

NATIONAL
PRESCRIPTION DRUG ABUSE
PREVENTION STRATEGY
2010

The
NATIONAL PRESCRIPTION DRUG
ABUSE PREVENTION STRATEGY

is presented by



CLAAD

Center for Lawful Access
and Abuse Deterrence

and endorsed by the following organizations:



American Chronic Pain Association

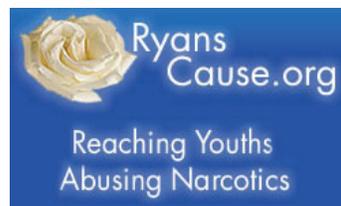
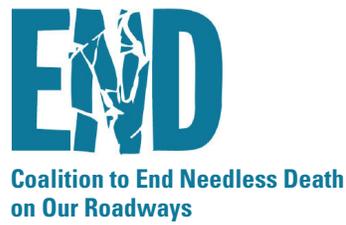
American Society of
Anesthesiologists 

AMERICAN SOCIETY FOR
Pain Management
Nursing



Dads Against Drug Dealers





For our kids' sake



The Center for Lawful Access and Abuse Deterrence (CLAAD) is a not-for-profit corporation. CLAAD has not sought recognition as a tax-exempt organization but is operated exclusively for educational purposes in accordance with Section 501(c)(3) of the Internal Revenue Code.

The principal writers of this report were Michael C. Barnes, Esq.; Andrea G. Barthwell, MD; Jennifer Marson; and Florence C. Paillard, PhD.

Through its 2009 National Prescription Drug Abuse Prevention Policy Consensus Meeting and direct interviews, the Center for Lawful Access and Abuse Deterrence sought input from the following organizations in researching and drafting this document: Alliance of State Pain Initiatives; American Academy of Pain Management; American Academy of Physician Assistants; American Society of Anesthesiologists; Americans for Safety and Efficacy; Analgesic Solutions; Dartmouth Center on Addiction Recovery and Education; Drug Free America Foundation; Educating Voices, Inc.; Federation of State Medical Boards, Inc.; American Pharmacists Association; Iraq and Afghanistan Veterans of America; King Pharmaceuticals, Inc.; National Association of Drug Diversion Investigators; National Family Partnership; National Masonic Foundation for Children; National Sheriffs' Association; Northeastern University Department of Pharmacy Practice; Northshore Recovery High School; Nurse Healthcare Practitioner's Association; Oregon Partnership; PhRMA; Spectrum; The Troy and Alana Pack Foundation; University of Washington Department of Anesthesiology and Pain Management; Washington State Medical Association Opioid Risk Workgroup.

Table of Contents

Introduction	6
Background	7
Policy Update	12
Risk Evaluation and Mitigation Strategies	18
Role of the Food and Drug Administration	21
Prescription Monitoring Programs	25
Pain Management as a Practice Specialty	32
Public Education	33
Patient Education	35
Medication Disposal	36
Preventing Illicit Distribution	40
Substance Abuse Treatment	45
Preventing Disparities in Health Care	47
Research	48
Conclusion	52
Recommendations	53
References	58

Introduction

Prescription medications are prevalent in homes throughout America. Although prescription medications can be easily obtained through legal channels, in contrast to illegal drugs, public health and safety rules do not mandate keeping them secure, disposing of them properly, or being cognizant of their potential risks.

A lack of knowledge in using prescription medications as well as holes in oversight of prescription distribution have also contributed to an increasing rate of prescription drug abuse and related harmful consequences.¹ One indicator of the significance of this problem is the recent finding that more people now die from drug-related causes than car accidents in 16 states.²

Diversion, or the illegal redirection of prescription medications away from the legal channels of distribution, leads to much of the illegal consumption of prescription medications. One study conducted between 1999 and 2004 found that 90 percent of unintended overdose cases studied involved opioid pain relievers, and less than half of these medications had been prescribed to the individual who overdosed.³

About 70 million Americans currently live with chronic pain,⁴ and many are undertreated.⁵ The United States is facing a paradoxical problem: Abuse and diversion of prescription pain relievers is rampant while many legitimate pain patients who need pain relievers do not have adequate access to care. There is a need for greater

controls barring access to prescription medications to individuals who will divert or abuse them. These controls, however, need to be designed to avoid hindering access to prescription medications for those who have a legitimate need for them.

The Center for Lawful Access and Abuse Deterrence (CLAAD) seeks to prevent prescription drug abuse while protecting safe and legal access to prescription medications by fostering collaboration among the many sectors of society concerned with this issue.

To identify effective strategies for preventing prescription drug abuse while protecting legitimate patient access to care, CLAAD, in December of 2009, convened experts and key opinion leaders representing various stakeholders. Over 40 groups present at the meeting represented law enforcement, health care practitioners involved in pain management, pharmacists, pharmaceutical companies, educators, and drug policy makers. The objective of the meeting was to reach a consensus on the most appropriate strategies that would help prevent prescription drug abuse while preserving lawful patient access to vital medications. Some of the most discussed topics included Risk Evaluation and Mitigation Strategies (REMS), prescriber education, prescription monitoring programs (PMPs), and medication disposal. The conclusions from the meeting—and recommendations set forth in this document—are based on published reports and expert input.

Background

Definitions

Pain relievers

This document addresses the abuse of all types of medications but focuses heavily on prescription pain reliever abuse, which constitutes 75 percent of the prescription drug abuse problem.⁶ The term “pain relievers” refers to opioid analgesics such as hydrocodone, oxycodone, morphine, fentanyl, hydromorphone, and methadone.*

Prescribers

“Prescribers” include not only physicians, but also nurse practitioners and physician assistants, who have prescribing authority in most jurisdictions. These members of the health care community facilitate patient access to care, especially in rural and low-income areas.^{7,8}

Abuse and misuse

The term “prescription drug abuse” is defined herein as “the intentional self-administration of a medication for a nonmedical purpose such as ‘getting high.’”⁹

This definition includes all degrees of medication use with the intention of experiencing a high, from teens swallowing pills from medicine cabinets to inveterate

addicts ‘shooting’ morphine. Abuse and nonmedical use are synonymous for the purpose of this article.

It is important to distinguish abuse from misuse, which is the use of a medication for a medical purpose other than as directed or indicated, whether willful or unintentional, and whether harm results or not.⁹ Misusing medications includes behaviors such as self-medicating without a prescription, using the medication for another indication than that for which it was prescribed, and increasing the dose of a prescribed medication. Terms such as “inappropriate use” do not distinguish the motives for the use (whether it is to get high or to treat a medical condition). Unfortunately, some documents, such as the National Survey on Drug Use and Health (NSDUH), use the terms abuse, misuse, and nonmedical use interchangeably.

Addiction and dependence

“Addiction” is defined as “a primary, chronic, neurobiologic disease [...] characterized by behaviors [such as] impaired control over drug use, compulsive use, continued use despite harm, and craving.”

Physical dependence, alternatively, is defined as “a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.”¹⁰

*Hydrocodone is the active ingredient in Vicodin® and Lortab®; oxycodone is the active ingredient in OxyContin® and Percocet®; morphine is the active ingredient in MS Contin®; fentanyl is the active ingredient in Actiq®, Duragesic®, and Fentora®; and hydromorphone is the active ingredient in Dilaudid®.

Though sometimes interrelated, addiction and physical dependence are not always co-occurring conditions. A person can be addicted without being physically dependent, or vice versa. The distinction between physical dependence and addiction is particularly important when addressing patients with pain. Some patients with chronic pain may be physically dependent on prescription pain relievers in order to carry out daily tasks; however, these patients may not experience craving, compulsive behavior, or other signs of addiction. Without health care providers' recognition of this distinction, addiction can be over-diagnosed.⁹

Trends in prescription drug abuse

Statistics from the National Survey on Drug Use and Health

About 2.5 million Americans began using prescriptions nonmedically in 2008, representing an average of 7,000 Americans who abused prescriptions for the first time every day in that one-year span.⁶

One reason for this rapid rise in prescription drug abuse is that Americans are viewing prescriptions as less dangerous. Adolescents are erroneously viewing prescription medications as a relatively safe way to experience euphoric side effects, while young professionals are abusing stimulants to get ahead in their careers, and military personnel are misusing prescription medications to help them cope with combat deployment or trauma.

Students are increasingly using prescription medication to enhance their performance on tests and homework, a practice known as "academic doping." A 2007 study of college campuses found that seven percent of undergraduates had used a prescription for Attention Deficit Hyperactivity Disorder (ADHD) for a nonmedical purpose. In 2008, 2.9 percent of American adolescents

aged 12 to 17 and 5.9 percent aged 18 to 25 had used prescription medications for nonmedical purposes in the last month.⁶

Young, motivated professionals are discovering that taking amphetamines increases their concentration and productivity more than does a shot of espresso. Eleven to 15 percent of adults in their twenties admit to using prescription medications for purposes other than those for which they were prescribed.¹²

Military personnel abusing prescription medications

Military service members are abusing prescription medications in even larger proportions than either adolescents or young professionals. In a recent survey, about 25 percent of soldiers admitted to abusing prescription medications within a one-year period.¹³ In that same period, 20 percent of marines also said they had abused prescription medications. The survey showed that pain relievers were the most abused substances in the military, at a rate triple that of marijuana or amphetamines, the next most widely abused substances. Research suggests that the heightened number of military personnel who abuse prescription medications is due to the stress relieving properties of certain prescriptions that help members of the military cope with deployment and trauma.¹³

Consequences of prescription drug abuse

Abuse of prescription medications, and pain relievers in particular, can result in serious health outcomes such as addiction, overdose, and death. In 2006, abuse of prescription opioids accounted for approximately 170,000 drug-related emergency department visits. Prescription drug abuse patients accounted for approximately 91,000 admissions to substance abuse treatment facilities in 2007, which is a five-fold increase from 1997. The number of overdose deaths from opioid pain relievers tripled from 1999 to 2006. This figure



amounts to almost 14,000 deaths yearly, or 7.8 deaths per 100,000 people. The death rate from pain reliever overdoses now exceeds overdose deaths due to cocaine and heroin.^{17,18}

Economic burden of prescription drug abuse

Prescription drug abuse has an enormous impact on society. It is responsible for decreased productivity and absence from work, health care costs, and law enforcement and criminal justice costs. The total costs of abusing prescription opioids are estimated at \$8.6 billion annually (in 2001 dollars). These costs include \$4.6 billion annually in workplace costs (due to lost wages, reduced productivity, and lower employment); \$2.6 billion in health care costs; and \$1.4 billion in criminal justice costs (law enforcement and correctional facilities).¹⁹ Another study showed that, in the early 2000s, the annual direct health care costs amounted to \$16,000 per prescription opioid abuser versus \$1,800 for nonabusers who had at least one insurance claim.²⁰

Source of prescription medication for abuse

Novice and non-addicted prescription medication abusers (oftentimes teens) regularly obtain prescription medications from their home, family members, friends, and prescribers.²¹ Addicted individuals, on the other

hand, report obtaining prescription medications mostly from dealers, but also substantially from friends or relatives' homes and from prescribers.²²

Doctor shopping

Individuals who abuse prescription medications often obtain their prescriptions by visiting several different health care providers and claiming to be experiencing pain. This practice, typically referred to as "doctor shopping," provides individuals with dangerous supplies of medications. Doctor shoppers themselves can be extremely dangerous, especially if they are addicted. Recently, a man who was doctor shopping for prescription pain relievers shot and killed a physician who refused to prescribe him medications.²³

Early refills

Another method of obtaining prescription medications is "shorting." This practice occurs when medication seekers ask for an early refill of their prescription, falsely claiming their prescription was not complete, they lost their medication, or they are going on vacation.^{24,25} In a 2009 study of Florida pharmacies, researchers found that pharmacists rarely over- or under-fill despite patients' complaints of being shorted.²⁶

Medication resale

Medication resale is now a significant source of prescription medication diversion. Instead of obtaining prescriptions from prescribers, people who abuse medications often find a ready supply from patients who legally obtained their medications. Individuals can sell their prescription medications on the black market for considerably more than they or their insurance providers paid for them. For example, the same quantity of OxyContin® that costs \$1,100 at the pharmacy can be sold illicitly for \$8,000.²⁷ Prescription resale is such a prevalent practice, in fact, that “pill ladies” is now a recognizable term for older women who illegally sell their prescriptions to make extra money.²⁸

Pill mills

In response to a heightened focus on illicit drugs by law enforcement, the demand for diverted legal medications has risen substantially.²⁹ One outcrop of this development is that dubious controlled substance dispensers posing as pain clinics have sprung up across the country. These organizations, called “pill mills,” have become very prevalent in south Florida in particular. They are often owned by someone other than a physician to circumvent regulations. They can further avoid government oversight by accepting only cash payments, bypassing supervision that applies only to insurance-accepting institutions.²⁹

Pill mills prescribe and often dispense pain relievers with little or no evidence of a medical need for the medications. Pill mill prescribers spend little time with patients (who may fake illnesses and complain of nonexistent pain), conduct an inadequate exam, prescribe a cocktail of various opioids to the patient, and directly dispense the pills. These appointments and exams are performed to provide apparent legitimacy when investigated by authorities.

The abundance of pill mills in south Florida has spurred drug dealers and users to travel from several states away to take advantage of the ease of access to prescription medications. From August 2008 to November 2009, a new pain clinic opened every three days in south Florida,²⁹ with oxycodone being the controlled substance of choice. Pain clinics dispensed almost nine million doses of oxycodone in south Florida in the second half of 2008, most of which is believed to be dispensed by pill mills.²⁹

The results of pill mill proliferation are distressing. Prescription drug abuse commonly leads to the use of more than one medication at a time, which increases the likelihood of overdose. Autopsy results showed that almost 5,000 deaths were related to prescription medications in south Florida in 2008.²⁹

Undertreatment of substance abuse

In 2006, 1.7 million Americans were classified as abusing or being dependent on prescription pain relievers, yet only 601,000 (35 percent) underwent substance abuse treatment.⁶ Two factors may explain the discrepancy between those who need treatment and those who receive it. First, the rapid increase in prescription drug abusers has left the substance abuse treatment community inadequately prepared. Second, individuals overlook prescription drug abuse because it is not commonly seen as a serious problem. Even health care professionals can be indolent in ensuring treatment of prescription drug abuse. A 2006 study showed that over 50 percent of individuals admitted to the emergency department for prescription drug abuse-related emergencies were treated and immediately released, while only 30 percent were admitted to inpatient hospital units for continuing care.¹⁵ These figures suggest that many individuals who abuse prescription medications are inadequately treated.

Drug Deaths Outpace Car Crashes in More States

Associated Press (reprinted with permission)
Sept. 30, 2009

(Atlanta, GA) Drug-related deaths outnumber those from motor vehicle accidents in a growing number of states, according to new government data that highlight a shift in the top cause of deaths after disease and illness. Crashes still cost more lives nationwide, but state-by-state calculations show the rate of drug-induced deaths outpaced vehicle accidents in 16 states in 2006, up from about a dozen states the year before and eight in 2003.

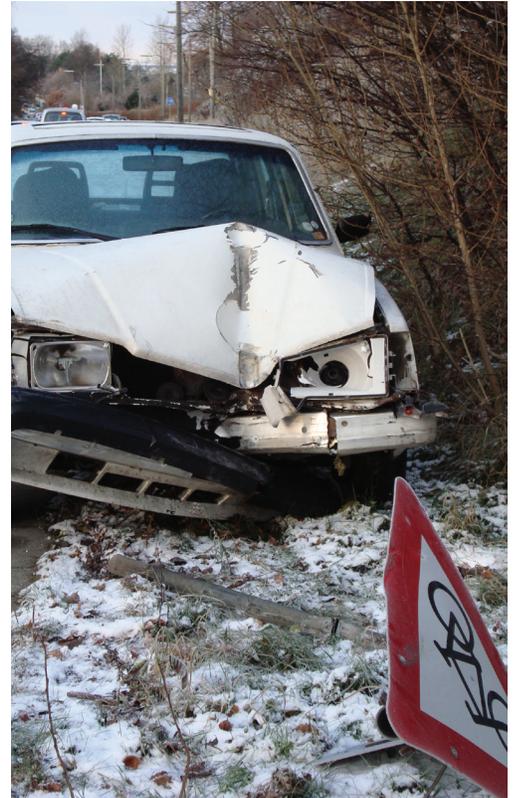
Drug overdoses make up the vast majority of the drug-related deaths, and there was a sharp increase in fatalities tied to cocaine and to drugs known as opioid analgesics -- including methadone, fentanyl, sedatives and prescription painkillers like Vicodin® and OxyContin®.

From 1999 to 2006, death rates for opioid analgesics increased for every age group. Deaths from methadone alone increased sevenfold, the U.S. Centers for Disease Control and Prevention said in a report released Wednesday. Based on death certificate data, CDC researchers counted more than 45,000 U.S. deaths from motor-vehicle crashes in 2006, and about 39,000 from drug-induced causes. The CDC does not have finalized data for 2007 or subsequent years.

About 90 percent of those drug fatalities are sudden deaths from overdoses, but the count includes people who died from organ damage from long-term drug use or abuse. The 2006 death counts and death rates were higher for drugs than for vehicle accidents in Massachusetts, New Hampshire, Rhode Island, Connecticut, New York, New Jersey, Maryland, Pennsylvania, Ohio, Michigan, Illinois, Colorado, Utah, Nevada, Oregon and Washington.

It's not clear why certain states have seen such a shift. There are probably a variety of reasons, and the explanation may vary a bit from state to state, said Bob Anderson, chief of the mortality statistics branch at the CDC's National Center for Health Statistics. Part of the story is that traffic death rates are going down. The death rate for people killed in motor vehicle crashes decreased by about 6.5 percent from 1999 through 2006 -- from 15.3 per 100,000 to 14.3 per 100,000, according to National Highway Traffic Safety Administration data.

Declines in motor vehicle fatalities "are considered one of the great public health triumphs" of the last few decades, said Margaret Warner, an epidemiologist who co-authored the new CDC report.



Policy Update

Government Accountability Office Medicaid Fraud Report

Evidence of Medicaid fraud

Medicaid, the government-funded health insurance plan that helps low-income individuals pay their medical bills,³⁰ is particularly susceptible to fraud involving prescription medications. Individuals diverting or abusing prescription medications acquire them from prescribers using Medicaid to cover the costs, spending tax payer dollars to do so.

A study of Americans in five states³¹ showed that approximately 65,000 individuals had visited six or more doctors to obtain the same type of controlled substances from 2006 to 2007. The individuals in this study alone incurred a total of \$63,000 in Medicaid charges. The same study found that 65 physicians banned from Medicaid charged \$2.3 million to Medicaid in that same one-year period. Additionally, from 2006 to 2007 Medicaid paid over \$700,000 for prescriptions that were prescribed by dead physicians or filled by dead patients.

Recommendations for Medicaid fraud prevention

The solution to Medicaid fraud is a reorganization of the current Medicaid oversight system, the Drug Utilization Review (DUR). Medicaid needs to more effectively track and communicate information about individuals who illegally obtain prescription medications

to public safety and health authorities to prevent diversion of medications paid for by Medicaid. **In order to accomplish this, the DUR should keep up-to-date databases on Medicaid providers and beneficiaries, record debarred providers and institutions, and detect duplicate enrollment of beneficiaries across state lines.**³¹

Policy recommendations for law enforcement

Law enforcement participation is an integral component of the effort to prevent prescription drug abuse. Recent cases of physicians who have been criminally charged with prescribing opioid pain relievers in violation of the law have raised concerns among prescribers. Consequently, some physicians have become reluctant to prescribe opioids for fear of sanctioning. This fear could potentially cause undertreatment. Therefore, balanced and careful intervention of law enforcement is needed to successfully prosecute rogue prescribers while ensuring that appropriate care is not diminished.

To this end, the Federation of State Medical Boards (FSMB) has developed a comprehensive set of strategies.³² The FSMB recommends that law enforcement perform all of the following:

- Distinguish criminal intent from medical error among health care providers using the FSMB's Procedural Template³² (See Table 1)

Table 1. FSMB's Procedural Template for Achieving the Policy of Balance* (reprinted with permission)

1. Assess the medical-needs aspect of the suspect behavior. Is the doctor knowingly prescribing controlled substances in the absence of or grossly in excess of medical needs? How do you know this fact?

At this point, unless there is a total absence of evidence of medical need, a consult with medical experts may be in order. Has the case been handled by the State Medical Board? Should it be reviewed by the Board prior to proceeding? Do you have a pain specialist to consult? Consultation with a doctor familiar and comfortable with pain management is important; not every doctor is an expert in this field (in fact, competency of physicians in pain management is quite variable).

2. Assess the medical-practice aspect of the suspect behavior. Does the suspect doctor take any of the steps required by normal practice standards (history, examination, record keeping, tests, lab work)?

As a law enforcement officer you must be familiar with medical standards of practice or have professionals with whom you can consult regarding those standards. If the patient presents with pain, and the suspect doctor complies with even minimal practice standards, the prescribing of controlled substances is probably NOT a criminal matter. Issues of poor record keeping, inadequate history-taking or skipped examinations are more properly considered by a state medical board.

If the doctor is reckless and re-prescribes when prescriptions are "lost" or "stolen," even if the patient is selling on the street, the doctor's actions will be criminal only if there is legal knowledge on his part.

Moreover, prescribing controlled substances to a patient with an addiction disorder or with known substance abuse is not per se illegal. For example, though such medical treatment would be complicated, a doctor could prescribe opioids to a drug dependent person with cancer or AIDS for the purpose of treating the pain. That doctor would not be prescribing for a non-medical purpose.

3. Assess the compensation aspect of the suspect behavior. Aside from and in addition to the normal fees and reimbursements associated with the practice of medicine, like office visit charges, fees for tests and time, does the suspect doctor receive anything of value in exchange for his prescription of controlled substances? For example, are his office visit charges inflated for a "pain" patient? Does he take cash? Is he trading drugs for personal favors? Is he splitting drugs with patients?

4. Carefully assess any negative medical outcomes. Even when a patient dies from an overdose involving prescription controlled drugs, the matter may be more appropriate for the state medical board, and steps 1, 2 and 3 above should receive primary emphasis. Medical outcomes, good or bad, are best evaluated and judged by medical experts, particularly in a field as complicated as pain medicine, and where patient behavior can play a significant role in such an outcome.

5. Decide whether to file criminal charges. Given answers to steps 1-4 above, if the doctor is prescribing for other than a medical reason, does not perform examinations or take medical histories (or if the exams and histories do not indicate medical need), and if the doctor has also been receiving extra financial or personal benefit from prescribing controlled drugs, criminal prosecution is appropriate. Law Enforcement personnel should take steps necessary to protect patients at this stage.[†]

[†]One of the consequences of the investigation and prosecution of physicians for prescription drug violations is that, often, patient records are seized for review or to use as evidence. In those cases, genuine pain patients are unable to immediately retrieve their records so that they can receive treatment from another physician. For this reason, it is suggested that law enforcement agencies establish a procedure to copy seized records and make them available to patients as soon as possible, and to post notices or otherwise advise patients how to retrieve their medical records.

*The original template was developed by Drew Edmondson, Attorney General of Oklahoma.

- Seek advice from medical experts
- Employ technological tools such as electronic prescription monitoring programs (PMPs)
- Collaborate with other agencies that may have already collected useful information

Federal legislation

Medication disposal

Two bills offering different avenues of prescription medication disposal were introduced in the U.S. House of Representatives in early 2009. Both bills would amend the Controlled Substances Act. H.R. 1191, sponsored by Rep. Jay Inslee (D-WA-1), would require the Drug Enforcement Administration (DEA) to create five different medication disposal programs to serve as models for individual states.³³ If this bill were passed, each state would then be required to implement one or more of these disposal programs. This bill also would ban pharmaceutical companies from recommending disposing of medications by flushing, as this practice has been linked to the presence of pharmaceutical traces in drinking water supplies.³³ Rep. Bart Stupak's (D-MI-1) bill, H.R. 1359, would require the DEA to provide prescription medication users or long-term care facilities with an authorized location or individual to accept and dispose of their outdated or unwanted medications.³⁴ While these bills are a positive effort towards reducing the amount of prescriptions available for diversion, neither bill offers methods for financing or management of these proposed disposal systems. Both bills currently remain in committee. For more details and CLAAD's recommendations on medication disposal, see page 36.

Methadone Treatment and Protection Act of 2009

Methadone, a synthetic opioid, has been used to treat opioid addiction for almost 40 years, yet it has recently been used carelessly for pain relief, leading to deaths.³⁵

The long half-life of methadone is the most concerning characteristic. Although methadone provides pain relief for six to 12 hours, its half-life is eight to 59 hours, which can yield potentially dangerous levels of the medication in the bloodstream when individuals take more methadone to relieve pain without waiting for the body to process the prior dose of methadone thoroughly.

Methadone-related deaths increased almost four fold from 786 in 1999 to 4462 in 2005, the fastest of all prescription opioid-related deaths. The 15 to 24 age group experienced the fastest increase in methadone-related deaths, multiplying 11 times in the five-year period.³⁶

The Methadone Treatment and Protection Act of 2009, introduced by Sen. John Rockefeller (D-WV), suggests legislative steps to curb the growing rate of methadone deaths.³⁷ If the Act were passed, it would create an opioid-related death registry. It would additionally create a commission to establish consumer and health care provider education and safe-use standards. The provisions of the Methadone Treatment and Protection Act will not be necessary if the FDA appropriately exercises its congressionally granted authority to require risk evaluation and mitigation strategies (REMS) for opioid medications, including methadone. For more details and CLAAD recommendations on REMS, see page 18.

Implementation of the Ryan Haight Act

New DEA regulations implementing the Ryan Haight Act, which regulates domestic internet pharmacies, went into effect in April 2009. The most significant new provisions of this act are requirements that controlled substances be dispensed only after proof of an in-person medical exam has been established, and that any person



who operates a domestic internet pharmacy must comply with specific DEA registration requirements.³⁸

State legislation

Several states have recently proposed legislation that aims to address prescription drug abuse. Notably, Florida, Utah, Virginia, and West Virginia have made significant gains in focusing governmental resources toward this end. These states are commendably making prescription drug abuse a priority, and the bills they are proposing should serve as examples of steps every state should be taking to tackle this nationwide concern.

Florida has passed legislation that will activate a prescription monitoring program in December of 2010. Florida legislators have proposed other bills that focus on stopping the proliferation of pill mills (see page 10). One such bill would require that only physicians with a clean medical record may own pain clinics.³⁹

A bill before the Utah House of Representatives requires any physician licensed to prescribe medication in the state to register with the state prescription monitoring program and learn how to use it. Currently 12,000 individuals are licensed to provide health care in the state, but only 20 percent of them are registered with the prescription monitoring program, and only about half of those use it. At least seven bills have been proposed in Utah to address prescription drug misuse, abuse, overdoses, and impaired driving.⁴⁰

In Virginia, a law passed in 2009 requires pharmacies and physicians to report their dispensing of any Schedule II to IV controlled substances to the prescription monitoring program.⁴¹

West Virginia, which currently holds one of the highest fatal medication overdose rates in the country, has organized a special task force of state senators to put together bills to prevent the diversion of prescription medications. One of the seven measures the task force proposed requires prescriptions to be written on tamper-proof pads, while another increases penalties for using false information to obtain medications. A third bill gives pharmacists access to prescription medication data to determine whether patients are obtaining prescription medications from multiple sources.⁴²

Utah prescription-drug deaths drop

Carrie A. Moore

Deseret News (reprinted with permission)

June 4, 2009

You may know her as the neighborhood soccer mom, who has the lowdown on what's happening in your area. Maybe he's the guy two streets over with the perfect lawn who hosts family barbecues and leads the Scout troop.

There were 40 more Utahns alive last year in the Beehive State than in 2007 because they didn't overdose on prescription pain medication. They didn't make the news or call 911. Their families haven't been to the morgue, the funeral home or the cemetery.

State health officials said this week there's really no accurate profile or predictor of who will abuse prescription drugs, but they do know that the number of deaths in Utah decreased 12.6 percent from 2007 to 2008.



Prescription Pain Medication
What you need to know.

Last year, unintentional prescription pain medication overdoses were the number one cause of injury deaths in Utah, even more than motor vehicle crashes.

How you can prevent death from overdose:

1. Never take prescription pain medication that is not prescribed to you
2. Never adjust your own doses
3. Never mix with alcohol
4. Taking sleep aids or anti-anxiety medications together with prescription pain medication can be dangerous
5. Always tell your healthcare provider about all medications you are taking from any source
6. Keep track of when you take all medications
7. Keep your medications locked in a safe place
8. Dispose of any unused medications

Signs of abuse/misuse:

- Experimenting with medications recreationally
- Sharing prescriptions with others
- Taking too much medication to try to control pain
- Mixing prescription pain medications with alcohol, street drugs, or other prescription medications

Signs of addiction (the 4 C's):

- Impaired control over drug use
- Compulsive use
- Continued use despite physical, mental, or social harm
- Craving

Signs of when to seek medical help:

Call 911 immediately if a person demonstrates any of the following signs while on prescription pain medication:

- Snores heavily and cannot be awakened
- Has trouble breathing
- Exhibits extreme drowsiness and slow breathing
- Has slow, shallow breathing with little chest movement
- Has a speeded up or slowed heartbeat
- Feels faint, very dizzy, confused or has heart palpitations

An antidote is available that can reverse the overdose. Call for medical help (call 911) immediately.



www.useonlyasdirected.org

Copyright © Utah Department of Health

It's the largest dip in non-illicit-drug overdose deaths in Utah in the 14 years, and though officials can only guess at why the number dropped after a jagged climb in recent years, they're still concerned about the 277 people who did die of what they consider "a preventable epidemic."

Erin Johnson, Utah Department of Health manager for the prescription medication program, said the majority of prescription-drug overdose deaths occur in Utahns ages 30 to 50, and that the gender split is roughly 50-50. Prescriptions that tend to kill those who overdose include drugs like oxycodone (such as OxyContin® and Percocet®), hydrocodone (such as Lortab® and Vicodin®) and methadone.

Utah Use Only As Directed is thought by some to have contributed to the drop in prescription drug abuse in the state with outreach and awareness efforts such as this information card.

Such deaths are “notably present throughout the state,” while those dying of illicit drug use are located in only nine counties, she said.

Because the numbers of prescription-drug deaths have grown rather rapidly until the past year, the health department has undertaken a study with the families of those who die from overdose, looking to determine what was happening in the deceased person’s life when he or she died, whether there was a history of substance abuse, why he or she was taking the drugs and any other underlying causes.

In the past, the only information health officials gathered on those who died was whether or not they had a legitimate prescription for the drug or drugs they had taken, she said.

“We want to develop a profile of them, so we’re interviewing next of kin for anyone who has died in last six months,” Johnson said. They’re trying to determine whether related health issues play into the deaths, including whether the deceased had sleep apnea or a higher body mass index.

While officials can’t know for sure why the number of deaths dropped in 2008, the health department did launch its “Use Only As Directed” public awareness campaign in May 2008, hoping to educate Utahns about the potential dangers of abusing prescription pain medication. They believe those efforts “have begun to pay off,” said Dr. David Sundwall, health department executive director.

Since word of the guidelines has spread, Utah has received requests from some 20 states for information about the initiative.

The issue has become so severe nationwide that by 2004, at least 20,000 unintentional drug poisoning deaths occurred annually, compared with just more than 17,000 homicides, according to the Centers for Disease Control and Prevention.

Dr. Leonard J. Paulozzi, a CDC epidemiologist, told a congressional panel in October 2007 that while cocaine- and heroin-related deaths had grown slowly or stabilized over time, prescription drug deaths rose from 2,900 in 1999 to 7,500 in 2004, a 160 percent increase in five years. By 2004, those deaths outnumbered the total deaths involving heroin and cocaine, he said.

Earlier this year, the health department released a set of clinical guidelines on prescribing opioids for pain, directed at health-care practitioners as a way to help limit the quantity and availability of the medications. Since word of the guidelines has spread, Utah has received requests from some 20 states for information about the initiative.

Risk Evaluation and Mitigation Strategies

Summary of events

Food and Drug Administration Amendments Act

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which authorizes the Food and Drug Administration (FDA) to impose new requirements to mitigate the risks of certain prescription medications.⁴³ These measures, termed “risk evaluation and mitigation strategies” (REMS), require the manufacturers of certain prescription medications to develop comprehensive plans to ensure the benefits of a medication outweigh its associated risks.⁴⁴

Risk evaluation and mitigation strategy contents

Standard REMS elements include a Medication Guide (or patient package insert) for distribution to patients when the medication is dispensed, and a communication plan to inform health care providers of known or potential serious risks.⁴⁴

The FDA may require that the REMS for a drug include “elements to assure safe use” (ETASU) if the drug would otherwise be too inherently dangerous to allow on the market.⁴⁴ These ETASU shall be commensurate with the specific serious risk listed in the labeling of the drug, not be unduly burdensome on patient access to the drug, and have minimal impact on the health care delivery system.⁴⁴ ETASU may include provisions that:

1. Health care providers who prescribe the medication have particular training, experience, or special certifications;
2. Dispensers be specially certified;
3. The medication be prescribed only in specific health care settings;
4. The medication be dispensed only to patients for whom safe-use conditions are verified;
5. Patients taking the medication be specially monitored;
6. Each patient using the medication be enrolled in a registry (a program that requires registering patients before dispensing a specific medication).

Class-wide risk evaluation and mitigation proposal

On February 6, 2009, FDA notified the manufacturers of long-acting and extended-release opioid products already on the market of its intent to mandate a single REMS that would cover all long-acting and extended-release, brand name and generic opioids. The FDA’s notice applied to medications containing fentanyl, hydrocodone, hydromorphone, methadone, morphine, or oxycodone.⁴⁵

Opposition to the FDA’s approach to a class-wide risk evaluation and mitigation strategy

CLAAD opposes the FDA mandate for a one-size-fits-all REMS for long-acting and extended-release opioid medications because it lacks the flexibility

to effectively address issues unique to specific medications. Additionally:

- It contravenes the FDAAA statute provisions;
- It does not take into account the relative risks of each medication and formulation, and places identical burdens on all products; and
- It is likely to restrict patient access to care.

Legalities

The FDAAA stipulates that the **REMS must address the risks of each individual medication and its generic equivalents**, taking into account the special characteristics of each medication. The FDA lacks the authority to mandate a single REMS to cover all long-acting and extended-release opioids.

Inherent risks versus diversion and abuse

Although there is a growing problem of diversion and abuse of prescription opioids in general, each long-acting or extended-release opioid product does not contribute equally to the problem of opioid abuse in the U.S. Hydrocodone and oxycodone are the most abused opioids, followed by morphine, hydromorphone, methadone, and fentanyl.⁴⁶

For various reasons, diversion and abuse rates may differ significantly within the same opioid class. For instance, OxyContin® has a high rate of diversion and abuse,⁴⁷ which may be attributable to the prior misbranding of the medication. In 2007, several executives of Purdue Pharmaceuticals pled guilty to the federal criminal charge of misbranding and misrepresenting the risks of their oxycodone product, OxyContin®.⁴⁸

Greater risks should be associated with greater restrictions, while fewer risks should be associated with fewer restrictions. The FDA's uniform REMS approach

does not take into account the relative risks of each medication and formulation, and places identical burdens on all such products. As mandated by the FDAAA, **the FDA should evaluate each medication independently, taking into account the specific characteristics and history of the product.**

Restrictions to access

Through the FDAAA, Congress has prohibited the FDA from imposing REMS elements that would “be unduly burdensome on patient access to the drug” and directed the FDA to “minimize the burden on the health care delivery system.” A single, class-wide REMS is likely to limit patient access to medications, as all opioid medications would be subjected to the same strict measures, regardless of their respective risks and histories. The class-wide REMS may also limit manufacturer competition that could yield greater safety of medications through unique risk management plans, and reduce incentives for the development of safer formulations.

More information regarding the class-wide REMS is available in the CLAAD memo entitled “A Review of the FDA's Approach to Implementing a Class-Wide REMS for Long-Acting and Extended-Release Opioids” at CLAAD's website, www.claad.org.

The right way forward

Coordination and cooperation for risk evaluation and mitigation strategies

Congress, through the FDAAA, has not given the FDA the authority to mandate the same REMS for all long-acting and extended-release opioid medications, regardless of their unique risk profiles. The only REMS that are required to be integrated by the FDAAA statute are those for a branded medication and its generic counterparts. The FDA has the authority to waive this requirement if

it considers that this rule results in an undue burden on health care providers, patients, or medication manufacturers.

Given that an innovative medication and its associated generics have the same abuse potential, the type and stringency of strategies to assure their safe use should be similar. **Manufacturers of innovative medications and those making generic equivalents should cooperate to provide strategies that are best suited to lessen the risks of the medication under a single REMS.** This integrative effort should minimize the burden on the health care system by providing uniform communication plans, Medication Guides, and surveillance systems.

Coordinated Medication Guides and communication plans for opioids

The FDA should inform all manufacturers of long-acting and extended-release prescription opioids that the most expeditious route to FDA approval of their individual products' REMS is for the manufacturer to propose programs that reflect industry collaboration on Medication Guides and communication plans.



Role of the Food and Drug Administration

General Role of the Food and Drug Administration

The Food and Drug Administration (FDA) is responsible for approving new medications on the basis of their safety and efficacy in clinical trials, and for protecting the public by ensuring that the medications on the market are, indeed, safe and effective. The FDA must ensure that the benefits of a new medication under consideration for approval outweigh the risks.⁴⁵

Under the Food and Drug Administration Amendments Act (FDAAA) of 2007, this risk-benefit assessment considers the risks of abuse of the medication. For new medications that are considered to have significant abuse potential, the FDA regulatory role may include:⁴⁵

- Requiring that the manufacturer conduct abuse liability studies before approval to evaluate the abuse potential of the medication
- Requiring that the manufacturer develop a REMS to mitigate the risks associated with the medication (see Section on REMS for more details)
- Imposing various restrictions on indication labeling
- Mandating that certain information be included in the label

Issue guidance to industry on approaches to abuse-deterrent formulations

Abuse-deterrent formulations for opioids

Abuse-deterrent formulations (ADFs) are medications formulated to introduce some limits or impediments to intentional abuse. Two types of features currently being used in opioid ADFs are:⁵⁰

- **Physical barriers** (such as hard capsules or waxy materials) that make it difficult to tamper with (chew, grind, crush, or dissolve) the medication or extract the opioid, or render the tampered medication unsuitable for injecting or snorting; and
- **Pharmacological modifications**, which contain compounds that will induce an unpleasant effect or prevent the abuser from getting high if excess doses are ingested. For instance, some ADFs contain niacin (vitamin B3), which will cause an unlikable (but not harmful) reaction when too many capsules or tablets are swallowed, inhaled, or injected. Other ADFs use naltrexone, an opioid antagonist, which is released when the formulation is tampered with and cancels (“antagonizes”) the effect of the active opioid.

A list of some of the current ADFs available on the market and in development is presented in Table 2.⁵¹

Experience with ADFs has shown that prescription opioid abusers are less interested in products with

Table 2. ADFs of opioid medications

Name (manufacturer)	Opioid compound	Features to impede abuse
ADFs with physical barriers		
OxyContin® OP (Purdue Pharma.)	Long-acting oxycodone	Coating designed to make the drug harder to crush and snort or inject
Remoxy® (Pain Ther. & King Pharma.)	Long-acting oxycodone	Highly viscous liquid intended to resist crushing
COL-003 (Collegium Pharma.)	Long-acting oxycodone	Waxy excipient intended to resist chewing
ADFs with pharmacological modifications		
EMBEDA®* (King Pharma.)	Morphine	Contains sequestered naltrexone
Suboxone®* (Reckitt Benckiser)	Buprenorphine	Contains sequestered naloxone
TALWIN-Nx®* (Sanofi-Aventis)	Pentazocine	Contains sequestered naloxone
ELI-216 (Elite Pharma.)	Long-acting oxycodone	Contains sequestered naltrexone
ADFs with both physical barriers and pharmacological modifications		
Acurox® (King Pharma.)	Short-acting oxycodone	Proprietary technology; contains niacin

*Already on the market

abuse-deterrent features.⁵² Therefore, ADFs may have the potential to reduce the abuse of prescription opioids. Moreover, ADFs may improve patients’ access to prescription opioids, as prescribers may be less reluctant to prescribe ADFs due to their lower abuse potential. ADFs also have cost-saving potentials. It is estimated that ADFs could save from \$600 million to 1.2 billion per year, assuming a privately insured cost structure.⁵³

Developing effective ADFs for opioid medications is a public health priority, and the FDA should actively support efforts in this area.

The Food and Drug Administration’s support in developing abuse-deterrent formulations

In developing effective ADFs with no added safety risks, the pharmaceutical industry faces many technical, scientific, regulatory, and economic hurdles.

One of the most important hurdles is the lack of clear direction from the FDA on obtaining a claim of abuse deterrence, and on demonstrating effective abuse deterrence after market approval. This lack of guidance has resulted in the inability of manufacturers to market ADF qualities and features as “detering abuse.” In light of the lack of abuse deterrence claim in an ADF label, prescribers are unlikely to change their prescribing habits to favor opioid ADFs instead of traditional opioid formulations.

CLAAD has proposed that the FDA grant interim labeling to new ADFs based on data from laboratory tests and abuse liability studies using human volunteers. The FDA should grant a final label claim of abuse deterrence on the basis of post-marketing epidemiologic data proving the relatively lower rate of abuse in comparison with relevant traditional formulations.⁵⁴ More information regarding interim labeling for ADFs can be found in CLAAD’s March 24,



2010, letter to Congress, available at CLAAD's website, www.claad.org.

A petition headed by the Tufts Health Care Institute (THCI) and reflecting the opinions of various stakeholders from the public health, pharmaceutical, pain management, and research fields was submitted to the FDA in May 2009.⁵⁵ The petition specifically requested FDA's input on the following topics:

- Ways to classify ADFs based on the degree of resistance to tampering
- Preclinical studies required to support the safety of ADFs by various routes of abuse
- Human studies required to prove the abuse deterrence of ADFs
- Human studies, if any, required to demonstrate the safety and efficacy of the ADFs, if the ADF is bioequivalent to the reference medication
- Methods or studies required to assess the abuse deterrence and potential impact on patient access after market approval

CLAAD strongly supports the call for FDA guidance on approaches to abuse-deterrent opioid formulations.

Create standards for effective labeling

As regards to labeling ADFs, there are two important issues: 1) the lack of clear guidance as to the requirements for interim and full claims of abuse deterrence, and 2) the lack of clear requirements as to what needs to appear in the label and in what form. Thus, **the THCI petition suggested the FDA develop and publish guidelines for obtaining a label claim of abuse deterrence.** Obtaining a claim of abuse deterrence in the label is a crucial marketing asset to increase the use of the formulation by the prescribing community. **The FDA must also provide sample content of what needs to be included in the label of an ADF using clear, meaningful language that allows prescribers to understand the differences between the ADF and non-ADF formulations.**

Grant priority status for the review of abuse-deterrent formulations

The FDA has approved for commercialization a few ADFs (see Table 2). The approval process for these products took a long time because their FDA applications did not receive the benefits of priority review. In light of the fact that tackling prescription opioid abuse is such an urgent matter, the FDA must act with expediency in evaluating new ADFs. **To this end, the FDA should grant priority review status to ADFs for opioid analgesics and complete their new drug evaluations within six months.**

Food and Drug Administration panel acetaminophen recommendations

On June 30, 2009, the FDA assembled a group of experts to discuss safety issues associated with acetaminophen, a non-opioid used to reduce mild to moderate pain. This meeting focused heavily on reducing deadly

overdoses with acetaminophen, the leading cause of liver failure in the U.S. Indeed, acetaminophen sends 56,000 people to the emergency room annually and is responsible for 200 deaths each year.⁵⁶ Among other recommendations made by the panel, one was to eliminate from the market two of the most prescribed pain relievers, hydrocodone/acetaminophen and oxycodone/acetaminophen formulations.⁵⁶ This recommendation was based on data that show that 60 percent of the acetaminophen-related deaths are associated with prescription combination products. It is not clear yet whether the FDA will follow the panel's recommendations.

The FDA's decision will have a very important impact on the treatment of pain in the U.S. given that hydrocodone/acetaminophen and oxycodone/acetaminophen formulations are two of the most widely used pain relievers on the market.⁵⁶ Removal of these products could leave million of Americans with undertreated pain. Members of the panel who did not approve this recommendation suggested reformulating the acetaminophen/opioid combination products with a lower dose of acetaminophen to make them safer.

CLAAD does not support the removal of hydrocodone/acetaminophen and oxycodone/acetaminophen formulations from the market. In the alternative, the FDA should exercise its authority under the FDAAA to require increasingly restrictive REMS for these medications. If, after implementing basic REMS and the more restrictive elements to assure safe use (ETASU), the risks of these medications still outweighed the benefits, the FDA would be justified in removing them from the market.

Expedient creation of non-opioid pain relievers

One way to curb the abuse of prescription opioid medications is to foster the development of non-opioid medications with a relative lower potential for abuse. There is currently a significant unmet medical need for non-opioid agents for the management of moderate to severe pain.

One important advance in the field of non-opioid pain relievers is the development of cannabinoid formulations which contain natural components of the cannabis plant. One such medication, Sativex®, is intended for the relief of pain in patients with advanced cancer who have inadequate pain relief despite optimized chronic opioid therapy. This product has a relatively low abuse liability (as demonstrated by data in Canada where it has been used for many years).⁵⁷ Sativex® is currently under clinical evaluation in the U.S. along with other cannabinoid products being developed by Alexa Pharmaceuticals, Inc.; Aphios Corporation; and Insys Therapeutics, Inc.⁵⁸

CLAAD supports the development and evaluation of safe and efficacious non-opioid pain relievers. Such non-opioid pain relievers could meet patients' needs for added pain relief without introducing a new potent opioid into the market.

Prescription Monitoring Programs

Prescription monitoring programs (PMPs) are statewide data collection systems that track patient-specific prescription information. PMPs are important tools to address prescription drug abuse at the state level. PMPs allow states to track patients' information to identify behaviors that point to abuse and diversion, such as doctor shopping and pharmacy hopping (people using many different doctors and pharmacies to obtain prescription medications for diversion and/or abuse), shorting (early refills), and prescription forgery. States may also look to prescribers' information in the PMP database to track unlawful practices such as rogue prescribing and pill mills. Limited data so far suggest that PMPs reduce prescription drug abuse.⁵⁸

As of January 2010, 34 state PMPs were operating, five had enacted legislation but were not fully operational, and six were at various stages of proposing or debating PMP legislation.⁵⁹ States control who has access to PMP data and for what purpose. Persons authorized to have access usually include the patient (access to his/her own data only), health care practitioners and pharmacists (who have access to their own patients' data only), law enforcement officials (for active investigations only), and sometimes licensing boards, Attorneys General, and Medicaid (on a need-to-know basis).⁶⁰

PMPs should be developed and utilized to their full potential in all 50 states.

Expanding PMPs to all 50 states and modernizing them using grants (see below) is a very attractive solution to complement risk evaluation and mitigation strategies (REMS) (see Table 3). PMP optimization could provide many of the public health benefits of the “elements to assure safe use” (ETASU) set forth in the Food and Drug Administration Amendments Act (see page 18 above) with relatively few burdens on patient care or the health care delivery system.

Support for prescription monitoring programs by pharmaceutical companies

Given that PMPs could help the manufacturers of prescription opioids reduce the abuse of their products, pharmaceutical companies could voluntarily provide financial support to state PMPs. Funding could be channeled to states through grants administered by not-for-profit organizations such as the Alliance of States with Prescription Monitoring Programs and the National Alliance for Model State Drug Laws. In turn, grant providers would require that grant recipients employ best practices for PMPs (see Table 4) and meet specific benchmarks to receive funding.

Using California's prescription monitoring program as a model

While some observers cite privacy concerns related to California's PMP, called Controlled Substance Utilization Review and Evaluation System (CURES), specific aspects

Table 3. Providing the benefits of ETASU using PMPs

ETASU as described in REMS	PMP feature that would meet the ETASU
<i>Educating prescribers</i>	Requiring that prescribers be trained in safe prescribing, abuse prevention, and in using the PMP database
<i>Training dispensers</i>	Requiring that pharmacists be trained in patient counseling and abuse prevention, and record all Schedule II-V dispensing in the PMP database
<i>Restricting dispensing for certain medications</i>	Mandating that dispensing of Schedule II-V medications be reported to the PMP database
<i>Verifying safe-use conditions before dispensing</i>	Requiring prescribers to check patients' PMP data and dispensers to counsel patients on safe use and abuse prevention
<i>Monitoring patients</i>	Mandating periodic checks of the patient's PMP data to determine which other controlled substances the patient has been prescribed a) to prevent medication interactions and b) to detect potential doctor shopping
<i>Enrolling patients in a registry</i>	Requiring pharmacists to report each controlled substance the patient receives to the state PMP database; employing one system for all controlled substances (state PMPs with interstate data sharing capability), as opposed to one system per medication (registries are product-specific), would be more convenient and cost-effective

of this program may serve as an example of what PMPs should aim for in facilitating timely and comprehensive prescription information sharing. CURES provides real-time information access to health care providers and pharmacists who are authorized to access the online database.⁶⁰ These authorized users must pre-register with the Department of Justice before they can view Schedule II-IV controlled substance information through an automated Patient Activity Report (PAR). California further ensures up-to-date information by requiring pharmacies to submit their controlled substance data to the CURES system at least once every seven days.

To build upon the example set forth by California's PMP, **CLAAD has issued recommendations, summarized in Table 4, below, for state PMPs.** These recommendations are described more fully in the sections below.

Expanding, improving, and reinforcing prescription monitoring programs

To maximize the utility of PMPs, **PMPs should be implemented in all 50 states and the District of**

Columbia, and have interstate data sharing capabilities.

Starting a PMP costs around \$350,000, and maintaining one costs between \$100,000 and \$1 million annually.⁶¹

Every state must allocate adequate resources to operate an effective PMP. One important source of funding for PMPs is the National All Schedules Prescription Electronic Reporting Act (NASPER), which was enacted in 2005 and is administered by the U.S. Department of Health and Human Services (DHHS).⁶⁰ This grant program enables states to create a PMP database or enhance an existing one. Congress allocated \$2 million in FY 2009 to start the NASPER grant program and allocated the same budget in 2010.⁶⁰

Another vital source of federal funding for PMPs is the Hal Rogers Prescription Drug Monitoring Program (HRPDMP) administered by the U.S. Department of Justice. The HRPDMP provides three categories of grants: planning, implementation, and enhancement. To be eligible for funding, the state must already have a statute or regulation permitting the establishment of a PMP. Since its inception in 2002, the HRPDMP has awarded over 100 grants for approximately \$48 million.

Table 4. CLAAD's recommendations for PMPs

- PMP in all 50 states and District of Columbia
- Include all Schedules II to V medications
- Interstate operability and data sharing
- Access limited to prescribers, pharmacists, and law enforcement (only as part of an active investigation)
- Mandatory training for all prescribers on prescription drug abuse prevention, safe prescribing, and interpretation of PMP data
- Mandatory reporting of dispensing
- Mandatory checking of patients' PMP data before first prescribing Schedule II to V medications, and periodically thereafter
- Real-time data access
- Patient identity verification prior to dispensing the medication to the patient
- Verification of safe use conditions and patient counseling by pharmacists (or other dispensers)

Congress allocated approximately \$5 million for FY 2010 for the grant program (no increase over 2009 levels), with up to \$400,000 per applicant.⁶³

Jurisdictions that do not have a PMP (District of Columbia, Delaware, Maryland, New Hampshire, South Dakota, and Washington)⁶⁰ should take advantage of these grants to start or resume a program, while **states that have a PMP but lack interstate data sharing capabilities and other best-practice features should seek funding to improve their programs.** Interstate data sharing systems should allow the monitoring of patients across state lines to curb doctor shopping across states, still allowing each state to regulate the practice of medicine within its boundaries.

All Schedule II-V medications

Considerable differences among states exist as to the types of scheduled medications state PMPs record. For example, New York, which operates one of the earliest established PMPs, monitors Schedule II, III, IV, and V medications. In contrast, the Massachusetts PMP only monitors Schedule II medications.⁵⁹ Some Schedule IV

and V products contain benzodiazepines or low levels of opioids (such as codeine, ethylmorphine, and opium),⁶⁴ which could be used by initiates experimenting with drugs or novice abusers. Also, the number of emergency department visits due to overdoses of Schedule IV drugs is around the same as that for Schedules II and III medications and is increasing. Non-monitored controlled substances could act as an easy point of entry into the downward cycle of abuse. Preventing initiation is especially important given that prescription opioid abusers are at great risk of progressively using stronger opioids and too often “graduate” to heroin.⁶⁶ **CLAAD recommends that state PMPs monitor Schedules II through V controlled substances.**

Requiring prescribers to check patients' history before prescribing controlled substances

Many practitioners prescribe opioid medications in good faith to abusers or diverters posing as patients by faking symptoms. Health care providers do not have any other data-driven means than PMPs to help determine whether the patient they are examining is doctor shopping.

Many doctors do not use PMP data for various reasons: 1) the PMP in their state does not provide data to physicians; 2) they may not know that the PMP exists or that they can use it, 3) using it is not mandated by law; 4) it is of minimal value to their practice because the program does not allow real-time access to data, 5) they are afraid to lose legitimate patients who will feel stigmatized or offended by the suspicion.⁶⁷ In order to take full advantage of their PMPs, **state laws should require all prescribers to check patients' prescription history before first prescribing controlled substances, to evaluate the patients' use of prescription medications.** Given that such a law would apply to

Pack's tragedy led to California's prescription monitoring program, CURES

In 2003, Bob Pack's two children Troy, 10, and Alana, 8, were killed by a woman who was driving under the influence of alcohol and Vicodin®. As a result of this personal tragedy, Pack began advocating for changes in prescription medication laws and ultimately played a significant role in effecting major legislative changes in his home state of California.



Troy and Alana Pack were killed by an individual driving under the influence of prescription medications.

Pack began his journey by pursuing the question of how the driver obtained the Vicodin® and how future deaths related to prescription medications could be prevented. His solution was to use an electronic software program that would provide a safe and expedient way to share patient medication records via the internet. "The actual technology and access to the data are what I thought could be accomplished from the very beginning," Pack said.

In honor of his children, Pack set up the Troy and Alana Pack Foundation. Pack used the foundation as a base for fundraising and legislative advocacy. It took years to get substantial support for his program. When Pack approached California Senator Tom Torlakson, he found a willing legislative sponsor. "Senator Torlakson was familiar with my family tragedy and really saw the vision of a real-time PMP for doctors and pharmacists," said Pack. Torlakson incorporated Pack's proposal into Senate Bill 734. This was the first version of what would become California's innovative Controlled Substance Utilization Review and Evaluation System (CURES).

California's legislative body passed the measure with the provision that further research be conducted to ensure the security of the database. Pack hired engineers to work out the technicalities of the system and then oversaw the creation of a feasibility report. The California Attorney General's office was satisfied, and the system went online on September 15, 2009.

Realizing he had implemented his vision for CURES, Pack was happy to have accomplished something that would prevent further unnecessary deaths. Pack continues working on the project. "New avenues for the long-term funding of CURES are in the works," Pack explained. "We also want to add new features, such real-time reporting of prescriptions into the database by pharmacists."

all patients who are being prescribed a controlled substance, it would eliminate patient stigmatization.

To date, 27 states out of 34 states that have an operational PMP have online (real-time) access to PMP data.⁶⁸ In order for PMP data to be valuable, **all prescribers must have real-time access to PMP data.** Real-time data access should allow physicians and their authorized staff to retrieve patients' PMP data during consultations, helping the practitioner make rapid decisions on whether or not to prescribe to the patient. With regards to data access, **patient confidentiality must be protected to the greatest extent possible.** To this end, **health care professionals should only be granted access to their own patients' PMP data,** which is presently the case for all PMPs which grant access to prescribers.⁵⁹

PMP database security is also crucial to prevent data tampering. In June 2009, a breach of security occurred in the Virginia PMP database, as it was accessed by an unauthorized user.⁶⁹ **Including features that secure PMP databases is vital to the accuracy and reliability of PMP data, as well as patient privacy.**

For PMPs to be effective, **prescribers should also be trained in interpreting PMP data.** For instance, prescribers should be able to distinguish patients who have several conditions that require complex pain management with various prescription pain relievers, from individuals who are trying to obtain a prescription for controlled substances for the purpose of abuse or diversion (practitioners should also be trained on how to handle these individuals safely). Although it is difficult to define a doctor shopper, the use of a large number of prescribers and a large number of pharmacies by a single individual to obtain prescription pain relievers is a preliminary indicator of doctor shopping.⁷⁰ For example, a patient who

in the past year received 250 prescriptions from 80 prescribers, dispensed by 70 pharmacies is likely to be a doctor shopper (and should be referred to substance abuse treatment or law enforcement), while a patient who receives 500 prescriptions from seven prescribers, dispensed by two pharmacies may be very ill (and could probably benefit from better management of his/her pain through a pain specialist).

Requiring universal training on safe prescribing and abuse prevention

There is currently a significant lack of prescriber education regarding pain management and prescription opioid treatment.⁷¹ Indeed, a study found that 57 percent of internal medicine residents had only fair or poor training on chronic pain.⁷² The lack of prescriber education on prescription opioid abuse and safe prescribing methods is likely one of the causes of the undertreatment of pain. Prescribers who are not comfortable treating patients with prescription opioids could refrain from prescribing them for fear of prosecution if their patients diverted their medication or became addicted. Thus, education and training on safe opioid prescribing is essential to preventing abuse of prescription medications while providing adequate access to pain relievers to patients.⁷³

Currently, the Substance Abuse and Mental Health Services Administration (SAMHSA) offers a continuing medical education course on opioid treatment accredited by the Accreditation Council for Continuing Medical Education (ACCME). Many organizations, such as universities and medical and pharmacy associations, also offer continuing medical education courses. To support these efforts, SAMHSA has awarded grants to 300 opioid treatment programs nationwide for accreditation services and education.⁷³

Many other organizations (public and private) offer educational tools to help physicians safely prescribe pain relievers. In February 2009, King Pharmaceuticals launched a new electronic resource designed to help health care professionals provide the most appropriate and complete treatments for patients with pain. The online educational tool, entitled PainBalance (www.painbalance.org), was formulated by experts in pain management and provides up-to-date pain care information including prescription opioid risk management.

Despite the availability of various training programs, training and education on prescription opioids remain insufficient in effectively preventing prescription opioid abuse. In most states, prescribers are not systematically required to be educated on safe prescribing and abuse prevention. **States should require education on safe prescribing and abuse prevention for all prescribers.** This training should include prescribers from all specialties, whether or not they intend to prescribe opioids, because all prescribers may at one point or another have to treat pain or see a patient with a prescription drug abuse problem.

Prescriber education should be provided as part of PMP training: All prescribers should be required by state law to learn how to use the PMP and should receive education on safe prescribing and abuse prevention as part of the PMP training.

Specifically, **health care professionals should be educated and trained on the following:**

- The various types of pain
- The undertreatment of pain
- Thorough patient assessment
- Treatment options
- Treatment guidelines (see Table 5)
- Abuse-deterrent formulations and how to use them

- How to check and interpret PMP data
- Testing for misuse or abuse
- Referrals to substance abuse treatment

Table 5. Universal precautions in pain medicine⁷⁷

<ol style="list-style-type: none"> 1. Diagnosis with appropriate differential 2. Psychological assessment, including risk of addictive disorders 3. Informed consent 4. Treatment agreement 5. Pre- and post-intervention assessment of pain level and function 6. Appropriate trial of opioid therapy, with adjunctive medicine where appropriate 7. Reassessment of pain score and level of function 8. Regular assessment of analgesia, aberrant behaviors, adverse effects, and activities of daily living 9. Periodic review of pain diagnosis and co-morbid conditions, including addictive disorders 10. Documentation

It is essential that health care practitioners learn about and utilize advanced urine or blood testing in the context of safe prescribing and abuse prevention. These technologies make it possible to identify individual drugs in a patient’s urine or blood, including oxycodone, methadone, fentanyl, and other medications;⁷⁴ traditional tests cannot distinguish between one opioid and another.⁷⁵ An advanced test, therefore, can detect whether a patient is taking any opioid medications in addition to the one he or she has been prescribed, or alert the prescriber to abnormally high levels of one or more medications in the patient’s system.⁷⁵ **Health care practitioners should test for substance abuse as part of standard clinical examination and assessment procedures. The results of these tests should be used for therapeutic purposes only.**

Requiring that pharmacists report all dispensing

To optimize the efficiency of PMPs, **pharmacists and other dispensers should be required to report the**

dispensing of Schedules II through V medications, and provide the Medication Guide and counseling.

Reporting requirements should also apply to Veterans Affairs facilities and methadone clinics. One of the most important challenges is to achieve these tasks with limited burden to the pharmacists. Currently, dispensing certain medications with high inherent risks is reported by pharmacists using product-specific registries, requiring the pharmacist to log into a different registry for each medication, a system which is cumbersome and unscalable.

The FDAAA section on medication risk management calls for minimizing the burden on the health care system,⁴³ which includes pharmacies. Solutions using single systems are the best avenue. Dispensing is typically facilitated by electronic “switch” systems that transmit the transaction details to third party payers (such as insurance companies) and wait for approval, a process similar to credit card transactions that generally takes less than one second. Real-time recording of prescription medication dispensing by the pharmacist into the PMP database could easily take advantage of this existing system, requiring no additional procedure to be added. This system could also integrate a “verification of safe use” tool that automatically prompts the pharmacist to provide the Medication Guide and risk counseling to the patient when a controlled substance in Schedules II through V is dispensed.

Integrating patient identity verification and electronic-prescribing into prescription monitoring programs

The success of PMPs in deterring forgery, doctor shopping, and other diversion rests, in part, on the ability to identify individuals receiving the medication. Currently, patients are seldom required to show proof of identity when filling their prescription at the

pharmacy. **State laws should require that prescription medications be dispensed only if the patient presents a valid ID.** This measure is also necessary to ensure that the PMP data recorded are accurate and useful. The Commonwealth of Virginia is currently considering passing a bill that would require individuals to present a photo ID to pick up prescriptions for some controlled substances.⁷⁸

There is currently no system in place to determine whether the ID provided by a patient is authentic, and individuals who divert prescription medications could use false IDs to receive multiple prescriptions, even with a PMP in place. ID verification technology could help close this loophole. To further improve the accuracy of the PMP data, **ID verification technology should be utilized in pharmacies.**

Integrating a patient identity verification system with electronic prescribing into the PMP electronic database would decrease data entry, reduce prescriber and pharmacist workload, and ensure the accuracy of data, thereby enhancing the usefulness of PMPs.

Swiping the patient’s ID at the *medical office* would verify the patient’s ID and provide access to the PMP data on the patient’s past prescriptions of controlled substances. Swiping the patient’s ID card at the *pharmacy counter* would verify the patient’s identity, bring up the current prescription, and allow the pharmacist to check the patient’s concomitant medications for potential drug interactions. If developed securely and effectively, the integrated system could become a powerful tool for identifying doctor shopping, preventing prescription forgery, and reducing diversion.

Pain Medicine as a Practice Specialty

Pain Medicine has been recognized as a distinct medical discipline since the early 1990s with its own subspecialty training programs and certifying examination. Physicians may become pain specialists by completing a one-year training program in an Accreditation Council Graduate Medical Education (ACGME) accredited pain medicine fellowship after their primary residency training. They are then eligible to take the board certification examination offered as a collaborative multidisciplinary effort by the American Board of Medical Specialties (ABMS) member boards, the American Board of Anesthesiology, the American Board of Physical Medicine and Rehabilitation, and the American Board of Psychiatry and Neurology.* The American Board of Pain Medicine (ABPM), an independent organization, also offers an examination leading to certification in pain medicine. The ABPM has an ongoing initiative to have pain medicine recognized as a primary medical specialty by the AMA and the ABMS. In addition, there are other groups offering certification in pain medicine or pain management without uniform eligibility criteria or rigorous uniform testing standards.*

Nursing has a long-standing interest in pain management and offers its own continuing education and national certification through the American Nurses Credentialing Center (ANCC) in partnership with the American Society for Pain Management Nursing (ASPMN).*

* Personal communications; James Rathmell, M.D.; Richard Rosenquist, M.D.; and Phyllis Zimmer, MN, FNP, FAAN; July 26, 2010.

There are pressing needs in pain management education and care for:

- Comprehensive initial training across the health professions in the evaluation and treatment of pain, and the prevention of abuse. Appropriate education in pain management and addiction should be provided as part of the core curriculum in provider training programs for all those licensed to prescribe, dispense, or administer prescription drugs.
- Continuing education for prescribers to maintain and increase competency over time. In order to promote best practices in pain management, providers must continually learn new information, and stay abreast of emerging policies and standards of care. Events and training sessions on the management of pain, safe prescribing, and abuse prevention are necessary to ensure and enhance quality across the spectrum of care. For more details and CLAAD's recommendations on mandatory prescriber education, see page 29.
- Comprehensive, coordinated pain management delivery systems that integrate diagnosis and treatment, research, safety standards, and patient and public education.

Pain clinics should be operated by health care professionals who are board-certified in pain management. When possible, members of their staff should also be credentialed in pain management in order to apply the standards of safe opioid prescribing to enhance the quality of patient care and reduce prescription opioid diversion and abuse.

Public Education

Safe Medication Use

Changing public perception of the potential risks and safe handling procedures of prescription medications is an important step in preventing misuse and thwarting diversion and abuse.

Americans, and teens in particular, are regularly exposed to messages that deter them from using tobacco, alcohol, and illegal drugs, but prescription medication abuse remains an issue with very low exposure and, therefore, it seems less dangerous.⁸⁰ Teens often feel they can experience a “safe high” using prescription medications.⁸¹ This is the type of misapprehension that public education efforts must focus on.

Medication abuse will not be substantially curbed unless the norms of society are altered at a fundamental level. **Education campaigns must focus on changing public perceptions and behaviors.**

More than half of non-addicted abusers of pain relievers were given the drugs they abused by family members or friends in 2007 and 2008.²¹ Stealing medications from others’ medicine cabinets is another significant source of diversion for drug seekers. Unlocked medicine cabinets pose a significant danger as they are easily accessible to family, friends, and other houseguests of all ages. **One solution to the problem of diversion by non-addicted individuals is to employ public education**



campaigns emphasizing the importance of securing medications.

The National Family Partnership (NFP), which sponsors the Red Ribbon Campaign, the longest-lasting drug abuse prevention campaign in the nation,⁸³ in 2008 launched the national “Lock Your Meds” campaign. While the title of NFP’s campaign is “Lock Your Meds,” its purpose is to educate Americans to make greater efforts to keep prescription medications secure; locking medications may not be the best approach to drug safety for everyone. This campaign takes direct aim at drug diversion and abuse at a grassroots level. The Lock Your Meds campaign promulgates the message that if every home in America secured its medications, then a major source of prescriptions for abusers, especially young people, could be cut off.

Prescription drug abuse prevention advocacy groups must support several preventative measures to complement other anti-diversion messages. Lockboxes



and “keep out of reach of children” labels are two precautionary devices that could help adults keep their medications from unauthorized individuals of all ages. Additional research on innovative approaches to deterring diversion and abuse, such as the novel dispensing mechanisms described in the *2009 National Prescription Drug Abuse Prevention Strategy*⁸⁴ has not progressed swiftly enough. **The National Institute on Drug Abuse (NIDA) should make research into further prescription medication safeguards a priority.**

National Education Campaigns

To catalyze change on a large scale, advocacy groups in different geographic areas and at different levels of society need to come together to create a broad-

reaching impact. Effective anti-smoking campaigns should serve as a model for how a national prescription drug abuse prevention campaign could be structured, as both smoking and prescription drug abuse require perceptions to be altered in order for changes in behavior to occur.⁸⁵ **Advocates for prescription drug abuse prevention should adopt effective anti-smoking campaign tactics by employing a variety of media outlets and messages.**

Given the national scope of the prescription drug diversion and abuse problem, it is reasonable to look to the federal government for support for a broad prevention campaign. **Congress should make National Youth Anti-Drug Media Campaign and other federal health and safety funds available to organizations that can diversify the message, media type, and reach.**

NFP, for example, has the ability to carry its messages into schools across the country. Grassroots exposure of this type could significantly expand the breadth of the campaign, achieving a high-impact, low cost application of federal funding.

Expansion of the Utah Use Only As Directed program, which has been linked to an almost 13 percent drop in prescription drug deaths,⁸⁶ into a national campaign could be another effective yet efficient use of limited federal resources.

Patient Education

In addition to public education campaigns, specific education must also be directed to patients. **Prescribers must educate each of their patients on the benefits and risks of their specific medicine, as well as on the importance of always following medication directions closely (see Table 6).** A patient-prescriber agreement may also be used during the clinical visit to acknowledge that the patient understands the information he or she has received.

Table 6. Health care providers should deliver the following patient education messages:

- Never over- or under-use medications (nearly half of patients misuse their medications)
- Secure medications to prevent access by children and adults
- Dispose of unused or outdated medications
- Never share or sell medications
- Report to the prescriber medication side effects
- Report to the prescriber medication inadequacy
- Report to the prescriber any history or signs of addiction

Verification and reinforcement of patient medication knowledge

Given that pharmacists dispense prescription medications to patients, they should act as gatekeepers against prescription medication diversion, misuse, and abuse. This gatekeeping role involves simple but **important steps pharmacists should take before**

dispensing powerful medications, especially Schedule II-V controlled substances:

- **Verify that the prescription is legitimate.** Most states now use tamper-proof prescription pads for controlled substances.⁸⁹ This step will become automated once all prescriptions for controlled substances are electronically sent to pharmacies.
- **Check the patient's prescription monitoring program record** to identify suspicious activity and potential medication interactions. When PMPs are integrated with pharmacy transaction software, this process will be significantly easier.
- **Verify the patient's identity.** When electronic systems for ID verification are in place, pharmacists will be able to do this by scanning an individual's ID.
- **Check that the patient understands how to safely use his or her medication** by reinforcing the messages the prescriber or medical staff should have delivered to the patient (see Table 6).

Medication Disposal

It is well documented that people often start abusing prescription medications after obtaining the medications from family or friends.⁸¹ Many patients suffering from pain accumulate prescription pain relievers in their homes, leaving easy access of the medication to family members (often children and adolescents) or guests. This is a scenario for accidental poisoning or diversion for purposes of abuse.

Patient education on medication disposal

Patient education (see Table 6) should include information regarding safe disposal of medicines.

Indeed, it is essential that people who accumulate outdated or unused medications understand the importance of disposing these medications to minimize the risks of diversion and abuse.

Medication labels typically do not contain information regarding disposal. **Medication labels and Medication Guides should contain explicit information on how to properly dispose of medications.**

Limited disposal options

Reverse distribution

In 2005, the Food and Drug Administration (FDA) finalized a law that created “reverse distribution,” a process that allows certain entities to return outdated, unusable, and unwanted controlled substances for

disposal.⁹⁰ This process involves a “reverse distributor,” an entity that is required to register with the Drug Enforcement Administration (DEA) and is entitled to implement reverse distribution. Only distributors, pharmacies, and doctors, but not the patients, can transfer controlled substances to the reverse distributor.⁹¹

Drug take-back programs

The only method that is available and convenient for the end-user to get rid of outdated, unwanted medications is the drug take-back program through which authorized law enforcement officials directly receive the medications from the end-user.

In July 2009, the Royal Oak Police Department in Oakland County, Florida, launched one of a growing number of prescription medication disposal programs across the country. The program provides secure disposal options intended to cut back on medication diversion and minimize prescription medication contaminants in the water supply. Individuals with unused or expired prescription medications may drop them off at three designated sites. A total of 300 pounds of medication was collected in less than 6 months.⁹¹ Additionally, in March 2010, the Oregon Partnership conducted a one-day take-back initiative that collected an estimated two tons of prescription medications from across Oregon (see profile on page 38). Currently 22 states have state-operated take-back programs.⁹²

Although these initiatives are very important to curb prescription medication abuse, most of these take-back programs are available at limited locations (usually in large metropolitan areas), reducing their usefulness.

Bills before Congress

In 2009, two bills that would authorize new ways of disposing medications were introduced in the U.S. House of Representatives.³³ These bills are intended to provide the ultimate user with a safe and convenient way to dispose of outdated and unwanted medications. H.R. 1191, sponsored by Rep. Jay Inslee (D-WA-1), would include five state model programs to allow the end-user to dispose of medications by delivering them to a designated facility.³³ The bill also would allow states to devise their own alternative take-back programs. According to the bill, these alternative programs would have to be authorized by state law, cost-effective, accessible to end-users, and environmentally sound. This bill represents a positive effort toward reducing the amount of medications available for diversion.³³

H.R. 1359, sponsored by Rep. Bart Stupak (D-MI-1), would enable end-users to dispose of controlled substances by delivering them to an authorized person or to authorized long-term care facilities, which may then dispose of the medications. This bill could put nursing home patients at risk by making their residences targets of invasion and theft.³⁴

Pharmacy-based disposal

Congress should authorize but not require all pharmacies to serve as medication disposal locations.*

Pharmacies should opt to serve as medication disposal sites, employing secure receptacles labeled and segregated from new medication stocks in the same way health care facilities secure, label, and separate contaminated “sharps” such as needles.*

Expelling versus flushing

In 2008, an Associated Press investigation found traces of a vast array of pharmaceuticals in the drinking water supplies of at least 43 million Americans. Although government officials and independent researchers believe that most of the pharmaceutical contamination in drinking water supplies comes from unmetabolized medications excreted by consumers (in urine),⁹³ it is the public perception that disposal of unused medications by flushing them down the toilet is an important contributor to the problem. Even when proper medication disposal is commonplace, wastewater will continue to be contaminated with excreted pharmaceuticals. With the proper technology, this problem could be handled by water treatment plants.

*CLAAD did not achieve full consensus on this recommendation at its December 2009 policy consensus meeting (see page 9).

Prescription Drug Turn-In Day a Major Success

Oregon Partnership News Release (reprinted with permission)

March 17, 2010

(Portland, OR) The statewide Prescription Drug Turn-In Day last Saturday is being called a rousing success by organizers as a result of record amounts of prescription drugs collected at some thirty sites.

Although the amount of drugs being disposed of continues to be tallied, organizers believe that about two tons of pills, tablets, and other drugs have been turned in.

The event was coordinated by the Oregon Medical Association Alliance, Community Action to Reduce Substance Abuse (CARSA) and Oregon Partnership.

“Thanks to community involvement throughout the state, the event was more successful than we ever thought it would be,” said Leanna Lindquist, President of the Oregon Medical Association Alliance. “Prescription drug abuse and the safe disposal of unused drugs are increasingly on the radar of Oregonians.”

Some sites received a steady stream of participants during the day. And the drugs collected ran the gamut - from a prescription dated 1936 to liquid morphine.

A photo from the Astoria site is at the end of this email.

At the Portland site, almost 3,000 tablets of controlled substance medication were turned in with an estimated street value of \$57,000.

In Hillsboro, 882 bottles of prescription drugs and 489 bottles on non-prescription drugs were collected.

While individual communities have sponsored similar turn-in events, this was the first statewide effort of its kind, hoping to attract thousands of people and increase awareness about the disposal of potentially dangerous and addictive drugs.

The US Geological Survey and Oregon DEQ water quality samplings have found trace amounts of pharmaceuticals in Oregon’s surface water, and focused studies have found pharmaceuticals in groundwater. Flushing unwanted drugs



A CLEAR BODY. MIND. CHOICE.

down the toilet - - at households, hospice and palliative care providers and long term care facilities - - are one way drugs reach wastewater treatment plants.

Today, the average American takes more than 12 different prescription drugs each year - - more than 3.8 billion prescriptions purchased annually, according to the Kaiser Family Foundation. One recent survey estimated the amount of wasted drugs is as high as 45 percent.

Oregon ranks among the top states for non-medical use of pain relievers among 12-17 year olds. Teens say prescription drugs are widely available from an array of sources, including their homes, friends and relatives.

Locking your meds is a household strategy that is gaining more popularity, as parents realize that most teens who abuse prescription drugs acquire them from medicine cabinets at the homes of parents, relatives, or friends.

Young people often perceive prescription drugs to be safer than illicit drugs to get high, leading them to casually share these drugs with friends. These include painkillers (OxyContin), depressants (Xanax) and stimulants (Adderall and Ritalin).

More teens abuse prescription drugs than cocaine, heroin, and methamphetamine combined. According to the National Institute on Drug Abuse (NIDA), prescription drug abuse is higher among 18-25 year olds than in any other age group.



Although the use of tobacco, alcohol and illicit drugs among youth has declined from 2002 through 2008, over this time many teens have turned to misusing prescription drugs, according to SAMHSA's National Survey on Drug Use and Health.

In fact, prescription drugs are misused more by this age group than any illicit drug, except marijuana. The nonmedical use of these medicines—the same drugs used to legitimately relieve pain, and treat conditions like anxiety, depression, sleep disorders, or ADHD in some people—is a growing and under-recognized problem that puts young lives at risk.

Preventing Illicit Distribution

Internet pharmacies

Drug seekers are increasingly using internet pharmacies as a source of prescription medications.⁹⁴ At many internet pharmacies, unlicensed individuals dispense prescription medications without consideration for medication quality, proper dosage, or the medical need of the drug seeker.⁹⁵ In fact, 96 percent of internet drug outlets sold prescription drugs without meeting pharmacy laws and practice standards in an assessment conducted between May 2008 and February 2009.⁹⁶

These illicit dispensers become lucrative by blatantly appealing to drug seekers.⁹⁶ Some cater to individuals who seek to abuse drugs by advertising that they dispense medications without requiring proper documentation of a legitimate need. Others, in order to appear authorized, use bogus medical diagnosis surveys and dishonestly cite endorsements from doctors.⁹⁵

Illegal prescription medication sales on the internet have become so lucrative that some pharmacies have closed their doors to walk-ins and have dedicated themselves solely to filling orders from fraudulent websites.⁹⁵ Not all websites have alignment with legitimate pharmacies, even. Many sell counterfeit drugs in place of those advertised, using substitutes of unspecified origin and effect.⁹⁵ Many internet pharmacies also typically fail to take necessary precautions such as warning about the negative

consequences of drug interactions, dependence, or overdose.⁹⁵

Legislative measures, such as the Ryan Haight Act (see page 14), have been implemented to curb the growing number of illicit internet pharmacies, but enhanced laws and enforcement are not sufficient to stop the practice altogether. **Health care practitioners must educate patients on the importance of safe prescription filling.** Most notably, this includes ensuring patients are acquiring medications only from a single source known to the health care provider and regularly questioning patients about which medicines they are taking and where they acquired them.⁸⁶

Barcoding of individual dosage units

A lack of identifying source information on prescription doses and a multi-party distribution system both contribute to the number of diversion cases that go unprosecuted.¹

Microscopic tracking of prescription dosage units could assist law enforcement in more effectively tracing diversion. The ability to track could help law enforcement identify and prosecute prescription medication diverters, a uniquely difficult challenge.¹

“On-dose” technology inserts information directly onto the medication dose itself, whether in capsule,



tablet, or vial cap form. With this technology, a large amount of data can be embedded in an individual prescription unit without adding any extra material to the pharmaceutical product. Data available on the dose itself could include the medication's strength, expiration date, manufacturing location, wholesaler, and distributor. On-dose technology is priced from \$0.005 to \$0.01 per unit.¹ **Pharmaceutical companies should begin employing and evaluating this technology as soon as possible to determine whether it helps to prevent and interrupt diversion.**

Limit pain clinics' dispensing authority

Confronted with the proliferation of pill mills, a Broward County, Florida, grand jury issued recommendations aimed at limiting pain clinics' dispensing of prescription medications. There are exceptions to this limitation that allow pain clinics 10 or more miles from a pharmacy to dispense prescriptions,

and that allow all pain clinics to dispense prescriptions in a three-day supply.²⁹

Broward County's proposed pain clinic dispensing limits reflect measured efforts to end illicit prescription distribution at pain clinics. **States should reasonably limit the dispensing authority of pain clinics to end the proliferation of pill mills.**

Symposium brings professionals together to seek solutions for drug addiction, workplace safety

Operation Unite News Release (reprinted with permission)

March 6, 2010



(Hazard, KY) Better utilization of the state's prescription drug monitoring program, increasing education about the disease of addiction, and providing greater collaboration and communication on available resources were all short-term priorities identified by medical professionals attending an Operation UNITE symposium held Saturday.

The symposium brought together more than 300 physicians, nurses, pharmacists, dentists, social workers, substance abuse counselors, adult care providers, coalition representatives and other professionals to address prescription drug abuse and workplace safety.

Sponsors included the University of Kentucky Center on Drug and Alcohol Research, the Kentucky Medical Association, the University of Kentucky College of Pharmacy and the Center for Lawful Access and Abuse Deterrence.

In addition to learning about current abuse trends, pending legislation, and treatment models, the symposium offered an opportunity to discuss issues and viewpoints related to substance abuse and workplace safety. While these issues are not new, interest and concerns were heightened following the murder of Dr. Dennis Sandlin at his Perry County clinic last December.

"This is a complex, ugly problem," said Karen Engle, director of UNITE, told those assembled at The Forum in Hazard.

Nearly 7 million people are using prescription drugs for non-medical purposes, said Fifth District Congressman Harold "Hal" Rogers. "Our region is crying out for ways to break free from the chains of addiction."

Addiction comes at a heavy price, Engle said. "Young people are dying almost every day. We can account for over 100 overdose deaths since January alone" in 22 of the 29 counties of the Fifth District.

"These numbers show only a snapshot of what we're up against," Engle said. "We do not pretend to have all of the answers, but working together we can find real solutions that give guidance and direction to medical professionals everywhere."

To that end, Engle announced the formation of a Medical Professional Advisory Council to provide input to UNITE's Board of Directors.

"We need your help and your partnership," Engle said. "Our goal is to reach out to you, get to know you, learn from you and ask you to lend us your expertise."

The symposium began with an emotional call to action by Dr. Sandlin's daughter, Denise.

"My father's patients were his love and joy," Denise Sandlin stated. "How do you help people who seemingly don't want to help themselves? I truly hope you leave here asking more questions and seeking more answers."

One of the most important short-term solutions is to better utilize the Kentucky All-Schedule Electronic Reporting (KASPER) system, considered as the best in the nation. Currently 33 states operate some type of prescription monitoring program, but noted there is not currently a way to easily share information.

That law enforcement component, said Dave Hopkins with the Kentucky Cabinet for Health and Family Services, is critical to identifying and stopping abuse.

"We've asked for legislation to allow states to share information," Rogers said, but stressed he opposes a proposed national program because it "locks out" the law enforcement use.

Another recurring theme during the morning presentations was the need to better educate all providers about addiction.

"Addiction is a chronic and relapsing disorder," said Dr. Sharon Walsh, director of the UK Center on Drug and Alcohol Research. "The longer treatment is provided the greater success. Sometimes it is a lifetime."

"Drug abuse is a preventable behavior (and) drug addiction is a treatable disease," agreed Bob Neri, senior vice president and chief clinical officer for WestCare, which operates a treatment facility in Pike County.

But, Neri noted, most of the power to change behavior is lost before the teenage years. And once addicted, the most successful rehabilitation is through a "10-month dose" of treatment – both residential and clinical. The problem is it takes funding to provide this level of service, and currently that money is not available.

Drug diversion is also a critical concern.

"Substance abuse is still being treated as a subculture, but it's permeating our culture. It has affected every family – including my own," said Daniel Mongiardo, Kentucky's lieutenant governor and a Perry County physician. "Most of the drugs that are on the street are coming from us, the providers."

While most of the narcotics are dispensed legally, an unacceptable amount reaches the streets through illegal activity or ignorance, Mongiardo said.

"There are things you may be doing that unknowingly leads to this type of behavior," Walsh said, noting it is important to enact practices that "reduce the risk" while maintaining appropriate levels of care to patients.



Dr. Lynn Webster speaks about safe opioid prescribing at Operation UNITE's Medical Symposium.

Dr. Lynn Webster, of the Utah-based Lifetree Clinical Research and Pain Clinic, called it a “pain paradox.”

“We are part of the problem,” Webster said.

“Diversion is not acceptable and needs criminal intervention. Misuse, abuse and addiction must be addressed by the medical community.”

“It is a public health commitment to balance prescription drug prescribing and meeting needs,” said Dr. Marsha Stanton, a registered nurse and volunteer for the Center for Lawful Access and Abuse Deterrence. “The patient does have a responsibility” to realize the potential for abuse.”

Abuse Deterrence. “The patient does have a responsibility” to realize the potential for abuse.”

“You work in the most violent procession in America,” said Bill Abney, who conducts risk management assessments. “It’s a frightening issue for which there are no easy answers. We need to draw the line on unacceptable behavior.”

Substance abuse is not just an Eastern Kentucky problem, but a national epidemic, the presenters stressed. There are, however, regional differences in the drugs of choice and how they are used.

“The rural folks and the urban folks really aren’t so different ... but they are,” said Dr. Carl Leukefeld, chair of the UK Department of Behavioral Science.

Leukefeld cited a recent study that found nine different ways drugs are used. Rural users tend to start younger, are mostly white, have no religious preference and tend to crush and snort pills.

Other recommendations, gleaned from a series of four town hall-style forums held leading up to the symposium, include:

- Address aggressive behavior by establishing a written agreement explaining what is to be expected from both patients and providers. After three incidents the relationship could be terminated and reported to a network to alert other physicians.
- Create a “Prescriber’s Bill of Rights” through collaboration between physicians and the legal profession.
- Expand education for individuals and professionals on such issues as Casey’s Law, the UNITE Treatment Voucher program, the disease of addiction and treatment options.
- Increase training and awareness of KASPER and give physicians access to Kentucky CourtNet, which lists a person’s criminal history.

Substance Abuse Treatment

Referral to treatment

Prescription drug abuse is further complicated by the fact that health care providers are not adequately recognizing and referring patients who abuse medication to substance abuse treatment. In 2006, patients who went to the emergency department for prescription drug abuse-related emergencies were released in 58 percent of cases, and only 5 percent of those released were referred to treatment.¹⁵ Also, only 30 percent of patients admitted to hospitals for

nonmedical prescription use were moved to another unit for further care after initial treatment.¹⁵

Health care practitioners must closely evaluate and routinely test patients for substance abuse and diligently refer them to substance abuse treatment when necessary.⁹⁷ The Substance Abuse and Mental Health Services Administration (SAMHSA) is uniquely qualified to promote referrals to treatment from emergency departments and all other public health settings as it manages the national Screening, Briefing,



Intervention, and Referral to Treatment (SBIRT) program.⁹⁸

Veterans

Pain is the most common complaint among veterans of Iraq and Afghanistan.¹³ Populations with chronic pain show a significantly elevated potential for prescription drug abuse.⁹⁹ In 2006, over seven percent of veterans were found to have experienced a substance-related disorder in the past year.¹⁰⁰ To prevent prescription drug abuse among veterans, **health care providers must ensure that current and former service members have access to and take advantage of psycho-social supports and receive adequate medical care, including the treatment of pain. Additionally, it is crucial to identify those veterans who abuse substances and then to provide them treatment that is specifically customized for veterans.**

Therapeutic courts

Within three years of release from prison, over two-thirds of drug offenders are rearrested.¹⁰¹ Therapeutic courts work to lower this rate by removing non-violent offenders on a path to incarceration and placing them into treatment programs.¹⁰² There is documented evidence that the therapeutic court system produces lower rates of recidivism than the criminal court system in cases involving drug abuse.¹⁰³ Therapeutic court programs increase direct supervision and expedite cases, providing addicted individuals with support networks and decreasing incarceration costs to the public.¹⁰⁴

The success of therapeutic courts revolves around targeting the root problems of individuals' drug abuse by first providing therapy rather than punishment. To accomplish effective treatment, a collaborative approach should be maintained among the courts,

treatment agencies, community corrections, prosecution, the defense bar, and local community leaders.¹⁰⁴ A large part of this collaboration among key parties addressing drug abuse should be devoted to ensuring that multiple treatment levels involving various elements of rehabilitation assistance are widely available. The Office of National Drug Control Policy (ONDCP) supports the creation and continuation of therapeutic courts.¹⁰⁵ CLAAD underscores ONDCP's endorsement.

Finally, there is evidence corroborating the common perception that minority groups receive both less intensive and less well-suited treatment than they need.¹⁰⁵ To stem this trend, **research is necessary to ensure that therapeutic court assessment instruments and treatment programs reflect the differences among people of distinct backgrounds. Organizations such as the National Drug Court Institute and the National Judicial College should continue to collect, analyze, and distribute information on best practices in therapeutic court systems.**

Preventing Disparities in Health Care

Minorities less likely to receive adequate treatment

Therapeutic court programs are not the only place where racial disparities in treatment may exist. Both pharmacies and emergency room doctors offer greater availability of opioid pain relievers to white than nonwhite patients.^{107,108} Two separate studies conducted in the last ten years show that pharmacies in mostly minority neighborhoods retained a smaller stock, on average, than pharmacies in predominantly white neighborhoods.^{106,107} These two studies, one sampling Michigan and one sampling New York, both found that pharmacies cited a lack of demand as the number one reason for low opioid supplies.

Similarly, a study of medical records from 1993 to 2005 found that emergency rooms prescribed fewer pain relievers to minorities than whites.¹⁰⁶ In this study, 31 percent of the time white patients were admitted to the emergency room they received opioid pain relievers while the same was true of only 23 percent of blacks, 24 percent of Hispanics, and 28 percent of Asians.¹⁰⁶

The results of these three studies indicate that people of color have less access to powerful pain medications than white people. **Health care providers must undergo training that emphasizes the importance of providing care that is race, culture, and gender neutral.**

The requirement of checking the prescription monitoring program database when first prescribing a controlled substance to a patient and periodically

thereafter (see page 27) could effectively remove racial or gender bias while fostering adequate prescribing. Searching the patient's records for drug abuse allows prescribers to rely on data rather than instincts when prescribing medications.

Medicaid step therapy

States often incorporate generic-medication promotion strategies into their Medicaid systems. One of these strategies, step therapy, is an additional hindrance to equal medical treatment across races.

Step therapy requires a beneficiary to try a generic drug before receiving a prescription for a brand name drug.¹⁰⁹ Due to drug patent lifespans, generic drugs typically are not available until approximately 12 years after the branded drug is approved.¹⁰⁹ Step therapy, then, prevents Medicaid beneficiaries from receiving new, and often more effective or safer, medications, such as abuse-deterrent formulations (see page 21).

As Medicaid covers approximately 25 percent of blacks and 22 percent of Hispanics, compared with only nine percent of whites, step therapy gives minority populations a distinct disadvantage in proper care.¹¹⁰

States should abandon blind cost-saving measures such as step therapy, as the detriments to patient medical care and the public health outweigh the financial benefits. Health care professionals must be able to prescribe medications that are best suited to their patients' unique medical needs.

Research

Study risk factors, intentions, and methods of prescription drug abuse

The policies and recommendations described above are a preliminary step toward addressing the complex issue of prescription drug abuse in a balanced way. Future policies and recommendations should be developed based on more thorough and precise research.

Table 7. Risk factors for prescription drug abuse¹¹²

Strength of factors	Factors
Strong factors	History of illicit drug & alcohol abuse
Positive predictors (when studied)	<ul style="list-style-type: none"> • Family history of medication and illicit drug abuse • History of childhood sexual abuse • History of DUIs or drug convictions • Lost or stolen prescriptions • Use of additional sources to obtain opioids
Mixed factors*	<ul style="list-style-type: none"> • Male • History of an anxiety disorder

*Positive in some studies but not others.

More research is necessary to identify groups at risk of prescription drug abuse. Complex epidemiological, societal, clinical, and personal factors are involved in prescription drug abuse (see Table 7),¹¹¹ making it difficult for physicians to predict and detect abuse when it occurs.

Given that mere intuitions about a patient’s risk of abuse are prone to error and can yield greater disparities in health care, it is imperative that these factors be studied to enable prescribers to gauge each patient’s risk. Moreover, it is crucial that universal precautions of safe opioid prescribing (see Table 5) be systematically applied to every patient considered for opioid therapy.

Currently a variety of surveys that study drug abuse in various populations are available. They include the National Survey on Drug Use and Health (NSDUH), the Center on Addiction and Substance Abuse at Columbia University (CASA) Annual Report, and Monitoring the Future (MTF). They are described in Table 8.

Currently these surveys do not clearly distinguish between misuse and abuse of prescription medications, which makes trend analysis difficult. **Surveys must distinguish between misuse and abuse by using terms such as “self-medicate” or “use for medical purpose but not as prescribed” to evaluate misuse, and terms such as “use for the purpose of getting high” to measure abuse.**

The term “abuse” should also be refined for research purposes. In order for study results to be effective, researchers must use one standard and explicit definition of abuse. Otherwise, trend analysis and comparisons can be difficult, if not impossible, among studies that use the term.

One subcategory of prescription misuse that little research has been conducted on is the incidence of individuals who have taken a medication as directed although it was not prescribed to them. Although doctors strictly advise not taking others' prescriptions, it is difficult to provide the public with compelling evidence that they should spend money on their own medications without scientific evidence supporting this warning.

Surveys often pool together all prescription medications and fail to separate classes of medications. Very few collect data on specific pharmaceutical products.

Surveys on prescription drug misuse and abuse should separate opioid pain relievers from other prescription drugs given that opioids have a particularly high risk of abuse and are the most commonly abused prescription medications. Knowing which opioid product is the most abused (especially in initiates and non-addicted abusers) would help determine which products would warrant expedient development of an abuse-deterrent formulation (ADF). As shown in Table 2, efforts in ADF development have mainly focused on long-acting oxycodone, which was the most abused prescription medication in 2004.⁴⁶ Following the trends of product abuse in the general population using surveys will not only provide for the assessment of the usefulness of ADFs after they are available on the market, but also identify new trends in medication abuse to target the next most abused medication.

Improving surveillance systems

Public surveillance systems such as DAWN, RADARS, and TEDS collect data on the medical consequences of the abuse of prescription medications (as well as other illegal and legal drugs). DAWN collects data on drug-related emergency department and hospital visits, and deaths; RADARS collects data on drug-related poison

Table 8. Surveys and surveillance systems

Surveys
<p><i>National Survey on Drug Use and Health (NSDUH)</i>¹¹²</p> <ul style="list-style-type: none"> • Sponsored by SAMHSA • Population: general population • Data collected: level and patterns of substance abuse (alcohol, tobacco, & illicit and prescription drugs), some product-specific data; some data on source of drugs for abuse; identification of groups at high risk
<p><i>National Center on Addiction and Substance Abuse at Columbia University (CASA Annual Report)</i>¹¹³</p> <ul style="list-style-type: none"> • Survey conducted at the Survey Research Center in the Institute for Social Research, Univ. of Michigan • Population: teens and their parents • Data collected: behaviors and attitudes toward drug abuse (alcohol, tobacco, & illicit and prescription drugs); some data on source of drugs for abuse
<p><i>Monitoring the Future (MTF)</i>¹¹⁴</p> <ul style="list-style-type: none"> • Survey conducted at the Survey Research Center in the Institute for Social Research, Univ. of Michigan • Population: secondary school students, college students, and other young adults. Each year, ~50,000 8th to 12th grade students are surveyed • Data collected: behaviors and attitudes toward drug abuse (alcohol, tobacco, & illicit and prescription drugs); some data on source of drugs for abuse
Surveillance systems/databases
<p><i>Drug Abuse Warning Network (DAWN)</i>¹¹⁵</p> <ul style="list-style-type: none"> • Public database operated by SAMHSA • Population: general population • Data collected: drug-related visits to emergency departments and drug-related deaths; product specific data; route of abuse data; geographic data
<p><i>RADARS® System—Poison Center</i>¹¹⁶</p> <ul style="list-style-type: none"> • Public database managed by the Rocky Mountain Poison and Drug Center (RMPDC) • Population: general population • Data collected: exposures reported to poison centers related to misuse, abuse, and diversion; medical outcomes & seriousness; product specific data; route of abuse data; source of drug; geographic data
<p><i>Treatment Episode Data Set (TEDS)</i>¹¹⁷</p> <ul style="list-style-type: none"> • Public database operated by SAMHSA • Population: patients in substance-abuse treatment • Data collected: substance abuse treatment admissions; product specific data; route of abuse data; geographic data



center calls; and TEDS collects data from individuals entering substance abuse treatment centers due to drug abuse and/or addiction (see Table 8).

Some of these surveillance systems, however, fail to collect important data (DAWN does not collect data on the source of the abused medications)¹¹⁸ or lack some important categories in data collection (DAWN data on route of administration lacks “ingestion” as a category). Also, nomenclature and definitions are often vague: For instance, DAWN does not list “abuse” as a cause for a drug-related visit to the emergency room, but has a category labeled “other” where abuse cases are listed.¹¹⁹ For data to be useful in determining trends in prescription drug misuse and abuse, **several improvements should be made in surveillance systems:**

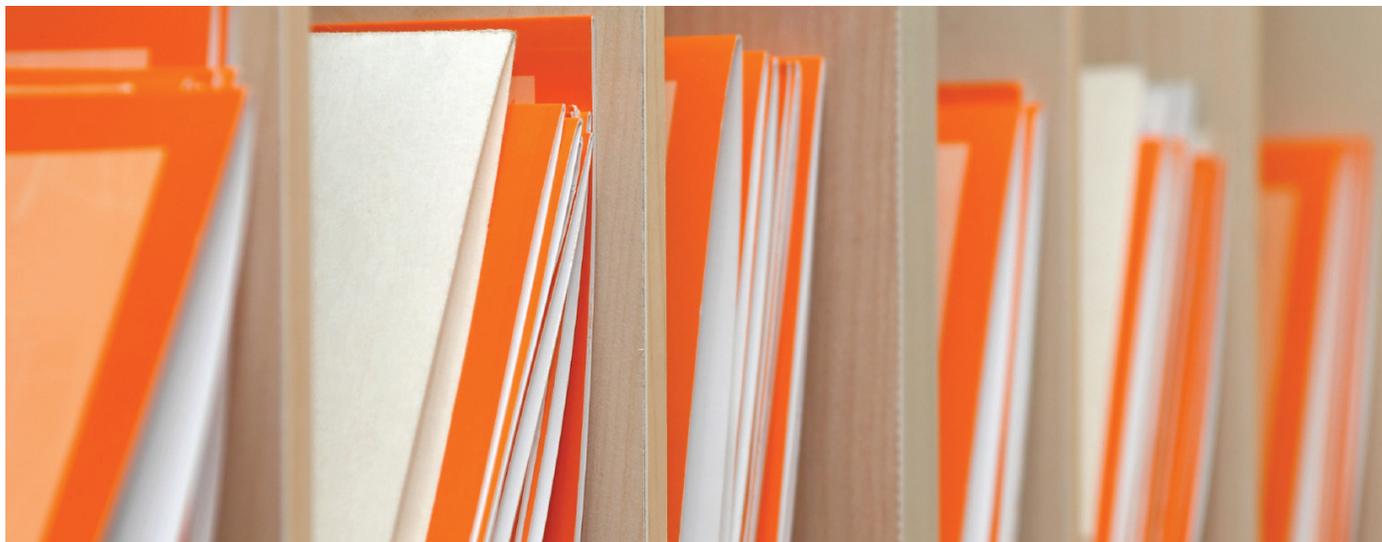
- Homogenizing definitions, nomenclatures, and data categories among the various surveillance systems.
- Whenever possible, collecting data on the type of behavior (misuse, abuse, suicide), type of product used (at least by compound, preferably by brand name), source of procurement of the medication, route of administration, and dose taken.

- Creating categories and subcategories that reflect real-world situations and do not overlap. For instance, within routes of administration, the category “ingestion” should be created and should be subdivided into “swallowing whole,” “chewing/ crushing and then swallowing.” Similarly, “source of the medication” should include medicine cabinets (which is currently absent from most surveys and surveillance systems).

Surveillance for prescription drug overdose deaths should also be improved. Currently, drugs listed on death certificates for overdoses are coded into broad categories, making identification of specific drugs difficult. **The use of uncoded text in the “cause-of-death” fields on death certificates should be implemented at the state and national levels.**¹²⁰

New sources of data

To complement improvements in data from existing sources, **new sources of data should be developed to better monitor trends in prescription drug abuse and its consequences on society.**¹²¹ These sources could include data from the general population (children,



parents, teachers), patients, law enforcement, persons entering drug abuse treatment programs, prescribers, poison centers, emergency departments, medical examiners, key informants, the media, the internet, and governments (through vital statistics and PMPs). **These sources need to be specific to geographic locations, populations, and products in order to be useful. Qualitative data should be integrated, when possible, with subjective knowledge gained from specific experiences to measure changes over time.**¹²²

Analyzing prescription monitoring program data

Prescription monitoring programs (PMPs) represent an important source of data on prescription medication, such as prescribing, dispensing, and patient usage. PMPs can be useful for public safety purposes, such as aiding active investigations of alleged criminal behavior in relation to prescription drugs, as well as for public health through the analysis of trends in prescription medication use and abuse.⁷¹ For instance, the analysis of 10 years of PMP data in Massachusetts has revealed trends in the number prescriptions, doses prescribed, and individuals receiving Schedule II medications over time and by product.⁷¹ Moreover, analyses of PMP data

may help define possible criteria for suspicious behavior (such as doctor shopping).⁷¹

Research on risk evaluation and mitigation strategy effectiveness

As risk evaluation and mitigation strategies (REMS) are starting to emerge, it will be important to **evaluate the efficacy of REMS in preventing and decreasing prescription drug diversion, misuse, and abuse.** Moreover, research should be conducted to **determine the unintended consequences of implementing REMS, in particular the impact of REMS on patient access to prescription medications and the burden on the health care system.**¹²²

To that effect, studies conducted by independent research organizations rather than pharmaceutical companies are preferable to prevent apparent conflicts of interest. Suitable government agencies may include the National Institute of Health (NIH) and the Agency for Health Care Research and Quality (AHRQ).¹²²

Conclusion

Death and addiction related to the misuse and abuse of prescription drugs will not be significantly curbed until multiple sectors of society work together to implement the abuse-prevention strategies outlined in this document. CLAAD's December 2009 meeting of experts and key opinion leaders produced a consensus on these approaches, which address federal, state, and local issues. Prescription monitoring program (PMP) optimization, carefully developed risk evaluation and mitigation strategies (REMS) based on scientific data, and broad public and patient education must take precedence. Prescription drug abuse must be transformed into a practice that is universally recognized as harmful if not deadly. Systems must be improved to make prescription drug abuse considerably more difficult to begin and sustain. Government, non-profit, and commercial organizations must devote substantial resources to preventing prescription drug abuse while simultaneously providing adequate patient care.

Recommendations

Congress

- Make National Youth Anti-Drug Media Campaign and other federal health and safety funds available to organizations that can diversify the message, media type, and reach.
- Authorize pharmacies to accept unused and expired medications from end users for reverse distribution.

Food and Drug Administration

- Abandon the current REMS mandate for long-acting and extended-release opioids in favor of an approach that reflects Congressional intent.
- Approve REMS for each medication independently, taking into account the specific characteristics of the product.
- Permit the manufacturers of prescription opioids to provide a common, class-wide Medication Guide to be given to each patient as part of each medication's REMS.
- Actively facilitate the development of ADFs to minimize prescription drug abuse.
- Enact an intermediate labeling convention for ADFs by which an interim label is granted to a new ADF based on abuse liability data from laboratory tests and human volunteer studies.
- Grant a final label claim of abuse deterrence to ADFs if epidemiologic data adequately prove a lower rate of abuse of an ADF in comparison with relevant traditional formulations.
- Provide methods to classify ADFs based on the degree of resistance to tampering.
- Supply input on preclinical studies that would sufficiently illustrate the abuse-deterrent qualities of ADFs.
- Supply input on human studies that would sufficiently illustrate the abuse-deterrent qualities of ADFs.
- Develop and publish guidelines for requirements for obtaining a label claim of abuse deterrence, including sample content of an approved ADF label.
- Mandate that medication labels and medication guides contain explicit information on proper medication disposal guidelines.
- Grant priority review status to NDAs for opioid analgesic ADFs and non-opioid analgesics, e.g., cannabinoids.
- Give REMS an opportunity to reduce adverse events involving hydrocodone/acetaminophen and oxycodone/acetaminophen formulations before removing those products from the market.
- Work with pharmaceutical companies and the DEA to employ on-dose technology to prevent and intervene in prescription drug diversion.

Drug Enforcement Administration

- Work with pharmaceutical companies and the DEA to employ on-dose technology to prevent and intervene in prescription drug diversion.

Office of National Drug Control Policy

- Encourage Congress to make National Youth Anti-Drug Media Campaign and other federal health and safety funds available to organizations that can diversify the message, media type, and reach.
- Promote research to ensure that therapeutic court assessment instruments and treatment programs reflect the differences among people of distinct backgrounds.
- Encourage collaboration among criminal courts, treatment providers, community corrections, prosecution, the defense bar, and local community leaders to ensure that a variety of treatment levels and techniques are available to non-violent drug abusers in therapeutic courts.

National Institute on Drug Abuse

- Make research into further prescription medication safeguards a priority.

State Governments

- Develop and improve PMPs so that they:
 - Monitor Schedule II-V controlled substances;
 - Provide for interstate operability and data sharing;
 - Provide real-time data access;
 - Allow access to the PMP database only for prescribers, pharmacists, and law enforcement (when PMP data pertains to an active investigation);
 - Grant prescribers and pharmacists access to their own patients' PMP data only;
 - Require education that includes prescription drug abuse prevention, safe prescribing, and PMP data interpretation for all prescribers as a condition for their license renewal; and
 - Utilize tight privacy and security controls.
- Require mandatory PMP database checks before prescribing opioid analgesics for the first time and periodically thereafter.
- Require dispensers to provide the Medication Guide and patient counseling when dispensing a Schedule II-V medication.
- Require patient identity verification prior to dispensing the medication to the patient.
- Reasonably limit the dispensing authority of pain clinics to end the proliferation of pill mills.

State Medicaid Programs

- Keep up-to-date databases on Medicaid providers and beneficiaries, record debarred providers and institutions, and detect duplicate enrollment of beneficiaries across state lines.
- Abandon cost-saving measures, such as step therapy, that limit patient access to new, safer prescription medications.

American Medical Association, American Board of Medical Specialties

- Support efforts to create a unified national pain medicine training and certification system.

Public Health Community

- Conduct research to identify groups at risk for prescription drug abuse.
- Help provide meaningful information to individuals committed to preventing prescription drug abuse by conducting surveillance on prescription medication diversion, misuse, abuse, and addiction that:
 - Uses clear definitions and terms to separate the behaviors of misuse and abuse;
 - Uses homogeneous definitions, nomenclatures, and data categories among the different surveillance systems;
 - Specifies the type of drug-related behavior, type of product used, source of medication, route of administration, and dose taken;
 - Uses non-overlapping categories and subcategories that reflect real world situations, such as “swallowing whole” and “chewing and swallowing;”
 - Separates data on opioid pain relievers from other prescription medications;
 - Uses uncoded text in the “cause-of-death” fields on death certificates so researchers can better identify specific medications that contributed to overdose; and
 - Integrates quantitative and qualitative data to measure trends over time.
- Develop new sources of data to better monitor real-world trends in prescription drug abuse that can be sorted by geographic location, population size, and product.
- Help law enforcement distinguish between prescribers who intentionally assist in the diversion process and those who do so accidentally.

Health Care Providers

- Complete continuing education on prescription drug abuse-related issues, including recognition of abuse, safe prescribing methods, use of PMP data, and use of abuse-deterrent medications.
- Implement a “universal precautions” approach to prescribing medications with abuse potential that incorporates:
 - Monitoring all such patients on an ongoing basis, utilizing tools such as urine drug tests;
 - Checking the patient PMP data before prescribing to determine which medications have been prescribed to the patient and when;

- Using technological advances, such as electronic prescribing; and
- Diligently referring patients to a pain management specialist or a substance abuse treatment facility, if necessary.
- Inform patients of the risks and benefits of each medication.
- Educate patients fully by instructing them to:
 - Use the medication only as prescribed;
 - Never over- or under-use medications;
 - Secure medications to prevent both children and adults from accessing them;
 - Dispose of unused or outdated medications properly;
 - Never share or sell medications;
 - Report to the prescriber any medication side effects that occur;
 - Let the prescriber know if the medication is not achieving its goal;
 - Inform the prescriber of any history or signs of addiction; and
 - Acquire opioids from only a single reliable dispenser.
- Utilize a patient-prescriber agreement to establish the patient's understanding of the prescribing instructions.
- Learn about disparities in treatment and give patients the most effective method of treatment, regardless of gender, race, age, socioeconomic status, etc.
- Test for substance abuse as part of standard clinical examination and assessment procedures and diligently refer patients to substance abuse treatment when necessary.

Pharmacists

- Confirm that each prescription is legitimate before dispensing medications.
- Check each patient's PMP record to identify suspicious activity and potential medication interactions before dispensing medications.
- Verify each patient's identity.
- Ensure that each patient understands how to safely use the medication and review the Medication Guide or patient package insert.

Pharmaceutical Companies

- Cooperate with other pharmaceutical companies to minimize the risks of innovative drugs and their generic equivalents under a single REMS.
- Collaborate with other pharmaceutical manufacturers to provide a degree of conformity within the Medication Guides and communication plans of various medications of the same class.
- Allocate resources to developing new ADFs.
- Develop new non-opioid pain relievers for moderate to severe pain.
- Work with the FDA and the DEA to begin employing and evaluating on-dose technology to determine whether it helps to prevent and intervene in prescription drug diversion.

- Provide financial support for state prescription monitoring programs through not-for-profit organizations such as the Alliance of States with Prescription Monitoring Programs and the National Alliance for Model State Drug Laws.

Medical Examiners

- Use uncoded text and provide details, such as product information, in the “cause-of-death” fields on death certificates to document overdose-related deaths.

Law Enforcement

- Prevent prescription drug diversion by developing procedures that:
 - Evaluate suspicious prescriber behavior;
 - Seek medical advice from medical professionals; and
 - Collaborate with other agencies to gain access to valuable information they may already have regarding prescription drug investigations.

Advocacy Groups

- Change public perception of the potential risks and safe handling procedures of prescription medications.
- Adopt effective public education campaign tactics by employing a variety of media outlets and messages.
- Employ public education campaigns emphasizing the importance of securing medications.
- Remain engaged with governmental entities, law enforcement, health care professionals, and pharmaceutical manufacturers to provide meaningful oversight and input.

References

- ¹ Glover J. The importance of on-dose technologies in the fight against misuse, abuse and illegal diversion of opioids. Available at: <http://www.nanoguardian.net/White%20Paper%20-%20On%20Dose%20Technology%20in%20the%20Fight%20Against%20Illegal%20Diversion%20of%20Opioid%20Meds.pdf>. Accessed March 15, 2010.
- ² Associated Press. MSNBC. Drug deaths outpace car crashes in more states. September 30, 2009. Available at: <http://www.msnbc.msn.com/id/33091645/ns/health-addictions/http://www.msnbc.msn.com/id/33091645>. Accessed March 5, 2010.
- ³ Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA*. 2008; 300(22):2613-20.
- ⁴ U.S. Department of Health and Human Services. Health, United States, 2006. Chartbook on trends in the health of Americans. Hyattsville, MD: National Center for Health Statistics. Available at: [http://www.cdc.gov/nchs/data/06.pdf](http://www.cdc.gov/nchs/data/hus/06.pdf). Accessed March 15, 2010.
- ⁵ American Pain Foundation. Voices of chronic pain. May 2006. Available at: <http://www.painfoundation.org/newsroom/reporter-resources/voices-survey-report.pdf>. Accessed March 29, 2010.
- ⁶ Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies. Results from the 2008 National Survey on Drug Use and Health: National findings. Rockville, MD. Available at: <http://www.oas.samhsa.gov/2k8/2k8Results.cfm>. Accessed March 15, 2010.
- ⁷ Grumbach K, Hart LG, Mertz E, Coffman J, Palazzo L. Who is caring for the underserved? A comparison of primary care physicians and nonphysician clinicians in California and Washington. *Ann Fam Med*. 2003;1:97-104.
- ⁸ Hooker RS, CIPHER DJ. Physician assistant and nurse practitioner prescribing: 1997-2002. *J Rural Health*. 2005;21(4):355-60.
- ⁹ Katz NP, Adams EH, Chilcoat H, Colucci RD, Comer SD, Goliber P, et al. Challenges in the development of prescription opioid abuse-deterrent formulations. *Clin J Pain*. 2007; 23(8):648-60.
- ¹⁰ Savage SR, Joranson DE, Covington EC, Schnoll SH, Heit HA, Gilson AM. Definitions related to the medical use of opioids: evolution towards universal agreement. *J Pain Symptom Manage*. 2003; 26(1):655-67.
- ¹¹ Utah Department of Health Programs. Rx: Use only as directed. Available at: http://useonlyasdirected.utah.gov/index.php?p_resource=resources_teens. Accessed March 15, 2010.
- ¹² Beil L. The dangers of energy pills. *Women's Health*. December 2009. Available at: <http://www.womenshealthmag.com/health/energy-pill-dangers>. Accessed March 15, 2010.
- ¹³ Zoroya G. U.S. troops admit abusing prescription drugs. *USA Today*. December 17, 2009. Available at: http://www.usatoday.com/news/military/2009-12-16-milhealth_N.htm. Accessed March 15, 2010.
- ¹⁴ Brownen J. Misuse of ADHD Medication, why college students should be warned. *Buzzle.com*. Available at: <http://www.buzzle.com/articles/misuse-of-adhd-medication-why-college-students-should-be-warned.html>. Accessed March 19, 2010.
- ¹⁵ Substance Abuse and Mental Health Services Administration (SAMHSA). Drug Abuse Warning Network (DAWN), 2006: national estimates of drug-related emergency department visits. DAWN Series D-30; DHHS Publication No. (SMA) 08-4339 2008. Rockville, MD. 2008. Available at: <http://dawninfo.samhsa.gov/files/ED2006/DAWN2k6ED.htm>. Accessed March 15, 2010.
- ¹⁶ Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies. Treatment Episode Data Set (TEDS). Highlights - 2007. National admissions to substance abuse treatment services, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD. 2009. Available at: <http://www.dasis.samhsa.gov/teds07/tedshigh2k7.pdf>. Accessed March 15, 2010.

- ¹⁷ Szabo L. Prescription now biggest cause of fatal drug overdoses. USA Today. September 30, 2009. Available at: http://www.usatoday.com/news/health/2009-09-30-drug-overdose_N.htm?csp=34. Accessed March 15, 2010.
- ¹⁸ Paulozzi LJ, Xi Y. Recent changes in drug poisoning mortality in the United States by urban-rural status and by drug type. *Pharmacoepidemiol Drug Saf.* 2008; 17(10):997-1005.
- ¹⁹ Birnbaum HG, White AG, Reynolds JL, Greenberg PE, Zhang M, Vallow S, Schein JR, Katz NP. Estimated costs of prescription opioid analgesic abuse in the United States in 2001: a societal perspective. *Clin J Pain.* 2006; 22(8):667-76.
- ²⁰ Strassels SA. Economic burden of prescription opioid misuse and abuse. *J Manag Care Pharm.* 2009; 15(7):556-62.
- ²¹ Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies. Results from the 2008 National Survey on Drug Use and Health (NSDUH): National findings. (NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD. 2009. Available at: <http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf>. Accessed March 15, 2010.
- ²² Rosenblum A, Parrino M, Schnoll SH, Fong C, Maxwell C, Cleland CM, Magura S, Haddox JD. Prescription opioid abuse among enrollees into methadone maintenance treatment. *Drug Alcohol Depend.* 2007; 90(1):64-71.
- ²³ Estep B, Hjalmarson D, Ward K. Perry doctor killed by patient. *Kentucky.com.* January 29, 2009. Available at: http://www.kentucky.com/181/story/1051568.html?storylink=omni_popular. Accessed March 15, 2010.
- ²⁴ South Dakota State Board of Pharmacy. Newsletter. April 2008. Available at: <http://doh.sd.gov/Boards/pharmacy/Newsletter/April08.aspx>. Accessed March 15, 2010.
- ²⁵ Morasco BJ, Dobscha SK. Prescription medication misuse and substance use disorder in VA primary care patients with chronic pain. *Gen Hosp Psychiatry.* 2008; 30(2):93-9.
- ²⁶ Reisfield G, Paulian G, Merlo L, Bertholf R, Wilson G. Opioid prescription underfilling among retail pharmacies. *Pain Med.* 2010; Jan 22.
- ²⁷ Beard D. W.Va. Senate fights drugs: Task force to combat abuse of prescriptions. *The Dominion Post.* January 31, 2010. Available at: <http://behavioralhealthcentral.com/index.php/20100131188315/Latest-News/wva-senate-fights-drugs-task-force-to-combat-abuse-of-prescriptions-the-dominion-post-morgantown-wva.html>. Accessed March 15, 2010.
- ²⁸ Wick JY. Drug-abuse deterrent formulations. *Consultant Pharmacist.* 2009; 24(5):356-65.
- ²⁹ Satz MJ, State Attorney. In the Circuit Court of the Seventeenth Judicial Circuit; In and for Broward County. Florida interim report of the Broward County Grand Jury. The proliferation of pain clinics in South Florida. November 19, 2009. Available at: <http://www.sao17.state.fl.us/Pill%20Mill%20Grand%20Jury.pdf>. Accessed March 15, 2010.
- ³⁰ Medline Plus. Medicaid. Available at: <http://www.nlm.nih.gov/medlineplus/medicaid.html>. Accessed March 15, 2010.
- ³¹ United States Government Accountability Office (GAO). Fraud and abuse related to controlled substances identified in selected states. Available at: http://www.smpresource.org/Content/NavigationMenu/HealthCareFraud/Medicaid/GAO_Medicaid_controlled_substances.pdf. Accessed March 15, 2010.
- ³² Center for Practical Bioethics. Balance, uniformity and fairness: effective strategies for law enforcement for investigating and prosecuting the diversion of prescription pain medications while protecting appropriate medical practice. Available at: <http://www.practicalbioethics.org/FileUploads/FINAL.Law%20Enforcement%20Pain%20Policy%20Brief.Feb%2009.pdf>. Accessed March 15, 2010.
- ³³ Library of Congress. Safe Drug Disposal Act of 2009. Available at: <http://thomas.loc.gov/cgi-bin/bdquery/D?d111:1:./temp/~bdtc7z:@@D&summ2=m&/bss/111search.html>. Accessed March 5, 2009
- ³⁴ Library of Congress. Secure and Responsible Drug Disposal Act of 2009. Available at: <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR01359:@@D&summ2=m&>. Accessed March 15, 2010.
- ³⁵ Kuehn BM. Safety plan for opioids meets resistance: opioid-linked deaths continue to soar. *JAMA.* 2010; 303(6):495-7.
- ³⁶ The Centers for Disease Control (CDC), National Center for Health Statistics (NCHS). Increases in methadone-related deaths: 1999-2004. December 2006. Available at: <http://www.cdc.gov/nchs/data/hestat/methadone1999-04/methadone1999-04.htm>. Accessed March 15, 2010.
- ³⁷ Library of Congress. Methadone Treatment and Protection Act of 2009. Available at: <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s754:>. Accessed April 2, 2010.
- ³⁸ Department of Justice; Drug Enforcement Administration. Implementation of the Ryan Haight - Online Pharmacy Consumer Protection Act of 2008; Final Rule. *Federal Register*; 74(64). April 6, 2009. Available at: http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf. Accessed March 15, 2010.

- ³⁹ Cox J. Florida's legislative proposals for medical care: a look at what's on the table for state health care reform. Florida Times Union. February 15, 2010. Available at: http://jacksonville.com/news/metro/2010-02-15/story/floridas_legislative_proposals_for_medical_care. Accessed March 15, 2010.
- ⁴⁰ Associated Press. Utah aims to curtail prescription drug abuse. The February 2, 2010. Available at: <http://www.cnbc.com/id/35195606>. Accessed March 15, 2010.
- ⁴¹ Virginia Department of Health Professions. Virginia prescription monitoring program: description of the program. Virginia.gov. Available at: http://www.dhp.state.va.us/dhp_programs/pmp/pmp_desc.asp. Accessed March 18, 2010.
- ⁴² Breen T. W.Va. Senate takes aim at prescription drug abuse. The Associated Press. January 27, 2010. Available at: <http://finance.yahoo.com/news/WVa-Senate-takes-aim-at-apf-2485121530.html?x=0&.v=1>. Accessed March 15, 2010.
- ⁴³ Food and Drug Administration Amendments Act of 2007, Public Law 110-85. Sept 27, 2007. Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110. Accessed March 15, 2010.
- ⁴⁴ US Food and Drug Administration. Sec. 505-1. [21 USC §355-1] Risk Evaluation and Mitigation Strategies. Available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm109090.htm>. Accessed March 15, 2010.
- ⁴⁵ US Food and Drug Administration. Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS). FDA Reviews Docket Submissions and Comments from Stakeholder and Public Meetings. November 2009. Available at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>. Accessed March 29, 2010.
- ⁴⁶ Cicero TJ, Inciardi JA, Muñoz A. Trends in abuse of OxyContin® and other opioid analgesics in the United States: 2002-2004. *J Pain*. 2005; 6:662-72.
- ⁴⁷ Joranson DE, Gilson AM. Drug crime is a source of abused pain medications in the United States. *J Pain Symptom Manage* 2005; 30:299-301.
- ⁴⁸ Meier B. In guilty plea, OxyContin maker to pay \$600 million. *New York Times*. May 10, 2007. Available at: <http://www.nytimes.com/2007/05/10/business/11drug-web.html>. Accessed March 29, 2010.
- ⁴⁹ US Food and Drug Administration. What does FDA do? Available at: <http://www.fda.gov/AboutFDA/Basics/ucm194877.htm>. Accessed April 2, 2010.
- ⁵⁰ Passik SD. Issues in long-term opioid therapy: unmet needs, risks, and solutions. *Mayo Clin Proc*. 2009; 84(7):593-601.
- ⁵¹ Webster L. Update on abuse-resistant and abuse-deterrent approaches to opioid formulations. *Pain Med*. 2009;10(Suppl 2):S124-33.
- ⁵² Butler SF, Benoit CM, Budman SH, Fernandez KC, McCormick C, Wing Venuti S, Katz N. Development and validation of an opioid attractiveness scale: a novel measure of the attractiveness of opioid products to potential abusers. *Harm Reduct J*. 2006; 3(1):5.
- ⁵³ White AG, Birnbaum HG, Rothman DB, Katz N. Development of a budget-impact model to quantify potential cost savings from prescription opioids designed to deter abuse or ease of extraction. *Appl Health Econ Health Policy*. 2009; 7(1):61-70.
- ⁵⁴ The Center for Lawful Access and Abuse Deterrence (CLAAD). CLAAD letter to congress on labeling of medications introducing impediments to abuse. <http://claad.org/downloads/Call%20for%20Congress%20to%20support%20interim%20labeling%20of%20ADFs%20032410.pdf>. March 24, 2010.
- ⁵⁵ Tufts Health Care Institute Program on Opioid Risk Management. Citizen petition. May 18, 2009. <http://www.thci.org/Opioid/citizenspetition.pdf>. Accessed March 15, 2010.
- ⁵⁶ Associated Press. FDA panel votes to eliminate Vicodin®, Percocet® - Overdoses of acetaminophen also lead experts to urge lower Tylenol® doses. July 1, 2009. Available at: <http://www.msnbc.msn.com/id/31664450/>. Accessed March 15, 2010.
- ⁵⁷ GW Pharmaceuticals. Sativex. Available at: <http://www.gwpharm.com/sativex.aspx>. Accessed March 15, 2010.
- ⁵⁸ Barthwell A, Barnes M. Marijuana dispensaries and the federal government: Recommendations to the Obama administration. *The Journal of Global Drug Policy and Practice*. 2009; 3(2): 23
- ⁵⁹ Wang J, Christo PJ. The influence of prescription monitoring programs on chronic pain management. *Pain Phys* 2009; 12(3):507-15.
- ⁶⁰ Department of Justice. Drug Enforcement Administration. Office of Diversion and Control. Questions & answers: state prescription drug monitoring programs. January 2010. http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#4. Accessed March 15, 2010.

-
- ⁶¹ Office of the Attorney General, State of California. CURES. Available at: <http://ag.ca.gov/bne/cures.php>; California Health and Safety Code, section 11165, January 12, 2009.
- ⁶² Florida Regional Prescription Drug Abuse Task Force. Prescription drug monitoring programs – Proposed legislation for the state of Florida. Available at: <http://www.docstoc.com/docs/12928932/Prescription-Drug-Monitoring-Program/>. Accessed April 19, 2010.
- ⁶³ Gillette G. Online drug monitoring targets ‘doctor shoppers’ - Danville family helps get pilot program off the ground. Danville Express. September 18, 2009. Available at: http://www.danvilleweekly.com/story.php?story_id=6678. Accessed March 15, 2010.
- ⁶⁴ U.S. Department of Justice. Harold Rogers Prescription Drug Monitoring Program FY 2010 competitive grant announcement. Available at: <http://www.ojp.usdoj.gov/BJA/grant/10PDMsol.pdf>. Accessed March 15, 2010.
- ⁶⁵ 21 USC Section 812 01/22/02. Title 21 - Food and Drugs Chapter 13 - Drug abuse prevention and control subchapter I - Control and enforcement Part B - Authority to control; standards and Schedules. Available at: <http://www.justice.gov/dea/pubs/csa/812.htm#c>. Accessed March 29, 2010.
- ⁶⁶ Drug Abuse Warning Network (DAWN). Detailed tables: National estimates, drug-related emergency department visits for 2004–2008. Available at: <https://dawninfo.samhsa.gov/data/default.asp?met=All>. Accessed March 29, 2010.
- ⁶⁷ The Massachusetts OxyContin and Other Drug Abuse Commission. Final report. Available at: http://www.maclearringhouse.com/PDFs/SubstanceAbuse/MA_oxycontin_otherdrug_report.pdf. Accessed March 15, 2010.
- ⁶⁸ Katz N, Houle B, Fernandez KC, Kreiner P, Thomas CP, Kim M, Carrow GM, Audet A, Brushwood D. Update on prescription monitoring in clinical practice: a survey study of prescription monitoring program administrators. *Pain Med.* 2008; 9(5):587-94.
- ⁶⁹ Personal communication, Alliance of States with Prescription Monitoring Programs, February 27, 2010.
- ⁷⁰ Department of Health Professions, State of Virginia. News release. Follow-up to statewide notification of prescription monitoring program security breach. Available at: www.dhp.virginia.gov. Accessed March 15, 2010.
- ⁷¹ Katz N, Panas L, Kim M, Audet AD, Bilansky A, Eadie J, Kreiner P, Paillard FC, Thomas C, Carrow G. Usefulness of prescription monitoring programs for surveillance--analysis of Schedule II opioid prescription data in Massachusetts, 1996-2006. *Pharmacoepidemiol Drug Saf.* 2010; 19(2):115-23.
- ⁷² Lebovits AH, Florence I, Bathina R, Hunko V, Fox MT, Bramble CY. Pain knowledge and attitudes of healthcare providers: practice characteristic differences. *Clin J Pain.* 1997; 13(3):237-43.
- ⁷³ Yanni LM, Weaver MF, Johnson BA, Morgan LA, Harrington SE, Ketchum JM. Management of chronic nonmalignant pain: a needs assessment in an internal medicine resident continuity clinic. *J Opioid Manag.* 2008; 4(4):201-11.
- ⁷⁴ Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA awards almost \$3 million to fund Opioid Treatment Program accreditation grants. Available at: <http://www.samhsa.gov/newsroom/advisories/0809093638.aspx>. Accessed March 15, 2010.
- ⁷⁵ Dominion Diagnostics. Test catalog. Available at: <https://www.dominiondiagnostics.com/labservices/testcatalog.php>. Accessed April 2, 2010.
- ⁷⁶ Personal communication, John Femino, M.D., January 15, 2009.
- ⁷⁷ Dominion Diagnostics LLC. Laboratory testing and testing methodologies. Available from: <https://www.dominiondiagnostics.com/labservices/labtechnology.php>. Accessed April 20, 2010.
- ⁷⁸ Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. *Pain Med.* 2005; 6(2):107-12.
- ⁷⁹ Harrison H. Lohr introduces drug abuse prevention bill. WHSV.com. February 2, 2010. Available at: <http://www.whsv.com/news/headlines/83413107.html>. Accessed March 15, 2010.
- ⁸⁰ American Board of Pain Medicine. Executive summary. Nearing our goal: pain medicine as a medical specialty. 2008-2009. Available at: http://www.abpm.org/pdfs/09_executive_summary.pdf. Accessed March 15, 2010.
- ⁸¹ Oregon Partnership. Alarming trend: Oregon partnership crisis lines report prescription medication abuse on the rise. Available at: <http://www.orpartnership.org/web/PDFs/News%20Releases/prescription%20calls%20news%20release.pdf>. Accessed March 15, 2010.
- ⁸² Utah Department of Health Programs. Use only as directed. Available at: http://useonlyasdirected.utah.gov/index.php?p_resource=resources_teens. Accessed March 15, 2010.
-

- ⁸³ National Center on Addiction and Substance Abuse (CASA) at Columbia University. National survey of American attitudes on substance abuse XIII: teens and parents. August 2008. Available at: http://www.casacolumbia.org/templates/publications_reports.aspx. Accessed March 15, 2010.
- ⁸⁴ The Florida Family Partnership. Red ribbon campaign 2009. Available at: <http://cmif.pictco.org/default.asp?PageNum=562>. Accessed March 15, 2010.
- ⁸⁵ Barthwell A, Barnes M, Leopold V, Wichelecki J. The Center for Lawful Access and Abuse Deterrence (CLAAD) and the Human Resources Development Institute (HRDI). National prescription drug abuse prevention strategy 2009. Available at: http://claad.org/downloads/Nat_Prescript_Drug_Abuse_Prev_Strat_2009.pdf. Accessed March 29, 2010.
- ⁸⁶ Katz N. US Strategy to prevent and manage prescription opioid abuse. Analgesic Research. Unpublished document.
- ⁸⁷ Moore C. Utah prescription-drug deaths drop. Deseret News. Available at: <http://www.deseretnews.com/article/705308557/Utah-prescription-drug-deaths-drop.html>. Accessed March 15, 2010.
- ⁸⁸ Broekmans S, Dobbels F, Milisen K, Morlion B, Vanderschueren S. Pharmacologic pain treatment in a multidisciplinary pain center: Do patients adhere to the prescription of the physician? *Clin J Pain*. 26(2), 2010: 81.
- ⁸⁹ Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C. American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009; 10(2):113-30.
- ⁹⁰ Smith M, Colucci S, Haddox J. Diffusion of tamper-resistant prescription pad usage among opioid analgesic prescribers in the U.S.: 2001-2005. *J Pain*. 2006; 7(4):S98.
- ⁹¹ 21 C.F.R. §1307.21. Disposal of controlled substances. Procedure for disposing of controlled substances. Government Printing Office. April 1, 2009. http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm. Accessed March 15, 2010.
- ⁹² Oakland county sheriffs operation medicine cabinet. Oakland County Health Division. Spring 2010. Available at: http://www.oakgov.com/health/assets/Documents/CHPIS/osas/in_touch_newsletter.pdf. Accessed March 15, 2010.
- ⁹³ The Drug-Take-Back Network. Local efforts. 2009. Available at: http://www.takebacknetwork.com/local_efforts.html. Accessed March 15, 2010.
- ⁹⁴ Donn J, Mendoza M, Pritchard J. Associated Press. Scant advice on disposal of meds. September 15, 2009. Available at: http://hosted.ap.org/specials/interactives/pharmawater_site/sept15a.html. Accessed March 15, 2010.
- ⁹⁵ Krebs B. 'Rogue' Internet Pharmacies Fueling Rx Abuse, Panel Told. The Washington Post. May 16, 2007. Available at: <http://www.washingtonpost.com/wp-dyn/content/article/2007/05/16/AR2007051602015.html>. <http://www.washingtonpost.com/wp-dyn/content/article/2007/05/16/AR2007051602015.html> Accessed April 10, 2010.
- ⁹⁶ Federal Register, Vol. 74, No. 64. April 6, 2009. 23 Rules and Regulations. Available at: http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf. Accessed March 15, 2010.
- ⁹⁷ Internet drug outlets on NABP not recommended list continue to grow. National Association of Boards of Pharmacy. March 2010. Available at: <http://www.nabp.net/ftpfiles/newsletters/NABP/nabp032010.pdf>. Accessed March 15, 2010.
- ⁹⁸ Marcus DA. Managing chronic pain in the primary care setting. *Am Fam Physician*. 2002;66(1):36-42. Available at: <http://www.aafp.org/afp/2002/0701/p36.html>.
- ⁹⁹ Substance Abuse and Mental Health Administration (SAMHSA). Screening, Brief Intervention, and Referral to Treatment (SBIRT). Available at: <http://sbirt.samhsa.gov/index.htm> Accessed April 2, 2010.
- ¹⁰⁰ Becker WC, Fiellin DA, Gallagher RM, Barth KS, Ross JT, Oslin DW. The association between chronic pain and prescription drug abuse in veterans. *Pain Med*. 2009; 10(3):531-6. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/19425211>.
- ¹⁰¹ National Institute on Drug Abuse. Substance Abuse among the Military, Veterans, and Their Families. July 2009. Available at: <http://www.drugabuse.gov/tib/vet.html>. Accessed April 2, 2010.
- ¹⁰² National Association of Drug Court Professionals (NADCP). Principles of evidence-based sentencing & other court dispositions for substance abusing individuals. Available at: <http://www.nadcp.org/learn/positions-policy-statements-and-resolutions/principles-evidence-based-sentencing-other-court-d>. Accessed January 2, 2010.
- ¹⁰³ Office of National Drug Control Policy (ONDCP). Drug courts. Available at: <http://www.whitehousedrugpolicy.gov/enforce/DrugCourt.html>. Accessed January 2, 2010

- ¹⁰⁴ United States Government Accountability Office (GAO). Adult drug courts - evidence indicates recidivism reductions and mixed results for other outcomes. February 2005. Available at: <http://www.gao.gov/new.items/d05219.pdf>. Accessed January 5, 2010.
- ¹⁰⁵ The White House. National Drug Control Strategy 2009 Annual Report. 2009. Available at: <http://www.whitehousedrugpolicy.gov/publications/policy/ndcs09/2009ndcs.pdf>. January 5, 2010.
- ¹⁰⁶ Pletcher MJ, Kertesz SG, Kohn MA, Gonzales R. Trends in opioid prescribing by race/ethnicity for patients seeking care in US emergency departments. *JAMA*. 2008; 299(1):70-78.
- ¹⁰⁷ Green CR, Ndao-Brumblay SK, West B, Washington T. Differences in prescription opioid analgesic availability: comparing minority and white pharmacies across Michigan. *J Pain*. 2005; 6(10):689-699.
- ¹⁰⁸ Morrison RS, Wallenstein S, Natale DK, Senzel RS, Huang LL. "We don't carry that" – failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *N Engl J Med*. 2000; 342(14):1023-1026.
- ¹⁰⁹ Levinson DR. Department of Health and Human Services' Office of Inspector General. Generic drug utilization in state medicaid programs. July 2006. Available at: <http://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf>.
- ¹¹⁰ Herper M. Solving the drug patent problem. *Forbes.com*. May 2, 2002. Available at: <http://www.forbes.com/2002/05/02/0502patents.html>.
- ¹¹¹ National Women's Law Center. Medicaid and minority communities: Why Medicaid is so important. July 2006. Available at: http://www.nwlc.org/pdf/Medicaid%20and%20Minority%20Communities%20_Jul%202006_.pdf.
- ¹¹² Turk DC, Swanson KS, Gatchel RJ: Predicting opioid misuse by chronic pain patients: a systematic review and literature synthesis. *Clin J Pain*. 2008; 24(6):497-508.
- ¹¹³ US Department of Health and Human Services (DHHS). Substance Abuse and Mental Health Services Administration (SAMHSA). Office of Applied Studies (OAS). National Survey on Drug Use & Health. Web site available at: <http://www.oas.samhsa.gov/NSDUH.HTM>. Accessed March 15, 2010.
- ¹¹⁴ The National Center on Addiction and Substance Abuse at Columbia University (CASA). Web site available at: www.casacolumbia.org. Accessed March 15, 2010.
- ¹¹⁵ Monitoring the Future. Web site available at: www.monitoringthefuture.org. Accessed March 15, 2010.
- ¹¹⁶ Drug Abuse Warning Network (DAWN). Web site available at: www.dawninfo.samhsa.gov. Accessed March 15, 2010.
- ¹¹⁷ The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System. Web site available at: www.radars.org. Accessed March 15, 2010.
- ¹¹⁸ US Department of Health and Human Services (DHHS). Substance Abuse and Mental Health Services Administration (SAMHSA). Office of Applied Studies (OAS). The Treatment Episode Data Set (TEDS). Web site available at: www.oas.samhsa.gov/2k2/TEDS/TEDS.cfm. Accessed March 15, 2010.
- ¹¹⁹ Drug Abuse Warning Network (DAWN). National estimates of drug-related emergency department visits, 2004 – 2008. Available at: https://dawninfo.samhsa.gov/data/tables-08/national/Nation_2008_NMUP.xls#'Cen Nerv System Drugs'!A1. Accessed March 15, 2010.
- ¹²⁰ Drug Abuse Warning Network (DAWN). Collecting data questions and answers. Available at: https://dawninfo.samhsa.gov/collect/collect_qas.asp#1. Accessed March 15, 2010.
- ¹²¹ Centers for Disease Control and Prevention (CDC). Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004-2007. *MMWR*. 2009; 58:1171-1175. *JAMA*. 2010; 303(1). Available at: <http://jama.ama-assn.org/cgi/content/full/303/1/21>. Accessed March 15, 2010.
- ¹²² Johanson CE, Balster RL, Henningfield JE, Schuster CR, Anthony JC, Barthwell AG, Coleman JJ, Dart RC, Gorodetzkyh CW, O'Keefe C, Sellers EM, Voccik F, Walsh SL. Risk management and post-marketing surveillance for the abuse of medications acting on the central nervous system: Expert panel report. *Drug Alc Depend*. 2009; 105(S1):S65-S71. Available at: http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T63-4X962TY-3&_user=10&_coverDate=12%2F01%2F2009&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1233683826&_rerunOrigin=google&_acct=C000050221&_version=1&_urlVersion=0&_userId=10&md5=07af079b99d0a8b4dd8ea1795c39c253. Accessed March 15, 2010.

Center for Lawful Access and Abuse Deterrence

2009 North 14th Street, Suite 414

Arlington, Virginia 22201

www.claad.org