



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

**“The Public Health Implications of Heroin  
and the Federal Response to the Opioid  
Overdose Epidemic”**

Tuesday July 28, 2015  
10:00 a.m.  
2141 Rayburn House Office Building

Statement of  
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Chairman Sensenbrenner, Ranking Member Jackson Lee, and members of the Subcommittee, thank you for this opportunity to address the public health issues surrounding heroin in the United States and the Federal response.

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 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 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 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 *National Drug Control 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. This statement focuses largely on the Administration's public health policy interventions to address opioid drug abuse, 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. The statement of the Drug Enforcement Administration (DEA) for this hearing will discuss supply and law enforcement approaches.

## **Trends and Consequences of 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 relievers were involved in over 16,200, while heroin was involved in over 8,200. Overall, drug overdose deaths now outnumber deaths from gunshot wounds (over 33,600) or motor vehicle crashes (over

32,700)<sup>1</sup> in the United States.<sup>2</sup> Moreover, overdose deaths related to opioid pain relievers and heroin are undercounted as around one quarter of death certificates do not list the drug responsible for the fatal drug overdose,<sup>3</sup> and until recently standards did not exist for death investigation reporting, and adoption of these standard is not universally practiced.<sup>4</sup>

The diversion and nonmedical use of prescription opioid medications has been of serious concern at the national, state, and local levels for over a decade. Increases in admissions to treatment for substance use disorders,<sup>5</sup> drug-related emergency department visits,<sup>6</sup> and, most disturbingly, overdose deaths<sup>7</sup> attributable to nonmedical prescription drug use place enormous burdens upon communities across the country. Heroin, in contrast, until very recently has been used at much lower rates, possibly because historically its use was generally via injection, which often was necessitated by its low purity. As heroin purity increases, heroin can be smoked or snorted.<sup>8</sup> Research shows that price reductions (resulting from greater availability) are closely related to overdose hospitalization rates; every \$100 decrease in the price of heroin per pure gram results in a 2.9 percent increase in the number of overdose hospitalizations.<sup>9</sup>

In 2013, over 4.5 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.<sup>10</sup> This makes nonmedical prescription pain reliever use more common than use of any category of illicit drug in the United States except for marijuana. Approximately 289,000 Americans reported past month use of heroin in 2013.<sup>11</sup> 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 681,000 in 2013 – is troubling.<sup>12</sup> These figures likely undercount the number of users, as national household surveys do not track all heroin-using populations such as homeless users. At least one community with a high level of chronic drug users among its homeless

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

<sup>2</sup> 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.

<sup>3</sup> See <http://s3.documentcloud.org/documents/1151267/heroin-project-2014-study-on-overdose-deaths.pdf>

<sup>4</sup> Goldberger BA1, Maxwell JC, Campbell A, Wilford BB. Uniform standards and case definitions for classifying opioid-related deaths: recommendations by a SAMHSA consensus panel. *J Addict Dis.* 2013;32(3):231-43. doi: 10.1080/10550887.2013.824334.

<sup>5</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>6</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#5.2>

<sup>7</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2013 on CDC WONDER Online Database, released 2015.

<sup>8</sup> Stöver HJ1, Schäffer D. SMOKE IT! Promoting a change of opiate consumption pattern - from injecting to inhaling. *Harm Reduct J.* 2014 Jun 27;11:18. doi: 10.1186/1477-7517-11-18. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4094754/>

<sup>9</sup> Unick G1, Rosenblum D, Mars S, Ciccarone D. Addiction. The relationship between US heroin market dynamics and heroin-related overdose, 1992-2008. *2014 Nov;109(11):1889-98.* doi: 10.1111/add.12664. Epub 2014 Aug 4.

<sup>10</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables.* Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabsIto45-2013.htm#tab7.3b>

<sup>11</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables.* Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabsIto45-2013.htm#tab7.3A>

<sup>12</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables.* Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabsIto45-2013.htm#tab7.2A>

population, Baltimore, revises their heroin count by 10 percent to adjust for heroin use among its homeless population.<sup>13</sup>

Nonetheless, the trend for increases in heroin users shown in the National Survey on Drug Use and Health (NSDUH), a household-based survey from the Substance Abuse and Mental Health Services Administration (SAMHSA), comports with other indicators, including recent reporting from the National Institute on Drug Abuse's (NIDA) Community Epidemiology Work Group, which found that a number of U.S. cities, including Atlanta, Baltimore, Boston, Chicago, Cincinnati, Denver, Miami, Minneapolis, San Diego, Seattle, and St. Louis, indicated increases in heroin use. In addition, heroin remained at relatively stable but high levels in Detroit, New York City, and Philadelphia.<sup>14</sup> DEA also reports an over 300 percent increase of heroin seizures at the Southwest border from 2008 to 2013.<sup>15</sup>

A recent report from CDC and FDA using NSDUH public-use data<sup>16</sup> shows a significant increase in heroin use from 2002 to 2004 and from 2011 to 2013. Rates remained highest among males, persons aged 18 to 25 years, persons with annual household incomes below \$20,000, persons living in urban areas, and persons with no health insurance or with Medicaid; however, rates increased significantly across almost all study groups. Moreover, the greatest increases in heroin use occurred in demographic groups that historically have had lower rates of heroin use, doubling among women and more than doubling among non-Hispanic whites. The rates of individuals who developed abuse or dependence on heroin, a near doubling during the decade-long study period, with a 35.7 percent increase during 2008–2010 alone, emphasize the addictive nature of this drug. This increase parallels the sharp increase in heroin-related overdose deaths reported since 2010.

This report also indicates that individuals who use heroin also use other drugs. People with past year abuse of or dependence on alcohol, marijuana, cocaine, or opioid pain relievers were at increased risk for past year heroin abuse or dependence. In 2013, 59 percent of the 8,257 heroin-related overdose deaths in the United States involved at least one other drug.<sup>17</sup> Data presented in this report indicate the relationship between heroin and opioid pain relievers, as well as the relationship between heroin and cocaine, are particularly strong. In fact, past year abuse or dependence on opioid pain relievers was the strongest risk factor for past year heroin abuse or dependence. These results, coupled with prior research on heroin use trajectories, underscore that heroin use has its roots in, and often exists alongside, other forms of substance misuse.

Research illustrates that heroin use today is one of the later steps in most personal drug use trajectories. An analysis of NSDUH data shows that 21,000 people nationally began using

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<sup>13</sup> Baltimore Mayor's Heroin Treatment & Prevention Task Force Report <http://health.baltimorecity.gov/sites/default/files/Mayor%20Heroin%20Treatment%20Prevention%20Task%20Force%20Final%20Report%20July%202013%202015.pdf>

<sup>14</sup> National Institute on Drug Abuse. Highlights and Summaries from January 2014 Reports. Available: <http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/highlights-summaries-january-2014-reports>

<sup>15</sup> National Seizure System, El Paso Intelligence Center, extracted January 25, 2014.

<sup>16</sup> Jones CM, Logan J, Gladden RM, Bohm MK. Vital Signs: Demographic and Substance Use Trends Among Heroin Users - United States, 2002-2013. MMWR Morb Mortal Wkly Rep. 2015 Jul 10;64(26):719-25 Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s\\_cid=mm6426a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s_cid=mm6426a3_w)

<sup>17</sup> CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2014. Available at <http://wonder.cdc.gov>.

heroin when 12 to 17 years old, 66,000 people began using when 18 to 25 years old, and 82,000 began when 26 years and older.<sup>18</sup> Past-year heroin users were most likely to be in the 26 and older demographic. A second study of treatment seekers found the average age of treatment seekers to be around 23, and 75 percent of these began by using prescription opioids first.<sup>19</sup> While the increases in overdose deaths among young people is disturbing, and pediatricians and doctors caring for people under the age of 25 need to be engaged on this issue, practitioners who treat adults normally past the typical age for developing substance use disorders need to monitor their patients for possible heroin use.

The nonmedical use of opioids translates into serious health consequences. In 2013 alone, approximately 1.9 million Americans met the diagnostic criteria for abuse of or dependence on prescription pain relievers, with heroin accounting for approximately 517,000 people with past-year abuse or dependence; both figures represent significant increases from just a decade earlier.<sup>20</sup> For the duration of this statement, the terms “opioid use disorder” and “heroin use disorder” will be used to describe people who meet the criteria for abuse and dependence, since the terminology in the Diagnostic and Statistical Manual, Fifth Edition (DSM 5), the U.S. standard for classifying mental health disorders, no longer makes a distinction between abuse and dependence.

Although only about 15 percent of people who have not used heroin in the past year believe it would be fairly or very easy to obtain, approximately 81 percent of people who have used it in the past year hold that belief.<sup>21</sup> Most Americans of all ages perceive great risk in using heroin once or twice a week.<sup>22</sup> Disturbingly, approximately 20 percent of people 12 to 17 years old do not believe using heroin once or twice weekly is harmful (compared to only 5 percent of people 26 or older).<sup>23</sup>

Beyond the many lives taken by fatal overdoses involving these medications, prescription opioids are associated with significant burden on our healthcare system. In 2011 alone, the last year for which these data are available, 1.2 million emergency department (ED) visits involved the nonmedical use of prescription drugs.<sup>24</sup> 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 7 years

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<sup>18</sup> R.N. Lipari and A. Hughes. The NSDUH Report: Trends in Heroin Use in the United States: 2002 to 2013. (2015). Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Rockville, MD. [http://www.samhsa.gov/data/sites/default/files/report\\_1943/ShortReport-1943.html](http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html) Available at linked to on 7-19-2015.

<sup>19</sup> Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*. 2014 Jul 1;71(7):821-6. doi: 10.1001/jamapsychiatry.2014.366. PMID: 24871348 available at <http://archpsyc.jamanetwork.com/article.aspx?articleid=1874575>

<sup>20</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DefTabsPDFWHTML2013/Web/HTML/NSDUH-DefTabsSect7peTabs1to45-2013.htm#tab7.40A>

<sup>21</sup> R.N. Lipari and A. Hughes. The NSDUH Report: Trends in Heroin Use in the United States: 2002 to 2013. (2015). Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Rockville, MD. [http://www.samhsa.gov/data/sites/default/files/report\\_1943/ShortReport-1943.html](http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html) Available at linked to on 7-19-2015.

<sup>22</sup> R.N. Lipari and A. Hughes. The NSDUH Report: Trends in Heroin Use in the United States: 2002 to 2013. (2015). Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Rockville, MD. [http://www.samhsa.gov/data/sites/default/files/report\\_1943/ShortReport-1943.html](http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html) Available at linked to on 7-19-2015.

<sup>23</sup> *Ibid.*

<sup>24</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#5.2>

earlier in 2004 (173,000). Among specific opioid drugs in 2011, oxycodone accounted for the largest share (31%) of ED visits; there were 100,000 more visits involving oxycodone in 2011 than in 2004, an increase of 263 percent. Heroin was involved in nearly 258,000 visits in 2011. Increases in hospitalizations for prescription opioid overdose within a community actually predicts subsequent year heroin overdose,<sup>25</sup> indicating that not only do people tend to migrate to heroin if it is available, but also entire communities may shift usage habits.

Similar trends concerning growth in heroin use are reflected in the country's specialty substance use disorder treatment system. Data show a more than double increase in the past ten years of treatment admissions for individuals primarily seeking treatment for prescription opioid use disorder, from 53,000 in 2003 to 127,000 in 2011. Heroin treatment admissions remained flat over the same time period, yet accounted for 285,451 admissions in 2012.<sup>26</sup> Although all states have not yet reported specialty treatment admission data for 2013 and 2014, the trend in those states that have is that many more people are seeking treatment for heroin use than in the past.<sup>27</sup> In contrast, the percentage of people seeking treatment for prescription opioid use disorder has declined. Not every state, however, has experienced this decline. In some states with particularly intransigent prescription opioid misuse problems (for example, Tennessee), treatment admissions remain high. In some states with historically high heroin treatment admissions (for example, New York), prescription opioid treatment admissions began an upward climb only in the late 1990s and at much lower levels.

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 a serious prescription opioid use disorder, will substitute heroin for prescription opioids. Heroin is cheaper than prescription opioids. A SAMHSA report found that four out of five recent heroin initiates had previously used prescription pain relievers nonmedically. However, only a very small proportion (3.6%) of those who recently had started using prescription drugs nonmedically initiated heroin use in the following five-year period.<sup>28</sup> Preventing the initiation of nonmedical opioid use nevertheless can help reduce the pool of people who may resort to heroin initiation later on because a large proportion of heroin users begin with abusing opioid pain relievers, even if this is a small subset of overall nonmedical opioid users.

We also know that substance use is often progressive, with some users rapidly escalating their use frequency, dosing, potency of drug and using through routes other than oral administration (e.g., sniffing, smoking or injecting) to achieve greater euphoria. Because the body rapidly develops tolerance to most effects of opioids and because withdrawal from opioids

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<sup>25</sup> Unick GJ, Rosenblum D, Mars S, Ciccarone D. Intertwined epidemics: national demographic trends in hospitalizations for heroin- and opioid-related overdoses, 1993-2009. *PLoS One*. 2013;8(2):e54496. doi: 10.1371/journal.pone.0054496. Epub 2013 Feb 6. PMID: 23405084.

<sup>26</sup> 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](http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_Treatment_Episode_Data_Set_National_Tables.htm)

<sup>27</sup> Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment extracted 6/2/2015 (Source: CAL TIC Presentation Primary Drug Treatment Admissions)*.

<sup>28</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: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

exerts the opposite effect (e.g., severe pain and gastrointestinal distress) regardless of whether the drug used is a relatively weak opioid like codeine or a stronger one like heroin, a vicious cycle can develop, where a user must keep using to avoid the severe flu-like and depressive symptoms associated with withdrawal. We know from survey data that as an individual's nonmedical use of prescription opioids becomes more frequent or chronic, that person is more inclined to purchase the drugs from dealers/prescriptions from multiple doctors, rather than simply getting them for free from a friend or relative.<sup>29</sup> Qualitative data indicates as tolerance, dependence, or craving increases, users tend to obtain more opioid sources and at times will select lower cost alternatives such as heroin as a way to meet and afford escalating opioid needs.<sup>30,31,32</sup> Research also suggests that the same dealers who deal in illicit pills often also supply heroin.<sup>33</sup>

## The Administration's Response

Since 2009, the Obama Administration has deployed a comprehensive and evidence-based strategy to address: (1) excessive and dangerous opioid prescribing for pain and its consequences; and (2) illegal importation and sales of heroin. These efforts have expanded as surveillance has revealed an uptick in deaths related to the laboratory-created synthetic drug fentanyl and its analogs.

The following discussion identifies the efforts in each of these areas as experts believe they are all important for addressing heroin and the public health of people and communities heroin impacts.

## Efforts to Stem the Prescription Opioid Crisis

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.<sup>34</sup>

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<sup>29</sup> Unpublished estimates from Substance Abuse and Mental Health Services Administration, *National Survey on Drug Use and Health*. 2009-2012, March 2014.

<sup>30</sup> Lankenau SE, Teti M, Silva K, Jackson Bloom J, Harocopos A, Treese M. Initiation into prescription opioid misuse amongst young injection drug users. *Int J Drug Policy*. 2012 Jan;23(1):37-44. doi: 10.1016/j.drugpo.2011.05.014. Epub 2011 Jun 20. PMID: 21689917 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3196821/>

<sup>31</sup> Lankenau SE1, 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/>

<sup>32</sup> Sarah G. Mars, Philippe Bourgois, George Karandinos, Fernando Montero, Daniel Ciccarone. "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting *Int J Drug Policy*. Author manuscript; available in PMC 2015 March 1. Published in final edited form as: *Int J Drug Policy*. 2014 March; 25(2): 257-266. Published online 2013 October 19. doi: 10.1016/j.drugpo.2013.10.004 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3961517/pdf/nihms533727.pdf>

<sup>33</sup> Sarah G. Mars, Philippe Bourgois, George Karandinos, Fernando Montero, Daniel Ciccarone. "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting *Int J Drug Policy*. Author manuscript; available in PMC 2015 March 1. Published in final edited form as: *Int J Drug Policy*. 2014 March; 25(2): 257-266. Published online 2013 October 19. doi: 10.1016/j.drugpo.2013.10.004 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3961517/pdf/nihms533727.pdf>

<sup>34</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>

Nonmedical use of prescription drugs still represents the bulk of illicit opioid use in America, and pharmaceutical opioids are responsible for the majority of opioid-related deaths. Our response to this public health emergency focuses on preventing the diversion and nonmedical use of prescription drugs, decreasing the number of Americans dying from opioid overdose every day, and expanding access to effective treatment, health care, and services for people with opioid use disorders.

In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*,<sup>35</sup> 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.

The Administration has made considerable progress in all four areas of the *Plan*. To start, much progress has been made in expanding available continuing education for prescribers. Managing patients' pain is a crucial area of clinical practice, but research indicates that health care practitioners receive little training on pain management or, safe opioid prescribing.<sup>36,37</sup> Ten states (Connecticut,<sup>38</sup> Delaware,<sup>39</sup> Iowa,<sup>40</sup> Kentucky,<sup>41</sup> Massachusetts,<sup>42</sup> New Mexico,<sup>43</sup> Ohio,<sup>44</sup> Tennessee,<sup>45</sup> Utah,<sup>46</sup> and West Virginia<sup>47</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 Department of Health and Human Services (HHS) has implemented 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 (HRSA), and personnel attending to biomedical research trial participants at the Clinical Center of the National Institutes of Health (NIH). Similar efforts have been implemented by the Bureau of Prisons and the Department of Defense (DoD). The Department of Veterans Affairs (VA) is making training available to clinicians although it is not currently required.

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<sup>35</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](http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf)

<sup>36</sup> Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

<sup>37</sup> U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: <http://www.gao.gov/assets/590/587301.pdf>

<sup>38</sup> CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

<sup>39</sup> 24 DEL. CODE ANN. § 3.1.1, available at

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

<sup>40</sup> IOWA ADMIN. CODE r. 253-11.4 (2011), available at <https://www.legis.iowa.gov/docs/ACO/chapter/07-22-2015.653.11.pdf>.

<sup>41</sup> 201 Ky. Admin. Reg. 9:250 (2013), available at <http://www.lrc.ky.gov/kar/201/009/250.htm>.

<sup>42</sup> MASS. GEN. LAWS ch. 94C, § 18(e) (2011), available at <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94c/Section18>.

<sup>43</sup> N.M. ADMIN. CODE § 16-10-14 (2012), available at <http://164.64.110.239/nmac/parts/title16/16.010.0014.htm>.

<sup>44</sup> OHIO REV. CODE ANN. § 4723.482

<sup>45</sup> TENN. CODE ANN. § 63-1-402 (2013), available at <http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>.

<sup>46</sup> 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](http://le.utah.gov/xcode/Title58/Chapter37/58-37-S6.5.html?v=C58-37-S6.5_1800010118000101).

<sup>47</sup> W. VA. CODE § 30-1-7A (2011), available at <http://www.legis.state.wv.us/wvcode/ChapterEntire.cfm?chap=30&art=1&section=7A>.

The Administration developed and has made available free and low-cost training options available for prescribers and dispensers of opioid medications via several sources, including SAMHSA and NIDA. 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 (REMS) for these drugs.

These efforts alone, however, cannot address the dearth of critical and necessary opioid prescriber training as it is an optional program. From 2010 to 2013, overdose deaths involving prescription opioids have decreased – but only by 2 percent.<sup>48</sup> We must do more to ensure all prescribers have the tools they need to prevent nonmedical prescription drug use. The Administration continues to support policies that mandate a continuing education requirement for prescribers, as outlined in the *Plan*, potentially linked to their registration to prescribe with the DEA.

In March, HHS announced a comprehensive, evidence-based initiative aimed at reducing opioid dependence and overdose. Among the three priority areas of the initiative are efforts to train and educate health professionals on safe opioid prescribing, including the development of prescribing guidelines for chronic pain by the CDC.

FDA has also taken a number of steps to help safeguard access to opioid analgesics while reducing risks of non-medical use and overdose. In April 2013, FDA approved updated labeling for reformulated OxyContin that describes the medication’s abuse-deterrent properties. These properties are expected to make the drug more difficult to inject or abuse nasally.<sup>49</sup> In September 2013, ONDCP joined the FDA to announce significant new measures to enhance the safe and appropriate use of ER/LA opioid analgesics.<sup>50</sup> FDA required class-wide labeling changes for these medications, including modifications to the products’ indication for pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate, 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. And in December 2013, FDA announced its recommendation that DEA reschedule hydrocodone combination products from Schedule III to Schedule II of the Controlled Substances Act; in August 2014, DEA issued a Final Rule implementing this recommendation, which became effective in October 2014.<sup>51</sup>

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<sup>48</sup> 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.

<sup>49</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: <http://www.gpo.gov/fdsys/pkg/FR-2013-04-18/pdf/2013-09092.pdf>

<sup>50</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: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>

<sup>51</sup> 21 CFR Part 1308 Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II. DEA. Final Rule. Available at <http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf>

The Administration is also educating the general public about the dangers of opioid use. ONDCP's Drug-Free Communities (DFC) Support Program currently funds 680 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 area of the Administration's *Plan* focuses on improving the operations and functionality of state-administered Prescription Drug Monitoring Programs (PDMPs). 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, and other methods of 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. For example, states where PDMPs are administered by a state health department showed especially positive results.<sup>52</sup>

In 2006, only twenty states had PDMPs. Today, the District of Columbia has a law authorizing a PDMP, and forty-nine states have operational programs.<sup>53</sup> The state of Missouri stands alone in not authorizing a PDMP. Kentucky<sup>54</sup>, New Jersey,<sup>55</sup> New Mexico<sup>56</sup>, New York<sup>57</sup>, Oklahoma<sup>58</sup>, and Tennessee<sup>59</sup> all require their prescribers to use their state's PDMP prior to prescribing 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 utilizers of opioid pain relievers from the fourth quarter of 2011 to the fourth quarter of 2013.<sup>60</sup>

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. Health IT integration will enable authorized healthcare providers to access PDMP data quickly and easily at the point of care. CDC is evaluating the SAMHSA grantees to identify best practices and determine the impact of the integration efforts.

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<sup>52</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. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904893/pdf/phr129000139.pdf>

<sup>53</sup> 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/>.

<sup>54</sup> Kentucky 201 KAR 9:260. 2012. Available at <http://www.lrc.ky.gov/kar/201/009/260.htm>

<sup>55</sup> P.L. 2015, c.74 (N.J. 2015), available at [http://www.njleg.state.nj.us/2014/Bills/AL15/74\\_.PDF](http://www.njleg.state.nj.us/2014/Bills/AL15/74_.PDF)

<sup>56</sup> 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](http://www.nmcpr.state.nm.us/new-mexico-register/prev_issues/prev_issuesxxiii/xxiii21/16.12.9amend)

<sup>57</sup> New York 3343-A. 2012. Available at <http://law.justia.com/codes/new-york/2012/pbh/article-33/title-4/3343-a>

<sup>58</sup> Oklahoma 3251. 2010. Available at [http://www.oklegislature.gov/cf\\_pdf/2009-10%20FLR/hflr/HB3251%20hflr.pdf](http://www.oklegislature.gov/cf_pdf/2009-10%20FLR/hflr/HB3251%20hflr.pdf)

<sup>59</sup> Tennessee 2253. 53-10-310. 2012. Available at <http://www.tn.gov/sos/acts/107/pub/pc0880.pdf>

<sup>60</sup> 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](http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf) Linked to 9-04-2014

The Department of Justice's (DOJ) Bureau of Justice Assistance (BJA) is also supporting expanded interstate sharing of PDMP data, which is especially important. Currently, at least thirty states have some ability to share data. PDMP administrators are working to better integrate these systems into other health IT programs. In FY 2014, BJA made fifteen site-based awards for states to implement or enhance a PDMP program or strategy to address non-medical prescription drug use, misuse and diversion within their communities. Since inception of the grant program in FY 2002, grants have been awarded to forty-nine states and one U.S. territory. In recent years, the grant program included tribal participation, and gave support to states and localities to expand collaborative efforts between public health and public safety professionals. For example, according to Maryland's Department of Health and Mental Hygiene,<sup>61</sup> the state used its grant funding to form local overdose fatality review (OFR) teams comprised of multi-agency, multi-disciplinary stakeholders who review information on individuals who died from drug and alcohol related overdose. The OFR teams meet monthly to review medical examiner and other data such as substance use disorder treatment records. They identify overdose risk factors, missed opportunities for prevention/intervention, and make policy recommendations. These teams work on both prescription opioid and heroin overdose deaths. Currently the PDMP cannot disclose its information directly to the fatality review teams but there is a proposal to change this law so the review team can request data directly. This is an excellent example of how the PDMP expansion can be useful in understanding and addressing what for some can be the second stage of opioid use disorders, heroin use.

In February 2013, the 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>62</sup> Since then, the VA has developed and installed software to enable VA pharmacies to transmit their data to PDMPs. As of April 2015, 67 VA facilities were sharing information with PDMPs in their respective states. VA providers have also begun registering and checking the state databases. However, the VA does not currently require prescribers to check the PDMP prior to prescribing.

While PDMP reporting is not required by IHS facilities, many tribes have declared public health emergencies and have elected to participate with the PDMP reporting initiative. Currently, IHS is sharing its pharmacy data with PDMPs in 18 states,<sup>63</sup> and IHS is in the process of negotiating data-sharing with more states.<sup>64</sup> As these systems continue to mature, PDMPs can enable health care providers and law enforcement agencies to prevent the non-medical use and diversion of prescription opioids.

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<sup>61</sup> Maryland Department of Health & Mental Hygiene. (2014). Overdose Fatality Review in Maryland. Harold Rogers PDMP National Meeting. Retrieved from [http://www.pdmpassist.org/pdf/PPTs/National2014/2-04\\_Baier.pdf](http://www.pdmpassist.org/pdf/PPTs/National2014/2-04_Baier.pdf). Accessed on 4-22-2015.

<sup>62</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>63</sup> Indian Health Service. (2014). Prescription Drug Monitoring Programs: Indian Health Service Update. Harold Rogers PDMP Annual Meeting. Retrieved from [http://www.pdmpassist.org/pdf/PPTs/National2014/2-14\\_Tuttle.pdf](http://www.pdmpassist.org/pdf/PPTs/National2014/2-14_Tuttle.pdf).

<sup>64</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>.

The third pillar of our *Plan* focuses on safely removing millions of pounds of expired and unneeded medications from circulation. Research shows that approximately 53 percent of past year nonmedical users of prescription pain relievers report getting them for free from a friend or relative the last time they used them, and for approximately 84 percent of these, that friend or relative obtained the pain relievers from one doctor. An additional 15 percent bought or took them from a friend or relative.<sup>65</sup> Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner.

From September 2010 through September 2014, the DEA partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold nine National Take-Back Days. Through these events, DEA collected and safely disposed of more than 4.8 million pounds of unneeded or expired medications.<sup>66</sup> DEA has scheduled its next National Take-Back Day for September 26, 2015.

In addition, DEA published a Final Rule for the Disposal of Controlled Substances, which took effect October 9, 2014.<sup>67</sup> These new regulations expand the options available to securely and safely dispose of unneeded prescription medications. They authorize certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. Collectors may operate a collection receptacle at their registered location, and anyone can distribute pre-printed/pre-addressed mail-back packages that go to mail-back program operators. Retail pharmacies and hospitals/clinics with on-site pharmacies and law enforcement to include Veterans Health Administration (VHA) and DoD police officers may operate their own disposal collection receptacles. In addition, long-term care facilities that offer disposal collection receptacles must partner with either a retail pharmacy or a hospital/clinic with an on-site pharmacy to operate collection receptacles in their facilities. Any person or entity may partner with law enforcement to conduct take-back events. Additionally, VHA is offering drug take back options to Veterans.<sup>68</sup>

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. In November 2014, ONDCP, DEA and the Alameda County California Superintendent's office hosted a webinar for community agencies to explain the new rule and discuss how local ordinances might define or fund disposal programs. Over 800 people registered for the program, and 436 viewed it live.<sup>69</sup> ONDCP and DEA will engage with Federal partners as well as with state and local entities to develop and implement a plan to develop disposal programs nationwide.

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<sup>65</sup> 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>

<sup>66</sup> Drug Enforcement Administration. "DEA and Partners Collect 309 Tons of Polls on Ninth Prescription Drug Take-Back Day." Department of Justice. [November 5, 2014]. Available: <http://www.dea.gov/divisions/hq/2014/hq110514.shtml>

<sup>67</sup> 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>

<sup>68</sup> Veterans Health Administration. "Joint Fact Sheet: DoD and VA Take New Steps to Support the Mental Health Needs of Service Members and Veterans." [August 26, 2014]. Available at: <http://www.va.gov/opa/docs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf>. Accessed on 12-01-2014.

<sup>69</sup> Office of National Drug Control Policy. "Website Blog Watch: Webinar DEA Final Rule on Disposal of Controlled Substances." Available at: <https://www.whitehouse.gov/blog/2014/11/17/watch-webinar-dea-s-final-rule-disposal-control-substances>. Accessed on 4-15-2015

The *Plan's* fourth pillar focuses on improving law enforcement capabilities to reduce the diversion of prescription opioids. Federal law enforcement, to include our partners at DEA, is working with state and local agencies across the country to reduce pill mills, prosecute those responsible for improper or illegal prescribing practices, and make it harder for unscrupulous registrants including pharmacies to remain in business. An unintended consequence of law enforcement efforts against pharmaceutical suppliers can occur when major enforcement actions happen, patients receiving medicines for legitimate conditions from those providers or pharmacies may be abandoned. Without being tapered off their opioid regimens they will experience withdrawal which can be profoundly disabling and is only alleviated by an opioid.<sup>70</sup> It is not known how many patients have resorted to heroin in these circumstances, but without coordination between law enforcement to ensure enforcement activities do not interrupt legitimate patient care, we are concerned about unintended consequences.

All of these efforts under the *Prescription Drug Abuse Prevention Plan* are intended to reduce the diversion, non-medical use, and health and safety consequences of prescription opioids. 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 use, as well as the larger opioid overdose problem facing this country.

### **Efforts to Stem the Heroin Crisis:**

Heroin was added to Schedule I of the controlled substances list in 1914, and efforts to address heroin use and trafficking have been reflected annually in our *National Drug Control Strategy*. Opium poppy, from which heroin is derived, is not grown in the United States, and manufacturing is based outside of the country, primarily in Mexico for U.S. sales. Drug seizure data suggest a great deal of heroin has been flowing into the United States in recent years, primarily from Mexico but also from South America.

Pharmaceutical opioids activate the same receptors in the brain as heroin, a reason why users can switch from one to the other and avoid withdrawal. Approximately 18 billion opioid pills were dispensed in 2012,<sup>71</sup> enough to give every American 18 years or older 75 pills.<sup>72</sup> Plentiful access to opioid drugs via medical prescribing and easy access to diverted opioids for nonmedical use help feed our opioid crisis. In fact, as discussed above, the majority of new users come to heroin with experience as nonmedical prescription drug users.<sup>73</sup> Prior to today's opioid epidemic, heroin largely had been confined to urban centers with larger heroin using populations. Many communities and states that have never had a heroin use problem are now dealing with this epidemic, as Vermont Governor Shumlin discussed in his 2014 *State of the State* address.

In 2012 ONDCP held an interagency meeting focused on heroin, as many agencies were concerned that prescription opioid users might migrate to heroin. The interagency prescription

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<sup>70</sup> American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington VA, American Psychiatric Association. 2013. Page 541.

<sup>71</sup> IMS Health, National Prescription Audit, 2012

<sup>72</sup> Estimate presented by Thomas Frieden during oral presentation at Preventing Prescription Drug Overdose: New Challenges, New Opportunities. National RX Drug Abuse Summit, Operation Unite. Atlanta GA. April 8, 2014.

<sup>73</sup> 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.

drug working group formed a research group to examine the nature of the transition from prescription opioids to heroin, and CDC and SAMHSA have increased their focus on this issue, developing additional analyses to help track and publicize the issue.<sup>74,75</sup>

In May 2015, the Administration held its inaugural meeting of the Congressionally-mandated interagency Heroin Task Force. This Task Force is co-chaired by ONDCP Deputy Director for State, Local and Tribal Affairs Mary Lou Leary and U.S. Attorney for the Western District of Pennsylvania David Hickton and includes Federal agency experts from law enforcement, medicine, public health and education. The Task Force report will highlight emerging evidence-based public health and public safety models for law enforcement engagement in activities that promote solutions to reduce demand or decrease spread of disease.

The *National Drug Control Strategy*'s efforts also include pursuing action against 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 acetyl-fentanyl and enhancing border efforts to decrease the flow of these drugs into the country.

### **Treatment, Overdose Prevention, and Other Public Health Efforts**

The public health consequences of nonmedical opioid and heroin use are often similar if not identical. Most notably, in both cases, some proportion of individuals escalate use and eventually develop a chronic opioid use disorder requiring treatment. The low rate of cases referred to treatment by medical personnel in the face of such a dangerous epidemic suggests that providers may ignore or miss the problems of nonmedical prescription opioid use and heroin use among their patients. The extent of the opioid use problem requires that health care providers work in tandem with law enforcement to address the issue.

People who escalate use are vulnerable to begin injecting, and this behavior dramatically increases their risk of exposure to blood-borne infections, including human immunodeficiency virus (HIV) and hepatitis C. It is noteworthy that in the latest HIV outbreak in rural Indiana, it was intravenous use of the strong prescription opioid oxycodone, not heroin, which accounted for most of the cases. Since the first patient in the outbreak was identified in January 2015, 174 people have tested positive for HIV. To combat the spread of HIV, Indiana instituted an emergency syringe services program, among other efforts to expand treatment for HIV and opioid use disorders. The Administration continues to support a consistent policy that would allow Federal funds to be used in locations where local authorities deem syringe services programs to be effective and appropriate. Studies show that comprehensive prevention and drug treatment programs, including syringe services program, have dramatically cut the number of new HIV infections among people who inject drugs.

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<sup>74</sup> R.N. Lipari and A. Hughes. The NSDUH Report: Trends in Heroin Use in the United States: 2002 to 2013. (2015). Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, Rockville, MD. [http://www.samhsa.gov/data/sites/default/files/report\\_1943/ShortReport-1943.html](http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html) Available at linked to on 7-19-2015

<sup>75</sup> Jones CM, Logan J, Gladden RM, Bohm MK. Vital Signs: Demographic and Substance Use Trends Among Heroin Users - United States, 2002-2013. *MMWR Morb Mortal Wkly Rep.* 2015 Jul 10;64(26):719-25. PMID: 26158353

Nonmedical use of opioids like heroin can produce overdose including fatal overdose especially when used in conjunction with other sedatives including alcohol and anti-anxiety medicines. People who have stopped using for a period of time, such as those who were in treatment, have been medically withdrawn, or have been incarcerated, are especially at risk of overdose because their tolerance has worn off but they use amounts similar to those prior to cessation. 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.

For these reasons, it is important to identify and treat people with prescription opioid use disorder quickly, ensure they are engaged in the most effective forms of evidence-based treatment, and make lifesaving tools like the overdose reversal antidote naloxone widely available. Fortunately, the treatments for heroin and prescription opioid use disorder are the same. The standard of care is behavioral treatment plus stabilization on one of three FDA-approved medicines, often called medication-assisted treatment (MAT). MAT may be tapered in time to produce abstinence, but a health care provider must make the decision that is right for his or her patient regarding whether to cease a medication.

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.<sup>76</sup> Newborns with NAS have more complicated and longer initial hospitalizations than other newborns.<sup>77</sup> Newly published data shows the problem nearly doubled from 2009 to 2012.<sup>78</sup> Additionally, the study showed that 80 percent of the cost for caring for these infants was the responsibility of state Medicaid programs during this time.

The Administration is focusing on several key areas to reduce and prevent opioid overdoses from prescription opioids and heroin, 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 opioid-involved overdose deaths across the country, it is increasingly important to prevent overdoses and make antidotes available.

It is important to note in some cases traffickers are combining heroin with the synthetic lab-produced opioid fentanyl or an analog, presumably as a way to increase user perception of

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<sup>76</sup> 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>.

<sup>77</sup> 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>.

<sup>78</sup> 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

product strength and thus user experience.<sup>79</sup> Fentanyl can produce overdose rapidly in naïve users and in such cases naloxone may be insufficient remedy for fentanyl or its analogs.<sup>80</sup>

The Administration is providing tools to local communities to deal with the opioid drug epidemic. In August 2013, SAMHSA released the *Opioid Overdose Prevention Toolkit*.<sup>81</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 for first responders, treatment providers, and those recovering from opioid overdose. In July 2014, Attorney General Holder issued a Memorandum urging Federal law enforcement agencies to identify, train and equip personnel who may interact with victims of an opioid overdose,<sup>82</sup> and in October 2014, the Attorney General announced the launch of the Department of Justice's *Naloxone Toolkit* to support law enforcement agencies in establishing a naloxone program.<sup>83</sup> In August 2014, the Administration announced that DoD was making a new commitment to ensure that opiate overdose reversal kits and training are available to every first responder on military bases or other areas under DoD's control.<sup>84</sup> And earlier this month, the Indian Health Service announced its own toolkit for use with American Indian and Alaskan Natives a population who has disparate rates of past year non-medical prescription pain reliever use (6.9 percent vs. 4.2 percent in the rest of the population).<sup>85</sup>

The Administration continues to promote the use of naloxone by those likely to encounter overdose victims and for them to be in the position to reverse the overdose, 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. Profiled in the 2013 *National Drug Control Strategy*, the Quincy Massachusetts Police Department 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 382 overdose events, resulting in 360 successful overdose reversals.<sup>86</sup> In the past year, we have witnessed an exponential expansion in the number of police departments that are training and equipping their police officers with naloxone. They now number in the hundreds.

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<sup>79</sup> Notes from the field: increase in fentanyl-related overdose deaths - Rhode Island, November 2013-March 2014.

Mercado-Crespo MC, Sumner SA, Spelke MB, Sugerman DE, Stanley C; EIS officer, CDC.

MMWR Morb Mortal Wkly Rep. 2014 Jun 20;63(24):531. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6324a3.htm>

<sup>80</sup> Zuckerman M, Weisberg SN, Boyer EW. Pitfalls of intranasal naloxone. *Prehosp Emerg Care*. 2014 Oct-Dec;18(4):550-4. doi: 10.3109/10903127.2014.896961. Epub 2014 May 15. Available at [linked to on](#).

<sup>81</sup> 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>

<sup>82</sup> Department of Justice, Office of Public Affairs. "Attorney General Holder Announces Plans for Federal Law Enforcement Personnel to Begin Carrying Naloxone." [July 31, 2014]. Available at <http://www.justice.gov/opa/pr/attorney-general-holder-announces-plans-federal-law-enforcement-personnel-begin-carrying-linked-to-10-18-2014>

<sup>83</sup> 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>

<sup>84</sup> <http://www.va.gov/opa/docs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf>

<sup>85</sup> SAMHSA. National Survey on Drug Use and Health. The CBHSQ Report, June 2015. Nonmedical use of prescription pain relievers varies by race. [http://www.samhsa.gov/data/sites/default/files/report\\_1972/Spotlight-1972.html](http://www.samhsa.gov/data/sites/default/files/report_1972/Spotlight-1972.html) linked to on 7-19-2015.

<sup>86</sup> Quincy (Massachusetts) Police Department Reporting. Email received 3/15/15.

Extraordinary collaboration is taking place in rural and suburban communities such as Lake County, Illinois. As part of the Lake County Heroin/Opioid Prevention Taskforce, the Lake County State's Attorney has partnered with various county agencies, including the Lake County Health Department; drug courts; police and fire departments; health, advocacy and prevention organizations; and local pharmacies to develop and implement an opioid overdose prevention plan.<sup>87</sup> Since July 2014, the Lake County Health Department has trained more than 34 police departments, 27 of which are carrying naloxone. As of February 2015, the Lake County Health Department had trained 828 police officers and 200 sheriff's deputies to carry and administer naloxone, and more departments have requested this training.<sup>88</sup>

Prior to 2012, just six states had any laws which expanded access to naloxone or limited criminal liability. Today, 35 states<sup>89</sup> 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-four states<sup>90</sup> have passed laws that offer criminal and/or civil liability protections for prescribing or distributing naloxone. Thirty-three states<sup>91</sup> have passed laws allowing naloxone distribution to third-parties or first responders via direct prescription or standing order. 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. Twenty-five states<sup>92</sup> and the District of Columbia have passed laws which offer protections from charge or prosecution for possession of a controlled substance and/or paraphernalia if the person seeks emergency assistance for someone that is experiencing an opioid induced overdose. As these laws are implemented, the Administration will carefully monitor their effect on public health and public safety.

The Affordable Care Act and Federal parity laws are extending access to mental health and substance use disorder benefits for an estimated 62 million Americans.<sup>93</sup> This represents the largest expansion of treatment access in a generation and could help guide millions into successful recovery. The President's FY 2016 budget request includes \$11 billion for treatment, a nearly seven percent increase over the FY 2015 funding level.

It is essential to identify and engage people who use prescription opioids non-medically early because the risks of being infected with HIV or hepatitis C increases dramatically once someone transitions to injection drug use. It is much less expensive to treat a person for just a substance use disorder early using evidence-based treatment, rather than to treat a person with a substance use disorder and provide lifetime treatment for HIV or a cure for hepatitis C.

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<sup>87</sup> Office of the State's Attorney, Lake County, Illinois, Michael G. Nerheim. "Call to Action Lake County Opioid Prevention Initiative." [May 29, 2013]. Available at: <http://lcsao.org/news/press-releases>

<sup>88</sup> Lake County Health Department Reporting. Email 2/19/15.

<sup>89</sup> 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.

<sup>90</sup> 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.

<sup>91</sup> 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.

<sup>92</sup> 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.

<sup>93</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 [http://aspe.hhs.gov/health/reports/2013/mental/rb\\_mental.cfm](http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm))

Medication-assisted treatment should be the recognized standard of care for opioid use disorders. Research shows that even heroin users can sustain recovery if treated with evidence-based methods. Studies have shown that individuals with opioid use disorders have better outcomes with maintenance MAT.<sup>94</sup> Yet for too many people, it is out of reach. For instance, only 26.2 percent (3,713) of treatment facilities provided treatment with methadone and/or buprenorphine.<sup>95</sup> Treatment programs are too often unable to provide this standard of care, and there is a significant need for medical professionals who can provide MAT in an integrated health care setting.

Medicines for opioid use disorder containing 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 physicians who have taken the training to administer the medicines are allowed to treat patients in an office-based setting, it allows patient care to be integrated with mainstream medicine. Injectable naltrexone offers similar advantages but only to patients who have been abstinent from opioids for 7-10 days. Special training required by DATA 2000 for prescribing buprenorphine is not required for injectable naltrexone.

We need to increase the number of physicians who can prescribe buprenorphine, when appropriate and the numbers of providers offering injectable naltrexone. Of the more than 877,000 physicians who can write controlled substance prescriptions, only about 29,194 have received a waiver to prescribe office-based buprenorphine. Of those, 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 narcotic treatment programs, far too few providers elect to use any form of medication-assisted treatment for their patients.<sup>96</sup> Injectable naltrexone was only approved for use with opioid use disorders in 2012, and little is known about its adoption outside specialty substance use treatment programs but use in primary care and other settings are possible. To date only about 3 percent of U.S. treatment programs offer this medicine for opioid use disorder.<sup>97</sup> Education on the etiology of opioid abuse and clinician interventions is critical to increasing access to treatments that will stem the tide of opioid misuse and overdose.

And there are some signs that these national efforts are working with respect to the prescription opioid problem. 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 1.5 million in 2013.<sup>98</sup> Additionally, according to the latest Monitoring the

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<sup>94</sup> 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.

<sup>95</sup> SAMHSA. *National Survey of Substance Abuse Treatment Services (N-SSATS): 2012 -- Data on Substance Abuse Treatment Facilities* (December 2013).

<sup>96</sup> Personal communication (email) from Robert Hill (DEA).

<sup>97</sup> Aletraris LI, 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.

<sup>98</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2013.htm#tab7.36A>

Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2014 is its lowest since 2002.<sup>99</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 nonmedical prescription opioid and heroin 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 this issue. I look forward to continuing to work with you on this pressing public health matter.

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<sup>99</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 2014]. Available: <http://www.monitoringthefuture.org/data/14data/14drfig11.pdf>