Testimony

of

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# "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?"

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Chairman Murphy, Ranking Member DeGette and members of the Subcommittee, thank you for this opportunity to discuss how the Department of Health and Human Services (HHS) is addressing the opioid abuse epidemic. Containing and eliminating the abuse of prescription opioids and heroin is a high priority for HHS and for Secretary Sylvia Mathews Burwell, and we are pleased to be here with you today to discuss this issue. This is also a critical issue for the Administration. In addition to the substantial expansion of substance abuse coverage through the Affordable Care Act and the implementation of mental health and substance abuse parity protections, the President's FY 2016 Budget proposes critical investments to intensify efforts to reduce opioid misuse and abuse, including $133 million in new funding.

I would like to use my time today to talk about how we at HHS view the challenge and describe how we are working to develop a multifaceted solution for this complex problem. It is going to take a lot of collaboration across partners, agencies, and the Congress to make progress, and you will be hearing from many of those partners today.

## Trends In Opioid Use and Abuse, Injury and Death

The United States is experiencing alarming trends in consequences stemming from the abuse of and addiction to opioids. Drug overdose deaths have been increasing over the past two decades and, in 2009, became the leading cause of injury death in the United States.[1] Approximately 37 percent of drug overdose deaths in 2013 involved prescription opioids, a number that has remained essentially unchanged from 2012. During this time the initiation of heroin use has grown modestly but mortality from heroin has spiked dramatically[2] – nearly tripling since 2010. Heroin overdose deaths increased by 39 percent from 2012 to 2013 alone, and accounted for about 19 percent of all drug overdose deaths in 2013.[3]

The highest use, highest risk nonmedical users of prescription pain medications obtain them from their physicians.[4] These medications have an important place in treating pain, but it is easy to become addicted to them. Chronic nonmedical use, or nonmedical use of 200 days or more in the past year, increased by roughly 75 percent between 2002-2003 and 2009-2010.[5] Prescription opioids taken with other misused or abused prescription drugs such as benzodiazepines (*e.g.* sedatives like Xanax) and antidepressants are also commonly linked to overdose deaths.[6]

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[1] Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS), 2014. Available at http://www.cdc.gov/injury/wisqars/fatal.html

[2] Rachel N. Lipari, Ph.D., and Arthur Hughes, MS. "Trends in Heroin Use in the United States: 2002 to 2013." Substance Abuse and Mental Health Services Administration. April 23, 2015. Available at http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html

[3] Hedegaard H, Chen LH, Warner M.; National Center for Health Statistics (NCHS). Drug-poisoning deaths involving heroin: States, 2000–2013. NCHS data brief, no190. Available at http://www.cdc.gov/nchs/data/databriefs/db190.pdf

[4] Jones CM, Paulozzi LJ, Mack KA. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use United States, 2008-2011. JAMA Intern Med. 2014 May;174(5):802-3.

[5] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267

[6] Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. JAMA. 2013 Feb 20;309(7):657-9

Existing evidence shows that individuals at greatest risk for prescription opioid overdose include:[7]

- People living in rural areas and having low income
- People with mental illness or history of alcohol or other substance abuse
- People who obtain multiple controlled substance prescriptions (especially the combination of opioid analgesics and benzodiazepines) from multiple providers
- People receiving high daily dosages of opioid pain relievers

Death from heroin overdose follows a somewhat different pattern. Deaths involving heroin increased across the country, but an analysis by the Centers for Disease Control and Prevention (CDC) shows heroin overdose death rates in 2013[8] highest among:

- Adults aged 25-44 years old
- White, non-Hispanic people
- Men
- People living in the Northeast and Midwest

## Opioid Prescribing Patterns and the Burden on the Health Care System

There were 259 million prescriptions written for opioids in the U.S. in 2012, a large increase from just a few years ago,[9] and Americans' use of prescription drugs has increased over the past half century. The increase is related to many factors, including a corresponding increase in insurance coverage for these drugs.[10] For example, the Medicare program (through Part D, implemented in 2006) spent $2.7 billion on opioids overall in 2011, and $1.9 billion of that total (69 percent) was accounted for by the top five percent of opioid users.[11] These data are consistent with the trend showing a sharp increase in nonmedical use of prescription pain relievers by a relatively small number of "heavy users."[12] It is vital that we balance combatting abuse with supporting health care providers in making the best clinical recommendations for their patients' pain management.

In addition to the tragic consequences of opioid abuse on families and communities, this epidemic is a drain on the Nation's health care system. The growth in abuse and misuse of these drugs is costly in terms of claims made on health care resources. For example, rates of

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[7] Risk Factors for Prescription Painkiller Abuse and Overdose. Centers for Disease Control and Prevention. Accessed April 2015. Available at http://www.cdc.gov/drugoverdose/epidemic/riskfactors.html.

[8] Hedegaard, Holly, Chen, Li-Hui, and Warner, Margaret. Drug-poisoning Deaths Involving Heroin: United States, 2000-2013. NCHS Data Brief No. 190, March 2015. Available at http://www.cdc.gov/nchs/data/databriefs/db190.pdf.

[9] Vital Signs: Opioid Painkiller Prescribing. Centers for Disease Control and Prevention, July 2014. Available at http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf.

[10] National Center for Health Statistics. Health, United States, 2013: With Special Feature on Prescription Drugs. Hyattsville, MD. 2014. Available at http://www.cdc.gov/nchs/data/hus/hus13.pdf.

[11] Suzuki, Shinobu. Potentially Inappropriate Opioid Use in Medicare Part D. MEDPAC. October 9, 2014. Available at http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-.pdf?sfvrsn=0

[12] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267

emergency department visits linked to misuse or abuse of pharmaceuticals increased 114 percent between 2004 and 2011: in 2011, more than 1.4 million emergency-department visits were due to the misuse or abuse of pharmaceuticals, with 420,000 involving prescription opioids and 425,000 involving benzodiazepines.[13]

## Heroin Patterns

Heroin presents an equally troubling, but different use and overdose pattern. Recent estimates from the Substance Abuse and Mental Health Services Administration (SAMHSA) show increases between 2002 and 2009 in the number of people using heroin, but that number has held fairly steady since 2009 (in 2013 it was 681,000 past-year users).[14] At the same time, deaths from heroin overdoses are increasing rapidly. Somewhat more encouraging are reports indicating that the numbers of people receiving treatment for heroin use has been increasing steadily since 2010.

## Connections Between Pain Treatment, Prescription Opioids and Heroin

The media has reported extensively on the relationship between pain treatment, prescription opioid abuse and heroin initiation. There are no clear paths, but the evidence points to some important associations. First, the majority – 75 percent – of heroin users began with a prescription for pain. [15] Even when used appropriately, these drugs run the risk of being highly addictive.

Second, many heroin users report past-year non-medical use of prescription drugs. Between 2002–2004 and 2008–2010, past-year heroin use increased among people reporting non-medical use of prescription opioids within the past year, but not among those reporting no non-medical use in the past year.[16] This stands in stark contrast to the heroin problem of the 1960s; although strong pain medications existed at the time, eight out of ten of the people who initiated opioid use in that decade began their opioid use with heroin.[17]

Third, although most heroin users report past-year non-medical use of pain medications, the evidence does not show that non-medical prescription opioid use leads to heroin use in the majority of cases. Current estimates are that less than 4 percent of those who initiated initiate prescription opioid use non-medically go on to initiate heroin use.

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[13] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Available at http://www.samhsa.gov/data/sites/default/files/DAWN127/DAWN127/sr127-DAWN-highlights.htm

[14] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. Available at http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm

[15] 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;71:821–6.

[16] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010. Drug Alcohol Depend 2013;132:95–100

[17] 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;71:821–6

Finally, heroin is easier and cheaper to get and to use these days, and its potency is much greater than many prescription opioids.[18] For example, according to the Office of National Drug Control Policy, the price per pure gram of heroin purchased at the "retail level" (10 grams or less) has dropped over the past few years, from $595 per pure gram in 2010 to $465 per pure gram in 2012.[19] This is a nearly 22 percent drop in the retail price of heroin. Like other products, reduced prices result in increased demand. Additionally, reports from Federal, state, and local law enforcement via the Drug Enforcement Administration indicate that the availability of heroin has increased across the country.

**The HHS Approach to the Problem: Secretary's Initiative**

Secretary Burwell's initiative is directly addressing the threat posed by opioids to the health of the American public and the costs imposed on public and private budgets. At her direction, we are taking steps where the evidence indicates we will have the greatest impact. We are focused on two clear outcomes: (1) reducing opioid overdoses and overdose-related mortality and (2) decreasing the prevalence of opioid use disorder.

To accomplish these clear but challenging goals, Secretary Burwell directed HHS senior leadership and staff from across the department to identify a focused set of actions using some basic decision rules:

- Include actions that the evidence indicates have a high likelihood of making a measureable difference.
- Aim to have an impact in the intermediate term, while establishing a platform for long-term effects.
- Make use of HHS' most promising levers and partner with other stakeholders to make a difference for the people who struggle with opioid use disorder and their families.

The Agencies that you will be hearing from have been collaborating on this problem for some time through an Administration-wide effort by the White House Office of National Drug Control Policy, HHS's Behavioral Health Coordinating Council, and through the Secretary's meetings on her initiative. Specifically, the actions in the initiative that we all will tell you about are grounded in the best research and clinical science available.

The areas for action were identified through a Department-wide effort that tapped all the scientific, analytical, and programmatic expertise found at HHS; as well as discussions with states and other stakeholders.

The Secretary's initiative includes actions in three priority areas to combat opioid abuse:

- Opioid prescribing practices to reduce opioid use disorders and overdose
- Expanded use and distribution of naloxone

[18] 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;71:821–6

[19] Office of National Drug Control Policy. National Drug Control Strategy: Data Supplement 2014, p. 81. Available at https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_data_supplement_2014.pdf

- Expansion of Medication-assisted Treatment (MAT) to reduce opioid use disorders and overdose

## Taking Actions Based on Evidence of What Works

The efforts are grounded in the best available science. There is a growing body of research that supports the effectiveness of several interventions to address opioid abuse. Continued monitoring, evaluation, and research are essential to further strengthen the evidence base and inform program and policy decision-making. We have particularly targeted three important tools in this work. The first is Prescription Drug Monitoring Programs (PDMPs) because they enable us to track prescribing patterns and intervene and train to turn things around. The second tool is expanding access to naloxone, which can reverse the effects of both prescription opioid and heroin overdose. And the third tool is MAT, which involves the combination of medications and therapeutic supports to help people recover from opioid addiction.

### *Prescription Drug Monitoring Programs*

Health care providers – prescribers – are on the front line and they are important allies in this effort. We are increasing investments in prescription drug monitoring programs (PDMPs), which are state-run electronic databases of prescriptions for controlled substances and are among the most promising clinical tools to curb prescription opioid abuse. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially abusing medications. The organization and operation of PDMPs varies among states. Different states have variations around how often the data are collected and reported, which state agency houses the PDMP, who is able to access it, and which controlled substances must be reported, among other variations.

Currently, 49 states, the District of Columbia, and one U.S. territory (Guam) have legislation authorizing the creation and operation of a PDMP and all but the DC program are operational.[20] We have seen promising steps taken by Missouri in the past few weeks to lay the ground work for a PDMP.

Existing evidence indicates the potential of PDMPs to identify high-risk patients and impact key prescribing behaviors.[21] Evaluations of a selected group of PDMPs have detected positive changes in prescribing patterns, decreased use of multiple providers and pharmacies, and decreased substance abuse treatment admissions. For example, a preliminary analysis of the impact of laws mandating use of PDMPs by prescribers in Kentucky, Tennessee, and New York showed reductions in multiple provider episodes (*e.g.*, approximately 75 percent decline in New York), a risk factor for opioid overdose. Controlled substance prescribing also declined in states

[20] PDMP Training and Technical Assistance Center. PDMP Frequently Asked Questions. Available at http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

[21] PDMP Center of Excellence at Brandeis University. Briefing on PDMP Effectiveness: Updated September 2014. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf

that mandated PDMP use (*e.g.*, in Kentucky doses dispensed declined for hydrocodone by approximately 10 percent, oxycodone by 12 percent, and oxymorphone by 35 percent).[22]

CDC and SAMHSA are providing grants to states to support development and use of PDMPs, and you will hear more about that from CDC and SAMHSA today.

Clinical decision support tools and health IT systems incorporating PDMP and other clinical data also show promise for improving prescribing behaviors and reducing adverse events.[23] As states work to adopt more evidence-based PDMP practices such as collecting data for all controlled substances, proactive reporting to physicians and pharmacists, interstate data sharing, and integration with other health IT systems to improve provider use, their effectiveness is likely to increase.[24]

*Guidelines*

There is a clear correlation between opioid prescribing rates and overdose death rates in the United States. From 1999 to 2010, opioid prescribing quadrupled in parallel to increasing opioid overdose death rates.[25] These data underscore the importance of prescribing guidelines that encourage the use of opioids when benefits outweigh risks and that promote safe use when opioids are needed.

A recent study of workers compensation patients in Washington State found that after the introduction of voluntary opioid guidelines in 2007, there was a 27 percent decline in the mean dose for long-acting opioids, a 35 percent decline in the percentage of patients receiving 120 morphine milligram equivalents per day or more, and a 50 percent reduction in opioid-related overdose deaths among injured workers.[26] If followed and universally implemented, integrating guidelines into electronic health records or clinical decision support platforms may help to reduce inappropriate prescribing of drugs commonly involved in overdose deaths.

*Naloxone*

Naloxone is an effective drug that can reverse overdose from both prescription opioids and heroin. This drug saves lives. It can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of heroin or prescription opioid overdose. Many overdose education and naloxone distribution programs have been developed to issue naloxone

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[22] PDMP Center of Excellence at Brandeis University. COE Briefing—Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States. Available at http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf

[23] PDMP Center of Excellence at Brandeis University. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, September 2012. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

[24] PDMP Center of Excellence at Brandeis University. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, September 2012. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

[25] Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487-1492.

[26] Franklin GM, Mai J, Turner J, Sullivan M, Wickizer T, Fulton-Kehoe D. Bending the prescription opioid dosing and mortality curves: impact of the Washington State opioid dosing guideline. Am J Ind Med. 2012;55(4):325-31.

and provide instructions on its use to law enforcement officers, opioid users, their friends and loved ones, and other potential bystanders.

As of July 2014, 24 states have statutes that allow for "third-party" prescriptions of naloxone (*i.e.* the prescription can be written to friend, relative or person in a position to assist a person at risk of experiencing an opioid overdose).[27] An evaluation of Massachusetts' overdose education and nasal naloxone distribution program, which trained potential overdose bystanders, found that opioid overdose death rates declined in communities where programs were implemented.[28] Given the effectiveness of naloxone in overdose reversal, the Food and Drug Administration (FDA) has encouraged innovations in more user-friendly naloxone delivery systems such as auto-injectors, made particularly for lay use outside of health care settings. FDA approved such an auto-injector in 2014.

*Medication-assisted Treatment (MAT)*

Studies have shown that the most effective treatments for opioid use disorders (including both prescription opioids and heroin) are those that include a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual.[29] MAT is the use of medications such as buprenorphine, methadone, and extended release naltrexone, among others, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of opioid use disorders.

MAT is a safe and effective strategy for decreasing the frequency and quantity of opioid use and reducing the risk of overdose and death.[30] Furthermore, recently published research indicates that the most prevalent forms of MAT, buprenorphine and methadone, are similar in terms of effectiveness.[31] A recent National Quality Forum workshop found that many psychosocial treatments are effective (such as cognitive behavioral therapy, structured family therapy, and 12-step facilitation therapy, among others) for certain substance use disorders. However, that same workshop explicitly recommended that patients with opioid dependence be offered pharmacotherapy directly linked to psychosocial treatments.[32] The evidence points to a

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[27] State Naloxone and Good Samaritan Legislation. Office of National Drug Control Policy, August 2014. Available at https://www.whitehouse.gov/sites/default/files/ondcp/Blog/naloxonecirclechart_august2014.pdf.

[28] Walley AY, Xuan Z, Hackman HH, Quinn E, Doe-Simkins M, Sorensen-Alawad A, Ruiz S, Ozonoff A. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ. 2013 Jan 30;346:f174. doi: 10.1136/bmj.f174

[29] Connery, HS. Medication-assisted treatment of opioid use disorder: review of the evidence and future directions. Harv Rev Psychiatry. 2015 March-Apr;23(2):63-75. Doi: 10.1097/HRP.0000000000000075. Available at http://www.ncbi.nlm.nih.gov/pubmed/25747920.

[30] National Institutes on Drug Abuse. Cost effectiveness of drug treatment. Retrieved from: http://www.drugabuse.gov/publications/teaching-packets/understanding-drug-abuse-addiction/sectioniv/6-costeffectiveness-drug-treatment

[31] Potter, J.S.; Marino, E.N.; Hillhouse, M.P., et al. Buprenorphine/naloxone and methadone maintenance treatment outcomes for opioid analgesic, heroin, and combined users: findings from Starting Treatment with Agonist Replacement Therapies (START). Journal of Studies on Alcohol and Drugs 74(4):605-613, 2013

[32] Power, Elaine J., Nishimi, Robyn Y., and Kizer, Kenneth W., Editors. National Quality Forum: Evidence-Based Treatment Practices for Substance Use Disorders, 2005. Available at http://www.apa.org/divisions/div50/doc/Evidence_-_Based_Treatment_Practices_for_Substance_Use_Disorders.pdf

combination of medication and psychosocial services. Using either of these two interventions alone is inconsistent with the evidence about what works best for opioid use disorders.

Although MAT has significant evidence to support it as an effective treatment, it remains highly underutilized, being used by only an estimated one million of the 2.5 million Americans who might benefit from receiving it.[33] The barriers to access to MAT are many and varied, including a lack of available prescribers, lack of support for existing prescribers, minimal counseling coverage, and workforce attitudes and misunderstandings about the nature and use of MAT.

With further research and investment in these areas, the Secretary's initiative will continue to build upon the evidence base for effective interventions and help reduce opioid related morbidity and mortality, while also balancing the need for effective and appropriate pain management for those who need it most.

**Next Steps to Keeping People Healthy**

HHS continues to address this complex public health epidemic. The FY 2016 President's Budget for HHS includes an increase of $99 million above FY 2015 for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders. As I mentioned, and as you will hear from my HHS colleagues, across the Department, we are working to implement the Secretary's initiative by developing prescribing guidelines, investing in demonstration programs to expand medication-assisted treatment services, and expanding utilization of naloxone for individuals at risk of overdose via grant programs, among other key activities.

Additionally, the Office of the Assistant Secretary for Planning and Evaluation is conducting research to further inform best practices for opioid prescribing. For example, we are funding a project to examine the impact of changing the default prescription quantity when a physician enters an opioid prescription into an electronic health record. Most systems prepopulate the number of days prescribed with a 30-day prescription. To our knowledge, there is no evidence-based reason for this default quantity.

This summer, HHS is also convening the 50 states and Washington, D.C. in a two-day working meeting on best practices for states to address opioid abuse and addiction. We are working with stakeholders to ensure that the convening focuses on the biggest challenges for state policy makers in this area, and helps to elevate many of the potential solutions and best practices underway or under development across the country.

HHS has also prioritized the development of an evaluation strategy to identify the most effective activities and inform future policymaking in order to have the greatest public health impact. Evaluation is a critical component of the initiative to identify what works and how the most effective interventions can be taken to scale. HHS leadership has joined together to aggressively implement the new initiative and monitor progress. Many activities are already underway, and the Department continues to seek opportunities to work with its partners on this critical issue.

[33] Volkow ND1, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies--tackling the opioid-overdose epidemic. N Engl J Med. 2014 May 29;370(22):2063-6. doi: 10.1056/NEJMp1402780. Epub 2014 Apr 23

## Conclusion

This is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.