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"Reponding to the Prescription Drug Abuse Epidemic"

Senate Caucus on International Narcotics Control

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

STATEMENT OF
R. GIL KERLIKOWSKE
DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

before the

CAUCUS ON INTERNATIONAL NARCOTICS CONTROL
UNITED STATES SENATE

"RESPONDING TO THE PRESCRIPTION DRUG ABUSE EPIDEMIC"

JULY 18, 2012

Chairman Feinstein, Co-Chairman Grassley, and distinguished members of the Caucus, thank you for this opportunity to appear before you to address the issue of prescription drug diversion and abuse in our country. As you know, the Office of National Drug Control Policy (ONDCP) was established by Congress with the principal purpose of reducing illicit drug use, illicit manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. Our Office establishes policies, priorities, and objectives for the Federal drug control program agencies. We also evaluate, coordinate, and oversee the international and domestic anti-drug efforts of executive branch agencies and ensure such efforts sustain and complement state and local anti-drug activities.

As you are also aware, my Office is charged with producing the *National Drug Control Strategy* (*Strategy*), which directs the Nation's anti-drug efforts and establishes programs, a budget, and guidelines for cooperation among Federal, state, and local entities. The Obama Administration recognizes that addiction is a disease, and that prevention, treatment, and law enforcement must all be included as part of a strategy to stop drug use, get help to those who need it, and ensure public safety. Building upon this national *Strategy*, the Administration has developed the comprehensive *Prescription Drug Abuse Prevention Plan*. As I will discuss later in further detail, this document establishes a plan to reduce diversion and abuse of prescription drugs, while continuing to ensure legitimate access to medications for patients who need them.

The Administration's inaugural *Strategy*, released in May 2010, committed to reducing drug use and its consequences through a science-based public health approach to policy. The *Strategy* established specific goals by which to measure our success and included action items that comprehensively address all areas of drug control. The 2012 *Strategy*, released this past April, provides a status update on the significant progress we have made on many of these action items. In addition, we have highlighted three signature initiatives in each year's *Strategy* – prevention, drugged driving, and, most pertinent for this hearing, prescription drug abuse.

The data around prescription drug abuse are showing some positive trends, particularly among young people. Past month non-medical use of prescription drugs among youth ages 12-17 was

significantly lower in 2010 (3.0%) compared to 8 years ago (2004, 3.6 %).[1] This is also true for past month non-medical use of pain relievers, which is significantly lower in 2010 (2.5%) compared to 2004 (3.0%). However, these decreases have not been seen across the board, and additional work is needed to expand on these indicators.

The Epidemic of Prescription Drug Abuse

Over the past decade, high rates of prescription drug abuse and misuse have had devastating consequences for public health and safety in this Nation. Communities across the country have witnessed increases in substance abuse treatment admissions, emergency department visits, and most disturbingly, overdose deaths attributable to prescription drug overdoses. As you all know, these consequences have led the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) to characterize prescription drug abuse as a public health epidemic, a label that underscores the need for urgent policy, program, and community-led responses.

The latest survey data show that approximately seven million Americans currently use prescription-type psychotherapeutic drugs non-medically – meaning use without a prescription of the individual's own or simply for the experience or feeling the drugs caused. In 2010, 2.4 million Americans aged 12 or older used psychotherapeutics non-medically for the first time, which averages nearly 6,600 new users per day. The largest share of these new users started with pain relievers (approximately 2.0 million, or 5,500 new users per day), a figure second only to the number of new marijuana users.[2]

These numbers translate into very real consequences. In 2010 alone, estimates indicate over 1.3 million emergency department visits involved the non-medical use of pharmaceuticals, more than double the estimate from 6 years earlier, and outnumbering visits involving all other types of controlled substances combined. Much of this increase is attributable to visits involving narcotic pain relievers, a class of drugs that includes oxycodone, hydrocodone, and methadone – increasing 156 percent from 2004 to 2010.[3] It is these pain relievers that are behind many of the negative consequences of prescription drug abuse. In fact, data indicate a six-fold increase in addiction treatment admissions for individuals primarily abusing prescription painkillers from

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[1] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Detailed Tables.* U.S. Department of Health and Human Services. [September 2011]. Available: http://www.samhsa.gov/data/nsduh/2k10NSDUH/tabs/LOTSect7pe.htm#TopOfPage

[2] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2011]. Available: *http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm*
and Health: Summary of National Findings. U.S. Department of Health and Human Services. [September 2011]. Available: http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm

[3] Substance Abuse and Mental Health Services Administration. *Highlights of the 2010 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits.* U.S. Department of Health and Human Services. [July 2012]. Available: http://www.samhsa.gov/data/2k12/DAWN096/SR096EDHighlights2010.pdf

1999 to 2009.[4] These increases span age groups, gender, race, ethnicity, education, employment level, and region.

In 2009, more than 37,000 Americans died from drug overdose deaths, with prescription drugs – particularly opioid painkillers – involved in a significant proportion of those deaths. This equates to approximately 100 overdose deaths every day in this country.[5] Opioid painkillers are involved in over 15,500 of these deaths, which is nearly 4 times the number of people who died from these drugs just a decade earlier in 1999.[6] Opioid pain relievers are now involved in more overdose deaths than heroin and cocaine combined. Remarkably, drug overdose deaths now outnumber deaths from gunshot wounds or from motor vehicle crashes.[7]

Substance use has also affected our military, Veterans, and their families. According to the latest Department of Defense survey in 2008, one in eight (12%) active duty military personnel reported past month illicit drug use, largely driven by the abuse or misuse of prescription drugs (reported by 11% of the total).[8] The Department of Housing and Urban Development estimates that there were 67,000 homeless Veterans in 2011[9] — and substance abuse is a factor in homelessness.

The human costs of prescription drug abuse are tragic and cannot be overstated for the families and friends that have experienced the loss of a loved one. In addition to this human devastation, this epidemic is placing a significant burden on budgets at all levels. One study found that prescription drug abuse cost the Nation nearly $56 billion in 2007, nearly $25 billion of which was direct health care expenses.[10] Financial consequences are yet another aspect of prescription drug abuse that cannot be ignored.

The widespread consequences of this issue have brought increased examination of the scope and origins of the problem. The vast majority of abused pharmaceutical drugs originally enter into circulation through a prescription. And we know that most prescription painkillers are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons, not pain

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[4] Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) 1999-2009, National Admissions to Substance Abuse Treatment Services*. U.S. Department of Health and Human Services. [2011]. Available: http://wwwdasis.samhsa.gov/teds09/teds2k9nweb.pdf

[5] CDC, National Center for Health Statistics. Underlying Cause of Death 1999-2009 on CDC WONDER Online Database. Extracted May 1, 2012.

[6] CDC, National Center for Health Statistics. Multiple Cause of Death 1999-2009 on CDC WONDER Online Database. Extracted May 1, 2012.

[7] National Center for Health Statistics. (2012). National vital statistics reports: Deaths: Final Data for 2009. Centers for Disease Control and Prevention: Washington, DC. Highlights/Detailed Tables available: http://www.cdc.gov/nchs/data/dvs/deaths_2009_release.pdf

[8] 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.

[9] U.S. Department of Housing and Urban Development, Office of Community Planning and Development. *The 2011 Point-in-Time Estimates of Homelessness: Supplement to the Annual Homeless Assessment Report.* [December 2011]. Available: http://www.hudhre.info/documents/PIT-HIC_SupplementalAHARReport.pdf

[10] Birnbaum HG, White, AG, Schiller M, Waldman T, et al. Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. *Pain Medicine*. 2011;12:657-667.

management specialists.[11] The quantity of prescription painkillers sold to pharmacies, hospitals, and doctors' offices approximately quadrupled between 1999 and 2010. In fact, CDC estimates that in 2010, enough opioid pain relievers were prescribed to medicate every American adult with a typical dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[12]

Unfortunately, once they are prescribed and dispensed, these drugs are frequently diverted and misused. The latest survey shows that in 2009 and 2010, approximately 55 percent of the non-medical users of prescription pain relievers obtained them "from a friend or relative for free." Another 11 percent bought them from a friend or relative, and 5 percent took them from a friend or relative without asking. This means that over 70 percent of people abusing or misusing prescription pain relievers obtained them from friends or family.[13] This same survey shows that 17 percent of Americans using prescription pain relievers non-medically obtained them from one doctor, while just over 4 percent got them from a drug dealer or other stranger, and 0.4 percent bought them online.[14]

Researchers have begun to identify risk factors for overdosing on opioids. The first of these is "doctor shopping" – obtaining multiple prescriptions from different providers.[15,16] Other predictors include taking one or more sedative/hypnotic (benzodiazepine-like) medications, high daily dosages of prescription painkillers, and multiple overlapping prescriptions, as well as prescriptions for certain drugs and visiting multiple pharmacies.[17,18,19,20,21,22] Individuals with histories of mental illness or other substance abuse are also at increased risk.[23]

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[11] Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SRB. "Characteristics of opioid prescriptions in 2009." JAMA 2011;305(13):1299–1301. Available: http://jama.ama-assn.org/content/305/13/1299.full

[12] Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008.* U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

[13] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm

[14] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm

[15] White AG, Birnbaum HG, Schiller M, Tang J, Katz NP. "Analytic models to identify patients at risk for prescription opioid abuse." Am J of Managed Care 2009;15(12):897-906. Available: http://www.ncbi.nlm.nih.gov/pubmed/20001171

[16] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, et al. "Patterns of abuse among unintentional pharmaceutical overdose fatalities." JAMA 2008;300(22):2613-20. Available: http://jama.ama-assn.org/content/300/22/2613.full

[17] Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of being prescribed controlled substances and risk of drug overdose death.Pain Med. 2012 Jan;13(1):87-95. Available: http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/22026451

[18] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, et al. "Patterns of abuse among unintentional pharmaceutical overdose fatalities." JAMA 2008;300(22):2613-20. Available: http://jama.ama-assn.org/content/300/22/2613.full

[19] Green TC, Graub LE, Carver HW, Kinzly M, Heimer R. "Epidemiologic trends and geographic patterns of fatal opioid intoxications in Connecticut, USA: 1997–2007." Drug and Alcohol Dependence 2011;115:221-8. Available: http://www.ncbi.nlm.nih.gov/pubmed/21131140

Regionally, the drug overdose epidemic is most severe in the Southwest and in Appalachia, and rates vary substantially between states. The highest drug overdose death rates in 2008 were found in New Mexico and West Virginia (27.0 and 25.8 deaths per 100,000 population, respectively), which had rates nearly five times that of the state with the lowest rate, Nebraska (5.5 deaths per 100,000). The national average for drug overdose death is 11.9 deaths per 100,000. California, at 10.4 deaths per 100,000, sits just below the national average, whereas Iowa, at 7.1 deaths per 100,000, is among the states with the lowest rates.[24]

It is important to note the socioeconomic trends in these overdose deaths. According to researchers at the CDC, those living in rural areas are at higher risk for overdose, [25,26] as are those in areas with higher proportions of impoverished residents.[27] Among individuals on Medicaid, studies have found disproportionate patterns of painkiller use as well as significantly higher risk of overdose on prescription pain relievers.[28,29] In addition, analysis of 31 states' poison control center calls shows that the percentages of residents living in poverty and unemployed correlate with prescription drug abuse reports, while the percentage with bachelor's degrees, and to a lesser extent high school diplomas, are related to less prescription abuse.[30]

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[20] Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. "A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia." Addiction 2009;104(9):1541-8. Available: http://www.ncbi.nlm.nih.gov/pubmed/19686524

[21] Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. "Association between opioid prescribing patterns and opioid overdose-related deaths." JAMA 2011;305(13):1315-1321. Available: http://jama.ama-assn.org/content/305/13/1315.full

[22] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, et al. "Opioid prescriptions for chronic pain and overdose: a cohort study." Ann Intern Med. 2010;152(2):85-92. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000551/

[23] Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. "Association between opioid prescribing patterns and opioid overdose-related deaths." JAMA 2011;305(13):1315-1321. Available: http://jama.ama-assn.org/content/305/13/1315.full

[24] Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008.* U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

[25] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ.Patterns of abuse among unintentional pharmaceutical overdose fatalities.JAMA. 2008 Dec 10;300(22):2613-20. Available: http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19066381

[26] Wunsch MJ, Nakamoto K, Behonick G, Massello W. Opioid deaths in rural Virginia: a description of the high prevalence of accidental fatalities involving prescribed medications. Am J Addict. 2009 Jan-Feb;18(1):5-14. Available: http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19219660

[27] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ.Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008 Dec 10;300(22):2613-20. Available: http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19066381

[28] Centers for Disease Control and Prevention. "Overdose deaths involving prescription opioids among Medicaid enrollees-Washington, 2004-2007." MMWR. 2010;59;705-9. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm

[29] Braden JB, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD. "Trends in use of opioids by noncancer pain type 2000-2005 among Arkansas Medicaid and HealthCore enrollees: results from the TROUP study." J Pain 2008;9(11):1026-1035. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661263/

[30] Spiller H, Lorenz DJ, Bailey EJ, Dart RC. Epidemiological trends in abuse and misuse of prescription opioids. J Addict Dis. 2009;28(2):130-6. Available: http://www.ncbi.nlm.nih.gov/pubmed/19340675

These figures highlight the continuing health and safety dangers that prescription drug abuse, misuse, and diversion pose for the country. The ease of access to prescription drugs, combined with a low perception of risk, make reducing prescription drug abuse especially difficult, particularly among youth. When properly and safely prescribed by healthcare professionals, prescription medications can provide enormous health and quality of life benefits to patients. Medical science has successfully developed medications that can alleviate suffering, such as opioids for cancer pain and benzodiazepines for anxiety disorders, and allowed more individuals to have access to the medicines they need. However, we all now recognize that these drugs can be just as dangerous and deadly as illicit substances when misused or abused.

An Improved Response

The considerable public health and safety consequences of prescription drug abuse underscore the need for action. In April 2011, the Administration released its comprehensive *Prescription Drug Abuse Prevention Plan*, entitled "Epidemic: Responding to America's Prescription Drug Abuse Crisis." This plan builds upon the Obama Administration's *National Drug Control Strategy* and brings together Federal, state, local, and tribal leaders to reduce diversion and abuse of prescription drugs. It strikes a balance between our need to prevent diversion and abuse of pharmaceuticals with the need to ensure legitimate access, focusing on four major pillars, each designed to intervene at a critical juncture in the process of diversion and abuse. These pillars include education for prescribers and the public; prescription monitoring; safe drug disposal; and effective enforcement. I am pleased to report that we are making significant progress in each of the four major pillars outlined in the plan.

The first pillar of this plan is education. As stated earlier, most prescription painkillers are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons, not pain specialists. Despite this reality, surveys of health care professionals and schools reveal significant gaps in education and training on pain management, substance abuse, and safe prescribing practices. For these reasons, the Administration continues to support mandatory prescriber education as called for in the *Prescription Drug Abuse Prevention Plan*. The urgency of this epidemic and the fundamental need for safe prescribing practices in modern medical care demand effective curricula for prescribers. Several states, including Iowa, Massachusetts, and Utah, now have mandatory prescriber education legislation. These laws require important education for health care providers and prescribers on the abuse potential of prescription medications and the best ways to deliver quality care while ensuring the safety of the patient and the general public. As state leaders take steps to require this important education, the Administration continues to support other education efforts across the country. The HHS Substance Abuse and Mental Health Services Administration (SAMHSA) is providing training on prescription drug abuse for physicians both in person and online. And since 2007, 49 courses have been offered in 31 states with particularly high rates of opioid dispensing.

These training programs are providing important knowledge and tools for medical professionals responsible for safely prescribing these medications. In addition, the HHS Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for extended-release and long-acting (ER/LA) opioids. Just last week, I joined FDA Commissioner

Margaret Hamburg to formally announce the REMS risk management plan for these medications. The centerpiece of this REMS is education and training for prescribers, which includes a requirement for all manufacturers of ER/LA opioids, more than 20 companies in total, to ensure that educational materials and continuing education (CE) courses are made available to prescribers of these medications. The manufacturers must also provide information that prescribers can use when counseling patients about the risks and benefits of opioid use. FDA expects that sponsors will meet this obligation by providing educational grants to accredited CE providers to offer training to prescribers at no or nominal cost. At least 60 percent of the approximately 320,000 prescribers of ER/LA opioids will be trained within 4 years from when training is available. This plan is designed to ensure that health care professionals are trained on how to properly prescribe these medicines and how to instruct their patients about minimizing risks associated with their use.

The other crucial aspect of this education effort involves the general public, particularly people using prescription medications, as well as parents and caregivers. We are educating Americans about the risks and prevalence of prescription drug abuse and about the safe use and proper storage and disposal of these medications. Through our National Youth Anti-Drug Media Campaign, ONDCP has developed materials for use by community anti-drug coalitions to educate youth about the dangers of prescription drug abuse. The Media Campaign is one of the most important national tools for educating young people and their parents about the dangers of prescription drug abuse. The Drug Free Communities (DFC) Support Program, which supports over 700 community coalitions across the country, is working with local youth, parent, business, religious, and other civic leaders to disseminate messaging about prescription drug abuse. However, we also know that the average age of first non-medical use of pain relievers is 21 years old.[31] Americans start abusing prescription drugs later in life than they do with illicitly produced drugs, so we need to ensure that prevention messaging targets adults as well. With these issues in mind, the Administration is producing educational materials, holding public events, and working with other government and private sector stakeholders to provide the right information to Americans who most need it.

Just a few months ago, Administration leaders participated in the National Prescription Drug Abuse Summit in Orlando, Florida, organized by Project UNITE. Attended by over 700 people from all sectors, public and private, this Summit provided participants, several members of Congress, and other local, state, and national leaders a venue to share best practices in data gathering, prevention, treatment, and enforcement, and better inform key policy makers from all levels. ONDCP served on the advisory committee, had prominent speaking roles at the Summit, and helped lay the groundwork connecting national efforts to curb prescription drug abuse to the Administration's *Prescription Drug Abuse Prevention Plan*.

The second pillar of the Administration's plan focuses on expanding and improving state Prescription Drug Monitoring Programs (PDMPs). As you know, these state-wide databases monitor the prescribing and dispensing of controlled substances and serve a multitude of

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[31] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm

functions. PDMPs can and should serve as a tool for patient care, a drug epidemic early warning system (especially when combined with other data), and a drug diversion and insurance fraud investigative tool. Information contained in the PDMP can be used by prescribers and pharmacists to detect drug-drug interactions and identify patients who may be doctor shopping or in need of substance abuse treatment. Under specific circumstances, regulatory and law enforcement officials can also use the information to pursue cases involving rogue prescribers or pharmacists, or "pill mills" and other forms of diversions.

In 2006, only 20 states had PDMPs. Today, 49 states have laws authorizing PDMPs, and 41 states have operational programs. And due to programs supported by the Bureau of Justice Assistance (BJA) and leadership from the National Association of Boards of Pharmacy, there are currently 11 states able to share data with other states, with several more pending. Despite this progress and the demonstrated benefits of PDMPs, some states lack operational programs, and many states that do operate PDMPs lack this critical interoperability. All states should have operational PDMPs with mechanisms in place for sharing between states. Additionally, health care providers must use these databases regularly and consistently, incorporating PDMP checks as a standard part of patient care. We are working with other Federal and state health care and law enforcement officials to expand and improve the operations of these PDMPs, as well as resolve issues concerning implementation and interoperability among state databases, as permitted by law. We continue to urge states to increase the number of unsolicited reports made available to prescribers, pharmacists, and licensing entities, grow the number of prescribers who check the PDMP database before they prescribe, and ensure that states' systems are ready to share data across state lines.

ONDCP is also working with the Office of the National Coordinator for Health Information Technology (ONC) at HHS to explore connecting PDMPs with health information technology systems and state Health Information Exchanges. Additionally, ONC and SAMHSA have launched a pilot program that will make existing prescription drug use data available to providers and pharmacists when treating patients in ambulatory and emergency departments. The pilot projects, announced just last month, will take place in Indiana and Ohio and will measure the effects of expanding and improving access to PDMPs. HHS also announced last month a $4 million funding opportunity for a program, Prescription Drug Monitoring Integration and Interoperability Expansion Program, which will support states in expanding interoperability and integration of PDMPs. We are also exploring ways to incorporate real-time PDMP data at the points of care and dispensing. These advances will maximize the public health and public safety benefits of PDMPs.

I am also pleased to report to the American people that the Administration worked with Congress to include language in the Consolidated Appropriations Act, 2012, allowing the Department of Veterans Affairs (VA) to share prescription drug data with state PDMPs — a shift that will allow medical providers to better serve the healthcare needs of our Veterans. The rulemaking process is currently underway, but in the meantime, VA has authorized its health care providers to access PDMP data, after obtaining signed voluntary informed consent from the Veteran or when otherwise consistent with Federal and state laws.

The third pillar of our plan focuses on safe disposal of unused and expired medications. As I mentioned earlier, over 70 percent of people misusing prescription pain relievers report getting their painkillers from a friend or relative. Unused medications sitting in our medicine cabinets are falling into the wrong hands. Safe medication disposal programs provide a clear mechanism through which to ensure unused or expired medications are disposed of in a timely, safe, and environmentally responsible manner. The Drug Enforcement Administration (DEA), in partnership with thousands of state and local entities, is providing more opportunities for safe disposal of unused or expired medications. Through coordinated, nationwide *National Prescription Drug Take Back Days*, DEA has collected and safely disposed of over one and a half million pounds of unused and unwanted pills, many of which were sitting in medicine cabinets across the country where they were vulnerable to misuse or abuse. The next "Take Back Day" is scheduled for September 29, and we are looking forward to safely collecting, disposing, and preventing diversion of unwanted medications.

The passage of the Secure and Responsible Drug Disposal Act in October 2010 was a critical step forward in expanding prescription drug disposal nationwide. A DEA rulemaking, currently under interagency review, would be intended to make safe disposal of prescription drugs more convenient and accessible for all Americans. In order to help safely reduce the amount of prescription drugs available for diversion and abuse, any drug disposal program should endeavor to be easily accessible to the public, environmentally friendly, and cost-effective. ONDCP will work with Federal, state, local, and tribal stakeholders to identify ways to establish take back programs in their communities upon completion of the rulemaking process.

The Administration also recognizes the significant role that "pill mills" and rogue prescribers play in this issue. For this reason, the fourth and final pillar of the Administration's plan focuses on enhancing law enforcement's ability to address diversion as the source of prescription drugs. ONDCP has worked with congressional partners and law enforcement and prosecutor groups to raise awareness of the scope of the prescription drug epidemic. The National Methamphetamine and Pharmaceutical Initiative (NMPI), funded through ONDCP's High Intensity Drug Trafficking Area (HIDTA) program, is providing critical training on pharmaceutical crime investigations to law enforcement agencies across the country. In FY 2011 alone, NMPI helped provide training in pharmaceutical crime investigations and prosecutions to over 2,500 law enforcement and criminal justice professionals. These efforts continue to disseminate critical knowledge to enforcement and prosecution professionals.

This enforcement and prosecution training is an important start to what requires a coordinated, long-term focus. One example of the ongoing challenges comes from Florida, which in 2010 was the epicenter of the Nation's pill mill epidemic. At the time, DEA reported that 90 of the top 100 oxycodone-purchasing physicians in the Nation were located in the State. In response to this situation, new State laws have stripped doctors operating at rogue pain clinics of their ability to dispense controlled substances. These State actions, combined with DEA's significant enforcement actions, have contributed to a decreased number of rogue pain clinics. As a result, oxycodone purchases by doctors in Florida have dropped dramatically. In fact, according to DEA, there was a 97 percent decrease in oxycodone purchases by doctors in Florida in 2011

compared to 2010, and the number of Florida doctors appearing on the list of the top 100 oxycodone purchasing physicians dropped from 90 in 2010 to only 13 in 2011.[32]

The combination of law enforcement, regulatory, and legislative actions are forcing doctor shoppers and others seeking sources for prescription drugs for abuse to turn from Florida to other states in the region. There have been notable increases in doctors purchasing oxycodone in Georgia, Tennessee, and Kentucky. Among oxycodone-purchasing doctors, 21 doctors located in Georgia and 11 in Tennessee are now among the top 100.[33] In order to prevent pill mill operators and rogue prescribers from simply popping up in other areas of the country, the Administration is working with state and local leaders to learn from Florida's experience and explore enforcement, regulatory, and legislative options to prevent diversion and its consequences.

There remain other challenges, including data limitations that inhibit our ability to construct a more detailed picture of the prescription drug diversion and abuse problem. In order to address these gaps, ONDCP is undertaking an analysis project that uses other data sources to fill in major information gaps. This project will examine methods by which prescription drugs are purchased, patterns in those purchasing behaviors, and whether those patterns are indicative of suspicious behavior. Examples of suspicious acquisition patterns that the project will examine include disproportionate numbers of cash-based purchases or the filling of multiple prescriptions for the same drug in an unusually short period of time. Identification and analysis of behaviors such as these will then be used to develop a complete profile of prescription drug diversion. Having first identified the ways in which the most commonly diverted prescription drugs are acquired, this project will then estimate the proportion of prescription drugs that are likely diverted from the legitimate market either for illicit resale or abuse.

We also recognize the important role the medication naloxone can play in reversing drug overdoses. With the tragic number of overdose deaths attributable to the non-medical use of opioids, as well as heroin, it is vitally important that we do what is necessary to assist appropriately trained personnel to prevent such drug overdose deaths without encouraging further drug use, and to refer people to the additional treatment they need. ONDCP, CDC, and SAMHSA are working with first responders to identify and address any gaps in training, access, and use of naloxone by first responders. Earlier this year, ONDCP participated in a public workshop sponsored by FDA, NIH's National Institute on Drug Abuse, and CDC, at which key stakeholders highlighted the importance of naloxone in reducing overdose deaths and examined avenues for the use of naloxone by non-medical personnel. The Administration is tracking best practices in naloxone distribution nationwide and providing guidance to researchers, community groups, and the pharmaceutical industry on potential routes for marketing approval for novel naloxone formulations.

In addition, the Administration is taking steps to develop an understanding of clinical and policy issues related to neonatal abstinence syndrome (NAS), the withdrawal symptoms exhibited by

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[32] *See* DEA Press Release, "Florida Law Enforcement Prescription Drug Efforts Produce Positive Results," January 30, 2012 Available: http://www.justice.gov/dea/pubs/states/newsrel/2012/mia013012.html

[33] *Ibid*.

infants born to drug-dependent mothers. A recent study showed that between 2000 and 2009, the rate of newborns diagnosed with NAS increased from 1.20 to 3.39 per 1,000 hospital births per year. [34] This translates to approximately one infant per hour born dependent on narcotic drugs. Moreover, the number of mothers using or dependent upon drugs increased from 1.19 to 5.63 per 1,000 hospital births per year. Hospital costs for treating these infants have increased from, on average, $39,400 in 2000 to $53,400 in 2009, a 35 percent increase. Medicaid was the primary payer for over 75 percent of these births. At the same time, a variety of state laws concerning child maltreatment and mandatory reporting discourages pregnant drug abusers from seeking prenatal care. Even in research settings where patients are assured confidentiality and anonymity, under-reporting of drug use by pregnant women is not uncommon, given the repercussions in certain states, such as loss of custody or jail time, if the provider reports drug use to child protective services.[35]

ONDCP will host a meeting in August that will examine the scope of this problem; discuss the state of the science concerning prevention, identification, and treatment; and solicit input from a variety of stakeholders and experts on potential policy and program interventions necessary to help address this problem. Decreasing the numbers of mothers and children affected is a critical metric for understanding the effect our policies are having on families. This meeting will provide valuable information to policymakers seeking to reduce diversion and its consequences.

Conclusion

As discussed above, we have made considerable progress in our efforts to address the prescription drug abuse problem. Health care providers, law enforcement, and the public at large are better aware of the epidemic, and monitoring, disposal, education and treatment, and enforcement efforts have produced results. And the data around prescription drug abuse are showing some positive trends, particularly among young people. However, these decreases have not been seen across the board. The trend in past month non-medical use among young adults ages 18-25 has remained relatively flat. And for adults aged 26 or older, rates of non-medical use of prescription drugs have increased significantly between 2004 (1.8%) and 2010 (2.2%).[36] These data underscore the need to redouble our efforts to achieve the as-yet unmet goals of the plan, such as mandatory prescriber education and improving PMDP utilization, and make needed enhancements to existing activities. The Administration is committed to maintaining its focus on prescription drug abuse as a signature initiative of the *National Drug Control Strategy*.

[34] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009" JAMA. 2012 May 9;307(18):1934-40. Available: http://www.ncbi.nlm.nih.gov/pubmed/22546608
[35] Grekin, ER, Svikis, DS, Lam, P, Connors, V, LeBreton, JM, Streiner, DL, Smith, C, Ondersma, SJ. "Drug use during pregnancy: Validating the drug abuse screening test against physiological measures." Psychology of Addictive Behaviors, 24(4), Dec 2010, 719-723. doi: 10.1037/a0021741
[36] Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health: Detailed Tables. U.S. Department of Health and Human Services. [September 2011]. Available: http://www.samhsa.gov/data/nsduh/2k10NSDUH/tabs/LOTSect7pe.htm#TopOfPage

In closing, I recognize the active support of Congress and thank you for your continued support of ONDCP's efforts, and continued support of the Drug Free Communities (DFC) Support Program and the National Youth Anti-Drug Media Campaign. I appreciate the opportunity to testify here today on this public health epidemic, and I look forward to continuing to work with you to reduce prescription drug abuse.