



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
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**“Examining Legislative Proposals to Combat
our Nation's Drug Abuse Crisis”**

Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

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2322 Rayburn House Office Building

Statement of
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Chairman Pitts, Ranking Member Green, and members of the Subcommittee, thank you for this opportunity to address the issues surrounding opioid drugs, including heroin, and new psychoactive substances in the United States and the Federal response. As you know, this is an important priority for the President, who used his weekly address last week to highlight this public health challenge.

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 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.

The considerable public health and safety consequences of nonmedical prescription opioid and heroin use 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 overdose deaths due to heroin use and prescription opioid misuse. The Administration has increased access to treatment for substance use disorders, expanded efforts to prevent overdose, and has coordinated a Government-wide response to the consequences of nonmedical prescription drug use. We also have continued to pursue actions against criminal organizations trafficking in opioid drugs.

The Administration is also working to increase public awareness of the dangers of new psychoactive synthetic drugs and reduce their availability in our communities through regulation, enforcement actions, bilateral and multilateral engagements, and community-based prevention efforts. These chemically-produced substances are modeled after illegal or controlled substances but with slightly modified molecular structures, in an attempt to circumvent existing laws and evade law enforcement efforts. They are often referred to as new psychoactive substances or designer drugs. These new psychoactive substances can cause serious and immediate harm to users and have a high potential for abuse.

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, including professional associations that are involved with opioid prescribing or the prevention and treatment of opioid misuse. It will also discuss Federal efforts to reduce use and availability of new psychoactive substances.

Trends and Consequences in Opioid Use

Opioids – a category of drugs that includes heroin and prescription pain medicines like oxycodone, oxymorphone and hydrocodone – are 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 120 Americans on average died from a drug overdose every day in 2013. Of the nearly 44,000 drug overdose deaths in 2013, opioid pain medicines were involved in more than 16,200, while heroin was involved in over 8,200. Overall, drug overdose deaths now outnumber deaths from firearms (more than 33,600) or motor vehicle crashes (more than 32,700)¹ in the United States.² Moreover, overdose deaths related to opioid pain medicines and heroin are likely undercounted. Of deaths where drug overdose is cited as the underlying cause of death, approximately one-quarter of the death certificates do not list the drug responsible for the fatal overdose.³

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, and in 2013 there were 4.5 million such reporting users, in contrast to rates as high as 5.3 million in 2009.⁴ The number of Americans 12 and older initiating the nonmedical use of prescription pain relievers in the past year has decreased since 2009, from 2.2 million in that year to 1.4 million in 2014.⁵ Additionally, according to the latest Monitoring the Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2014 is its lowest since 2002.⁶ Despite these developments, nonmedical prescription pain reliever use is more common than use of any category of illicit drug in the United States except for marijuana.

Approximately 435,000 Americans reported past month use of heroin in 2014.⁷ Heroin use remains relatively low in the United States when compared to other drugs; however, the increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 914,000 in 2014 – and the high rate of overdose deaths are troubling.⁸ These figures likely undercount the number of users, as national household surveys do not track all heroin-using populations, such as homeless users.

¹ Fatality Analysis Reporting System (FARS) Encyclopedia Available at: <http://www-fars.nhtsa.dot.gov/Main/index.aspx>

² Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2013 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on January 30, 2015.

³ Warner, Margaret, Leonard Paulozzi, Kurt Nolte, Gregory G. Davis, Lewis Nelson; State Variation in Certifying Manner of Death and Drugs Involved in Drug Intoxication Deaths, AFP, June 2013. Available at: <http://s3.documentcloud.org/documents/1151267/heroin-project-2014-study-on-overdose-deaths.pdf>

⁴ 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] Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DefTabs2014/NSDUH-DefTabs2014.htm#tab7-3a>

⁵ 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] Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DefTabs2014/NSDUH-DefTabs2014.htm#tab4-5b>

⁶ The Monitoring the Future study. *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12*. University of Michigan. [December 2014]. Available: <http://www.monitoringthefuture.org/data/14data/14drfig11.pdf>

⁷ 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*.

⁸ 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*.

Similar trends concerning growth in heroin use are reflected in the country's substance use disorder treatment system. Data show a more than tripling in the past 10 years of treatment admissions for individuals primarily seeking treatment for substance use disorder, from 53,000 in 2003 to 170,000 in 2012. Heroin treatment admissions remained flat over the same time period, yet accounted for 285,451 primary admissions in 2012.⁹ Although all states have not yet reported specialty treatment admission data for 2013 and 2014, the states that have reported show a rise in the number of people seeking treatment for heroin use.¹⁰

The nonmedical use of prescription opioids and heroin translates into serious health consequences. Beyond the many lives taken by fatal overdoses involving these drugs, prescription opioids place a significant burden on our healthcare system. In 2011 alone, the latest year for which these data are available, 1.2 million emergency department (ED) visits involved the nonmedical use of prescription drugs.¹¹ Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class, accounting for approximately 488,000 visits. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just seven years earlier in 2004 (173,000). Heroin was involved in nearly 258,000 visits in 2011.

The public health consequences of nonmedical use of opioids and heroin use are often similar. Some proportion of individuals who escalate use will develop a chronic opioid use disorder. Additionally, some people who escalate use will begin injecting. This behavior dramatically increases their risk of exposure to blood-borne infections, including human immunodeficiency virus (HIV) and hepatitis C. Intravenous use of the prescription opioid oxymorphone recently spurred an HIV outbreak in southeast Indiana. Since the first patient in the outbreak was identified in January 2015, 181 people have tested positive for HIV.¹²

When used chronically by pregnant women, both prescription opioids and heroin can cause withdrawal symptoms in newborns upon birth, and if these opioids are withdrawn during pregnancy, fetal harm may result. The Administration continues to focus on vulnerable populations affected by opioids, including pregnant women and their newborns. 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.¹³ Newborns with NAS have more complicated and longer initial hospitalizations than other newborns.¹⁴ Newly published data shows the problem increased 40 percent from 2009 to 2012.¹⁵

⁹ Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment Admissions by Primary Substance of Abuse, United States* [2002 through 2012 – Table 1.1a]. U.S. Department of Health and Human Services. [July 2014]. Available:

http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_Treatment_Episode_Data_Set_National_Tables.htm

¹⁰ 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>

¹¹ 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#5.2>

¹² Morbidity and Mortality Weekly Report (MMWR), Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone — Indiana, 2015, 64 (16): p 443-444, May 1, 2015. Data from State of Indiana <https://secure.in.gov/isdh/26649.htm>

¹³ Epstein, R.A., Bobo, W.V., Martin, P.R., Morrow, J.A., Wang, W., Chandrasekhar, R., & Cooper, W.O. (2013). Increasing pregnancy-related use of prescribed opioid analgesics. *Annals of Epidemiology*, 23(8): 498-503. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/23889859>.

¹⁴ Patrick, S., Schumacher, R.E., Benneyworth, B.D., Krans, E.E., McAllister, J.M., & Davis, M.M. (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>.

¹⁵ Patrick, SW, Davis, MM, Lehman, CU, 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

Trends and Consequences in Use of New Psychoactive Substances (NPS)

Because of the sheer number of new psychoactive substances (more than 500 have been identified by the United Nations) and the constant molecular modifications, determining current use rates is challenging. To get a better understanding of use trends, in 2012 ONDCP funded a pilot study, the Community Drug Early Warning System (CDEWS). More than 1,000 subjects from the criminal justice population (arrestees, probationers, parolees, drug court participants) who had been previously tested for a limited panel of drugs, were retested for more than 30 illicit drugs, controlled medications, and 12 synthetic cannabinoids. Results indicated that synthetic cannabinoids were as likely to be found in persons who had initially tested positive for marijuana, cocaine, heroin, methamphetamine, or PCP as in persons who had initially tested negative for these drugs.¹⁶ The CDEWS study was replicated in 2014. The 2014 study found that the types of detected synthetic cannabinoids had changed, and varied significantly from one community to the next.¹⁷

The CDEWS study results attest to the value of expanded testing of specimens already collected by local criminal justice system drug testing programs, and the difficulties inherent in keeping up with the constantly evolving nature of NPS. These results suggest that many adults and juveniles in local criminal justice system drug testing programs turn to synthetic cannabinoids to avoid detection. It is also likely that programs using similar protocols to test urine specimens in other contexts, such as schools, hospitals and treatment programs, are missing synthetic cannabinoid use in their populations, leading to lost opportunities for diagnosis and intervention. Planning for a third study is currently underway. The new study will expand the number of testing sites and will include testing from EDs.

The health risks of using NPS can be significant – including serious injury and even death. The contents and effects of synthetic cannabinoids and synthetic cathinones (stimulant drugs with effects similar to amphetamines) are unpredictable due to a constantly changing variety of chemical compounds used in manufacturing processes that are devoid of quality controls and regulatory oversight. These substances can also contain toxic impurities, byproducts or adulterants, and the potency can vary significantly from batch to batch, even within the same product.

The use of these substances can cause vomiting, anxiety, agitation, irritability, seizures, hallucinations, tachycardia, elevated blood pressure, and loss of consciousness.¹⁸ They have also caused significant organ damage as well as overdose deaths.¹⁹

¹⁶ Wish, E.D., Artigiani, E.E. and Billing, A. S. (2013). Community Drug Early Warning System: The CDEWS Pilot Project. Office of National Drug Control Policy. Washington, DC: Executive Office of the President.

¹⁷ Wish, E.D., Artigiani, E.E. and Billing, A. S. (2015). Community Drug Early Warning System: The CDEWS-2 Replication Study. Office of National Drug Control Policy. Washington, DC: Executive Office of the President.

¹⁸ Drug Enforcement Administration, *Updated Results from DEA's Largest-Ever Global Synthetic Drug Takedown Yesterday*. June 2013. Available: <http://www.justice.gov/dea/divisions/hq/2013/hq062613.shtml>

¹⁹ *Id.*

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.²⁰ In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*,²¹ 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.

Since graduate medical education programs may not necessarily provide a comprehensive focus on 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 educated on the dangers of misuse and abuse of prescription drugs. Much progress has been made in expanding available continuing education for prescribers. At least ten states (Connecticut,²² Delaware,²³ Iowa,²⁴ Kentucky,²⁵ Massachusetts,²⁶ Nevada,²⁷ New Mexico,²⁸ Tennessee,²⁹ Utah,³⁰ and West Virginia³¹) have passed legislation mandating education for prescribers.

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 the Substance Abuse and Mental Health Service Administration (SAMHSA) and NIH's National Institute on Drug Abuse (NIDA). 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 (REMS) for these drugs.

Building on these initiatives, the Administration supports mandatory education for prescribers, as called for by the 2011 *Prescription Drug Abuse Prevention Plan* and re-emphasized in the 2014 *National Drug Control Strategy*.

In order to better detect the misuse of prescription drugs by individuals who may be getting prescriptions from more than one doctor and direct these individuals into treatment for a

²⁰ 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>

²¹ 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

²² CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

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

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

²⁴ IOWA ADMIN. CODE r. 253-11.4 (2011), available at <https://www.legis.iowa.gov/docs/ACO/chapter/07-22-2015.653.11.pdf>.

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

²⁶ MASS. GEN. LAWS ch. 94C, § 18(e) (2011), available at <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94c/Section18>.

²⁷ NV. SB 459 (2015), available at <https://www.leg.state.nv.us/Session/78th2015/Reports/history.cfm?BillName=SB459>

²⁸ N.M. ADMIN. CODE § 16-10-14 (2012), available at <http://164.64.110.239/nmac/parts/title16/16.010.0014.htm>.

²⁹ TENN. CODE ANN. § 63-1-402 (2013), available at <http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>.

³⁰ 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.

³¹ W. VA. CODE § 30-1-7A (2011), available at <http://www.legis.state.wv.us/wvcode/ChapterEntire.cfm?chap=30&art=1§ion=7A>.

substance use disorder, the second area of the Administration's *Plan* focuses on improving the operations and functionality of state-administered prescription drug monitoring programs (PDMP). PDMPs 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, 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.³²

In 2006, only 20 states had PDMPs. Today, the District of Columbia has a law authorizing a PDMP, and 49 states have operational programs.³³ Kentucky³⁴, New Jersey,³⁵ New Mexico³⁶, New York³⁷, Oklahoma³⁸, and Tennessee³⁹ all require their prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances. In Tennessee, where the requirement to check the PDMP went into effect in 2013, there was a drop in the number of high-utilizing patients of opioid pain relievers compared to 2011.⁴⁰

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 National Association of Boards of Pharmacies, at least thirty-two states have some ability to share data. HHS has invested significant resources to make PDMPs more user-friendly, so healthcare providers can access them quickly and easily as part of their clinical workflow. Notably, SAMHSA and HHS's Office of the National Coordinator for Health Information Technology have supported PDMP and health IT integration efforts to enable healthcare providers to effortlessly check the PDMP from their health IT system (e.g., electronic health record or pharmacy system) without having to sign into multiple systems and to have actionable PDMP data that is readily available when making prescribing choices.

In FY 2014, BJA made 15 site-based awards for states to enhance a PDMP program or implement a strategy that addresses non-medical prescription drug use and diversion within their communities. Since inception of the grant program in 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 gave support to states and localities to expand collaborative efforts between public health and public safety professionals.

³² 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>

³³ 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/>.

³⁴ Kentucky 201 KAR 9:260. 2012. Available at <http://www.lrc.ky.gov/kar/201/009/260.htm>

³⁵ P.L. 2015, c.74 (N.J. 2015), available at http://www.njleg.state.nj.us/2014/Bills/AL15/74_.PDF

³⁶ New Mexico Register. 16.12.9.9. November 15, 2012. Available at http://www.nmcpr.state.nm.us/new-mexico-register/prev_issues/prev_issuesxxiii/xxiii21/16.12.9amend

³⁷ New York 3343-A. 2012. Available at <http://law.justia.com/codes/new-york/2012/pbh/article-33/title-4/3343-a>

³⁸ Oklahoma 3251. 2010. Available at http://www.oklegislature.gov/cf_pdf/2009-10%20FLR/hflr/HB3251%20hflr.pdf

³⁹ Tennessee 2253. 53-10-310. 2012. Available at <http://www.tn.gov/sos/acts/107/pub/pc0880.pdf>

⁴⁰ Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2014 Report to the 108th Tennessee General Assembly, February 1, 2014. Page 5. Available at http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf Linked to 9-04-2014

In addition, the President's FY 2016 Budget request includes a total of \$65 million (an increase of \$45 million) to expand the CDC's *Prescription Drug Overdose Prevention for States* program to all 50 states. 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.

Research shows 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.⁴¹ Therefore, the third area of the *Plan* focuses on safely removing millions of pounds of expired and unneeded controlled substances 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, most recently on September 26. At the first 9 events, DEA collected and safely disposed of more than 4.8 million pounds of unneeded or expired medications.⁴² In addition, DEA published a Final Rule for the Disposal of Controlled Substances, which took effect October 9, 2014.⁴³ These new regulations expand 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 increase awareness and educate the public about the new rule.

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 across the country to reduce pill mills, prosecute those responsible for illegal prescribing practices, and make it harder for unscrupulous registrants to remain in business. In May 2015, the Administration held its inaugural meeting of the Congressionally-mandated interagency Heroin Task Force, which is co-chaired by ONDCP and DOJ. The Task Force includes Federal agency experts from law enforcement, medicine, public health and education. At the end of 2015, the Task Force will produce a report focused on evidence-based public health and public safety models to reduce the health and safety consequences of opioid use and the supply and demand of opioids.

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 naloxone, an emergency opioid overdose reversal medication; working with states to promote Good Samaritan laws; and connecting overdose victims and persons with an opioid use disorder to treatment.

⁴¹ 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>

⁴² Drug Enforcement Administration. "DEA and Partners Collect 309 Tons of Pills on Ninth Prescription Drug Take-Back Day." Department of Justice. [November 5, 2014]. Available: <http://www.dea.gov/divisions/hq/2014/hq110514.shtml>

⁴³ 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>

The Administration is providing local communities with resources and tools to deal with the opioid crises. In August 2013, SAMHSA released the *Opioid Overdose Prevention Toolkit*.⁴⁴ This toolkit helps communities and local governments develop policies and practices to prevent opioid-related overdoses and deaths and contains resources for first responders, treatment providers, and persons recovering from an opioid overdose. In October 2014, Attorney General Eric Holder announced the launch of DOJ's *Naloxone Toolkit* to support law enforcement agencies in establishing a naloxone program.⁴⁵ In August 2014, the Administration announced that the Department of Defense (DoD) was making a new commitment to ensure that opiate overdose reversal kits and training are available to every responder on military bases or other areas under DoD's control.⁴⁶ Additionally, NIDA continues to address these issues by supporting the development of a nasal formulation of naloxone to enhance access and proper use of this medication and by funding research to develop non-opioid based pain medications.

The Administration continues to promote the use of naloxone by those likely to encounter overdose victims, especially first responders and caregivers. The Administration's FY 2016 Budget requests \$12 million in grants to be issued by SAMHSA to states to purchase naloxone, equip first responders in high-risk communities, and provide education and the necessary materials to assemble overdose kits, as well as cover expenses incurred from dissemination efforts. Prior to 2012, just six states had any laws which expanded access to naloxone or limited criminal liability for persons that took steps to assist an overdose victim. As of May 2015, 36 states⁴⁷ and the District of Columbia have passed laws that offer criminal and/or civil liability protections to lay persons or first responders who administer naloxone. Twenty-five states⁴⁸ have passed laws that offer criminal and/or civil liability protections for prescribing or distributing naloxone. Thirty-four states⁴⁹ have passed laws allowing naloxone distribution to third-parties or first responders via direct prescription or standing order. And 25 states⁵⁰ and the District of Columbia have passed laws which prevent arrest, charge, or prosecution for possession of a controlled substance or paraphernalia if a person seeks emergency assistance for someone who is experiencing an opioid induced overdose.

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.⁵¹ This represents the largest expansion of treatment access in a generation, and could help guide millions into successful recovery.

⁴⁴ Substance Abuse and Mental Health Services Administration. Opioid Overdose Prevention Toolkit. Department of Health and Human Services. [August 2013]. Available: <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>

⁴⁵ Department of Justice, Office of Public Affairs. "Remarks by Attorney General Holder at the International Association of Chiefs of Police Annual Conference." [October 27, 2014]. Available at: <http://www.justice.gov/opa/speech/remarks-attorney-general-holder-international-association-chiefs-police-annual-conference>

⁴⁶ <http://www.va.gov/opa/docs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf>

⁴⁷ NH, CA, CO, ID, OR, UT, WA, AZ, NM, OK, GA, KY, LA, MS, NC, TN, VA, WV, CT, DE, MA, MD, ME, NJ, NY, PA, RI, VT, IL, IN, MI, MN, MO, OH, SD, and WI.

⁴⁸ NH, CA, CO, ID, UT, AZ, NM, GA, MS, NC, TN, VA, WV, CT, MA, NJ, NY, PA, VT, IN, MI, MN, OH, SD, and WI.

⁴⁹ NH, CA, CO, ID, OR, UT, WA, AZ, OK, GA, KY, LA, MS, NC, TN, VA, WV, CT, DE, MA, MD, ME, NJ, NY, PA, VT, IL, IN, MI, MN, MO, OH, SD, and WI.

⁵⁰ AK, CA, CO, UT, WA, NM, FL, GA, KY, LA, NC, WV, CT, DE, MA, MD, NJ, NY, PA, RI, VT, IL, IN, MN, and WI.

⁵¹ 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)

Additionally, the President's FY 2016 Budget request includes \$11 billion for treatment, a nearly seven percent increase over the FY 2015 funding level. In July, HHS announced an additional \$11 million in grants for states to expand the use of medication-assisted treatment (MAT), and an additional \$100 million to improve and expand substance use disorder services at community health centers, with a focus on MAT. The President's FY 2016 Budget includes \$25 million, an increase of \$13 million, for SAMHSA for new state grant funding to expand or enhance MAT and other clinically appropriate services for persons with opioid use disorders. This program will fund technical assistance and treatment services for communities with the greatest need. The President's FY 2016 Budget also includes \$5 million in new funding for HHS's Agency for Healthcare Research and Quality to conduct a robust evaluation of MAT in primary care settings, as well as grants to develop and test new methods, processes, and tools to implement treatment programs.

The Administration is working with regional and international partners to address the dynamic problems being caused by the manufacture and use of new psychoactive substances. Federal agencies are working closely with China and other countries to reduce the production of these substances and have been encouraged by recent discussions with the Chinese government. They are also working with regional and international organizations, such as the Inter-American Drug Abuse Control Commission, the United Nations Office on Drugs and Crime, and the International Narcotic Control Board, to monitor and reduce the supply of these substances. Additionally, Federal agencies are working with: corporate entities to monitor and track the manufacture of these substances and their precursors; Congress to improve regulatory tools and schedule newly-identified NPS; law enforcement to support their investigations domestically and abroad; the science and research community to better understand the pharmacology of these substances and to develop antagonists to counteract their toxic effects; and prevention partners to inform communities about the dangers of NPS.

Improvements in Treatment

The low rate of cases referred to treatment by medical personnel in the face of such a dangerous epidemic suggests that, among other factors, healthcare providers may not always perceive the signs of nonmedical prescription opioid use and heroin use among their patients. The extent of the opioid use crisis requires health care providers to step up their efforts by screening their patients for substance use and incipient substance use disorders. Additionally, registering for the state PDMP and checking it prior to prescribing controlled substances is important for preventing abuse and diversion.

Medication-assisted treatment should be the recognized standard of care for opioid use disorders. Research shows that individuals with opioid use disorders, including heroin users, can sustain recovery if treated with evidence-based methods. Studies have shown that individuals with opioid use disorders have better outcomes with MAT.⁵² Additionally, MAT reduces

⁵² Weiss RD, Potter JS, Griffin ML, McHugh RK, Haller D, Jacobs P, Gardin J 2nd, Fischer D, Rosen KD. Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial Published in final edited form as: Arch Gen Psychiatry. 2011 December; 68(12): 1238–1246.

overdose mortalities⁵³ and individuals' risks for blood-borne infections like HIV and hepatitis.⁵⁴ Yet too many people are not connected to this care. In 2013, only 9 percent (1,282) of treatment facilities provided treatment with methadone and/or buprenorphine.⁵⁵ There is a significant need for medical professionals who can provide MAT in primary care and integrated health care settings. To help address this need, Secretary Burwell recently announced that HHS will engage in rulemaking related to the prescribing of buprenorphine to expand access to opioid dependence treatment. It is important that any expansion of such prescribing be accompanied by a range of therapy services and recovery supports.

The Administration's interest in expanding the use of MAT for justice-involved individuals while retaining judicial discretion is reflected in the FY15 drug court solicitations issued by the SAMHSA and BJA that encourage drug court grantees to pay for FDA-approved medications for the treatment of substance use disorders when the client is unable to cover this expense. The new grant solicitation language also prevents drug court grantees from denying a client access to their program based on the client's use of FDA-approved medications.

Medicines for opioid use disorder containing the drug buprenorphine are important advancements that have only been available since Congress passed the Drug Addiction Treatment Act of 2000 (DATA 2000). They expand the reach of treatment beyond the limited number of heavily regulated Opioid Treatment Programs that generally dispense methadone. Also, because those physicians who have taken the requisite training and have obtained a waiver as part of DEA registration to prescribe controlled substances are allowed to administer the medicines to treat patients in an office-based setting, it allows patient care to be integrated with other medical care. Injectable naltrexone offers similar advantages to patients who have been abstinent from opioids for 7 to 10 days. The special training that is required under DATA 2000 for prescribing buprenorphine is not required for injectable naltrexone, since this formulation is not associated with the development of tolerance or dependence.

We need to increase the number of healthcare providers who can prescribe buprenorphine when appropriate, combined with behavioral therapies, and the numbers of healthcare providers who can offer injectable naltrexone. Of the more than 877,000 physicians who can write controlled substance prescriptions, only about 29,194 have received a waiver as authorized in DATA 2000 to prescribe office-based buprenorphine. Of that number, only 9,011 had completed the requirements to serve up to 100 patients; the remainder can serve up to 30. Although they are augmented by an additional 1,377 opioid treatment programs, far too few providers elect to use any form of medication-assisted treatment for their patients.⁵⁶ Injectable naltrexone was only approved for use with opioid use disorders in 2010, and little is known about its adoption outside specialty substance use treatment programs, but use in primary care and other settings is

⁵³ Schwartz RP, Gryczynski J, O'Grady KE, Sharfstein JM, Warren G, Olsen Y, Mitchell SG, Jaffe JH., Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009, *Am J Public Health*. 2013

⁵⁴ Woody GE, Bruce D, Korthuis PT, Chhatre S, Poole S, Hillhouse M, Jacobs P, Sorensen J, Saxon AJ, Metzger D, Ling W., HIV risk reduction with buprenorphine-naloxone or methadone: findings from a randomized trial., *J Acquir. Immune Defic Syndr*. 2014

⁵⁵ SAMHSA. *National Survey of Substance Abuse Treatment Services (N-SSATS): 2013 -- Data on Substance Abuse Treatment Facilities* (September 2014). Retrieved from http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf.

⁵⁶ Personal communication (email) from Robert Hill (DEA).

possible. To date, only about three percent of U.S. treatment programs offer this medicine for opioid use disorder.⁵⁷

It is also important to continue our efforts to educate the public about the risks and consequences of nonmedical prescription opioid and heroin use as well as the availability of options for treatment for opioid use disorders, to help stem the impact of the opioid crisis and save lives.

Addressing NPS

The Administration's efforts to reduce use and availability of NPS include data collection, research, prevention, treatment; and domestic and foreign law enforcement actions and international cooperation to reduce the manufacture and distribution of these substances.

The development of NPS for the U.S. market may be the result of attempts to circumvent Federal, state, and local laws that comprehensively ban recognized synthetic compounds. Authorities under the Controlled Substances Act (CSA) and the Controlled Substances Analogue Enforcement Act (CSAEA) of 1986, as well as the authority given to the Attorney General by Congress to temporarily place a substance onto Schedule I of the CSA, helped reduce availability of specific new psychoactive substances. More recently, the Food and Drug Administration Safety and Innovation Act of 2012, which included the Synthetic Drug Abuse Prevention Act, provided a mechanism for scheduling 5 classes of synthetic cannabinoids and placed 26 specific synthetic cannabinoids, synthetic cathinones, and other synthetic substances into Schedule I of the CSA. It also permitted DEA to administratively schedule substances for 36 months, thereby doubling the 18 months previously allowable under its temporary scheduling authority.

At present, under these authorities the DEA has temporarily scheduled 32 synthetic designer drug substances upon the finding they posed an imminent hazard to public safety. Eight of these substances were subsequently controlled on a permanent basis. Of those eight, seven were permanently controlled by Congress. As demonstrated, Congress can have an immediate effect on the protection of public health and safety.

Although the Federal Government and all 50 states have developed regulatory responses to place these substances in Schedule I, there are a number of challenges related to the current domestic scheduling framework. For example, the statutory definition of a controlled substance analogue requires prosecutors to utilize experts in chemistry and pharmacology to prove their cases. There is also no precedent or carry-over from case-to-case or district-to-district, which means prosecutors must start each case anew, an unnecessarily time consuming and resource intensive process.

Placing more NPS in Schedule I and making more efficient the process by which substances may be scheduled permanently under the CSAEA would significantly improve law enforcement's capability to reduce the sale and availability of these substances in the United States. We are happy to work with Congress on ways to address these issues legislatively.

⁵⁷ Aletraris L1, Bond Edmond M1, Roman PM1., Adoption of injectable naltrexone in U.S. substance use disorder treatment programs. *J Stud Alcohol Drugs*. 2015 Jan;76(1):143-51.

Since NPSs are such a dynamic and evolving global challenge, an examination of more significant reforms to both international and domestic scheduling frameworks would also provide additional mechanisms to help address the threat of these substances.

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 NPS use. 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 these issues. I look forward to continuing to work with you on these pressing public health matters.