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Subcommittee on Health

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Written Statement
of
R. Gil Kerlikowske
Director of National Drug Control Policy

Chairman Pallone, Ranking Member Shimkus, distinguished members of the Subcommittee, thank you for providing me the opportunity to appear before you today to address the current state of prescription drug abuse and recommend action that can be taken to address this epidemic. I am encouraged by your Subcommittee's focus on this topic. Reducing prescription drug diversion and abuse has been a major focus for the Office of National Drug Control Policy (ONDCP) since my arrival, and I have directed all National Drug Control Program agencies to address these vital issues in our drug control efforts.

The Growing Problem of Prescription Drug Abuse

Prescription drug abuse is the fastest-growing drug problem in the United States and is a serious public health concern. In recent years, the number of individuals who, for the first time, consumed prescription drugs for a non-medical purpose, exceeded the number of first-time marijuana users.¹ Monitoring the Future, a study of youth attitudes and drug use, shows that seven of the most commonly used drugs reported by 12th graders are pharmaceutical drugs used non-medically.² From 1997 to 2007, there was a 400 percent increase in addiction treatment admissions for individuals primarily abusing prescription pain killers.³ The increase in the percentage of admissions for abuse of pain relievers spans every age, gender, race, ethnicity, education, employment level, and region. The study also shows a more than tripling of pain reliever abuse among patients who needed treatment for opioid dependence. According to a Department of Defense survey in 2008, one in eight (12%) active duty military personnel reported past month illicit drug use, largely driven by the misuse of prescription drugs (reported by 11%).⁴ It is noteworthy that the Department of Veterans Affairs (DVA) does not currently participate in state Prescription Drug Monitoring Programs, however, ONDCP has engaged the DVA in conversations about this issue and the DVA has provided a positive response to address factors that may inhibit its participation in state PDMPs.

1 SAMHSA 2009 Results from the 2008 National Survey on Drug Use and Health: National Findings.

2 University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

3 Highlights for 2007 Treatment Episode Data Set (TEDS) Table 1b Admissions by primary substance of abuse: TEDS 1997-2007 Percent distribution, <http://www.drugabusestatistics.samhsa.gov/TEDS2k7highlights/TEDSHigh12k7Tb11b.htm>

4 Bray et al., 2008 Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel. (2009). Research Triangle Institute, Research Triangle Park, NC.

Between 2004 and 2008, the estimated number of emergency department visits linked to the non-medical use of prescription pain relievers doubled. This dramatic rise in emergency department visits associated with the non-medical use of these drugs occurred among men and women of all age groups.⁵

One major difficulty in deterring prescription drug abuse is the relative ease with which these drugs are obtained. In 2007-2008, among persons aged 12 or older who used pain relievers non-medically in the past 12 months, 55.9 percent got the pain relievers they most recently used from a friend or relative for free, 8.9 percent bought them from a friend or relative, and 5.4 percent took them from a friend or relative without asking. Nearly one-fifth (18.0 percent) indicated they got the drugs they most recently used through a prescription from one doctor. About 1 in 20 users (4.3 percent) obtained pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet. These percentages are similar to those reported in 2006-2007.⁶ Most distressingly, more than 26,000 Americans died from unintentional drug overdoses in 2006, and prescription drugs—particularly opioid painkillers—are considered a major contributor to the total number of drug deaths; in 2006 they represented 42 percent of unintentional drug overdoses.⁷ In 2006, the number of drug-induced deaths exceeded deaths from motor vehicle crashes in 16 states and the District of Columbia, including large States such as Illinois, Pennsylvania, New York, and Michigan.

As these statistics demonstrate, the abuse of prescription drugs is a problem of ever-increasing concern. Although beneficial when used as prescribed by a health professional for legitimate purposes, the relative ease of access to prescription drugs, coupled with a misperception of the potential harms resulting from their misuse and abuse, requires a comprehensive public health and public safety approach to reducing this problem.

We must change public perception so the societal norm shifts to one where prescription drugs are only used for their intended purpose, and unused or expired medications are disposed of in a

5 Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs — United States, 2004–2008. June 18, 2010.

6 SAMHSA Results from the 2008 National Survey on Drug Use and Health: National Findings, 2008.

7 CDC, National Center for Health Statistics, “National Vital Statistics Report”, 2009.

timely, safe, and environmentally responsible manner. We envision a future where disposal of these medications is second-nature to most Americans. Creating a method for disposal of expired or unused prescription drugs could benefit public health, public safety, and the environment.

We also believe every state should have a prescription drug monitoring program. H.R. 5710, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010, which the Subcommittee will consider this afternoon, would reauthorize one of two Federal programs that funds prescription drug monitoring programs. Prescription drug monitoring programs, also called PDMPs, are state-wide databases of the dispensed controlled substances prescribed by doctors, nurse practitioners, and other prescribers. Information contained in the PDMP can be used by prescribers to guard against prescribing two or more drugs that might have negative interactions; by pharmacists or prescribers to identify patients who may be shopping for prescriptions to sustain a prescription drug addiction; and, under specific circumstances, by regulatory and law enforcement officials when pursuing cases involving rogue prescribers or “pill mills”. We must ensure every state has a PDMP in place, prescribers and pharmacists use these databases, and PDMPs are developed with the capability to share information across state lines.

While the realities of prescription drug abuse demand action, any policy response must be approached thoughtfully, as it must strike a balance between our desire to minimize diversion and abuse of pharmaceuticals and the need to maximize their legitimate benefits. As science has successfully developed valuable medications to alleviate suffering, such as opioids for cancer patients and benzodiazepines for anxiety disorders, it has also led to the unintended consequence of increased pharmaceutical abuse.

The 2010 National Drug Control Strategy

Recently, the Obama Administration released its inaugural *National Drug Control Strategy (Strategy)*. The *Strategy* is the result of a nine-month consultative effort with Congress, Federal agencies, state and local partners, and hundreds of individuals across the country. It serves as a bold call to action for all Americans who share in the desire and the responsibility to keep our

citizens -- especially our vulnerable youth -- safe, healthy, and protected from the terrible costs of substance abuse, while ensuring our seniors, as well as those who are ill or vulnerable, have access to the prescription drugs they need to reduce pain, mitigate disease, and preserve life.

This *Strategy* is balanced, comprehensive, and recognizes prevention, treatment, and enforcement are all essential components of an effective approach to addressing drug use and its consequences. Our efforts incorporate science and smarter strategies to better align policy with the realities of drug use and its consequences in communities throughout this country. Research shows addiction is a complex, biological, and psychological disorder. It is chronic and progressive, and negatively affects individuals, families, communities, and our society as a whole. In 2008, over 23 million Americans ages 12 or older were estimated to need treatment for an illicit drug or alcohol use problem.

The *Strategy* sets specific goals by which we will measure our progress. Over the next five years, working with dozens of agencies, departments, Members of Congress, State and local organizations, and the American people, we intend to make significant reductions in illicit drug use and its consequences.

The 2010 National Drug Control Strategy Addresses Prescription Drug Abuse

The *Strategy* specifically acknowledges that prescription drug abuse is the fastest-growing drug problem in the United States, and, therefore, outlines an approach to address the unique issues surrounding the growing problem. One aspect of our *Strategy* relates directly to the disposal of unused or unwanted prescription drugs. The family medicine cabinet (e.g., the pain pill prescription that was never finished, the tranquilizers that are used occasionally) is a significant source of diversion for those seeking to abuse prescription drugs. Yet, the difficulty in disposing of such medications in a fashion that is simple, legal, and environmentally responsible is a challenge. In some communities, law enforcement professionals, in conjunction with grassroots organizations, have held “take-back” events at which such medications are safely collected and disposed of according to state and Federal environmental standards.

The drug disposal legislation you are exploring today will facilitate the establishment of

pharmaceutical take-back programs around the country by making a statutory change to the Controlled Substances Act (CSA) (P. L. 91-513). This step is required before the Drug Enforcement Administration (DEA) can fully implement the legitimate take-back of frequently abused prescription drug products containing controlled substances.

The Closed System of the Controlled Substances Act

I am encouraged by the Subcommittee's intent to amend the CSA, to permit promulgation of more systematic policy responses. Currently, the CSA establishes a closed system of distribution to provide security and accountability for the Nation's controlled substance supply. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration, until they are dispensed to the ultimate user. After a DEA-registered practitioner, such as a physician or a dentist, prescribes a controlled substance to a patient (i.e., the ultimate user), the patient can fill that prescription at a retail pharmacy. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants to participate in the process.

Under the CSA, if an individual has been prescribed a controlled substance, he or she cannot legally transfer the controlled substance to a pharmacist or any other non-law enforcement person for any reason, even if the person intends to dispose of the drug. Consumers, therefore, often retain unused controlled substances in their homes, which can lead to diversion and abuse. As already discussed, the 2009 Monitoring the Future Study found that seven of the most commonly used drugs reported by 12th graders are pharmaceutical drugs used non-medically.⁸ Another survey indicated that a majority of the youth surveyed said that they had obtained the drug from a friend or relative, either free, purchased, or taken without asking. Legislative action to amend the CSA will be a step forward in preventing drug abuse because it will allow the DEA to accommodate the growing desire at the community level to properly dispose of pharmaceuticals. This may serve to limit the potential for diversion, abuse, and decrease potentially negative environmental issues.

⁸ University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

Community-based Efforts to Control Prescription Drug Abuse

We know legitimate prescriptions from the family medicine cabinet are often the source of drugs that get abused, and the difficulty in disposing of these medications contributes to this problem. Therefore, proper disposal of unused or expired medications must be made easier. Disposing of unused or expired medications in a fashion that is simple, legal, and environmentally responsible is a challenge. Currently, the Federal government advises controlled substance users to dispose of controlled substances in one of three ways – throw them in the trash, after taking proper precautions; flush them down the toilet, in limited cases of very dangerous drugs; or participate in a take-back event.

As discussed, one method of disposal is to flush controlled substances down the toilet. This method of disposal is only recommended for exceptionally dangerous drugs. The FDA advises this because it has determined that the misuse of these prescription drugs creates a high risk of immediate harm, and so their potential danger outweighs the potential environmental impact. These prescription drugs are very dangerous and can be lethal if used improperly, especially by youth.

Take-back or community drug disposal events are community-based activities that accept prescription drugs. If controlled substances such as Vicodin or OxyContin are accepted, the events must be conducted in accordance with DEA guidelines, with the permission of the DEA Special Agent in Charge for the region, and under the supervision of authorized law enforcement officials. Any methods utilized to destroy the collected controlled substances must comply with all applicable Federal and state laws and regulations.

Currently, there are three types of take-back programs designed to assist in the disposal and destruction of prescription drugs. Under the Controlled Substances Act, any type of take-back that accepts controlled substances requires a waiver from the DEA. Programs range from: permanent sites where unused medication is received; one day events at various locations, such as pharmacies or hazardous waste collection sites; and in Maine, a mail/ship back program where ultimate users send their unused drugs to a central location using a pre-issued label or through a private carrier, such as UPS or FedEx.

EPA has awarded two grants for pilot take-back programs. From January to December 2008, the Regional eXcess Medication Disposal Service (RxMEDs) project, managed by the Area Resources for Community and Human Services (ARCHS) in St. Louis, collected more than 10,000 bottles of over-the-counter and non-controlled prescription drugs during collection days held at pharmacies.⁹ In addition, through a mail-back return envelope system, the Safe Medicine Disposal for ME (SMDME) program collected more than 2,300 lbs of drugs, including controlled substances.¹⁰

Several states and many localities have organized one-day take-back events in coordination with appropriate law enforcement officials. In 2009, New Jersey held one of the most ambitious take back efforts, called Operation Medicine Cabinet. Throughout all of New Jersey's 21 counties, over 440 local police and sheriff departments hosted collection sites. Over 9,000 pounds of prescription drugs (both controlled and non-controlled substances) were collected at the one day take-back event. This event was organized through the Special Agent in Charge DEA New Jersey Division, the New Jersey Office of the Attorney General (OAG), and the Partnership for a Drug-Free New Jersey.

In March of this year, Oregon organized a Statewide Prescription Drug Turn-In Day. More than 2,300 individuals took part, turning in more than 4,000 pounds of pills, tablets, and other drugs. The event was coordinated by the Oregon Medical Association Alliance, Community Action to Reduce Substance Abuse, and the Oregon Partnership. Several other States, including Montana and Missouri, have conducted similar take-back days.

By taking legislative action, you will allow DEA to rewrite its rules, and, consequently, make it easier for local communities to do the right thing – dispose of pharmaceuticals, including controlled substances. Just as the Federal government took on the challenge of changing societal attitudes about wearing seat belts, so, too, does this Administration need to change societal attitudes about proper and timely disposal of prescription drugs. EPA is an important partner in

⁹ Prudent Disposal of Unwanted Medications (RxMEDS): Final Report, 2009, <http://www.epa.gov/aging/grants/winners/rx-meds-technical-report508.pdf>

¹⁰ Executive Summary: Reducing Prescription Drug Misuse Through the Use of a Citizen Mail-Back Program in Maine, 2010, <http://www.epa.gov/aging/RX-report-Exe-Sum/>

the disposal of pharmaceuticals and will continue to be involved in any efforts to improve the methods by which Americans dispose of unused prescription drugs.

Prescription Drug Monitoring Programs

Beyond the issue of disposal of excess medications, ONDCP is also focused on other effective measures which can be implemented to curtail prescription drug abuse and its consequences. PDMPs are a focus for ONDCP because we believe they can be a highly effective tool for medical professionals, patients, the public health community, and law enforcement. PDMPs are state-level, controlled substance prescription data collection systems which allow authorized users (such as prescribers, pharmacists, regulatory and law enforcement entities, and professional licensing agencies) access to the data under certain conditions and with varying restrictions. PDMPs gather controlled substance prescription data from pharmacies within their states on regular intervals (1, 2, or 4 times monthly).

Generally, PDMPs can generate two different kinds of reports: solicited and unsolicited. Solicited reports, which can be done with most PDMPs, occur when authorized users query or obtain information from the PDMP system for information about controlled substance prescriptions for individuals.

Unsolicited reports are automatically generated when certain thresholds, which might indicate abuse of a controlled substance, doctor shopping, or errant prescribing practices, are reached. Different states and Federal agencies are experimenting with different thresholds. For instance, the Substance Abuse and Mental Health Service Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) proposes unsolicited reports be sent to prescribers and pharmacies when an individual has filled six or more controlled substance prescriptions of the same drug class, from six or more different prescribers, or six or more different pharmacies in a state, within a one month period. ONDCP believes all PDMPs should produce and disseminate unsolicited reports.

The bill the Subcommittee will consider this afternoon (H.R. 5710) reinforces Federal support for state controlled substance monitoring programs as invaluable public health and public safety tools. Specifically, it will:

1. authorize Federal funding to support state surveillance systems for an additional 5 years;
2. expand the allowable uses of funds to include program maintenance;
3. compel interoperability between state programs;
4. increase prescriber education about using the state systems to inform patient care; and
5. permit grant funding to Territories of the United States.

NASPER's interoperability requirement will further an important goal of ONDCP's efforts to decrease prescription drug abuse. Criminal activity does not respect state borders, and state PDMPs must allow for information sharing across state lines. Currently, information sharing is done on an *ad hoc* basis between states. The Department of Justice, including DEA, has invested considerable resources to develop the technology for states to share PDMP data via a hub (currently located at the Ohio Board of Pharmacy). Kentucky and Ohio have shared test data via this hub (transactions occurred within 30 seconds) and currently have a memorandum of understanding in place to exchange real data. It is anticipated this will start occurring regularly by the end of 2010. Other states will be able to implement this technology once it is tested and found to be operationally sound. ONDCP has also invested resources in ensuring other states have the technology needed to be able to interact with the hub and engage in interstate information sharing.

PDMPs are authorized in 43 States, but only 34 have programs that are operational. The PDMP authorizing legislation in each state determines where and how the PDMP in that state functions or will function. In some states, this is done by regulation. Recently, I traveled to Delaware, where Governor Jack Markell signed PDMP authorizing legislation, thereby making Delaware the 43rd State with such authority.

PDMPs can be effective in decreasing prescription drug diversion and abuse, and the Administration is seeking to ensure new and existing PDMPs are used effectively to help the

communities with access to the data to use the data. A study sponsored by DOJ indicated that PDMPs reduce the amount of prescription pain relievers and stimulants available for diversion, thus reducing the probability of abuse. Evidence also suggests states which are proactive in their approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach.¹¹ PDMPs can and should serve a multitude of functions, including serving as a: tool for patient care, drug epidemic early warning system (especially when combined with other data), drug diversion investigative tool (although PDMP data cannot be used as evidence in court), and an insurance fraud investigative tool. H.R. 5710 will help further these goals.

Conclusion

Prescription drug take-back programs, along with prescription drug monitoring programs, play an important role in a comprehensive effort to reduce prescription drug abuse. ONDCP has worked with DOJ, DEA, HHS, FDA, EPA, and Congress to further refine Federal laws and regulations to foster an expansion of comprehensive and cost-effective prescription monitoring and take-back programs across the country. To be effective, these programs must be consumer friendly and protect patients' privacy.

The *National Drug Control Strategy* provides a blueprint for reducing prescription drug diversion and abuse. Other equally important parts of the *Strategy* include prescriber and patient education; enforcement efforts against illegal Internet pharmacies; enforcement efforts to crack down on rogue pain clinics and pill mills, and public education efforts aimed at increasing the awareness of the dangers of prescription drug misuse.

I look forward to continuing to work with the Committee to address these challenging and important issues. I recognize that none of the many things ONDCP and my Executive Branch colleagues want to accomplish for the Nation are possible without the active support of Congress. Thank you very much for the opportunity to testify and for your support of these vital issues.

¹¹ Ronald Simeone and Lynn Holland, "An Evaluation of Prescription Drug Monitoring Programs." Simeone Associates, Inc. [2006] <http://www.simeoneassociates.com/simeone3.pdf>