EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
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"Drug Waste and Disposal: When Prescriptions Become Poison"

Senate Special Committee on Aging

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Written Statement of

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Chairman Kohl, Ranking Member Corker, distinguished members of the Committee, thank you for providing me the opportunity to appear before you today to address prescription drug abuse and disposal. I am encouraged by your Committee's focus on this topic. Prescription drug abuse and proper methods of disposal have been a major focus for ONDCP since my arrival, and I have directed 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 top ten drugs reported abused by 12th graders are prescription drugs.[2] From 1997 to 2007, there was a 400 percent increase in treatment admissions for individuals primarily abusing prescription pain killers.[3] 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]

Between 2004 and 2008, the estimated number of emergency department visits linked to the nonmedical use of prescription pain relievers has more than doubled. The dramatic rise in emergency department visits associated with nonmedical use of these drugs occurred among men and women of all age groups.[5]

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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/TEDSHighl2k7Tbl1b.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.

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.

Further troubling, an estimated 1.9 million adults aged 50 or older, or 2.1 percent of adults in that age range, used prescription-type drugs non-medically in the past year. Intentional misuse of prescription drugs among those 65 and older is more pervasive than marijuana use. This is the only age group for which this is so. [6]

The Substance Abuse and Mental Health Services Administration's Treatment Episode Data Set (TEDS) reveals that between 1992 and 2008 the proportion of substance abuse treatment admissions involving older Americans (aged 50 and older) nearly doubled -- from 6.6 percent of all admissions in 1992 to 12.2 percent in 2008. For the same timeframe, the proportion of admissions among this age group due primarily to prescription drug abuse rose from 0.7 percent to 3.5 percent.[7]

Among persons aged 12 or older in 2007-2008 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. Another 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) got 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.[8] 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.[9]

As these statistics demonstrate, the misuse of controlled substances and more broadly pharmaceuticals is a problem of ever-increasing concern, and the problem does not lend itself to traditional interventions. These drugs are dispensed for legitimate purposes and too often, the public's perception is that they are safe for uses other than those for which they are prescribed. We must change public perception so the societal norm shifts to one where unused or expired

6 NSDUH Report, "Illicit Drug Use Among Older Adults," December 29, 2009.

7 SAMHSA 2009 The TEDS Report - Changing Substance Abuse Patterns among Older Admissions: 1992 and 2008.

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

9 CDC, National Center for Health Statistics, "National Vital Statistics Report", 2009.

medications are disposed of in a timely, safe, and environmentally responsible manner. We envision a future where disposal of these medications is second-nature to most Americans, in much the same way as proper and responsible recycling of aluminum cans has become. Creating a method for disposal of expired or unused prescription drugs is essential to public health, public safety, and the environment.

While these realities demand action, any policy response must be approached thoughtfully, as it must strike a balance between our desire to minimize misuse 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.

Last month, the Obama Administration released its inaugural *National Drug Control Strategy.* This *Strategy* is balanced and comprehensive and recognizes that prevention, treatment, and enforcement are all essential components of an effective approach to addressing drug use and its consequences. The *2010 National Drug Control 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.

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.

Our efforts are balanced, incorporating 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. However, only 10 percent were estimated to have received the necessary treatment for their disorders.[10]

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. The following are specific steps outlined in the *Strategy*:

Increase Pharmaceutical Return/Take-Back and Disposal Programs

One aspect of our *Strategy* relates directly to the focus of today's hearing. Increasingly, many of the abused prescription drugs are found in the family medicine cabinet (e.g., the pain pill prescription that was never finished, the tranquilizers that are used occasionally). 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 days" in which such medications are safely collected. At the Federal level, Congress is exploring legislative proposals to facilitate the establishment of pharmaceutical take-back programs around the country, and EPA has awarded two grants for pilot pharmaceutical take-back programs. However, a statutory change to the Controlled Substances Act (CSA) is required before the Drug Enforcement Administration (DEA) can fully implement the legitimate take-back of frequently abused prescription drug products containing controlled substances. These grassroots, legislative, and agency efforts will be intensified as part of the Administration's effort to combat prescription drug abuse. The private sector will be engaged as a potential partner in take-back programs. These efforts will also be complemented by activities of several other Federal partners, including the work done by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to educate patients and family members on the most appropriate methods of disposal when take-back programs are not available.

10 Results from the 2008 National Survey on Drug Use and Health: National Findings, Substance Abuse and Mental Health Services Administration (SAMHSA), 2008, http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm

The Closed System of the Controlled Substances Act

These steps are all temporary approaches until Congress acts to amend the Controlled Substances Act (CSA) (P. L. 91-513) 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, issues a prescription for 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 to another 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 of the prescription drug. As already discussed, the 2009 Monitoring the Future Study found that, among 12th graders surveyed, 7 of the top 10 drugs abused by youth were prescription drugs, with a majority of the youth surveyed saying that they had obtained the drug from a friend or relative.

Community-based Efforts to Control Prescription Drug Abuse

We know that legitimate prescriptions from the family medicine cabinet are often the source of drugs that get abused. 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. Only exceptionally dangerous drugs should

be flushed down the toilet. 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 and certified law enforcement officials. Any methods utilized to destroy the collected controlled substances must comply with all applicable Federal and State laws and regulations, including, but not limited to, laws and regulations relating to public health and the environment.

Currently, there are three types of take-back programs designed to assist in the disposal and destruction of prescription drugs. All require a waiver from the DEA if they accept controlled substances. 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.[11] In addition, through a mail-back return envelope system, the Safe Medicine Disposal for Maine (SMDME) program collected more than 2,300 lbs of drugs, including controlled substances.[12]

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

[12] 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/

Several States and many localities have organized one-day take-back events in coordination with appropriate law enforcement officials. In 2009, New Jersey held Operation Medicine Cabinet. Throughout all of New Jersey's 21 counties, over 440 local police departments 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.

Just as the Federal government, along with national partners, took on the challenge of changing societal attitudes about wearing seat belts, so, too, does this Administration, along with national, State, and local partners, need to change societal attitudes about proper and timely disposal of prescription drugs.

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. The following are some examples of initiatives currently underway by Executive Branch Departments and Agencies.

Educate Physicians about Opiate Painkiller Prescribing

The FY 2011 Budget proposes for SAMHSA, through the Physician Clinical Support System (PCSS) program, to train prescribers on how to instruct patients in the use and proper disposal of pain killers, observe signs of dependence, and use prescription monitoring programs to detect doctor shopping. FDA, the agency responsible for reviewing and approving drug applications for prescription pain medications, plays an important role in providing effective information about the proper use and disposal of opioids through approved product labeling. Furthermore,

Federal agencies that support their own healthcare systems, such as the Department of Veterans Affairs, will increase continuing medical education for their prescribers on proper prescribing and disposal.

Expand Prescription Drug Monitoring Programs and Promote Links among State Systems and to Electronic Health Records

Prescription drug monitoring programs (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. With most PDMPs, authorized users can query or obtain information from the PDMP system for information about controlled substance prescriptions for individuals. ONDCP believes that all PDMPs should also produce and disseminate unsolicited reports. These unsolicited reports can be generated when certain thresholds are reached which might indicate abuse of a controlled substance, doctor shopping, or errant prescribing practices. Different States and Federal agencies are experimenting with different thresholds. For instance, the SAMHSA's Center for Substance Abuse Treatment (CSAT) proposes that unsolicited reports be sent to prescribers when any individual that has filled six or more controlled substance prescriptions from six different prescribers, or six different dispensers in a State, within a six month period.

There are currently two Federal funding programs for PDMPs. The Harold Rogers Prescription Drug Monitoring Program, administered by DOJ's Bureau of Justice Assistance, has been operating since 2003 and competitively funds State PDMP planning, implementation, and enhancement, and also can and does fund research, training, and technical assistance. The National All Schedules Prescription Electronic Reporting Act (NASPER) program, administered by SAMHSA's CSAT, has been funding PDMP programs since 2009 and awards funds to States with operational programs based on a formula applied annually.

Criminal activity does not respect State borders, and it is critical that State PDMPs share information across State lines. This is currently being done on an *ad hoc* basis between States. The Department of Justice 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. ONDCP has also invested resources in ensuring other States have the technology needed on their end to be able to interact with the hub and also begin engaging in interstate information sharing.

Currently, prescription drug monitoring programs are authorized in 42 States, but only 34 have operational programs. 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, Wisconsin's Governor Doyle signed PDMP authorizing legislation making Wisconsin the 42nd State with such authority. ONDCP supports the establishment of PDMPs in every State.

PDMPs can be effective at decreasing prescription drug abuse and the Administration is seeking to ensure new and existing PDMPs are effectively using the data they acquire. 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. The evidence also suggests that 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.[13] PDMPs can and should serve a multitude of functions including: 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 insurance fraud investigative tool.

Assist States to Address Doctor Shopping and Pill Mills

Criminal organizations have established a thriving business of transporting individuals from

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

States with strong prescription-monitoring programs to States with less monitoring and regulation. Areas with little regulation are often populated by "pill mills", which distribute prescriptions indiscriminately. This is an extremely difficult problem for State-level law enforcement to handle, due to resource constraints and difficulties navigating cases across multiple State, local, and tribal jurisdictions. It also creates significant problems for prescribers trying to determine whether a patient is doctor shopping. ONDCP, through our High Intensity Drug Trafficking Area Program (HIDTA) Program, and DEA continue to work with State, local, and tribal officials to suppress this aspect of the drug trade through training provided by the National Methamphetamine and Pharmaceuticals Initiative (NMPI) and DEA's Tactical Diversion Squads.

Drive Illegal Internet Pharmacies Out of Business

Proper and safe prescribing of medications rests on a triangle of responsibility comprising the patient, the prescriber, and the pharmacist. However, those internet pharmacies that sell prescription pharmaceuticals without a valid prescription and/or personal contact between a patient and a physician are a threat to public health and a source of significant criminal revenue. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires that all internet pharmacies, unless exempted by statute, must obtain a modification of their DEA pharmacy registrations in order to operate online, must include certain declarations on their website designed to provide clear assurance that it is operating legitimately, and must not provide pharmaceuticals to individuals who have not had at least one face-to-face evaluation by a prescribing medical practitioner. The Act requires that internet pharmacies report to the DEA monthly and include all controlled substances dispensed by any means, not just controlled substances over the internet, unless the pharmacy does not meet the threshold of either (A) 100 or more prescriptions for controlled substances filled by the pharmacy or (B) 5,000 or more total dosage units of controlled substances dispensed. DEA will continue to partner with international, State, and local law enforcement agencies to further suppress these sources of prescription drug diversion and abuse.

Crack Down on Rogue Pain Clinics that Do Not Follow Appropriate Prescription Practices

In recent years, pain management clinics that operate outside the scope of acceptable medical

practices have increased. Currently, these "rogue pain clinics" are now a major source of controlled substance pharmaceuticals for drug seekers. Although rogue pain clinics are operating throughout the United States, DEA has identified three major hubs where these illegal schemes are flourishing: the Houston, TX, area; the Los Angeles, CA, area; and, most significantly, the tri-county area of South Florida (Palm Beach, Broward, and Miami-Dade counties).

The vast majority of "patients" who visit these clinics come from out-of-State. The opiate-based pharmaceutical controlled substances most frequently illegally dispensed at the clinics in the Texas and California regions are a combination of hydrocodone and alprazolam (Xanax®). In the South Florida region, oxycodone products are most frequently dispensed. DEA, in coordination with other Federal, State, and local agencies, will investigate these rogue clinics through expanded Tactical Diversion Squads and will shut down these rogue operations, via criminal, civil, or administrative actions, when they violate Federal prescribing and dispensing requirements and endanger the American public.

State legislative approaches, like the law recently enacted in Florida, can also play an important role in reining in rogue pain management clinics. The Florida law mandates greater regulation of pain clinics by the Florida Department of Health and allows the Department to shut down clinics if they violate established standards. The Florida law also allows the Florida Department of Health to prevent felons and disciplined physicians from owning and operating pain management clinics, and allows law enforcement to be informed of possible "doctor shopping" and potential criminal conduct by practitioners.

Conclusion

Prescription drug take-back programs play an important role in a comprehensive effort to reduce prescription drug abuse. ONDCP is working with DEA, FDA, EPA, and Congress to further refine Federal laws and regulations to foster an expansion of comprehensive and cost-effective prescription drug take-back programs across the country. To be effective, prescription drug take-back programs must be consumer friendly. Unless take-back programs are easy to access and

regularly occur, large quantities of unneeded prescription drugs will remain in the community, subject to diversion, misuse, and abuse.

The *National Drug Control Strategy* provides the blueprint for reducing prescription drug abuse, primarily by: focusing on prescriber education; limiting controlled substance prescriptions to those who have the greatest potential for abuse; and reducing, through take-back programs, the quantity of unused and expired prescription controlled substances from remaining accessible in homes and long term care facilities.

I look forward to continuing to work with the Committee to address these challenging and important issues, while balancing the safety of the public with the protection of the environment. 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 the support of the Committee on these vital issues.