controlled Substances Act.” In this recommendation, the HHS presented its eight-factor analysis as required under 21 U.S.C. 811(b), and recommended that

² For simplicity’s sake, from this point forward in the document, “tramadol” is used to refer to 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms.

¹ See *infra* footnote 2.

tramadol be added to Schedule IV of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS and all other relevant data, and completed an eight-factor review document pursuant to 21 U.S.C. 811(c) in February 2011. Included below is a brief summary of each factor as analyzed by the HHS in its 2010 transmittal and the DEA in its 2011 analysis, and as considered by the DEA in its proposed scheduling decision. Please note that both the DEA and HHS analyses are available in their entirety under “Supporting and Related Material” of the public docket for this rule at <http://www.regulations.gov> under docket number “DEA-351.” Full analysis of, and citations to, information referenced in the summary may also be found in the supporting material.

1. *The Drug’s Actual or Relative Potential for Abuse:* Data gathered by the DEA and HHS indicate that since the initial marketing of tramadol in 1995, tramadol has been, and currently is, abused for its opioid effects. The DEA has considered all relevant data and found that:

a. Individuals Are Taking Tramadol in Amounts Sufficient To Create a Hazard to Their Health or to the Safety of Other Individuals or to the Community

Published case reports, case series, and data from databases such as the Drug Abuse Warning Network (DAWN) suggest that individuals are taking tramadol in amounts sufficient to create a hazard to their health, to the safety of other individuals, and to the community. Tramadol abuse is associated with serious adverse events including death, drug dependence, drug withdrawal symptoms, seizures, serotonin syndrome, and other serious medical problems.

DAWN is a database, managed by the Substance Abuse and Mental Health Services Administration (SAMHSA), which collects data on drug-related emergency department (ED) visits from a nationally representative sample of hospitals in the United States and a selection of metropolitan areas. The HHS reviewed and analyzed DAWN data from 2004 through 2008 and found that the estimated annual non-medical³

³ As defined by the DAWN glossary, non-medical use of pharmaceuticals includes prescription and over-the-counter pharmaceuticals in ED visits that are of the following types of cases:

Overmedication—Patient took too much of his/her prescription medication.

Malicious poisoning—Drug use in which the patient was administered a drug by another person for a malicious purpose.

Other—This category includes all drug-related ED visits that could not be assigned into any of the

Emergency Department (ED) visits from non-medical use of tramadol and its combinations (hereinafter “tramadol/ combinations”) continually increased from 4,849 ED visits to 11,850 ED visits. The DEA also evaluated more recent DAWN data and found that this increasing trend for tramadol continued in 2009 and 2010 (15,349 and 16,251 ED visits, respectively).

The American Association of Poison Control Centers (AAPCC) manages the National Poison Data System (NPDS), which is the only near real-time comprehensive poisoning surveillance database in the United States. The NPDS collects information from the poison centers across the United States. The HHS reviewed the NPDS data and found that the number of case mentions of human toxic exposures to tramadol during 2004 through 2008 increased annually from 3,769 to 9,623. The DEA reviewed the more recent NPDS data and found that in 2009, 2010, and 2011, the number of reported tramadol poison exposures, alone and in combination with other drugs, totaled 10,255; 11,225; and 12,424, respectively. Of these totals, intentional exposures to tramadol alone (i.e., exposures not including tramadol/ combinations or tramadol in combination with any other substances) were 2,677; 2,867; and 3,170, resulting in four deaths in 2009, three deaths in 2010, and six deaths in 2011.

b. There Is a Significant Diversion of Tramadol From Legitimate Drug Channels

The National Forensic Laboratory Information System (NFLIS) is a DEA database that collects scientifically verified data on analyzed samples in state and local forensic laboratories. It also includes data from the System to Retrieve Information from Drug Evidence (STRIDE), which includes data on analyzed samples from DEA laboratories. The data show that for each of the years from 2000 through 2012, tramadol was present in drug exhibits seized in the course of law enforcement activity.⁴ The tramadol exhibits seized

other classifications used by DAWN (suicide, attempt, seeking detox, alcohol only (under 21), adverse reaction, overmedication, malicious poisoning, and accidental ingestion).

Non-medical use may involve pharmaceuticals alone or pharmaceuticals in combination with illicit drugs or alcohol.

⁴ Because the primary focus of law enforcement agencies (with respect to drugs) is on investigating the *unlawful* distribution of drugs, the incidents in which tramadol has been seized in the course of law enforcement investigations supports a finding that the drug is being abused and/or diverted from legitimate channels. Moreover, because tramadol is not controlled in most states there is reason to believe that many laboratories may not report those incidents in which they have identified a substance

by law enforcement involving drug abuse indicate the diversion of tramadol in the United States.⁵ Tramadol exhibits increased from a total of 82 in 2000 to 1,806 in 2012 (NFLIS data). In 2010, this number was greater than the number of exhibits shown to contain pentazocine (96, Schedule IV), but less than the number of hydrocodone (45,627, Schedule III), codeine (3,679, Schedules II, III, V), and buprenorphine (10,167, Schedule III) exhibits (NFLIS data). The number of tramadol exhibits is similar to that of propoxyphene (1,320, Schedule IV) (2010 NFLIS data). However, the reduced number of propoxyphene exhibits (561) in 2011 is significantly less than that of tramadol (1,704) due to the FDA’s recommendation to withdraw propoxyphene from the United States market.

A post-marketing study published in 2002 and cited by the HHS’s review document reported that among 140 health care professionals who had at least one positive tramadol urine specimen, 87 cases were associated with illegal prescriptions for obtaining tramadol. Another study referred to in the HHS review noted that from January 2002 through March 2004 there were 72 cases involving the diversion of tramadol from all 50 state law enforcement agencies. However, the number of tramadol diversion cases was less than the number of diversion cases associated with hydrocodone and oxycodone.

c. Individuals Are Taking Tramadol on Their Own Initiative Rather Than on the Basis of Medical Advice From a Practitioner Licensed by Law to Administer Such Drugs

The DEA’s evaluation found that current evidence indicates that individuals take tramadol on their own initiative without medical consultation. This evidence includes case reports of abuse and dependence on tramadol in the medical literature, national drug abuse monitoring systems, and epidemiological data (DAWN, NFLIS, STRIDE, AAPCC, and the National Survey on Drug Use and Health (NSDUH)).

DAWN data show that from 2004 to 2010, the national annual estimates of ED visits related to non-medical use or

as tramadol. This suggests that tramadol would likely rank substantially higher in NFLIS data were it controlled nationally.

⁵ While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted or abused. 76 FR 77330, 77332, Dec. 12, 2011.

abuse⁶ of tramadol/combinations increased from 4,849 to 16,251. Upon normalization of the number of non-medical ED visits relative to 100,000 prescriptions dispensed, the rate of ED visits for tramadol/combinations was found similar to the rates for propoxyphene.

The NSDUH, operated by SAMHSA, provides information on the non-medical use of drugs in the United States population age 12 and older and its database provides annual estimates on the lifetime non-medical use of opioids and pain relievers. The estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 994,000 in 2002 to 2,614,000 in 2011.

The NPDS from AAPCC reported that the number of tramadol exposures increased each year between 2004 (3,769 cases) and 2011. In 2011, the number of reported tramadol poison exposures totaled 12,424. Of these total poison exposures in 2011, the intentional exposures to tramadol alone (i.e., not tramadol/combinations or in combination with other substances) were 3,170—six of which resulted in death. These findings indicate that tramadol poses a significant threat to the public health.

d. Tramadol is so Related in Its Action to a Drug or Other Substance Already Listed as Having a Potential for Abuse To Make It Likely That It Will Have the Same Potential for Abuse as Such Substance, Thus Making It Reasonable To Assume That There May Be Significant Diversions From Legitimate Channels, Significant Use Contrary to or Without Medical Advice, or That It Has a Substantial Capability of Creating Hazards to the Health of the User or to the Safety of the Community

According to the HHS review, tramadol shares many similar pharmacological activities with some opioids scheduled under the CSA. As such, the abuse potential of tramadol would be expected to be related to its opioid properties. As a result, tramadol would be expected to be diverted from legitimate sources, be used without medical supervision, and consequently be a safety concern to individuals and the community.

The opioid activity of tramadol is primarily due to the “M1” metabolite. Compared to other opioids, tramadol showed a longer onset of action due to

accumulation of the active metabolite and its effects include analgesia, respiratory depression, miosis, cough suppression, and inhibition of bowel motility. Preclinical studies demonstrate that tramadol, like other opioids in Schedules I through IV, exhibits complete generalization to morphine and is able to produce some reinforcing effects. Repeated administration of tramadol in animals caused dependence development, evidenced by a withdrawal syndrome similar in intensity to pentazocine (Schedule IV) or propoxyphene (Schedule IV). Human studies reveal that tramadol produces some reinforcing subjective effects at high doses. A similar dose response pattern at high doses with propoxyphene to produce reinforcing subjective effects was also observed. Thereby, propoxyphene may serve as an appropriate comparator drug for tramadol with respect to generating reinforcing effects. According to the HHS review, several studies examining chemical abuse potential suggest that the subjective reinforcing effect of tramadol is less than that of Schedule II opioids and more comparable to that of propoxyphene.

In summary, the abuse potential of tramadol is similar to that of substances in Schedule IV (such as propoxyphene) of the CSA. The accumulated information demonstrates that individuals take tramadol non-medically and in amounts sufficient to create a hazard to their health. Tramadol is diverted from legitimate sources and produces effects similar to other CSA-controlled opioids known to have an abuse potential. Furthermore, the available information regarding reinforcing effects and drug dependence shows that the abuse potential of tramadol is less than that of morphine (Schedule II), oxycodone (Schedule II), or buprenorphine (Schedule III), but similar to that of propoxyphene (Schedule IV). Additionally, epidemiological data also support an abuse potential for tramadol that is similar to substances in Schedule IV of the CSA. These data suggest that tramadol has an abuse potential warranting control under the CSA.

The DEA and HHS believe that an evaluation of the accumulated information demonstrates that the indicators of a drug's potential for abuse, as described in the legislative history of the CSA, are present for tramadol. Obtained or diverted from legitimate sources, individuals take tramadol in the absence of medical supervision and in amounts sufficient to create a hazard to their health. Tramadol produces effects similar to opioids

known to have an abuse potential and that are controlled under the CSA.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known: The DEA and HHS recognize tramadol as an opioid analgesic with monoaminergic activity that contributes to its analgesic effects. The M1 metabolite of tramadol contributes to its opioid effects and may be the cause of the delayed and prolonged activity associated with tramadol administration. Tramadol can block the reuptake of norepinephrine and serotonin, effects also produced by such opioids as meperidine (Schedule II), methadone (Schedule II), and levorphanol (Schedule II).

Preclinical animal studies found that tramadol demonstrated a dose-related anti-nociceptive effect. Its analgesic effects were compared to other Schedule III and IV opioid analgesics. In clinical trials for treatment in human subjects, tramadol was less effective than hydrocodone/acetaminophen (Schedule III), but displayed an analgesic effect similar to that of pentazocine (Schedule IV), and superior or similar to the propoxyphene/acetaminophen combination (Schedule IV) in relieving postoperative pain.

Tramadol produces abuse liability-related effects in various animal models and humans. It has been self-administered by monkeys, producing reinforcing effects which qualitatively show a similarity to opioids. In a drug discrimination study using rats, tramadol was shown to produce systematic generalization to morphine. Similar to other opioids in Schedules II through IV, tramadol fully substituted for discriminative effects of morphine and morphine fully substituted for tramadol. Drug discriminative studies showed that tramadol is comparable to other Schedule III and IV opioids. Physical dependence of tramadol has been demonstrated in studies on animals and humans.

Most adverse effects are related to tramadol's opioid activity including sedation, nausea, vomiting, constipation, and respiratory depression. However, a small but significant portion of individuals who use tramadol will experience seizures. The risk of seizures increases with dose and is relatively common among tramadol abusers. Further, clinical studies show that tramadol, at a single dose greater than the therapeutically prescribed-dose, produces subjective reinforcing effects that are significantly greater than those of placebos, and are similar to or approach those produced by morphine and oxycodone. A similar dose dependency in producing subjective reinforcing effects was also

⁶ Since 2004, DAWN has defined “drug misuse or abuse” as a group of ED visits including all visits associated with the non-medical use of pharmaceuticals.

observed with propoxyphene at doses greater than the therapeutically prescribed dose. This similarity between tramadol and propoxyphene provides support for a similar abuse potential and placement of tramadol into Schedule IV.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* The chemical name of tramadol hydrochloride is (±)-*cis*-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride. Tramadol hydrochloride has a molecular formula of C₁₆H₂₅NO₂ HCl with a molecular weight of 299.84. Because of tramadol's chemical structure, it can exist as different isomeric forms. Thus, various prefixes can be associated with the name. Some examples of these prefixes include dextro, levo, d, l, R, S, cis, trans, erythro, threo, (+), (-), racemic, and may include combinations of these prefixes sometimes with numerical designations. Any such isomer is, in fact, 2-[(dimethylamino) methyl]-1-(3-methoxyphenyl)cyclohexanol. It is typically formulated as a racemic mixture identified as (±)-*cis*-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride. Tramadol hydrochloride is a white, crystalline, and odorless powder soluble in water and ethanol.

Tramadol is readily absorbed from the gastrointestinal tract, with both enantiomers as well as the M1 metabolite found in the blood following administration. Tramadol undergoes extensive metabolism in the liver, while 90 percent of tramadol and its metabolites are excreted via the kidneys. Approximately 10 to 30 percent of the parent drug is excreted un-metabolized with an elimination half-life of about 5.5 hours. This extensive metabolism, in part, provides for possible interactions between tramadol and a variety of other drugs that undergo metabolism by the CPY2D6 enzyme.

4. *Its History and Current Pattern of Abuse:* Tramadol has been abused since its marketing approval in 1995 by a wide spectrum of individuals of different ages, alone and in combination with other psychoactive substances. Data from Surveillance Data, Inc. (SDI)'s prescription database comparing tramadol and other analgesics in terms of annual prescriptions dispensed show that in 2007 and 2008, more prescriptions were written for tramadol than for any other opioid other than hydrocodone combination products⁷

⁷ The various studies cited throughout this rule interchangeably use the terms "hydrocodone products," "hydrocodone combinations," and "hydrocodone combination products" to refer to the

(Schedule III) and oxycodone (Schedule II). The annual number of prescriptions for tramadol surpassed the annual number of prescriptions for propoxyphene (Schedule IV) and codeine (Schedules II, III, V) in 2007 and 2008. Over each of the five years from 2003 to 2007, there was a consistent multi-fold greater number of prescriptions written for tramadol compared to such analgesics as morphine (Schedule II), fentanyl (Schedule II), methadone (Schedule II), hydromorphone (Schedule II), buprenorphine (Schedule III), meperidine (Schedule II), butorphanol (Schedule IV), pentazocine (Schedule IV), and oxymorphone (Schedule II). Updated information from another major national prescription database, IMS Health's National Prescription Audit Plus™, demonstrated a similar trend from 2009 to 2011: more prescriptions were written for tramadol than for any other opioid other than hydrocodone and oxycodone.

According to the HHS, abuse-related ED visits involving tramadol as reported in DAWN increased from 1995 (645 cases) to 2002 (1,714 cases), peaking in 2001 (2,329 cases).⁸ Tramadol abuse-related deaths increased from 45 cases in 1997 to 88 cases in 2002. Over the period of 2004 through 2008, the number of estimated ED visits from non-medical use of tramadol/combinations showed a continuous increase from 4,849 ED visits to 11,850 ED visits. The DEA further reviewed the DAWN data for 2009 and 2010 and found that the national annual ED visits involving tramadol increased to 15,349 in 2009 and 16,251 in 2010.

The HHS reviewed DAWN data and calculated the rates of estimated non-medical ED visits per 100,000 prescriptions dispensed for tramadol/combinations as well as other selected opioids. The HHS found that from 2004 to 2007, the annual rates of non-medical tramadol/composition ED visits ranged between 28.4 and 33.9. In 2008, there was a substantial increase in the rate of ED visits of tramadol/combinations to 45.8 ED visits per 100,000 prescriptions. Over the five year period (2004 to 2008), annual rates of tramadol ED visits were

controlled substance hydrocodone combined with one or more active ingredients (Schedule III). The DEA uses the term "hydrocodone combination products" to refer to these controlled substances.

⁸ DAWN was redesigned in early 2003, which resulted in a permanent disruption in trends for the years prior to 2003. Therefore, comparisons cannot be made between the previous DAWN system (before 2002) and the current DAWN system. Additionally, before 2002, DAWN collected data on "drug abuse cases" whereas now it collects data on all types of "drug-related" ED visits" (i.e., "non-medical visits").

substantially below that of rates for oxycodone/combinations (Schedule II), methadone (Schedule II), hydromorphone (Schedule II), morphine (Schedule II), fentanyl/combinations (Schedule II), meperidine/combinations (Schedule II), hydrocodone/combinations (Schedule III), and buprenorphine/combinations (Schedule III).⁹ Over the period of 2004 through 2008, the rates of estimated non-medical ED visits for tramadol/combinations were more closely in the range for the rates of codeine/combinations (Schedules II, III, V) and propoxyphene/combinations (Schedule IV). For example, in 2008, the rate of non-medical ED visits per 100,000 prescriptions of tramadol/combinations was 45.8 which was between that for propoxyphene/combinations (62.7 ED visits per 100,000 prescriptions) and that for codeine/combinations (40.2 ED visits per 100,000 prescriptions). Overall, these data suggest that the abuse potential of tramadol is less than that of Schedule II and III substances and most similar to that of propoxyphene (Schedule IV).

According to the annual NSDUH report, the number of individuals who used tramadol non-medically at least once in their lifetime increased from approximately 994,000 in 2002 to 2,614,000 in 2011. For each year surveyed, the absolute number regarding tramadol was lower than that of hydrocodone combination products or oxycodone products. Additionally, for each of the years from 2002 to 2007, the estimated number of individuals who initiated use and reported non-medical use of tramadol was less than 100,000 (with the highest at 95,000 in 2003 and the lowest at 22,000 in 2006). By contrast, for each of the years from 2002 to 2007, the number of past year initiates for use of any pain reliever who also used hydrocodone (>1,200,000) and oxycodone (>450,000) non-medically was greater than that of tramadol. The DEA further analyzed the updated NSDUH data and found that the estimated number of individuals who have used tramadol products non-medically at least once in their lifetime are 1,990,000; 2,181,000; 2,282,000; and 2,614,000 in 2008, 2009, 2010, and 2011, respectively. Furthermore, these numbers are lower than that of oxycodone (Schedule II) and hydrocodone combination products (Schedule III). Collectively, the information from NSDUH shows that tramadol is used non-medically and supports placement of tramadol in a

⁹ Only data from 2006 to 2008 was available for buprenorphine/combinations.

schedule less restrictive than Schedule III.

NFLIS and STRIDE databases provide evidence that tramadol has been diverted from legitimate use and encountered by law enforcement personnel. Furthermore in 2010, forensic laboratories analyzed 1,485 such exhibits and the tramadol-containing exhibits were close in number to that of exhibits for propoxyphene (Schedule IV) (1,320). The relative lower number of propoxyphene exhibits in 2011 and 2012 is because in November 2010, the FDA recommended that propoxyphene be withdrawn from the United States market due to the risk of cardiac toxicity. These exhibits from criminal investigations involving tramadol provide evidence of the significant diversion and non-medical use of tramadol in the United States.

The NPDS demonstrates that from 2004 to 2011, the number of human poison exposures to tramadol increased annually from 3,769 to 12,424. However, the number of exposures for tramadol is also less than the number of exposures for hydrocodone combination products (Schedule III) or oxycodone (Schedule II). The HHS calculated the number of case mentions per 100,000 prescriptions for tramadol and several other opioids and found that the tramadol case mentions per 100,000 prescriptions increased from 22 in 2004 to 37 in 2008. The HHS also found that from 2004 to 2007, the NPDS rates of tramadol case mentions per 100,000 prescriptions were lower than for oxycodone (Schedule II), morphine (Schedule II), and methadone (Schedule II). For the years 2004, 2005, and 2006, the rates of tramadol cases were similar to that of propoxyphene (Schedule IV). In 2007 and 2008, tramadol surpassed codeine (Schedules II, III, V) and propoxyphene (Schedule IV) in the number and rate of case mentions. These data indicate that tramadol represents a significantly growing risk to the public.

Collectively, data from DAWN, NSDUH, NFLIS, STRIDE, and AAPCC-NPDS databases demonstrate the misuse, abuse, and diversion of tramadol in the United States. With respect to the rates of non-medical ED visits found in DAWN, the number of NFLIS exhibits, and the increasing rates of AAPCC's NPDS reporting, tramadol data most closely resembles that of propoxyphene (Schedule IV).

5. *The Scope, Duration, and Significance of Abuse:* The scope, duration, and significance of tramadol abuse is evidenced by findings of national monitoring databases for drug

abuse, review of studies of abuse potential, and clinical case reports. The HHS concluded its 15 years of post-marketing epidemiologic abuse-related data in the scientific literature and from the adverse events reporting system (AERS) since tramadol's commercial availability in the United States. The case reports describe abnormal behavior that demonstrates an addiction liability of tramadol: drug craving, increasing the tramadol dose, performing self-injury in order to be prescribed more tramadol, taking high doses despite adverse effects that result, and visiting multiple physicians in order to obtain more prescriptions for tramadol. Approximately 15 years of post-marketing history now show that tramadol can be, and is being, abused both in the United States and other countries.

Clinical case reports in the medical literature provide information on patterns of tramadol abuse when prescribed for clinical pain management. The case reports listed by the HHS review describe abuse of tramadol for its euphorogenic and sedating effects. The depicted behavior illustrates an addiction to tramadol: Drug craving, increasing the tramadol dose, inflicting self-injury in order to be prescribed more tramadol, taking high doses despite adverse effects that result, and visiting multiple doctors in order to obtain more prescriptions for tramadol. These reports provide information on characteristics and patterns of actual tramadol abuse with the development of dependence. Development of iatrogenic addiction to tramadol due to medical treatments is also reported.

The NSDUH data, discussed in detail in Factor 4, also provides evidence of the non-medical use of tramadol. According to the NSDUH data, the estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 994,000 in 2002 to 2,614,000 in 2011. For each year from 2002 to 2007, the number of individuals reporting either lifetime non-medical use or past-year non-medical use of tramadol was lower than the number of that of hydrocodone or oxycodone. The estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 2008 to 2011, but these numbers for tramadol are still lower than that of oxycodone (Schedule II) and hydrocodone combination products (Schedule III).

According to DAWN data, in 2010, an estimated 16,251 ED visits nationally were for non-medical use of tramadol. There is an increasing annual trend of

non-medical ED visits from 2004 through 2010. Furthermore, the HHS reviewed the national estimates of ED visits related to non-medical use and to rates of these visits per 100,000 prescriptions from 2004 to 2008, and found tramadol most closely compares to propoxyphene (Schedule IV) and to codeine (Schedules II, III, V).

Collectively, the data shows that tramadol has less abuse potential than other pure mu-receptor agonists currently controlled in Schedule II. As evaluated by the HHS and the DEA, the DAWN data indicates tramadol most closely compares to propoxyphene (Schedule IV) and codeine (Schedules II, III, V). The NSDUH data from 2002 to 2007, cited by the HHS, also indicates the number of individuals reporting non-medical use of tramadol was lower than that of individuals using hydrocodone combination products (Schedule III) and oxycodone (Schedule II) products, suggesting an abuse potential less than that of Schedule III.

Tramadol's similarity to other controlled opioids and clear evidence of significant non-medical use and abuse, accompanied by serious adverse events, indicate that tramadol has sufficient abuse potential and incidence of drug dependence and addiction to warrant control as a Schedule IV controlled substance under the CSA.

6. *What, if any, Risk There is to the Public Health:* The DEA analysis indicates that there are numerous risks to the public health that may result from tramadol abuse. Tramadol and its M1 metabolite are opiate agonists devoid of opioid antagonist activity. Adverse effects occurring with tramadol are consistent with adverse effects associated with other opioids. The incidence of reported adverse effects increased as the time of tramadol therapy increased. The overall incidence rates of adverse effects of tramadol were similar to that of codeine containing drugs. Other adverse effects associated with tramadol included seizures, serotonin syndrome, and respiratory depression. Case studies of tramadol overdoses from United States poison centers reported that tramadol overdoses presented multiple systematic symptoms ranging from cardiovascular toxicity to significant neurologic toxicity including lethargy, nausea, tachycardia, agitation, seizures, coma, hypertension, and respiratory depression. The toxic mechanism of tramadol overdose is closely related to its μ -opioid receptor activity and its monoamine oxidase inhibition activity.

Information from the DAWN database shows that the rates of ED visits due to non-medical use of tramadol have been

similar to that of propoxyphene (Schedule IV) but lower than that of Schedule II and III opioids from 2004 to 2008. The HHS reviewed DAWN data and found that a total of 395 tramadol abuse-related deaths were reported to DAWN from 1997 to 2002 in selected areas. The result demonstrates a risk to the public health associated with the non-medical use of tramadol that is similar to that of propoxyphene (Schedule IV).

An increased number of exposure and death cases were reported by the AAPCC's NPDS database. It showed that from 2004 to 2011, annual tramadol exposures increased from 3,769 to 12,424. The HHS found that tramadol ranked third behind hydrocodone combination products (Schedule III) and oxycodone (Schedule II) in terms of the number of poison case mentions of opioids in 2007 and 2008. Over this period, the rates of case mentions per 100,000 prescriptions for tramadol increased from 22 to 37. In addition, the rate of tramadol case mentions was lower than for oxycodone (Schedule II), morphine (Schedule II), and methadone (Schedule II). For the years 2004, 2005, and 2006, the rates of tramadol case mentions were similar to that of propoxyphene (Schedule IV).

The labeling information approved by the FDA states that tramadol in excessive doses, alone or in combination with other central nervous system depressants, including alcohol, is a cause of drug-related deaths. Deaths associated with tramadol were also documented in the medical literature. Other reports document tramadol as a contributing factor to deaths in combination with other drugs such as, but not limited to, benzodiazepines, serotonergic drugs, and other antidepressants. The annual number of tramadol-related deaths reported by medical examiners in the DAWN database gradually increased from 1997 to 2004.

Reports of tramadol associated deaths from the Florida Department of Law Enforcement (FDLE) were also reviewed by the HHS and it was found the number of deaths involving tramadol increased from 106 in 2003 to 235 in 2008. According to FDLE's data, tramadol-related deaths were higher than heroin-related deaths between 2005 and 2008. For each of those years, the number of deaths involving tramadol was less than the number of deaths involving hydrocodone combination products (Schedule III), fentanyl (Schedule II), morphine (Schedule II), oxycodone (Schedule II), methadone (Schedule II), and propoxyphene (Schedule IV). The DEA

reviewed the data for the years 2009 to 2011, and found that tramadol-related deaths continued to increase. There were 268 tramadol-related deaths in 2009, 275 tramadol-related deaths in 2010, and 379 tramadol-related deaths in 2011.

In summary, the collected data from a number of sources indicate that tramadol presents risks to the public health and, as such, supports the scheduling of tramadol. The DAWN, AAPCC, and FDLE data suggest a lower schedule for tramadol than Schedule III.

7. Its Psychic or Physiological Dependence Liability: The HHS reviewed available information from pre-clinical and clinical studies and found that repeated dosing with tramadol resulted in dependence development, and withdrawal syndromes resulted from termination of tramadol treatment. Additionally, medical literature also documents numerous case reports of physiological and physical dependence to tramadol.

Preclinical studies using monkeys and rats found that the tested animals displayed withdrawal signs after the termination of tramadol. Tramadol's potential to produce physical dependence was evidenced by naloxone precipitated withdrawal in observed animals. The results also supported that tramadol produced a degree of physical dependence similar to that of propoxyphene (Schedule IV). Infusion of tramadol in rats found that the total withdrawal scores of tramadol were lower than that of morphine (Schedule II) following naloxone administration. By comparing physical dependence development resulting from repeated subcutaneous administration of either morphine or tramadol to mice, another study concluded that tramadol produced a lesser degree of physical dependence than morphine. These findings suggest that tramadol can produce mild to moderate levels of physical dependence and the degree of dependence of tramadol is less than that of Schedule II, but similar to that of Schedule IV drugs such as pentazocine and propoxyphene.

A number of clinical studies examined the ability of tramadol to substitute for other opioids in individuals who are opioid dependent. A study compared the effectiveness of tramadol versus buprenorphine (Schedule III) in the treatment of opiate withdrawal and found that tramadol and buprenorphine effectively managed acute opioid withdrawal syndrome displayed by patients with mild to moderate addiction to heroin. Another study compared the use of tramadol to that of clonidine (not controlled under

the CSA) for management of acute heroin (Schedule I) withdrawal and found that tramadol was more effective in managing withdrawal than clonidine. One study revealed a cross dependence development between tramadol and morphine (Schedule II) in opioid-dependent adults. A modest suppression of opioid withdrawal produced by tramadol was also reported in subjects with a mild to moderate degree of opioid physical dependence and this finding was also supported by several published case reports.

According to the HHS review, as of September 9, 2009, "Withdrawal symptoms may occur" was documented in the "Warning" section of the label for a tramadol containing product. Combining studies of cross dependence, tramadol produces a modest suppression of withdrawal in subjects dependent on other opioids and this suppression appears less than that produced by morphine (Schedule II) or buprenorphine (Schedule III).

In conclusion, the HHS states that collectively the data shows tramadol can produce a modest level of physical dependence, with the studies suggesting a degree of physical dependence development less than that of Schedule II and III opioids but similar to opioids in Schedule IV.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA: Both the HHS and DEA state that tramadol is not an immediate precursor of any substance already controlled under the CSA.

Conclusion: Based on consideration of the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of tramadol. As such, the DEA hereby proposes to schedule tramadol as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA outlines the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1. Tramadol has a low potential for abuse relative to the drugs or substances in Schedule III. The abuse potential of

tramadol is comparable to the Schedule IV substance propoxyphene;

2. Tramadol has a currently accepted medical use in treatment in the United States. Tramadol and other tramadol-containing products were approved for marketing by the FDA to manage moderate to moderately severe pain; and

3. Abuse of tramadol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Based on these findings, the Deputy Administrator of the DEA concludes that tramadol [2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol, warrant control in Schedule IV of the CSA (21 U.S.C. 812(b)(4)).

Requirements for Handling Tramadol

If this rule is finalized as proposed, persons who handle tramadol would be subject to the CSA's Schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, import, export, research, and conduct of instructional activities, including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research with, or conducts instructional activities with) tramadol, or who desires to handle tramadol would need to be registered with the DEA to conduct such activities, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles tramadol, and is not registered with the DEA, would need to be registered with the DEA to conduct such activities by the effective date of the final rule.

Security. Tramadol would be subject to Schedules III–V security requirements and would need to be handled and stored in accordance with 21 CFR 1301.71–1301.93 pursuant to 21 U.S.C. 821, 823, and 871(b).

Labeling and Packaging. All labels and labeling for commercial containers of tramadol distributed on or after finalization of this rule would need to be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825, and 958(e).

Inventory. Every DEA registrant who possesses any quantity of tramadol on the effective date of the final rule would be required to take an inventory of all stocks of tramadol on hand as of the effective date of the rule, pursuant to 21 U.S.C. 827, 958(e), and in accordance

with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Any person who becomes registered with the DEA after the effective date of the final rule would be required to take an initial inventory of all stocks of controlled substances (including tramadol) on hand at the time of registration, pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b). After the initial inventory, every DEA registrant would be required to take a biennial inventory of all controlled substances (including tramadol) on hand, pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records. All registrants would be required to maintain records for tramadol or products containing tramadol pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR parts 1304 and 1312, including reports to Automation of Reports and Consolidated Orders System (ARCOS).

Prescriptions. All prescriptions for tramadol or prescriptions for products containing tramadol would be required to be issued pursuant to 21 U.S.C. 829 and in accordance with 21 CFR part 1306.

Importation and Exportation. All importation and exportation of tramadol would need to be done in accordance with 21 CFR part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958.

Liability. Any activity with tramadol not authorized by, or in violation of, the CSA, occurring on or after finalization of this proposed rule would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity,

minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule will not have tribal implications warranting the application of Executive Order 13175. The proposed rule will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this proposed rule is to place tramadol, including its salts, isomers, salts of isomers, and all isomeric configurations of possible forms, into Schedule IV of the CSA. No less restrictive measures (i.e., non-control or control in Schedule V) would enable the DEA to meet its statutory obligations under the CSA.

This proposed rule affects approximately 1.5 million DEA registrants. If finalized, the proposed rule on the placement of tramadol into Schedule IV of the CSA will affect all persons who handle, or propose to handle, tramadol. Tramadol handlers primarily include: manufacturers, distributors, pharmacies, individual practitioners, mid-level practitioners, and hospital/clinics. For the purpose of this analysis, the DEA assumes all legally operating manufacturers, distributors, importers/exports, pharmacies, individual practitioners, mid-level practitioners, and hospitals/clinics that handle tramadol are registered with the DEA and all distributors, importers/exports, pharmacies, individual practitioners, mid-level practitioners, and hospital/clinics registered with the DEA are tramadol handlers. While the number of

DEA registrations forms the basis of the number of businesses affected by this rule, the number of manufacturers affected by this rule is based on industry data. Other than manufacturers, the DEA-estimated “Business-to-Registrant Ratio” is used to estimate the number of businesses represented by DEA registrants, and the “Percent of Business Below SBA Size Standard” is used to determine the number of businesses that are below the Small Business Administration (SBA) size standard (or number of businesses represented by DEA registrants that are small business.” The DEA estimates that approximately 367,046 of these to be small entities. When there are no special considerations for “substantial number” or criteria prescribed by external sources, the DEA uses a general criteria based on percentage. For the purposes of this analysis, a “substantial number” is defined as greater than 30 percent. Therefore, the DEA has determined that this proposed rule will not have an impact on a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this proposed rule on small entities. Specifically, the DEA examined the registration, storage, inventory and recordkeeping, and disposal requirements for the 367,046 small businesses estimated to be affected by the proposed rule. (While approximately 1.5 million DEA registrations are estimated to be affected by this rule, 273,485 registrations are in the 10 states that currently control tramadol as a Schedule IV controlled substance under state law, with requirements that meet or exceed the DEA’s requirements for Schedule IV controlled substances. These states include Arkansas, Illinois, Kentucky, Mississippi, New Mexico, New York, North Dakota, Oklahoma, Tennessee, and Wyoming. Therefore, only approximately 1.2 million registrations are estimated to be *economically impacted* by this rule.) The DEA estimates that 298,354 small businesses total (across all States) would be *economically impacted* by this rule.

When there are no special considerations for “significant economic impact” or criteria prescribed by external sources, the DEA uses one of two general criteria, revenue-based or profit based. The revenue-based criteria are widely used, while the profit-based criteria can be used for some high-profit industries. For the purposes of this analysis the revenue-based general criteria is used, where if the cost of the rule is greater than one percent of annual revenue, the rule has a “significant” economic impact of the

business. To estimate the number of businesses “significantly” impacted by the proposed rule, the DEA first estimated the revenue level associated with the 1 percent criteria for each North American Industry Classification System (NAICS) code associated with the affected entities. Then, using the revenue profile from the 2007 Economic Census, estimated the number of businesses where the cost of the rule is one percent or more than the revenue. This methodology was applied to all NAICS codes, except manufacturers. The estimate of small business manufacturers with significant economic impact is based on publically available data for annual sales data. The DEA estimates that the proposed rule would have a significant economic impact on 573 small businesses (0 manufacturers, 47 distributors/importers/exporters, 74 pharmacies, and 452 practitioners). Based on the DEA’s estimate of 376,904 businesses to be affected by the proposed rule, and 367,046 of these estimated to be small businesses, including businesses located in states where tramadol is controlled as Schedule IV under state law, 573 (0.2 percent) of the 367,046 small businesses affected by the proposed rule are estimated to be significantly impacted economically.

The DEA examined the disproportionality of the economic impact. The DEA did not have a basis for differentiating costs for different business sizes, thus one cost estimate was made for each of the registrant business activities. The estimate suggests disproportionality, where smaller (of the small) businesses will bear a larger economic impact as a percentage of revenue. However, the DEA believes that the disproportionality will be mitigated by business volume. A smaller business will handle a lower volume of tramadol, thus requiring less secure storage.

Based on the DEA’s understanding of its registrants’ operations and facilities, the DEA estimates a non-recurring expense for system modification and initial inventory of \$172.24 for all businesses and an additional \$10,000 for secure storage for 50 percent of distributors, importers, and exporters. (Fifty percent of distributors, importers, and exporters are estimated to meet the requirements of the proposed rule without the need to expand secure storage area.) The DEA estimates these costs will have significant economic impact on 0 percent of small business manufacturers, 3.3 percent of small business distributors, 0.1 percent of small business pharmacies, and 0.1 percent of practitioners (other than

pharmacies), totaling 0.2 percent of all businesses if the proposed rule were finalized. The percentage of small businesses with significant economic impact is below the 30 percent threshold for all registrant categories.

The annual economic effect on the economy is the annual cost per business times the number of affected businesses. The DEA estimated that 306,375 businesses, in States where tramadol is not controlled, were economically affected by the proposed rule. The annual cost of \$974.39 is applied to the assumed 50 percent (588) of 1,175 Distributor/Importer/Exporters affected by the proposed rule. Annual cost of \$30.46 is applied to remaining businesses affected by the proposed rule: 51 Manufacturer, 587 Distributor/Importer/Exporter, 40,797 Pharmacy, and 264,352 businesses that employ or hold Individual Practitioner, Mid-level Practitioner, and/or Hospital/Clinic registrations. To be conservative in analysis, the higher values for annual costs of \$974.39 and \$30.46 at 7 percent discount and interest rates is used rather than the annual costs of \$698.22 and \$26.06 at 3 percent discount and interest rates. The total annual cost is estimated to be \$9,887,561.

The DEA’s assessment of economic impact by size category indicates that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), that this action would not result in any federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year[. . .]” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

- 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

- 2. Amend § 1308.14 by adding a new paragraph (b)(3) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(b) * * *

(3) Tramadol [2-(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers]—9752

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Dated: October 25, 2013.

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2013-25933 Filed 11-1-13; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 300**

[REG-144990-12]

RIN 1545-BL37

User Fees for Processing Installment Agreements and Offers in Compromise; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations that amend the provider user fees for installment agreements and offers in compromise.

DATES: The public hearing originally scheduled for October 1, 2013 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622-7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on Friday August 30, 2013 (78 FR 53702) announced that a public hearing was scheduled for October 1, 2013, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is under sections 6159 and 7122 of the Internal Revenue Code.

The public comment period for these regulations expired on September 30, 2013. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. The hearing was not held on October 1, 2013, due to the closure of the Federal Government. As of October 17, 2013, the date of the reopening of the Federal Government, there were no requests to speak. Therefore, the public hearing scheduled for October 1, 2013, is cancelled and will not be rescheduled.

Martin V. Franks,

Chief, Publications and Regulations Branch,
Legal Processing Division, Associate Chief
Counsel, (Procedure and Administration).

[FR Doc. 2013-26280 Filed 11-1-13; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Parts 1910 and 1926**

[Docket No. OSH-2013-0005]

RIN No. 1218-AC77

Updating OSHA Standards Based on National Consensus Standards; Signage

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; withdrawal.

SUMMARY: With this notice, OSHA is withdrawing the proposed rule that accompanied its direct final rule revising its signage standards for general industry and construction.

DATES: Effective November 4, 2013, OSHA is withdrawing the proposed rule published June 13, 2013 (78 FR 35585).

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Contact Frank Meilinger, Director, OSHA Office of Communications, Room N-3647, U.S.

Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

Technical information: Contact Ken Stevanus, Directorate of Standards and Guidance, Room N-3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693-2260; fax: (202) 693-1663; email: stevanus.ken@dol.gov.

SUPPLEMENTARY INFORMATION:

Copies of this Federal Register notice: Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also is available at OSHA's Web page at <http://www.osha.gov>.

Withdrawal of the proposal: On June 13, 2013, OSHA published a companion proposed rule (NPRM) along with the direct final rule (DFR) (*see* 78 FR 35585) updating its signage standards for general industry and construction. In the DFR, OSHA stated that it would withdraw the companion NPRM and confirm the effective date of the DFR if it received no significant adverse comments to the DFR by the close of the comment period, July 15, 2013. OSHA received eight favorable and no adverse comments on the DFR by that date (*see* ID: OSHA-2013-0005-0008 thru -0015 in the docket for this rulemaking). Accordingly, OSHA is withdrawing the proposed rule. In addition, OSHA is publishing two separate **Federal Register** notices, one confirming the effective date of the DFR, and the other making minor, nonsubstantive additions and corrections to 29 CFR 1910.6, 1926.6, and 1926.200(b) and (c).

List of Subjects in 29 CFR Parts 1910 and 1926

Signage, Occupational safety and health, Safety.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this document. OSHA is issuing this document pursuant to 29 U.S.C. 653, 655, and 657, 5 U.S.C. 553, Secretary of Labor's Order 1-2012 (77 FR 3912), and 29 CFR part 1911.