

## EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF NATIONAL DRUG CONTROL POLICY

Washington, D.C. 20503

# "America's Addiction to Opioids: Heroin and Prescription Drug Abuse"

### Caucus on International Narcotics Control United States Senate

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Written Statement
of
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Chairman Feinstein, Co-Chairman Grassley, and distinguished members of the Caucus, thank you for this opportunity to address the public health and safety issues surrounding the diversion and abuse of opioid drugs – including prescription painkillers and heroin - in the United States.

As you know, the Office of National Drug Control Policy (ONDCP) was established in 1988 by Congress with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, our office establishes policies, priorities, and objectives for the Nation's drug control programs. We also develop, 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 drug policy activities.

At ONDCP, we are charged with producing the *National Drug Control Strategy* (*Strategy*), the Administration's primary blueprint for drug policy, along with a national drug control budget. The *Strategy* is a 21<sup>st</sup> century plan that outlines a series of evidence-based reforms that treat our Nation's drug problem as a public health challenge, not just a criminal justice issue. It moves beyond an outdated "war on drugs" approach and is guided by what experience, compassion, and science demonstrate about the true nature of drug use in America.

The considerable public health and safety consequences of opioid misuse and abuse underscore the need for action. Since the Administration's inaugural 2010 National Drug Control Strategy, we have deployed a comprehensive and evidence-based strategy to address overdose deaths and opioid abuse. The Administration has significantly bolstered support for medication-assisted opioid treatment and overdose prevention, coordinated a government-wide response to the prescription drug abuse epidemic, and pursued action against criminal organizations trafficking in opioid drugs.

#### Trends and Consequences of Opioid Misuse and Abuse

The abuse of opioids – a category of drugs including heroin and prescription pain relievers like oxycodone and hydrocodone – is having a considerable impact on public health and safety in communities across the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 100 Americans on average died from overdose every day in 2010. Of the more than 38,300 overdose deaths in 2010, opioid pain relievers were involved in over 16,600, while heroin was involved in approximately 3,000. (See Figure at the end of this statement.) Overall, drug overdose deaths now outnumber deaths from gunshot wounds (31,000) or motor vehicle (35,000) crashes in the United States. <sup>1</sup>

As this Caucus knows, the diversion and abuse of prescription opioid medications have been of serious concern at the national, state, and local levels. Increases in substance abuse

<sup>&</sup>lt;sup>1</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 2000-2010 on CDC WONDER Online Database. Extracted May 2013.

treatment admissions,<sup>2</sup> emergency department visits,<sup>3</sup> and, most disturbingly, overdose deaths<sup>4</sup> attributable to prescription drug abuse place enormous burdens upon communities across the country.

In 2012, approximately 4.9 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.<sup>5</sup> This makes prescription pain reliever misuse more common than use of any type of illicit drug in the United States except for marijuana. By comparison, approximately 335,000 Americans reported past month use of heroin.<sup>6</sup> Heroin use remains relatively low in the United States when compared to other drugs; however, there has been a troubling increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 669,000 in 2012.<sup>7</sup> This trend comports with other indicators, including preliminary reporting from the National Institute on Drug Abuse's Community Epidemiology Work Group, which finds that several U.S. cities, including Atlanta, Baltimore, Boston, Chicago, Cincinnati, Denver, Miami, Minneapolis, San Diego, Seattle, and St. Louis, indicate increases in heroin use. In addition, heroin remains at relatively stable but high levels in Detroit, New York City, and Philadelphia.<sup>8</sup> The Drug Enforcement Administration (DEA) also reports an over 300 percent increase of heroin seizures at the Southwest border from 2008 to 2013.<sup>9</sup>

The use of these opioids translates into very real health consequences. In 2012 alone, approximately 2.1 million Americans met the diagnostic criteria for abuse or dependence on prescription pain relievers, while heroin accounted for approximately 467,000 people with past year abuse or dependence. Both of these figures represent significant increases from just a decade earlier.<sup>10</sup>

<sup>&</sup>lt;sup>2</sup> Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) 2001-2011, National Admissions to Substance Abuse Treatment Services*. U.S. Department of Health and Human Services. [2013]. Extracted April 2013

<sup>&</sup>lt;sup>3</sup> Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits.* U.S. Department of Health and Human Services. [May 2013]. Available: <a href="http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2">http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2</a>

<sup>&</sup>lt;sup>4</sup> CDC, National Center for Health Statistics. Underlying Cause of Death 2000-2010 on CDC WONDER Online Database. Extracted October 2012.

<sup>&</sup>lt;sup>5</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: <a href="http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect1peTabs1to46-2012.htm#Tab1.1A">http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect1peTabs1to46-2012.htm#Tab1.1A</a>

<sup>&</sup>lt;sup>6</sup> *Ibid*.

<sup>&</sup>lt;sup>7</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: <a href="http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.2A">http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.2A</a>

<sup>&</sup>lt;sup>8</sup> National Institute on Drug Abuse. Highlights and Summaries from January 2014 Reports. Available: <a href="http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/highlights-summaries-january-2014-reports">http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/highlights-summaries-january-2014-reports</a>

<sup>&</sup>lt;sup>9</sup> National Seizure System, El Paso Intelligence Center, extracted January 25, 2014.

<sup>&</sup>lt;sup>10</sup> Substance Abuse and Mental Health Services Administration. Results from the 2012 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2013]. Available: <a href="http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.40A">http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.40A</a>

Beyond the many lives taken by overdoses involving these medications, prescription opioids are also associated with significant consequences to our health care system. In 2011 alone, 1.2 million emergency department (ED) visits involved the non-medical use of all prescription drugs. Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class involved in these medical emergencies, accounting for approximately 488,000 visits alone. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just 7 years earlier in 2004 (173,000). Among specific opioid drugs in 2011, oxycodone accounted for the largest share (31 percent) of ED visits; there were 110,000 more visits involving oxycodone in 2011 than in 2004, an increase of 263 percent. While ED admissions involving heroin have remained relatively flat over the past several years, the drug was still involved in nearly 260,000 visits in 2011.

Similar trends are reflected in the country's substance use disorder treatment system. Data show a nearly five-fold increase in treatment admissions for individuals primarily abusing prescription pain relievers, from 36,000 in 2001 to nearly 181,000 in 2011. Heroin treatment admissions remained flat over the same time period, but still account for 278,000 admissions in the United States.<sup>14</sup>

There has been considerable discussion around potential connections between the non-medical use of prescription opioids and heroin use. There is evidence to suggest that some users, specifically those with chronic opioid addictions, will substitute heroin for prescription opioids, since heroin is often cheaper than prescription drugs. While research into the potential nexus between these two types of opioids remains sparse, a recent report from the Substance Abuse and Mental Health Services Administration (SAMHSA) found that four out of five recent heroin initiates had previously used prescription pain relievers non-medically. However, only a very small proportion (3.6%) of those who had started using prescription drugs non-medically initiated heroin use in the following five-year period. This suggests that while most new heroin users have previously used prescription opioids non-medically, a very small portion of all non-medical prescription drug users transitions to heroin.

We also know that substance use disorders, including those driven by opioids, are a progressive disease. Most people who develop a substance use disorder begin using at a young age and often start with alcohol, tobacco, and/or marijuana. This is important when examining the progression of opioid use. We know from survey data that as an individual's abuse of

<sup>&</sup>lt;sup>11</sup> Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits.* U.S. Department of Health and Human Services. [May 2013]. Available: <a href="http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2">http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2</a>
<sup>12</sup> *Ibid.* 

<sup>&</sup>lt;sup>13</sup> Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits.* U.S. Department of Health and Human Services. [May 2013]. Available: http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#3.1

<sup>&</sup>lt;sup>14</sup> Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment Admissions by Primary Substance of Abuse, According to Sex, Age Group, Race, and Ethnicity, United States* [2001 through 2011 tables]. U.S. Department of Health and Human Services. [2013]. Extracted April 2013.

<sup>&</sup>lt;sup>15</sup> Substance Abuse and Mental Health Services Administration. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Department of Health and Human Services. [August 2013]. Available: <a href="http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf">http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf</a>

prescription opioids becomes more frequent or chronic, that person is more inclined to purchase the drugs from dealers/the internet/prescriptions from multiple doctors, rather than simply getting them from a friend or relative for free/without asking. <sup>16</sup> This progression of an opioid use disorder may lead an individual to pursue lower cost alternatives, such as heroin.

#### The Administration's Response

Since 2009, the Obama Administration has deployed a comprehensive and evidence-based strategy to address the threat posed by opioid drugs. Within 30 days of his confirmation, then-Director of National Drug Policy Kerlikowske declared combatting prescription drug abuse a top drug control priority for the Administration. Since then, the Administration has coordinated a Government-wide response to the prescription drug abuse epidemic, significantly bolstered support for medication-assisted opioid treatment and overdose prevention, and pursued action against criminal organizations trafficking in opioid drugs. President Obama's inaugural *National Drug Control Strategy*, released in May 2010, labeled opioid overdose a "growing national crisis" and laid out specific actions and goals for reducing the abuse of prescription opioids and heroin.<sup>17</sup>

As I described earlier, prescription drugs represent the bulk of opioid abuse in America, and our response to this public health emergency focused not only on preventing the diversion and abuse of prescription drugs, but also decreasing the number of Americans dying from opioid overdose every day. In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan*, <sup>18</sup> which created a national framework for reducing prescription drug diversion and abuse. This *Plan* built upon the goal identified in the *National Drug Control Strategy* to reduce drug-induced deaths by 15 percent by 2015 and augmented that goal with a distinct goal to reduce unintentional overdose deaths related to opioids by 15 percent within 5 years. The *Plan* focuses on improving education for patients and healthcare providers, supporting the expansion of state-based prescription drug monitoring programs, developing more convenient and environmentally responsible disposal methods to remove unused medications from the home, and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

The Administration has made considerable progress in all four areas of the *Plan*, including expanding available continuing education for prescribers. Managing patients' pain is a crucial area of clinical practice, but unfortunately, research indicates that health care practitioners receive little training on pain management, safe opioid prescribing, or recognizing and treating

<sup>&</sup>lt;sup>16</sup> Unpublished estimates from Substance Abuse and Mental Health Services Administration, *National Survey on Drug Use and Health*, 2009-2012, March 2014.

<sup>&</sup>lt;sup>17</sup> Office of National Drug Control Policy. 2010 National Drug Control Strategy. Executive Office of the President. [2010]. Available: http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf#page=49

<sup>&</sup>lt;sup>18</sup> Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx\_abuse\_plan.pdf

substance use disorders. <sup>19,20</sup> Several states, including Iowa, <sup>21</sup> Kentucky, <sup>22</sup> Massachusetts, <sup>23</sup> Ohio, <sup>24</sup> Tennessee, <sup>25</sup> and Utah, <sup>26</sup> have passed legislation mandating education for prescribers, and we strongly encourage other states to explore this as an option. At the Federal level, the *Plan* calls for amending Federal law to require practitioners (such as physicians, dentists, and others authorized to prescribe), who request DEA registration to prescribe controlled substances, to be trained on responsible opioid prescribing practices as a precondition of such registration. Currently, Department of Health and Human Services (HHS) is implementing education requirements for its agency health care personnel, including professionals serving tribal communities through the Indian Health Service (IHS), those working with underserved populations through the Health Resources and Services Administration, and personnel attending to biomedical research trial participants at the Clinical Center of the National Institutes of Health (NIH). Similar efforts are underway at the Bureau of Prisons, and education efforts are being planned at the Department of Defense (DOD) and the Department of Veterans Affairs (VA).

The Administration has also made free and low-cost training options available for prescribers and dispensers of opioid medications. SAMHSA provides such training. In addition, ONDCP worked with NIH's National Institute on Drug Abuse (NIDA) to develop two free, online training tools on safe prescribing for pain and on managing pain patients who abuse prescription opioids. Since their launch in late 2012, thousands of doctors, nurses, and pharmacists have completed these training modules, which are eligible for continuing medical education and continuing education credit. The Food and Drug Administration (FDA) now requires manufacturers of extended-release and long-acting (ER/LA) opioid pain relievers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy for these drugs. Through these innovative training programs, FDA expects to train at least 60 percent of the approximately 320,000 prescribers of these medications within the first four years of the program.<sup>27</sup>

The FDA has also taken a number of steps to help safeguard access to opioid pain relievers while reducing risks of non-medical use and overdose. In September 2013, ONDCP

<sup>&</sup>lt;sup>19</sup> Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

<sup>&</sup>lt;sup>20</sup> U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: http://www.gao.gov/assets/590/587301.pdf

<sup>&</sup>lt;sup>21</sup> Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available:

 $<sup>\</sup>frac{\text{http://medicalboard.iowa.gov/Board\%20News/2011/New\%20rules\%20physicians\%20to\%20complete\%20training\%20chronic\%20pain 08182011.pdf}{\text{http://medicalboard.iowa.gov/Board\%20News/2011/New%20rules\%20physicians\%20to\%20complete\%20training\%20chronic\%20pain 08182011.pdf}$ 

<sup>&</sup>lt;sup>22</sup> Kentucky Board of Medical Licensure. "House Bill 1." Commonwealth of Kentucky. [2012]. Available: http://kbml.ky.gov/hb1/Pages/default.aspx

<sup>&</sup>lt;sup>23</sup> Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available:

http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html 
<sup>24</sup> General Assembly of the State of Ohio. "129<sup>th</sup> General Assembly – Amended Substitute Senate Bill Number 83." [2012].

Available: <a href="http://www.legislature.state.oh.us/bills.cfm?ID=129">http://www.legislature.state.oh.us/bills.cfm?ID=129</a> SB 83

25 State of Tennessee. "Public Chapter No. 430 – Senate Bill 676." [April 18, 2013]. Available: <a href="http://www.tn.gov/sos/acts/108/pub/pc0430.pdf">http://www.tn.gov/sos/acts/108/pub/pc0430.pdf</a>

<sup>&</sup>lt;sup>26</sup> Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act*, 58-37-6.5. State of Utah. [May 2012]. Available: http://www.dopl.utah.gov/laws/58-37.pdf#page=24

<sup>&</sup>lt;sup>27</sup> Food and Drug Administration. "Questions and Answers: FDA approves a Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics." Department of Health and Human Services. [updated March 2013]. Available: <a href="http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm#Q8">http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm#Q8</a>

joined the FDA to announce significant new measures to enhance the safe and appropriate use of ER/LA opioid analgesics. FDA required class-wide labeling changes for these medications, including modifications to the products' indication for severe pain, warnings around use during pregnancy, as well as post-market research requirements. FDA also announced that manufacturers of ER/LA opioids must conduct further studies and clinical trials to better assess risks of misuse, addiction, overdose, and death. In April 2013, FDA approved updated labeling for reformulated OxyContin that describes the medication's abuse-deterrent properties, which are expected to make abuse via injection difficult and to reduce abuse via the intranasal route. And in December 2013, after an extensive review of scientific literature and hundreds of public comments and several public meetings, FDA announced its recommendation that the DEA should reschedule hydrocodone combination products into Schedule II of the Controlled Substances Act, which requires more stringent standards for storage, record keeping, and prescribing. On February 27th, DEA issued a Proposed Notice of Public Rulemaking to begin the process of this rescheduling.

The Administration is also educating the general public around opioid abuse. The Drug-Free Communities (DFC) Support Program currently funds 643 community coalitions to work with local youth, parent, business, religious, civic, and other groups to help prevent youth substance use. Grants awarded through the DFC program are intended to support established community-based coalitions capable of effecting community-level change. All DFC-funded grantees are required to collect and report data on past 30-day use; perception of risk or harm of use; perception of parental disapproval of use; and perception of peer disapproval of use for four substances, including prescription drugs.

The second pillar of the Administration's *Plan* focuses on improving the operations and functionality of state-administered Prescription Drug Monitoring Programs (PDMPs) across the country. PDMP data can help prescribers and pharmacists identify patients who may be at-risk for substance use disorders, overdose, or other significant health consequences of misusing prescription opioids. State regulatory and law enforcement agencies may also use this information to identify and prevent unsafe prescribing, doctor-shopping (seeing multiple doctors to obtain prescriptions), and other methods of illegally diverting controlled substances. Aggregate data from PDMPs can also be used to track the impact of policy changes on prescribing rates. The Prescription Behavior Surveillance System, funded by CDC and FDA, is developing this surveillance capacity for PDMPs. Research also shows that PDMPs may have a role in reducing the rates of prescribing for opioid analgesics and that states whose PDMPs were administered by a state health department, rather than another government agency such as the bureau of narcotics or board of pharmacy, showed especially positive results. <sup>30</sup> In 2006, only 20 states had PDMPs. Today, 49 have laws authorizing PDMPs, and 48 states have operational

<sup>&</sup>lt;sup>28</sup> Food and Drug Administration. "ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements – Letter to ER/LA opioid application holders." Department of Health and Human Services. [September 2013]. Available: <a href="http://www.fda.gov/downloads/DrugSafety/InformationbyDrugClass/UCM367697.pdf">http://www.fda.gov/downloads/DrugSafety/InformationbyDrugClass/UCM367697.pdf</a>

<sup>&</sup>lt;sup>29</sup> "Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20–553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness." Federal Register 78:75 (April 18, 2013) p. 23273. Available: <a href="http://www.gpo.gov/fdsys/pkg/FR-2013-04-18/pdf/2013-09092.pdf">http://www.gpo.gov/fdsys/pkg/FR-2013-04-18/pdf/2013-09092.pdf</a>

<sup>&</sup>lt;sup>30</sup> Brady, JE, Wunsch, H, Dimaggio, C, Lang, BH, Giglio, J, and Li, G. Prescription drug monitoring and dispensing of prescription opioids. Public Health Reports 2014, 129 (2): 139-47.

programs. Building upon this progress, the HHS Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA are working with state governments and private sector technology experts to integrate PDMPs with health information technology (health IT) systems such as electronic health records. Heath IT integration will enable authorized healthcare providers to access PDMP data quickly and easily at the point of care to support more informed clinical decision-making about prescribing or dispensing prescription opioids. To date, SAMHSA has provided funding to 16 states, and ONC has conducted 13 pilots focusing on integration with health IT systems. Integration with health IT systems also requires maintaining the privacy of the public health information in the PDMP as it transits within systems, since PDMP data in most states are held to the same privacy standard as all other health care information.

The Bureau of Justice Assistance (BJA) of the Department of Justice (DOJ) is also supporting expanded interstate sharing of PDMP data. PDMPs in 24 states can share data with other states' systems, and many PDMP administrators are working to better integrate these systems into other health IT programs. In February 2013, VA issued an Interim Final Rule authorizing VA physicians to access state PDMPs in accordance with state laws and to develop mechanisms to begin sharing VA prescribing data with state PDMPs. The interim rule became final on March 14, 2014.<sup>31</sup> IHS clinics are now sharing data with state PDMPs in many states, and IHS is in the process of negotiating data-sharing with more states.<sup>32</sup> As these systems continue to mature, PDMPs can enable health care providers and law enforcement agencies reduce and prevent the diversion and abuse of prescription opioids.

The third pillar of our *Plan* focuses on safely removing millions of pounds of expired and unwanted medications from circulation. Research shows that approximately 70 percent of recent initiates and occasional users misusing prescription pain relievers in the past year report getting them from a friend or relative the last time they abused them.<sup>33</sup> Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner.

Since September 2010, DEA has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold seven National Take-Back Days. Through these events, DEA has collected and safely disposed of more than 3.4 million pounds of unneeded or expired medications.<sup>34</sup> As part of the Secure and Responsible Drug Disposal Act of 2010, DEA has published proposed regulations that, once finalized, will expand the safe and effective disposal of prescription drugs nationwide. ONDCP will work with Federal, state, local, and tribal stakeholders to identify ways to establish disposal

<sup>&</sup>lt;sup>31</sup> Disclosures to Participate in State Prescription Drug Monitoring Programs, 78 Fed. Reg. 9589 (Feb. 11, 2013); 79 Fed. Reg. 14400 (Mar. 14, 2014).

<sup>&</sup>lt;sup>32</sup> Cynthia Gunderson, Prescription Drug Monitoring Programs & Indian Health Service, Barriers, Participation, and Future Initiatives, Presentation at Third Party Payer Meeting, December 2012. http://www.pdmpexcellence.org/sites/all/pdfs/Gunderson.pdf

<sup>&</sup>lt;sup>33</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2013]. Available: <a href="http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2.16">http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2.16</a>

<sup>&</sup>lt;sup>34</sup> Drug Enforcement Administration. "Americans Turn Out in Droves for DEA's Seventh National Prescription Drug Take-Back Day." Department of Justice. [November 6, 2013]. Available: http://www.justice.gov/dea/divisions/hq/2013/hq110613.shtml

programs in their communities upon completion of the rulemaking process. DEA sponsored its most recent Take Back Day on April 26<sup>th</sup>.

The *Plan's* fourth pillar focuses on improving law enforcement capabilities to reduce diversion of prescription opioids. Federal law enforcement is partnering with state and local agencies across the country to reduce pill mills and prosecute those responsible for improper or illegal prescribing practices. The National Methamphetamine and Pharmaceuticals Initiative (NMPI), funded through ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program, provides critical training on pharmaceutical crime investigations to law enforcement agencies across the country. Since 2009, NMPI has provided training in pharmaceutical crime investigations and prosecutions to over 26,000 law enforcement and criminal justice professionals. These efforts continue to disseminate critical knowledge to enforcement and prosecution professionals.

All of these efforts under the *Prescription Drug Abuse Prevention Plan* are intended to reduce the diversion, abuse, and health and safety consequences associated with prescription opioids. Given their substantial role in overall opioid abuse and their nexus with heroin use, the Administration has worked tirelessly to address the problem at the source and at an array of intervention points. This work has been paralleled by efforts to address heroin trafficking and abuse, as well as the larger opioid overdose problem facing this country.

In June 2012, ONDCP convened top officials from NIDA, CDC, and other leaders from HHS, DOJ, DOD, and VA to discuss the latest data regarding heroin trends in the United States and the Administration response. ONDCP directed Federal public health and safety officials to increase data sharing, identify trends in substitution between prescription opioid misuse and heroin use, and coordinate a timely and evidence-based response to any emerging trends in the use of opioids. This meeting also reinforced the existing overdose prevention and opioid use disorder treatment goals outlined in the *National Drug Control Strategy*.

The Administration is focusing on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions; increasing access to naloxone, an emergency opioid overdose reversal medication; and working with states to promote Good Samaritan laws and other measures that can help save lives. With the recent rise in overdose deaths across the country, it is increasingly important to prevent overdoses and make antidotes available.

The Administration is providing tools to local communities to empower them to save lives. In August 2013, SAMHSA released the *Opioid Overdose Prevention Toolkit*.<sup>35</sup> This toolkit provides communities and local governments with material to develop policies and practices to help prevent opioid-related overdoses and deaths. It contains information specifically for first responders, treatment providers, and those recovering from opioid overdose. This kit will enable state and community leaders to implement effective overdose prevention initiatives, saving lives and connecting people to the treatment they need.

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<sup>&</sup>lt;sup>35</sup> Substance Abuse and Mental Health Services Administration. Opioid Overdose Prevention Toolkit. Department of Health and Human Services. [August 2013]. Available: <a href="http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742">http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742</a>

In addition, working closely with ONDCP, the American Society of Anesthesiologists (ASA) has created an informational card on recognizing and responding to an opioid overdose.<sup>36</sup> The ASA's "Opioid Overdose Resuscitation" card lists symptoms to look for when an opioid overdose is suspected, and details step-by-step instructions for assisting a person suspected of an overdose prior to the arrival of emergency medical personnel. The Administration is working with ASA and other key stakeholders to provide this card to those who may encounter and can intervene with victims of opioid overdoses.

The Administration continues to promote the use of naloxone, the emergency opioid overdose reversal medication, among those likely to encounter overdose victims. Profiled in the 2013 *National Drug Control Strategy*, the Police Department in Quincy, Massachusetts, has partnered with the State health department to train and equip police officers to resuscitate overdose victims using naloxone. The Department reports that since October 2010, officers in Quincy have administered naloxone in more than 220 overdose events, almost all of them resulting in successful overdose reversals.<sup>37</sup> The Police Department and Sheriff's Office in Lorain, Ohio, working with county public health and substance abuse leaders, started a similar pilot program in October 2013, and officers have already reversed approximately 20 overdoses.<sup>38</sup> In addition, the New York/New Jersey HIDTA, a grant program funded by ONDCP, provided funding for a pilot program in a New York City Police Department precinct on Staten Island to train and equip police officers with naloxone. Other major jurisdictions are exploring naloxone programs as well. Boston Mayor Marty Walsh announced on February 11<sup>th</sup> that Boston police and firefighters will be equipped with naloxone,<sup>39</sup> and Vermont Governor Peter Shumlin recently announced that the Vermont State Police will have a similar training program for officers.<sup>40</sup>

The Administration is also working with health care leaders to identify and promote other promising naloxone distribution models. For example, a joint program with the University of Rhode Island's College of Pharmacy, the Rhode Island Pharmacy Foundation, the State Board of Pharmacy, and Walgreens, has created a continuing education program and collaborative practice agreement that allows pharmacists to initiate naloxone therapy for patients who may be at risk for an opioid overdose. A DOD-led program, Operation Opioid Safe at Fort Bragg, North Carolina, educates patients about the risks and abuse issues surrounding long-term use of prescription opioids and distributes naloxone to high-risk patients.

<sup>31</sup> 

<sup>&</sup>lt;sup>36</sup> American Society of Anesthesiologists. "Opioid Overdose Resuscitation Card." [September 2013]. Available: <a href="http://www.asahq.org/WhenSecondsCount/~/media/For%20the%20Public%20Media/Patient%20Education/Opioid%20Overdose%20Card.pdf">http://www.asahq.org/WhenSecondsCount/~/media/For%20the%20Public%20Media/Patient%20Education/Opioid%20Overdose%20Card.pdf</a>

<sup>&</sup>lt;sup>37</sup> Quincy (Massachusetts) Police Department Reporting

<sup>&</sup>lt;sup>38</sup> Personal Communication, Lorain County (Ohio) Police Department

<sup>&</sup>lt;sup>39</sup> Associated Press. "Boston mayor wants 1<sup>st</sup> responders to carry Narcan." Boston Herald. [February 11, 2014]. Available: <a href="http://bostonherald.com/news-opinion/local-coverage/2014/02/boston-mayor-wants-1st-responders-to-carry-narcan-narcan-wants-1st-responders-to-carry-narcan-n

<sup>&</sup>lt;sup>40</sup> Krantz, L. "State Unveils Easier Access to Overdose-Reversing Drug." VTDigger.org. [March 3, 2014]. Available: <a href="http://vtdigger.org/2014/03/03/state-unveils-easier-access-overdose-reversing-drug">http://vtdigger.org/2014/03/03/state-unveils-easier-access-overdose-reversing-drug</a>

<sup>&</sup>lt;sup>41</sup> University of Rhode Island College of Pharmacy. "Opioids: Addiction, Overdose Prevention (Naloxone) And Patient Education." [November 2011]. Available: <a href="http://prescribetoprevent.org/wp-content/uploads/2012/11/naloxoneCEU\_vURI\_CE.pdf">http://prescribetoprevent.org/wp-content/uploads/2012/11/naloxoneCEU\_vURI\_CE.pdf</a>

<sup>&</sup>lt;sup>42</sup> Anthony Dragovich, M.D., Womack Army Medical Center, Fort Bragg, NC, personal communication, 2011, cited in Centers for Disease Control and Prevention. "Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010." MMWR 2012;61:101-105 [February 17. 2012] Available: <a href="http://www.cdc.gov/mmwr/pdf/wk/mm6106.pdf">http://www.cdc.gov/mmwr/pdf/wk/mm6106.pdf</a>

Seventeen states<sup>43</sup> and the District of Columbia have passed laws that have made it easier for medical professionals to prescribe and dispense naloxone, or for third party individuals to possess and administer the medication. They do this by limiting civil or criminal liability for prescribers or third parties, permitting prescribers to prescribe naloxone to third parties or via standing order, and removing liability for possession of naloxone without a prescription.

ONDCP is collaborating with state health and law enforcement officials to promote best practices and connect officials interested in starting their own naloxone programs. The odds of surviving an overdose, much like the odds of surviving a heart attack, depend on how quickly the victim receives treatment. At least 14 states<sup>44</sup> have passed Good Samaritan laws, which protect victims and witnesses who seek medical aid for an individual who is overdosing.<sup>45</sup> As these laws are implemented, the Administration will carefully monitor their effect on public health and public safety. In April, I participated in a webinar with the American College of Emergency Physicians to discuss the potential value of overdose education and naloxone prescription to high-risk patients who visit the ED. While it is legal to prescribe naloxone to patients with the expectation that family members or loved ones will assist with emergency administration, such prescription is underutilized. On April 3, FDA approved a hand-held auto-injector naloxone delivery product that comes with a trainer device to teach administration before it is needed. Once turned on, the device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators. This device could facilitate naloxone use by family members and caregivers in emergency situations.

The Affordable Care Act and Federal parity laws are extending access to and parity for mental health and substance use disorder benefits for an estimated 62 million Americans. This will help integrate substance use treatment into mainstream health care. <sup>46</sup> This represents the largest expansion of treatment access in a generation and could help guide millions into successful recovery.

We are also seeking to ensure that the treatment people may receive for their opioid use is evidence-based and effective. Medication-assisted treatments for prescription drug and heroin abuse and dependence are effective treatment tools. Several FDA-approved medications, including methadone, buprenorphine, and naltrexone, are proven treatment tools, and are helping thousands of people in long-term recovery. Medication-assisted treatment may also help reduce deaths from opioid drugs; a study found that increased access to medication-assisted treatment in Baltimore, Maryland, was associated with a reduction in heroin deaths.<sup>47</sup> The Administration is

<sup>&</sup>lt;sup>43</sup> States with Naloxone Laws: NM, NY, IL, WA, CA, RI, CT, MA, NC, OR, CO, VA, KY, MD, VT, NJ, OK, and DC

<sup>44</sup> States with Good Samaritan Overdose Laws: NM, WA, NY, CT, IL, CO, RI, FL, MA, CA, NC, NJ, VT, and DE

<sup>&</sup>lt;sup>45</sup> The Network for Public Health Law. "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws." [updated January 2014]. Available: <a href="http://www.networkforphl.org/asset/qz5pvn/network-naloxone-10-4.pdf">http://www.networkforphl.org/asset/qz5pvn/network-naloxone-10-4.pdf</a>

<sup>&</sup>lt;sup>46</sup> Berino, K., Rosa, P., Skopec, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief.* Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at <a href="http://aspe.hhs.gov/health/reports/2013/mental/rb\_mental.cfm">http://aspe.hhs.gov/health/reports/2013/mental/rb\_mental.cfm</a>)

<sup>&</sup>lt;sup>47</sup> Schwartz, RP, Gryczynski, J, O'Grady, KE, Scharfstein, JM, Warren, G, Olsen, Y, Mitchell, SG, and Jaffe, JH. Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009 *Am J Public Health*. 2013;103:917–922.

committed to promoting medication-assisted treatment in treatment systems at the Federal, state, and local levels.

Reducing and preventing opioid diversion, abuse, overdose, and the array of public health and safety consequences requires collaboration with a broad range of stakeholders. The Administration has worked closely with a number of associations and groups, including the National Governors Association, the National Association of Attorneys General, the American Medical Association, the American Dental Association, the American College of Emergency Physicians, the National Safety Council, the National Conference of State Legislatures, the National Association of Boards of Pharmacy, the Association of State and Territorial Health Officials, state medical boards, and countless community groups in states, localities, and tribes across the country. All of these groups and the constituencies they represent have recognized the urgency of this national problem and are helping to bring about the changes we need to prevent more abuse, more arrests, and more deaths.

And there are some signs that these national efforts are working. The number of Americans 12 and older initiating the nonmedical use of prescription opioids in the past year has decreased significantly since 2009, from 2.2 million in that year to 1.9 million in 2012. 48 Additionally, according to the latest Monitoring the Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2013 is its lowest since 2002. 49

State actions are also taking effect. Innovative monitoring, enforcement strategies, and collaboration across Federal, state, and local law enforcement agencies and criminal justice leaders are helping many communities shut down illegal pain clinic operations. Florida is a great example of this success. According to DEA, 90 of the top 100 oxycodone purchasing physicians in the Nation were located in the State in 2010.<sup>50</sup> State leaders like Attorney General Pam Bondi and state legislators worked for passage of laws that stopped doctors operating at these pain clinics from being able to dispense controlled substances. These state actions, combined with a number of significant enforcement actions led by DEA, and state and local agencies, had an effect. By 2011, only 13 of the top 100 resided in Florida, and by the end of 2012, not one Florida doctor appeared on the top 100 list.<sup>51,52</sup> These efforts have also helped dramatically reduce opioid overdose deaths in the state. According to the Florida Attorney General's office, state reporting shows that between 2005 and 2010, overdose deaths involving prescription drugs were increasing in Florida on average by 12 percent each year, with deaths involving oxycodone

<sup>&</sup>lt;sup>48</sup> Substance Abuse and Mental Health Services Administration. Results from the 2012 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2013]. Available: <a href="http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.36A">http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.36A</a>

<sup>&</sup>lt;sup>49</sup> The Monitoring the Future study. *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12.* University of Michigan. [December 2013]. Available: <a href="http://www.monitoringthefuture.org/data/13data/13drfig8.pdf">http://www.monitoringthefuture.org/data/13data/13drfig8.pdf</a>

<sup>&</sup>lt;sup>50</sup> Drug Enforcement Administration. (2013) Automation of Reports and Consolidated Orders System (ARCOS) Data. Retrieved: January 2013.

<sup>&</sup>lt;sup>51</sup>Ibid.

<sup>&</sup>lt;sup>52</sup> Florida Office of the Attorney General. *Statewide Task Force on Prescription Drug Abuse & Newborns: 2014 Progress Report.* State of Florida. [2014]. Available: <a href="http://myfloridalegal.com/webfiles.nsf/WF/JMEE-9GUS2X/\$file/ProgressReportOnline.pdf">http://myfloridalegal.com/webfiles.nsf/WF/JMEE-9GUS2X/\$file/ProgressReportOnline.pdf</a>

increasing an average of 35 percent each year.<sup>53</sup> Since the 2011 implementation of state enforcement, monitoring, and public health efforts to address the prescription opioid epidemic, there has been a 23 percent decline in prescription drug overdose deaths, with a remarkable 52 percent decline in the number of oxycodone overdose deaths alone.<sup>54</sup>

However, while all of these trends are promising, the national data cited earlier concerning increases in emergency department visits, treatment admissions, and overdoses involving opioids bring the task ahead of us into stark focus. Continuing challenges with prescription opioids, and concerns about a reemergence of heroin use, particularly among young adults, underscore the need for leadership at all levels of government.

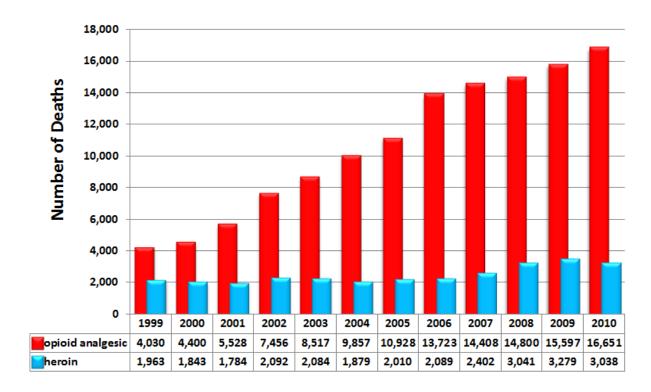
#### **Conclusion**

We continue to work with our Federal, state, local, and tribal partners to continue to reduce and prevent the health and safety consequences of prescription opioid and heroin abuse. Together with all of you, we are committed partners, working to reduce the prevalence of substance use disorders through prevention, increasing access to treatment, and helping individuals recover from the disease of addiction. Thank you for the opportunity to testify here today, and for your ongoing commitment to this issue. I look forward to continuing to work with you on this pressing public health matter.

<sup>53</sup> Ibid.

<sup>&</sup>lt;sup>54</sup> Florida Department of Law Enforcement. (2013). Drugs Identified in Deceased Persons by Florida Medical Examiners: 2012 Report. September 2013. Retrieved from: <a href="http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx">http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx</a>

Figure. Drug Poisoning Death Rates Involving Opioid Analgesics and Heroin in the United States, 1999-2010



Source: CDC WONDER Online Mortality Database, extracted February 11, 2014