What Is Being Done to Address the New Drug Epidemic?

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As osteopathic physicians care for patients with complaints of pain, they commonly prescribe controlled substances. The use of these agents presents special challenges for providers, patients, and communities. The US Drug Enforcement Administration (DEA) has provided testimony to the US Congress in regard to the growing problem of diversion and misuse of such medications. Joseph T. Rannazzisi, the deputy assistant administrator in the Office of Diversion Control, appeared before the House Government Reform Committee’s Subcommittee on Criminal Justice, Drug Policy, and Human Resources on July 26, 2006.

This review summarizes the important points that Mr Rannazzisi raised in the DEA’s testimony, “Prescription Drug Abuse: What Is Being Done to Address This New Drug Epidemic?” (http://www.dea.gov/pubs/cngrtest/crngertest/ct072606.html). Excerpts have been edited to conform with the JAOA’s house style. In addition, the author has added some details to the excerpts for clarification. One relevant addition notes the law that now requires physicians to use tamper-proof prescription pads to reduce counterfeiting and forging prescriptions, thus helping to reduce diversion of prescription drugs.

The author has also added a bar chart to illustrate abuse of two leading painkillers by teenagers and anecdotal case scenarios illustrating abuse and diversion of controlled prescription drugs.

Addressing the growing problem of the diversion and abuse of controlled pharmaceuticals continues to be one of the top priorities of the US Drug Enforcement Administration (DEA); it has made great strides in dealing with this ever-changing global drug issue. The DEA continues to concentrate on identifying, targeting, and dismantling large-scale organizations that seek to divert and distribute controlled pharmaceuticals in violation of the Controlled Substances Act (CSA).

The most recent report from the Monitoring the Future study,1 the survey of youth supported by the National Institute of Drug Abuse (NIDA), reveals that the percentage of young Americans abusing prescription drugs (Figure) is second only to the percentage abusing marijuana and greater than that abusing cocaine, heroin, methamphetamine, and other drugs. The DEA, as the nation’s primary law enforcement agency, is dedicated to ensuring that controlled substances are prescribed and dispensed only for legitimate medical purposes in accordance with the CSA. By carrying out this obligation, the DEA strives to minimize the diversion of these medications for abuse while ensuring that they are fully available to patients in accordance with sound medical judgments of their physicians. In this manner, the DEA is committed to balancing the requirement for prevention, education, and enforcement with the need for legitimate access to these drugs.

Controlled pharmaceuticals are readily available for legitimate purposes through a patient’s physician and pharmacy. Distribution channels that are otherwise legal (eg, Internet prescribing, on-call providers, urgent care centers, emergency departments) are often manipulated to acquire controlled prescription drugs for illegal purposes. Compounding this matter is the erroneous perception, particularly among teenagers and young adults, that such medications are safe even when used “recreationally.” Abusers of controlled pharmaceuticals take them for nonmedical purposes for which they were never intended.

Drug Enforcement Administration Initiatives

The DEA has been active in response to this growing threat, making it a priority to disrupt and dismantle organizations that illegally traffic in controlled pharmaceuticals. Part of this strategy is to attack the economic basis of illicit drug trade by inflicting on this industry what every legal business fears: escalating costs, diminishing profits, and unreliable suppliers. To do so, the DEA uses all of the tools at its disposal. Through regulatory authority, the DEA has subjected registrants to significant civil fines, licensing restrictions, or

This continuing medical education publication is supported by an educational grant from Purdue Pharma LP.
even suspended registrations. Such civil remedies have proven to be an effective deterrent to potential violators.

As the pharmaceutical controlled substances abuse problem grew, the DEA significantly increased the amount of resources and personnel dedicated to investigating this diversion. Specifically, this agency increased the number of special agent work-hours on diversion investigations by 114% between FY 2003 and FY 2005. It expanded the number of intelligence analyst work-hours by 234% during that same period.

The DEA has also undertaken enforcement efforts aimed at the economic base of drug traffickers; strong emphasis is placed on seizures of financial and other assets. In FY 2002, the DEA seized approximately $1.8 million in assets related to diversion investigations. In FY 2005, that sum increased to approximately $32.4 million, an 1800% increase. The DEA has legislative approval to use these confiscated funds (and items) to continue the mission of the DEA, including financing DEA expenses and items (cars, etc) that can be used for drug interdiction activities.

In early FY 2005, the DEA began working with pharmaceutical manufacturers, media organizations, and Partners for a Drug Free America participants to develop public service announcements (PSAs) that now appear automatically during Internet prescription drug searches. The PSAs are designed to alert consumers of the potential dangers and illegality of purchasing controlled substances, particularly pharmaceuticals, over the Internet. Both Yahoo and Google have responded by instituting voluntary compliance measures and corporate commitments to take affirmative steps to curtail this illicit type of sale on their respective networks.

In addition, the DEA’s Demand Reduction office has produced an antidrug Web site for teens, www.justthinktwice.com. It provides young people with straightforward information on the consequences of drug use and trafficking, including health, social, and legal problems. This continually updated site has been a valuable resource for teens seeking information on drugs for their own education or for school research projects. The Demand Reduction Program also continues to provide school-age children with a variety of demand-reduction presentations on a national and local level regarding abuse of controlled prescription drugs.

Finally, the DEA met with the Office of National Drug Control Policy, the White House Drug Policy office. The 2006 meeting had representatives from such organizations and agencies as the American Osteopathic Association, American Osteopathic Academy of Addiction Medicine, American Medical Association, American Academy of Family Physicians, American Academy of Addiction Psychiatry, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, and others and leading certifying medical boards and encouraged them to develop educational programs concerning the prescribing of controlled substances, especially high-dose opioids. (See article by Wyatt and Dekker, beginning on page ES27 for a culmination of this report.)

**Figure.** Issues of concern: Past year nonmedical use of oxycodone hydrochloride and hydrocodone bitartrate-acetaminophen combination remains high, with nearly 1 in 10 seniors having abused the latter drug. (Source: Monitoring the Future study. Table 15 available at http://monitoringthefuture.org/data06 data/pr06t15.pdf.)
Sources of Abused Pharmaceuticals
Pharmaceutical investigations and surveys of state and local law enforcement agencies and state medical boards have revealed that the most common methods of diversion of controlled prescription drugs include the following:

- "doctor shopping" or other prescription fraud
- illegal online pharmacies
- theft and burglary (from residences, pharmacies, etc)
- stereotypical drug dealing (selling pills to others)
- receiving from friends or family
- negligent or intentional overprescribing by physicians or other practitioners

The relative proportion of these methods, however, is not yet adequately understood.

Doctor Shopping and Prescription Fraud
Doctor shopping by drug addicts is one of the most common ways that addicts obtain illegal controlled substances. Generally, the term doctor shopping refers to the visit by an individual—who may or may not have legitimate medical needs—to several physicians, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically to feed an addiction.

Associated illegal activities may include forging prescriptions or selling or transferring drugs to others. Unfortunately, in many states, physicians and pharmacists have not been able to automatically cross-check multiple prescriptions given to the same patient. On May 25, 2007, President George W. Bush signed into law Section 7002(b) of the US Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007. Section 7002(b) amends the requirements for states to provide reimbursement for most Medicaid outpatient medications. Physicians will be required to use tamper-resistant prescription pads (this does not include e-prescriptions, faxed prescriptions, or prescriptions called into the pharmacy) for written prescriptions that patients present to the pharmacy. To be considered tamper resistant, a prescription pad must have one or more industry-recognized features to prevent electronic copying of completed or blank prescriptions, to prevent erasure or modifications to completed prescriptions, and to prevent the use of counterfeit prescription forms (Dennis G. Smith, director, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, Department of Health and Human Services; letter to all state Medicaid directors; August 17, 2007).

To address the problem of illegal activities associated with doctor shopping, the US Congress first appropriated funds to the US Department of Justice in 2003 to promote the deployment of Prescription Drug Monitoring Programs (PDMPs) by states. That commitment continues as part of the DEA’s National Drug Control Strategy for 2006. The PDMPs reduce prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient’s prescriptions for controlled substances.

While the specifics of these programs vary from state to state, a generally shared characteristic is to allow prescribers and dispensers to input and receive accurate and timely controlled prescription drug history information while ensuring patient access to needed treatment. Most states also have some mechanism for law enforcement to receive these data in cases where criminal activity is suspected. Some states also allow healthcare providers to use this knowledge as a tool for early identification of patients at risk for addiction in order to initiate appropriate medical interventions. In other states, the justice system can use the gathered facts to assist in enforcement of laws controlling the sale and use of controlled prescription medication.

The PDMP program has steadily expanded through the Harold Rogers Prescription Drug Monitoring Program, with a total of 32 states with active or planned PDMPs as of January 26, 2007.2

Improper Prescribing
Improper prescribing is another method of controlled substance diversion. This problem differs from doctor shopping and prescription fraud in that the latter situations involve abusers attempting to deceive or mislead those medical professionals who are doing their jobs responsibly.

The overwhelming majority of prescribing in the United States is conducted properly. Often, these responsible physicians and pharmacists are the first to alert law enforcement to potential prescription problems. However, the small number of physicians (less than 1%) who overprescribe controlled substances—carelessly at best, knowingly at worst—help expand the United States’ second most widespread drug addiction problem.

Sharing Among Family and Friends
As the DEA increases its understanding of where abusers acquire prescription drugs, preliminary data suggest that the most common method is through diversion from friends and family. For example, a person with a lawful and genuine medical need for a controlled substance may use only a portion of the prescribed amount. When a family member or friend then complains of similar symptoms, the patient subsequently shares excess medication. Alternatively, for someone addicted to controlled prescription drugs or to an inquisitive youngster, the mere availability of unused controlled prescription drugs in the house may prove to be an irresistible temptation.

The solution to this aspect of substance abuse lies both with the medical community and patients. Greater educational efforts are needed regarding quick and safe disposal of unused and unneeded medications. Health professionals need to carefully consider the potential for abuse of controlled substances and prescribe only that amount required medically. Patients must also be educated about legal and social ramifications of providing these medications to friends or family members. It is not merely illegal, but it could lead to or expand an addiction, thus placing that loved one in a life-threatening situation.

Illegal Online Pharmacies
Perhaps the most potentially dangerous and increasingly used method for the

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diversion of controlled pharmaceuticals is through the Internet. As the number of Americans with Internet access has increased, so too have opportunities for individuals to acquire controlled prescription drugs from this source. There exist strong societal benefits to allowing individuals with a valid prescription to obtain their prescriptions over the Internet, as long as the pharmacy that fills these prescriptions is legitimate and a valid physician-patient relationship exists. This source for obtaining controlled prescription drugs may be helpful for individuals who live in rural areas or for those who are homebound because of illness or other factors. However, Internet anonymity and proliferation of Web sites that facilitate illicit transactions in controlled pharmaceuticals have given drug abusers the ability to circumvent both the law and sound medical practice.

There are legal pharmacies that provide services over the Internet and operate legal and sound medical practices. The National Association of Boards of Pharmacy (http://www.nabp.net) has established a registry of pharmacies that operate online and meet certain criteria, including compliance with licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

Of particular concern is the cursory and abbreviated nature of medical interaction. Often, if there is any communication with a medical professional, it will be only a brief physician consultation by computer or telephone. This short interaction is not designed to elicit meaningful health information; it is generally accomplished by a “questionnaire” filled out by the “patient” without any face-to-face meeting between physician and patient. In the absence of a direct meeting, it is not possible for a physician who is writing the prescription to verify information provided by the individual and to assess legitimate medical need. This situation is particularly troubling in the context of youth drug abuse; a minor can easily log onto a Web site and provide an inaccurate age.

Physicians, who are often paid by the number of prescriptions written in these situations, have no incentive to spend time seeking additional patient information. Law enforcement has discovered Web site-affiliated physicians who sign hundreds—even thousands—of prescriptions daily. After receiving this prescription, the facilitator will then submit it to a cooperating pharmacy. Because there is often no identifying information on these rogue Web sites, it is very difficult for law enforcement to track any individuals operating them.

The DEA employs all available tools to prosecute operators of these rogue Internet-facilitator Web sites. It conducts investigations and works to intercept controlled prescription drugs illegally sent into the United States through the mail system. For example, the DEA’s Internet investigation unit at its Special Operations Division continues to coordinate Internet cases; also, the DEA has issued a number of immediate suspensions of its registrations of physicians and pharmacies operating illegally via the Internet. The US Department of Justice has prosecuted physicians and pharmacies who illegally distribute via the Internet.

Additional clarification of responsibilities for professionals seeking to use the Internet to accommodate the needs of patients would allow the DEA more readily to identify legitimate online pharmacies and persons operating and promoting them; it would also assist in gathering information to identify abuse patterns. Such clarification would also help the DEA investigate drug traffickers hiding behind the facade of an otherwise legitimate practice.

Another factor is lack of a statutory definition of a valid “doctor-patient” relationship. Last, penalties associated with illegal sale of Schedule III through V substances—those most commonly sold controlled substances over the Internet—are not as significant as may be warranted.

States can play a significant role in addressing the problem of online facilitators, particularly through PDMPs. The DEA will work during the next several years with states regarding PDMPs to encourage them to consider addressing—either by statute, regulation, or interstate agreement—a number of scenarios that primarily involve pharmacies dispensing or delivering controlled prescription drugs to patients across state lines. To be effective, laws must be updated to reflect the changing ways people live and in which business is conducted.

Coordinating Regulatory Responsibilities

As the DEA fights national diversion and drug abuse, proper regulatory control of new pharmaceuticals is vital. Appropriate such mechanisms are particularly important given the strength and formulations of products as they become available to patients. This is important to the DEA as there has been an overall increase in the commercial availability of pharmaceuticals resulting in a significant increase of doses available for diversion. Understanding the differences—and also the similarities—between prescription drugs and controlled substances is an important aspect of evaluating the causes and possible policy solutions regarding the rise in prescription drug abuse.

The US Congress signaled its full recognition of the abuse potential of certain prescription drugs in 1914, when it passed the Harrison Narcotic Act, which regulated opioid sales for the first time. After passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1938 and subsequent amendments, the US Congress recognized the critical importance of identifying clinically proven uses of prescription drugs for legitimate medical needs.

The CSA is the legal foundation for US action against abuse of drugs and other substances. It was passed to minimize the quantity of powerful drugs available to those likely to abuse them, while providing for legitimate medical, scientific, and industrial needs. Control under the CSA encompasses both licit and illicit substances; it also regulates chemicals used in clandestine production of controlled substances. The US Department of Justice, through the DEA, and the US Department of Health and Human Services (HHS), through the US Food and Drug Administration (FDA), both have a role in implementing the CSA.

The CSA requires that substances be scheduled by a determination made by the US Attorney General after a scientific and medical evaluation and rec-
ommendation by the Secretary of HHS (21 USC section 811[b]). Substances with substantial potential for abuse are considered for control under Schedules II through V. Schedule II substances have the highest abuse potential and dependence profiles with the most restrictive regulatory requirements, while Schedule III through V drugs have progressively less abuse potential and dependence profiles and are subjected to less-restrictive regulatory requirements.

Placement of a substance in a given schedule is based on its medical use, safety, potential for abuse, or dependence liability, and consideration of specific factors as listed in the CSA. For drug products containing substances that are not already controlled under the CSA, as in the case of new molecular entities, HHS will forward its scientific and medical evaluation and a scheduling recommendation to the DEA. The FDA has the statutory responsibility to determine the safety and effectiveness of new drug products for medical use in the United States. As a part of its evaluation, the FDA also examines the abuse potential of drug products.

The CSA includes seven major control mechanisms: scheduling, registration, quotas, records and reports, import and export authorizations, security, and investigational authority. It allows the DEA to monitor and regulate a controlled substance and its movement: for the most potentially dangerous legal drugs, those substance and its movement: for the most potentially dangerous legal drugs, those substances continues to be a significant challenge. Nevertheless, the DEA is committed to using all necessary tools at its disposal to fight this growing problem on all fronts, while simultaneously ensuring their uninterrupted supply for legitimate demands. The DEA’s core competency, disruption and dismantlement of drug-trafficking organizations impacting the United States, is an integral component of the Synthetic Drug Control Strategy. The DEA will continue to implement this aspect of the strategy with its interagency partners to combat diversion of controlled pharmaceuticals.

Illustrative Case Presentations
Following are scenarios in which opioid abuses and diversion typically occur.

Case Presentation 1
Amanda, a 34-year-old nurse, was injured in a rear-end motor vehicular accident 1 month ago. She had whiplash but no fractures were identified. Amanda returned to work at the hospital after 2 weeks of physical therapy. In the hospital hall, she sees a physician who has provided care to her and her family in the past. She has no history of alcohol or substance abuse. She is a hard worker and is well respected in the hospital. She asks the physician for a prescription to refill her hydrocodone bitartrate and acetaminophen, 7.5/750-mg tablets, (originally from the Emergency Department). She is taking six tablets per day and says that she can work full time when taking the medication. The hospital is short-staffed for nursing and may have to close a unit because of the nursing shortage.

Discussion
The CSA requires that the prescribing provider examine and diagnose the condition of all patients who receive scheduled medications. In this case, the physician that Amanda met in the hall provided no examination for her injury. The physician needs to document the history and findings of the physical examination and make a diagnosis so that treatment could then be appropriate. Follow-up and the type of monitoring also need to be addressed. Osteopathic physicians have been trained to address the patient in a holistic fashion. Issues of the medical evaluation blended with the holistic assessment would include Amanda’s home, work, emotional, social, and spiritual settings. It may be completely appropriate to treat Amanda with opioids, but the provider must be cognizant of all these settings and be assured that Amanda is not impaired in her performance of her duties. Patients stabilized on opioid therapy can function safely.

Case Presentation 2
William, a 45-year-old salesman, has chronic pain. He has a herniated disc at L5-S1. He had surgery for the herniated nucleus pulposus 2 years ago, but the pain has increased (on a scale of 0 to 10), and he states that he cannot travel without some pain relief. William is now taking oxycodone hydrochloride, 40 mg twice a day, and four oxycodone-acetaminophen (5 mg/325 mg) tablets per day for breakthrough pain. He always keeps his office appointments, and results of his urine drug screens (immunoassay) are always negative for the presence of illegal drugs. His prescribing physician has seen him monthly. William reports that the airline lost his suitcase and he has a lost luggage receipt to prove this. His medication (3-week supply) was in his luggage. Bill admits that he recently had a ticket for driving under the influence (blood alcohol level, 0.08 mg/dL) and is pending a court appearance. He also admits that he has been drinking heavily to relax his back muscles, and then he asks for a prescription for medication refill. Without the medications, he will not be able to travel on his next business trip.

Discussion
William is a patient with chronic pain who has had a recent alcohol abuse event. Further evaluation should identify that he is alcohol-dependent. The Controlled Substance Act has clear regulations for treating chemically dependent patients with controlled substances. The requirement for patient assessment, monitoring compliance, and appropriate treatment for drug and alcohol abuse needs to be addressed. The assessment for alcohol abuse can be done by the physician in concert with a behavioral health professional who has expertise in the field of addictions.

The physician must use care in prescribing opioids to anyone abusing alcohol, and opioids would in most cases be seen as inappropriate for a patient actively abusing ethanol. Most of the
deaths in the United States that are attributed to opioid overdose are in persons who have taken opioids in combination with alcohol or a benzodiazepine.\textsuperscript{3,4} Urine drug testing in addition to behavioral evaluation and compliance to the treatment program needs to be part of the intervention. The patient also needs to sign a release of information to and from his primary care physician so the intervention may continue. If the patient refuses this plan, he is at high risk for misuse or abuse of opioids.

Case Presentation 3
Dr Jones has seen his practice income gradually decrease during the past 10 years. He has contracted with several managed care organizations, and his revenue is down to 60\% of FY 2000 revenue per visit. He increased the number of patient visits and reduced staff and overhead to make ends meet. Dr Jones has been contacted by a licensed Internet pharmacy that is offering him $30 per prescription that he will sign. Each patient provides a health summary filled in and submitted electronically via the Internet. Some of the medications are for “lifestyle modification,” such as sildenafil citrate, but most are for scheduled medications for pain and anxiety (opioids and benzodiazepines). Dr Jones does not know these patients except for the two-page histories that they filled out, but he can call them via telephone if he wishes. The pharmacy promises a minimum of 100 prescriptions per week.

Discussion
Internet pharmacy relationships, as noted in this article, are high risk. Typically, there is no patient contact. As the CSA requirements for a patient assessment are not being met, the physician is in harms way and could be punished for violations.

Case Presentation 4
Dr Smith is a well-respected member of her community. She is the first physician in her family. She was reared in a small farming community and has chosen to return to that community to practice. She often sees her patients in social settings. She is approachable and available to her patients. Dr Smith consistently refers patients to her office if they contact her in the community. On Friday night, Dr Smith’s husband, John, reinjures his knee. The injury initially occurred in college and was classified as “knee instability.” He has intermittently taken acetaminophen (325 mg) with codeine (30 mg) for pain as prescribed by his orthopedic specialist. However, the prescription has expired, and the orthopedic specialist is not on call. Dr Smith calls the local pharmacy for a refill of the acetaminophen-codeine prescription.

Discussion
The DEA and most states have regulations regarding prescribing scheduled medication to family members. There is a need for personal physician care. Dr Smith could obtain it with a call to a colleague in the same or nearby community. The emergency department could also provide the assessment and care.

References