EPIDEMIC: RESPONDING TO AMERICA’S PRESCRIPTION DRUG ABUSE CRISIS

2011
Background

Prescription drug abuse is the Nation’s fastest-growing drug problem. While there has been a marked decrease in the use of some illegal drugs like cocaine, data from the National Survey on Drug Use and Health (NSDUH) show that nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically.\(^1\) The same survey found that over 70 percent of people who abused prescription pain relievers got them from friends or relatives, while approximately 5 percent got them from a drug dealer or from the Internet.\(^2\) Additionally, the latest Monitoring the Future study—the Nation's largest survey of drug use among young people—showed that prescription drugs are the second most-abused category of drugs after marijuana.\(^3\) In our military, illicit drug use increased from 5 percent to 12 percent among active duty service members over a three-year period from 2005 to 2008, primarily attributed to prescription drug abuse.\(^4\)

Although a number of classes of prescription drugs are currently being abused, this action plan primarily focuses on the growing and often deadly problem of prescription opioid abuse. The number of prescriptions filled for opioid pain relievers—some of the most powerful medications available—has increased dramatically in recent years. From 1997 to 2007, the milligram per person use of prescription opioids in the U.S. increased from 74 milligrams to 369 milligrams, an increase of 402 percent.\(^5\) In addition, in 2000, retail pharmacies dispensed 174 million prescriptions for opioids; by 2009, 257 million prescriptions were dispensed, an increase of 48 percent.\(^6\) Further, opiate overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers.\(^7\)

These data offer a compelling description of the extent to which the prescription drug abuse problem in America has grown over the last decade, and should serve to highlight the critical role parents, patients, healthcare providers, and manufacturers play in preventing prescription drug abuse.

These realities demand action, but any policy response must be approached thoughtfully, while acknowledging budgetary constraints at the state and Federal levels. The potent medications science has developed have great potential for relieving suffering, as well as great potential for abuse. There are many examples: acute medical pain treatment and humane hospice care for cancer patients would be impossible without prescription opioids; benzodiazepines are the bridge for many people with serious anxiety disorders to begin the process of overcoming their fears; and stimulants have a range of valuable uses across medical fields. Accordingly, any policy in this area must strike a balance between our desire

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to minimize abuse of prescription drugs and the need to ensure access for their legitimate use. Further, expanding effective drug abuse treatment is critical to reducing prescription drug abuse, as only a small fraction of drug users are currently undergoing treatment.

This Prescription Drug Abuse Prevention Plan expands upon the Administration’s National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. First, education is critical for the public and for healthcare providers to increase awareness about the dangers of prescription drug abuse, and about ways to appropriately dispense, store, and dispose of controlled substance medications. Second, enhancement and increased utilization of prescription drug monitoring programs will help to identify “doctor shoppers” and detect therapeutic duplication and drug-drug interactions. Third, the development of consumer-friendly and environmentally-responsible prescription drug disposal programs may help to limit the diversion of drugs, as most non-medical users appear to be getting the drugs from family and friends. Fourth, it is important to provide law enforcement agencies with support and the tools they need to expand their efforts to shut down “pill mills” and to stop “doctor shoppers” who contribute to prescription drug trafficking.

I. Education

A crucial first step in tackling the problem of prescription drug abuse is to raise awareness through the education of parents, youth, patients, and healthcare providers. Although there have been great strides in raising awareness about the dangers of using illegal drugs, many people are still not aware that the misuse or abuse of prescription drugs can be as dangerous as the use of illegal drugs, leading to addiction and even death.

Parents and youth in particular need to be better educated about the dangers of the misuse and abuse of prescription drugs. There is a common misperception among many parents and youth that prescription drugs are less dangerous when abused than illegal drugs because they are FDA-approved. Many well-meaning parents do not understand the risks associated with giving prescribed medication to a teenager or another family member for whom the medication was not prescribed. Many parents are also not aware that youth are abusing prescription drugs; thus, they frequently leave unused prescription drugs in open medicine cabinets while making sure to lock their liquor cabinets. These misperceptions, coupled with increased direct-to-consumer advertising, which may also contribute to increased demand for medications, makes effective educational programs even more vital to combating prescription drug abuse.

In addition, prescribers and dispensers, including physicians, physicians assistants, nurse practitioners, pharmacists, nurses, prescribing psychologists, and dentists, all have a role to play in reducing prescription drug misuse and abuse. Most receive little training on the importance of appropriate prescribing and dispensing of opioids to prevent adverse effects, diversion, and addiction. Outside of specialty addiction treatment programs, most healthcare providers have received minimal training in how to

recognize substance abuse in their patients. Most medical, dental, pharmacy, and other health professional schools do not provide in-depth training on substance abuse; often, substance abuse education is limited to classroom or clinical electives. Moreover, students in these schools may only receive limited training on treating pain.

A national survey of medical residency programs in 2000 found that, of the programs studied, only 56 percent required substance use disorder training, and the number of curricular hours in the required programs varied between 3 to 12 hours. A 2008 follow-up survey found that some progress has been made to improve medical school, residency, and post-residency substance abuse education; however, these efforts have not been uniformly applied in all residency programs or medical schools.

Educating prescribers on substance abuse is critically important, because even brief interventions by primary care providers have proven effective in reducing or eliminating substance abuse in people who abuse drugs but are not yet addicted to them. In addition, educating healthcare providers about prescription drug abuse will promote awareness of this growing problem among prescribers so they will not over-prescribe the medication necessary to treat minor conditions. This, in turn, will reduce the amount of unused medication sitting in medicine cabinets in homes across the country.

The following action items will be taken to improve educational efforts and to increase research and development:

Healthcare Provider Education:

- Work with Congress to amend Federal law to require practitioners (such as physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration. This training would include assessing and addressing signs of abuse and/or dependence. (ONDCP/FDA/DEA/SAMHSA)

- Require drug manufacturers, through the Opioid Risk Evaluation and Mitigation Strategy (REMS), to develop effective educational materials and initiatives to train practitioners on the appropriate use of opioid pain relievers. (FDA/ONDCP/SAMHSA)

- Federal agencies that support their own healthcare systems will increase continuing education for their practitioners and other healthcare providers on proper prescribing and disposal of prescription drugs. (VA/HHS/IHS/DOD/BOP)

- Work with appropriate medical and healthcare boards to encourage them to require education curricula in health professional schools (medical, nursing, pharmacy, and dental) and continuing education programs to include instruction on the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. Additionally, work with relevant medical, nursing, dental, and pharmacy student groups to help disseminate educational materials, and establish student programs that can give community educational presentations

on prescription drug abuse and substance abuse. (HHS/SAMHSA/ONDCP/FDA/HRSA/NIDA/DOD/VA)

- In consultation with medical specialty organizations, develop methods of assessing the adequacy and effectiveness of pain treatment in patients and in patient populations, to better inform the appropriate use of opioid pain medications. (HHS/CDC/SAMHSA/FDA)

- Work with the American College of Emergency Physicians to develop evidence-based clinical guidelines that establish best practices for opioid prescribing in the Emergency Department. (CDC/FDA/ONDCP/NIDA/SAMHSA/CMS)

- Work with all stakeholders to develop tools to facilitate appropriate opioid prescribing, including development of Patient-Provider Agreements and guidelines. (HHS/FDA/SAMHSA/NIDA)

Parent, Youth, and Patient Education:

- Enlist all stakeholders to support and promote an evidence-based public education campaign on the appropriate use, secure storage, and disposal of prescription drugs, especially controlled substances. Engage local anti-drug coalitions, and other organizations (chain pharmacies, community pharmacies, boards of pharmacies, boards of medicine) to promote and disseminate public education materials and to increase awareness of prescription drug misuse and abuse. (ONDCP/CDC/FDA/DEA/IHS/ED/SAMHSA/DOD/VA/EPA)

- Require manufacturers, through the Opioid Risk Evaluation and Mitigation Strategy (REMS), to develop effective educational materials for patients on the appropriate use and disposal of opioid pain relievers. (FDA/ONDCP/SAMHSA)

- Working with private-sector groups, develop an evidence-based media campaign on prescription drug abuse, targeted to parents, in an effort to educate them about the risks associated with prescription drug abuse and the importance of secure storage and proper disposal of prescription drugs (including through public alerts or other approaches to capture the attention of busy parents). (ONDCP/ONC)

Research and Development:

- Expedite research, through grants, partnerships with academic institutions, and priority New Drug Application review by FDA, on the development of treatments for pain with no abuse potential as well as on the development of abuse-deterrent formulations (ADF) of opioid medications and other drugs with abuse potential. (NIDA/FDA)

- Continue advancing the design and evaluation of epidemiological studies to address changing patterns of abuse. (CDC/FDA/NIDA)

- Provide guidance to the pharmaceutical industry on the development of abuse-deterrent drug formulations and on post-market assessment of their performance. (FDA)
II. Tracking and Monitoring

Forty-three states have authorized prescription drug monitoring programs (PDMPs). PDMPs aim to detect and prevent the diversion and abuse of prescription drugs at the retail level, where no other automated information collection system exists, and to allow for the collection and analysis of prescription data more efficiently than states without such a program can accomplish. However, only thirty-five states have operational PDMPs. These programs are established by state legislation and are paid for by a combination of state and Federal funds. PDMPs track controlled substances prescribed by authorized practitioners and dispensed by pharmacies. PDMPs can and should serve a multitude of functions, including: assisting in patient care, providing early warning of drug abuse epidemics (especially when combined with other data), evaluating interventions, and investigating drug diversion and insurance fraud.12

In 2002, a General Accounting Office report concluded that state PDMPs provide a useful tool to reduce drug diversion, based largely on the opinion of PDMP managers and law enforcement agencies.13 Three ecologic studies have since examined PDMP effects on overall state rates. An analysis in 2006 found that PDMPs were associated with lower rates of substance abuse treatment admission.14 A later study used poison control center contacts and abuse/misuse exposures in states with and without PDMPs to evaluate how PDMPs affected abuse/misuse rates for long-acting opioids versus immediate release opioids. The study found that PDMPs were associated with slower rates of increase in abuse/misuse over time.15 Most recently, a study found no association between having a PDMP and lower rates of overdose mortality, although the study was evaluating PDMPs between 1999 and 2005.16 One additional study has examined the effect of a trial of using PDMP data in an emergency department. It found that PDMP data changed clinical management in 41 percent of cases. Of these, 61 percent received fewer or no opioid pain medications than had been originally planned by the physician prior to reviewing the PDMP data, and 39 percent received more opioid medication than previously planned because the physician was able to confirm the patient didn’t have a recent history of opioid use.17 In summary, PDMPs appear to be a promising approach, but more work is needed to determine how to maximize their effectiveness.

Reducing prescription drug abuse requires a combination of Federal, state, and local action. All involved need to be informed on how to use available data sets to identify areas on which to concentrate their efforts. For example, in Massachusetts, the PMP Center of Excellence at Brandeis University developed geospatial mapping of PDMP data, combined with data on prescription drug overdose ED visits and

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12. PDMP data cannot be used as evidence in court.
prescription drug overdose deaths, to identify concentrations in three suburban areas of the state. Coordination of efforts like this enables maximization of limited resources.

A major effort must be undertaken to improve the functioning of state PDMPs, especially regarding real-time data access by clinicians, and to increase inter-state operability and communication. Furthermore, we must identify stable financial support to maximize the utility of PDMPs, which will help reduce prescription drug diversion and provide better healthcare delivery.

To further these goals, the following actions will be taken:

- Work with states to establish effective PDMPs in every state, including leveraging state electronic health information exchange activities, and to require prescribers and dispensers to be trained in their appropriate use. Encourage research on PDMPs to determine current effectiveness and identify ways to improve effectiveness. (ONDCP/SAMHSA/DOJ/NIDA/CDC/ONC)

- Support the National All Schedules Prescription Electronic Reporting (NASPER) Act reauthorization in Congress. NASPER is a formula grant program administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) that funds state PDMPs. The program outlines specific, uniform criteria states must have in place to be awarded funding, which increases consistency among state PDMPs. (SAMHSA/ONDCP)

- Work with Congress to pass legislation to authorize the Secretary of Veterans Affairs (VA) and the Secretary of Defense (DOD) to share patient information on controlled substance prescriptions with state PDMPs. (VA/DOD/ONDCP)

- Encourage federally funded healthcare programs such as IHS and DOD and VA (when authorized to do so) to provide controlled substance prescription information electronically to the PDMPs in states in which they operate healthcare facilities or pharmacies. In addition, DOD, VA, and IHS are encouraged to evaluate the practice of having prescribers check PDMPs for patient controlled substance prescription histories before generating prescriptions for controlled substances. (DOD/HHS/IHS/VA)

- Explore the feasibility of providing reimbursement to prescribers who check PDMPs before writing controlled substance prescriptions for patients covered under insurance plans. (ONDCP)

- Evaluate existing programs that require doctor shoppers and people abusing prescription drugs to use only one doctor and one pharmacy. The PMP Center of Excellence at Brandeis University will convene a meeting in 2011 with private insurance payers to begin discussions on these topics. (ONDCP/DOJ/HHS/SAMHSA)

- Work with HHS and CMS to evaluate the utility of state PDMPs for reducing Medicare and Medicaid fraud, as suggested in the 2009 GAO report—Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. (HHS/CMS/DEA/ONDCP)

- Issue the Final Rule on DEA Electronic Prescribing of Controlled Substances. (DEA/ONC/CMS)

- Increase the use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) programs to help healthcare providers identify and prevent prescription drug abuse problems in primary healthcare settings by working with healthcare providers to increase awareness and training
for these programs, and incorporating the use of Health Information Technologies (HIT) such as Electronic Health Records to enhance SBIRT programs. (HHS/SAMHSA/HRSA/CMS/ONC)

- Identify ways in which Health Information Technologies (HIT) such as Electronic Health Records can improve prescription drug abuse information. (ONC/CMS/SAMHSA).

- Test the usefulness of CDC’s real-time BioSense surveillance system for generating timely, population-based measures of prescription drug abuse in selected communities. In addition, use information from the NIDA Community Epidemiology Workgroup to monitor and detect locations where increased abuse is occurring to help target limited resources. (HHS/CDC/ONDCP/SAMHSA/FDA/NIDA)

- Assess the usefulness of the Drug Abuse Warning Network (DAWN) and how it can best be used for community epidemiology. (HHS/SAMHSA/CDC)

- Expand upon DOJ’s pilot efforts to build PDMP interoperability across state lines, including leveraging state electronic health information exchange activities. Work to expand interstate data sharing among PDMPs through the Prescription Drug Information Exchange (PMIX). (DOJ/BJA/DEA/HHS/SAMHSA/ONC)

- Evaluate current databases that measure the extent of prescription drug use, misuse, and toxicity, clinical use of safe opioid prescribing practices, and access to high-quality pain management services, focusing on improving these databases and identifying new sources of data (HHS/ONDCP/CDC)

III. Proper Medication Disposal

Prescription drug abuse is a significant public health and public safety issue, and a large source of the problem is a direct result of what is in Americans’ medicine cabinets. SAMHSA’s 2009 National Survey on Drug Use and Health found that over 70 percent of people who used prescription pain relievers non-medically got them from friends or relatives, while approximately 5 percent got them from a drug dealer or from the Internet. The same survey showed the scale of the problem is vast with more than 7 million Americans reporting use of a prescription medication for non-medical purposes in the past 30 days. Therefore, a comprehensive plan to address prescription drug abuse must include proper disposal of unused, unneeded, or expired medications. Providing individuals with a secure and convenient way to dispose of medications will help prevent diversion and abuse, and help to reduce the introduction of drugs into the environment.

In order to protect human health and the environment, it is vital that collected prescription drugs be appropriately disposed of in an environmentally safe manner. Thus, prescription drugs collected from individuals are to be disposed of in accordance with Federal, state, and local laws and regulations. Until prescription drug disposal programs are available to all communities, an important environmental safety message in the fight against improper medication disposal is to recommend against flushing prescription drugs with the few exceptions noted by the Food and Drug Administration (FDA). Instead

of flushing, prescription drugs should be disposed of in sealed plastic bags with filler such as coffee
grounds or kitty litter. However, due to public health concerns, the FDA does recommend disposal via
flushing for certain opioid pain relievers that can pose life-threatening risks from accidental ingestion.

The following actions will be taken to increase proper disposal of prescription drugs and prevent
diversion:

- While the administrative process to establish the DEA medication disposal rule is underway,\(^{19}\) DEA and other Federal agencies shall conduct additional take-back activities. Information
  about the take-back events shall be distributed to local anti-drug coalitions, HIDTAs, and other
  organizations (chain pharmacies, boards of pharmacies, boards of medicine, environmental
  agencies, etc). (DEA/ONDCP)

- Once DEA regulations on controlled substance prescription drug disposal have been estab-
  lished, develop and execute a robust public education initiative to increase public awareness
  and provide education on new methods of safe and effective drug return and disposal. (ONDCP/
  EPA/DEA/FDA/CDC/HHS/SAMHSA/NIDA)

- Once DEA regulations have been established, engage PhRMA and others in the private sector
  to support community-based medication disposal programs. (ONDCP/FDA/DEA/HHS/CDC/
  SAMHSA/EPA)

IV. Enforcement

Along with the increased legitimate use of prescription opioid medications in healthcare settings,
there is also a small group of practitioners who abuse their prescribing privileges by prescribing these
medications outside the usual course of professional practice or for illegitimate purposes. This has, in
some areas, resulted in practitioners illegally prescribing and/or dispensing prescription controlled
substances and other prescription drugs under the banner of medical care. These providers and clinics
not only endanger the individuals receiving these medications, but also pose serious threats to the
communities where they are located.

In addition, a number of “patient”-centered abuses have evolved, most notably “doctor shopping.” Doctor
shoppers visit multiple prescribers, in different locations within and outside of their states of residence,
in order to receive controlled substances and other prescription drugs for diversion and/or abuse. These
community-based problems require community-based solutions.

The following actions will be taken to assist states to address doctor shopping and pill mills:

- ONDCP, the National Methamphetamine and Pharmaceutical Initiative (NMPI), a law enforce-
  ment training initiative funded by HIDTA, and DEA will contribute to the curriculum for the
  pharmaceutical crime investigation and prosecution training program sponsored by BJA in
  2011. Target training to states with the highest need. (ONDCP/DOJ/DEA/HIDTA)

\(^{19}\) The DEA rule-making process is expected to take 12 to 24 months. Before final regulations can be implemented
DEA must issue a Notice of Proposed Rule-Making and then consider public comments submitted on the Proposed Rule.
Once this has occurred, DEA can issue a Final Rule.
• Increase training to law enforcement and prosecutor groups at national and regional conferences. (ONDCP/DEA)

• Continue aggressive enforcement actions against pain clinics and prescribers who are not prescribing within the usual course of practice and not for legitimate medical purposes. (DOJ/DEA, HHS, State Medical Boards)

• Work with the appropriate groups to write and disseminate a Model Pain Clinic Regulation Law taking into consideration: 1) registration of these facilities with a state entity; 2) guidance for rules regarding number of employees, location, hours of operation; 3) penalties for operating, owning, or managing a non-registered pain clinic; 4) requirements for counterfeit-resistant prescription pads and reports of theft/loss of such pads; 5) disciplinary procedures to enforce the regulations; and 6) a procedure to allow patient records to be reviewed during regular state inspections. (ONDCP)

• Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking, and increase joint investigations by Federal, state, and local agencies. (ONDCP/HIDTA/DOJ/DEA)

• Identify and seek to remove administrative and regulatory barriers to “pill mill” and prescriber investigations that impair investigations while not serving another public policy goal. (ONDCP/DOJ/DEA/HHS/FDA)

• Expand the use of PDMP data to identify criminal prescribers and clinics by the volume of selected drugs prescribed. Encourage best practices for PDMPs, such as PDMP reporting of such prescribers and clinics to pharmacies, law enforcement, and insurance providers. (DOJ/DEA)

• Use PDMP data to identify “doctor shoppers” by their numbers of prescribers or pharmacies. Encourage best practices such as identifying such individuals to their prescribers and pharmacies, law enforcement and insurance providers. (DOJ/BJA)

V. Prescription Drug Abuse Plan Goals

**National Drug Control Strategy Five Year Goal for Prescription Drug Abuse**

• 15 percent reduction in non-medical use of prescription-type psychotherapeutic drugs in the past year among people 12 years of age and older.

**Prescription Drug Abuse Prevention Plan Goals**

• Have an approved and implemented Risk Evaluation and Mitigation Strategy for certain long-acting and extended release opioids within 12 months;

• Write and disseminate a Model Pain Clinic Regulation Law within 12 months;

• Engage and work with Federal agencies and stakeholders to develop and implement a national public education campaign on prescription drug abuse and safe and proper medication disposal within 24 months;
IHS will increase the number of collaborative practice agreements that involve pharmacists prescribing privileges and monitoring of pain medication prescribing within 18 months;

- Complete rule-making and implement regulations for medication disposal within 24 months;
- Have legislation passed that requires prescribers applying for DEA registration to complete training on the appropriate and safe use, and proper storage and disposal of schedule II and III opioids. Legislation to be passed within 24 months;
- FDA intends to issue a guidance document on developing abuse deterrent drug formulations and on post-market assessment of their performance within 24 months;
- Have DOD, VA, and IHS provide controlled substance prescription information electronically to PDMPs in states in which they operate healthcare facilities and pharmacies within 24 months;
- Increase by 25 percent the number of states reimbursing for SBIRT within 24 months;
- Increase by 25 percent the number of HIDTAs involved in intelligence gathering and investigation around prescription drug trafficking and participation on statewide and regional prescription drug task forces within 24 months;
- Have legislation in all 50 states establishing Prescription Drug Monitoring Programs within 36 months;
- Expand by 10 percent, within 36 months, the available funding for treatment to increase access since only a small fraction of drug users currently undergo treatment;
- Decrease by 15 percent the number of unintentional overdose deaths related to opioids within 60 months.

Summary and Call to Action

Research and medicine have provided a vast array of medications to cure disease, ease suffering and pain, improve the quality of life, and save lives. This is no more evident than in the field of pain management. However, as with many new scientific discoveries and new uses for existing compounds, the potential for diversion, abuse, morbidity, and mortality are significant. Prescription drug misuse and abuse is a major public health and public safety crisis. As a Nation, we must take urgent action to ensure the appropriate balance between the benefits these medications offer in improving lives and the risks they pose. No one agency, system, or profession is solely responsible for this undertaking. We must address this issue as partners in public health and public safety. Therefore, ONDCP will convene a Federal Council on Prescription Drug Abuse, comprised of Federal agencies, to coordinate implementation of this prescription drug abuse prevention plan and will engage private parties as necessary to reach the goals established by the plan.\(^\text{20}\)

\(^{20}\) Accomplishment of the plan and its goals is dependent on the availability of resources.