THE JOURNAL OF GLOBAL DRUG POLICY AND PRACTICE

VOLUME 3, ISSUE 1 - Spring 2009

In the Journal of Global Drug Policy and Practice, our authors have presented insights that illumine the many aspects of the international drug problem. At this juncture in our world political history, the editors asked for their contributions to a special edition.

Some of our experts, coming from many different fields and representing many different nations, addressed new or re-elected world leaders in our Winter 2009 edition. They each presented a unique perspective on drug treatment, policy or prevention and gave advice about the most critical issues in the drug arena.

This issue focuses on a troubling and increasingly widespread problem – controlling prescription drug abuse. Its complexity requires a more in-depth examination and a longer treatment; hence, the editors decided to include both parts of a two part series in one issue. In our commentary piece, Dr. Robert DuPont reviews the current administration's approach to medical marijuana.

The Journal of Global Drug Policy and Practice, a joint effort of the Institute on Global Drug Policy and the International Scientific and Medical Forum on Drug Abuse, is an international, open access, peer-reviewed, online journal with the goal of bridging the information gap on drug policy issues between the medical/scientific community, policymakers and the concerned lay public.

Edited by Eric A. Voth, MD, FACP and David A. Gross, MD, DFAPA, our intended readership includes clinicians, clinical researchers, policymakers, prevention specialists and the interested public.

IN THIS ISSUE

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A Vital Balancing Act: Multi-Sector Approaches to Preventing Prescription Drug Abuse in the United States while Ensuring Adequate Patient Access to Medications: Part 1

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Abstract

Prescription drug abuse is an increasing public health concern in the United States. Research shows that many Americans view prescription medications, such as opioid pain relievers, as easier to acquire than illegal drugs and safe to use; meanwhile, studies have documented widespread undertreatment of pain. Due to the complex nature of this problem, the participation of multiple sectors of society – the medical community, state and federal governments, law enforcement, advocacy organizations, and private enterprise – is necessary to adequately address the issue. The Center for Lawful Access and Abuse Deterrence (CLAAD) is an alliance of diverse organizations that aims to develop a balanced approach to preventing prescription drug abuse while simultaneously ensuring sufficient access to medications for patients with a legitimate medical need. This article will describe the consensus recommendations developed by CLAAD. Prescription drug abuse is primarily a public health problem, which must be addressed as such through universal precautionary measures.

Keywords: Prescription drug, opioid, opiate, medicine, pharmaceutical, prescription medication, abuse, misuse, diversion, prescription monitoring, e-prescribing, prescribing, universal precautions, undertreatment of pain, chronic pain, disparities, Medicaid, insurance, fraud, abuse-deterrent, tamper-resistant, formulations, dispensing mechanisms, Ryan Haight, controlled substances, medication disposal, CPT codes, standards of care, online pharmacies, Internet pharmacies, patient identity, urine drug testing, DEA, ONDCP, FDA, doctor shopping, pill mill, rogue pharmacies, national policy, public policy, drug control, multi-sector collaboration, public health, pain relievers, reverse pharmaceutical distribution, academic doping, research, development

I. Introduction

The abuse of prescription medications is a growing public health concern in the United States. While White House reports show that use of many illegal drugs recently declined (1), the number of people abusing prescription medications has more than doubled over the past decade (2). Unlike illegal drugs, prescription medications are often readily available because people use them for legitimate medical purposes. Studies suggest most prescription drug abusers get medications free from a friend or relative who holds a prescription (3). Meanwhile, as pain relievers are increasingly abused, chronic pain patients continue to be undertreated for their conditions. Taken together, these facts demonstrate the urgent need for a national policy that reduces prescription drug misuse and abuse without restricting safe access to medications for patients who need them. To ensure balance in addressing this dual challenge, collaboration among many sectors of society is necessary.

The Center for Lawful Access and Abuse Deterrence (CLAAD) is an alliance that seeks to develop a balanced approach to prescription medication policy by deterring prescription drug abuse while simultaneously protecting safe, lawful medication access for patients. The CLAAD partnership includes concerned parents and grandparents, members of the pharmaceutical industry, medical practitioners, pain patients, veterans, consumer groups, and drug abuse prevention advocates. Through CLAAD, these members of the broader family, scientific, health, safety, education, and technology communities have united and reviewed expert recommendations to reach agreement on best practices for reducing the incidence of prescription drug abuse.

CLAAD has worked intensively since early 2008, using expert input from its diverse member groups, to develop these recommendations for addressing prescription drug abuse in a comprehensive and balanced

way. This paper is based on the July 2008 National Prescription Drug Abuse Prevention Policy Consensus Meeting.(4) The policy approaches discussed herein represent the consensus from the meeting.

That which follows is a brief summary of the current state of prescription drug abuse in the United States, as well as specific recommendations on how the medical community, state and federal governments, law enforcement, advocacy organizations, and private enterprise must work together to mitigate this escalating problem.

II. Background

A. Definitions

This article will focus on the abuse of prescription medications, mainly prescription pain relievers. The authors use the term "pain relievers" to refer to opioid medications such as Vicodin®, OxyContin®, and Percocet®. People also abuse sedatives, tranquilizers, stimulants, and other pharmaceutical products. Most of the following discussion and policy recommendations, though, will focus on pain relievers, as they are thought to be the most common type of prescription drug abused, constituting 75 percent of abuse (3).

The "prescriber" includes not only physicians, but also nurse practitioners and physician assistants, who have prescribing authority in most cases. These members of the medical community are essential to patient access to care, especially in rural or low-income areas (5,6).

This article will use the term "prescription drug abuse" to include any inappropriate use of prescription medications, as this phrase is commonly known to the news media, the general public, and policymakers. We realize that there are several other scientific terms and types of improper use incorporated in this general terminology. No survey data is available, however, to distinguish these different uses so that they could be effectively addressed.

Additionally, CLAAD regards as imprecise the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH) definition of *nonmedical use* of prescription medications, which is "use without a prescription of the individual's own or simply for the experience or feeling the drugs caused" (3). This definition of nonmedical use does not differentiate between misuse and abuse. Katz et al.'s definitions of misuse and abuse are more precise (7). Katz et al. define *misuse* as "use of a medication (for a medical purpose) other than as directed or as indicated, whether willful or unintentional, and whether harm results or not." They define *abuse* as "any use of an illegal drug; the intentional self-administration of a medication for a nonmedical purpose such as altering one's state of consciousness, *e.g.*, getting high" (7). Katz et al.'s well-delineated definitions should be used when describing misuse and abuse. For the general purposes of this article, however, we will often use the phrase "prescription drug abuse" to encompass these various related definitions.

There are many different motives for improper prescription drug use; people may improperly use prescription medications unintentionally, to self-medicate a problem without a prescription, to experiment, to get high, or because they have become addicted. Such distinctions are important, as remedial efforts must account for motives. In its present form, the NSDUH definition of nonmedical use does not provide enough information to help practitioners and policymakers understand which motives are more or less prevalent and to whom preventive or interventional measures must be directed. **Future NSDUH surveys should include questions on motives for use.**

It is essential to acknowledge in this paper the distinction between addiction and physical dependence. The Liaison Committee on Pain and Addiction (LCPA) – which includes representatives of the American Society of Addiction Medicine, the American Academy of Pain Medicine, and the American Pain Society – has developed a group of definitions for addiction-related terms that distinguish addiction from dependence (8). According to LCPA, *addiction* is defined as:

> [...] a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

Though sometimes interrelated, addiction and physical dependence are separate from one another. *Physical dependence* is defined as follows:

> [...] 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 (8).

LCPA specifies that these two phenomena are not mutually dependent 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, leading to undertreatment of pain.

B. Trends

1. Abuse

In 2006 alone, over two million people began using pain relievers improperly (1). The incidence of abuse is especially high among teens, young adults, and those over 60. National figures show that since 2002, prescription drug abuse among young adults has increased dramatically (3). Over the past three years, abuse of prescription medications among 18- to 25-year-olds increased by 17 percent (3). Additionally, through a review of research published between 1990 and 2006, Simoni-Wastila and Yang concluded that up to 11 percent of older female adults may use prescription medications inappropriately (9).

Increasingly, adolescents are "discovering" and experimenting with prescription medications. In 2006, according to Substance Abuse and Mental Health Services Administration (SAMHSA) figures, new users aged 12 or older of pain relievers outnumbered new users of marijuana (10). It is estimated that more than three million teens currently abuse prescription medications (3). The initiation rates of young people suggest that prescription drug abuse will continue to be an issue well into the future. Other disturbing trends are appearing as well; for example, the practice of "academic doping" – using medications such as Ritalin® and Adderall® without a prescription with the intent to improve performance on papers or tests – is becoming more prevalent among high school and college students across the country (11).

2. Diversion

Diversion can be defined as the unlawful channeling of regulated pharmaceuticals from legal sources to individuals who abuse these controlled medications. It can occur at any time as prescription medications travel from the source to the recipient—at the point of the manufacturer, the doctor's office, the patient, and anywhere in between (12).

A common type of diversion is medication-sharing with family and friends. According to the 2007 NSDUH, over 70 percent of prescription drug abusers got the medications free from a friend or relative. By contrast, only four percent of users purchased medications from a drug dealer or other stranger, highlighting the fact that methods used to prevent illicit drug trafficking will not necessarily be appropriate when addressing prescription drug abuse. New approaches will, therefore, be needed for policymakers tackling prescription drug abuse (3).

The relative availability of prescription medications when compared with illegal drugs and the prevalence of people sharing medications with family members or friends (13) are thought to contribute to prescription drug abuse in the United States. Another major factor is a problem of perception. As prescription medications are legal and commonly prescribed, many people may believe that they are inherently safe and do not have harmful effects (14).

3. Consequences

Taking a medication without an individualized, up-to-date prescription can lead to severe consequences. Prescription medications may have a harmful – even potentially fatal – effect on one person that the original prescription holder did not experience, especially when multiple medications are taken at once. The risk increases when people combine prescription medications with illegal drugs or alcohol, as studies show roughly half of teenage users do (15).

The misconception of safety can lull users into taking more and more pills to get high, and overdoses can occur. Opioid pain relievers are particularly dangerous because they can be very habit-forming, especially for teens, and have a high potential for fatal overdose. Reports show that teen admissions to treatment facilities for addiction to prescription pain relievers have increased by 300 percent since the mid-1990s, and the number of overdoses brought into emergency departments has also jumped over a similar period of time (10).

A little-discussed danger of misusing prescription medications is that people who abuse opioids, such as OxyContin®, are at risk of graduating to heroin, which has a similar chemical composition and produces a similar high. OxyContin® is a synthetic opioid that resembles morphine, the organic substance from which heroin is derived (16,17). In 2006, New England states saw a rash of young people overdosing on opioids and heroin in small towns and suburban areas; for example, the number of opioid-related deaths among young people in Massachusetts that year was five times greater than in 1997. This increase may be attributed to the growing number of teens trying prescription opioids to get high and the availability of inexpensive heroin (18).

Additionally, an increasing number of accidents connected with prescription drug abuse is being documented. Drug tests of intoxicated drivers involved in 784 car accidents in West Virginia indicated the presence of prescription medications in their systems more often than illicit drugs (19). People driving under the influence of prescription medications can cause fatal accidents and harm to others much the same as drivers using alcohol or illegal drugs due to increased reaction time, drowsiness, or confusion.

Recent legislation and advocacy organizations have been named for people who lost their lives due to prescription drug abuse-related incidents. The Troy and Alana Pack Foundation is a California-based

nonprofit organization that was named in tribute to two children who were killed by a driver who was both drunk and high on prescription medications (20). The organization, founded by Troy and Alana's parents, aims to educate the public about traffic safety and to help develop and support traffic safety-related legislation. To date, the foundation has contributed to the passage of California DUI laws as well as legislation bolstering the state of California's Prescription Monitoring Program (21,22). The Coalition to End Needless Death on Our Roadways (also known as END) is another traffic safety nonprofit organization that is committed to reducing impaired driving-related deaths, including incidents in which prescription drug abuse is involved (23).

C. Undertreatment of Pain

Opioids, despite their potential for abuse, are essential to the management of pain for patients with chronic pain, cancer, or other ailments, including acute pain. Unfortunately, pain is undertreated for many patients. For example, in a literature review of publications on cancer-related pain from 1987 through 2007, Deandrea et al. concluded that one out of two patients with cancer-related pain is undertreated (24). In another study, Won et al. found that while 49 percent of nursing home residents had persistent pain, a quarter of these residents with pain received no pain relievers (25).

Studies have found that practitioners' concerns about the regulatory scrutiny surrounding pain relievers due to prescription drug abuse could cause prescribers to undertreat pain (26). This finding highlights the need for balance in addressing the abuse of prescription medications.

D. Disparities in Treatment

Data on disparities in pain management bring another dimension to the interconnected issues of prescription drug abuse and undertreatment of pain. Disparities in the prescribing of opioid pain relievers for persons from racial/ethnic minority groups and women have been documented (27). Studies have found that, of prescription drug abusers, 91 percent are Non-Hispanic white, less than five percent are black, and two percent are Hispanic (28). In one study of data from the National Hospital Ambulatory Medical Care Survey, however, researchers found that 31 percent of Non-Hispanic white emergency room patients with pain received an opioid, compared with 23 percent of black patients and 24 percent of Hispanic patients (27). In addition, in their 2003 pain management survey, Green and Wheeler found that physicians were more likely to choose the optimal pain management response for men who underwent prostate surgery than for women following uterine surgery (29). **Health care practitioners must be trained to better assess and implement care that is gender, culturally, and linguistically appropriate.**

III. Consensus on National Policy

The abuse of prescription medications is a thorny issue to address because pain relievers and other prescription medications provide needed relief and treatment for many patients. It is estimated that 50 million Americans suffer from chronic pain per year, and chronic pain is the most common cause of long-term disability in the United States. Still, research suggests that three out of four chronic pain sufferers do not receive appropriate therapy (30). Opioid pain relievers are currently the optimal medications used to manage moderate to severe pain as well as to improve the quality of life for people with chronic pain. At the same time, these opioid medications are among the most commonly abused and sought for diversion (31). It is imperative that policies and programs be crafted to deal with prescription drug abuse, while simultaneously ensuring that legitimate patient access to medications is not restricted in any way.

The development of effective prescription medication policies requires multi-sector collaboration, incorporating input from groups that approach the problem from several angles. To achieve a central principle of balance between patient access and abuse prevention, members of the family, scientific, health, safety, education, and technology communities – in addition to government – must be involved in developing and implementing solutions (32). **This national policy sets forth a systems approach with multiple action-oriented strategies and was developed based on expert input from the pain management field, in addition to the general medical/scientific and drug abuse prevention communities.**

CLAAD's recommendations take a public health approach to the issue of prescription drug abuse and focus on universal precautionary measures. The policies recommended herein are necessarily broad, derived from commonalities – yet not unanimity – among numerous groups. Future studies must collect and analyze outcomes data to craft more specific strategies. As this paper outlines, the medical community, state and federal governments, law enforcement, advocacy organizations, and private enterprise all must play important roles in addressing the problem of prescription drug abuse. For example, researchers and the medical community can study the best approach for monitoring pain management, while private enterprise can develop new products that deter abuse. To prevent duplication of current efforts, all future work to reduce the incidence of prescription drug abuse must build on the existing activities and accomplishments of those committed to solving the problem.

IV. Lawful Access

The diversion and abuse of prescription medications have criminal and legal consequences in numerous scenarios. Given the intertwined issue of sufficient health care and pain management for patients with a legitimate medical need, however, traditional law enforcement alone can be inadequate, counterproductive, and even harmful. Prescription drug offenses must, therefore, be pursued with an awareness of the sensitive nature of the situation.

A. Appropriate Involvement of Law Enforcement

Preventing certain types of diversion of prescription medications, especially as the incidence of abuse grows in the U.S., requires the commitment and attention of law enforcement. Abusers get access to prescription medications in a variety of ways; while drug-sharing among friends and family is a common source, many other types of illicit diversion also occur such as outright theft. Pills can be stolen in residential or hotel guest situations by cleaning and repair personnel, in home burglaries, in pharmacy robberies and night break-ins, while in transit to their destination, from hospital inventories by workers, and through many other means (12,33). Studies point to pharmacy theft as a main source of primary diversion – diversion that happens along the distribution chain before a medication ever is prescribed for patient use (34).

People also manipulate or circumvent the prescription process to illicitly obtain medication, constituting another type of diversion. Forgery occurs when users provide false identities and information to get access to medication or when patients or health care workers alter prescriptions. "Doctor shopping," in which people get prescriptions from multiple doctors simultaneously in order to accumulate a larger-than-normal supply of pills, has become a major problem as well. So-called "pill mills" are clinics that have a reputation for providing prescriptions to patients who do not have a legitimate medical need or for writing prescriptions beyond the legitimately needed number of pills or duration of treatment (12,33).

Despite the many illicit means by which prescription medications reach abusers, most major U.S. cities do not have law enforcement officers assigned to the prevention of prescription drug diversion or abuse (35). This lack of attention to the problem is due to a number of factors. Uncovering and stopping prescription medication diversion is seen as less exciting or glamorous than work in illicit drug units to stop street dealers and trafficking. Other preconceived notions, such as the belief that prescription drug abuse prevention work is too complicated or time-consuming to have a real impact, may be in play as well. Perhaps most importantly, however, many law enforcement officials—like the general public—simply may not realize that the "almost silent" issue of prescription drug abuse is a problem in their jurisdiction (35).

In order to correct this deficiency in oversight by the law enforcement system, the following steps should be taken:

> State and local investigators must be dedicated to pursuing prescription theft, forgery, and manipulation cases as well as intervening in other cases of criminal diversion, possession, and distribution of prescription medications.
>
> To direct investigation resources effectively, it is essential to quantify diversion through further research and categorize the different types of illicit access to prescription medications.
>
> New technology solutions that can achieve heightened coverage of the prescription medication supply chain, such as radio frequency identification, must be employed (36-38).

Law enforcement can make other regulatory gains simply by streamlining the process by which they pursue diversion cases. Form 106, the only information system that directly measures primary diversion offers an example (39). Registered suppliers of prescription medications that are controlled substances, such as distributors, pharmacies, and hospitals, are required to use Form 106 to report to the U.S. Drug Enforcement Administration (DEA) any losses or thefts of medication. Formerly, the registrant had to fill out the form by hand and send it to the regional DEA office, which then forwarded it to Washington, D.C., to be manually entered into a database. This time-consuming process was sped up considerably in October 2008, when the DEA switched to an electronic form, thereby improving the quality and efficiency of data collection (40).

CLAAD applauds the DEA for adopting the policy recommendations on Form 106 that it received from the Pain & Policy Studies Group, CLAAD, and Tufts Health Care Institute. There are still many improvements that could be made at the federal level, however, to optimize data collection and subsequent diversion investigations. A 2005 study, for example, found that the DEA's electronic database, which compiles annual data from Form 106, only contained analyzable data from 22 states (34). Additionally, federal law currently places the investigation of pharmacy theft – a very common type of primary diversion – under the purview of the Federal Bureau of Investigation, even though the DEA is the agency charged with receiving and compiling the data on those pharmacy thefts and losses (personal communication, David Joranson, January 13, 2009). **The federal government must eliminate this jurisdictional split through legislation, giving the DEA jurisdiction to respond to pharmacy thefts, as the DEA has access to the data necessary for investigating these crimes.**

Cases Beyond the Reach of Law Enforcement

In criminal cases like those described above, the involvement of law enforcement is clearly necessary. Cases of prescription-sharing among family members and friends, however, are not pursued by law enforcement, nor would law enforcement's involvement in these cases be the most appropriate intervention. Prescription-sharing often stems simply from public misinformation and a lack of understanding about the potential for, and dangers of, prescription drug abuse. Efforts to address diversion due to medication-sharing should focus on developing and implementing education initiatives to raise public awareness and change the cultural norm (see Section V.C, "Public Education and Awareness Initiatives").

To maintain the principle of balance between preventing prescription drug abuse and ensuring adequate pain treatment, law enforcement must avoid interfering in medicine and legitimate patient care, just as medical professionals have a duty to avoid contributing to opioid diversion (39). In cases where doctors are prescribing to abusers, whether intentionally or without knowledge of the abuse, law enforcement must take care to collaborate with the medical community – and, specifically, pain management experts – because of the complex nature of the situation. Physicians must be approached from a perspective distinct from other parties accused of diversion (34). It is essential to take into consideration those helped by the doctor as well as those harmed.

Investigators must work with medical experts to differentiate between a case of a doctor purposely prescribing drugs inappropriately, which would constitute a criminal case, and a case of a well-intentioned doctor who needs training on recognizing abuse and/or prescribing opioids, which can be handled administratively. Arrests and investigations of medical practitioners can leave many legitimate pain patients without the care they need when their doctor's services are interrupted. The medical community, law enforcement, and resources in the local community must cooperate with each other to ensure a smooth transition to another provider for such patients and to provide treatment and recovery services for abusers who had been using that doctor as a source of opioids.

B. Insurance Fraud

As part of the multi-sector collaboration that is needed, it is appropriate and essential for insurance companies to identify and pursue cases of insurance fraud related to prescription drug abuse. Insurance companies have great incentive to be more involved in addressing the issue, not just as a public health concern but for their own protection. The Coalition Against Insurance Fraud reports that health insurers lose up to $72.5 billion every year because of prescription drug diversion of opioids alone (41). Insurance carriers would not only realize significant cost savings by better addressing fraud, they also would reduce their liability; insurance company executives could be held liable for a patient death or injury if they knew, or should have known through due diligence, that they were enabling drug abuse (41).

Although insurance companies are somewhat aware of the problem of diversion, many insurers have not taken any consistent or effective steps to address it. Given that recent studies have described insurance fraud as the "main financier and enabler" of prescription drug diversion, this inaction must be remedied (41). Companies must form pain management work groups in their special investigation units in order to distinguish between patients with legitimate chronic and ongoing pain needs and insurance clients who are abusing the system. **Insurance companies also must develop protocols and implement better training for their investigators in recognizing and handling prescription drug diversion.** Such training can be facilitated through the National Association of Drug Diversion Investigators, an organization that provides cooperative education and training about the prevention, investigation, and prosecution of pharmaceutical drug diversion (42).

Several types of insurance fraud involving prescriptions have been documented, including the following: doctors intentionally prescribing medications patients do not need for non-diagnosed conditions (43-45), prescription forgery (46), people using someone else's identity to get medical care and prescriptions through that person's insurance coverage (41), and patients doctor shopping (47). There are often warning signs that indicate a possible case of prescription drug diversion. The amount and frequency of prescriptions written for individuals should be monitored for detectable patterns such as repeated early refills or large quantities of pills. Insurers also should question prescriptions under the following circumstances:

> When prescriptions have no logical relationship to the diagnosis;
>
> When medications with significant abuse potential are "off-label," or prescribed for treatment outside of typical usage; or
>
> When a patient is using multiple prescribers and/or pharmacies at once.

Additionally, states can reduce the diversion and abuse of prescription medications, as well as their Medicaid expenses, through increased monitoring. Prescription data is readily accessible to all states through their Medicaid databases; in fact, U.S. General Accounting Office (GAO) reports that date back over a decade have recommended that states monitor Medicaid databases (48). Investigators can search these databases to identify trends that could indicate diversion, such as patients who are recipients of the same or similar medications from multiple prescribers at once (personal communication, David Joranson, January 13, 2009).

C. Internet Pharmacy Oversight

Online pharmacies are another source of prescription medication diversion, as some so-called "rogue pharmacies" illicitly sell medications over the Internet without a prescription, attracting new customers through spam email and online advertising. In 2008, the National Center on Addiction and Substance Abuse found that 85 percent of websites advertising or selling controlled prescription medications online did not require a prescription from a patient's doctor (48). Of the remaining websites, half allowed patients simply to fax a prescription, leaving an opening for fraud or other manipulation of prescriptions.

Reports suggest that comparatively few prescription drug abusers use these rogue pharmacies as their source (3). Also, a 2004 study showed that only four percent of Americans ever bought prescription medications over the Internet and that most of the sites they used required a prescription from a doctor

(49). The rogue pharmacies that are in existence, however, are persistent; the same 2004 study found that 55 percent of Internet users reported receiving unsolicited email advertising a prescription medication (49). For the prescription medication users ensnared by these advertisements, rogue pharmacies can lead to devastating consequences.

The case of Ryan Haight is an example of these potential consequences. The federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was named for an 18-year-old who died from an overdose of hydrocodone, a generic form of Vicodin® that he bought online from a pharmacy website without seeing a doctor. The act seeks to eliminate rogue pharmacies by criminalizing the use of the Internet to advertise illicit selling of controlled substances. The act also places stricter requirements on pharmacies that sell controlled substances online, mandating that they first receive a modification of their existing DEA registration and that they make monthly reports of quantities dispensed to the Attorney General. Internet pharmacies must clearly post their compliance, licensure, and contact information on their websites, and prescription medications can only be dispensed over the Internet to a patient with a valid prescription who has seen a doctor at least once in person (50).

The Ryan Haight Act is an excellent example of what can be achieved through multi-sector collaboration, as many organizations from different communities came together to advocate for its successful passage Instrumental groups and individuals that took on leadership roles in advocating for the act included CLAAD; Educating Voices, Inc.; Save Our Society From Drugs; Ryan's mother, Francine Haight; and JVP Memorial Fund (51), an organization created by Dan Pearson, whose son also died from the use of prescription pain relievers he bought online and who had pushed a similar bill through the state legislature in Minnesota (52). These invested parties communicated with DEA officials for assistance in analyzing the bill's provisions and educated influential members of Congress on the urgent need for the legislation.

Beyond legislation, private service providers must prevent rogue pharmacy websites from utilizing their services to conduct their business. There are many ways for service providers to discourage and even interrupt the activities of rogue pharmacies, including the following:

> Financial institutions can flag business entities that have been identified as illicit vendors and refuse to make payments processed by credit or debit cards.
> **Internet service providers can block non-certified pharmacy websites.**
> **Pharmacies legitimately selling prescription medications online must signal their legality to consumers by complying with the requirements of the Ryan Haight Act (see discussion above) and displaying that they are accredited by the National Association of Boards of Pharmacy (NABP) as Verified Internet Pharmacy Practice Sites™.** The NABP maintains an online searchable listing of such certified, recommended sites, as well as a listing of non-recommended sites (53).

Efforts to combat rogue pharmacies also must address international pharmaceutical trafficking, as many illicit websites are run from outside U.S. borders. The Ryan Haight Act requires the DEA to provide annual reports to Congress on the agency's efforts to collaborate with multinational pharmaceutical companies to address global online trafficking of controlled substances. This provision is a good first step towards dealing with illicit international trafficking; however, more work is needed, and the DEA must collaborate with its foreign counterparts in order to be successful.

D. Electronic Systems and Controls

Electronic information-sharing systems hold promise to prevent diversion through secure, interlinked electronic tracking and monitoring systems and must be developed further. Those dedicated to preventing prescription drug abuse should support these innovative methods of detecting diversion, which include e-prescribing, Prescription Monitoring Programs (PMPs), and patient identity tracking systems.

1. E-Prescribing

E-prescribing, in which doctors electronically send their prescriptions directly to pharmacies from the point of care, can improve the prescribing process while minimizing diversion and abuse. The ability to forge or alter prescriptions is reduced, and e-prescription records can be integrated into other medical records, increasing efficiency and cutting down on paperwork. Also, studies have suggested that e-prescribing can significantly lower patients' medical costs by helping prescribers to find generic or lower-cost medications. The Agency for Healthcare Research and Quality has concluded that use of a complete e-prescribing system could save $3.9 million per 100,000 patients per year (54).

Additionally, e-prescribing offers a key public health benefit by reducing the likelihood of medication errors. The persistent problem of doctors' illegible handwriting is a familiar joke. Misreading of prescriptions, however, can lead to very serious consequences. According to a 2006 study by the Institute of Medicine, nearly 7,000 people die annually in the United States due to medication errors, often from improperly read or filled prescriptions (55). The associated costs to the health care system of these errors are estimated to be in the billions (56).

While the technology for e-prescribing already exists, it continues to be underutilized. Only two to three percent of prescriptions are issued electronically (57). Most community pharmacies already use a prescription transmission network called SureScripts-RxHub, meaning they are prepared to receive

electronic prescriptions without having to update their technology (59). Prescribers, however, have been slow to adopt e-prescribing, due to the associated costs and fees for installing the necessary equipment and software (60). It is estimated that only 10 percent of medical practitioners currently use e-prescribing (61).

In July 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008, which includes incentives for physicians to switch to an e-prescribing system. The act is expected to increase the number of physicians using e-prescribing by giving a two percent bonus in 2009 and 2010 to doctors who use e-prescribing for their Medicare patients – with smaller bonuses awarded in subsequent years – and implementing a pay reduction thereafter for those who still do not (62). CLAAD praises Congress for passing this provision, as the monetary bonus should provide encouragement for more doctors to move to an e-prescribing system.

Medical practitioners also may underutilize e-prescribing because the DEA currently prohibits e-prescribing of certain prescription medications under the Controlled Substances Act (CSA). Controlled substances are medications or other substances that are regulated by the federal government under the CSA because of their risks and potential for abuse (62). Controlled medications are categorized into different schedules according to their level of risk. For example, several opioids that are commonly prescribed to treat chronic pain – such as prescription pain relievers like Percocet® and OxyContin® – are regulated by the DEA because they are derivatives of morphine, a Schedule II (high potential for abuse) controlled substance (63). Doctors' offices are often reluctant to maintain both paper systems and e-prescription systems because of the doubled workload, so they rely on paper for all prescriptions.

In June 2008, the DEA proposed a rule that would address this concern by revising their regulations to allow practitioners to use one e-prescribing system to write prescriptions for all medications, including Schedule II controlled substances (64). As of January 16, 2009, the rule had not been finalized.

Privacy and Security

E-prescribing systems must include a number of safeguards to protect patient privacy and information security. Without proper security measures, these systems could facilitate new, more anonymous routes of diversion that would be even harder to prevent, detect, and/or prosecute. As e-prescriptions are transmitted through a series of intermediaries, unauthorized release of sensitive information due to an error is possible. Authentication of system users is also a necessity.

Safeguards can be instituted for e-prescribing to handle these security concerns. They must be balanced, however, with the overall usability of the system. The DEA-proposed rule, for example, would require two forms of identification (entering a password and scanning a physical device) each time a prescriber uses the system. Such strict measures, though, could negatively impact the feasibility of prescribers' offices operating such a system. A comprehensive e-prescribing system must be practical for medical facilities to utilize, especially in light of the DEA's mandate that only a prescriber registered with the DEA can electronically "sign" e-prescriptions, not a non-registered assistant. E-prescribing also must preserve the prescribing authority of nurse practitioners and physician assistants.

An effective, secure e-prescribing system that protects patient privacy holds great potential for reducing prescription forgery and prescription medication diversion. E-prescribing is an important first step to reducing errors, as well as ensuring the legitimacy of prescriptions.

2. Prescription Monitoring Programs

Prescription Monitoring Programs (PMPs) are statewide data collection systems that track patient-specific prescription information. States can use the data to identify trends that likely point to diversion such as people using many different doctors and pharmacies to obtain the same medication. **PMPs are an initiative that already has proven effective in deterring doctor shopping and prescription forgery in many states across the U.S., and CLAAD advocates for their continued use and improvement.**

The programs have confidentiality safeguards such that information in the system can only be retrieved by authorized users. These authorized users vary by state, but usually include the patient, their physicians and pharmacists, and law enforcement officials. Other users allowed in certain states include licensing boards, Attorneys General, and Medicaid (65).

According to the DEA, 38 states had enacted legislation to mandate a Prescription Monitoring Program as of November 2008, and 11 others had legislation in the developmental stages. These states that now require PMPs represent 98 percent of all pharmacies that are registered with the DEA and 98 percent of medical practitioners and prescribers. Only one state, Wisconsin, had not taken any steps to create a PMP (66). This state, however, uses a different system to monitor the distribution of prescription medication.

While Wisconsin's system for detecting diversion is not compatible with other state PMPs for data-sharing, its effectiveness and success in multi-agency collaboration suggest that other states should consider incorporating similar strategies into their diversion prevention plans. Since the 1970s, Wisconsin has operated a program by which key agencies with authority to manage different aspects of the state's controlled substance distribution system collaborate to share data. By integrating crime lab drug evidence, Automation of Reports and Consolidated Orders System—commonly known as ARCOS—data, and information from Wisconsin's Medicaid database, the agencies are able to identify regions of the state with unusual trends in their prescription medication data, and then flag these areas for further investigation.

Through this approach, state officials are able to better identify sources of diversion without putting additional regulatory pressure on medical professionals and patients (personal communication, David Joranson, January 13, 2009).

Electronic PMPs also have been successful. Kentucky runs a particularly effective PMP known as Kentucky All Schedule Prescription Electronic Reporting (KASPER). In 2007, KASPER processed more than 361,000 requests for patient prescription reports, over 93 percent of which were requested by physicians (xxi). The system also provides prescribers with real-time data access, a capability that all states must develop.

Improvements to the implementation of state PMPs would make them even more effective. Training of medical professionals and prescribers in how to interpret and use PMP data would facilitate efficient use of these systems. **CLAAD applauds those select state medical boards that currently provide this education and calls on others to follow suit. Also, to encourage more prescribers to embrace PMPs, the American Medical Association (AMA) must update the Current Procedural Terminology® (CPT®) codes to allow for proper record-keeping and reimbursement for the additional administrative time that prescribers use to access PMP data as a billable procedure.** CPT® codes are numerical codes assigned by the AMA to every task or procedure that a doctor may conduct; they ensure uniformity and are used by providers, insurance companies, and Medicare (67).

Abusers may attempt to move their doctor shopping to a neighboring state after PMPs take effect in their home state. They also may seek prescriptions from doctors in multiple states, preventing single-state PMPs from revealing a pattern. To reduce these trends, states have begun to coordinate interstate data-sharing systems so that prescription information can be searched across state lines. Through a U.S. Department of Justice (DOJ) pilot program, four states—Kentucky, Nevada, New York, and Ohio—will exchange PMP data in 2009 to test the potential for interstate data-sharing (65). As these capabilities develop, states should establish consistent standards so that data will be accessible, yet secure and confidential.

The average start-up cost for a Prescription Monitoring Program is $350,000, and ongoing costs to maintain the system run from $100,000 to almost $1 million annually (65). Two grant programs are available for states seeking funding to create and maintain their PMPs. The federal Harold Rogers Prescription Drug Monitoring Program grant, administered by the DOJ, awards funds to states while allowing them to set their own requirements for the PMP. The National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) also established a grant program for PMPs within the U.S. Department of Health and Human Services. In contrast to the Harold Rogers grant, NASPER requires that state applicants collect data on certain types of prescriptions and have the capability to share data with other states (69). While NASPER was passed, it has not currently been funded or implemented.

CLAAD applauds the leadership of members of Congress in sponsoring and working to push NASPER through the federal legislature as well as their ongoing efforts to establish and fund a grant program that is administered from a public health perspective and that encourages interstate data sharing. Indeed, the issue of prescription drug abuse is best approached from such a public health standpoint. The U.S. Department of Health and Human Services certainly must play a key role in reducing the incidence of prescription drug abuse. The current Harold Rogers grant program, however, has largely been successful, and the DOJ is handling funding and implementation systems for prescription monitoring grants very appropriately. Based on its admirable progress so far, the Harold Rogers grant should be continued without interruption.

As with the e-prescribing systems discussed previously, officials administering PMPs must ensure that the systems do not create barriers to pain care patients' access to their medications. Increased regulatory scrutiny by way of monitoring programs may deter medical professionals from prescribing pain relievers, leaving patients who have a legitimate need without sufficient pain treatment (25). The following guidelines for state PMPs, adapted from the Alliance of State Pain Initiatives' list of principles, should help differentiate and protect legitimate prescribing while identifying cases of abuse and diversion:

> Patient confidentiality must be protected to the greatest extent possible.
>
> Individual health care professionals must be granted access to PMP data about their individual patients so they can evaluate those patients' use of controlled substances.
>
> Law enforcement agencies should be allowed access to the data, but only when probable cause justifies such access in the course of investigating possible abuse or diversion or when public health officials alert law enforcement to apparent criminal activity (30).

3. Patient Identity Tracking Systems

The success of Prescription Monitoring Programs and e-prescribing in deterring forgery, doctor shopping, and other diversion rests, in part, on the ability to identify individuals and the prescriptions written for them. Electronic records, therefore, must successfully match up with the person physically receiving the prescription. An identity loophole currently exists that undermines that matching. Patients are seldom required to show a driver's license or other ID as proof of identity when visiting health care facilities or stopping by the pharmacy counter. When patients do show their ID at a clinic, doctor's office, or pharmacy, there is currently no system in place to determine whether the ID is authentic. It is possible that people could use false identities to receive multiple prescriptions even when a PMP is in place.

ID technology exists to close this loophole. Under the federal Real ID Act of 2005(70), states are required to meet minimum ID verification and security criteria for drivers' licenses by 2011 at the latest (71). Private companies already produce the scanner technology needed to verify IDs, which could be installed in pharmacies and doctors' offices. Casinos, for example, often have an identity verification system in place to confirm a person's identity before paying his or her winnings. These systems transmit the ID to a secure database, which then sends back an "OK" or "not OK" message to the staff accessing the system.

Opportunities exist to integrate a patient identity tracking system with Prescription Monitoring Program data and e-prescribing into a comprehensive electronic prescription medication database. The swipe of a patient's ID card at the medical facility or pharmacy counter would then verify identity, bring up his or her prescription data in real time, and allow the practitioner to determine whether any alerts have been placed on the account. If developed securely and effectively, the three systems together would become a powerful tool for identifying doctor shopping, falsified or improper prescriptions, and other forms of diversion. Equally important, such a system would alert prescribers and pharmacists to the existence of drug interactions or other errors, thereby further protecting patient health.

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Acknowledgements: The authors would like to thank Dr. John Femino of Meadows Edge Recovery Center, David Joranson of the Pain & Policy Studies Group, and Dr. Nathaniel Katz of Analgesic Research for lending their expertise in the development of this paper.

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THE JOURNAL OF
GLOBAL DRUG POLICY AND PRACTICE

A Vital Balancing Act: Multi-Sector Approaches to Preventing Prescription Drug Abuse in the United States while Ensuring Adequate Patient Access to Medications: Part 2

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V. Appropriate Use

A. Best Practices

To begin to solve the dual problem of prescription drug abuse and undertreatment of pain, as well as to address disparities in pain treatment, the medical community must implement universal precautions in prescribing. The adoption of universal precautions for bloodborne pathogens in the late 1980s is a commendable example of the medical community's successfully implementing a set of universal precautions (1). Prior to the adoption of these universal precautions, the Centers for Disease Control and Prevention had recommended "Blood and Body Fluid Precautions," which included such basic practices as wearing gloves when dealing with blood and washing hands after any contact with blood, to be used only with patients who were infected or suspected to be infected with bloodborne pathogens, such as HIV (2).

Taking medical histories and performing medical examinations do not always identify patients with bloodborne pathogens. Due to this fact, health care professionals concluded through medical discourse that blood and bodily fluid precautions should be taken with all patients (1). These universal precautions effectively reduced stigma for patients, decreased risk for health care workers and patients, and also improved patient care (3). When applied to prescription drug abuse, the same concept of universal precautions can be implemented to effectively reduce the stigma of pain or substance use disorders, decrease risks and liabilities for prescribers, and improve patients' pain treatment.

Implementing a universal precautions approach to prescribing – such as Gourlay et al.'s 10 Steps of Universal Precautions in Pain Management – can effectively reduce the incidence of prescription drug abuse while preventing disparities in the treatment of pain (3). Universal precautions, like those outlined in Figure 1, must apply to all patients during all stages of treatment with medications that have the potential to be abused, including initial risk assessment and ongoing monitoring during therapy.

Figure 1: Gourlay's 10 Steps of Universal Precautions in Pain Medicine (3)

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 four A's of pain medicine.*

9. Periodic review of pain diagnosis and co-morbid conditions, including addictive disorders.

10. Documentation.

* "Four A's" refers to the technique developed by Passik and Weinreb ( ), in which analgesia, aberrant behaviors, adverse effects, and activities of daily living are assessed to help classify patients' levels of risk.

1. Assessment

Assessing patient risk as an essential element of universal precautions in prescribing must be incorporated into the medical community's best practices. Preexisting problems, such as mental illness or substance abuse history, are risk factors that can lead to opioid addiction. All treatments necessarily involve risks and benefits; an appropriate risk-benefit strategy assesses whether the benefits of a medication outweigh the potential risks. If patients' risk factors are effectively assessed, their risk level can be determined, and therapy can be designed and monitored accordingly.

Current literature on opioid abuse has identified three categories of risk factors for misuse or abuse (5,6):

Biological risk factors include age (younger than 45 years), gender, family history of prescription drug or alcohol abuse, and cigarette smoking.

Psychiatric risks include substance use disorders, preadolescent sexual abuse (in women), and major psychiatric disorder (e.g., personality disorders, anxiety or depressive disorders, bipolar disorders).

Social risk factors include prior legal problems, a history of motor vehicle accidents, poor family support, and involvement in a problematic subculture.

Several assessment tools have been developed to assess these risk factors before patients are prescribed an opioid (7). **Assessing risk should be a universal precaution taken with all patients and should be incorporated as a standard practice when prescribing not just opioids, but any prescription medications with significant abuse potential.**

2. Monitoring

Ongoing monitoring of patient opioid therapy also must be incorporated into best practices in pain management. In order to prevent or stop prescription drug abuse, all patients undergoing opioid therapy must be monitored by their physicians. Based on the risk level of each patient, monitoring should include different components. For example, for moderate-risk patients, monthly prescriptions and doctor visits should be required. For high-risk patients, weekly visits should be required. Also, rapid onset formulations should not be prescribed to high-risk patients, while short-acting formulations should be limited (8). The following should be included in routine monitoring for all patients:

• Urine drug tests, which can substantiate abuse by identifying levels of specific drugs in a patient's system through advanced technology,

Prescription Monitoring Programs (as described in Part 1, Section IV.D.2, "Prescription Monitoring Programs") to monitor patients' access to pain medications.

Treatment agreements, which set forth in writing the mutual expectations and obligations of the patient and prescriber and clarify boundaries for the patient (3). Such agreements are an essential part of monitoring.

Ongoing monitoring that utilizes tools such as urine drug tests, Prescription Monitoring Programs (PMPs), and treatment agreements must be a universal precaution taken with all patients who have been prescribed opioids or any medications with significant abuse potential.

CPT® Codes

Incentives for delivering quality care also should be implemented, such as pay for performance for monitoring and documentation of opioid patient functioning. The American Medical Association (AMA) must ensure that new CPT® codes are developed that allow for proper medical documentation and reimbursement for the associated costs of technologically advanced urine/blood testing and analysis of PMP data. It is essential that advanced urine/blood testing be incorporated into current best practices, as these technologies make it possible to identify individual drugs in a patient's urine or blood, including oxycodone, methadone, fentanyl, and other medications (9); traditional tests cannot distinguish between

one opioid and another (personal communication, Femino, January 15, 2009). 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 if there are abnormally high levels of the prescribed medication in their system (10).

CPT® codes are updated by the AMA's CPT® Editorial Panel, a 17-member panel authorized by AMA's Board of Trustees to revise, update, or modify CPT® codes, descriptors, rules, and guidelines (11). In 2007, the AMA updated its CPT® codes to provide for a Screening, Brief Intervention, and Referral to Treatment (SBIRT) code in a faster-than-normal process as a result of collaboration among various groups, including the federal government and practitioners (12). **The AMA, the federal government, medical practitioners, and insurance companies should make a similar full-force effort to update CPT® codes to provide for advanced drug testing and PMP data checks, as conducting and documenting these procedures are essential to the prevention of prescription drug abuse.**

3. Universal Precautions to Eliminate Disparities

Universal precautions in prescribing also would help to address the current disparities that exist in the treatment and management of patient pain. Through literature review, Green et al. concluded that across all settings and all types of pain – including acute, cancer, and nonmalignant chronic pain – African Americans and Hispanics/Latinos as a group experience disparities in pain perception, assessment, and treatment (13). As noted in Part 1 (section II.D, "Disparities in Treatment"), disparities also have been documented in pain management for women (14,15).

One method of addressing racial and ethnic disparities in treatment is for medical schools to increase their efforts to recruit racial and ethnic minorities, as patient-provider racial concordance is associated with improved patient satisfaction (16). While CLAAD supports these efforts as necessary across the board, medical professionals also must receive training in culturally and linguistically appropriate care in order to effectively address treatment disparities. A universal precautions approach to prescribing, in which consistent assessment and monitoring practices are applied to all patients, is essential to preventing physician bias in pain management and prescribing. **Increased recruitment of racial and ethnic minorities into the medical field and cultural competence training, along with universal precautions, must be implemented to eliminate disparities in pain management.**

4. Use of Technology

The growing incidence of prescription drug abuse has led to the development of new medications and ways of dispensing them. **These technological and scientific advances must be part of universal precautions in prescribing, and CLAAD supports further development in these areas.**

Abuse-deterrent Opioid Formulations

New opioid formulations that are less susceptible to abuse can be a technologically-based universal precaution if made available on a wide scale. There are two main types of abuse-deterrent formulations – those that employ a pharmacologic barrier and those that employ a physical barrier. Pharmacologic barriers include:

- Sequestered opioid antagonists, which would release substances that prevent opioids from binding with receptors in the brain if the pills are crushed (17);
- Aversive agents, which would cause unpleasant side effects if taken at higher than therapeutic doses (17); and
- Opioid prodrug formulations, which would contain an opioid that could only be activated in the digestive tract (17).

Formulations that utilize physical barriers, such as hard shells and viscous gels, do not allow full release of the opioid dose if users attempt to crush or otherwise tamper with the pill (18).

Embeda™, developed by Alpharma Inc. (Bridgewater, New Jersey)(19) , is an example of an abuse-deterrent formulation that utilizes a sequestered opioid antagonist. This formulation consists of extended release morphine and sequestered naltrexone. When taken intact orally, the naltrexone, an opioid antagonist, would pass through the body. If Embeda™ were crushed, the naltrexone would be released for the purpose of blocking the effect of the morphine. The user's inability to experience euphoric effects when this medication is crushed, chewed, or converted to a liquid could deter these forms of tampering for purposes of abuse (20). **CLAAD applauds Alpharma Inc. for developing this abuse-deterrent formulation and calls on other pharmaceutical companies to follow its lead.**

Abuse-deterrent opioid formulations are an important tool to prevent or reduce prescription drug abuse. Despite their promise, however, these formulations can only be effective in addressing prescription drug abuse as part of a comprehensive plan that includes implementation of informed and consistent assessment, monitoring, and prescribing practices. **Prescribing of abuse-deterrent formulations must be incorporated into a universal precautions approach that helps reduce disparities in access to medications.**

Novel Dispensing Mechanisms

In addition to abuse-deterrent formulations of pain relievers, new dispensing technologies can be developed to aid in mitigating risk of opioid abuse. Advanced dispensing technologies can be applied in hospitals, clinics, nursing homes, clinical trials, and throughout the supply chain to prevent or reduce opioid

addiction and overdose (21).

One such device, called the Advanced Dispensing System (ADS), is currently under development by GW Pharmaceuticals Limited (Salisbury, Wiltshire, U.K.) (22). The ADS is a small device that dispenses medication in a tamper-resistant and secure way. This device, which can be handheld or placed in a fixed location, has features that allow it to provide drug reminders to patients and to recognize and eliminate inappropriate patterns of medication consumption (20). Such mechanisms can be applied as part of universal precautions in prescribing by allowing practitioners to monitor the patient's progress remotely.

During the July 2008 consensus meeting, CLAAD members listed desirable capabilities for an advanced dispensing device, which include:

- Preventing dose escalation and overdose by locking the patient out if dose or interval is disregarded;
- Documenting patient compliance by tracking when dosages are taken;
- Determining that the intended patient is the one consuming the drug; and
- Facilitating tapering of dosage when an exit strategy is required.

These devices also could be used to coordinate physician and pharmacy record-keeping and to manage the supply chain by locking patients out in cases of product recall or expiration. These **devices are an essential element in a universal precautions approach; it is important to highlight, however, that they are not a substitute for the comprehensive risk management offered in a universal precautions approach.**

B. Training for Medical Professionals

Medical professionals and prescribers need to receive more specialized training in identifying and managing prescription drug abuse. While pharmacists play a key role in dispensing prescription medications, only about half of pharmacists receive training on the identification of prescription drug misuse, abuse, and diversion (23). Additionally, a study of an internal medicine resident clinic found that 57 percent of survey respondents rated their chronic non-malignant pain training as "fair" or "poor" (24). This lack of training is a detriment to efforts to curb prescription drug abuse, as well as efforts to effectively treat chronic pain.

Continuing medical education (CME) should include training for practitioners and pharmacists in recognizing opioid abuse in patients. Also, to equip health care providers with the skills needed for monitoring pain management, they should be trained to interpret and use Prescription Monitoring Program data. Prescribers also should receive training related to abuse-deterrent formulations, including instruction that these medications have risks despite their abuse-deterring qualities. Abuse-deterrent medication training for pharmacists should highlight that prescriptions for abuse-deterrent medications must only be filled with those medications and must not be substituted with traditional formulations. As advanced dispensing mechanisms are adopted, use of these mechanisms also should be incorporated into CME training. Additionally, medical professionals must receive training in culturally and linguistically appropriate care in order to effectively address treatment disparities. Medical schools should incorporate all such training in universal precautions, much like their incorporation of universal precautions for bloodborne pathogens.

In addition to the federal Substance Abuse and Mental Health Services Administration (SAMHSA), there are many non-governmental organizations that are interested in helping to develop and implement training on handling prescription drug abuse, including the Federation of State Medical Boards (25) and individual state medical boards, the American Academy of Physician Assistants, the American College of Nurse Practitioners, major pain associations (e.g., the American Pain Society, the American Academy of Pain Management), the Association for Medical Education and Research in Substance Abuse, the Pain & Policy Studies Group (26,27), and Zero Unintentional Deaths.

C. Public Education and Awareness Initiatives

As mentioned in Part 1 of this article (Section II.B, "Trends"), people tend to perceive prescription medications as safe because they are legal, prescribed by physicians, and widely present in homes; therefore, many people do not recognize the risks associated with improper use (28). These misconceptions are widespread and are held not only by teens and young people, but by parents, law enforcement officers, and the public in general. **It is essential for people to be aware of the danger of their medications being passed on to others, and of the risk involved with misuse of those medications.** To end the common occurrence of prescription drug-sharing, people must come to view misusing prescription medications as a practice that is just as potentially addictive and dangerous as illegal drug use. Just as wearing a seatbelt is now a recognized public safety measure, so should the locking up and proper disposal of prescription medications become an assumed part of U.S. cultural practices.

Advocacy organizations from the family, anti-drug, and environmental communities, as well as federal and state governments, must develop and implement public education initiatives to change the cultural norm and teach the public that prescription medications must be used only as prescribed, safely stored, and properly disposed of. Prescribers and pharmacists should reinforce these messages when they interact directly with patients to write or fill prescriptions. Given the high prescription drug abuse rates among adolescents (29), consistent drug abuse prevention programs also

must be implemented in schools. Prescription drug abuse prevention should be integrated into the curriculum of health, science, math, and physical education classes throughout the school year and should start in earlier grades, middle school at latest.

Commendable national initiatives have already begun. The ZeroDeaths.org campaign calls consumers' attention to six principles to help reduce unintentional overdose deaths from prescription medications (30). Also, the U.S. Drug Enforcement Administration (DEA) has opened a toll-free international hotline where any person suspecting illegal sale and abuse of pharmaceutical drugs can call anonymously to report it. The number, 1-877-Rx-Abuse, is also open for anyone with information about suspicious Internet pharmacies, especially families who have lost a loved one because he or she obtained prescription medications over the Internet. People can make a report online through the DEA webpage as well (31).

Academic Doping

With the advent of academic doping at colleges and universities, members of the higher education community must become well-informed on the issue of prescription drug abuse. More students are taking medications such as Ritalin® and Adderall® without a medical need or prescription, with the intent of enhancing their concentration or improving their performance on a paper or test to compete in school (32). As this misuse becomes more prevalent, a creeping normalcy is taking hold on campuses, with students claiming that it is just "something people do." The misconception mentioned earlier, that prescription medications are inherently safe, plays a role as well.

The higher education community must act on this growing problem of academic doping. The use of medication without a prescription must be incorporated into university academic integrity policies and subject to consequences as a form of cheating.

VI. Safe Storage

A heightened public awareness of prescription drug abuse could help reduce medication-sharing among family and friends. Many teens who abuse medications, however, steal pills from the medicine cabinets of parents, other family members, or friends without their knowledge. A 2006 study found that more than three in five teens say prescription pain relievers are easy to get from parents' medicine cabinets, and over 50 percent of teens say pain relievers are "available everywhere" (27). Education efforts focused on the community also must emphasize the safe storage and disposal of prescription medications to prevent theft and misuse. Public opinion must be changed to adopt a cultural norm more like that of Germany, where people commonly keep medications locked up, and there are few problems with children and teens accidentally or purposely taking parents' medications (personal correspondence, Albert Kern, German Federal Ministry of Health, July 4, 2008).

Parents and others legitimately using prescription medications must employ precautions such as taking regular inventory of their pills and locking their medicine cabinets. The national Lock Your Meds campaign, sponsored by the National Family Partnership, educates parents on safe storage practices and encourages them to use word of mouth to compel others in their community to also take action. The National Family Partnership offers parents tips for protecting their children from prescription drug abuse (33) and useful resources, such as a home medicine inventory card (34). **Other advocacy organizations and federal and state governments must undertake similar public education initiatives to ensure that the locking of medicine cabinets becomes standard practice nationwide.**

From a policy perspective, the issue of prescription medication storage parallels the 1990s issue of gun violence and the initiatives to encourage gun owners to lock up their weapons. The success of those efforts, so that it is now commonplace for those legally owning guns to use safety locks or locked cabinets, shows that it is possible to effect a change in the U.S. cultural norm. The comparison is encouraging, as prescription drug abuse prevention is a less controversial societal issue than gun violence prevention. In the past, parental behavior has changed often as a result of public policies on safety, such as in the use of seatbelts, bicycle helmets, and child car seats. Changing behavior to lock up medications should be no different.

Safe storage options include medicine cabinets designed with a lock, lockboxes that can be screwed into the medicine cabinet, and small standalone safes or lockboxes. Lockboxes are readily available at retail stores, but not in pharmacies – the point of sale of pharmaceutical drugs, where consumers are most likely to remember the need for the item. **Pharmacies must routinely stock lockboxes and encourage consumers buying over-the-counter or prescription medications to purchase one.**

Purchase of a separate lockbox could be avoided entirely if medicine cabinets had a locking capability; most cabinets currently do not. **Bathroom fixture manufacturers and home builders must make locking medicine cabinets standard in every home.**

VII. Responsible Disposal

Most Americans are aware that they should not throw used car batteries in the trash or pour motor oil down the drain. This awareness is due in large part to public policy, consumer education, and efforts by businesses and constituency groups to educate the public that these practices are harmful. Careless disposal of prescription medications also is harmful, and can serve as a source for individuals who seek to divert pharmaceuticals to inappropriate uses, i.e., prescription drug abuse; similar efforts must be undertaken to teach people how to dispose of their unused medications properly.

People often incorrectly dispose of pills by flushing them down the toilet, which poses an environmental hazard and threat to drinking water, or by simply throwing them away in the bottle, which may permit diversion, in addition to unknown ecological consequences. The misconception that prescription medications can be flushed to safely dispose of them has led to the contamination of drinking water in many areas with low levels of multiple medications, including hormones, anti-depressants, and antibiotics. A 2008 investigative report by The Associated Press found that levels of such drugs could be detected in the drinking water supplies of 17 major metropolitan areas (35). No sewage treatment systems are capable of filtering out pharmaceutical materials; landfills and incinerators release substances from medications into the environment as well. It is not known what health effects the ongoing exposure to small amounts of these drugs may be causing.

The U.S. government, the pharmaceutical industry, medical practitioners, and waste disposal authorities have yet to develop a consistent message or systematic method for consumers to properly dispose of pharmaceutical products. The only advice on disposal currently available to consumers is to mix old medications with cat litter or coffee grounds to make them unpalatable before throwing them away. The U.S. Food and Drug Administration, the U.S. Drug Enforcement Administration (DEA), and the U.S. Environmental Protection Agency – under the coordination of the Office of National Drug Control Policy – must improve this rudimentary, insufficient approach.

Patients are not the only ones left with extra or unwanted medication. Pharmacies, hospitals, hospices, and wholesalers also need to dispose of their recalled or expired pharmaceutical products. In a process known as reverse pharmaceutical distribution, DEA registrants can return medications for potential credit from the manufacturer (36). A number of third-party companies also are registered with the DEA to operate as reverse distributors; they collect the medications and then either send them to the manufacturer or incinerate them (37,38). Consumers, however, are unable to use this system, as the Controlled Substances Act (CSA) prohibits reverse distributors from accepting prescription medications that are controlled substances from consumers who are non-DEA registrants (38).

Small take-back programs for prescription medications, by which consumers can give back their old and unwanted medication, exist in the states of Washington, Maine, Oregon, and California, and in a number of localities (39). The administration of these programs is challenging, though, as systems are not often in place to ensure proper disposal, and there is a substantial risk of diversion due to the large number of individuals involved. One-day prescription medication collection events that are held in some areas, similar to hazardous waste pick-up days, may not be sustainable because they rely on the availability of volunteers and local law enforcement.

To solve this complex problem, CLAAD calls on the DEA to create and administer a national program for medication take-backs from consumers that is easily accessible, uses current infrastructure, tracks the data, and is adequately funded. Unlike in smaller take-back programs, the DEA has the process controls available to ensure the prescription medications are not diverted and are properly disposed. A precedent already exists for an exception to the CSA rule, whereby a reverse distributor can accept from a consumer controlled substance products that are on manufacturer recall (39). **The DEA should modify the CSA to allow reverse distribution of any type of unused and expired medications from consumers, based on the existing model for taking back medications that need to be recalled.**

Such a program would be greatly beneficial but would require a funding mechanism. Consumer motivation to participate is also a challenge. A take-back program would have to be coupled with strong public education efforts on the importance of safe, environmentally conscious medication disposal. A buy-back program or providing pharmacy coupons in exchange for the unused medication could offer an incentive.

While a reverse distribution program would move old and expired medications out of the reach of potential abusers, it still would not address the issue of final disposal of pharmaceutical products. Government has a responsibility to find a viable solution for this woefully overlooked public health risk. Some reverse distributors are using the incineration of take-back medications to generate energy (40); incineration, however, still releases small amounts of the substances into the air. **Environmental organizations and community health advocacy groups must join the effort to modify the CSA to permit national medication take-backs and to develop safe environmental standards for the products' subsequent disposal. A multi-sector, national policy framework must be developed for prescription medication disposal that prevents environmental contamination as well as prescription drug diversion, abuse, and their public health consequences.**

VIII. Research

The policies and practices described above will make an excellent start to addressing the complex issue of prescription drug abuse in a balanced way. Moving forward, however, these policies must be built upon the results of ongoing research into the problem. As noted earlier in this paper, significant research is clearly still needed in many areas of prescription drug diversion and abuse. The long-term need to balance legitimate access to needed medications with the prevention of their diversion and abuse makes careful research and expert input from many invested parties imperative. Government, the private sector, researchers, advocacy groups, and citizens must continue to collaborate to identify and implement optimal solutions that address this public health threat. Only by compiling the following research can invested parties identify best practices and further refine this comprehensive plan.

By developing evidence-based interventions utilizing data about motives for inappropriate use, methods of diversion, and sources of diversion, we can effectively address prescription drug abuse as a public health problem (41). First, research into the differing motives for the improper use of prescription medications is essential to our understanding of the issue. Future NSDUH surveys should seek to separate its general category of nonmedical use into more specific motivation groupings, such as to get high, to self-medicate, or because the individual cannot stop using, among a number of other motives. Several other scientific terms and types of improper use are incorporated into NSDUH's general terminology, including recreational use, extramedical use, accidental addiction, addiction, and iatrogenic addiction; these should be separately documented. More documentation is especially needed on the incidence of academic doping, an increasingly common phenomenon. By clarifying people's reasons for illicit use, invested parties can identify and tackle the most common motives for prescription drug abuse as well as develop strategies geared toward addressing each grouping in the most effective way.

Uncovering trends in motives also may reveal a sector of society that is being undertreated for pain and, therefore, driven to find relief through other means. Large, methodologically rigorous, and well-controlled prospective studies should be conducted to determine the rates of opioid misuse and abuse among chronic pain patients. Accidental dependence and addiction to prescription pain relievers also should be studied, along with unintentional opioid-related poisoning deaths. These studies will help to elucidate the interconnection of opioid misuse and legitimate pain care. More studies also are needed to document the undertreatment of pain among various age, gender, and racial/ethnic groups.

Quantifying diversion also is necessary to appropriately direct resources to address the problem. Data must be systematically compiled to determine how many pills are diverted through thefts and losses from the supply chain, the Internet, international smuggling, prescription forgery, doctor shopping, and patients selling or sharing their medication. The Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH) definitions and questions must be improved so that the data provides an accurate estimate of how many prescription opioid dosage units are ingested per year. This number should also be broken down into dosage units for the various means of diversion.

Electronic prescribing and prescription tracking systems offer great potential to reduce fraud, doctor shopping, and other types of diversion; as these systems are implemented more extensively in the U.S., however, we must evaluate the impact of their use. To address critics' concerns and to continue to improve Prescription Monitoring Programs (PMPs), these programs' effect on the incidence of drug diversion and abuse must be evaluated. Research must focus on the effect of PMPs on physician prescribing, exploring whether PMPs reduce prescribing due to prescribers' regulatory concerns. In addition, researchers must evaluate the effect of PMPs on patients with a legitimate medical need for prescription medications that are controlled substances. Based on this research into PMP outcomes, states must modify these monitoring systems to reduce any adverse effect.

The long-term feasibility of a nationwide PMP network and an interlinked patient identity tracking system must be investigated as well. An evaluation of feasibility must include a calculation of the associated costs of a large amount of data-hosting, implementation of the necessary privacy and security infrastructure, and access for all prescribers and pharmacists. These studies will aid in developing a system that is affordable and feasible for prescribers, pharmacists, states, and the federal government.

In the realm of medical treatment, more research is needed, both into technological developments and best practices in prescribing medications with abuse potential. Following the example of universal precautions that was established in the 1980s for blood and bodily fluids, today's medical community should implement universal precautions in prescribing through professional discourse. Careful research should help to refine the standards of care and best practices that are applied universally to all patients. Researchers can develop and implement a universal precautions pilot program in order to evaluate these new practices and identify areas that need improvement.

The growing field of pharmacogenomics research must include significant attention to pain management as it moves forward. Pharmacogenomics is a branch of pharmacology that seeks to develop treatments that are based on an individual's genetic responses to various medications. Research in this field will allow practitioners to develop individualized, targeted approaches to pain treatment (42). Through pharmacogenomics, practitioners will be able to assess patients' likelihood for physical dependence and abuse based on their genetics and the type of medication to be used. Prescribers also will be able to select the type of medication that is most likely to be effective in treating a patient's pain.

Researchers must seek to develop alternative methods of pain relief delivery, such as pain-relieving medications and advanced dispensing systems that can meet patients' needs while deterring abuse. One such product under development, GW Pharmaceuticals Limited's Sativex®, utilizes cannabinoids, tetrahydrocannabinol (THC) and cannabidiol (CBD) that act on specific receptors in the brain to provide pain relief without producing significant psychotropic effects (43). Future research should focus on further developing such medications. In addition, the pharmaceutical industry must focus on researching and developing new abuse-deterrent opioid formulations. The private sector must cooperate with the medical community to design advanced dispensing mechanisms that reduce the potential for abuse. **The pharmaceutical industry, along with the medical community, must collect and analyze outcomes data related to the effects of novel medications and advanced dispensing mechanisms on the individual level as well as the societal level.**

Finally, invested parties must raise awareness in multiple sectors of society about the problem of prescription drug abuse. Researchers can further demonstrate the significance of this problem by assessing the societal costs of prescription drug misuse and abuse in detail. Pilot programs and preliminary data on educational interventions geared toward law enforcement, the medical community, and patients and parents can help researchers to develop the best techniques for reaching different sectors of society. For example, outcomes data on public awareness interventions that focus on the securing and disposing of medications in the home will help researchers to develop further initiatives.

Summary and Conclusion

The involvement required from multiple sectors of society in implementing many of CLAAD's recommended policies demonstrates that extensive collaboration will be necessary among government and other invested parties to effectively deal with the issue of prescription drug abuse. The U.S. Drug Enforcement Administration (DEA) and other government agencies must seek novel, creative approaches to dealing with this urgent problem. For example, a nationwide take-back system for consumers' prescription medications would require the DEA to pair with reverse distributors to implement the program nationally, with invested non-profit organizations to use a variety of media for a wide-scale educational push, and with the retail sector to distribute coupons or other incentives.

Multi-sector collaboration, though challenging, is the only way to effectively deal with the complex issue of prescription drug abuse while ensuring the well-being of patients who legitimately need these medications. Policies must reflect that just as anyone can suffer from pain, anyone can also be susceptible to prescription drug abuse. In the future, maintaining the principle of balance between legitimate access and abuse prevention will help the United States make strides towards significant public health improvements, both by better serving pain patients and by deterring potential prescription drug abusers more effectively.

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THE JOURNAL OF
GLOBAL DRUG POLICY AND PRACTICE

COMMENTARY
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Barack Obama on Medical Marijuana

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President Barack Obama is thoughtful and deliberate. During the presidential campaign, he commented on the issue of medical marijuana. The formal policy position of his administration on medical marijuana will be determined over the coming months, after his team is in place at the White House Office of National Drug Control Policy (ONDCP). In the meantime, his words on the campaign trail are instructive.

The supporters of medical marijuana are picking and choosing to interpret what he said without presenting his words in context. Mr. Obama, for whom words are important, was asked by a Willamette Week reporter, "Would you stop the DEA's raids on Oregon medical marijuana growers?" Obama replied, "I would because I think our federal agents have better things to do, like catching criminals and preventing terrorism. The way I want to approach the issue of medical marijuana is to base it on science, and if there is sound science that supports the use of medical marijuana and if it is controlled and prescribed in a way that other medicine is prescribed, then it's something that I think we should consider."

Mr. Obama addressed this issue again in March, 2008, telling an editorial page editor of the Medford Mail Tribune, "When it comes to medical marijuana, I have more of a practical view than anything else. My attitude is that if it's an issue of doctors prescribing medical marijuana as a treatment for glaucoma or as a cancer treatment, I think that should be appropriate because there really is no difference between that and a doctor prescribing morphine or anything else."

Further he said, "I think there are legitimate concerns in not wanting to allow people to grow their own or start setting up mom and pop shops because at that point it becomes fairly difficult to regulate. Again, I'm not familiar with all the details of the initiative that was passed [in Oregon] and what safeguards there were in place, but I think the basic concept that using medical marijuana in the same way, with the same controls as other drugs prescribed by doctors, I think that's entirely appropriate...

"I would not punish doctors if it's prescribed in a way that is appropriate. That may require some changes in federal law. I will tell you that – I mean I want to be honest with you – whether I want to use a whole lot of political capital on that issue when we're trying to get health care passed or end the war in Iraq, the likelihood of that being real high on my list is not likely... What I'm not going to be doing is using Justice Department resources to try to circumvent state laws on this issue simply because I want folks to be investigating violent crimes and potential terrorism. We've got a lot of things for our law enforcement officers to deal with."

These are not the words of someone who has endorsed smoked marijuana as a medicine. It is unlikely that President Obama will tell the Drug Enforcement Administration (DEA) to stop enforcing the law. Mr. Obama said that as President he will follow the science, and further that should science demonstrate that smoking marijuana is a medicine, he would want it to be treated like an actual medicine, meaning as a physician's prescription that is filled by a pharmacist for a medicine that is approved by the Food and Drug Administration (FDA).

Three central questions will be involved in the review of this issue by President Obama and the White House Office of National Drug Control Policy:

> 1) Is smoke a safe and effective means of drug delivery? If it is, why doesn't the FDA approve smoking for other "medicines?" Why are there no countries in the world that approve smoke as a means of drug delivery for any "medicine?" Why did the Institute of Medicine a decade ago, when considering medical marijuana, reject smoke as a way to deliver drugs except in an extremely narrow set of circumstances and then for only 6 months?
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> 2) Are state and local ballot initiatives an appropriate way to approve medicines? The careful science-based review of safety and efficacy is vital to the nation's health. Why should smoked marijuana not be subject to this time-tested system of drug approval? If smoked marijuana passes that test (which is all but impossible from a scientific perspective), why should smoked marijuana be made available in any way other than

within the closed distribution used for other prescribed medicines with abuse potential, as Barack Obama said "like morphine."

3) Is it good public health policy to have drug approval at a state's discretion -- even when a drug is not approved by the FDA? Under current law, states can be more restrictive than the federal government, meaning they can limit drugs that the federal government approves, but states cannot approve medicines that the federal government has not approved. Is it wise to overturn this established body of law?

After this review I believe that President Obama and his team in the White House as well as in the Departments of Justice and Health and Human Services will answer each of these three questions with a resounding "No."