



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

The Epidemic of Prescription Drug and Heroin Abuse in the United States

Committee on Oversight and Government Reform
United States House of Representatives

Tuesday, March 22, 2016
10:00 a.m.

Statement of
Michael P. Botticelli
Director of National Drug Control Policy

Chairman Chaffetz, Ranking Member Cummings, and members of the Committee, thank you for this opportunity to address the issues surrounding opioid drugs, including heroin and fentanyl, in the United States, and the Federal response. As you know, this is an important concern for President Obama, who traveled to West Virginia in October to highlight this public health and public safety challenge. During his State of the Union address in January, the President specifically mentioned addressing prescription drug and heroin abuse as a priority – and an opportunity to work with Congress in a bipartisan manner on this issue that transcends political party, income level, gender, and race.

The Office of National Drug Control Policy (ONDCP) was established by Congress in 1988 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, ONDCP establishes policies, priorities, and objectives for the Nation's drug control programs and ensures that adequate resources are provided to implement them. 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 21st 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 is guided by what science, experience, and compassion demonstrate about the true nature of drug use in America. We recognize that any policies to limit the prescribing of opioids need to take into account patients' legitimate need for pain medications.

The considerable public health and safety consequences of nonmedical use, and inappropriate prescribing, of prescription opioids and the use of heroin and illicit fentanyl, underscore the need for action. Since the Administration's inaugural 2010 *Strategy*, we have deployed a comprehensive and evidence-based strategy to address opioid use disorders and opioid induced overdose deaths. The Administration has increased access to treatment for substance use disorders, expanded efforts to prevent overdose, and coordinated a Government-wide response to address the consequences of opioid misuse. We also have continued to pursue actions against criminal organizations trafficking in opioid drugs.

This statement focuses largely on the Administration's interventions to address opioid drug misuse, as well as those of our Federal, state, and local partners that are involved with opioid prescribing or the prevention and treatment of opioid misuse.

Opioid Use Trends and Consequences

Opioids – a category of drugs that includes heroin and prescription pain medicines like oxycodone, oxymorphone, hydrocodone, and fentanyl – are having a considerable impact on public health and safety in communities across the United States. Their misuse has evolved into an epidemic that transcends locality, income level, gender, and race. According to the Centers for Disease Control and Prevention (CDC), approximately 129 Americans on average died from a

drug overdose every day in 2014.¹ Of the 47,055 drug overdose deaths in 2014, heroin was involved in 10,574 drug overdose deaths, while opioid analgesics were involved in 20,808 drug overdose deaths. Among the opioid analgesic category, there were more than 5,544 drug overdose deaths involving synthetic narcotics other than methadone, which includes fentanyl. This number has more than doubled from two years earlier (2,628 in 2012). Deaths from opioids in 2010 were 57 per day, and by 2014 they were 78 per day. Additionally, overdose deaths involving opioids are likely undercounted. Of deaths where drug overdose is cited as the underlying cause of death, approximately one-fifth of the death certificates do not list the drug responsible for the fatal overdose.²

The Administration continues to focus on vulnerable populations affected by opioids, including pregnant women and their newborns. When used chronically by pregnant women, both prescription opioids and heroin can cause withdrawal symptoms in newborns at birth; if these opioids were withdrawn during pregnancy, fetal harm could result. From 2000 to 2009 the number of infants displaying symptoms of drug withdrawal after birth, known as neonatal abstinence syndrome (NAS), increased approximately threefold nationwide.³ Newborns with NAS have more complicated and longer initial hospitalizations than other newborns.⁴ Newly published data show the rate of NAS incidence per 1,000 births increased 40 percent, from 3.4 in 2009 to 5.8 in 2012.⁵

Overdose rates in the United States are much too high; however, the Nation is making some progress in addressing prescription opioid misuse. In 2014, more than 4.3 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month, down from 5.3 million in 2009.⁶ The number of Americans 12 and older initiating the nonmedical use of prescription pain relievers in the past year also has decreased from 2009 to 2014, from 2.2 million to 1.4 million.⁷ Additionally, according to the latest Monitoring the Future survey, the rate in 2015 of past-year use among high school seniors of narcotics other than heroin, including OxyContin or Vicodin, is its lowest since 2002.⁸

While progress has been made in reducing nonmedical use of prescription opioids, it has been counteracted by a rise in availability and use of heroin, although nonmedical prescription opioid use continues to far surpass heroin use. The number of past-year heroin users increased

¹Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2014 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on December 9, 2015.

² Rudd, RA, Aleshire, N, Zibbell, JE, and Gladden, RM. Increases in Drug and Opioid Overdose Deaths – 2000-2014. Centers for Disease Control and Prevention: Mortality and Morbidity Weekly Report. Jan. 1, 2016. 64(50):1378-82. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w

³ Patrick, Stephen W., et al. Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009 (2012). Journal of the American Medical Association. 2012 May 9;307(18):1934-40. doi:10.1001/jama.2012.3951. Epub 2012 Apr 30. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/22546608>.

⁴ Patrick, SW, Schumacher, RE, Benneyworth, BD, Krans, EE, McAllister, JM, & Davis, MM. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. Journal of the American Medical Association, 307(18): 1934-40. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22546608>.

⁵ Patrick, SW, Davis, MM, Lehman, CU, and Cooper, WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012. Journal of Perinatology (2015): 1-6 online publication, April 30, 2015; doi:10.1038/jp.2015.36

⁶ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] *Table 7.3A – Types of Illicit Drug Use in the Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014* Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab7-3a>

⁷ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] *Table 7.44A – Past Year Initiation of Substance Use among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014* Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab7-44a>

⁸ The Monitoring the Future study. *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12*. University of Michigan. [December 2015]. Available: <http://www.monitoringthefuture.org/data/15data/15drfig8.pdf>

from 373,000 in 2007 to 914,000 in 2014,⁹ and approximately 435,000 Americans reported past-month use of heroin in 2014.¹⁰ These figures likely undercount the number of users, as national household surveys do not track all heroin-using populations, such as homeless users.

Heroin use and deaths involving heroin are rising significantly throughout the United States among men and women, in most age groups, and regardless of income level.¹¹ Since 2007, there has been a 340 percent increase in heroin-involved overdose deaths, from 2,402 in 2007 to 10,574 in 2014.¹² Additionally, heroin purity has been rising since 2010, while prices have remained low.¹³ This increase in purity permits heroin use by snorting or smoking, which broadens the drug's appeal to a population that previously was disinclined to inject the drug intravenously.

Similar trends concerning growth in heroin use are reflected in the country's substance use disorder treatment system. Data show a near tripling in the past 10 years of treatment admissions for individuals primarily seeking treatment for non-heroin opiate use disorder, from 52,768 in 2003 to 154,778 in 2013. During the same period, the number of admissions for primary heroin use increased by 15 percent (from 274,459 to 316,797).¹⁴ Although all states have not yet reported specialty treatment admission data for 2013 and 2014, the states that have reported show an increase in the proportion of primary treatment admissions that are for heroin use.¹⁵

The heroin crisis is being compounded by the reemergence of illicit fentanyl, a powerful Schedule II synthetic opioid analgesic more potent than morphine or heroin.¹⁶ Fentanyl is sometimes added to heroin to increase the product's potency, or mixed with adulterants and sold as "synthetic heroin" with or without the buyer's knowledge. Since fentanyl is more potent than heroin, its use increases risks for overdose death, even among individuals who are chronic opioid users.¹⁷

Some states are being hit especially hard by fentanyl-related overdoses. For example, Ohio state medical authorities report there were 514 fentanyl-related overdose deaths in Ohio in 2014 alone – up from 92 in the previous year.¹⁸ And in New Hampshire, the Office of the Chief

⁹ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] *Table 7.2A – Types of Illicit Drug Use in the Past Year among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014*. Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DET-Tabs2014/NSDUH-DET-Tabs2014.htm#tab7-2a>.

¹⁰ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *National Survey on Drug Use and Health, 2013 and 2014: Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014*.

¹¹ Jones et. al., Vital Signs: Demographic and Substance Use Trends Among Heroin Users – United States, 2002-2013, Morbidity and Mortality Weekly Report (July 2015) 64(26); 719-725.

¹² Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2014 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on December 9, 2015.

¹³ Drug Enforcement Administration, El Paso Intelligence Center, National Seizure System, 2008-2014; and Drug Enforcement Administration, Strategic Intelligence Section. 2015 National Heroin Threat Assessment. DEA-DCT-DIR-039-15.

¹⁴ Substance Abuse and Mental Health Services Administration, *Treatment Episode Data Set (TEDS): 2003-2013. National Admissions to Substance Abuse Treatment Services*. [Table 1.1a. Admissions aged 12 and older, by primary substance of abuse: Number, 2003-2013]. U.S. Department of Health and Human Services. [December 2015]. Available:

http://www.samhsa.gov/data/sites/default/files/2003_2013_TEDS_National/2003_2013_Treatment_Episode_Data_Set_National.pdf.

¹⁵ Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment extracted 6/2/2015* <http://www.dasis.samhsa.gov/webt/newmapv1.htm>

¹⁶ Zuurmond WW, Meert TF, and Noorduyn H. (2002). Partial versus full agonists for opioid-mediated analgesia--focus on fentanyl and buprenorphine. *Acta Anaesthesiol Belg*, 53(3):193-201.

¹⁷ U.S. Department of Justice, Drug Enforcement Administration, *DEA Issues Nationwide Alert on Fentanyl as Threat to Health and Public Safety*, 2015. <http://www.dea.gov/divisions/hq/2015/hq031815.shtml>

¹⁸ 2014 Ohio Drug Overdose Preliminary Data: General Findings, Ohio Department of Health, Office of Vital Statistics; Analysis Conducted by Injury Prevention Program. Available at:

Medical Examiner reports that out of 385 drug deaths in 2015 (an additional 45 are pending toxicology results), 351 involved opioids. Of those deaths involving opioids, 253 involved fentanyl and 74 involved heroin.¹⁹

It is important to note the complex relationship that exists between nonmedical prescription opioid use and heroin use. A report from the Substance Abuse and Mental Health Services Administration (SAMHSA) found that 80 percent of new heroin users reported nonmedical prescription opioid use, but less than four percent of nonmedical prescription opioid users transitioned to heroin use.²⁰ However, a review article in the *New England Journal of Medicine* concluded that the transition from nonmedical prescription opioid use to heroin use appears to be part of the progression of substance use disorder in a subgroup of nonmedical users of prescription opioids, primarily among persons with frequent nonmedical use and those with prescription opioid misuse or dependence.²¹ This suggests that a certain segment of the population is at higher risk of developing an opioid use disorder or likely to transition from nonmedical prescription opioid use to heroin use. Moreover, research indicates that some prescription opioid users will initiate heroin use if it is accessible, and especially if it is inexpensive relative to prescription opioids, but they will also use prescription opioids and prescription tranquilizers when heroin is hard to find or of poor quality.²²

This behavior also dramatically increases the risk of exposure to blood-borne infections from injection drug use, including human immunodeficiency virus (HIV) and hepatitis C. Intravenous use of the prescription opioid oxycodone recently spurred an HIV outbreak in southeast Indiana. Since the first patient in the outbreak was identified in January 2015, 190 people have tested positive for HIV.²³

Additionally, an evaluation of recent healthcare claims data found that a majority of non-fatal opioid overdose victims were receiving an opioid from a prescriber at the time of their overdose and that 91 percent of victims received an opioid prescription again from a prescriber following their overdose.²⁴ This includes overdose due to a prescription opioid or heroin. This study also found that the percentage of people who overdosed a second time was double among those with an active prescription compared to those without one, and those on the highest doses of opioids were at significantly greater risk of overdosing.

This interrelationship between prescription opioids and heroin indicates that we must continue to push for mandatory education and training of opioid prescribers to alleviate the circumstances that lead to prescription opioid misuse, heroin use and its consequences.

<http://www.healthy.ohio.gov/~media/HealthyOhio/ASSETS/Files/injury%20prevention/2014%20Ohio%20Preliminary%20Overdose%20Report.pdf>. Accessed 11-24-15.

¹⁹ Personal Communication. January 14, 2016. New Hampshire Office of the Chief Medical Examiner.

²⁰ Muhuri, P.K., Gfroerer, J.C., Davies, MC. SAMHSA CBHSQ Data Review. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. Available at: <http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>.

²¹ Compton, W.M., Jones, C.M., and Baldwin, G.T.. *Relationship Between Nonmedical Prescription Opioid Use and Heroin Use*. *N Engl J Med* 2016; 374:154-163. January 14, 2016. DOI: 10.1056/NEJMra1508490. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMra1508490>

²² Lankenau SE, Teti M, Silva K, Bloom JJ, Harocopos A, Treese M J Patterns of prescription drug misuse among young injection drug users. *Urban Health*. 2012 Dec;89(6):1004-16. doi: 10.1007/s11524-012-9691-9. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3531346/pdf/11524_2012_Article_9691.pdf. Downloaded 2-8-2016.

²³ Morbidity and Mortality Weekly Report (MMWR), Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxycodone — Indiana, 2015, 64 (16): p 443-444, May 1, 2015. Data from State of Indiana <https://secure.in.gov/isdh/26649.htm>

²⁴ Larochelle, Mark R., et al. *Opioid Prescribing After Nonfatal Overdose and Association with Repeated Overdose*. *Annals of Internal Medicine*. doi: 10.7326/M15-0038. Published: December 29, 2015.

Mexico is a primary supplier of heroin to the United States, with Mexican drug traffickers producing heroin in Mexico and smuggling the finished product into the United States.²⁵ Opium poppy cultivation in Mexico has increased substantially in recent years, rising from 11,000 hectares in 2013, with an estimated potential pure heroin production of 26 metric tons, to 17,000 hectares in 2014 with potential production of 42 metric tons of pure heroin.²⁶

Fentanyl used for illicit purposes comes from several sources including pharmaceutical fentanyl diverted from legal medical use, which accounts for a small percentage of the fentanyl in the illicit market, and clandestine fentanyl that is manufactured in Mexico or China and smuggled into the United States.²⁷ A portion of illicit fentanyl that is smuggled into the U.S. market is ordered via the internet and shipped to the buyer using legal shipping companies.²⁸

The Administration's Response

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 nonmedical prescription opioid and heroin use.²⁹ In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*³⁰, which created a national framework for reducing prescription drug diversion and misuse. 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 and unneeded medications from the home; and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

Graduate medical education programs may not provide a comprehensive focus on the identification or treatment of substance use disorders, and since the opioid drug epidemic is connected to overprescribing of prescription opioid drugs in the United States, the first pillar of the *Plan* focuses on ensuring that prescribers are better trained on the dangers of misuse and abuse of prescription drugs. Much progress has been made in expanding available continuing education for prescribers. At least fifteen states (Arkansas,³¹ Connecticut,³² Delaware,³³ Florida,³⁴ Iowa,³⁵ Kentucky,³⁶ Maryland,³⁷ Massachusetts,³⁸ Nevada,³⁹ New Hampshire,⁴⁰ New

²⁵ Drug Enforcement Administration. Strategic Intelligence Section. 2015 National Heroin Threat Assessment. DEA-DCT-DIR-039-15.

²⁶ US Department of State, Bureau of International Narcotics and Law Enforcement Affairs. International Narcotics Control Strategy Report - 2015 [INCSR] (March 2015) for data from 2013 - 2014 and unpublished U.S. Government Estimates.

²⁷ Drug Enforcement Administration. Strategic Intelligence Section. 2015 National Heroin Threat Assessment. DEA-DCT-DIR-039-15.

²⁸ DEA Background Briefing on Fentanyl. Presentation made at ONDCP on March 14, 2016.

²⁹ 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>

³⁰ 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

³¹ A.C.A. § 20-7-704 (2015), available at: <http://www.lexisnexis.com/hottopics/arcodes/Default.asp>.

³² CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

³³ 24 DEL. CODE ANN. § 3.1.1, available at

<http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.pdf>.

³⁴ Florida Administrative Code, Rule 64B15-13.001, available at: <https://www.flrules.org/gateway/ruleno.asp?id=64B15-13.001>

³⁵ IOWA ADMIN. CODE r. 253-11.4 (2011), available at <https://www.legis.iowa.gov/docs/ACO/chapter/07-22-2015.653.11.pdf>.

³⁶ 201 Ky. Admin. Reg. 9:250 (2013), available at <http://www.lrc.ky.gov/kar/201/009/250.htm>.

³⁷ Maryland Department of Health and Mental Hygiene. Maryland Board of Physicians. CME Mandate (2015). available at:

<http://www.mbp.state.md.us/pages/overdose.html>

³⁸ MASS. GEN. LAWS ch. 94C, § 18(e) (2011), available at <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94c/Section18>.

³⁹ NV. SB 459 (2015), available at <https://www.leg.state.nv.us/Session/78th2015/Reports/history.cfm?BillName=SB459>

⁴⁰ SB 576 (2016) [318-B:40], available at: http://gencourt.state.nh.us/bill_status/billText.aspx?id=949&txtFormat=html

Mexico,⁴¹ North Carolina,⁴² Tennessee,⁴³ Utah,⁴⁴ and West Virginia⁴⁵) now require education for prescribers.

At the Federal level, in October 2015 President Obama announced a Presidential Memorandum requiring all Federal agencies, to the extent permitted by law, to provide training on the appropriate and effective prescribing of opioid medications to all employees and certain contractors who are health care professionals and who prescribe controlled substances as part of their Federal responsibilities and duties.⁴⁶ Also, CDC has issued a guideline for the prescribing of opioid pain medication for patients 18 and older in primary care settings, focusing on the use of opioids in treating chronic pain outside of active cancer treatment, palliative care, and end-of-life care.⁴⁷ Additionally, the Administration has developed and made available free and low-cost training options for prescribers and dispensers of opioid medications via several sources, including SAMHSA and the National Institute on Drug Abuse at the National Institutes of Health. Also, the Food and Drug Administration (FDA) now requires manufacturers of extended-release and long-acting opioid pain relievers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy for these drugs. And over 40 prescriber groups organized by the American Medical Association agreed to boost the number of prescribers trained to 500,000.

In order to 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, the second area of the Administration's *Plan* focuses on improving the operation and functionality of state-administered prescription drug monitoring programs (PDMP). PDMPs provide prescribers with information on the types and frequency of prescribed controlled substances. State regulatory and law enforcement agencies may also use this information to identify and prevent unsafe prescribing, doctor shopping, and other methods of diverting controlled substances. Research also shows that PDMPs may have a role in reducing the rates of prescribing for opioid analgesics.⁴⁸

In 2006, only 20 states had PDMPs. Today, the District of Columbia has a law authorizing a PDMP, and 49 states have operational programs.⁴⁹ To drive PDMP utilization, 28 of the 49 states with PDMPs currently require prescribers to query the PDMP in certain circumstances.⁵⁰ Given this growing national trend, the need for integration of PDMP data into the health care setting has never been more critical. Integrating with provider health IT systems (e.g., electronic health records or EHRs) will help drive the success of mandatory use

⁴¹ N.M. ADMIN. CODE § 16-10-14 (2012), available at <http://164.64.110.239/nmac/parts/title16/16.010.0014.htm>.

⁴² HB 97 (2015)(12F.16.(b)), available at: <http://www.ncleg.net/PED/LegislativeTracking/H97Section12F16.pdf>

⁴³ TENN. CODE ANN. § 63-1-402 (2013), available at <http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>.

⁴⁴ UTAH ADMIN. CODE r. 58-37-6.5 (2012), available at http://le.utah.gov/xcode/Title58/Chapter37/58-37-S6.5.html?v=C58-37-S6.5_1800010118000101.

⁴⁵ W. VA. CODE § 30-1-7A (2011), available at <http://www.legis.state.wv.us/wvcode/ChapterEntire.cfm?chap=30&art=1§ion=7A>.

⁴⁶ Presidential Memorandum -- Addressing Prescription Drug Abuse and Heroin Use (October 21, 2015). Available at: <https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin>.

⁴⁷ CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Available at:

<http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.htm>.

⁴⁸ 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. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904893/pdf/phr129000139.pdf>

⁴⁹ National Alliance of Model State Drug Laws. (2014). Status of State Prescription Drug Monitoring Programs (PDMPs). Retrieved from <http://www.namsdl.org/library/16666FCC-65BE-F4BB-A2BBAD44E1BC7031/>.

⁵⁰ See Prescription Drug Monitoring Training and Technical Assistance Center, List of State Criteria for Mandatory Enrollment or Query of PDMP. Available at: http://www.pdmpassist.org/pdf/Mandatory_conditions.pdf.

requirements by reducing the burden placed on providers.⁵¹ For example, in Tennessee, there has been a 38 percent decrease in the number of high-utilizing patients of opioid pain relievers since the mandatory requirement to check the PDMP went into effect on January 1, 2013.⁵²

The Department of Justice's (DOJ) Bureau of Justice Assistance (BJA) is supporting expanded interstate sharing of PDMP data. Currently, due to efforts of BJA, the Department of Health and Human Services (HHS), ONDCP, and stakeholders such as the National Association of Boards of Pharmacies, at least 34 states have some ability to request and share data across state lines.⁵³ HHS has invested resources to make PDMP information readily available in health IT systems like EHRs; this enables physicians and pharmacists to more quickly and easily check a patient's PDMP report before prescribing or dispensing a prescription pain medication. Since the inception of BJA's grant program in Fiscal Year (FY) 2002, grants have been awarded to 49 states and 1 U.S. territory. In recent years, the grant program has been expanded to include tribal participation and to give support to states and localities to expand collaborative efforts between public health and public safety professionals.

In addition, the Consolidated Appropriations Act, 2016 (Pub. L. 114-113) includes a total of \$70 million (an increase of \$50 million) to scale up CDC's *Prescription Drug Overdose Prevention for States* program. This program provides grants to states to help implement tailored, state-based prevention strategies such as maximizing PDMPs, enhancing public insurer mechanisms to prevent overdoses, and evaluating state policies and programs aimed at addressing the opioid epidemic.

Data show that approximately 66 percent of past-year nonmedical users of prescription pain relievers report getting them from a friend or relative the last time they used them, and approximately 84 percent of the time, that friend or relative obtained the pain relievers from one doctor.⁵⁴ Therefore, the third area of the *Plan* focuses on safely removing millions of pounds of expired and unneeded prescription medications from circulation. Since September 2010, the Drug Enforcement Administration (DEA) has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold 10 National Prescription Take-Back Days. Cumulatively, these events allowed DEA to collect and safely dispose of more than 5.5 million pounds of unneeded or expired medications.⁵⁵ In addition, DEA published a Final Rule for the Disposal of Controlled Substances, which took effect October 9, 2014.⁵⁶ This regulation expands the options available to securely and safely dispose of unneeded prescription medications. ONDCP and DEA have engaged with Federal, state, and local agencies, and other stakeholders to educate the public about the new rule and expand local drug disposal programs. State and local agencies throughout the country have implemented disposal programs and prescription medication collection boxes. Additionally,

⁵¹ Haffajee, RL, Jena, AB, and Weiner, SG. Mandatory Use of Prescription Drug Monitoring Programs. *JAMA*. 2015;313(9):891-892. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=2107540>

⁵² Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2015 Report to the 109th Tennessee General Assembly, February 1, 2015. Page 10. Available at https://www.tn.gov/assets/entities/health/attachments/CSMD_AnnualReport_2015.pdf

⁵³ Association of Boards of Pharmacy. Three Additional States Sign Agreement to Participate in NABP PMP Interconnect. (December 24, 2015). Available at: <https://www.nabp.net/news/three-additional-states-sign-agreement-to-participate-in-nabp-pmp-interconnect>

⁵⁴ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm#2.16>

⁵⁵ Drug Enforcement Administration. "DEA's Prescription Drug Take-Back Effort - A Big Success." Department of Justice. [October 1, 2015]. Available: <http://www.dea.gov/divisions/hq/2015/hq100115.shtml>

⁵⁶ Disposal of Controlled Substances, 79 Fed. Reg. 53519 (Sep. 9, 2014). Available: <https://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances>

Alameda County, California, and King County, Washington, have passed product stewardship laws that require prescription drug manufacturers to develop and pay for county prescription drug disposal programs.

The final part of the *Plan* focuses on improving law enforcement capabilities to reduce the diversion of prescription opioids. Federal law enforcement, including our partners at DEA, are working with state and local agencies to reduce pill mills, and prosecute and eradicate unscrupulous registrants or anyone engaging in illegal prescribing practices.

Additionally, the Administration has focused on several key areas to reduce and prevent opioid overdoses from prescription opioids and heroin, including educating the public about overdose risk and interventions; increasing third-party and first responder access to the opioid overdose reversal medication naloxone; working with states to promote Good Samaritan laws; and connecting overdose victims and persons with an opioid use disorder to treatment.

The Administration continues to promote the use of naloxone by those likely to encounter overdose victims, especially first responders and caregivers. Prior to 2012, just six states had any laws that expanded access to naloxone or limited criminal liability for persons that took steps to assist an overdose victim. Today, 46 states and the District of Columbia have enacted statutes that expand access to naloxone or provide “Good Samaritan” protections for possession of a controlled substance if emergency assistance is sought for a victim of an opioid overdose.⁵⁷ In 2014, FDA approved a naloxone auto-injector, Evzio, and in 2015, a nasal formulation of naloxone, Narcan. These two delivery methods should facilitate administration of naloxone by third parties who would be hesitant to administer the drug via injection when they encounter an overdose. Additionally, the National Association of Counties, the National League of Cities, and the United States Conference of Mayors, in conjunction with U.S. Communities Purchasing Alliance and Premier, Inc., have secured discounts on naloxone and medications for treatment through the purchasing program for state and local governments.

The expansion of treatment services for persons with opioid and other substance use disorders has been a key focus of the Administration. The Affordable Care Act and Federal parity laws are extending access to mental health benefits and substance use disorder services for an estimated 62 million Americans.⁵⁸ This represents the largest expansion of treatment access in a generation, and could help guide millions into successful recovery.

The FY 2016 appropriations act provides an increase of approximately \$100 million over the previous year to address the prescription opioid and heroin epidemic. As part of increased investments in the HHS Opioid Initiative, it includes a \$35 million increase for SAMHSA to expand medication-assisted treatment for opioid use disorders in high-risk communities, increase the use of the overdose-reversal drug naloxone, and improve prevention efforts. It also continues to include \$1 million for a Bureau of Prisons pilot program to provide appropriate substance use disorder treatment for eligible inmates. In addition, the appropriation continues to provide \$7 million in funding for the DOJ Community Oriented Policing Services’ Anti-Heroin Task Force grants to help communities form innovative partnerships that address the opioid epidemic, and a \$38 million increase for SAMHSA’s Substance Abuse Block Grant, which distributes funding to

⁵⁷ Only IA, KS, MT and WY do not have such laws.

⁵⁸ 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 http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm)

all 50 states to prevent and treat substance use disorders. The act also allows certain high-risk communities to use Federal funds for services associated with syringe service programs and increases funding for general drug prevention, anti-trafficking and treatment programs. Building on this commitment, in his FY 2017 Budget President Obama proposed \$1 billion in new mandatory funding over two years to expand the availability of opioid use disorder services, target areas of highest need, and allow states to implement evidence-based strategies that best meet local needs, such as medication-assisted treatment and expansion of the availability of substance abuse treatment providers (through enhanced loan repayment for healthcare providers that offer medication-assisted treatment). Such efforts will help individuals seek treatment, successfully complete treatment, and sustain recovery. These resources will support states in expanding access to medication assisted treatment, include the placement of substance use disorder providers in areas of the country that need them most, and invest in evaluation

Leadership and innovation is taking place at the local level as well. For example, in Dayton, Ohio, Police Chief Richard Biehl implemented a community-based initiative, “Conversation for Change,” where Dayton police officers collaborate with addiction and recovery professionals, mediators, and family members to provide education, resources, and assistance to people who are struggling with an opioid use disorder. In Gloucester, Massachusetts, Police Chief Leonard Campanello launched an “Angel” initiative, where anyone with a substance use disorder can enter a police station and ask for help. He or she will then be assigned to a social services volunteer for placement into a treatment program. Police departments across the country are now implementing similar programs.

To address the emerging rise in heroin and illicit fentanyl use and availability, the *National Drug Control Strategy* focuses on identifying, disrupting and dismantling criminal organizations trafficking in opioid drugs; working with the international community to reduce cultivation of poppy; identifying labs creating dangerous synthetic opioids like fentanyl and its analogues; and enhancing efforts along the Nation’s borders to decrease the flow of these drugs into our country.

Expanding on these efforts, in October 2015, ONDCP created the National Heroin Coordination Group, a multi-disciplinary team of subject matter experts to lead Federal efforts to reduce the availability of heroin and fentanyl in the United States. This hub of interagency partners is leveraging their home agency authorities and resources to disrupt the heroin and illicit fentanyl supply chain coming into the United States and is establishing mechanisms for interagency collaboration, and information-sharing focused on heroin and fentanyl.

This past December, the Administration released the report of the Congressionally-mandated interagency Heroin Task Force, which was co-chaired by ONDCP and DOJ. The report includes recommendations of Federal agency experts in law enforcement, medicine, public health and education, providing emerging evidence-based public health and public safety models for Federal agency engagement in activities that promote solutions to reduce demand or decrease spread of disease.

In addition, this past summer, ONDCP committed \$2.5 million in High Intensity Drug Trafficking Areas (HIDTA) Program funds to develop a strategy to respond to the Nation’s heroin epidemic. This unprecedented project by ONDCP combines prevention, education, intelligence, and enforcement resources to address the heroin threat across 15 states and the

District of Columbia. The effort will be carried out through a unique partnership of five regional HIDTAs – Appalachia, New England, New York/New Jersey, Philadelphia/Camden, and Washington/Baltimore. The HIDTA Program is a locally-based program that responds to the drug trafficking issues facing specific areas of the country. Law enforcement agencies at all levels of government share information and implement coordinated enforcement activities; enhance intelligence sharing among Federal, state, local, and tribal law enforcement agencies; provide reliable intelligence to law enforcement agencies to develop effective enforcement strategies and operations; and support coordinated law enforcement strategies to maximize available resources and reduce the supply of illegal drugs in designated areas. The HIDTA Heroin Response Strategy will foster a collaborative network of public health-public safety partnerships, sharing best practices, innovative pilots, and identifying new opportunities to leverage resources.

Our Federal law enforcement agencies are aggressively addressing the heroin and fentanyl issue here and abroad through a variety of means. The DEA and other U.S. Federal law enforcement agencies have co-located Special Agents with international partners such as Mexico, in South America, and in other parts of the world to assist in criminal investigations targeting drug trafficking organizations, and to help develop their capacity to conduct the full range of narcotics interdiction activities within their countries to target both heroin and fentanyl. Our Federal law enforcement agencies, in conjunction with the Department of State, are working with the countries that supply fentanyl and the precursor chemicals used in its manufacture to stem the flow of these dangerous chemicals to the Western Hemisphere. And along our southwest border, U.S. Customs and Border Protection continues to detect and interdict heroin and illicit fentanyl entering the United States, and to apprehend those attempting to bring these dangerous drugs into our communities. DEA, Federal Bureau of Investigation, Homeland Security Investigations, and Department of Justice’s Organized Crime Drug Enforcement Task Forces (OCDETF) target, disrupt, and dismantle international drug trafficking organizations that manufacture, transport, and distribute heroin and fentanyl destined for and distributed across the United States. In addition, OCDETF’s National Heroin Initiative, starting in December 2014, vets and funds innovative regional approaches that improve information sharing and data collection and support multi-agency, multi-jurisdictional enforcement actions.

This month, I traveled to Mexico City with Ambassador Brownfield, Assistant Secretary of State for International Narcotics and Law Enforcement Affairs, and Chargé d’Affaires Duncan, our acting Chief of Mission in Mexico. The primary purpose of the trip was to gain agreement with the Government of Mexico on tangible, near-term actions to address the heroin and fentanyl entering the United States from Mexico. We agreed to work closely together to address the issue. Bilateral coordination is beneficial for both our countries, and we look forward to working closely with our Mexican partners to reduce the flow of heroin and fentanyl into the United States.

Conclusion

The Administration continues to work with our Federal, state, local, and tribal partners to reduce and prevent the health and safety consequences of nonmedical prescription opioid, heroin, and fentanyl use. Together with all of you, we are committed partners, working to reduce the prevalence of substance use disorders and the number of overdose deaths through prevention, increasing access to treatment, helping individuals recover from the disease of addiction, and

working with law enforcement to reduce diversion of prescription opioids and the supply of heroin and fentanyl. Thank you for the opportunity to testify here today, and for your ongoing commitment to these issues. I look forward to continuing to work with you on these pressing public health matters.

Michael Botticelli

Director of National Drug Control Policy

Michael Botticelli was sworn in as Director of National Drug Control Policy on February 11, 2015. Previously, he served both as Acting Director and Deputy Director of National Drug Control Policy. He joined the Office of National Drug Control Policy (ONDCP) as Deputy Director in November 2012.

Mr. Botticelli has more than two decades of experience supporting Americans who have been affected by substance use disorders. Prior to joining ONDCP, Mr. Botticelli served as Director of the Bureau of Substance Abuse Services at the Massachusetts Department of Public Health, where he successfully expanded innovative and nationally recognized prevention, intervention, treatment, and recovery services for the Commonwealth of Massachusetts. He also forged strong partnerships with local, state, and Federal law enforcement agencies; state and local health and human service agencies; and stakeholder groups to guide and implement evidence-based programs. These programs include the establishment of a treatment system for adolescents, early intervention and treatment programs in primary healthcare settings, jail diversion programs, re-entry services for those leaving state and county correctional facilities, and overdose prevention programs.

Mr. Botticelli has served in a variety of leadership roles for the National Association of State Alcohol and Drug Abuse Directors. He was also a member of the Advisory Committee for the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention and the National Action Alliance for Suicide Prevention. He has also co-authored many peer-reviewed articles that have significantly contributed to the substance abuse field .

In 2008, Mr. Botticelli was the first recipient of the annual Ramstad/Kennedy National Award for Outstanding Leadership in Promoting Addiction Recovery. In 2012, he was awarded the Service Award from the National Association of State Alcohol and Drug Abuse Directors.

Born in Upstate New York, Mr. Botticelli holds a Bachelor of Arts degree from Siena College and a Master of Education degree from St. Lawrence University. He is also in long-term recovery from a substance use disorder, celebrating more than 25 years of sobriety.