

AMERICA'S HEROIN AND OPIOID ABUSE EPIDEMIC

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM HOUSE OF REPRESENTATIVES

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AMERICA'S HEROIN AND OPIOID ABUSE EPIDEMIC

Tuesday, March 22, 2016

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
Washington, DC

The committee met, pursuant to call, at 10:01 a.m., in Room 2154, Rayburn House Office Building, Hon. John Mica presiding.

Present: Representatives Mica, Turner, Jordan, Walberg, Amash, Gowdy, Massie, Meadows, DeSantis, Buck, Walker, Blum, Hice, Carter, Grothman, Hurd, Palmer, Cummings, Maloney, Norton, Clay, Lynch, Connolly, Cartwright, Lawrence, Lieu, Watson Coleman, DeSaulnier, Boyle, and Lujan Grisham.

Mr. MICA. Good morning. I would like to welcome everyone this morning to the Committee on Oversight and Government Reform, and to a hearing which is entitled "America's Heroin and Opioid Abuse Epidemic." I would like to welcome our ranking member, Mr. Cummings, and all the members and our witnesses this morning to this hearing and call the hearing to order.

Without objection, the Chair is authorized to declare recesses at any time.

The order of business this morning will be as follows. We will begin the hearing with opening statements from myself and the ranking member. Other members are welcome to submit opening statements, and with Mr. Cummings' support we will leave the record open for 5 days, legislative days, for additional comments or statements.

Without objection, so ordered.

And when we complete the opening statements, we will turn to our panel of witnesses. We have five distinguished witnesses today, three at the Federal level, one at the state, and one at the local level for our hearing. We will swear those witnesses in, and then we will hear their testimony, and then we will proceed with questions. So that will be the order of business that will follow.

So again, welcome, and I will start with my opening statement.

Unfortunately, the United States is experiencing an historic epidemic of drug overdose deaths. Today, drug overdoses are the leading cause of accidental death in the United States. In 2014—I don't have the 2015 figures yet, but in 2014 there were—listen to this—47,055 deaths caused by drug overdose. That means if this hearing lasts for two hours, 10 people will die in the next two hours in the United States from drug overdose deaths.

This is a little chart showing you the increase since 1999. I remember I chaired Criminal Justice Drug Policy Oversight Sub-

committee from 1998 to 1999, and we thought we had an epidemic back in 1999 with 16,000, and I can show you some of the headlines from my local newspapers where we had many people dying over a weekend. Unfortunately, that is what we are seeing again in my community and across the United States.

Unfortunately, more Americans have died from drug-related overdoses in one year than all that were killed in the lengthy Korean War. If the current trend continues, the annual death rate could climb beyond those killed in Vietnam over that multi-year struggle in one year.

The graph from the Washington Post illustrates the disturbing rise in drug overdoses between 1999 and 2014. Now, of the 47,000, more than 10,000 Americans died of heroin-related overdoses. Heroin use is increasing at a faster rate. If you want to talk about a war on women and a war on our young people, the heroin deaths are killing our women at twice the rate of men and 109 percent more with our youth.

Unfortunately, we have seen, according to the Centers for Disease Control and Prevention, that again with heroin deaths among our youth between 18 and 25 in the past decade have soared and again lead the statistics, the deadly statistics. Across all demographics, the rate of heroin-related overdose deaths has increased 286 percent.

While the exact cause of this epidemic is up for debate, many experts believe the use of other drugs is also a driving factor. Addiction to other drugs such as prescription painkillers and marijuana potentially open the door to an epidemic now destroying families and communities.

Those addicted to other drugs turn to heroin to get a similar high because it is cheaper and more readily available. Mexican drug cartels have established heroin trafficking routes here in the United States and coming across our borders. Now we see increased supplies in recent years.

I had a chance to talk with my police chiefs and law enforcement folks in the district, our HIDTA folks, our DEA folks, and we are seeing an incredible supply, and we will have some questions about where that is specifically coming from. We know a lot of it is coming across the Mexican border.

The impact, unfortunately, is felt in communities across the nation. Just a few weeks ago I met again with all of the local officials, and we have one of my local officials who we will hear from in a few minutes, Teresa Jacobs, our county mayor in Orange County, who has been forced to deal with the heroin epidemic in Central Florida in her county. In Orange County alone, and you will hear more about this, we had 475 related heroin bookings in 2013. By the end of 2015, last year, we had 840. The majority of those arrested were between the age of 18 and 44.

The Obama Administration, unfortunately, I believe, has been sending mixed signals about the use of substances such as marijuana, which is one of the gateway drugs. Talk to anyone who is in counseling, treatment, rehabilitation, and you will find out that marijuana is a gateway drug, and many of the heroin users start there and work their way up the chain of deadly drugs.

According to the National Institute on Drug Abuse—now listen to this—more high school seniors are now using marijuana than cigarettes. A policy that has been adopted, unfortunately, has consequences. The “Just Say No” drug policy which was championed by the late First Lady, Nancy Reagan, has turned into a “Just Say Okay” policy, and now we are seeing the consequences.

While improving treatment is a key, enforcement is and must remain an essential part of combatting the heroin epidemic. When I talked to the police chief and I saw the numbers in our locale, I said, well, it looks like you have been able to keep the lid on some of this, although it is now at epidemic proportions. And they told me, Mr. Mica, he said this is only because we now have antidotes that can bring these people back. The only reason we aren’t seeing double or triple the deaths is because our law enforcement and our first responders can bring these people back if they can get to them in time.

Not only illegal immigrants are flowing over the Mexican border but also illegal drugs. We know that is the main source of the supply of heroin, cocaine, marijuana, and a host of other deadly narcotics. Stopping deadly drugs from entering the United States is a Federal responsibility, and we will hear from some of those officials engaged in that war.

New statistics show Federal drug prosecutions, unfortunately, are down 6 percent in the last year, 2015. This comes after a 14 percent drop since the beginning of the Obama Administration’s so-called Smart On Crime initiative.

Our frontline law enforcement officers, if we are going to save more of these kids and others who are overdosing, they should be equipped with the resources to prevent and save them from overdose deaths, not just our emergency medical officers. The EMS people get there usually after the first responders, and it may be too late. So this is something else we have learned from our local task force and law enforcement officials.

One of the police chiefs in my district informed me that just within the last month or so, we had one student who had to be revived from overdosing three times in one week. That is astounding. What is astounding is he is still alive and we were able to catch that.

Speaker Ryan announced addressing this current epidemic as a priority, and the Senate has acted on some legislation. I believe that this is absolutely critical, that this whole drug situation, including the heroin epidemic, become a priority for this Congress.

I look forward to hearing from our witnesses today as we examine how to protect our communities from this fast-growing and skyrocketing national epidemic.

I am now pleased to yield to our ranking member, Mr. Cummings. Mr. Cummings was my ranking member. We together led the effort from 1998 to 2000. I remember going into Baltimore with him and conducting hearings there when people were dying on the streets in huge numbers. But, Mr. Cummings, we are unfortunately backsliding, and here we are today. But he did a great job of trying to save people in his community, and he is now the ranking member of our full committee.

Mr. Cummings?

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank you for holding a hearing on America's heroin and opioid epidemic.

I want to take a moment before I start to extend our prayers to the people of Brussels, Belgium.

Mr. MICA. I would join you, and I would ask everyone for just a moment of silence, if we could.

[Moment of silence observed.]

Mr. MICA. Thank you, Mr. Cummings.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Today's hearing is about a national public health emergency, and we need to treat it like one. People are dying in Baltimore, Orlando, Salt Lake City, Manchester, and cities all across our nation. We can no longer ignore this public health emergency.

The Congress needs to put its money where its mouth is and actually help, help our states fund treatment programs to stop this epidemic in its tracks. Drug treatment facilities without adequate funding are like firemen trying to put out a raging inferno without enough water. Last week, Leader Pelosi sent a letter urging Speaker Ryan to schedule a vote on \$600 million in emergency funding to help states address this epidemic before this recess week.

Our colleague from Connecticut, Representative Courtney, has already introduced this bill in the House, and Senator Shaheen has been pressing this legislation in the Senate. Congress should not leave town until we take emergency action to increase funding to help states combat this epidemic.

We must also fully fund President Obama's budget request for \$1.1 billion in 2017. This crisis will not end in a day. It will take our sustained commitment, and every one of us owes it to our constituents to make that a priority. They want us to take action, and they want us to take action now.

Let me tell you why Federal funding is so important. In my hometown of Baltimore, I witnessed with my own eyes, in my own neighborhood, the destruction drug addiction inflicts on our communities. The first time I ever heard of a drug overdose death was 55 years ago from heroin, 55 years ago. I didn't understand it then. It was a young man in our neighborhood who we looked up to who turned to heroin, named Bey-Bey, and I can remember being so confused as to what this was all about.

So I have seen vibrant neighborhoods and hard-working families and communities destroyed. In Baltimore, where many of the victims were poor and black, this went on for decades. Our nation treated this issue like a war rather than a public health emergency. We incarcerated generations rather than giving them the treatment they needed.

Now, things are changing. Between 2006 and 2013, the number of first-time heroin users nearly doubled. About 90 percent of these first-time users were white. This epidemic has become a runaway train barreling through every family and every community in its path. It has no respect for barriers. It is now responsible for the deaths of 78 Americans every single day, every single day.

Why is this happening? In part, it is a result of doctors over-prescribing pain medication and drug companies urging them on so they can make massive profits. I would like to enter into the record

an op-ed by Emily Narciso that appeared in the Baltimore Sun on March 19th.

Mr. MICA. Without objection, so ordered.

Mr. CUMMINGS. I just want to read just a paragraph from this article. It says, "Prescriptions of opioids have been traditionally limited to cancer pain and comfort measures. But in the mid-'90s, companies began marketing these pills as a solution to a new plethora of ailments. In their efforts to expand the market, producers understated and willfully ignored the powerfully addictive properties of their drugs. The promotion of OxyContin by Purdue Pharma was the most aggressive marketing of a Schedule II drug ever undertaken by a pharmaceutical company. The Sackler family, which owns Stanford, Connecticut-based Purdue Pharma, achieved a place on Forbes' 2015 List of America's Wealthiest Families. The Sacklers, the richest newcomers to the list, are worth an estimated \$14 billion," \$14 billion.

Now, going on, as she explains, the United States has only 5 percent of the world's population, but we consume 80 percent of the world's painkillers. Five percent, ladies and gentlemen, of the world's population, but 80 percent of the painkillers we consume.

So, yes, I believe it was unconscionable that our nation ignored this issue for decades, but now Republicans and Democrats are starting to work together, and I thank God that this day has finally come and the stars are starting to align for meaningful change.

We now have people like Orrin Hatch, Chris Christie, Rob Portman, Kelly Ayotte, and Mike Pence realizing the severity of this crisis and supporting more funding to help our cities and states. They are beginning to realize that this is not an urban issue, a rural issue, a black issue, an Hispanic issue, or a white issue. This is an American issue that affects your sisters, your brothers, your sons, and your daughters.

There is something else we must do. We can no longer allow drug companies to keep ripping off taxpayers for life-saving medications. The Chairman mentioned just a moment ago the drug naloxone and its life-saving effects. Cities all around the country have recognized the need to equip their first responders, police officers and public health officials with naloxone, a drug that can reverse opioid overdoses in a matter of minutes. But their efforts have been directly undermined by corporate greed.

As more first responders began using this drug, the company that makes it, Amphastar, began to increase its prices by staggering amounts. In May 2014, a 10-dose pack cost the Baltimore City Health Department roughly \$190. Guess what? Today, it costs more than \$400 for the life-saving drug. Despite repeated efforts by my home state of Maryland, this company continues to over-charge for this drug. The company also continues to obstruct congressional oversight by refusing to produce all of the documents I requested last May, last May, about their massive price increases.

Mr. Chairman, today's hearing is rightly focused on the heroin and opioid epidemic, but I hope the committee will turn next to my request for documents, as well as my request for a hearing with executives from Amphastar.

With that, let me welcome our esteemed panel of witnesses today, and I thank you for being here. In particular, I would like

to welcome Dr. Leana Wen, the Baltimore City Health Commissioner, who has done an outstanding job. She is a true national leader in developing and carrying out effective solutions to the opioid crisis. We are very fortunate to have her heading our health efforts in Baltimore, and we are very pleased to have her here today.

And with that, Mr. Chairman, I yield back.

Mr. MICA. Thank you, Mr. Cummings.

Again, we will leave the record open for members who came in late for 5 legislative days if you would like to submit them at this point in the record.

Mr. MICA. We now want to again welcome our witnesses. Let me first introduce them, and then we will swear you in.

I am pleased to welcome the Honorable Michael Botticelli, and he is the Director of Office of National Drug Control Policy at the White House.

We have Mr. Lou Milione, and he is the Deputy Assistant Administrator for Diversion Control at DEA, the Federal Drug Enforcement Administration at the Department of Justice.

And then we have Ms. Kana Enomoto, and she is the Principal Deputy Administrator of Substance Abuse and Mental Health Services Administration at the U.S. Department of Health and Human Services.

And then we have Ms. Leana Wen, and she is the Health Commissioner for Baltimore City Health Department.

And then I would like to also welcome my requested witness, the Honorable Teresa Jacobs, Mayor of Orange County, Florida.

Some of you have been before us before, some of you haven't. We ask you that you limit your statements to approximately 5 minutes. You will see the little monitor. You can also request from the Chair additional statements or information be added to the record. So if you have a statement and you want to summarize it, you are welcome to do that.

Since this is an oversight and investigations panel of Congress, I would like you to stand now and be sworn. Can you raise your right hand?

Do you solemnly swear or affirm that the testimony you are about to give before this committee and Congress is the whole truth and nothing but the truth?

[Witnesses sworn.]

Mr. MICA. All of the witnesses have answered in the affirmative, and we will let the record reflect that.

We will first turn to our ONDCP representative, the Director of the Office of National Drug Control Policy from the White House, Mr. Botticelli.

Welcome, and you are recognized.

WITNESS STATEMENTS

STATEMENT OF MICHAEL BOTTICELLI

Mr. BOTTICELLI. Chairman Mica, Ranking Member Cummings, and members of the committee, thank you for the opportunity to appear here today to discuss the issues surrounding opioid drugs,

including heroin and illicit fentanyl, in the United States, as well as our Federal response.

During his State of the Union address, President Obama specifically mentioned addressing prescription drug and heroin use as a priority and an opportunity to work with Congress in a bipartisan manner on this issue that transcends party, income level, gender, race, and geography.

The Office of National Drug Control Policy produces the National Drug Control Strategy, which is the Administration's blueprint for reducing drug use and its consequences. Using our role as the coordinator of Federal drug control agencies, in 2011 the Administration released a plan to address the sharp rise in prescription opioid drug misuse that coincided with a surge in opioid drug prescribing at the beginning of this century. As this crisis has evolved with an increase in heroin and fentanyl use and overdose deaths, the Administration continues to put forward new initiatives to help deal with emerging issues.

For example, in October the Administration announced a series of commitments it obtained from state, local, and private-sector partners, as well as Federal agencies, aimed at addressing this epidemic.

Opioids are having an unimaginable impact on public health and safety in communities across the United States. Fifty-seven people died each day from opioids in 2010, and by 2014 that figure was up to 78 people. The number of drug overdose deaths involving synthetic opioids other than methadone, a category including fentanyl, has more than doubled since 2012.

These overdose rates are harrowing. However, we are making some progress. Past-month non-medical use of opioids by Americans 12 and older was significantly lower in 2014 than during its peak in 2009, and the number of people initiating the non-medical use of prescription pain relievers in the past year also decreased significantly during that time.

Unfortunately, this progress has been counteracted by an increase in the availability and use of heroin. Heroin purity has been rising while prices have remained low. The heroin crisis is compounded by the reemergence of illicit fentanyl, a powerful synthetic opioid that is sometimes added to heroin to increase its potency or used unsuspectingly on its own. Since fentanyl is far more potent than heroin, its use increases risk for overdose death.

While prescription opioid misuse far surpasses heroin use, and the transition from non-medical prescription opioid use to heroin occurs at a very low rate, a recent review article concluded that this transition appears to be a part of the transition of addiction among those with frequent use or dependence rather than a response to the reduction and availability of prescription medications, as some have speculated.

Graduate medical education programs do not provide a comprehensive focus on the identification or treatment of opioid use disorders. A startling evaluation of health care claims data found that a majority of non-fatal opioid overdose victims were receiving an opioid from a prescriber, and 91 percent received an opioid prescription again from a prescriber following their overdose.

In response last year, President Obama issued a Presidential Memorandum requiring all Federal agencies to provide training on the appropriate and effective prescribing of opioid medications to staff who prescribed controlled substances as part of their Federal duties.

Just last week, the Centers for Disease Control issued recommendations for primary care clinicians on the prescribing of opioids to treat chronic pain. The Administration also obtained commitments by more than 40 provider groups that more than 500,000 health care providers will complete opioid prescriber training in the next two years. And the Administration continues to work with Congress to make mandatory prescriber education part of their controlled substance licensure.

The Administration has also focused on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions, increasing third-party and first responder access to the opioid overdose reversal medication naloxone, promoting Good Samaritan laws, and connecting overdose victims and persons with an opioid overdose to treatment.

Yet, there remains in this country a considerable gap that inhibits many victims of this epidemic from accessing the treatment they so desperately need. Therefore, the President's Fiscal Year 2017 budget proposes \$1 billion in new funding over two years to support cooperative agreements with states to expand access to medication-assisted treatment and to expand access to substance use treatment providers in areas across the country most in need of providers.

And just a few days ago, HHS Secretary Burwell announced \$94 million in Affordable Care Act funding to health centers to expand the delivery of substance use services, with a specific focus on medication-assisted treatment for opioid use disorders in underserved populations.

While we appreciate Congress' support, the President's proposal underscores the need for additional funding to address this epidemic.

To address the increase in heroin and illicit fentanyl use and availability, the National Drug Control Strategy focuses on identifying, disrupting, and dismantling criminal organizations trafficking opioid drugs, working with the international community to reduce the cultivation of poppy, and identifying labs creating synthetic opioids like fentanyl and its analogs.

In addition, last year ONDCP created the National Heroin Coordination Group, which is a multi-disciplinary team of subject-matter experts to lead Federal efforts to reduce the supply of heroin and fentanyl in the United States, and we have also committed \$2.5 million in high-intensity drug trafficking area programs to develop a heroin response strategy, providing law enforcement resources to address the heroin threat across 15 states and the District of Columbia.

We have also been actively engaged with the government of Mexico on efforts to reduce the flow of heroin and fentanyl into the United States. Earlier this month, I met with Mexican Attorney General Gomez and other interagency representatives. We agreed to further collaboration on efforts to disrupt the production of her-

oin and fentanyl. This bilateral cooperation will be mutually beneficial to both our countries.

Members of the committee, we remain committed to working with our Federal, state, local, tribal, and private-sector partners to reduce and prevent the health and safety consequences of non-medical prescription opioid, heroin, and illicit fentanyl use. Thank you very much.

[Prepared statement of Mr. Botticelli follows:]



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

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

Committee on Oversight and Government Reform
United States House of Representatives

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

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

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

The Office of National Drug Control Policy (ONDCP) was established by Congress in 1988 with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, ONDCP establishes policies, priorities, and objectives for the Nation's drug control programs and ensures that adequate resources are provided to implement them. We also develop, evaluate, coordinate, and oversee the international and domestic anti-drug efforts of Executive Branch agencies and ensure such efforts sustain and complement state and local drug policy activities.

At ONDCP, we are charged with producing the *National Drug Control Strategy* (*Strategy*), the Administration's primary blueprint for drug policy, along with a national drug control budget. The *Strategy* is a 21st century plan that outlines a series of evidence-based reforms that treat our Nation's drug problem as a public health challenge, not just a criminal justice issue. It is guided by what science, experience, and compassion demonstrate about the true nature of drug use in America. We recognize that any policies to limit the prescribing of opioids need to take into account patients' legitimate need for pain medications.

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

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

Opioid Use Trends and Consequences

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

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

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

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

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

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

² Rudd, RA, Aleshire, N, Zibbell, JE, and Gladden, RM. Increases in Drug and Opioid Overdose Deaths – 2000-2014. Centers for Disease Control and Prevention: Mortality and Morbidity Weekly Report. Jan. 1, 2016. 64(50):1378-82. Available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?ts_cid=mm6450a3_w

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

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

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

⁶ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] Table 7.3A – Types of Illicit Drug Use in the Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014 Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DeTTab2014/NSDUH-DeTTab2014.htm#tab7-3a>

⁷ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] Table 7.44A – Past Year Initiation of Substance Use among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014 Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DeTTab2014/NSDUH-DeTTab2014.htm#tab7-44a>

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

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

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

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

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

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

⁹ Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] *Table 7.2A – Types of Illicit Drug Use in the Past Year among Persons Aged 12 or Older: Numbers in Thousands, 2002-2014*. Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DeTTab2014/NSDUH-DeTTab2014.htm#tab7-2a>.

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

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

¹² Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2014 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-10d10.html> on December 9, 2015.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

²¹ Compton, W.M., Jones, C.M., and Baldwin, G.T.. *Relationship Between Nonmedical Prescription Opioid Use and Heroin Use*. *N Engl J Med* 2016; 374:154-163. January 14, 2016. DOI: 10.1056/NEJMr1508490. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMr1508490>

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

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

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

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

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

The Administration's Response

President Obama's inaugural *National Drug Control Strategy*, released in May 2010, labeled opioid overdose a "growing national crisis" and laid out specific actions and goals for reducing nonmedical prescription opioid and heroin use.²⁹ In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*³⁰, which created a national framework for reducing prescription drug diversion and misuse. The *Plan* focuses on: improving education for patients and healthcare providers; supporting the expansion of state-based prescription drug monitoring programs; developing more convenient and environmentally responsible disposal methods to remove unused and unneeded medications from the home; and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

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

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

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

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

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

²⁹ Office of National Drug Control Policy, *2010 National Drug Control Strategy*, Executive Office of the President, [2010]. Available: <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf#page=49>

³⁰ Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf

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

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

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

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

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

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

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

³⁷ Maryland Department of Health and Mental Hygiene, Maryland Board of Physicians, CME Mandate (2015), available at: <http://www.mbp.state.md.us/pages/overdose.html>

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

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

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

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

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

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

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

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

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

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

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

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

⁴⁶ Presidential Memorandum -- Addressing Prescription Drug Abuse and Heroin Use (October 21, 2015). Available at:

<https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin>.

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

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

⁴⁸ Brady, JE, Wunsch, H, Dimaggio, C, Lang, BH, Giglio, J, and Li, G. Prescription drug monitoring and dispensing of prescription opioids. Public Health Reports 2014, 129 (2): 139-47. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904893/pdf/phr129000139.pdf>

⁴⁹ National Alliance of Model State Drug Laws. (2014). Status of State Prescription Drug Monitoring Programs (PDMPs). Retrieved from <http://www.namsdl.org/library/16666FCC-65BE-F4BB-A2BBAD44E1BC7021/>

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

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

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

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

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

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

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

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

⁵⁴ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2014]. Available:

<http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFHTML2013/Web/NSDUHresults2013.htm#2.16>

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

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

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

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

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

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

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

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

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

⁵⁸ Berino, K., Rosa, P., Skopee, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief*. Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm)

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

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

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

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

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

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

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

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

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

Conclusion

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

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

Mr. MICA. Thank you, and we will withhold questions until we have heard from everyone.

Let me recognize Mr. Milione and welcome him, our DEA representative.

STATEMENT OF LOU MILIONE

Mr. MILIONE. Thank you, Chairman Mica, Ranking Member Cummings, and distinguished members of the committee.

DEA views the combined prescription opioid and heroin abuse epidemic as the number-one drug threat facing the country. I appreciate the opportunity to appear before you today and talk about what we at the DEA are doing to address that threat.

Prescription opioids are walking users up to heroin's door, across that threshold, and into heroin's deadly embrace. Mexican cartels are entrenched in communities throughout our country, exploiting the prescription opioid abuse epidemic and flooding the country with high-purity, low-cost heroin. Those cartels are forming a toxic business relationship with the violent distribution cells that are slinging that dope in our communities.

What is the end result? In one year, almost 30,000 of our fellow Americans died from a prescription opioid or heroin overdose. As everyone has acknowledged, this is an unimaginable tragedy.

DEA understands that we need a balanced, holistic approach to this epidemic. We stand with our interagency partners, including those represented here today, and embrace prevention, treatment, and education as critical to our success. However, enforcement must be a key component of our overall strategy. We need to investigate and bring to justice not those suffering from opioid use disorder but those that are exploiting human frailty for profit.

Our answer to dealing with this drug threat: attack supply, reduce demand, and empower communities, DEA's 360 Strategy. There are three prongs to the strategy: law enforcement, diversion control, and community outreach. My comments today focus primarily on the Office of Diversion Control's role in that strategy, but we would be more than happy to follow up with details about Operation Rolling Thunder.

Rolling Thunder is the heroin enforcement prong of the 360 Strategy that is focused on the violent distribution cells that are pushing heroin in our communities and the Mexican cartels that are supplying the heroin that is killing so many Americans.

With 1.6 million DEA registrants, DEA diversion is uniquely positioned to assist in this fight with enforcement, education, and engagement. The vast majority of those 1.6 million registrants are law-abiding citizens. These are our practitioners, pharmacists, manufacturers and distributors working in all our communities. We investigate the very small percentage of those that are operating outside the law but yet inflict considerable harm on our country: for example, practitioners not prescribing for a legitimate medical purpose outside the usual course of professional practice; pharmacists not performing their corresponding responsibility to ensure that the prescription is valid; manufacturers and distributors not upholding the regulatory obligations to prevent diversion.

How do we do that? With our tactical diversion squads, our diversion groups, and our great Federal, state, and local counter-

parts. Our tactical diversion squads are specialized units made up of agents, diversion investigators, and intel analysts. We have 69 of them nationally. We are going to add eight, bringing our number up to 77 within the next six to nine months.

We are creating two mobile tactical diversion squads that can deploy where the need is, giving us a fluid enforcement capability.

We have almost 700 skilled diversion investigators spread across this country in our diversion groups. Both the tactical diversion squads and the diversion groups work with their respective U.S. Attorney's Office to bring criminal and/or civil charges against those registrants that are operating outside the law; and, where appropriate, they bring administrative actions, DEA's Orders to Show Cause or immediate suspension orders, potentially revoking a registrant's DEA registration.

As I said earlier, enforcement will be a key part of the overall strategy, but engaging with that large registrant community and educating them are just as critical. In the last two years, DEA diversion has conducted more than 300 events, providing education and guidance to thousands of DEA registrants and industry leaders. Since 2011, with our great partners at the National Association of Boards of Pharmacy, we have conducted more than 64 pharmacy diversion awareness conferences in 29 states and have had the privilege of interacting with almost 10,000 pharmacy employees about the risks of diversion.

Finally, we will continue engaging with our interagency partners on important initiatives, including expanding access to treatment, mandatory prescriber education, and the safe and responsible disposal of unwanted, unused prescription drugs. Early in February, a leading national chain pharmacy announced that they would place drug kiosks in 500 drugstores in 39 states and Washington, D.C. We see that as a very positive step in the right direction. We look forward to the day when those secure kiosks are so commonplace throughout our communities that people can dispose of their unwanted and unused or expired prescriptions frequently, safely, and conveniently.

DEA will also continue our national take-back initiative with national events every approximately six months. During our September 2015 take-back, from 5,202 collection sites we collected more than 370 tons of unwanted, unused prescription drugs. Our next national take-back event is April 30th, about five weeks from now.

For almost 20 years, I have had the privilege of working with the brave men and women of the DEA, along with our Federal, state, local, and foreign counterparts, investigating some of the most entrenched domestic and foreign criminal organizations threatening our country. This current drug threat, the subject of this hearing, is unlike anything I have ever seen.

We at the DEA will do whatever it takes to fight this epidemic. We will attack supply, we will work to reduce demand, we will do our best to empower communities.

I thank you for the opportunity to appear before you and look forward to answering any questions you have.

[Prepared statement of Mr. Milione follows:]



Department of Justice

STATEMENT OF

**LOUIS J. MILIONE
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION**

BEFORE THE

**COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES**

FOR A HEARING ON

THE HEROIN USE AND OPIOID ABUSE EPIDEMIC

PRESENTED

MARCH 22, 2016

**Statement of Louis J. Milione
Deputy Assistant Administrator
Drug Enforcement Administration
Before the Committee on Oversight and Government Reform
United States House of Representatives
March 22, 2016**

INTRODUCTION

Chairman Chaffetz, Ranking Member Cummings, and Members of the Committee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss our Nation's most pervasive drug issue of the day: the opioid overdose epidemic, spurred by nonmedical abuse of prescription opioids, heroin, and illicit fentanyl use. This is a problem that is worsening.¹

Drug overdoses are the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.² There were over 47,000 overdose deaths in 2014, or approximately 129 per day, over half (61%) of which involved either a prescription opioid or heroin.³ These are our family members, friends, neighbors, and colleagues.

According to the 2014 National Survey on Drug Use and Health (NSDUH), 6.5 million people over the age of 12 used psychotherapeutic drugs (i.e., pain relievers, tranquilizers, stimulants, and sedatives) for non-medical reasons during the past month. This represents 24 percent of the 27 million current illicit drug users and is second only to marijuana (22.2 million users) in terms of usage. There are more current users of psychotherapeutic drugs for non-medical reasons than current users of cocaine, heroin, and hallucinogens combined.⁴

Approximately 435,000 Americans reported past month use of heroin in 2014.⁵ The increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 914,000 in 2014 – is troubling.⁶ The misuse of controlled opioid prescription drugs (CPD) and the growing use of heroin are being reported in the United States in unprecedented numbers. According to the United Nations' body that monitors treaty compliance, the International Narcotics Control Board (INCB), the United States consumes 78 percent of the

¹ Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths - United States, 2000–2014. *Morbidity and Mortality Weekly Report*, 2016;64:1378–1382.

² Centers for Disease Control and Prevention, Web-based Injury Statistics Query and Reporting System (WISQARS) [online], (2014), available at: <http://www.cdc.gov/injury/wisqars/fatal.html>.

³ Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths - United States, 2000–2014. *Morbidity and Mortality Weekly Report*, 2016;64:1378–1382.

⁴ Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from <http://www.samhsa.gov/data/>.

⁵ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2013 and 2014. Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014.

⁶ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality,

world's oxycodone and 99 percent of the world's hydrocodone⁷, despite having only five percent of the world's population.

CONTROLLED PRESCRIPTION DRUGS (CPDs)

In 2014, over 4.3 million Americans aged 12 or older reported using prescription pain relievers non-medically within the past month. This makes nonmedical prescription opioid use more common than use of any category of illicit drug in the United States except for marijuana. Whereas the vast majority of nonmedical opioid CPD users do not go on to use heroin, this information provides valuable insight into the role that CPDs play in the opioid epidemic and underscores the need to ensure that practitioners are educated on proper prescribing of CPDs.

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the “street” cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)⁸ can be purchased for \$5 to \$7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for \$7 to \$10 per tablet on the street. Even stronger prescription drugs are sold for as much as \$1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost \$30 to \$40 per tablet on the street. The costs that ensue with greater tolerance make it difficult to purchase these drugs in order to support a developing substance use disorder, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Data from NSDUH show that chronic and frequent users are more likely than recent initiates to buy opioid drugs from a dealer.⁹ Not surprisingly, a small number of people who use prescription opioids non-medically – primarily those who are frequent nonmedical users or those with a prescription opioid use disorder – turn to heroin, a much cheaper opioid, generally \$10 per bag, which provides a similar “high” and can keep some individuals who are dependent on opioids from experiencing painful withdrawal symptoms. This cycle has been repeatedly observed by law enforcement agencies. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began using prescription opioids non-medically.¹⁰

Healthcare providers, as well as nonmedical users of CPDs are confirming this increase. According to some reporting by treatment providers, many individuals with serious opioid use

⁷ International Narcotics Control Board. March, 2015. “Report 2014: Estimated World Requirements for 2015—Statistics for 2013,” available at www.incb.org.

⁸ On October 6, 2014, DEA published a final rule in the *Federal Register* to move hydrocodone combination products from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services.

⁹ SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2012-2013. Unpublished special tabulations (March 2015).

¹⁰ U.S. Department of Justice, Drug Enforcement Administration, 2015 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2015, available at: http://www.dea.gov/divisions/hq/2015/hq052215_National_Heroin_Threat_Assessment_Summary.pdf.

disorders will use whichever drug is cheaper and/or available to them at the time.¹¹ Individuals who have switched to heroin are at high risk for unintentional overdose. Heroin purity and dosage amounts vary, and heroin is often cut with other substances (e.g. fentanyl), all of which could cause unintentional overdose because users simply cannot predict the dosage of opioid in the product they purchase on the street as heroin.¹² It should be noted as well that the same could be said of diverted or counterfeit prescription opioids purchased on the street.

Some CPD users become dependent on opioid medications originally prescribed for a legitimate medical purpose.¹³ Moreover, a Substance Abuse and Mental Health Services Administration (SAMHSA) study found that four out of five recent new heroin users had previously used prescription pain relievers non-medically (although a very small proportion (3.6%) of people who reported nonmedical use of prescription pain relievers had initiated heroin use within five years of initiating nonmedical use of pain relievers).¹⁴ The reasons an individual may shift from one opiate to another vary, but today's heroin is high in purity, and less expensive and often easier to obtain than illegal CPDs. High-purity heroin can be smoked or snorted, thereby circumventing a barrier to entry (needle use) and avoiding the stigma associated with injection. However, many who smoke or snort are vulnerable to eventually injecting. Heroin users today tend to be younger and more ethnically and geographically diverse than ever before.¹⁵

Overdose deaths involving heroin are increasing at an alarming rate, having almost tripled since 2010. Today's heroin at the retail level costs less and is more potent than the heroin that DEA encountered two decades ago. It comes predominantly across the Southwest Border (SWB) and is produced with greater sophistication from powerful transnational criminal organizations (TCOs) like the Sinaloa Cartel. These Mexican-based TCOs are extremely dangerous and violent and continue to be the principal suppliers of heroin to the United States.

DEA RESPONSE TO THE NONMEDICAL USE OF CPDs

Nonmedical drug use cannot be addressed through law enforcement action alone. Any successful drug control strategy must be balanced and comprehensive, including a focus on both public health and public safety. It requires a coordinated effort by DEA together with our federal, state, and local government partners as well as private stakeholders.

¹¹ U.S. Department of Justice, Drug Enforcement Administration, 2014 National Drug Threat Assessment Summary, November, 2014.

¹² Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, *Int J Drug Policy*, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: *Int J Drug Policy*, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi: 10.1016/j.drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D, "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, *Int J Drug Policy*, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

¹³ Pain, 2015 Apr; 156(4):569-76, doi: 10.1097/01.j.pain.0000460357.01998.f1. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Vowles KE1, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN.

¹⁴ 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, and [August 2013], available at: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>.

¹⁵ Cicero, T., Ellis, M., Surratt, H, Kurtz, S. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, July, 2014.

The Office of National Drug Control Policy's (ONDCP) 2011 Prescription Drug Abuse Prevention Plan, together with the 2014 National Drug Control Strategy and initiatives such as SAMHSA's Drug Free Communities program, comprise a multi-pronged approach that includes education, tracking and monitoring, proper medicine disposal, and enforcement, which represents a science-based and practical way to address this national epidemic.

Education of the Drug Supply Chain:

DEA provides education and guidance to registrants, professional associations, and industry organizations on current pharmaceutical diversion and nonmedical use, new and existing programs, policies, legislation, and regulations. In fiscal year (FY) 2014, DEA conducted over 150 such events. In FY 2015, DEA conducted 221 events, and for the first quarter of FY2016, DEA conducted 42 outreach and public education events raising the awareness of prescription drug abuse and the relationship to heroin, which reached thousands of DEA registrants, professional students, and the general public.

DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conferences address pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of these conferences is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. In FY2015, DEA hosted 14 PDACs in seven states. So far in FY2016, DEA has hosted eight PDACS in four different states. Ten additional PDACS are planned in five more states during this fiscal year. Since DEA began hosting the PDACS, over 10,000 pharmacy employees have been trained.

DEA has also routinely hosted its annual Manufacturers/Importers/Exporters Conference, with its most recent event culminating on September 23-24, 2015. This conference provides a forum to present federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. This event was attended by approximately 300 individuals representing this subset of DEA registrant community.

DEA also established its Distributor Initiative Program in 2005 to educate this registrant population on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA educates distributors about their obligations under the Controlled Substances Act (CSA), as well as provides registrants with current trends and "red flags" that might indicate that

an order is suspicious. The Distributor Conference was recently held on April 15-16, 2015, and consisted of approximately 265 industry leaders from over 130 companies.

DEA will continue to engage with and educate industry. On February 29, 2016, DEA's Office of Diversion Control hosted a meeting with the leadership of drug supply chain trade associations to discuss areas of mutual concern.

Monitoring

Prescription drug monitoring programs (PDMPs) are typically State-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMPs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other diversion. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users).

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge, as many drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous pain clinics and physicians.

We and our federal partners are working to address these problems. SAMHSA funds grants to improve interoperability between PDMPs and Electronic Health Record (EHR) technology and provide real-time provider access. ONDCP and the Bureau of Justice Assistance (BJA) also offer assistance for interstate and state-tribal PDMP linkages. We also understand that CDC supports work in 16 states to enhance and maximize PDMPs as public health and clinical tools in its *Prevention for States* program. Further, the Alliance of States with Prescription Drug Monitoring Programs, Brandeis University's PDMP Center of Excellence, and the Indian Health Service are also partnering to improve interoperability between IHS, its pharmacies and PDMPs. The National Association of Boards of Pharmacy (NABP) hosts NABP Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of PDMP data across state lines to authorized users. The program allows users of participating PMPs to securely exchange prescription data between certain states. As of February 2016, 37 states have executed MOUs to participate in NABP's InterConnect program, and 31 of these states are currently live.

These programs, however, are only as good as the data that is in each system and the willingness of practitioners and pharmacists to use such systems on a consistent basis. At least Kentucky,¹⁶ New Jersey,¹⁷ New Mexico,¹⁸ New York,¹⁹ Oklahoma,²⁰ and Tennessee²¹ require all

¹⁶ Kentucky 201 KAR 9:260, 2012. Available at <http://www.lrc.ky.gov/kar/201/009/260.htm>

¹⁷ P.L. 2015, c.74 (N.J. 2015), available at http://www.nileg.state.nj.us/2014/Bills/AL15/74_PDF

controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance.²² DEA encourages all practitioners and pharmacists to use their state PDMP program.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of nonmedical use of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet, as 50.5% of persons aged 12 or older who used pain relievers non-medically in the past year got the pain relievers from a friend or relative for free²³, and provides a safe and legal method for the public to dispose of unused or expired CPDs.

Since 2010 DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on September 26, 2015. As a result of all ten National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of 5.6 million pounds (2,789 tons) of medications from circulation. The next National Drug Take Back Day is scheduled for April 30, 2016.

Enforcement: Tactical Diversion Squads

DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and practitioners and pharmacists who knowingly divert controlled substance pharmaceuticals). Between March 2011 and March 2014, DEA increased the number of operational TDSs from 37 to 69.

¹⁸ 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

¹⁹ New York 3343-A. 2012. Available at <http://law.justia.com/codes/new-york/2012/pbh/article-33/title-4/3343-a>

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

²¹ Tennessee 2253. 53-10-310. 2012. Available at <http://www.tn.gov/sos/acts/107/pub/pc0880.pdf>

²² PDMP Center of Excellence, Brandeis University. <http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>, retrieved September 30, 2015.

²³ Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health, Table 6.47B, Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older, by Age Group: Percentages, Annual Averages Based on 2011-2012 and 2013-2014.

Enforcement: Diversion Groups

When DEA was established in 1973, DEA regulated 480,000 registrants. Today, DEA regulates more than 1.6 million registrants. The expansion of the TDS groups has allowed Diversion Groups to concentrate on the regulatory aspects of enforcing the CSA. DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; importers; exporters; and narcotic treatment programs. This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the CSA and its implementing regulations.

HEROIN AVAILABILITY TO THE U.S. MARKET

There are four major heroin-producing areas in the world, but heroin bound for the U.S. market originates predominantly from Mexico and, to a lesser extent, Colombia. The heroin market in the United States has been historically divided along the Mississippi River, with western markets using Mexican black tar and brown powder heroin, and eastern markets using white powder which, over the last two decades has been sourced primarily from Colombia. The largest, most lucrative heroin markets in the United States are the white powder markets in major eastern cities: New York City and the surrounding metropolitan areas, Philadelphia, Chicago, Boston and its surrounding cities, Washington, D.C., and Baltimore. With the growing number of individuals with an opioid use disorder in the United States, Mexican TCOs have seized upon a business opportunity to increase their profits. Mexican TCOs are now competing for the East Coast and Mid-Atlantic markets by introducing Mexican brown/black tar heroin as well as by developing new techniques to produce highly refined white powder heroin.

DEA has also seen a 62 percent increase in poppy cultivation in Mexico between 2013 and 2014, primarily in the State of Guerrero and the Mexican “Golden Triangle” which includes the states of Chihuahua, Sinaloa, and Durango. The increased cultivation results in a corresponding increase in heroin production and trafficking from Mexico to the United States, and impacts both of our nations by supporting the escalation of heroin use in the United States, as well as the instability and violence associated with drug trafficking in Mexico.

The majority of Mexican and Colombian heroin bound for the United States is smuggled into the United States via the SWB, and heroin seizures at the border have more than doubled, from 1,016 kilograms in 2010 to 2,188 kilograms in 2014.²⁴ During this time, the average seizure at the Border also increased from 2.0 kilograms to 3.5 kilograms. Most heroin smuggled across the border is transported in privately-owned vehicles, usually through California, as well as through south Texas. In 2014, more than half of U.S. Customs and Border Protection (CBP) heroin seizures at the Southwest Border were seized in the southern California corridors of San Diego and El Centro. The distribution cells and the Mexican and South American traffickers who supply them are the main sources of heroin in the United States today. The threat of these

²⁴ Drug Enforcement Administration, Unclassified Summary, 2015 National Drug Threat Assessment, Pg. 35, available at: <http://www.dea.gov/resource-center/dir-ndta-unclass.pdf>.

organizations is magnified by the high level of violence associated with their attempts to control and expand drug distribution operations.

DEA has become increasingly alarmed over the addition of fentanyl into heroin sold on the streets as well as the use of fentanyl analogues such as acetyl fentanyl. The more potent opioids like fentanyl²⁵ present a serious risk of overdose death for a user. In addition, this drug can be absorbed by the skin or inhaled, which makes it particularly dangerous for law enforcement, public safety, or health care personnel who encounter the substance during the course of their daily operations. On March 18, 2015, DEA issued a nationwide alert to all U.S. law enforcement officials about the dangers of illicit fentanyl and fentanyl analogues and related compounds. In addition, due to a recent spike in overdose deaths related to the use of acetyl fentanyl, on July 17, 2015, DEA used its emergency scheduling authority to place acetyl fentanyl in Schedule I of the CSA.

DEA RESPONSE TO THE HEROIN THREAT

Additional Resources in Fiscal Year 2017

DEA plays an important part in the U.S. government's drug control strategy that includes enforcement, treatment, and prevention. While there are complex issues affecting spikes in heroin use and overdoses, including prescription drug abuse, the same significant poly-drug trafficking organizations responsible for other illicit drug threats are also responsible for the vast majority of the heroin supply. Additionally, drug trafficking has a proven linkage to gangs and other violent criminal organizations. Funding includes \$12.5 million and 42 positions, including 32 special agents, to create new enforcement groups in DEA domestic field divisions.

Heroin Task Force Program

As directed by Congress, the Department of Justice joined with ONDCP to convene an interagency task force to confront the growing use and trafficking of heroin in America. DEA and more than 28 Federal agencies and their components participated in this initiative. The task force provided its Report to Congress on December 31, 2015.

International Enforcement: Sensitive Investigative Units

DEA's SIU program, nine of which are in the Western Hemisphere, helps build effective and vetted host nation units capable of conducting complex investigations targeting major TCOs. DEA currently mentors and supports 13 SIUs, which are staffed by over 900 foreign counterparts. The success of this program has unquestionably enhanced DEA's ability to fight drug trafficking on a global scale.

²⁵ Centers for Disease Control, Emergency Response Safety and Health Database, FENTANYL: Incapacitating Agent, http://www.cdc.gov/niosh/ersbdb/emergencyresponsecard_29750022.html, accessed March 19, 2015; U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Drug & Chemical Evaluation Section, Fentanyl, March 2015.

International Enforcement: Bilateral Investigations Units

Bilateral Investigations Units (BIUs) are one of DEA's most important tools for targeting, disrupting, and dismantling significant TCOs. The BIUs have used extraterritorial authorities to infiltrate, indict, arrest, and convict previously "untouchable" TCO leaders involved in drug trafficking.

DEA'S 360 STRATEGY

DEA is rolling out the 360 Strategy to address the opioid, heroin, and violent crime crisis. The strategy leverages existing federal, state, and local partnerships to address the problem on three different fronts: law enforcement, diversion control, and community relations. The strategy is founded upon our continued enforcement activities directed at the violent street gangs responsible for feeding the heroin and prescription drug abuse epidemic in our communities.

While law enforcement plays a central role in the 360 Strategy, enforcement actions alone are not enough to make lasting changes in our communities. The 360 Strategy, therefore, also focuses on preventing diversion by providing education and training within the pharmaceutical community and to pursue those practitioners who are operating outside of the law. The final component of the strategy is a community effort designed to maximize all available resources to help communities turn around the recurring problems that have historically allowed the drug and violent crime problems to resurface after enforcement operations. Following is a summary of the three key facets of the 360 Strategy.

Enforcement: A commitment to stopping violence associated with drug trafficking

The enforcement component of the strategy is built around Rolling Thunder, a DEA-lead enforcement initiative, which targets the link between the cartels and violent gangs – these two elements have become the "New Face of Violent Crime." To execute the enforcement, DEA will rely upon all of its resources, including its Task Force Officers from local and state partners in the area.

The 360 Strategy will address the increased violence and drug trafficking on American streets. In the past, DEA would put its emphasis on working toward the Mexico-based organizations pushing drugs into the United States. As part of Rolling Thunder, DEA Agents will shut down the violent street gangs which regulate the drug trafficking business through the barrel of a gun.

Diversion: Enlisting DEA's Registrant Population in the Fight against Opioid Abuse

As stated above, the nonmedical use of prescription opioids is a strong risk factor for heroin use, and the 1.6 million registrants involved in the manufacture, wholesale distribution, and prescribing, are partners in our efforts to reduce opioid abuse.

DEA will engage with industry, practitioners, and government health organizations to facilitate an honest and frank discussion about the CPD abuse contributing to the current heroin epidemic. Additionally, DEA is studying ways, in collaboration with public health partners, to

improve access to information that will help identify the nature of the drug abuse problem plaguing a particular area.

Further, DEA will remain vigilant in identifying and pursuing prescribers and other registrants operating outside of the law. This process will be enhanced locally through the use of TDSs, which can mobilize to address regional or local issues, and additional diversion investigators.

Community: Leaving something lasting and positive in the communities we serve

After an enforcement operation targeting violent criminals, there's an opportunity for a prepared community to take advantage of the space and time created to better itself and prevent new traffickers from moving in.

This program enables communities to achieve long-term solutions by addressing not only the immediate drug-trafficking problems, but also the underlying conditions that allow drug trafficking, drug use and related violence to flourish. DEA will not only work with federal, state and local agencies to bring greater enforcement resources to bear, but also marshal community groups and their resources to identify local drug abuse problems, barriers to dealing with those problems and treatment solutions. DEA will partner with other federal agencies and sources of expertise and funding to broaden the resources available to the community.

The 360 Strategy is being implemented in four cities—West Memphis, Arkansas; St. Louis, Missouri; Pittsburgh, Pennsylvania; and, Milwaukee, Wisconsin—allowing us to gauge the success of the strategy, and to adjust the strategy as necessary in order to prepare for implementation nationwide. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

CONCLUSION

The supply of heroin entering the United States feeds the increasing user demand for opioids. DEA will continue to address this threat by attacking the crime and violence perpetrated by the Mexican-based TCOs which have brought tremendous harm to our communities. DEA's 360 strategy will address the opioid and heroin epidemic with a multi-faceted approach, by stopping the violence associated with drug trafficking, and enlisting DEA's registrant community in the fight against opioid abuse. Additionally, DEA's Office of Diversion Control will work with DEA registrant community to address the prescription opioid side of this problem, and DEA will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for violating the Controlled Substances Act. DEA will continue to work on the recommendations from the Heroin Task Force by developing a comprehensive strategy that will combine education, law enforcement, treatment and recovery, and a coordinated community response.

Mr. MICA. Thank you, and we will get to questions after all of our witnesses.

Let me recognize Ms. Enomoto. She is the Deputy Administrator for the Substance Abuse and Mental Health Services Administration at the Department of Health and Human Services.

Welcome, and you are recognized.

STATEMENT OF KANA ENOMOTO

Ms. ENOMOTO. Thank you. Good morning, Acting Chairman Mica. Good morning, Ranking Member Cummings and members of the committee. My name is Kana Enomoto, and I am SAMHSA's Principal Deputy Administrator, and I am honored to have been delegated the duties and authorities of the SAMHSA Administrator by Secretary Burwell.

Many thanks to all of you for your leadership to raise awareness and catalyze action on the nation's opioid crisis. As you have noted, this truly is a matter of life or death.

I know prescription drugs, heroin, and illicit fentanyl have had devastating consequences in many of your districts. I know this because SAMHSA partners with leaders in your communities as they implement life-saving programs for individuals with or at risk for opioid use disorders.

For example, the State of Maryland and the City of Baltimore are addressing high rates of opioid-related emergency room visits and utilizing peers to recruit patients into medication-assisted treatment. In Florida, SAMHSA's Prescription Drug Monitoring Program Interoperability Grant helped get critical data to the front lines of the fight to prevent prescription drug misuse. In Wyoming, we have seen fantastic progress as the state has implemented our Strategy Prevention Framework using data and science to focus their efforts. And at the Odyssey House in Utah, with SAMHSA's help, it is increasing access to family-based, family-centered residential treatment for pregnant and parenting women with substance use disorders. Healthy babies are being born, and progress is being made.

And while treatment admissions are increasing, overdose deaths have reached record numbers, and not enough people are getting treatment. As a nation, we will not stem the rising tide of this public health crisis if only two out of ten people with an opioid use disorder have access to the treatment they need. It wouldn't work for diabetes, it wouldn't work for HIV, and it will not work for addiction. We must join together to ensure that every person with an opioid use disorder who seeks treatment finds an open door.

Toward this end, SAMHSA is proud to support the President's National Drug Control Strategy and Secretary Burwell's Opioid Initiative. In HHS, the Secretary's initiative focuses on three high-impact areas: changing prescribing behavior, increasing access to naloxone, and expanding the use of medication-assisted treatment and recovery.

It is simple: to prevent prescription opioid misuse, we need to reduce the number of pills in people's medicine cabinets. SAMHSA will encourage the use of CDC's guidelines for prescribing opioids in order to chart a safer, more effective course to management of chronic pain.

We know the vast majority of physicians and other prescribers are dedicated, well-trained professionals committed to their patients' good health. We must give them the tools they need to deliver high-quality, safe and effective care.

Since 2007, SAMHSA has provided continuing education to over 72,000 primary care physicians, dentists, and other health care professionals. We also reach local communities through Drug-Free Community Grants we administer together with ONDCP. These coalitions do yeoman's work to create environments that promote health and prevent drug use, including the misuse of prescription drugs, heroin, and illicit fentanyl.

The second aim of the Secretary's initiative is increasing access to naloxone. As you have noted, naloxone can reverse a potentially fatal opioid overdose, but it only works if it is there when you need it. In SAMHSA's Overdose Prevention Course for Prescribers and Pharmacists, one of the targeted strategies we promote is co-prescribing of naloxone with opioid analgesics, particularly for patients with high risk of overdose. We also let states know that they may use their SAMHSA block grant funds to purchase and disseminate naloxone, as well as for training and education on its use, and soon we will be issuing a funding announcement for states to purchase naloxone and equip and train first responders. We appreciate Congress' strong support in this area.

The third area of the Secretary's opioid initiative is expanding the use of medication-assisted treatment. Research tells us that medications, along with behavioral therapies and recovery supports, are important components of an evidence-based treatment plan. However, resources are limited, and MAT remains significantly underutilized.

As Director Botticelli noted, the President's Fiscal Year 2017 budget requests \$1 billion in new mandatory funding which would focus on the continuum of prevention, treatment, and recovery services, expanding the use of MAT, expanding the use of telehealth, and building the substance abuse treatment workforce. The initiative also includes, importantly, \$30 million in new mandatory funding to evaluate the effectiveness of medication-assisted treatment programs under different real-world situations.

On the discretionary side, SAMHSA proposes to maintain and grow investments made by Congress in 2015 and 2016. We are providing funding for 23 more states to expand treatment capacity for MAT, and we are preserving the behavioral health safety net by maintaining increases to the Substance Abuse Prevention and Treatment Block Grant.

We have also worked with ONDCP and DOJ to clarify and enhance the connection between MAT and the criminal justice system. Drug courts are the most successful criminal justice response to addiction in our nation's history. This year we will prioritize treatment that is less susceptible to abuse and diversion and expand our technical assistance to ensure that evidence-based practices are fully implemented.

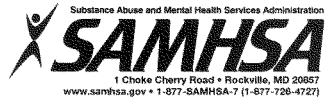
With all this new care, who is there to provide it? We must ensure that the substance use workforce is sufficient to meet growing demand. As such, we are requesting \$10 million for a buprenorphine prescribing authority demonstration to test the safe-

ty and effectiveness of expanding buprenorphine prescribing to nurses and physician assistants, and the Administration has requested \$20 million for our colleagues at the Health Resources and Services Administration to grow the addictions workforce via the National Health Service Corps.

Finally, SAMHSA is proposing a new regulation to increase the patient limit for physicians who have a waiver to prescribe buprenorphine.

Members of the committee, thank you for convening this important hearing. I look forward to working with you to ensure that we are using our investments strategically, responsibly, and effectively to deliver the greatest possible impact for the American people.

[Prepared statement of Ms. Enomoto follows:]



Testimony Before the
U.S. House Committee on Oversight and Government Reform
Hearing to Examine the Current Epidemic of Heroin and Opioid Use in the
United States and the Federal Government's Response
March 22, 2016

Statement of Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Good morning Chairman Chaffetz, Ranking Member Cummings, and distinguished members of the Committee. My name is Kana Enomoto, and I am the Principal Deputy Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am pleased to be here—along with my colleagues from the Office of National Drug Control Policy (ONDCP), and the Drug Enforcement Administration (DEA)—to discuss the current public health crisis related to opioids.

The problems of prescription opioid misuse, heroin and fentanyl use, and substance use disorders are complex and require epidemiological surveillance, prevention, interventions, policy changes and further research. No organization or agency can address these problems alone; a coordinated response is required. The Federal Government, medical and other health partners, public health officials, state governments, and community organizations all are needed to implement educational outreach and intervention strategies targeted to a range of discrete audiences, including physicians, pharmacists, patients, educators, parents, students, adults at high risk, older adults, and many others. Outreach to prescribers, as well as pharmacists, on proper prescribing and dispensing of opioid pharmacotherapies needs to be complemented by education, screening, intervention, and treatment services for those who use heroin and/or prescription opioids non-medically.

SAMHSA

SAMHSA's mission is to reduce the impact of substance misuse and mental illness on America's communities. SAMHSA was established in 1992 and directed by the Congress to target substance use prevention and treatment and mental health services to people most in need of them and to enhance the delivery of behavioral health services to all. Substance misuse, substance use disorders, poor emotional health, and mental illnesses take a toll on individuals, families, and communities. These conditions cost lives and productivity, and strain families and resources in the same way as untreated physical illnesses, yet the majority of those who need treatment do not receive it. SAMHSA strives to close this gap by raising awareness that:

- Behavioral health is essential to health;
- Prevention works;
- Treatment is effective; and
- People recover.

SAMHSA is working with its partners across the Administration to address the current opioid public health crisis. SAMHSA is participating in the cross-departmental and intra-departmental workgroups to ensure coordination of policy and programs. SAMHSA also supported the Department of Justice's National Heroin Task Force, as well as ONDCP's four-part Prescription Drug Abuse Prevention Plan and is an active participant in the Interagency Workgroup on Prescription Drug Abuse.

SAMHSA also works across HHS through the Behavioral Health Coordinating Council's Prescription Drug Abuse Subcommittee. As a result, SAMHSA has partnerships with the Centers for Disease Control and Prevention (CDC), the Food and Drug

Administration (FDA), the National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services (CMS), the Office of the National Coordinator for Health Information Technology (ONC), the Office of the Assistant Secretary for Health (OASH), including the Office of the Surgeon General (SG), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) working to prevent and treat the non-medical use of prescription drugs and heroin.

As you may know, in October, the Surgeon General announced that he would be developing a report on substance use, addiction and health. SAMHSA is providing technical assistance with the development of this report and we look forward to its release.

SAMHSA's Role in the Secretary's Evidence-Based Opioid Initiative

SAMHSA is a key player in Secretary Burwell's initiative to address opioid misuse. This initiative focuses on three specific areas targeted for their potential to produce the most impact:

- (1) Improving opioid prescribing practices;
- (2) Increasing the use of naloxone; and
- (3) Expanding use of medication-assisted treatment (MAT) and recovery support services for individuals with an opioid use disorder.

According to the 2014 National Survey on Drug Use and Health (NSDUH), which SAMHSA conducts annually, 4.3 million individuals (aged 12 and older) reported non-medical use of prescription pain relievers during the past month and 435,000 reported using heroin.¹ That equals 1.6 percent of the population non-medically using prescription pain relievers and 0.2 percent of the population using heroin. Although reports of heroin use are significantly lower than reported prescription opioid non-medical use, the numbers have been increasing fairly steadily since 2007. In fact, reported heroin use more than doubled in seven years from 161,000 individuals in 2007 to 435,000 in 2014.

Of the individuals admitted to treatment in 2013, 18.8 percent of admissions were for heroin. Another 9.2 percent of admissions were for other opioids.² What these data do not fully reflect is the pain felt at losing a job, a home, or a cherished family member. Opioid and heroin use destabilizes families, disrupts the health care system, and imposes enormous financial and human costs on American society.

SAMHSA's Opioid Proposals in the President's FY17 Budget

Addressing the crisis of opioid overdose from prescription pain relievers, heroin, and fentanyl is a major priority for SAMHSA. The President's Budget recognizes the need for immediate action

¹ Center for Behavioral Health Statistics and Quality. (2015). *Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health* (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from <http://www.samhsa.gov/data/>

² Center for Behavioral Health Statistics and Quality. (2015). *Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health* (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from <http://www.samhsa.gov/data/>

and proposes to address the opioid epidemic with a \$1 billion two-year investment in new mandatory funding. This investment of mandatory funds makes a bold commitment to build the addictions workforce and bolster the continuum of services for prevention, treatment, and recovery.

Of the \$1 billion in new mandatory funding, SAMHSA proposes \$920 million over two years to support cooperative agreements with states to expand access to treatment for opioid use disorders. In each of FY 2017 and 2018, SAMHSA would provide \$460 million in new mandatory funding toward State Targeted Response Cooperative Agreements for states to help individuals seek and successfully complete treatment and sustain recovery from opioid use disorders. Evidence-based strategies that states might consider include training and certifying opioid use disorder treatment providers, supporting delivery of MAT, employing telehealth strategies, implementing prevention efforts, developing health information technology systems. Program goals include: reducing the cost of care, expanding access, engaging patients, and addressing the negative attitudes associated with accessing opioid use disorder treatment.

Another component of the Administration's two-year initiative includes \$30 million in new mandatory funding for SAMHSA to implement Cohort Monitoring and Evaluation of MAT, to evaluate the effectiveness of treatment programs employing medication-assisted treatment under real-world conditions. This program will help identify opportunities to improve treatment for patients with opioid use disorders.

In addition to the new mandatory investments, SAMHSA continues and expands existing strategies to address opioid use disorders. SAMHSA is requesting \$50.1 million to double the size of the Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA) program. The funding will support 23 new MAT-PDOA state grants in providing FDA-approved MAT in conjunction with psychosocial interventions to those living with opioid use disorders.

To help further expand access to treatment, SAMHSA's Budget Request includes a \$10 million pilot project, the Buprenorphine-Prescribing Authority Demonstration, aimed at increasing the types of practitioners able to prescribe buprenorphine for opioid use disorder treatment, where allowed by state law. This demonstration will test the safety and effectiveness of allowing prescribing buprenorphine by non-physician advance practice providers.

In conjunction with these treatment efforts, SAMHSA is also proposing continued investments to prevent the misuse and overdose deaths related to prescription drugs, heroin, and fentanyl. The FY2017 Budget maintains investments in the Prevention of Prescription Drug and Opioid Overdose Related Deaths program at \$12 million. This program focuses on overdose death prevention strategies such as naloxone distribution and education of first responders on its use along with other prevention strategies. Additionally, SAMHSA requests continued support (\$10 million) of the Strategic Prevention Framework-Rx program which enables states to enhance, implement, and evaluate strategies to prevent prescription drug misuse. These continued and expanded efforts build upon SAMHSA's numerous activities geared toward preventing prescription drug and opioid misuse and treating opioid use disorders, including: courses for healthcare professionals on prescribing opioids for pain, prescription drug monitoring program

interoperability enhancement, development and implementation of the Opioid Overdose Prevention Toolkit, and clarification on the allowable use of SABG funds to support equipping first responders with naloxone.

SAMHSA's Ongoing Work to Address the Opioids Epidemic

Improving Prescriber Practices

SAMHSA understands the importance of modifying prescribing behavior and providing prescribers with the information and the tools that are needed to appropriately treat patients with chronic pain.

Since 2007, over 72,000 prescribing primary care physicians and other healthcare professionals have received continuing education credits from SAMHSA's courses on prescribing opioids for chronic pain. This technical assistance is provided through SAMHSA's Providers' Clinical Support System for Opioid Therapies, a free national training and mentoring network that provides clinical support to physicians, dentists, and other medical professionals in the appropriate use of opioids for the treatment of chronic pain and screening and treating opioid use disorder.

SAMHSA has also addressed the issue of prescribing practices through various efforts related to increasing Prescription Drug Monitoring Program (PDMP) interoperability among states and intra-operability among the PDMP, electronic health records (EHR), health information exchanges and pharmacies. The Enhancing Access to PMDPs Project was funded by SAMHSA and managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. SAMHSA also funded the PDMP EHR Integration and Interoperability Cooperative Agreement program in Fiscal Year (FY) 2012 and the Electronic Health Record and PDMP Data Integration Cooperative Agreement in FY 2013. These programs bring funding directly to states to complete integration projects.

The Congress recently provided the additional funding SAMHSA requested for opioid misuse prevention that will allow PDMPs to be utilized to target localities where states should focus their prevention efforts. In FY 2016, the Congress appropriated \$10 million for a new initiative, the "Strategic Prevention Framework Rx" (SPF Rx), which will allow states to enhance the use of data from PDMPs by identifying communities by geography and high-risk populations (e.g., age group), including those in need of prevention programs, connect patients to treatment resources, and complement CDC's Prescription Drug Overdose: Prevention for States program, which has a component that focuses on using PDMP data to inform the prescribing behaviors of practitioners.

SAMHSA expects grantees to continue to use the Strategic Prevention Framework (SPF) process at both the State/tribal and community levels to meet the goals of the SPF Partnerships for Success (PFS) Program. There are five steps in this process: (1) assess needs; (2) build capacity; (3) plan; (4) implement; and (5) evaluate. Using the SPF process is critical to ensuring that states/tribes and their communities work together to use data driven decision making processes to develop effective prevention strategies and sustainable prevention infrastructures. The SPF PFS grantees are using these funds to target two priorities:

(1) underage drinking among persons aged 12-20; and (2) prescription drug misuse among persons aged 12-25. At their discretion, states/tribes may also use their SPF PFS funds to target an additional data driven priority (e.g., heroin, marijuana use). States and tribes developed an approach to funding communities of high need that ensures all funded communities will receive ongoing guidance and support from the state/tribe, including technical assistance and training for the duration of the SPF PFS project.

Another core aspect of the Secretary's initiative is to provide guidance on opioid prescribing practices focusing on inappropriate or excessive prescribing. Recently, CDC released the *Guideline for Prescribing Opioids for Chronic Pain*, to educate prescribers on the appropriate prescribing of opioids to improve pain management and patient safety. SAMHSA supports CDC in this effort and will help disseminate and encourage uptake of the new guideline.

Opioid Overdose Prevention – Expanding the Use of Naloxone

SAMHSA is also working to carry out a significant portion of the Opioid Initiative's second priority area – preventing opioid overdoses by expanding the use and distribution of naloxone. When administered in a timely manner, naloxone rapidly restores breathing to a victim in the throes of an opioid overdose. Because police are often the first on the scene of an overdose, local law enforcement agencies can train their personnel on overdose prevention and equip them with naloxone as a means of improving response.

In 2014, SAMHSA clarified that at the state's discretion its Substance Abuse Prevention and Treatment Block Grant (SABG) funds may be used to support first-responder naloxone initiatives. For example, SABG primary prevention set-aside funds may be utilized to support overdose prevention education and training. Additionally, SABG funds other than primary prevention set-aside funds may be used to purchase naloxone and materials to assemble overdose kits as well as to cover the dissemination of such kits. However, SAMHSA encourages public and private insurers to pay for this medication for those at risk or for those living with people at risk.

SAMHSA also published an Opioid Overdose Prevention Toolkit to educate individuals, families, first responders, prescribing providers, persons in recovery from substance use disorders (SUD), and community members about steps to take to prevent opioid overdose and respond to overdoses (including the use of naloxone). The toolkit is the most downloaded document on the SAMHSA website, and SAMHSA continues to promote its availability through various social media outlets to reach a wide range of populations. SAMHSA also offers a naloxone and overdose prevention course for prescribers and pharmacists.

The Congress provided SAMHSA an additional \$12 million in FY 2016 to initiate a Prevention of Prescription Drug/Opioid Overdose-Related Deaths grant program which will provide funds to states for the purchase of naloxone and for training first responders in communities of high need.

Expanding MAT and Recovery Services

MAT is an evidence-based approach which combines behavioral therapy with medications to treat SUDs, including opioid use disorders. Research shows that medications are effective for decreasing opioid craving and withdrawal symptoms, blocking euphoria if relapse occurs, and augmenting the effect of counseling.³

SAMHSA has a key role in ensuring access to MAT for opioid use disorders and last year, \$12 million was provided to SAMHSA for new grants to increase capacity and provide accessible, effective, comprehensive, coordinated care, and evidence-based MAT and recovery support services to individuals with opioid use disorders. In FY 2015, the program supported grants in 11 states (including Maryland, Kentucky, Massachusetts, and Wyoming) at \$1.0 million for each of three years. In addition, SAMHSA used \$1.0 million to support a contract to provide technical assistance to new grantees.

In FY 2016, the Congress appropriated \$25 million for MAT-PDOA, an increase of \$13 million over FY 2015. The FY 2016 funding will increase the number of states receiving funding from 11 to 22, and will serve an additional 24 high-risk communities. This increased investment in the fight against opioid and heroin use disorders is similar to provisions in the Comprehensive Addiction and Recovery Act of 2016, introduced by Senators Whitehouse and Portman in the Senate, and by Representatives Sensenbrenner and Tim Ryan in the House, which recently passed the Senate 94-1.

The President's 2017 budget includes \$1 billion in mandatory funding to expand access to treatment. It also proposes more than \$90 million in additional discretionary funds that will help the federal government strengthen state-level programs to prevent addiction and treat residents. We look forward to working with Congress to make the necessary new investments to tackle this crisis.

A number of other SAMHSA programs enhance access to opioid use disorder treatment, including MAT. Through the Pregnant and Postpartum Women's (PPW) initiative, SAMHSA encourages grantees to accept pregnant women with opioid use disorders into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering MAT onsite to the women admitted to their programs due to an opioid use disorder. As a result, pregnant women recovering from opioid use disorders are remaining in treatment longer, resulting in healthier births.⁴

³ Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Methadone: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2; and Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Buprenorphine: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2. & Kraus et al., 2011; NIDA, 2012.

⁴ Substance Abuse and Mental Health Services Administration (2014) *Preliminary Cross-site Data Analysis*

SAMHSA has also worked with ONDCP and the Department of Justice (DOJ) to expand access to MAT for justice-involved individuals with opioid use disorders by adding language to our drug court grant applications ensuring clinically beneficial MAT with FDA-approved medications is not denied or restricted. However, a judge retains judicial discretion to mitigate/reduce the risk of misuse or diversion of these medications. These Drug Court program grantees are encouraged to use up to 20 percent of their grant awards for MAT.

SAMHSA also funds the Providers' Clinical Support System for Medication Assisted Treatment which provides technical assistance on proper dispensing and prescribing of FDA-approved medications for opioid use disorders. Recognizing that there is a need to further educate providers regarding the use of injectable extended-release naltrexone in addition to the more heavily regulated opioid agonist therapies, methadone and buprenorphine, SAMHSA has developed a wide variety of guidelines. These include "Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorders: A Brief Guide" released in January 2015. SAMHSA also plans to convene a meeting on the use of opioid antagonist therapies, like naltrexone, in May to bring together researchers, clinicians, and others specifically to review the literature and clinical experiences with naltrexone.

SAMHSA also has primary responsibility for regulating Opioid Treatment Programs (OTPs). OTPs provide all three FDA-approved opioid use disorder medications (methadone, buprenorphine and naltrexone) and counseling services for opioid use disorders directly to their respective patients. OTPs must maintain certification with SAMHSA in order to operate. SAMHSA cooperates with state agencies, the Drug Enforcement Administration (DEA) and approved accrediting organizations to accomplish this. Currently there are 1,402 OTPs in operation, with an additional 51 pending SAMHSA certification.

Consistent with the Controlled Substances Act, as amended by the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians wishing to treat opioid use disorders with buprenorphine in a practice setting not subject to OTP regulations, such as a private practice or non-OTP treatment program, must submit a notice of intent to SAMHSA. Initially physicians in these settings are restricted to treating a maximum of 30 patients at a time. After one year of experience, physicians desiring to increase their patient limit to 100 may submit a second notification to SAMHSA of the need and intent to treat up to 100 patients. SAMHSA coordinates processing of these notifications with DEA. Of the approximately 1,189,000 physicians registered with DEA to prescribe controlled substances, there are currently 32,243 physicians with a waiver to prescribe buprenorphine for opioid dependence.⁵ Of these, 10,473 are authorized to treat up to 100 patients.

SAMHSA is working to find other ways to expand access to MAT. On September 17th, 2015, Secretary Burwell announced that the Department would be drafting a regulation to increase the highest patient limit for physicians that have a waiver to prescribe buprenorphine. As the Secretary noted, in drafting the regulation the Department's goals are to increase access to MAT, ensure the provision of quality care, and at the same time prevent diversion. SAMHSA has led

⁵ SAMHSA, Retrieved March 21, 2016, from <http://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/physician-program-data>

this effort for the Department working in close partnership with ASPE. Because we are currently in the rulemaking phase, we are limited in what we can say about the content of the impending Notice of Proposed Rulemaking (NPRM). We are pleased to say that due to the urgency of the opioid public health crisis, we worked on an expedited timeline and the NPRM is at the Office of Management and Budget (OMB) for interagency review at this time.

Finally, SAMHSA has done significant work to ensure that behavioral health treatment is appropriately financed and implemented to support integrated care across an array of health systems and programs. SAMHSA's report, "Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders," provides clinicians and policy makers a resource guide for developing beneficial medication coverage and financing policies. The report presents innovative coverage and financing approaches that are being used to ensure cost-effective and treatment-effective outcomes. To complement this effort, SAMHSA engaged with its Federal partners (CMS, CDC, NIDA, National Institute on Alcohol Abuse and Alcoholism) to issue a CMS Informational Bulletin on MAT to inform states and other stakeholders about effective practices for identifying and treating mental and substance use disorders covered under Medicaid. Additionally, CMS and SAMHSA jointly issued an Informational Bulletin on coverage of behavioral health services for youth with substance use disorders to assist states in designing a benefit that meets the needs of youth with substance use disorders and their families and to help states comply with their obligations under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment requirements. The services described were designed to enable youth to address their substance use disorders, to receive treatment and continuing care, and participate in recovery services and supports.

Criminal Justice Activities

A public health approach to addressing the opioid crisis is vital and the Secretary's initiative takes such an approach. At the same time, public health agencies and organizations understand the importance of working with our colleagues in the criminal justice field. SAMHSA's criminal justice portfolio includes several grant programs that focus on diversion, alternatives to incarceration, drug courts, and re-entry from incarceration for adolescents and adults with substance use disorders, and/or co-occurring substance use and mental disorders.

Drug Courts

SAMHSA's adult drug court programs support a variety of services, including treatment for diverse populations at risk; wraparound/recovery support services designed to improve access and retention; drug testing for illicit substances required for supervision, treatment adherence, and therapeutic intervention; education support; relapse prevention and long-term management; MAT; and HIV testing conducted in accordance with state and local requirements.

SAMHSA's treatment drug court grant programs focus on Tribal Healing to Wellness Courts, Juvenile Treatment Drug Courts, and SAMHSA's collaboration with DOJ's Bureau of Justice Assistance. In FY 2015, SAMHSA supported the continuation of 103 drug court grants, and provided funding to 35 new adult and family drug court grants and 10 new BJA jointly funded drug court grants. The Congress expanded this provision – new in FY 2015 – from \$50 million for Drug Courts to a new total of \$60 million in FY 2016.

Offender Reentry Program

In addition to SAMHSA's drug court portfolio, criminal justice funds also support Offender Reentry Program (ORP) grants, which provide screening, assessment, comprehensive treatment, and recovery support services to offenders reentering the community, as well as offenders who are currently on or being released from probation or parole. Funding for ORP may be used for a variety of services, including but not limited to screening, comprehensive individual assessment for substance use and/or co-occurring mental disorders, case management, referrals related to substance abuse treatment for clients, alcohol and drug treatment, wrap-around services, drug testing, and relapse prevention and long-term management support.

In FY 2015, SAMHSA supported 30 three-year ORP grant continuations, and up to 18 new ORP grants, which will have a particular emphasis on opioid overdose prevention.

Conclusion

On behalf of SAMHSA, I appreciate the opportunity to testify today and share with you our prevention, treatment and recovery support strategies. We look forward to partnering with you as well and thank you for your leadership on this issue.

I welcome any questions that you may have.

Mr. MICA. Thank you.

We will now recognize Dr. Wen, who is with the Baltimore Health Department, the City Health Department.

Welcome, and you are recognized.

STATEMENT OF LEANA S. WEN, M.D., MSC., FAAEM

Dr. WEN. Thank you very much, Chairman Mica and Ranking Member Cummings, and members of the committee. Thank you for calling this important hearing. I am here as an emergency physician who has treated hundreds of patients with opioid addiction. I am also here as the Health Commissioner in Baltimore, where I have declared the epidemic to be a public health emergency.

Last year, Baltimore launched our three-pronged approach to fight this on the front lines. First, we have to save lives. That is why we are making the opioid antidote, naloxone, available to every single resident. In the ER, I have given naloxone to patients who are about to die and have watched them revive within seconds. Naloxone should be part of everyone's medicine cabinet. In 2015, we trained 8,000 people in the city on how to use it, including our police officers, who within six months have saved 21 citizens. In October, I issued a blanket prescription for naloxone to all 620,000 residents of Baltimore.

But saving a life without connecting to treatment is just treading water. So our second approach is to increase on-demand addiction treatment. We believe that treating addiction as a crime is unscientific, inhumane, and ineffective. So our city's criminal justice and public health teams have partnered on drug treatment courts and on a pilot project where individuals caught with small amounts of drugs will be offered treatment instead of incarceration.

The science is clear: addiction recovery requires medication-assisted treatment, psychosocial support, and wraparound services. Yet nationwide, only 11 percent of patients with addiction get the treatment that they need. Imagine if only one in ten cancer patients could get chemotherapy. Yet my patients come to the ER seeking addiction treatment, and I tell them that they must wait weeks or months. I have had patients overdose and die while they are waiting because we failed to get them help at the time that they asked.

In Baltimore, we have started a 24/7 phone hotline that includes immediate access to an addiction counselor or social worker, and a direct connection to make an appointment. Our phone line was started less than six months ago and already receives about 1,000 calls per week, including from police officers and family members asking for resources.

We have ample evidence to show what works for treating addiction, but we are nowhere near getting everyone treated, and we are still very limited, especially when it comes to wraparound services. Take housing. Every year we estimate that there are 18,000 turnaways for less than 100 recovery beds. Addiction treatment reduces crime and saves society money. We should invest in treating today rather than spending it on incarcerating tomorrow.

Our third approach is to reduce addiction through educating the public and doctors. We launched a campaign to reduce stigma and encourage treatment at DontDie.org that also includes bus and bill-

board ads and targeted outreach at libraries, churches, and bars. Dontdie.org now has the first-of-its-kind naloxone training so that anyone who watches a short 10-minute video can print out my prescription to get naloxone.

We are also targeting education to physicians. As the Administrator said, doctors want to do the right thing. We have to give them the tools to do so. So I have sent best practice letters to every doctor in Baltimore to set prescribing guidelines and require the co-prescribing of naloxone with opioids.

We are also alerting doctors to emerging trends. Nationwide, one in three fatal overdoses from opioids involves benzodiazepines like Valium and Xanax, yet physicians routinely prescribe this dangerous combination together. Last month, I co-led a petition to the FDA with 40 other city and state health officials to call for a black-box warning, which is the FDA's strongest risk communication, on opioids and benzodiazepines.

There is a lot that Baltimore has done to emerge as a model of overdose response and addiction recovery, but we need further support from Congress, including expanding funding for on-demand treatment and wraparound services like housing and peer recovery specialists; directly funding local jurisdictions, those of us on the front lines with highest need; removing regulatory barriers like the cap on buprenorphine and IND exclusion; regulating the escalating price of naloxone; and funding a national stigma reduction campaign.

The epidemic of opioid addiction is a national public health emergency, and we know that addiction does not discriminate. We are all in this together. So I thank you for calling this hearing and look forward to answering your questions.

[Prepared statement of Dr. Wen follows:]



Baltimore City Health Department
1001 E. Fayette Street • Baltimore, Maryland 21202
Stephanie Rawlings-Blake, Mayor
Leana Wen, M.D., Commissioner of Health

America's Heroin and Opioid Abuse Epidemic
Testimony of Dr. Leana Wen, Baltimore City Health Commissioner
March 22, 2016

Baltimore City Health Department's "3-Pillars" of Combating Opioid Addiction

1. Prevent deaths from overdose and save lives. I have declared opioid overdose a public health emergency in Baltimore City and led the charge in one of the most aggressive opioid overdose prevention campaigns across the country. We have trained over 8,000 people how to use naloxone. Through a "Standing Order" approved by the Maryland State Legislature, I have written a blanket prescription for naloxone to 620,000 residents, and have started the first-of-its-kind online naloxone training.


2. Increasing access to on-demand treatment and long-term recovery support. Baltimore City has taken several actions to improve access to on-demand treatment, including a 24/7 crisis, information and referral phone line (with approximately 1,000 calls/week); securing \$3.6M to build a sobering center; hiring of community-based peer recovery specialists; and universal screening for addiction in our hospitals. We strive to establish a 24/7 "Urgent Care" for addiction and mental health disorders and for increased evidence-based programs including diversion from incarceration and wrap-around services such as housing.

3. Provide education to reduce stigma and prevent addiction. We must change the dialogue around substance use disorder. We are leading a citywide effort to educate the public and providers on the nature of addiction: that it is a disease, recovery is possible, and we all must play a role in preventing addiction and saving lives. We have launched a public education campaigns-- "DontDie.org". We have brought together hospitals and ER leaders and have implemented citywide best practices to reduce opioid prescribing.

Working with the Federal Government

While we have made significant progress, there are areas where we face continued challenges. We have four specific areas that should be more comprehensively addressed by the federal government:

1. **Expand funding for and availability of on-demand and wrap-around addiction treatment services**
 - a. Allow funding to establish 24/7 treatment centers for addiction and mental health
 - b. Ensure equitable insurance coverage for evidence-based addiction services
 - c. Expanded funding for wrap-around services (including housing) and diversion programs
2. **Directly fund local jurisdictions with highest need**
 - a. Allow innovations with new care delivery models
 - b. Encourage community resources for recovery including peer recovery specialists
3. **Improve federal regulations around addiction and overdose treatment**
 - a. Monitor and regulate the price of naloxone
 - b. Require co-prescription of naloxone to every individual receiving opioid medications
 - c. Require "black box warning" on opioids and benzodiazepines
 - d. Remove barriers to prescribing Buprenorphine
4. **Fund a national stigma-reduction and opioid-awareness campaign**

<p>CITY OF BALTIMORE STEPHANIE RAWLINGS-BLAKE, Mayor</p>		<p>HEALTH DEPARTMENT Leana S. Wen, M.D., M.Sc., FAAEM Commissioner of Health 1001 E. Fayette St. Baltimore, MD 21202 health.commissioner@baltimorecity.gov Tel: 410-396-4387</p>
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March 22, 2016

TO: Members of the House Oversight Committee

FROM: Dr. Leana Wen, Baltimore City Health Commissioner

RE: Testimony: America's Heroin and Opioid Abuse Epidemic

Chairman Chaffetz, Ranking Member Cummings and Members of the Committee:

Thank you for inviting me to testify on the epidemic of opioid abuse that is sweeping across our country. Opioid abuse is a public health emergency that is claiming the lives, the livelihoods, and the souls of our citizens.

As an emergency room (ER) doctor, I have witnessed firsthand the effects of substance addiction on individuals and families, including treating hundreds of patients who have overdosed on opioids. I remember well my patient, a 24-year old mother of two who came to the ER nearly every week requesting addiction treatment. She would be told there was nowhere for her to go that day or the next, and would be offered an appointment in three weeks time. Because she lacked housing and other supportive services, she would relapse. One day, her family found her unresponsive and not breathing. By the time she arrived in the ER, it was too late for us to save her, and she died.

I always think back to my patient now: she had come to us requesting help, not once, not twice, but over and over again, dozens of times. Because we do not have the treatment capacity, people looking to us for help fall through the cracks, overdose, and die. Why has our system failed her, just as it is failing so many others who wish to get help for their addictions?

My colleagues and I frequently felt frustrated by the limitations of clinical practice; by the time patients made their way to us, society had missed significant opportunities to intervene farther upstream in that individual's life. We treat addiction differently than we treat any other illness. Would we ever tell someone who has had a heart attack to wait three weeks to get treatment? Despite scientific studies showing that addiction is a disease and that recovery is possible, many still question why people "choose" a lifestyle of using drugs. Would we impose such stigma on any other disease? These are the experiences that drove me to public health: a desire to tackle the epidemic of addiction at a community level, and, in doing so, save lives while also redefining our societal approach to the treatment of addiction.

As the Health Commissioner of Baltimore City, I work every day with my dedicated staff at the Health Department and partners across our city, to prevent overdose and stem the tide of addiction. I am encouraged that the approach to the opioid epidemic is shifting away from the

rhetoric of the “war on drugs” and instead focusing on treating addiction as a disease. But while our rhetoric is changing, funding for treatment lags behind. Of the more than 20 million people who abuse some form of drug, only about 1 in 10 is able to receive treatment. In Baltimore and around the country, our patients come requesting assistance, but are forced to wait weeks, even months, to access needed care.

This struggle is not unique to Baltimore; millions of Americans struggle to find treatment when they are ready to seek it. Ensuring those struggling with addiction can access treatment on-demand requires systems change. We can learn from cities that have taken the lead across the country using innovative approaches to address this national issue; Baltimore is one such city that is at the cutting edge of addiction prevention and treatment.

The Opioid Problem in Baltimore

With over 20,000 active heroin users in Baltimore and far more who misuse and abuse prescription opioid medications, opioid addiction and overdose is a critical health priority in our city. In 2014, 303 people died from drug and alcohol overdose, which is more than the number of people who died from homicide. Drug addiction impacts our entire community and ties into nearly every issue facing our city including crime, unemployment, poverty, and poor health. It claims lives every day and affects those closest to us—our neighbors, our friends, and our family. (For more information about the state of health of the city, please see Appendix A)

Since my appointment in January 2015, I have made overdose prevention and addiction treatment my top priority. I worked closely with Mayor Stephanie Rawlings-Blake to guide the work of the Mayor’s Heroin Treatment and Prevention Task Force that released ten bold and progressive recommendations in July 2015. These ambitious recommendations form the framework and guide the roadmap of our efforts, which are led by the Baltimore City Health Department and Behavioral Health System Baltimore, a nonprofit that is the designated behavioral health authority of the city (of which I serve as Chair of the Board), in close coordination with our public and private partners across the city.

Baltimore’s Response to Addiction and Overdose

Our work in Baltimore is built on three pillars:

- First, we have to prevent deaths from overdose and save the lives of people suffering from addiction.
- Second, we must increase access to quality and effective on-demand treatment and provide long-term recovery support.
- Third, we need to increase addiction education and awareness for the public and for providers in order to reduce stigma and encourage prevention and treatment.

Our work in each of these areas is multifaceted because addressing a disease like addiction requires a comprehensive approach. We are working tirelessly to change the conversation, and our efforts serve as a model nationally and for other local and state jurisdictions. We know what works for combating addiction but we need help to make sure all who seek treatment are able to

get it. We are all in this together, and Baltimore is happy to share our innovations and lessons learned.

1. Preventing deaths from overdose

In Baltimore, I have declared opioid overdose a public health emergency and led the charge in one of the most aggressive opioid overdose prevention campaigns across the country.

- a. The most critical part of the opioid overdose prevention campaign is expanding access to naloxone – the lifesaving drug that reverses the effect of an opioid drug overdose. Naloxone is safe, easily administered, not addictive, and nearly 100% effective at reversing an overdose. In my clinical practice as an emergency physician, I have administered naloxone to hundreds of patients and have seen how someone who is unresponsive and about to die will be walking and talking within seconds.

Since 2003, Baltimore City has been training drug users on using naloxone through our Staying Alive Program. Last year, we successfully advocated for change in State law so that we can train not only individuals who use drugs, but also their family and friends, and anyone who wishes to learn how to save a life. This is critical because someone who is overdosing will be unresponsive and friends and family members are most likely to save their life.

Our naloxone education efforts are extensive. In 2015, we trained over 8,000 people to use naloxone: in jails, public housing, bus shelters, street corners, and markets.

We were one of the first jurisdictions to require naloxone training as part of court-mandated time in Drug Treatment Court. We have trained federal, state and city legislators so that they can not only save lives, but also serve as ambassadors and champions to their constituents.

- b. We use up-to-date epidemiological data to target our training to “hotspots”, taking naloxone directly into the most at risk communities and putting it in the hands of those most in need. This was put into effect in 2015, when we saw that 39 people died from overdose to the opioid Fentanyl between January and March of 2015. Fentanyl is many times stronger than heroin, and individuals using heroin were not aware that the heroin had been laced with Fentanyl. These data led us to target our messaging so that we could save the lives of those who were at immediate risk. We coordinate our data with agencies across the city including the police department, fire department, and hospitals, so as to ensure our information is complete and our efforts are unified.
- c. As of October 1, 2015, I have the authority to write blanket prescriptions for naloxone for the roughly 620,000 residents in Baltimore City under a “Standing Order” approved by the Maryland State Legislature. This is one of the single largest efforts in the country to achieve citywide naloxone distribution. A Standing Order means that someone can receive a short training (which can be done in less than five minutes) and immediately

receive a prescription for naloxone, in my name, without having seen me personally as their doctor.

In order to train even more people in the use of naloxone, we have launched an online platform that now allows residents to get trained online and immediately receive a prescription for naloxone. This online platform, which is the first-of-its-kind around the country and the world, is the next step to reduce barriers to naloxone. In Baltimore, we believe that naloxone should be part of everyone's medicine cabinet and everyone's First Aid kit.

- d. Already, our naloxone outreach and trainings are changing the way our frontline officials approach addiction treatment, with a focus on assessment and action. In addition to training paramedics, we have also started to train police officers. The initial trainings were met with resistance from the officers who were hesitant to apply medical interventions that some did not see as part of their job description. However, in the first month of carrying naloxone, four police officers used naloxone to save the lives of four citizens. Recently, I attended a training where I asked the officers what they would look for if they were called to the scene for an overdose. In the past, I would have received answers about looking for drug paraphernalia and other evidence. This time, officers answered that their job was to find out what drugs the person might have taken, to call 911 and administer naloxone, because their duty is to save a life. By no means is naloxone training the panacea for repairing police and community relations. However, it is one step in the right direction as we make clear that addiction is a disease and overdose can be deadly. We are changing the conversation so that all of our partners can join in encouraging prevention, education, and treatment.
- e. We successfully advocated for Good Samaritan legislation, which expanded protections for those who assist in the event of an overdose, and malpractice protection for doctors who prescribe naloxone.
- f. Our state Medicaid program has agreed to set the co-pay for naloxone at \$1. While we still struggle with the pricing for naloxone (see below), this has allowed us to provide prescriptions to patients and others at a greatly reduced cost. We have to get naloxone into the hands of everyone who can save a life—which we believe is each and every one of us.

Some people have the misconception that providing naloxone will only encourage a drug user by providing a safety net. This dangerous myth is not based on science but on stigma. Would we ever say to someone whose throat is closing from an allergic reaction, that they shouldn't get epinephrine because it might encourage them to eat peanuts or shellfish? An Epi-Pen saves lives; so does naloxone, and it should be just as readily available. Our mantra is that we must save a life today in order for there to be a better tomorrow.

2. Increasing access to on-demand treatment and long-term recovery support

Stopping overdose is only the first step in addressing addiction. To treat people with substance addiction, we must ensure there is adequate access to on-demand treatment. Nationwide, only 11% of patients with addiction get the treatment they need. There is no physical ailment for which this would be acceptable—imagine if only 11% of cancer patients or 11% of patients with diabetes were being treated. If we do not increase access to quality treatment options we are merely treading water, waiting for the person who has overdosed to use drugs and overdose again.

The evidence is clear: addiction treatment requires a combination of medication-assisted treatment, psychosocial support, and wrap-around services including supportive housing. All of these must be in place for individuals suffering from addiction to recover, and they must be available at the time the individual is seeking these services—the same as for any medical condition.

- a. In Baltimore, we have started a 24/7 "crisis, information, and referral" phone hotline that connects people in need to a variety of services including: immediate consultation with a social worker or addiction counselor; connection with outreach workers who provide emergency services and will visit people in crisis at homes; information about any question relating to mental health and substance addiction; and scheduling of treatment services and information. This hotline is not just for addiction but for mental health issues, since these issues in behavioral health are so closely related and there is a high degree of co-occurrence. Those who are seeking treatment for behavioral health should be able to easily access the services they need, at any time of day. This 24/7 line has been operational since October 2015; already, there are approximately 1,000 phone calls every week. It is being used not only by individuals seeking assistance, but by family members seeking resources, and police and providers looking to connect their patients to treatment.
- b. We have implemented the Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach, which provides universal screening of patients presenting to ERs and primary care offices. Three of our hospitals are early pioneers in SBIRT; we are looking to expand it to all hospitals and clinics in the city to ensure delivery of early intervention and treatment services for those with or at risk for substance use disorders.
- c. We are developing a real-time treatment dashboard to obtain data on the number of people with substance use disorders, near-fatal and fatal overdoses, and capacity for treatment. This will enable us to map the availability of our inpatient and outpatient treatment slots and ensure that treatment availability meets the demand. The dashboard will be connected to our 24/7 hotline that will immediately connect people to the level of treatment that they require—on demand, at the time that they need it.
- d. We have secured \$3.6 million in capital funds to build a "stabilization center"—also known as a sobering center—for those in need of temporary service related to intoxication. This is the first step in our efforts to start a 24/7 "Urgent Care" for addiction and mental health disorders—a comprehensive, community-based "ER" dedicated to

patients presenting with substance abuse and mental health complaints. Just as a patient with a physical complaint can go into an ER any time of the day for treatment, a person suffering from addiction must be able to seek treatment on-demand. This center will enable patients to self-refer or be brought by families, police, or EMS—a “no wrong door” policy ensures that nobody would be turned away. The center would provide full capacity treatment in both intensive inpatient and low-intensity outpatient settings, and connect patients to case management and other necessary services such as housing and job training.

- e. We are expanding and promoting medication-assisted treatment, which is evidence-based and a highly effective method to help people with opioid addiction recover. This combines behavioral therapy with medication, such as methadone or buprenorphine, along with other support. Taking medication for opioid addiction is like taking medication to control heart disease or diabetes. When prescribed properly, medication does not create a new addiction, but rather manages a patient’s addiction so that they can successfully achieve recovery. Baltimore has been at the leading edge of innovation for incorporating medication-assisted treatment, including providing medications in structured clinical settings through the Baltimore Buprenorphine Initiative. This year, we expanded access to buprenorphine treatment by offering services in low-barrier settings, such as recovery centers, emergency shelters, and mental health facilities. Providing access to buprenorphine services in these settings allows us to engage people who are more transient or unstably-housed into much needed treatment.
- f. We are expanding our capacity to treat overdose in the community by hiring community-based peer recovery specialists. To build trust, these individuals will be recruited from the same neighborhoods as individuals with addiction, and will be trained as overdose interrupters who can administer overdose treatment and connect patients to treatment and other necessary services.
- g. We are working to expand case management and diversion programs across the city so that those who need help get the medical treatment they need. In our city of 620,000, 73,000 people are arrested each year. The majority of these arrests are due to drug offenses. Of the individuals in our jails and prisons, 8 out of 10 use illegal substances and 4 out of 10 have a diagnosed mental illness. Addiction and mental illness are diseases, and we should be providing medical treatment rather than incarcerating those who have an affliction.

Baltimore already has highly-effective diversion efforts such as Drug Treatment Courts and Mental Health Treatment Courts. We are starting to implement a Law Enforcement Assisted Diversion Program (LEAD), a pilot model that has been adopted by a select group of cities, which establishes criteria for police officers to identify eligible users and take them to an intake facility that connects them to necessary services such as drug treatment, peer supports, and housing – rather than to central booking for arrest. Cross agency partnerships will be key in making these programs successful. LEAD implementation in Baltimore involves not only the Health Department and our behavioral health providers but the Police Department, State’s Attorney’s Office, Public Defender’s

Office, and many more entities that together recognize the importance of addiction treatment.

- h. We are increasing our capability for case management services for every individual leaving jails and prisons. These individuals are in a highly vulnerable state, and must be linked to appropriate physical and behavioral health care, social and supportive services, employment, mentoring and housing. Our outreach workers already target a subset of this population; we need to expand capacity to every one of these individuals. Additionally, we are deploying community health workers who are individuals in recovery themselves in order to reach people where they are in the community as well as provide a credible messenger. In deploying this tactic, we are also excited to bring jobs and opportunities to vulnerable individuals and neighborhoods that otherwise have limited employment opportunities.

3. Providing education to reduce stigma and prevent addiction

In addition to treating patients, we must also change the dialogue around the nature of substance use disorders. The Baltimore City Health Department is leading a citywide effort to educate the public and providers on the nature of substance addiction: that it is a disease, recovery is possible, and we all must play a role in preventing addiction and saving lives.

- a. We have been at the forefront of changing public perception of addiction so those in need are not ashamed to seek treatment. We have launched a public education campaign "DontDie.org" to educate citizens that addiction is a chronic disease and to encourage individuals to seek treatment. This was launched with bus ads, billboard ads, a new website, and a targeted door-to-door outreach campaign in churches and with our neighborhood leaders. We are working with restaurants and bar owners to post "Don't Die" posters in their establishments.
- b. "DontDie.org" has also become our portal for online trainings and for dispensing of naloxone through the Standing Order mentioned above. Any resident can watch a short (10 minute) video, take a 4-question quiz, and receive a standing order prescription to receive and to use naloxone to save lives.
- c. We have also launched a concerted effort to target prevention among our teens and youth. This involves a campaign called "BMore in Control," and we are also incorporating prevention into the public school curriculum.
- d. We have established permanent prescription drug drop boxes at all nine of the city's police stations and have conducted educational awareness campaigns around not using prescriptions that were given to anyone else. This means that anyone can drop-off their unused, unwanted, or unnecessary prescription drugs—no questions asked. Drugs left in the home can end up in the wrong hands—spouses, elderly family members, or even our children. I have treated 2-year olds who were dying from opioid overdose, again underscoring that all of us can be at risk and must play a role.

- e. We are targeting our educational efforts to physicians and other prescribers of opioid medications. Nationwide, over-prescribing and inconsistent monitoring of opioid pain medications is a major contributing factor to the overdose epidemic. According to the Centers for Disease Control and Prevention (CDC), there were 259 million prescriptions written for opioids in 2014. That is enough for one opioid bottle for every adult American. Every day, people overdose or become addicted to their prescription opioids.

To address this, I have sent “best practice” letters to every doctor in the city. The letter addressed the importance of the Prescription Drug Monitoring Program and judicious prescribing of opioids, including not using narcotics as the first line medication for acute pain and emphasizing the risk of addiction and overdose with opioids. Importantly, this best practice requires co-prescribing of naloxone for any individual taking opioids or at risk for opioid overdose. Hospitals keep naloxone on hand if patients receive too much intravenous morphine or fentanyl. Patients must also receive a prescription for naloxone if they are to be discharged with opioid medications that can result in overdose.

These best practices were developed through convening ER doctors, hospital CEOs, and other medical professionals in the city. To reach practicing doctors, we have been presenting at Grand Rounds, medical society conferences, and have also launched physician “detailing”, where we deploy teams of public health outreach workers and people in recovery to visit doctors to talk about best practices for opioid prescribing. We are working on a convening for pharmacists to set pharmacy best practices, and have supported statewide legislation to require the use of Prescription Drug Monitoring Programs by physicians and pharmacists. All of us—as providers, patients, and family members—must play our part to prevent addiction and overdose.

- f. As part of our “best practices” recommendations, we are leading efforts to warn patients and prescribers against combining opioids and benzodiazepines. Nationwide, one in three fatal overdoses is due to this combination—a little known but extremely dangerous phenomenon. Physicians routinely prescribe these two medications together, yet because they both result in respiratory depression and sedation, overdoses are common and fatal.

In February, I co-led a group of over 40 City Health Commissioners and State Health Directors across the country urging the U.S. Food and Drug Administration (FDA) to require a “black box warning” on opioids and benzodiazepines that states that concurrent use of the medications increases the risk of fatal overdose. Black box warnings appear on the labels of prescription drugs and call attention to serious or life-threatening risks. We started a public petition and have over 3,000 signatures from people showing their support for this public warning. This is a first-of-its kind petition delivered to the FDA by frontline health officials. (See Appendix B)

While we wait for the FDA to require a “black box warning,” we are also calling on prescribers to warn patients about the risks of combined opioid and benzodiazepine use. Patients with chronic pain are often prescribed opioids to treat their pain and benzodiazepines to treat their associated symptoms, such as anxiety and sleep disorders.

Educating patients about this potentially lethal drug interaction is an important step to reduce the toll of addiction and fatal overdose in communities across the country.

Working with the Federal Government

The Baltimore City Health Department, together with our partners across the city and state, has made significant progress in tackling the opioid epidemic. However, there are some areas where we face continued challenges. Though there is much that can be done on the city and state levels, the federal government plays a critical role in combating America's heroin and opioid abuse epidemic.

Recently, the Senate passed the Comprehensive Addiction and Recovery Act (CARA) which focuses on prevention and treatment efforts. I urge the House to pass this critical legislation. This is a great first step towards promoting prevention, treatment, and more inclusive communities. Although the bill provides for additional funding, far more resources are needed. We have four specific areas that should be more comprehensively addressed:

1. Congress can expand funding for and availability of on-demand and wrap-around addiction treatment services

We must treat addiction as a disease and not a crime or a moral failing. In order to successfully treat the disease, we need to ensure there are sufficient high-quality treatment options available to those in need, at the time that they need it. The science is unambiguous and unequivocal: addiction treatment requires medication-assisted treatment, psychosocial support, and wrap-around services. The problem is that we are nowhere near capacity to get everyone treatment at the time they need it.

- a. Federal funding could expand treatment on-demand. There is often a small window of opportunity to get an individual with substance abuse or mental health issues into treatment. Additional money should be made available to establish 24/7 treatment centers dedicated to substance addiction and mental health. These centers will provide a one stop shop for those in need at the time they need it, and will also alleviate pressure from emergency rooms and jails, both of which are ill-equipped to handle these patients.
- b. Congress can push for equitable insurance coverage for evidence-based addiction services. Medicare pays for pain medications that can lead to addiction, yet many states do not cover medication-assisted treatment and other evidence-based interventions for addiction recovery. Congress can ensure that Medicaid, Medicare, and private payers cover on-demand treatment for acute care (such as sobering, urgent care, and residential services), as well as ongoing treatment and services like medication-assisted treatment and case management. These rates should also be equivalent to mental health and physical health care rates (which they are not currently, leading to a dearth of providers and inadequate care). Services that are not science- and evidence-based—including rapid detoxification or sobriety-only programs—should not be federally funded.

- c. Congress can expand funding for wrap-around services. Access to social needs like housing and employment is just as crucial to a person's recovery as medical treatment. These wrap-around services are especially important for those re-entering society after incarceration. Funding for case managers and care coordinators to help those in recovery access services is necessary for those with addiction to have a path to recovery. Housing remains a major challenge. In Baltimore, it is estimated that there are over 18,000 turn-away's each year for individuals seeking recovery housing. Providing stable housing will help to break the cycle of addiction, homelessness, and incarceration, and is critical for supporting those with addiction.
- d. Congress can expand funding to diversion programs and ensure that individuals with substance use disorders receive addiction treatment. With the recognition that incarceration is not the solution to addiction, Congress can increase funding to diversion programs such as LEAD and Drug Treatment Courts. Individuals who are incarcerated should also receive evidence-based treatments. Those who enter prison being treated with buprenorphine are often switched to methadone due to its lower cost—a consideration that would not occur for other diseases. Patients should be allowed to continue treatments that work for them upon entering prison, and all who have addictions should be directed to evidence-based treatment options.

2. Congress can directly fund local jurisdictions with highest need

While States have traditionally received block grants from the federal government, local jurisdictions are the closest to the ground in service delivery, and understand the needs of residents the best. We urge Congress to consider direct support for local jurisdictions, particularly those in areas of greatest need, and providing cities and counties with the autonomy to innovate and provide real-time care for our residents. These services include innovative models that are not covered by Medicaid, Medicare, or private insurance, such as:

- a. New care delivery models. There is research on new treatment options such as starting buprenorphine from ERs, mobile buprenorphine induction, or telemedicine treatment that would not be eligible for existing reimbursement yet offer much promise. These are examples of delivery models that local and state agencies should have the option of providing grant funding for, with the option of being included in Medicaid formulary after sufficient time and evidence.
- b. Peer recovery specialists. In Baltimore, we are aiming to provide a peer recovery specialist for every individual who presents for overdose or addiction-related condition to our ERs and other facilities. However, we are limited by the lack of funding for these individuals. There should be opportunities for expanded funding and reimbursement for services rendered by these trained community health workers; grant funding to local and state agencies can be one way to pursue this.
- c. Case management services. Individuals leaving incarceration or inpatient stays are at very high risk; they must receive wrap-around services that connect them immediately to needed medical and psychiatric assistance. These case management services have

inconsistent reimbursement; innovative programs including with telemedicine and use of peer recovery specialists should be encouraged.

- d. Community resources for recovery. Recovery from addiction involves more than clinical treatment but also support and long-term care. Local jurisdictions can also innovate with interventions such as recovery housing and reentry support; federal funding can assist in these necessary steps.
 - e. Prevention. Grant support for tailored and targeted prevention support including public education and provider education must also be a critical component.
3. **Congress can change critical federal regulations around addiction and overdose treatment**

- a. Congress can monitor and regulate the price of naloxone. Naloxone, the opioid overdose antidote, is part of the World Health Organization's (WHO) list of essential medications. Over the last two years, the price of naloxone has dramatically increased. The cost of naloxone skyrocketing means that we can only save a fraction of the lives we were able to before. This is particularly problematic for cities and counties that must purchase naloxone for use by paramedics, police officers, and other front-line workers.

Manufacturers have claimed that this price increase is related to increased demand. However, it is unclear why the cost of a generic medication that is available for much lower costs in other countries will be suddenly so expensive. Congress can join efforts by Senator Sanders and Congressman Cummings to call for investigation into the price increase of naloxone, which would otherwise prohibit us from saving lives at a time that we need to the most.

- b. Naloxone should be co-prescribed to every individual receiving opioid medications. This is part of Baltimore's best practices, and we urge this standard to be implemented nationwide. This could be implemented through policy recommendation through the CDC, regulation through the FDA, or through federal legislation. However, we urge federal legislation requiring co-prescribing of naloxone given the escalating rate of opioid overdose deaths.
- c. Congress can join local and state health officials to call for a prompt decision by the FDA for "black box warning" labels on opioids and benzodiazepines. This is a rapidly escalating dangerous trend that is fueling the overdose epidemic. (See Appendix B)
- d. Congress can remove barriers to prescribing Buprenorphine. Buprenorphine is a medication-assisted treatment option with a much lower chance of overdose than methadone. Importantly, it can be administered by a primary care provider rather than in a designated drug-treatment clinic. This helps to increase the accurate perception that substance use disorder is a medical condition. Unfortunately, at the moment, only medical doctors can prescribe buprenorphine, and a doctor can only provide buprenorphine to a maximum of 100 patients. This barrier does not exist for any other medication, and significantly limits the ability of patients to access a life-saving treatment

option and leaves many patients with methadone as their only option for medication-assisted treatment. Methadone requires administration in a designated treatment clinic, which often becomes a point of contention within the communities in which they operate due to the stigma associated with drug addiction.

We strongly support current efforts underway at the Department of Health and Human Services to eliminate the limits on buprenorphine prescription, and urge further support of broadened access to this proven treatment including for Congress to consider broadening prescription authority of buprenorphine to Nurse Practitioners and other providers.

4. Congress can fund a national stigma-reduction and opioid-awareness campaign

Many local jurisdictions like Baltimore have launched public education campaigns. There is much more education that must be done in order to encourage people with addiction into care and to disband stigmas that are leading many communities to avoid providing treatment altogether. Local jurisdictions are limited by funding constraints. Congress can push for the launch of a national campaign to reduce stigma and to increase awareness of opioid addiction. This national campaign will provide the spotlight this critical issue requires. Such national public health campaigns have had dramatic success in the past, including with reducing drunk driving.

Conclusion

While some of the challenges facing Baltimore are unique, we join our counterparts around the country in addressing the epidemic of opioid abuse and addiction. According to the CDC, the number of people dying from overdose has quadrupled from 15 years ago. In many states, there are more people dying from overdose than from car accidents or suicide.

There are some who say the opioid problem is too big and too complicated—that it cannot be solved. It is true that treating the opioid epidemic requires many approaches. However, this is an issue that requires our attention. According to the WHO, treating opioid addiction saves society \$12 for every \$1 spent on treatment. Treatment also impacts communities by reducing excess healthcare utilization, increasing productivity and employment rates, and decreasing poverty and unnecessary cost to the criminal justice system. Furthermore, treating addiction is a moral imperative and a matter of life and death.

Baltimore has been fighting the heroin and opioid epidemic for decades and we continue to make progress with bold ideas and innovative strategies. Our efforts to address opioid addiction seek to change the face of Baltimore from the "heroin capital" to the center of addiction recovery. Our goal is to make sure all those who suffer from addiction get the services they need to recover.

We are glad to share our lessons with our counterparts around the country and with our national leaders. With dedicated partners like you in Congress, we can fight the epidemic, save lives and reclaim people and their families.

I want to thank you for calling this important hearing. I look forward to working with you to stop the epidemic of heroin and opioid addiction in the United States.

APPENDIX A



Baltimore City Health Department -White Paper-

State of Health in Baltimore: Summary of Key Issues, Services and Policies Winter 2016

State of Health in Baltimore: It is impossible to discuss the health and well-being of Baltimore City's residents without applying the lens of health equity and systemic disparities. While the overall mortality rate in Baltimore City has declined over the past decade, the City still has a mortality rate 30% higher than the rest of the state, and ranks last on key health outcomes compared to other jurisdictions in Maryland.

This reality is compounded by a series of complicated systemic social, political, economic, and environmental obstacles. With more than 1 in 3 of Baltimore's children living below the federal poverty line and more than 30% of Baltimore households earning less than \$25,000/year, income, poverty, and race have enormous impact on health outcomes.

This state of health is especially urgent when we consider that Baltimore houses some of the best healthcare institutions in the country. We know that healthcare alone cannot drive health: while 97% of healthcare costs are spent on medical care delivered in hospitals, only 10% of what determines life-expectancy takes place within the four walls of a clinic. Where we live, work, and play each day drives our health and well-being.

As the local health authority, the Baltimore City Health Department (BCHD)'s mission is to serve Baltimore by promoting health and advocating for every individual's well-being, in order to achieve health equity for all residents. We work every day to improve the health of our community and address the disparities we face.

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A current snapshot of health in the City includes:

- The leading causes of death are heart disease, cancer, and stroke, HIV/AIDS, and chronic lower respiratory disease;
- Across the City, there exists as much as a 20 year difference in life expectancy between neighborhoods;
- Although HIV rates in the City have declined over the past decade, Baltimore consistently ranks in the top five cities world-wide for infections. About 13,400 residents are estimated to be living with HIV; and while African Americans constitute 62% of the population, they account for more than 85% of those living with HIV;
- One in three youths is either obese or overweight. One in four children drinks a regular soda every day, and less than one in five eats recommended servings of fruits and vegetables;
- 19% of adult residents in Baltimore City have been diagnosed with asthma, compared to a statewide average of 14%;
- 12.3% of babies born in the City are low birthweight, compared to a national average of 6%;
- 30% of children in Baltimore have Adverse Childhood Experience (ACE) scores of 2 or more, meaning that they have experienced more than two incidences of events such as domestic violence, living with someone with an alcohol/drug problem, the death of a parent, or being a victim/witness of neighborhood violence.
- 25% of adults living in Baltimore are regular smokers, compared to a national average of 17%.
- Baltimore has one of the highest rates of heroin use and overdose in the country – in 2014, 192 deaths were heroin-related. Over 60,000 people in the City are estimated to have a drug or alcohol addiction.

About BCHD

Founded in 1793, BCHD is the oldest, continuously-operating health department in the country, with more than 1,000 employees and an annual budget of \$130 million. BCHD aims to promote health and improve well-being through education, policy/advocacy, and direct service delivery for the residents of Baltimore City. BCHD's wide-ranging responsibilities include maternal and child health, youth wellness, school health, senior services, animal control, restaurant inspections, violence prevention, emergency preparedness, STI/HIV treatment, and acute and chronic disease prevention.

Over the past year, under the leadership of Health Commissioner Dr. Leana Wen, BCHD has made major strides in addressing the public health challenges facing Baltimore City. Several programs have moved the needle on health outcomes in the City and are serving as national models for public health innovation. This white paper captures those accomplishments and is intended to serve as an overview of the City's priority public health issues and how the health department addresses these challenges.

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Principles

BCHD's work is driven by three principle tenets:

- 1) *We go to where people are.* We believe that services and public health information should be delivered directly to community members. BCHD delivers health services in schools to ensure children don't miss class, deploys home-visiting services to ensure people receive critical maternal and child health care, and sends Safe Streets outreach workers into the neighborhoods where conflicts occur in our community.
- 2) *We engage the community in setting goals.* Our long-term goals are based on scientific best practices, but our short-term metrics are developed and shaped by the community. We adopt a robust community engagement approach to all of our work, partnering with neighborhood associations, faith-based organizations, and issue-specific stakeholders to ensure that the work we do is informed by –and responsive to-- the needs of Baltimore's citizens.
- 3) *We go "upstream" and tackle the root causes of poor health.* Public health is a powerful tool to fight injustice, and we embrace every opportunity to level the playing field of inequality. We know that health impacts every issue, from education to crime to unemployment – if our youth and adults are not healthy, they cannot learn or work productively. By investing in public health, we can ensure that Baltimore reaches its maximum potential.

Baltimore's Public Health Priorities

Issue 1: Addressing the Opioid Epidemic

Background: With approximately 19,000 active heroin users in Baltimore and far more who misuse and abuse prescription opioid medications, our city cannot be healthy without addressing opioid addiction and overdose. In 2014, 303 people died from drug and alcohol overdose, which is more than the number of people who died from homicide. Drug addiction impacts our entire community and ties into nearly every issue facing our city including crime, unemployment, poverty, and poor health.

Victories: BCHD has developed a comprehensive, 3-pillar strategy to combat opioid addiction that led the way in Maryland and that serves as a national model of innovation:

- **Prevent deaths from overdose and save lives.** In 2015, Commissioner Wen declared opioid overdose a public health emergency and the most critical part of BCHD's opioid overdose prevention campaign has been expanding access to naloxone – the lifesaving drug that reverses the effect of an opioid drug overdose. In October 2015, a new law went into effect that allowed Dr. Wen to issue a "standing order" and prescribe naloxone to the City's 620,000 residents. Baltimore City became the first jurisdiction in Maryland to expand access to naloxone using a standing order.

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In 2015, BCHD and partner organizations trained over 8,000 people at street markets, metro stops, jails, and neighborhood meetings on how to administer naloxone. BCHD assisted the Baltimore Police Department to incorporate naloxone training into the police academy and within the first month of carrying this remedy, officers used naloxone to save the lives of four of our citizens. Baltimore City was also one of the first jurisdictions to require naloxone training as part of court-mandated time in Drug Treatment Court. We have trained federal, state and city legislators so that they can not only save lives, but also serve as ambassadors and champions to their constituents.

We use up-to-date epidemiological data to target our training to “hotspots”, taking naloxone directly into the most at-risk communities and putting it in the hands of those most in need. This was put into effect in 2015, when we saw that 39 people died from overdose to the opioid Fentanyl between January and March of 2015. Fentanyl is many times stronger than heroin, and individuals using heroin were not aware that the heroin had been laced with Fentanyl. Unfortunately, Fentanyl continues to be an issue and an additional spike in Fentanyl deaths occurred in October 2015, where there were 14 deaths related to fentanyl—a 133 percent increase over last year. To address this spike in Fentanyl related deaths, BCHD launched aggressive outreach efforts in “hotspot” areas and announced a new platform that will allow Baltimore City residents to be trained online in how to use naloxone and receive the “standing order” prescription.

- **Increasing access to on-demand treatment and long-term recovery support.** Stopping overdose is only the first step in addressing addiction. To adequately treat people with substance use disorders, we must ensure there is adequate access to on-demand treatment. Nationwide, only 11% of patients with addiction get the treatment they need. In collaboration with Behavioral Health System Baltimore, the local behavioral health authority, BCHD has already taken several actions to ensure access to treatment, including:
 - Created a 24/7 Crisis, Information and Referral phone line for anyone with addiction and mental health concerns that receives nearly 1,000 calls every week for crisis services and referral to appointments;
 - Secured \$3.6M in capital funds to build a stabilization center which will be the first step towards creating a 24/7 “Urgent Care” for behavioral health
 - Hired community-based peer recovery specialists and piloted universal addiction screening in our hospitals;
 - Implementing the Law Enforcement Assisted Diversion Program (LEAD) with City partners, to establish criteria for police officers to identify and connect individuals to services such as drug treatment and housing, rather than to central booking for arrest.
- **Provide education to reduce stigma and prevent addiction.** In addition to treating patients, the dialogue around substance use disorder must also change and BCHD has been at the forefront of changing public perception of addiction so those in need are not ashamed to seek treatment. BCHD is leading a city-wide effort to educate the public and providers on the nature of addiction: that it is a disease, recovery is possible, and we all must play a role in preventing addiction and saving lives.

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Key activities include:

- A public education campaign, “DontDie.org”, that educates citizens that addiction is a chronic disease and to encourage individuals to seek treatment;
- Conversations with emergency doctors across the City to create awareness about best approaches to prescribing opioid medication;
- Educational programs for doctors and providers of all specialties around careful prescribing of opioid medications and need for training in anti-overdose medication naloxone.

Baltimore City was the first jurisdiction in Maryland to take this proactive approach to address addiction and has one of the most ambitious overdose response and addiction treatment programs in the country. The United States Senate and the Centers for Disease Control and Prevention (CDC) have both highlighted BCHD’s innovative approaches to address the opioid epidemic, as a best practice for other cities to learn from.

Challenges and Aspirations: While we have made important strides in responding to substance abuse and overdose within the city, there is still urgent imperative to respond to this crisis by:

- *Ensuring naloxone accessibility* by ensuring that the cost of this life-saving antidote, which has quadrupled over the past two years in Baltimore, remains affordable.
- *Increasing access to on-demand treatment* – we must ensure sufficient high-quality treatment options are available to those suffering from opioid addiction. BCHD ultimately intends to establish a 24/7 emergency room dedicated to behavioral health and on-demand access to addiction support, as well as proven intervention models such as LEAD and expanded case management for individuals being released from jail.
- *Additional funding for prevention and stigma reduction* – to stop the cycle of addiction, we must continue to invest in prevention services and anti-stigma education.

Issue 2: Youth Violence Prevention

Background: Addressing violence and public safety are key priorities for Baltimore City, and BCHD strongly believes that preventing violence is an essential function of public health. The hallmark model for violence prevention at BCHD is the Safe Streets program, a program designed to combat shootings and homicides in targeted communities in Baltimore.

Victories: Safe Streets takes a public health approach to violence and maintains that violence is a learned behavior that can be prevented using disease control methods; as violent events often “cluster” similar to an infectious disease outbreak. The program has proven successful in significantly reducing incidences of shootings and homicides. In 2014 alone, the program had 15,000 client interactions and 800 mediated conflicts, more than 80% of which were deemed likely or very likely to have resulted in gun violence. In addition to neighborhood-level impact, the program also prevents the intensive trauma and often costly city-wide ripple effects associated with a major event of violence.

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In light of these results, BCHD has developed a strategic framework for youth violence prevention across the City, including:

- **Scaling what works.** Given Safe Streets' success to date, BCHD believes it is essential to continue supporting and developing the program's current operations as well as investing in expansion to additional sites. We are currently pursuing multiple sources of funding to sustain and potentially expand this program and ensure that we can continue to prevent incidents of violence across the City.
- **Leveraging additional entry points.** To reach people where they are and prevent additional violence, we must identify additional entry points by working with partners throughout the City, including the:
 - Healthcare System— building off of the Safe Streets model, we seek to deploy "hospital interrupters" when youth come into the emergency room as a result of a violent incident. Additionally, we will pilot implementation of Maryland Shock Trauma's Violence Intervention Program, a youth violence prevention model that uses the hospital as an entry point for intervention conversations and services.
 - Justice System – the B'MORE FOR YOUTH Collaborative, drives the City of Baltimore's comprehensive plan to prevent violence affecting youth and reduce the number of people going into the criminal justice system. It is the product of collaboration among local, state, and federal partners, and identifies root causes and recommends a coordinated, multi-sector, multi-tiered approach.
- **Violence as a public health issue.** We know violence is a generational challenge impacted by the social determinants that shape people's lives. BCHD's approach to violence prevention starts as far "upstream" as possible. One such example is ensuring that Baltimore's youth have access to appropriate eye care and equipment – if a child cannot see, then they are unlikely to be motivated to come to school and may turn to other activities within their neighborhood that increase their likelihood of becoming involved in a violent incident later in life. Similarly, other studies have shown that home visiting programs for pregnant women and lead poisoning prevention will improve educational outcomes and reduce violence in the child. We have also developed a robust youth health and wellness campaign within BCHD that will ensure that all youth are healthy and engaged.

Challenges and Aspirations:

- *Sustaining the Safe Streets Program* – Safe Streets has historically been funded by grants, including those from the US Department of Justice and Centers for Disease Control and Prevention (CDC), all of which come to a close this year.
- *Support to pilot and scale new violence prevention initiatives* – Safe Streets, while a best-in-class model, is one innovative way to tackle youth violence. We must also invest in programs similar to MD Shock Trauma's Violence Intervention Program, Hospital Interrupters, and other public health initiatives that lead to reductions in violence—including home visiting programs for pregnant women and lead poisoning prevention programs.

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Issue 3: Youth Health and Wellness

Background: A decade ago, Baltimore City's infant health outcomes ranked as one of the poorest in the country, with an infant mortality rate nearly twice the national average and huge disparities between black and white birth outcomes. In response, BCHD in partnership with the Family League of Baltimore City and Health Care Access Maryland, developed a city-wide public-private partnership called B'More for Healthy Babies. The goal of the initiative is to ensure that all of Baltimore's babies are born at a healthy weight, full-term, and ready to thrive in healthy families. It is a comprehensive, evidence-based solution that builds cross-sector partnerships for strategic planning and implementation; strengthens systems and streamlines interventions to assure maximum effectiveness, ensures community and client participation in planning and emphasizes proactive monitoring and data-driven decision-making.

Victories:

- **B'More for Healthy Babies** Since its inception, B'More for Healthy Babies has experienced extraordinary success in:
 - Reducing the infant mortality by an astonishing 28%, bringing it to its lowest point in Baltimore's history;
 - Closing the disparity between black and white infant deaths by almost 40% between 2009 and 2012;
 - Decreasing the teen birth rate in the City by an unprecedented 36%.
 - Reducing sleep-related infant deaths by 50%

The program's success has been widely recognized and was recently awarded the Academy for Excellence in Local Governance County Best Practices Award, presented by Governor Larry Hogan at the 2015 Winter Maryland Association of Counties Conference, in addition to receiving the 2015 Spirit of Service Award from the Healthy Teen Network.

Building upon the success of B'More for Healthy Babies, BCHD seeks to take a comprehensive approach to youth health and wellness through:

- **Youth Health and Wellness Plan** BCHD has developed a comprehensive youth health and wellness plan that applies the same principles that have made the B'More for Healthy Babies program so successful, to the full youth life course of 0-19 years old. This plan will focus on three categories of long-term outcomes:
 - **Healthy Minds**- including improved social and emotional development as well as improved behavioral health;
 - **Healthy Bodies**-including continuation of reduced teen births and improved physical health outcomes including immunizations and oral health;
 - **Healthy Connections**-including improved peer relationships, community connectedness, and connections with trusted adults.
- **School Health** The Bureau of School Health at BCHD provides health services in all Baltimore City Public Schools. We have helped children better achieve their potential by

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supporting mental health services to 119 schools, providing students with access to health suite services, with nearly 300,000 annual visits in 180 schools. However, capacity is severely limited: several school-based health centers must share one nurse practitioner or provide care via the school health suites, which do not have nurse practitioners or physicians readily available to provide diagnosis, treatment, and preventative services.

Telemedicine is an innovative and effective way to address this gap in capacity and expand the level of care offered across schools without having to staff each with a full-time primary care provider. BCHD seeks to launch a telemedicine pilot to improve care coordination by virtually connecting community physician providers to over 1,500 school children, allowing them to stay in class and keep their parents at work. This will enable regular evaluation and treatment of both acute and chronic illnesses, as well as enhance availability of key behavioral and mental health services.

- **Reproductive Health** BCHD and a broad coalition of partners in the City, including Baltimore City Public Schools, were awarded an \$8.5 million grant from the U.S. Department of Health and Human Services that will be used to ensure comprehensive sex education in middle schools and high schools, with the aim of reducing the teen birth rates as well as provide accurate, evidence-based reproductive health education.

Challenges and Aspirations:

- *B More for Healthy Babies Sustainability* - With state and federal budgets steadily decreasing, this critical program faces a \$1.5 million deficit in the upcoming fiscal year. To ensure that all of Baltimore's babies are born healthy, we must fill this gap by pursuing multiple funding streams, including philanthropic, government, and billable services.
- *School Health Telemedicine Pilot* – Deploying telemedicine will significantly expand the capacity of the school health program and ensure the improved health of hundreds of schoolchildren. We are pursuing grant and other funding opportunities to support this initiative.

Issue 4: Behavioral Health

Background: Baltimore City faces significant behavioral health challenges and disparities. Baltimore City residents, despite making up only 11% of Maryland's total population, have consistently represented 30% of all statewide inpatient hospital discharges for individuals with mental illness. In 2013, 28% of Baltimore City students reported symptoms of mental illness, compared to 23% of Maryland students. Over 60,000 residents are estimated to have a drug or alcohol addiction.

Victories:

- **Establishment of a stabilization center** BCHD has secured \$3.6 million in capital funds to build a "stabilization center" – also known as a sobering center – for those in need of temporary service related to intoxication. This is the first step in our efforts to start a 24/7 "Urgent Care" for addiction and mental health disorders – a comprehensive, community-

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based “ER” dedicated to patients presenting with substance abuse and mental health complaints. Just as a patient with a physical complaint can go into an ER any time of the day for treatment, a person suffering from addiction must be able to seek treatment on-demand. This center will enable patients to self-refer or be brought by families, police, or EMS – a “no wrong door” policy ensures that nobody would be turned away. The center would provide full capacity treatment in both intensive inpatient and low-intensity outpatient settings, and connect patients to case management and other necessary services such as housing and job training.

- **Increased focus on treatment and case management** Three hospitals in Baltimore City participate in the Screening, Brief Intervention, and Referral to Treatment (SBIRT) project, an evidence-based public health approach to providing early intervention and treatment services to at-risk of substance use and mental health disorders. BCHD is leading a city-wide effort to expand use of SBIRT to all healthcare institutions in the city to delivery of early intervention and treatment services for those with or at risk for behavioral health and substance use disorders.

BCHD seeks to increase case management capability for every individual leaving jails and prisons. These individuals are at a highly vulnerable state, and must be connected to medical treatment, psychiatric and substance abuse treatments if appropriate, housing and employment support, and more. We know that deploying community health workers in order to reach people where they are in the community as well as provide a credible messenger works: in deploying this tactic, BCHD also aspires to bring jobs and opportunities to vulnerable individuals and neighborhoods that otherwise have limited employment opportunities.

- **Trauma-Informed Care** There is growing recognition in Baltimore City that generations of exposure to poverty, racism, violent crime and domestic violence has resulted in extremely high levels of traumatic stress for individuals, families and communities across the City. Recognizing that trauma is a major underlying factor of behavioral health issues and violence, BCHD has launched a trauma-informed care training initiative across city government, which has already reached more than 1,200 city employees including police officers and other front-line city workers. The goal of this initiative is to educate all front-line city workers educated in trauma-informed approaches, including:

- Understanding trauma
- Understanding the impact of traumatic stress on brain development
- Integrating trauma-informed practices into work with City residents

Challenges and Aspirations:

- *Operational budget for the stabilization center* – While we have secured capital funding, the stabilization center requires \$2.5M in operating dollars to successfully launch and begin providing services to potential attendees.
- *Increased investment in trauma-informed care* – Trauma is prevalent in Baltimore, and a driving factor of many other obstacles and systemic issues in the City. To ensure city-wide resilience, it is imperative that we invest further in this approach and provide trauma and resilience training for all city employees and partners.

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- **24/7 Substance Abuse and Mental Health Center** – Building upon the idea of the stabilization center, this facility would be a one step closer to on-demand treatment for addiction and mental health services, which are significant unmet needs in Baltimore. The center will also alleviate pressure from emergency rooms and jails, which are ill-equipped to address these patients' needs.

Issue 5: Chronic Disease Prevention

Background: BCHD is committed to fighting one of the most pervasive challenges and leading cause of death and poor health in Baltimore City: chronic disease. We take a multi-pronged approach to addressing chronic disease that encompasses direct services, education and policy actions. Our chronic disease efforts encompass the following:

- **Cardiovascular Disease/Tobacco Cessation** Smoking is the number one preventable contributor to early death from heart disease, stroke, and cancer. BCHD provides smoking cessation services, community education, school-based projects, and enforcement of retailer compliance with tobacco control ordinances. Programs are community-based and deploy health educators and youth educators to engage community members in cessation campaigns, in recognition that 90% of adult smokers started smoking before age 18.
 - Related to this tobacco work is ongoing education and awareness for chronic disease including projects such as a cancer awareness education and cross-city hypertension initiative to provide screening for high blood pressure in vulnerable communities.
- **Food Access Baltimarket** is a suite of community-based food access and food justice programs through BCHD. The program envisions a Baltimore with communities that have equitable access to healthy, affordable, and culturally-specific foods every day. The mission of the program is to improve the health and wellness of Baltimore City residents by using food access and food justice as strategies for community transformation. The three programs that make up Baltimarket include:
 - Virtual Supermarket – a grocery delivery service that serves over 600 customers at 6 sites and manages over \$200,000 in orders, which are handled by 21 trained community-based advocates.
 - Healthy Corner Stores – 10 stores located in Upton/Druid Heights, Harlem Park, and Franklin Square communities that engage in promotion of healthy eating via community nutrition education, PSAs about healthy snacking, and more.
 - Neighborhood Health Advocates and Food Justice Forum – This summer, the Food Justice Community Conversation Guide will launch with the goal of 25 community-run conversations about food justice in the next year. These conversations are facilitated by BCHD-trained Neighborhood Health Advocates—members of the community who work to help others to get access to healthy, affordable and fresh food through BCHD.

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- **Lead Prevention** BCHD seeks to reduce lead poisoning in the City through primary prevention and aggressive enforcement of the city's lead laws. More than 56,000 children under age 6 are at risk for lead poisoning in Baltimore. Lead poisoning can cause permanent brain damage and no amount of lead in children is safe. BCHD educates and encourages families and providers to test children ages 1 and 2 for lead levels, outreach to pregnant women to evaluate potential lead hazards, and with other partners, including Baltimore Housing, conducts home visits and develops strategies to reduce lead paint hazards in homes.
- **Asthma** 12.4 % of Baltimore City adults currently have asthma, compared to 8.4% statewide and 8.6 % nationally. The hospitalization rate for adult asthmatics in the City was 3.3 times higher than the state rate (42.9 vs. 13.2 per 10,000 people). BCHD's asthma programs focus on disease management and access to key resources for patients struggling with asthma. BCHD conducts home visits for children with asthma to educate caregivers about preventing asthma triggers and reducing ER visits for children.

Victories: We have made significant progress in tackling chronic disease through public health campaigns and advocating for policy changes at all levels of government:

- **Lead prevention reforms:** Childhood lead poisoning has decreased significantly and are currently at the lowest levels since Maryland's lead law was implemented in 1994 and enhanced enforcement began at the City level in 2000. Since then, the number of lead poisoning cases has decreased by 98%. Additionally, a BCHD-led pilot to test children's jewelry revealed extreme levels of lead in many readily available products at local stores. Based on the results of this testing, BCHD implemented regulatory action against lead in children's jewelry which prohibits the sale of such jewelry if measuring over 600ppm of lead.
- **Sugar-sweetened beverages:** one in three children in Baltimore are overweight or obese, and a major contributor is sugar-sweetened beverages (SSBs). With the support of BCHD, legislation has been introduced to the City Council that would require retailers to post warning labels stating the fact that sugar-sweetened beverages lead to tooth decay, obesity, and diabetes. The legislation is based on scientific evidence that warning labels influence consumer behavior and ensures that consumers can make informed choices about their purchase. This is particularly important in Baltimore City with rising rates of obesity among children and with beverage companies' practices of disproportionate marketing in communities of color and low-income communities.
- **Alcohol and tobacco regulation:** BCHD has advocated for several policy initiatives to address the harmful effects of tobacco and alcohol. These include regulation of hookah establishments, a state-wide tobacco tax to be used for medical care, a ban on indoor smoking, including e-cigarettes, buffer zones around schools, and increased enforcement funding and capacity. In the last year, BCHD's advocacy has resulted in a statewide ban of powdered alcohol and a citywide ban of the sales of the dangerous compounds known as synthetic drugs.

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Challenges and Aspirations:

- **Lead prevention** – Despite significant progress, our work is far from done: over 5% of children test positive for lead. Building upon current lead prevention efforts, additional funding is necessary at the local, state and federal levels in order to implement universal screening and provide primary prevention services. Most importantly, additional efforts are needed to support lead abatement in homes, as lead paint hazard is the leading cause of childhood lead poisoning.
- **Sugar-sweetened beverages labels** – As mentioned above, legislation has been introduced to the City Council that would require retailers to post warning labels noting the connection between sugar-sweetened beverages and health conditions such as obesity. We have experienced pushback from the American Beverage Association and similar special interests, despite the scientific foundation on which this legislation was developed. We are continuing to work with community partners on this and other efforts to reduce the scourge of childhood obesity and reduce disparities in Baltimore.
- **Local tobacco authority** – Due to a previous ruling, Baltimore City is unable to successfully enforce tobacco violations locally. We are currently pursuing legislation in the Maryland General Assembly that would permit local jurisdictions to enact and enforce measures regulating the sale and distribution of tobacco products, with measures at least as stringent as those enacted in state law.

Issue 6: Senior Health and Wellness

Background: As with youth health and wellness, BCHD is committed to providing health education and services for our city's older adults. The Division of Aging and Care Services serves as the local Area Agency on Aging and coordinates funds from the federal Older Americans Act to ensure an adequate service delivery system. Additionally, the Division ensures essential services for seniors, including health evaluation, personal care, transportation, and volunteer opportunities.

Victories: BCHD has piloted several innovative approaches to ensure improved health outcomes amongst the elderly, including:

- **Falls** The Robert Wood Johnson Foundation recently awarded a \$200,000 grant to a BCHD-led partnership with local hospitals and community partners such as the American Association of Retired Persons (AARP) that will use predictive data to track patients and reduce falls by one-third over three years. This project involves interventions in senior housing buildings and through hospitals and ERs to educate about falls prevention and provide services to reduce the risk of falls.
- **Community Resources** A growing concern among many Baby Boomers is taking on the role of caregiver for their parents. BCHD has teamed up with the city's libraries to offer a "[Caregiver Corner](#)" for anyone looking to find information on aging. This project was designed to provide caregivers with information and resources through several different initiatives by BCHD. The goal is to broaden outreach and support to family caregivers. Caregiver Corner is one initiative under the "Project Taking Care

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of Mom and Dad” designed to provide caregivers and older adults who visit the library with relevant resources and information.

- **Advocacy and Planning** BCHD has lead advocacy efforts to oppose cuts to State funding for Baltimore City, including funding for senior centers. We will develop a strategic plan for care for older adults in Baltimore, in a similar vein as the Youth Health and Wellness Plan, that will tie together efforts across the city and present a blueprint for ensuring that our most vulnerable seniors have access to the comprehensive care and community they need.

Challenges and Aspirations:

- *Senior Center Funding* – currently, the state distribution model for senior center funding is based on total unemployment and income rates rather than total population. We have pursued legislation in the Maryland General Assembly to change the formula so that it is based off of a population’s total elderly population, *as well as* the elderly population living 150% below the federal poverty line. We are also proposing that a state task force be created to examine the state funding distribution for seniors.
- *Older Americans Act* - The Older Americans Act was created to ensure that preference is given to providing services to older persons with the greatest economic and social need, particularly low-income minority persons. Funding has not kept up with the aging impoverished population, and it is essential that those dollars are aligned with those who have the greatest economic need and that the right balance is struck among need and costs. The current intrastate funding formula does not adequately target this vulnerable population and we have proposed revisions so that it is more responsive to the need of Baltimore City seniors.

Issue 7: Acute Communicable Disease and Public Health Preparedness

Background: BCHD provides several essential functions for the City, including: communicable disease tracking, education and prevention, emergency preparedness and response, restaurant inspections, and animal control. Our field staff, from animal control officers; to sanitarians; to outbreak investigators, have tackled emergencies ranging from Legionnaire’s, measles, and Ebola investigations to transporting patients to life-saving treatment during severe weather. These activities are core to Baltimore City’s safety and preparedness response.

Victories:

- **HIV Prevention and Education.** In the fall of 2015, BCHD secured two grants totaling \$22 million to bring HIV prevention, prophylaxis and treatment to underserved populations while creating 70 new jobs in the City. The White House has acknowledged Baltimore’s leadership in this area, and Baltimore was one of a handful of cities to join the Fast Track Cities coalition to end AIDS by 2030. Our HIV team will continue to partner directly with community and provider groups, provide education and treatment, in one of the largest collaborations to combat HIV.

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BCHD has a long history of providing innovative services to prevent and treat HIV/AIDS. As one of the first jurisdictions in the country to implement a Needle Exchange Program (NEP), the program has exchanged over one million syringes annually with a 75% return rate. The NEP program is credited with significantly moving the needle on HIV transmission with injecting drug users in Baltimore since its inception. The NEP is also the test bed for the Staying Alive Program, naloxone training, and directly observed therapy for non-compliant patients on HIV medications. In 2015, almost 3,000 individuals received naloxone training by NEP staff.

While the Affordable Care Act has improved access to health insurance and Medicaid, many of our residents with HIV/AIDS need additional support. BCHD provides clinical and support services for people living with HIV/AIDS and their contacts through programs like Linkage to Care and the Ryan White Program. Linkage to Care staff members identify patients who test HIV positive and patients are then taken directly to a participating physician to educate the patient and initiate the appropriate therapy. This program has linked over 1200 patients to primary care, an important step in stopping the transmission of HIV. In 2015, the Maryland Department of Health and Mental Hygiene recognized this program by awarding them with two state-wide awards, "Most Encounters with HIV Positive Clients" and "Most Referrals to HIV Primary Care". The Ryan White Program receives approximately \$17 million annually to provide HIV-related medical and support services to over 10,000 individuals living in Baltimore City and the five surrounding counties.

The Baltimore City Health Department has hosted the "Get Yourself Tested" Ball, annually for the last 6 years. This event is aimed at the "House and Ball community", which is made up of gay and transgender individuals. Each year, approximately 600 individuals attend the event, with hundreds of people volunteering for HIV testing. These events have yield between 4%-6% new HIV diagnoses. At all other venues where testing occurs in Baltimore – emergency departments, CBOs, clinics, our outreach testing and STD clinics – the new diagnoses rate is 1% or less. Because of this extremely high rate infection found at this event, we have identified the Ball as a key event that reaches both a viable high risk population group of undiagnosed individuals and useful arm into the community to address HIV. All individuals with new diagnoses are able to be linked to care through our Linkage to Care Program.

- **Vaccines** In the aftermath of the Disneyland measles outbreak last spring, BCHD took the lead in coordinating the Baltimore Statement on Childhood Vaccinations through a coalition of pediatric chiefs and chairs in the City, as well as the Maryland Chapter of the American Academy of Pediatrics. The statement highlighted BCHD's unequivocal message regarding the safety and effectiveness of childhood vaccines.
- **Public Health Preparedness** BCHD's Office of Public Health Preparedness and Response (OPHPR) is equipped to steward the City through any major public health emergency. This program trains staff and during times of emergency convenes and communicates with the City's healthcare infrastructure. In the aftermath of the unrest following Freddie Gray's death, BCHD lead the public health response; setting up a

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prescription access line to assist seniors whose pharmacies were closed and arranged shuttles to and from senior buildings for food and banking needs.

Recently, in response to record-breaking blizzard that hit Baltimore City, BCHD led a city-wide response to ensure that patients were able to access life-saving medical treatments, including dialysis and chemotherapy. Working in tandem with the Baltimore City Fire Department, the Office of Emergency Management and the National Guard, BCHD was able to deploy resources to safely and successfully transport 300+ patients in the midst of snow-covered roads and hazardous driving conditions. Baltimore City was recognized as the only jurisdiction state-wide that provided medical transports immediately post-blizzard.

Other ongoing efforts include BCHD's response to emerging diseases like the Zika virus; and the essential core public health activities that include investigation and surveillance of foodborne illness, animal bites/rabies and other infectious diseases such as Legionnaire's disease; and tracking of HIV, syphilis, gonorrhea, chlamydia and other sexually-transmitted diseases. In 2015, Acute Communicable Disease Program investigated over 50 outbreaks and hundreds of potential rabies exposures. Outbreaks occur in many settings, including restaurants, hospitals, schools and daycares and often the health impact of a reportable disease is significant. Large outbreaks, like a foodborne outbreak that occurred at the City's Convention Center a few years ago required the Department to reassign staff to interview as many 5,000 conference attendees and collect samples from all of those with symptoms.

Challenges and Aspirations:

- *Funding for emergency preparedness* – We can and should be prepared for all severe emergencies, particularly unanticipated ones. We advocate for continued funding to prepare for emergencies and outbreaks, particularly in anticipation of an upcoming Zika virus outbreak. After 9/11 and the Anthrax Attack, the federal government made available significant grant funding to build public health capacity to train staff, plan for emergencies and respond. In 2012, the BCHD OPHPR had a staff of 12. In 2016, OPHPR is staffed by 4, severely impacting the department's capacity to respond to any sustained emergency. As the federal funding decreases, the program's capacity decreases leaving the City vulnerable.
- *Funding for clinic safety net* - The decrease in State and Federal funding is not limited to just the emergency preparedness program, but also many of the safety net programs our vulnerable citizens depend on. As mentioned previously, the Affordable Care Act was intended to provide all citizens access to health insurance and healthcare. While there have been some successes, many of our very low income, vulnerable citizens rely on our grant funded safety net programs, such as tuberculosis control, syphilis and gonorrhea testing and family planning clinics. Failure to support essential public health services will dramatically impact very visible public health measures and the lives of all of our citizens.

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Issue 8: Population Health and Health in All Policies

Background: We know that medical care accounts for only 20% of a patient's health outcomes; social, behavioral, and environmental factors comprise the remaining 80%. Where we live, work, and play is the major driver of health outcomes, and as the public health authority for the City, BCHD is leading the way on initiatives that address the "upstream" factors of health—the social determinants—from housing to food to transportation to education.

We view health as foundational to every issue – unhealthy children cannot learn in school, and unhealthy adults cannot be a productive part of the workforce. As we examine critical issues across the City – the economy, public safety, education— health is an essential driver that cuts across all of them.

This is particularly significant in Maryland, where we are already leading the way on public health due to the establishment of global budgeting. Global budgeting shifts virtually all of the hospital revenue from a "fee-for-service" model to a global payment model, incentivizing hospitals to work in partnership with other providers and the community to prevent unnecessary hospitalizations and readmissions. The goal of the model is to promote quality healthcare, better patient health and lower cost, and as a result creates incentives for treatment of the whole person as well as the intersection of health with other policy priorities.

Victories:

Our current initiatives include:

- **Coordination with hospitals.** BCHD works closely with local healthcare providers, including hospitals and federally qualified health centers to identify shared priorities: behavioral health, for example. From creating a stabilization center to tracking patients who are the highest utilizers of care, coordination with our healthcare partners is key to ensuring that patients are receiving essential public health services. As the neutral convener, BCHD is positioned to coordinate citywide initiatives and collaborations that involve competing hospital systems and other health organizations. Department leaders participate in grant planning and visioning sessions with local hospital systems to ensure the City's public health priorities are included. In September 2015, BCHD convened over 100 hospital and healthcare leaders to discuss behavioral health priorities and coordination of case management services for high utilizers. BCHD is engaged with hospitals, clinics, and community groups in a number of other state, federal, and private grants to provide coordinated services to our residents.
- **Social determinants of health.** All of BCHD's programs, from B'More for Healthy Babies, to Safe Streets, to HIV prevention and treatment programs adopt this approach of comprehensive attention to social needs and services ---and as a result have experienced significant success to date. We are in the process of implementing a city-wide initiative to ensure that every patient can get access to the services they need: just as a doctor connects a patient to a pharmacy for medication, there should be simple ways to connect a patient to food to take with that medication.

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- **Health in all policies.** Health touches every issue. As a result, BCHD's health perspective must be a consideration in all policies in the City. For example, if the City is considering implementing bike paths, or placing an incinerator into the community, the health impact should be considered. Previously, a cross-agency task force for health existed within the city, with representation from every agency. BCHD proposes re-launching this task force, to be chaired by the Health Commissioner, to ensure an ongoing city-wide dialogue regarding the role of health in all policies.

Challenges and Aspirations:

- *Unified approach to addressing patients' social needs* – While efforts are underway across the City that integrate social needs into clinical care, there is still significant variation in the quality of those programs as well as their ability to sync with one another. We are currently leading a city-wide proposal to the Centers for Medicaid and Medicare Services, the federal agency responsible for overseeing services, payments, and innovations for Medicaid and Medicare patients, in partnership with all of the Baltimore City hospitals and federally qualified health centers, that will unify these efforts and ensure that all patients can benefit from services that address the realities of their daily lives.
- *Coordination and alignment* – Speaking about cross-agency or cross-issue collaboration is easy; actually implementing it from a standard operating perspective is much more complicated. To facilitate this, we propose re-launching a Cross-Agency Taskforce that can systematically bring the Health in All Policies philosophy to bear in conversations taking place within the City.
- *Strategic plan for health* – In addition to the initiatives above, we must also establish our forward-looking vision for health in the City. BCHD has launched Healthy Baltimore 2020, a comprehensive process that will build on the successes listed in this document to establish a five-year blueprint for health and well-being. This blueprint will pull on data that is produced by our ongoing epidemiology work -- including our Neighborhood Health Profiles, which provide snapshots of key health outcomes in each city neighborhood—as well as input from key community stakeholders that we collect via numerous community conversations.

Conclusion

While Baltimore City faces a number of public health challenges, we also have invaluable assets: one of the strongest healthcare infrastructures in the country, invested community members and partners, and a willingness –borne of necessity—to test and implement new, innovative approaches to keep our citizens healthy. As the City's health authority, BCHD is fortunate to work directly with excellent partners and leaders in every sector: government, business, community advocacy, healthcare, faith-based, and more – all of whom share a deep commitment to ensuring the health of our citizens. We hope that this briefing serves as a valuable tool to you and look forward to answering any questions you may have. Thank you for your partnership in ensuring that all of Baltimore's citizens are healthy.

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APPENDIX B

February 22, 2016

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

The undersigned submit this petition pursuant to Title 21, Chapter 9, Subchapter V, Part A of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 10.30 to request that the Commissioner of the U.S. Food and Drug Administration (FDA) place a black box warning on pharmaceuticals in the opioid and benzodiazepine classes warning patients of the potential serious risks with concomitant use of both classes of medications.

ACTION REQUESTED

The Petitioner requests the FDA to:

1. Amend current black box warnings on all opioid analgesic and benzodiazepine class medications to state:
 - a. *Labeling for all Opioid Class Medications should read:*

WARNING: CONCURRENT USE WITH BENZODIAZEPINES REDUCES THE MARGIN OF SAFETY FOR RESPIRATORY DEPRESSION AND CONTRIBUTES TO THE RISK OF FATAL OVERDOSE, PARTICULARLY IN THE SETTING OF MISUSE.
 - b. *Labeling for all Benzodiazepine Class Medications should read:*

WARNING: CONCURRENT USE WITH OPIOIDS REDUCES THE MARGIN OF SAFETY FOR RESPIRATORY DEPRESSION AND CONTRIBUTES TO THE RISK OF FATAL OVERDOSE, PARTICULARLY IN THE SETTING OF MISUSE.
2. Require medication guides for both classes of medications that specifically warn patients of the potential dangers of combined use of opioids and benzodiazepines.

STATEMENT OF GROUNDS

I. OVERVIEW

Concurrent misuse of benzodiazepines and opioids is contributing to the epidemic of fatal overdose in the United States. Biological data indicate that these two drug classes have synergistic effects in producing sedation and respiratory depression. Epidemiological data show polysubstance overdose fatalities involving both opioids and benzodiazepines are common and increasing.

FDA guidance indicates that a black box warning is appropriate in several circumstances, including when:¹

- “There is an adverse reaction so serious in proportion to the potential benefit from the drug (e.g., a fatal, life-threatening, or permanently disabling adverse reaction) that it is essential that it be considered in assessing the risks and benefits of using the drug;”

OR

- “There is a serious adverse reaction that can be prevented or reduced in severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation)”

Both of these conditions are met in this case. Clinicians should consider the serious adverse reaction of fatal overdose when assessing the risks and benefits of co-prescribing benzodiazepines and opioids. Moreover, clinicians can prevent fatal overdose by reducing rates of co-prescribing these classes of medications.

The labels and medication guides of only a few drugs in these two classes contain specific information on the dangers of concurrent use; none contain black box warnings. Accordingly, we are petitioning the FDA to add black box warnings for all medications in the opioid and benzodiazepine classes that appropriately warn prescribers and patients about a

¹ Food and Drug Administration. “Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products-Content and Format.” 6 October 2011. Accessed January 18, 2016 at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm075096.pdf>

reduced margin of safety and increased risk of fatal overdose when these classes of medication are used together.

II. BIOLOGY

Benzodiazepines and opioids operate on different receptors and have been long-understood to have synergistic effects on sedation and respiratory depression, such that concurrent use lowers the margin of safety.

Benzodiazepines. The primary allosteric mechanism of action for benzodiazepines is through binding to gamma-amino-butyric acid (GABA) receptors. This increases the activity of GABA, the principal, endogenous, inhibitory neurotransmitter in the central nervous system.² Benzodiazepines are known to decrease oropharyngeal muscle tone and blunt the arousal response to hypoxia and hypercapnia during sleep and thus increase risk of sleep apnea, even among healthy individuals.^{3,4} In addition to their other properties, such as anti-seizure activity, benzodiazepines are known to enhance the sedating effects of other medications and substances, including: full-agonist opioids, partial agonist opioids such as buprenorphine, alcohol, barbiturates, and sedating antihistamines.⁵

Opioids. Opioids, in addition to acting as potent analgesics, cause sedation up to and including complete loss of consciousness and respiratory arrest. Opioids function primarily through stimulation of the Mu (μ), Kappa (κ), and Delta (δ) receptors that are normally activated in response to noxious stimuli by endogenous molecules (endorphins, enkephalins, and dynorphins). In addition to analgesia, stimulation of Mu receptors in the brainstem and medial thalamus causes respiratory depression and sedation, particularly in non-tolerant individuals. Kappa receptors (found in limbic and other diencephalic areas of the brain, the brainstem, and spinal cord) mediate spinal analgesia, sedation, dyspnea, and respiratory depression.⁶

² Mehdi, T. Benzodiazepines Revisited. *BJMP*. 2012; 5(1):a501.

³ Hedemark LL, Kronenberg RS. Flurazepam attenuates the arousal response to CO₂ during sleep in normal subjects. *Am Rev Respir Dis*. 1983 Dec;128(6):980-3.

⁴ Drummond, GB. Comparison of sedation with midazolam and ketamine: effects on airway muscle activity. *British Journal of Anaesthesia*. 1996; 76:663-667.

⁵ Olsen, Y, Adams, J, Alvanzo, A, et al. Clinical Guidelines for the Use of Benzodiazepines Among Patients Receiving Medication-Assisted Treatment for Opioid Dependence." *Baltimore Substance Abuse Systems, Inc*. May 2013. Accessed January 18, 2016 at <http://www.bhsbaltimore.org/site/wp-content/uploads/2013/02/Benzo-Guidelines-FINAL-May-2013.pdf>.

⁶ Trescot, AM, Datta, S, Lee, M, Hansen, H. Opioid Pharmacology. *Pain Physician: Opioid Special Issue*. 2008; (11): S133-S153.

Laboratory and Human Subject Studies on Concurrent Use. Receptors for both opioids and benzodiazepines are highly concentrated in the respiratory centers of the medulla.⁷ Multiple laboratory studies in animals and humans have indicated that co-administration of these drugs decreases the margin of safety with respect to respiratory depression.

For example, a study in rats demonstrated that while high doses of an opioid (buprenorphine) and a benzodiazepine (midazolam) alone both resulted in mild, but significant increases in PaCO₂, the combined administration of these two drugs resulted in rapid, substantial and prolonged respiratory depression and hypoxia.⁸

Studies of human subjects have found synergistic effects in combining opioids with benzodiazepines:

- An experimental study on the effects of administering sedative doses of fentanyl, midazolam, or fentanyl plus midazolam, in 12 healthy adult males found fentanyl alone produced hypoxemia in 50% of subjects and apnea in none; the combination produced hypoxemia in 11 of 12 participants and apnea in half of the subjects.⁹
- An experimental study on the effects of co-administering high dose diazepam (40mg) with high dose methadone among patients maintained on regular opioid therapy (buprenorphine or methadone) found decreased SpO₂ levels in the methadone group at 150% of normal dose, demonstrating a synergistic effect on respiratory depression.¹⁰ (This effect was not seen with buprenorphine in this study.)
- Utah researchers conducted diagnostic polysomnographies on 140 patients with chronic pain who had been maintained on daily opioid therapy for at least 6 months, with a stable dose for at least 4 weeks. The patients were taking a variety of medication regimens, including benzodiazepines, muscle relaxants, and others. Of assessed combinations, the only medication usage pattern that had a statistically significant impact on the central apnea index was the combined use of methadone and

⁷ White JM, Irvine RJ. Mechanisms of fatal opioid overdose. *Addiction*. 1999; 94(7):961–972.

⁸ Gueye, PN, Borron, SW, Risede, P, et al. Buprenorphine and Midazolam Act in Combination to Depress Respiration in Rats. *Toxicol. Sci.* 2002; 65(1):107-114. doi: 10.1093/toxsci/65.1.107.

⁹ Bailey, PL, Pace, NL, Ashburn, MA, Moll, JWB, East, KA, Stanley, TH. Frequent Hypoxemia and Apnea after Sedation with Midazolam and Fentanyl. *Anesthesiology*. 1990; 73:826-830.

¹⁰ Lintzeris N, Mitchell T, Bond A, Nestor L, Strang J. Pharmacodynamics of diazepam co-administered with methadone or buprenorphine under high dose conditions in opioid dependent patients. *Drug Alcohol Depend.* 2007;91(2-3):187- 94.

benzodiazepines. The authors reported that "...benzodiazepines appeared to have an additive effect to the prevalence of methadone-related central sleep apnea."¹¹

Of note, the danger of combining benzodiazepines and opioids has not always been observed at therapeutic doses of both medication classes. For example, in one study, therapeutic doses of diazepam in 16 patients on stable methadone or buprenorphine regimens caused sedation and subtle performance deficits in reaction time, but not physiologic changes in pulse, blood pressure, respiratory rate, or SpO₂.¹²

Investigators have proposed potential mechanisms to explain the synergistic impact of opioids and benzodiazepines. It is generally thought that buprenorphine, a partial opioid agonist that is normally rarely associated with overdose death due to its natural ceiling effect for respiratory depression, loses this ceiling effect when taken in combination with benzodiazepines, resulting in risk of respiratory depression and death.^{13,14} Other potential mechanisms include: (1) benzodiazepines may alter the pharmacokinetics of opioids through noncompetitive inhibition of opioid metabolism, (2) the analgesic, hyperphagic/hyperdipsic, anxiolytic, and rewarding effects of benzodiazepines may be partially mediated via opioidergic mechanisms, and (3) benzodiazepines may amplify the Mu agonist effects of opioids.¹⁵

¹¹ Webster, LR, Choi, Y, Desai, H, Webster, L, Grant, BJB. Sleep-Disordered Breathing and Chronic Opioid Therapy. *Pain Medicine*. 2008;9(4): 425-32.

¹² Lintzeris N, Mitchell T, Bond A, Nestor L, Strang J. Interactions on mixing diazepam with methadone or buprenorphine in maintenance patients. *J Clin Psychopharmacol*. 2006;26(3):274- 83.

¹³ Lintzeris N, Nielsen S. Benzodiazepines, methadone and buprenorphine: interactions and clinical management. *Am J Addict*. 2010; 19(1):59-72.

¹⁴ DiPaula, B, Love, R. Lethal Mixtures-Benzodiazepines and Opioids, including Buprenorphine. University of Maryland-School of Pharmacy. June 2014. Accessed January 18, 2016 at http://bha.dhmdh.maryland.gov/OVERDOSE_PREVENTION/Documents/2014.06.11%20-%20Letter%20to%20Boards%20re%20Benzos%20and%20Opioids.pdf.

¹⁵ Jones JD, Mogali S, Corner SD. Polydrug abuse: A review of opioid and benzodiazepine combination use. *Drug Alcohol Depend*. 2012; 125(1-2): 8–18.

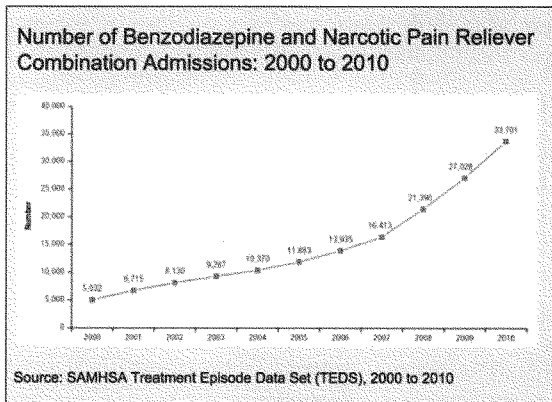
III. EPIDEMIOLOGY

Complementing the biological evidence, data from multiple sources indicate that concurrent use and misuse of benzodiazepines and opioids is associated with addiction and overdose.

Data from Treatment Admissions. Studies of patient perception have shown that benzodiazepines potentiate the intensity and duration of the analgesic, euphoric, and sedative effects of opioids in a dose-response pattern, indicating potential for misuse and addiction.¹⁶

Indeed, substance use disorders involving both opioids and benzodiazepines appear to be sharply increasing. According to the Substance Abuse Mental Health Services Administration, treatment admissions due to co-occurring addiction to benzodiazepines and

opioids increased 569.7% from 2000 to 2010, while admissions due to all other substance use disorders decreased by 9.6% in the same time period.¹⁷ (see Figure). During the month prior to treatment admission, of patients admitted for co-use of opioids and benzodiazepines, 57.1% and 45.5% reported daily use of opioids and benzodiazepines, respectively.¹⁸



Data from Death Certificates and Autopsies. The combination of benzodiazepines and opioids is becoming increasingly common in overdose deaths. Moreover, there is epidemiological evidence of a synergistic effect of the combination on the risk of death.

¹⁶ *Ibid.*

¹⁷ Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality. *The TEDS Report: Admissions Reporting Benzodiazepine and Narcotic Pain Reliever Abuse at Treatment Entry*. 13 December 2012. Accessed January 18, 2016 at <http://archive.samhsa.gov/data/2k12/TEDS-064/TEDS-Short-Report-064-Benzodiazepines-2012.htm>.

¹⁸ *Ibid.*

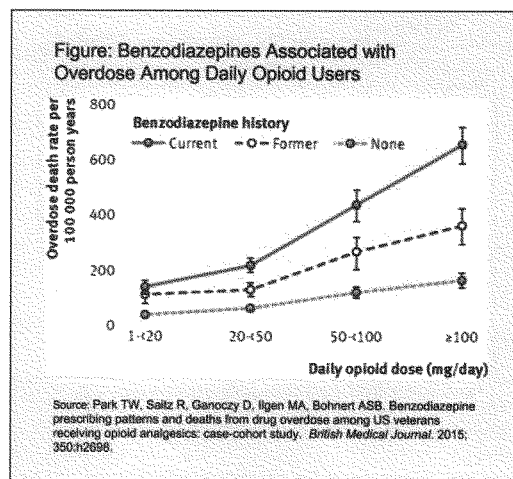
A recently published six-year case-cohort study of U.S. veterans nation-wide analyzed the relationship between history of benzodiazepine prescription, dose, type, and schedule and the associated risk of death from a drug overdose among patients who received treatment with opioid analgesics from the Veterans Health Administration. Study groups included veterans who died of a drug overdose and received opioids (n=2400) and a random sample of veterans who received opioid analgesics and services (n=420,386) from 2004 to 2009. During this study period, "...about half of the deaths from drug overdose (n=1185) occurred when veterans were concurrently prescribed benzodiazepines and opioids."

Significantly, the risk of death from drug overdose increased in a synergistic, dose-response fashion as daily benzodiazepine dose increased, as shown in the Figure. This risk was independent of dosing schedule.

The authors also found risk of death from overdose increased with history of benzodiazepine prescription, with the greatest risk associated with a current prescription.¹⁹

Epidemiological data show a high rate of involvement of benzodiazepines in opioid-related overdose deaths. For example:

- According to data from the National Vital Statistics System, 17% of the 13,800 opioid analgesic related deaths in 2006 involved concurrent use of benzodiazepines.²⁰ This rate of benzodiazepine involvement increased to 30% by 2010.²¹



¹⁹ Park TW, Saitz R, Ganoczy D, Ilgen MA, Bohnert ASB. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. *British Medical Journal*. 2015;350:h2698.

²⁰ Warner M, Chen LH, Makuc DM. Increase in fatal poisonings involving opioid analgesics in the United States, 1999–2006. NCHS data brief, no 22. Hyattsville, MD: National Center for Health Statistics. 2009.

²¹ Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. *Journal of the American Medical Association* 2013 Feb 20;309(7):657-9.

- In 2012 in New York State, of 883 opioid analgesic-related deaths, 308 (34%) involved benzodiazepines.²²
- According to data from the Rhode Island Department of Health, benzodiazepines were involved in 33% of prescription opioid fatalities from 2014 to 2015.²³
- Maryland found benzodiazepines to be associated with 17.4% of prescription opioid deaths in 2012, 15.8% in 2013 and 18.5% in 2014.^{24,25}

These data complement older data showing high rates of concurrent use of benzodiazepines in opioid overdose:

- A study reviewing death certificate data from 1999 to 2009 using the CDC Wide-Ranging Online Data for Epidemiologic Research database found benzodiazepines with opioids to be the most common polysubstance overdose fatality among 15 to 64 year olds.²⁶
- A review of 493 methadone-associated deaths in New York City from 2003 found 32% involved benzodiazepines,²⁷ a review of 139 methadone-associated deaths in Palm Beach from 1998 to 2002 found 33% involved benzodiazepines,²⁸ and a review of 84

²² Sharp MJ, Melnik TA; Centers for Disease Control and Prevention (CDC). Poisoning deaths involving opioid analgesics – New York State, 2003–2012. *MMWR*. 2015; 64:377–380

²³ Rhode Island Governor's Overdose Prevention and Intervention Task Force. Rhode Island's Strategic Plan on Addiction and Overdose Four Strategies to Alter the Course of an Epidemic. 4 November 2015. Accessed January 18, 2016 at <http://www.health.ri.gov/news/temp/RhodeIslandsStrategicPlanOnAddictionAndOverdose.pdf>.

²⁴ Maryland Department of Health and Mental Hygiene. Drug and Alcohol-Related Intoxication Deaths in Maryland, 2013. June 2014. Accessed January 10, 2016 at http://bha.dhmm.maryland.gov/OVERDOSE_PREVENTION/Documents/2014.07.07%20-%202013%20final%20intoxication%20report_updated.pdf.

²⁵ Maryland Department of Health and Mental Hygiene. Drug and Alcohol-Related Intoxication Deaths in Maryland, 2013. May 2015. Accessed January 10, 2016 at http://bha.dhmm.maryland.gov/OVERDOSE_PREVENTION/Documents/2015.05.19%20-%20Annual%20OD%20Report%202014_merged%20file%20final.pdf

²⁶ Calcaterra S, Glanz J, Binswanger IA. National trends in pharmaceutical opioid related overdose deaths compared to other substance related overdose deaths: 1999–2009. *Drug Alcohol Depend*. 2013; 131(3): 263–270.

²⁷ Chan G, Stajic M, Marker E, Hoffman R, Nelson L. Testing Positive for Methadone and Either a Tricyclic Antidepressant or a Benzodiazepine Is Associated with an Accidental Overdose Death: Analysis of Medical Examiner Data. *Acad Emerg Med*. 2006;13(5).

²⁸ Wolf BC, Lavezzi WA, Sullivan LM, Flannagan LM. Methadone-related deaths in Palm Beach County. *J Forensic Sci*. 2004;49(2):375–378.

methadone-associated deaths in Australia from 1993 to 1999 found 74% involved benzodiazepines.²⁹

- In a comprehensive assessment of 117 fatalities from 1996 to 2000 involving high-dose buprenorphine in France, benzodiazepines were involved in at least 91 (78%).³⁰
- A 1999 study of 82 opioid-related deaths in Ireland found benzodiazepines identified in 52 (61%) of the deaths.³¹

While most studies and attention have focused on the involvement of benzodiazepines in opioid-related deaths, the converse is also true: There is an extraordinarily high rate of opioid involvement in benzodiazepine associated deaths. For example, in Maryland, 74.0% of benzodiazepine associated deaths in 2012, 72.5% in 2013, and 59.2% in 2014 involved prescription opioids.^{32,33}

IV. CLINICAL EDUCATION

Prescribers need to consider the serious adverse reaction of fatal overdose when assessing the risks and benefits of co-prescribing benzodiazepines and opioids. However, existing educational measures have not been sufficient for this purpose. As a result, a black box warning would provide significant benefit.

Prescribing Trends. The CDC's 2014 Vital Signs brief reported that prescribers wrote 82.5 opioid prescriptions and 37.6 benzodiazepine prescriptions per 100 persons in the United States in 2012.³⁴ Evidence indicates rates of co-prescription are rising. According to a study based on a database of 3.1 billion primary care visits, from 2002 to 2009, concurrent prescription of benzodiazepines with opioids increased by 12.0% per year, and benzodiazepine

²⁹ Ernst E, Bartu A, Popescu A, Ilett K, Hansson R, Plumley N. Methadone-related deaths in Western Australia 1993–99. *Aust Nz J Publ Heal.* 2002;26(4):364–370.

³⁰ Kintz P. Deaths involving buprenorphine: a compendium of French cases. *Forensic Sci Int.* 2001;121(1–2):65–69.

³¹ Ward M, Barry J. Opiate-related deaths in Dublin. *Irish Journal of Medical Science.* 2001; 170 (1):35–37.

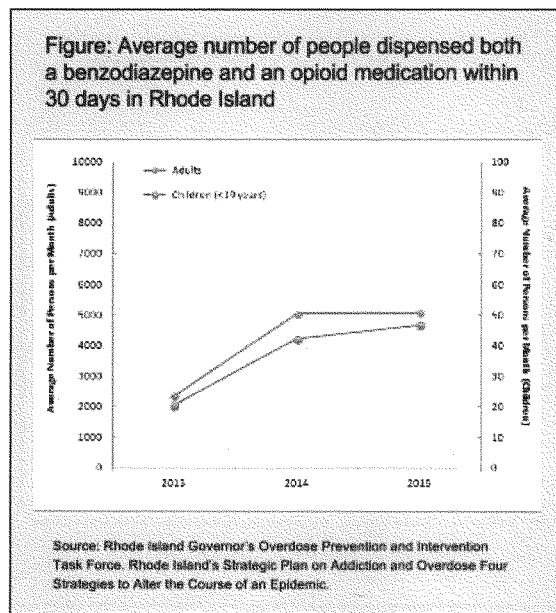
³² Maryland Department of Health and Mental Hygiene 2014, *op. cit.*

³³ Maryland Department of Health and Mental Hygiene 2015, *op. cit.*

³⁴ Paulozzini LJ, Mack KA, Hockenberry JM, Centers for Disease Control and Prevention. Vital Signs: Variation among states in prescribing of opioid pain relievers and benzodiazepines — United States, 2012. *Morbidity and Mortality Weekly Report (MMWR).* 2014; 63(26):563–568.

prescriptions increased by 12.5% per year. During this time, 12.6% of all primary care visits involved benzodiazepine or opioid prescriptions.³⁵

Rhode Island has also seen increasing numbers of patients receiving both benzodiazepines and opioids, as shown in the figure below.



Data from the Rhode Island Department of Health illustrate the frequency of co-prescription. Among all patients dispensed an opioid in the state in 2015, 27% also were dispensed a benzodiazepine at least once within 30 days of receiving an opioid. Of those dispensed a benzodiazepine, 59% were also dispensed an opioid at least once within 30 days of receiving a benzodiazepine.³⁶

Based on such data, Rhode Island has set a priority of reducing co-prescription of benzodiazepines with opioids as a key component of their state's strategy to reduce prescription drug-related deaths.³⁷ As part of its citywide overdose prevention and response plan, the Baltimore City Health Department issued best

³⁵ American Academy of Pain Medicine (AAPM). Prescriptions for benzodiazepines rising and risky when combined with opioids, researchers warn. *ScienceDaily*. 6 March 2014. Accessed January 18, 2016 at www.sciencedaily.com/releases/2014/03/140306211040.htm.

³⁶ Rhode Island Governor's Overdose Prevention and Intervention Task Force, *op. cit.*

³⁷ Rhode Island Governor's Overdose Prevention and Intervention Task Force, *op. cit.*

practice letters to clinicians that emphasize the necessity of judicious prescribing of these two classes of medications.³⁸

A common clinical scenario for co-prescription of opioids and benzodiazepines is the patient with chronic pain. Patients who receive opioids for chronic pain are often also prescribed benzodiazepines for associated symptoms including muscle spasms, anxiety and sleep disorder despite little evidence for therapeutic benefit in this clinical situation. In a national sample of chronic non cancer pain patients prescribed opioids, approximately one-third were current users of benzodiazepines.³⁹

Yet there are hazards to this clinical practice. Concurrent benzodiazepine use in opioid users is not associated with improved symptoms; instead daily benzodiazepine users have reported higher pain severity and less coping with their pain.⁴⁰ While benzodiazepines are primarily indicated for sleep and anxiety disorders, Lintzeris and Nielsen of the University of Sydney have written that the evidence for these clinical recommendations is primarily, "...confined to short-term controlled trials of up to several months duration in non-opioid-dependent populations, and long-term observational studies of [benzodiazepine] treatment for these indications are difficult to interpret due to imprecision in the differentiation of relapse, rebound, and withdrawal phenomena."⁴¹ A clinical guideline from the American College of Physicians and the American Pain Society in 2007 highlighted that benzodiazepines are not FDA-approved for treating low back pain and highlighted the risk for addiction and misuse if used for more than short-term relief for acute or chronic back pain. The guideline recommended benzodiazepines should only be used for a time-limited course of therapy.⁴²

A second common clinical scenario is co-prescribing in the setting of co-existing psychiatric illness. Chronic pain patients using benzodiazepines frequently have comorbid mental health conditions. One study found that active benzodiazepine users were 50% more likely to have used antidepressants and three times more likely to have taken antipsychotic

³⁸ Committee Hearing: Opioid Abuse in America: Facing the Epidemic and Examining Solutions, 114th Cong. (2015) (testimony of Dr. Leana Wen). Accessed February 23, 2016 at <http://www.help.senate.gov/imo/media/doc/Wen1.pdf>.

³⁹ Nielsen, S., Lintzeris, N., Bruno, R., et al. Benzodiazepine use among chronic pain patients prescribed opioids: Associations with pain, physical and mental health, and health service utilization. *Pain Medicine* 2015; 16(2), 356-366.

⁴⁰ *Ibid.*

⁴¹ Lintzeris N, Nielsen S. 2010, *op. cit.*

⁴² Chou R, Qaseem A, Snow V, Casey D, Cross JT, Shekelle P, et al. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007;147(7):478-491.

medication in the past month.⁴³ According to the Treatment Episode Dataset, a national data system that captures all admissions to addiction treatment centers in the U.S., almost half (45.7 percent) of all patients admitted for combined opioid and benzodiazepine use in 2010 reported having a co-occurring psychiatric disorder.⁴⁴ A black box warning will draw greater attention to the risks of combined use in this population.

Alternative approaches to combined use of opioid analgesic and benzodiazepines include nonpharmacologic treatment modalities for pain such as manipulation therapy, physical therapy, and massage. Similarly, use of other medication classes, meditation, and cognitive behavioral therapy for anxiety and sleep disorders may reduce concurrent use of benzodiazepines in patients with chronic pain.⁴⁵ A black box warning would help clinicians to consider alternatives to combined prescribing of opioids and benzodiazepines.

A black box warning would also lead specialty societies and others to focus on the risks of co-prescribing in their guidelines and educational programs to clinicians, supplementing existing measures to improve appropriate prescribing. In recent years, several clinical guidelines have been released advising providers and patients of the dangers of concurrent use. A CDC Brief assessing commonalities in recently-issued provider guidelines about opioids in chronic pain found the Utah State Clinical Guidelines on Prescribing Opioids for Treatment of Pain, the Washington State Agency Medical Directors Group Interagency Guideline on Opioid Dosing for Chronic Noncancer Pain, the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Noncancer Pain, the New York City Department of Health and Mental Hygiene Opioid Prescribing Guidelines, and the American Society of Interventional Pain Physicians Guidelines for Responsible Opioid Prescribing in Chronic Noncancer Pain all recommended against co-prescription of benzodiazepines and opioids or urged caution or tapering one medication class.⁴⁶ The December 2015 draft of draft guidelines from the CDC on opioids for chronic pain

⁴³ Nielsen S, Lintzeris N, Bruno R., et al. 2015, *op. cit.*

⁴⁴ Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality. *The TEDS Report: Admissions Reporting Benzodiazepine and Narcotic Pain Reliever Abuse at Treatment Entry*. 13 December 2012. Accessed January 18, 2016 at <http://archive.samhsa.gov/data/2k12/TEDS-064/TEDS-Short-Report-064-Benzodiazepines-2012.htm>.

⁴⁵ Gudin, JA, Mogali, S, Jones, JD, Comer, SD. Risks, Management, and Monitoring of Combination Opioid, Benzodiazepines, and/or Alcohol Use. *Postgrad Med*. 2013;125(4): 115–130.

⁴⁶ CDC: National Center for Injury Prevention and Control. Common Elements in Guidelines for Prescribing Opioids for Chronic Pain. 2016 January. Accessed February 7, 2016 at: http://www.cdc.gov/drugoverdose/pdf/common_elements_in_guidelines_for_prescribing_opioids-20160125-a.pdf

recommend against co-prescription whenever possible because “[c]oncurrent use is likely to put patients at greater risk for potentially fatal overdose.”⁴⁷

In January 2014, Institutes for Clinical Systems Improvement released an Acute Pain Assessment and Opioid Prescribing Protocol document for providers that specifically included benzodiazepine use in their ABCDPQRS Opioid risk assessment due to the increased risk of sedation and overdose with concurrent use leading to their clinical recommendation that “...patients using [benzodiazepines] and opioids should be counseled not to combine these medications...”⁴⁸

With these guidelines buttressed by a black box warning, clinicians will be more likely to review their patients’ medication lists, including medications prescribed by others, to avoid this potential hazard. A few examples of current risk assessment and mitigation tools include: the use of Prescription Drug Monitoring Programs, integration of appropriate urine drug tests into practice, increased consideration for non-opioid and non-pharmacological alternatives for pain management, and educational initiatives to increase provider awareness of Screening, Brief Intervention, and Referral to Treatment (SBIRT) initiatives and other referral resources.

A black box warning would enhance educational efforts by public health officials. In June 2014, the Maryland Department of Health and Mental Hygiene sent a letter to all licensed physicians warning of the “potentially lethal combination of benzodiazepines and opioids.”⁴⁹ Other states and localities are planning similar efforts.

⁴⁷ Dowell, D, Haegerich, TM, Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 [Draft]. 15 December 2015.

⁴⁸ Thorson D, Biewen P, Bonte B, Epstein H, Haake B, Hansen C, Hooten M, Hora J, Johnson C, Keeling F, Kokayeff A, Krebs E, Myers C, Nelson B, Noonan MP, Reznikoff C, Thiel M, Trujillo A, Van Pelt S, Wainio J. Institute for Clinical Systems Improvement. Acute Pain Assessment and Opioid Prescribing Protocol. January 2014. Accessed February 7, 2016 at: <https://www.icsi.org/asset/dvp5wm/Opioids.pdf>.

⁴⁹ Sharfstein J, Jordan-Randolph G, Gahunia M, Hadley L. Maryland Department of Health and Mental Hygiene Public Letter. 11 June 2014. Accessed January 18, 2016 at http://bha.dhmdh.maryland.gov/OVERDOSE_PREVENTION/Documents/2014.06.11%20-%20Cover%20Letter%20to%20Boards%20re%20Benzos%20and%20Opioids.pdf

V. EXISTING LABELING

Only a few labels and medication guides contain specific information on the dangers of concurrent use of these two classes of medications; none contain black box warnings.

Opioids. The labels or guides for buprenorphine, fentanyl, and methadone specifically mention the risk of concurrent use with benzodiazepines. For example, the buprenorphine label, in warnings, states, "A number of deaths have occurred when addicts have intravenously misused buprenorphine, usually with benzodiazepines concomitantly." Suboxone (buprenorphine) also has a medication guide that informs patients about the risk of benzodiazepines, stating: "You have a higher risk of death and coma if you take Suboxone with other medications, such as benzodiazepines." The label for methadone states, "Deaths associated with illicit use of methadone frequently have involved concomitant benzodiazepine abuse." The medication guide for methadone, however, does not mention this risk. The labels and medication guides for other commonly prescribed opioids, including oxycodone, hydrocodone, and codeine, only make general and inconsistent mention of interactions with Central Nervous System (CNS) depressants and sedatives.

Benzodiazepines. There is scattered and inconsistent mention of potential problems with concurrent use of opioids on the labels of some benzodiazepine medications. For example, the label for midazolam states, in the interaction section, "the sedative effect....is accentuated by any concomitantly administered medication which depresses the central nervous system, particularly narcotics (e.g., morphine, meperidine and fentanyl)..." The label of diazepam states, in the precautions section, "If diazepam is to be combined with other psychotropic agents...careful consideration should be given to the pharmacology of the agents to be employed, particularly with known compounds which may potentiate the action of diazepam, such as....narcotics." The medication guide for diazepam generically cautions against simultaneous use with alcohol and other CNS-depressant drugs.

Existing warnings on concurrent use of benzodiazepines and opioids are inconsistent, infrequent, and insufficient. They fail to reflect the strong biologic and epidemiological data on risks to patients of respiratory depression and fatal overdose from combining these classes of medications.

VI. PUBLIC EDUCATION

A black box warning would help patients recognize the risks of concurrent use of benzodiazepines and opioids and would emphasize the need to discard old or expired medications that could be otherwise combined with new prescriptions for dangerous effects. It

would support education efforts aimed at informing the general public about the epidemic of fatal overdose and the importance of judicious prescribing.

VII. POTENTIAL OBJECTIONS

Some may object to class warnings when all possible combinations between opioids and benzodiazepines have not been fully studied. However, it is our view that the basic science and epidemiology support class effects that obviate the need for additional research. Moreover, clinicians and patients should generally be aware of the dangers; a strong black box warning will provide a clear general message to improve care and save lives.

VIII. FDA AUTHORITY

The Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Section 901(a) of the FDAAA added Section 505(o)(4) to the FDCA, granted FDA authority to mandate post-approval safety-related labeling changes for both individual drugs and classes of drugs.⁵⁰

IX. CONCLUSION

FDA guidance⁵¹ supports the use of black box warnings in several circumstances, including when:

- "There is an adverse reaction so serious in proportion to the potential benefit from (e.g., a fatal, life-threatening or permanently disabling adverse reaction) that it be considered in assessing the risks and benefits of using the drug;"
- or
- "There is a serious adverse reaction that can be prevented or reduced in severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation)"

Both of these conditions are met for the risk of fatal overdose from co-prescribing of benzodiazepines and opioids. Biological and epidemiological data support the urgency of action to warn prescribers and the public about this risk.

Based on this scientific record, we petition that the FDA:

1. Create and mandate black box warnings for all opioids and benzodiazepine class medications to read as follows:

Labeling for all Opioid Class Medications should read:

⁵⁰ Danzis, SD, Pitlyk, SE. FDAAA's Safety Labeling Provisions. *Update Magazine*. 2009; 10-13. Accessed February 7, 2016 at <https://www.cov.com/~media/files/corporate/publications/2009/01/fdaas-safety-labeling-provisions.pdf>

⁵¹ Food and Drug Administration 2011, *op. cit.*

WARNING: CONCURRENT USE WITH BENZODIAZEPINES REDUCES THE MARGIN OF SAFETY FOR RESPIRATORY DEPRESSION AND CONTRIBUTES TO THE RISK OF FATAL OVERDOSE, PARTICULARLY IN THE SETTING OF MISUSE.

Labeling for all Benzodiazepine Class Medications should read:

WARNING: CONCURRENT USE WITH OPIOIDS REDUCES THE MARGIN OF SAFETY FOR RESPIRATORY DEPRESSION AND CONTRIBUTES TO THE RISK OF FATAL OVERDOSE, PARTICULARLY IN THE SETTING OF MISUSE.

2. Require medication guides for both classes of medications that specifically warn patients of the potential dangers of combined use of opioids and benzodiazepines.

As physicians, public health officials, and researchers who have both analyzed the evidence and seen the impact of opioid overdose first-hand in our patients and loved ones, we urge the FDA to promptly consider these changes.

ENVIRONMENTAL IMPACT

According 1921 CPR Sec. 25.31(a), this Petition qualifies for a categorical exclusion from the requirement that an environmental impact statement be submitted.

ECONOMIC IMPACT

According to 21 CFR Sec 10.30(b)~ an economic impact statement is to be submitted only when requested by the Commissioner following reviewing of this Petition.

CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition that are unfavorable to the petition.

Respectfully submitted,



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Olivia Kasirye, M.D., M.S. County Public Health Officer Sacramento County	Richard H. Opper, State Health Officer and Director, Montana Department of Public Health and Human Services	
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	Jay C. Butler, M.D. Chief Medical Officer, and Director, Division of Public Health Alaska Department of Health And Social Services	
	Cara Christ, M.D., M.S. State Health Official, Arizona Director, Arizona Department of Health Services	
	Nathaniel Smith, M.D., M.P.H. Director and State Health Officer, Arkansas Department of Health	

Mr. MICA. Thank you.

You are not allowed, unfortunately, in these committee hearings, to express your opinion or your approval or disapproval. I just have to let the public know that. Only your representatives can do that.

Please now to welcome and recognize from my district, the Mayor of Orange County, Florida. Some of you have asked where that is. Of course, Orlando is the principal city, and we have our mayor who started a heroin task force when we were hit with this epidemic.

She is also accompanied by our—but they are not going to testify. George Ralls, raise your hand, who is our Public Health Director. David Siegal, who lost a daughter to a drug overdose and has turned that tragedy into a concerted public effort. And Karen Diebold Sessions is the former City Commissioner from my fair city of Winter Park.

So I welcome the guests accompanying our mayor and recognize Mayor Jacobs. Welcome.

STATEMENT OF TERESA JACOBS

Ms. JACOBS. Thank you, Mr. Chairman. Chairman Mica, Ranking Member Cummings, members of the committee, thank you for calling this hearing, and thank you for this opportunity to discuss a serious threat facing our cities and counties across the country.

As Mayor of Orange County, Florida, allow me to share a few statistics. But first, Mr. Chairman, I would like to ask that a statement from one of our constituents who you just introduced, Mr. David Siegal, be added to the record. Mr. Siegal is President of Victoria's Voice Foundation, and he is father of Victoria Siegal, who died last summer from a drug overdose at the young age of 18.

Mr. MICA. Without objection, so ordered.

Ms. JACOBS. Thank you.

Many of you know Orange County as the home to Orlando and 12 other municipalities. We have a population of 1.2 million people. Last year we broke a national record for tourism, entertaining more than 62 million visitors.

But many of you probably don't know that last year we also lost 84 lives to heroin overdoses, and probably nobody will know that that was a 600 percent increase since 2011.

Four years ago, like so many other counties across the country, we were fighting pill mills. We worked hard. We adopted tough regulations at a local and state level. We provided resources to break opiate addiction, and we were pretty successful.

Today, the front line has moved but the battle is tougher than ever. Too many prescription drug abusers have found an inexpensive and often deadly alternative, heroin. Despite Central Florida's strong economy and our extraordinary quality of life, heroin has absolutely exploded. Last year, approximately 2,000 heroin users moved through our county jail. Many of these arrests, in fact most of them, were not heroin possession, but they were other related offenses resulting from the debilitating effect that heroin use has on its users.

Tragically, in 2015 we housed 100 expectant mothers addicted to opioids and heroin.

Quite frankly, our county jail has become the treatment center of last resort for so many people. Yet too many people still don't realize the severe threat that heroin poses not only to the lives of the addicts but to the fabric of our community.

For the good of our citizens and our whole community, we are fighting, and we are fighting hard. Last summer I convened the Orange County Heroin Task Force, and I asked our Sheriff Demings to co-chair the effort. We have 22 high-ranking officials who served on the task force, from our chief judge to our state attorney, to medical professionals in all of our hospitals to our superintendent of public schools to representatives of our three colleges. I commend the effort of the Orange County Sheriff's Office and the Orlando Police Department, as well as our Metropolitan Bureau of Investigation, because since we formed this task force through collaboration and dedication, they have arrested more than 370 heroin-related incidents just in six months, 370.

Last week our task force concluded its efforts, and it made 37 recommendations. Similar to the comments that you have heard from my colleagues here, we recommend bond increases for trafficking, and we recommend media and social media campaigns warning about the deadly nature of heroin.

Heroin is a serial killer in our community, and so few people recognize it for that.

Coordinated efforts to avoid fatal overdoses by demanding access to naloxone. I commend the work of my colleague here, Dr. Wen. Congratulations. Naloxone, as you have heard, is a life-saving drug that is used in severe overdose situations; and also to look for new opportunities to fight addiction by coupling detox at our jail with addiction treatment programs using the drug Vivitrol. Vivitrol is a long-acting opioid antidote.

In addition to moving forward with the implementation of these recommendations, we are working with our partners at the National Association of Counties, which has teamed up nationally with the National League of Cities. We are working with HIDTA, and we are working with other organizations to implement the best practices.

We know there is no single solution, but there are some universal effective approaches. Enforcement is absolutely critical to combatting heroin use. In keeping with what we learned with pill mills, we must be tireless in educating people that addiction is an illness. It is an illness that requires serious medical treatment.

From law enforcement to families, the life-saving drug naloxone needs to be more accessible without a prescription and available at a reasonable cost.

And one final point. I want you to know that in Orange County, through our collaborative effort, we are committed to doing everything we can with the resources that we have. Here is where we need your help.

Help stop the influx of drugs across the border. We need you to continue to expand your efforts to stop these deadly drugs before they enter our communities. Local treatment and law enforcement will do their part, but the Federal Government must do everything possible to keep this plague from our shores and our communities.

Help us treat more addicts. With a regional population of 2.5 million, we have only 26 beds for the uninsured, 26 beds, and yet 62 percent of the overdoses in our community are among the uninsured.

And help us raise awareness so that more people will choose not to try this deadly drug in the first place.

To end this crisis and to save lives, we all need to be engaged.

I thank you for your attention to this critical issue, I thank you for your leadership, and I thank you for your service to our country.

[Prepared statement of Ms. Jacobs follows:]

**U.S. House of Representatives
Committee on Oversight and Government Reform
Witness Testimony by Orange County, Florida Mayor Teresa Jacobs
Remarks as Prepared**

Chairman Chaffetz, ranking member Cummings and members of the committee, thank you for calling this important hearing, and for allowing me to share the deadly impact that heroin is having on the Orange County metro area.

Like many parts of the country, we were initially fighting pill mills. Orange County worked to “outlaw” them, and to provide resources for breaking opioid addiction.

But today, the battle is tougher than ever, as too many prescription drug abusers are able to find an inexpensive alternative: heroin.

The result? Despite Central Florida’s strengthening economy, extraordinary quality of life, and soaring reputation, heroin use has exploded.

In 2015, we had 82 heroin-related deaths in Orange County, compared to 14 in 2011.

The Ninth District, which includes Orange and Osceola Counties, also had a substantial increase, reporting 101 heroin related deaths in 2015, up from 19 in 2011.

Barely a week goes by without more deaths, including 3 overdoses in a recent weekend. Also this month, a suspected foreign drug dealer with six pounds of heroin was arrested at our international airport.

For the good of our community, and especially for young people who simply do not understand the severe threat posed by heroin – including the wildly unpredictable nature of what they might be buying – we are fighting.

Last summer I convened the Orange County Heroin Task Force, and asked our Sheriff to Co-Chair the effort, so we could bring local resources together to address the surge of heroin.

As we began our work, local law enforcement increased joint operations between the Orange County Sheriff's Office, our MBI and the Orlando Police Department, resulting in over 370 heroin-related arrests.

We've also seen an increase in bookings at the Orange County Jail, which is operated by Orange County.

- In 2013, we had 475 heroin-related bookings, and at the end of 2015, we had over 840 bookings, with the majority of those arrested between the ages of 18-44.
- From January 2015 to January 2016, there were approximately 2,000 unduplicated heroin users at our Jail.
- Not surprising, many of their arrests were for petty offenses – unrelated to an actual heroin arrest, but directly related to the treadmill of infractions and jail time that is the norm for so many heroin addicts.
- And tragically, on any given day at Corrections, we will have pregnant heroin users. In 2015, we housed 100 expectant mothers who were addicted to opiates or heroin.

And as you can imagine, our Jail has become a “treatment center of last resort” for too many cases.

Our Task Force concluded its efforts last week, delivering 37 targeted recommendations – from increased bond for trafficking penalties to social media campaigns warning young people about the deadly nature of heroin, as well as ways to fight addiction – including treatment and medically-assisted detox at our jail.

In addition to moving forward with implementation of critical recommendations, we are also working with our partners at the National Association of Counties, as well as HIGH-DAH (HIDTA) and other organizations to identify best practices, from interdiction to treatment.

Already we've learned that while no single solution works, there are some universally effective approaches:

- Enforcement is critical to combating heroin use in our community, but as we heard from our law enforcement partners, we simply cannot arrest our way out of this problem. We must address the demand.
- And in a continuation of what we learned with the pill mills, we must be tireless in educating people that addiction **is an illness** – an actual disease of the brain.

- From law enforcement to families, the life-saving drug naloxone needs to be readily available, at a reasonable cost. Standing medical orders for this makes sense.
- We need to increase funding for substance abuse treatment and resources, including detox beds and ambulatory detox.

To save lives, Orange County needs an engaged community, as well as strong partners at the federal and state level.

Thank you, ladies and gentlemen of the Committee.

Mr. MICA. I thank you, Mayor Jacobs, for participating today, and all of our witnesses.

Now we will turn to questions, and I will lead off.

The scope of the problem that we are facing, I don't think people are comprehending this. From 16,000, when we chaired the Criminal Justice Policy Subcommittee, 16,000 to 47,000. We are approaching 50,000 in one year. Heroin is only 20 percent of that, 10,000 deaths. When are the 2015 figures coming out?

Mr. BOTTICELLI. We hope to have the 2015 figures by the end of the year. But part of what —

Mr. MICA. By the end of the year. We can't get them until the end of the year?

Mr. BOTTICELLI. Well, unfortunately, a part of the issue is that these data get reported from county —

Mr. MICA. And 47,000 from 2014, and I am afraid it is going to be off the charts. That does not count, folks, that does not count—there are 35,000 automobile deaths in the United States. Half of those, people have some kind of substance in their system when they are killing themselves. It used to be that teens, the biggest killer of teens was automobile accidents. Now it is drugs. Isn't that right?

Mr. BOTTICELLI. That is correct.

Mr. MICA. Yes. It is killing our youth. We haven't even gotten into firearms. Firearms are the tool of the drug trade, and they have illegal weapons that they are using to commit robberies, mayhem. Again, it is an astounding number. We haven't killed this many in multiple-year wars as we are killing in one year.

We will lose, guys, a half-a-million people in a decade at the rate we are going, or more. Every family has been affected by it, and now it is just a slaughter out of control.

Now, we have lots of responsibility, and I am all for treatment. Treatment is at the end of the process. They have already been addicted. We have got to stop this stuff at our borders.

I sat with our police chief. I sat with our HIDTA people. We put in place the HIDTA. I had to do that by legislation a number of years ago because they play political games with even the creation of high-intensity drug traffic areas, but we did it years ago. And here we are back where we—we are far beyond where we ever were then.

This is out of our newspaper from just a few days ago, six pounds of heroin at OIA. They are bringing this deadly, these deadly substances, and it is not just heroin.

Mexico, you talked about Mexico, and I said it is not just illegals coming across the border, but they are coming across with drugs. Isn't that right, Mr. Milione?

Mr. MILIONE. Yes, that is correct.

Mr. MICA. I sat with the HIDTA folks and saw the pattern. These are cartels. They are organized.

What I just heard—did you all see what's his name, El Chapo? He said he came across the border, it was like a sieve. That was the major drug dealer, the most sought-after drug dealer, and he transits the border like it is some kind of a holiday visit to the United States. So somehow we have to get a handle on this.

I just looked up the prosecutions. The prosecutions, when we looked at trafficking with illegal weapons, is down, and prosecution—I talked to some of my DEA folks; they won't tell you this on the record. They are not going to say this, but it is very hard to make cases on these guys. A lot of cases are dropped on the traffickers. These are dealers in death.

You are aware, sir, that we have prosecutions. You build the case, you give them to the district, and I am going to demand a meeting with my U.S. Attorney in the central district and see why the prosecutions are down, but they are down. Did you know that?

Mr. MILIONE. I have seen that they are down. However, I have also seen that sentences have gone up, and I have seen that we are focused on the —

Mr. MICA. But they are telling me it is hard sometimes to make a case. These are murderers, and we can't stop them. They are bringing deadly substances in, and the trafficking pattern, too, trying to find out—some is coming through the U.S. mail. I will say they told me the mail is starting to crack down. It gets across the border, and then they transit it in the United States like they are sending some kind of a gift package. Is that correct, sir?

Mr. MILIONE. There are many ways that it comes across into —

Mr. MICA. Through packaging services? Who are also intent on getting the package there on time, have to get the deadly drugs there on time.

So we have to look at every avenue. These guys are using the border. I was in Mexico years ago. I don't know if you came with me on that trip, Mr. Cummings, but we warned them.

Now, you can do a DEA signature of heroin and cocaine, can't you?

Mr. MILIONE. Yes.

Mr. MICA. And you have looked at the stuff coming across. Where is it coming from?

Mr. MILIONE. Mexico.

Mr. MICA. And 15 years ago it was all Colombia, wasn't it?

Mr. MILIONE. It still comes from Colombia —

Mr. MICA. But there was very little. I forget, it was black heroin or something, coming out of Mexico. But Mexico was like the amateur hour in this game. Now they have become the pros, and they are dumping this stuff in our communities. By the time we get to treatment, it is way too late, and it is kind of sad. I mean, I am all for the naloxone and having that with our first responders, where it should be. But I told you the story one police chief told me, three times in one week a student, they had to revive him.

We have to change our prescription drugs in the cabinet to naloxone so people are reviving their surviving kids and family.

Where is the chart? Now, we have done a good job. Put the chart up on heroin versus—okay. Look at the opioid drugs at the top, and heroin. We have actually brought that down a little bit when it went up. So we have been somewhat effective on cracking down on prescription drugs. But look at what is happening with heroin; it is off the charts. It is being replaced by a cheaper and more available drug.

They told me, sir, and you verify this from DEA, they said the price is down.

Mr. MILIONE. That is correct.

Mr. MICA. Yes, it is down. When is the price down when the supply is all over the place?

So it is not just Baltimore. It is not Washington, D.C. It is not Orange County. It is New Hampshire, Kentucky, every state in the United States we are seeing this. Aren't we, sir?

Mr. MILIONE. That is correct.

Mr. MICA. Yes. So again, I get a little hot to trot over this, but our job is protecting the citizens of the United States, primarily national defense. We saw what happened with a terrorist attack in Brussels. We are being attacked in our streets, in our schools, in our families.

I mean, again, they killed today 40 people. They killed 50,000 people in the latest statistics we have, which are more than a year old. I know tough enforcement works. It worked with Mayor Giuliani in New York. They stopped a lot of the crime, the drugs, with zero tolerance. Now we have Just Say Maybe, and I just announced the new Federal policy, Just Say Okay instead of Just Say No.

Doesn't it have to start, ONDCP Director, with families and communities?

Mr. BOTTICELLI. I would agree that part of our strategy is to focus on primary prevention, that we know that by delaying when people use, particularly kids use alcohol, marijuana or tobacco, we substantially increase the fact that they are going to have a life free of drug —

Mr. MICA. And were you aware that high school seniors now abuse marijuana more than cigarettes?

Mr. BOTTICELLI. Yes, I have —

Mr. MICA. That is great commentary on our success in combating this with our youth.

I would like to yield now to Mr. Clay.

Mr. CLAY. Thank you, Mr. Chair. And thank you and the ranking member for your comments on the heroin and opioid epidemic.

Let me start with Dr. Wen, and I want to commend you for the groundbreaking work that you are doing in Baltimore. You are not just talking the talk when it comes to speaking out about ending the stigma related to addiction, you are walking the walk when it comes to expanding access to treatment for your residents.

In your testimony, you discuss your efforts to provide treatment on-demand on a 24/7 basis for Baltimore residents. I would imagine that ensuring someone can access treatment as soon as they present themselves as willing to do so is a powerful tool for making sure that they actually begin treatment, and that your approach will save hundreds or thousands of lives as a result.

Today, one of the barriers to treatment is the Medicaid IMD exclusion which prohibits Medicaid from paying for community-based, non-hospital inpatient residential treatment in a facility of 60 or more beds. Unfortunately, the IMD exclusion means that if you are on Medicaid, you are treated like a second-class citizen, unable to access what may be the appropriate care for your substance use disorder.

For the residents you are responsible for in Baltimore, do you agree that they should have access to the medically appropriate care they need whether or not they are on Medicaid?

Dr. WEN. Thank you, Congressman Clay. I absolutely agree, and I thank you for acknowledging that addiction is a disease. If a patient came to the hospital with a heart attack, we would never say wait three weeks and maybe if there is a bed available we will get you in then. The same thing should apply, and the IMD exclusion is not based on evidence. We desperately need residential substance use disorder treatments, and removing the waiver on the Federal level will allow us to increase the ability to treat all of our patients regardless of their insurance status.

Mr. CLAY. And that would put those patients on equal footing with everyone else so that we don't seem to be discriminating based on level of care.

Dr. WEN. Yes, and it would also increase more providers whom we desperately need at the time, when our treatment capacity is just 1 in 10 nationwide.

Mr. CLAY. Yes, and let me thank you for appearing here today.

Every city and county, Mayor Jacobs, should have a health commissioner raising the alarm as forcefully and as effectively as Dr. Wen is, and hopefully Orange County has that, and Congress will finally heed the call and do something significant about the opioid epidemic because it seems as though we as a country have come together and have decided this is a national emergency. We should sit up and pay attention. So let me thank you, too, Mayor Jacobs, for being here and for what you have done to raise the level of awareness in your community.

Let me go to Ms. Enomoto. You testified about the work that SAMHSA does. Can you describe that work in additional detail? You testified that of the \$1 billion in mandatory funding, SAMHSA proposes \$920 million over two years to support cooperative agreements with states to expand access to treatment for opioid use disorders. Why is it important that SAMHSA receive these funds?

Ms. ENOMOTO. As you have so articulately stated, the need far exceeds the capacity of our treatment system today, and we believe that every person who has an opioid use disorder who seeks treatment, just as Dr. Wen has done, 24-hour access to treatment, that should be the standard of care for everyone. With this President's proposal for \$920 million to be infused across two years, we think that would super-charge the capacity of our states, of our communities with the greatest need so that individuals who are seeking treatment would have an open door window when they are ready to get that treatment, because, as we know, the window can be small for some people, and we need to take advantage of that opportunity when they come knocking.

Mr. CLAY. Thank you so much for your response.

Mr. Chairman, I yield back.

Mr. MICA. I thank the gentleman.

Let me recognize Mr. Turner from Ohio.

Mr. TURNER. Mr. Chairman, thank you for holding this hearing. Mr. Cummings, thank you for your comments. This is certainly a scourge that is affecting everyone.

In my community, I was touring a brand-new hospital, Medical Hospital, and was taken back to a conference room to meet with the leadership of the brand-new hospital and asked them what is their most significant challenge, and they told me babies being born addicted to opiates. A brand-new hospital. Out of all the Federal regulations, of all the funding issues that they would have, you would not have thought that the biggest challenge a brand-new hospital was having was babies addicted to opiates.

Mr. Botticelli, thank you for all of your efforts. I appreciate your leadership. I think you are doing a great job and appreciate your advice to Congress as to how we might be able to formulate our to-do list.

Mayor, I am a former mayor. Thank you. You live in your to-do list, so thank you for your representation of the community.

Ms. Enomoto, I would like to put up a few slides that come from your Fiscal Year 2017 congressional budget justification, the first one being a quote that says that approximately 1 million Americans need but do not access treatment for an opioid abuse disorder. Again, these slides come from your Fiscal Year 2017 congressional budget justification.

Ms. Enomoto, when we hold these hearings, we don't do them just merely for increased community awareness. We do them for a congressional to-do list, but also for an agency to-do list. So that is why I am turning to your budget justification. We know 1 million Americans need but do not access treatment.

The next slide.

For example, more than 80 percent of state prisoners, 72 percent of Federal prisoners, and 82 percent of jail inmates meet the criteria for having either a mental health or substance abuse issue. Those are staggering numbers, 80 percent of state prisoners, 72 percent of Federal, 82 percent of jail inmates, a mental or substance use issue.

The next slide.

Studies show—again, your budget justification, Ms. Enomoto. Studies show that only 8.3 percent of individuals involved with the criminal justice system who are in need of substance use disorder treatment receive it as part of their justice system supervision.

Ms. Enomoto, after I left that hospital, I then began the quest of trying to find out in my community where are the resources, how can we find resources to provide treatment. In our criminal justice system, in our community, I was introduced to people who were struggling to try to provide treatment to those who are incarcerated, and then I was introduced to a prohibition in your agency's funding that prevents it from being utilized for those people who are incarcerated.

So in your very agency's documents, it indicates that the problem—we have a self-sorting, right? We have people who present themselves in the criminal justice system with this problem. We have an understanding that without treatment, they will not be able to transition and we will, as our chairman has said, once again be providing assistance to them in either an overdose situation or see them again in the criminal justice system. And yet in your funding, there is an exclusion that prevents communities from

using dollars that they receive from you to actually address that for people who are incarcerated.

To Mr. Clay's comments, in Medicare and Medicaid, there are also similar exclusions that prevent people who are entitled to receive their treatment from receiving that treatment.

I have a bill, H.R. 4076, that would eliminate those restrictions, that would say this is funding that is already there, it is not an increase in funding, although I am for increasing the funding, but these are funds that are already there that would just allow those people to receive it.

Now, Ms. Enomoto, your agency, by rule, could eliminate that restriction. Why don't you?

Ms. ENOMOTO. You know, I think the issue that you have pointed out is clearly so important to communities all across the country. We know that people in our jails, in our prisons are over-represented with mental illnesses and substance use disorders, and getting them adequate care is absolutely important for this nation.

At the same time, we strongly support approaches such as drug courts, diversion, early diversion, as well as reentry programs, and we have made significant investments to ensure that evidence-based —

Mr. TURNER. Ms. Enomoto, I appreciate all that. But before I completely lose my time, could you please tell me why your agency won't waive the requirement and allow your funding to be able to be utilized for those who are incarcerated who need it most?

Ms. ENOMOTO. You know, I want to make sure that I get you an accurate answer to that, so I am happy to follow up further either for the record or in person.

Mr. TURNER. Excellent, and I do appreciate your hard work. I know you are trying to assist us also, and I would encourage members to please co-sponsor 4076, because it would help the agency have the momentum to waive the prohibition themselves. Thank you.

Mr. MICA. Thank you, Mr. Turner.

I now recognize our ranking member, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Dr. Wen, again, I want to thank you for being here. At the beginning of today's hearing we put into the record an op-ed from the Baltimore Sun. "The Effects of Opioid Over-Prescription Are Evident in the Emergency Room" it is entitled. The author explains that one reason we are now seeing such a huge increase in heroin overdoses is because legal prescription painkillers are being over-prescribed. She says, and I quote, "Once a patient is hooked, he or she often turns to street drugs, which can be easier and less expensive to acquire." I think you and just about everybody else has said that this morning.

I want to be clear: I am not trying to blame the doctors. They have a very difficult job. But, Dr. Wen, do you agree that one reason we are seeing an uptick in heroin overdoses is because of the abuse of prescription opioids? Yes or no?

Dr. WEN. Yes.

Mr. CUMMINGS. The op-ed has a startling stat. It says, and I quote, "With only 5 percent of the world's population, we are consuming over 80 percent of the world's painkillers." The op-ed ex-

plains that drug companies are actively promoting this problem. It says, and I quote, "Prescriptions for opioids have been traditionally limited to cancer pain and comfort measures, but in the mid-'90s drug companies began marketing these pills as the solution to a new plethora of ailments. In their efforts to expand the market, producers understated and willfully ignored the powerful addictive properties of their drugs."

Now, that sounds like drug companies are almost like drug pushers. The op-ed cites several examples. For instance, it says this, and I quote, "The promotion of OxyContin by Purdue Pharma was the most aggressive marketing of a Schedule II drug ever undertaken by a pharmaceutical company."

Dr. WEN, this is big business. How in the world do we combat this massive and aggressive effort by drug companies when they are making billions? Go ahead, I am listening.

Dr. WEN. Congressman Cummings, thank you for asking that question. I appreciate your saying that doctors want to do the right thing. We want to do the right thing. And actually, when we talk to our communities, our youth also recognize—if you ask our youth in schools is heroin good or bad, they are going to say that heroin is bad. But we have a culture of excess. We have, because of the aggressive marketing of drug companies, we have this expectation that there should be a pill prescribed for every pain. This is what we have to change.

So we have to make sure that doctors get the resources, the tools that they need, including prescription drug monitoring programs, including guidelines that can help with safe prescribing. But also we need the resources when we are in the ER. We need the resources to connect our patients to treatment, because otherwise we also feel frustrated knowing that our patients need care but we can't deliver it to them.

Mr. CUMMINGS. Now, you talked about some guidance you sent out. Does that guidance also include using painkillers that are not so addictive or not addictive at all?

Dr. WEN. Yes. Our guidelines include three things. The first is the necessity of co-prescribing naloxone with any opioids, because somebody could die from this, so they should get that as well. The second is to be careful about the opioid medications knowing that they are not first-line medications. They should only be prescribed for severe pain. And the third is for the danger of benzodiazepines, which are also killing our residents.

Mr. CUMMINGS. So the op-ed goes on to explain why drug companies are doing this, and that is no surprise. It is about profit. It says, "The Sackler family, which owns Purdue Pharma, achieved a place on the Forbes 2015 list of America's Wealthiest Families. The Sacklers, the richest newcomers to the list, are worth an estimated \$14 billion." That is appalling. I call that blood money, because people are dying big-time.

I want to go back to something, Ms. Enomoto, and maybe some of you others can answer this. Yesterday I was talking to a reporter and he was saying that, Cummings, aren't you concerned that with even more money being requested for treatment and to deal with this problem, because there are so many more people getting into

opioids and heroin, that money will be spread so thin that it will not have the kind of impact that you are hoping for?

Mr. Botticelli?

Mr. BOTTICELLI. To your point, I think we have to have a comprehensive response to this. First and foremost, we need to rein in prescribing behavior in the United States. The Centers for Disease Control just put out recommendations last week that closely follow the guidance that Dr. Wen put out, because that is where we know the significant driver is to the problem.

But we also know that despite all of our efforts, we still have too many people overdosing and dying, largely because they can't access treatment programs when they need treatment programs, and this is why the President has put forward a significant proposal to expand treatment capacity in the United States.

I hear this wherever I go. I just did a town hall forum in Toledo, Ohio where the sheriff—I asked the sheriff what one single thing the Federal Government should be doing to address this opioid epidemic, and he didn't say we need more police officers. He said we need more treatment capacity because we are arresting too many people who haven't been able to access treatment.

So we took a careful look at how many people need treatment and tried to adjust the proposal to really focus on making sure that as many people as possible had access to treatment when they needed it.

Mr. CUMMINGS. Just one more question. Dr. Wen, what happened? In other words, this was not a problem before, not as much of a problem, but then something happened. Can you tell me what happened? I mean, the numbers that the Chairman cited—and I realize that people are moving from the opioids to the heroin, but what happened with regard to the opioids to get so many people on them, and then for them to move to the heroin? Do you know?

Dr. WEN. My understanding is that there was aggressive marketing by drug companies, so that the pain scale is something that is asked of every patient all the time in the course of their hospital stay, but the goal should not be getting to pain free. The goal should be appropriate treatment, yet this is the expectation that is placed on patients and on doctors. So doctors are put in a hard place, too, of satisfying those requirements when all of that was done for drug companies' benefit.

Mr. CUMMINGS. So doctors have a tough time. In other words, the patient keeps coming in, and the pain could be at a 2, being the mildest. The patient has a 2, and then he or she comes in and doesn't tell the truth and says I am at a 9. Is that the kind of thing that happens?

Dr. WEN. That definitely happens, and then doctors feel that they have to get the patient's pain to zero, which includes over-prescribing of narcotic painkillers in order to do so.

Mr. CUMMINGS. Wow.

Mr. Botticelli, it seems like you wanted to say something.

Mr. BOTTICELLI. Yes. It seems like we set up an expectation whereby opioids are the first-line defense around pain therapies, and I think what we are trying to do through the guidance and through Dr. Wen is, particularly for people with chronic pain, that opioids are not the first-line defense to really substantially reduce

pain and we have to focus on other—and the evidence seems to be pretty strong that people who are in chronic pain don't have significantly better functioning when they are on opioids, that we need to be thinking about things like exercise and diet and cognitive behavioral therapy and non-opioid-based therapies, particularly for people with chronic pain.

Mr. CUMMINGS. My last question. Mr. Turner asked a critical question, Ms. Enomoto. I guess he was talking about treatment in prison—is that right?—and what stops you from providing treatment in prison. Is that what he was asking you?

Ms. ENOMOTO. Yes.

Mr. CUMMINGS. There is a regulation that says you can't do that?

Ms. ENOMOTO. Yes, and I guess I want to check into that so I make sure I get you a complete and accurate answer.

Mr. CUMMINGS. Yes, please do, please do, because I am wondering whether it is something that Congress should be dealing with. I don't know whether that should be in your control or our control. You follow me?

Ms. ENOMOTO. Yes.

Mr. CUMMINGS. But I would appreciate an answer as soon as possible.

Do you know, Mr. Botticelli?

Mr. BOTTICELLI. I do not.

Mr. CUMMINGS. Okay. Thank you.

Mr. MICA. I think Mr. Turner said it is in their control, and he has a bill to remedy that.

Let me recognize Mr. Walker now. You are recognized, sir.

Mr. WALKER. Thank you, Mr. Chairman. I appreciate this hearing. I appreciate the panel of witnesses being here today.

Mr. Botticelli, you just talked a few minutes earlier about treatment. I think you mentioned that that is the one thing the Federal Government could do. Treatment is good, and we need more of it, but that is reactive after the problem already exists. Is that fair to say?

So let's start from the very basis. I married into the medical community. My wife can write prescriptions as a family nurse practitioner. She works in a Level I trauma center. One of the things that I have seen as a minister for two decades is the introduction of marijuana. We heard the statistic today already that more high school seniors now do weed instead of cigarettes.

You recently discussed, I believe, the legalization of marijuana during a 60 Minutes profile, if I remember correctly. Do you believe that this could potentially lead to future drug use among the youth?

Mr. BOTTICELLI. I do, and I think the evidence is pretty clear, that when you are talking particularly about early drug use by youth, particularly alcohol, tobacco and marijuana, that that significantly increases the probability that people are going to have more significant problems later in life. In that episode I talked about the fact that I and the Federal Government do not support legalization of marijuana because I do believe that when you look at the data in terms of the high levels of marijuana use that we have among youth in the country, and particularly when we have an industry that is, quite honestly, targeting our youth with things

like funny cartoon characters and edibles, that we are in for more significant problems in the United States.

Mr. WALKER. Part of our pop culture now, you could say.

Mr. BOTTICELLI. I hear that we are replicating kind of what has happened in the past.

Mr. WALKER. Do we have to worry that legalizing marijuana could lead to more drug use in the future for not just youth but for people in general?

Mr. BOTTICELLI. We have been tracking data for the past 40 years, and what it has shown is that when youth perceive using drugs, and particularly marijuana, as less risky, we often see an increase in drug use, and not only have we had very high and historically high levels of marijuana use among youth, we are also seeing historically low levels of perception of risk of marijuana use among the youth in our country.

Mr. WALKER. And just a question, and then I will let you go, really quick. I don't want to use all my time here. Does anybody disagree with the findings of Mr. Botticelli? Just for the record, does everybody agree that this marijuana usage is the beginning of what potentially could be a greater problem? So just for the record, I am seeing everybody say yes, except for Dr. Wen.

Dr. Wen, you have a different opinion?

Dr. WEN. It is one contributor. Another contributor is our prescription drug crisis. Eighty percent of people who start using heroin first start using prescription painkillers.

Mr. WALKER. True, but most high school students are not going to the doctor and getting prescribed major types of pain relievers. Sometimes their first introduction is through purchasing marijuana. Is that fair to say?

Dr. WEN. Yes, and also through misusing other prescription drugs.

Mr. WALKER. A nice transition. I do want to come to that. I want to make sure that we are not painting the doctors as the bad guys here today. In counseling some of the people who have gone through some of this, as good people as they are, they have learned to become master manipulators as far as going into the various doctors' offices and the emergency rooms. Mr. Cummings talked about the different pain levels, sometimes the threshold. Obviously, there are also scoring systems by customer satisfaction indexes that hospitals have to worry about.

Dr. Wen, would you speak to that? Is that something that is fair to say?

Dr. WEN. Most doctors are—by far, the majority of doctors are trying to do the right thing. And similarly, most patients are just trying to get the care that they want. Unfortunately, patients have the expectation that they have to be pain free. But if I fall down and bruise my knee, I will have some pain. Getting opioids is not the right answer.

Mr. WALKER. I agree, and I love what you said, a pill for every pain. We have to get away from that culture, as you mentioned a little earlier.

We have seen kind of a plateau even though it is a large number of prescriptions. We have to continue to do better, and I think people in the community—I think of Richard and Jennifer

Kaffenberger in Central North Carolina. They had a son who had no drugs in his system except one thing. He had played a football game the night before. He had taken one prescription pain pill methadone from his grandmother's medicine cabinet, and it killed him. Sad story, but they have taken that message throughout all—they are two educators, two teachers in a middle school in Burlington, North Carolina, and they have traveled different parts of the state to bring more awareness of what that can do.

So I am glad to see that that has plateaued, and we need to continue to stay on top of that, but I am overwhelmingly alarmed at the spike, and I would like to see those 2015 numbers as soon as those are available of where we are going with this heroin epidemic. It is something—it is a problem for all of us, and we have to continue to do more.

With that, I yield back the balance of my time. Thank you, Mr. Chairman.

Mr. MICA. I thank the gentleman.

Let me recognize now the gentle lady from New York, Mrs. Maloney.

Mrs. MALONEY. I thank the chairman and ranking member and all of the panelists for focusing on this real crisis in health care in our country, and it is encouraging to hear your testimony and the efforts that are taking place in the city, state, and Federal governments across our country.

But we in Congress need to put money where our mouth is. In the short term, I urge my colleagues to approve the \$600 million in emergency funding which the professionals are asking for to combat this epidemic. From what I am hearing from Dr. Wen and others is if we hit the treatment level when they are becoming addicted to the painkillers, if you hit it then, then it doesn't get to another level of the opioid. So I think if we could fund it, that would be important.

Now, the Senate recently acted on this crisis. They passed the Comprehensive Addiction and Recovery Act of 2016 to help prevent and treat the opioid addiction, but it does not provide any funding. So what good is a program, Mayor Jacobs, that doesn't provide any funding? Does this program help people suffering in your city or your area?

Ms. JACOBS. Obviously, Congresswoman, funding is a necessary component of any program that we offer. If I could add just one thing, because we talked a lot about treatment, and we have mentioned that that is on the tail end, that is reactive.

This country came together, it galvanized around tobacco use, and it profoundly changed the way our youth looked at that. If this country would come together, if the Congress, if the state and local level, if we would come together around a campaign of awareness about how very serious heroin use is, opioid addiction, painkillers, all of those things, I think we could make a bigger impact at that level and stem the tide of this. But it —

Mrs. MALONEY. I think that is a very important point, but that whole tobacco effort, a lot of it stemmed access. It stemmed access to tobacco, and they made it more difficult to have access to tobacco. I know the CDC just came out with some guidelines that basically say don't prescribe this so easily, you should have a higher

threshold for it, as Dr. Wen said. When you fall down, you hurt yourself, you bruise yourself, you are not always completely—you are going to have pain sometimes. We have to lower the expectation that no one can have any pain. If you have an operation, you are going to have pain. It is certainly better to have pain than to become addicted to heroin or something worse.

But maybe some concrete guidelines on access to it, that maybe the scientific community should define what pain level should have access to opioids and that it should not be something that everyone should expect to be pain free the whole time they are in a hospital.

How would you react to that, Dr. Wen, to having guidelines that really stemmed access to very severe pain levels? Because what we are doing is, for someone to be comfortable for a week, we are turning them into addicts. I mean, this is a national health crisis. This has got to stop, and I would say to my colleagues on the other side of the aisle and on my side of the aisle, we shouldn't leave here until we vote that \$600 million that is needed for the program. What good is a program if you don't fund it? It makes it sound like we are doing something when we are not really doing something. What they need is the treatment in the field.

But I would like to ask Dr. Wen, what do you think about reversing it, not just education but giving doctors help in knowing what threshold of pain would be necessary before this dangerous addictive drug is allowed?

Dr. WEN. Congresswoman Maloney, thank you for the excellent point. I agree with you that doctors need further guidance and tools in order to make the best decisions possible for their patients, and having guidance would also be useful because we don't want to punish doctors who are doing the right thing. Currently, when reimbursement is tied to getting the doctor or getting the patient to become pain free, that becomes very difficult for the doctor to practice appropriately.

But I also want to caution that there are appropriate uses for opioid medications for cancer pain, for surgery, so we don't want to eliminate that altogether.

Mrs. MALONEY. Absolutely. But direct guidelines—now, who would be the one to do that? The CDC? Have you looked at the guidelines that they just came forward with?

Dr. WEN. I have, and the CDC guidelines we agree with and actually hope that they would go further in requiring the co-prescribing of naloxone, and also in helping us to put further warnings, including black-box warnings, on benzodiazepines and opioids, which are the FDA's highest risk recommendation, to alert both patients and doctors.

Mrs. MALONEY. Well, my time is up. Thank you.

Mr. MICA. Let me see. We have Mr. Buck of Colorado. You are recognized.

Mr. BUCK. Thank you, Mr. Chairman.

Mr. Milione, I have a few questions for you. In 1970, Congress enacted the Poison Prevention Packaging Act to address aspirin overdose cases with children, and as part of that a tamper-resistant container was developed for that purpose. We are now dealing with a situation where there are a huge number of young people who get these opioids from their parents' medicine cabinet, and I have

been made aware of a product that I am holding right there that costs less than \$1. It would increase the cost of the prescription less than \$1, and it has a combination on it. It would require the parents to open that. If a child that didn't have the combination tried to get into something like this, it would be evident to the parent that this was opened by someone that didn't have the combination. Has DEA looked into packaging like this?

Mr. MILIONE. Congressman, obviously as a father of three, we support anything that would serve that purpose, and we are aware of that company and that device.

Mr. BUCK. You are probably aware that the company comes from the great state of Colorado also.

Mr. MILIONE. I almost said that.

Mr. BUCK. Thank you.

[Laughter.]

Mr. MILIONE. So we are aware of it, and we were happy to listen to them about that technology. We would support that. We would support, obviously, the take-back kiosks to get drugs out of the medicine cabinet. That is a critical part of our overall strategy. But certainly any technology that would prevent those dangerous drugs getting in the hands of children or anyone we would support.

Mr. BUCK. And what needs to be done? Do we need a law for that? And I am not a big proponent of administrative regulations, believe me; but can you, by regulation, require that dangerous drugs be dispensed in packaging like this?

Mr. MILIONE. We can require that they are disposed of. The regulations cover that, cover the disposal. As far as requiring how it is dispensed, I don't believe we can. I can certainly take that back and look at it. We have to navigate somewhat carefully because if this technology were made widely available, that would be great, but that would have to come from a private entity. It wouldn't be something that we would be able to mandate necessarily.

Mr. BUCK. So would you need an act of Congress to require—obviously we are not going to name a company or a particular technology, but we would certainly require opioids to be dispensed in some kind of safe container. Would that be something that would help you in furthering this goal?

Mr. MILIONE. It would certainly help prevent it from getting in the hands of, like you say, children. It is something we would be happy to talk to you about or follow up if there was some pending legislation.

Mr. BUCK. I would appreciate that very much.

I want to make sure I pronounce this correctly—Mr. Botticelli?

Mr. BOTTICELLI. Yes.

Mr. BUCK. Great. Wow. The Federal Government dispenses drugs through the VA and other agencies. Again, would it require an act of Congress, or could the Federal Government, for purposes of its dispensing drugs to Federal employees or veterans, use packaging like this without a Federal law from Congress?

Mr. BOTTICELLI. I don't know that, and similarly, I think we would have to go back and look at what kind of authority we would have or if the Federal Government needs additional authority to do that.

You know, I will say that part of what we have been trying to do at the Federal level is ensure that every Federal prescriber at least has some level of mandatory education as it relates to those. But as far as mandating a package, I don't know if we either have the authority or we need additional authority to be able to do that. I could look into it.

Mr. BUCK. If you could work with my office on that, I would very much appreciate that and look forward to working with you to try to develop this in this area.

I thank the chairman and I yield back.

Mr. MICA. I thank the gentleman.

We will recognize now Mr. Lynch, the gentleman from Massachusetts.

Mr. LYNCH. Thank you, Mr. Chairman.

I do want to associate myself with the words of the chairman and the ranking member earlier on on this issue. I think there is much we can do on the treatment side, but up front, there is also the opportunity to reduce the number of people who require treatment, and I think we really have to double our efforts in that regard.

Mike Botticelli, good to see you again.

Mike, for those who don't know, headed up our efforts in Massachusetts for quite a few years, did great work, and I want to thank Mr. Milione for the DEA's help. My district has been overrun, so you have actually been kind enough to assign DEA officers and agents up in my area, working with our local police. So we really appreciate the help there.

Obviously, any individual state doesn't have impact on the border, but you do, so that has been an enormous help for us in trying to interdict some of the heroin pipeline that has been coming up into the Boston area.

I had the honor of co-founding the Cushing House in Boston for Boys and Girls. It is actually an adolescent treatment facility because our kids are coming in so young with addictions to both opioids and heroin. We have basically 24 beds for boys, 20 for girls, but the problem is I have a line out the door, and it is happening over and over and over again.

I do want to say, just as a sidelight here, as I talk to our young people—and we have put thousands of kids through our home, and it is a long-term rehab facility. While I don't know if marijuana is a gateway drug to heroin, every single kid that I am dealing with who is on opioids and on heroin started with marijuana. So there is a perfect match, 100 percent. Every kid I am dealing with for heroin and for opioids, when I ask them what did you start out with, they all say marijuana. So maybe there is a susceptibility there or something, I am not sure. It is not anecdotal; it is more than that. It is empirical, over thousands of kids, but it certainly points in that direction. So I think it deserves a cautionary note in terms of some of this marijuana legalization. I think we are buying ourselves a huge problem.

One thing I want to talk about and get your opinion, we haven't talked about the power of these opioids, and I will give you a couple of examples. A young woman in my district had a tooth problem. She had an extraction. They gave her a very large prescription of OxyContin. She consumed that, went back and complained,

falsely she tells me now, of continued tooth pain, got another prescription, and actually went back in and complained that another tooth was hurting, which was not. So she is yanking teeth out of her head just so she could get prescriptions of OxyContin. That is unbelievable.

I talked to some of my docs in the Boston area, and they tell me that the chemical changes in the brain, it overrides—the OxyContin and hydrocodone actually overrides the endorphin creation in the brain. So it is more powerful than the endorphins that the brain can produce on its own. So when they come off that, when they need that, that is why they are going for more OxyContin or heroin, because that is the only thing that can scratch that itch.

So we have to think about this. These drug companies are creating customers for life, customers for life.

Another young father in my district, shoulder pain. Same deal, gave him too much OxyContin prescription. Two or three prescriptions later, bam, now he is buying it on the street. A good dad, good family, just totally fell into that trap.

So we have to figure out—I think it is a huge commercial advantage for some of these companies to produce a product that creates a customer for life. We have to think about what we are doing in that regard. That is a huge commercial advantage.

I think that Governor Baker in the Massachusetts legislature just came out and said if you are going to prescribe this stuff, you can only give so many pills, and we are not going to let you refill them. It is also part of our drug monitoring piece that we are doing along those lines as well.

But is there anything on the front end, Mike, that we could be doing to stop the number of people? Because once they get in there, we are having a terrible, terrible, terrible problem. We have a lot of recidivism, a lot of relapse, a lot of money we are spending for rehab, and we need to do that, I am not discounting that. But on the front end, to stop these kids from being trapped, and other unsuspecting patients from being trapped into this cycle, is there anything else we can do up front to stop that from happening?

Mr. BOTTICELLI. Sure, and I thank you for that question because I think it is really important. Again, the CDC just released guidelines, but they are only guidelines. I agree that I think the vast majority of physicians and dentists are well meaning, and part of what Massachusetts has done, 16 other states, there is legislation in Congress now. We would love to work with you on mandatory prescriber education because we feel, again, this is not about bad docs, but they have gotten a lot of misinformation, largely from drug companies, that these are not addictive medications, and that we can continue to hand them out.

I don't think, quite honestly, in the middle of an epidemic, it is unreasonable to ask a prescriber to take a minimal amount of education as it relates to safe and effective opioid prescribing. If you look at the overdoses that we have seen here, there is a direct correlation between the amount of prescriptions that we are giving out and overdose deaths, and this has been going on for 10 years, and I think the medical community has a role to play, and that is a good starting point.

Mr. LYNCH. What about liability? What about having joint and several liability for drug companies and the docs that push this stuff out there? Because these people are unsuspecting and they are getting addicted like that.

Mr. BOTTICELLI. I agree, and there has been legal action against Purdue Pharmaceutical for precisely that reason. They have a role to play not only in terms of making sure they are meeting the letter of the law about marketing, but also encouraging abuse-deterrent formulations, another particularly important area.

We do need to work with the DEA and others to go after outlying prescribers who are wantonly ignoring the law on this. But you are right, we need prescriber education, good prescription drug monitoring programs so physicians can identify people who might be going from doctor to doctor to do that.

But to your point, if we are really going to reduce the magnitude of the problem, we have got to scale back on the prescribing and identify people who are starting to develop problems.

Mr. LYNCH. Thank you, and I yield back.

Mr. MICA. I thank the gentleman.

Also, Mr. Lynch, I went into one of the drug programs in my community, talked to every kid I could in the treatment program. Every kid told me the same thing, he started with marijuana, then they go on to all the rest of it. So we have a very serious situation in this country.

Let me recognize—Mr. Walberg is next, the gentleman from Michigan.

Mr. WALBERG. Thank you, Mr. Chairman. I apologize for being out but Rosie the Riveter showed up at the Capitol and I wanted to say hi to four of them from my district.

An interesting issue because it does affect all of us. My district in Southeast, South Central Michigan has tremendous challenges there, and I appreciate the efforts that all of you have shown toward this issue.

Mr. Milione, how long has the DEA been aware of the increased prevalence of fentanyl-laced drugs, and how are you responding to this problem specifically?

Mr. MILIONE. Thank you for the question. We have been aware of fentanyl going back a number of years, and we have seen its increasing use and have seen it flood the country.

What are we doing? We are doing basically what we do with all our criminal investigations. We look to target the worst of the worst, criminal trafficking organizations, identify them, infiltrate them, indict them, capture, convict them. We are trying to educate, certainly, our state and locals about the risks associated with fentanyl. It is a multi-pronged approach, and it is definitely something we are concerned about.

We certainly are concerned about the unsuspecting users that are being exposed to it when it is combined with heroin or when it is put into an exact replica of an opioid pill.

Mr. WALBERG. Are those the special enforcement challenges that you have, or are there others beyond that?

Mr. MILIONE. There is a whole panoply of different challenges, and that is certainly one of them. It also poses a risk to my law enforcement brothers and sisters that encounter increasingly

fentanyl in an enforcement operation. As you know, it can be inhaled, it can be absorbed through your skin, with tragic consequences. So it certainly is a major problem for us, for users, for the country, and then also for law enforcement.

Mr. WALBERG. What has the DEA learned about the source of fentanyl when it appears in heroin?

Mr. MILIONE. Two primary sources. The majority of it is coming up from Mexico, with precursors and actual fentanyl shipped from China, from Asia, into Mexico for production, and then across the Southwest border, all over the country, particularly up in the Northeast, but also directly from China. So those are the two primary threats.

Mr. WALBERG. It is my understanding that Mexico has been a primary source. Is that true?

Mr. MILIONE. That is true.

Mr. WALBERG. How are you working to decrease this trafficking? Any additional efforts that you can talk about in regards to what is coming across the border?

Mr. MILIONE. We have a great relationship with one of our largest, if not our largest, office in Mexico. We have a great relationship with our counterparts. We continue to work with them on those trafficking organizations. The Sinaloa Cartel is probably the most powerful cartel down there. It has a tremendous distribution network spread across the country. They are capitalizing on the prescription opioid abuse epidemic. They are flooding the country with heroin, but they are also now flooding it with fentanyl.

So we are just going to continue an aggressive approach from the law enforcement side and do what we do with our state and local counterparts every day.

Mr. WALBERG. Okay. Mr. Botticelli, what efforts is the U.S. engaging in to work with governments where heroin is produced to cut off the supply? And then secondly, does this involve identifying labs in countries like Mexico which may be a trafficking bonanza of heroin and fentanyl in the United States, and what are the biggest barriers to stopping that?

Mr. BOTTICELLI. As we have looked at this issue, particularly heroin and fentanyl, having an aggressive approach that reduces the supply is particularly important. I actually was just in Mexico a few weeks ago meeting with the Attorney General and high-level folks in the government, calling for enhanced action particularly as it relates to heroin, looking at enhanced eradication efforts, looking at how we go after both heroin and fentanyl labs, and how we continue to support mutual collaboration in going after the organizations that deal with it.

We have also been working with the DEA and our high-intensity drug trafficking areas domestically to look at reducing and going after those organizations that are trafficking heroin and fentanyl domestically. I think it is really important for us to have this holistic approach and to really focus on a robust law enforcement response to reduce the availability of heroin and fentanyl.

We have to really look at how we work with our Customs and Border Protection folks to increase the detection of both heroin and fentanyl. And I think, to Mr. Milione's point, we have to look at our

international work with China that often produces these precursor chemicals as it relates to particularly fentanyl production.

We were actually pleased that China just moved to schedule over 130 new substances, including one of the precursors, acetyl fentanyl. So it really is important for us to work with our international partners, particularly China, Mexico, and working with our domestic law enforcement folks.

Mr. WALBERG. Thank you. I yield back.

Mr. MICA. I thank the gentleman.

The gentleman from Pennsylvania, Mr. Cartwright.

Mr. CARTWRIGHT. Thank you, Acting Chair Mica, and thank you to all the witnesses for coming today. I have listened to all of your testimony, and it is well taken.

I come from Pennsylvania. In Pennsylvania, hospitalizations for overdoses due to pain medication increased 225 percent from 2000 to 2014. Drug overdose deaths in Pennsylvania increased by 12.9 percent between 2013 and 2014, compared to a 6.5 percent increase nationally in the same time period. It is a huge problem in Pennsylvania.

Director Botticelli, you mentioned attending a town hall. Earlier this year I did a town hall in my district in Coaldale, in Schuylkill County, Pennsylvania. It is a rural place. Typically we get between 30 and 40 people out for routine town halls. At this one, we had over 100 people come out, and nobody was smiling. Every family is touched by this crisis, by this epidemic.

The question is, what can be done to combat it? In Pennsylvania, there is a company, Iroko Pharmaceuticals, that is right now using nanotechnology and is following the FDA directive to use the lowest effective dose of NSAIDs for chronic pain. Iroko is an African American-owned company which is growing by the month, providing not only jobs in Pennsylvania but also a logical solution to our national opioid epidemic.

I also believe there are legislative solutions to help address the issue, like H.R. 953, the Comprehensive Addiction and Recovery Act. This was introduced in the House by Representative Sensenbrenner of Wisconsin. In the Senate, the same bill was introduced by Senator Whitehouse of Rhode Island. That bill passed the Senate, and in the House I am a co-sponsor of 953. It is a bill that would adjust existing authorizations and programs to provide a series of resources and incentives to help health care providers, law enforcement officials, states and local governments expand drug treatment prevention and recovery efforts, and throw funding toward those efforts. I wish to urge Republican leadership to move H.R. 953 to the House floor for a vote. It is a concrete step we can take in the right direction.

Now, my colleague, Mr. Lynch, talked about New England, and the New England area has been referred to as "the cradle of the heroin epidemic" by the New York Times, and I see you nodding your head, Mr. Milione. You are aware of that, I take it.

Mr. MILIONE. Yes, sir, I am.

Mr. CARTWRIGHT. According to the DEA's 2015 National Heroin Threat Assessment Summary, 63.4 percent of New England law enforcement agencies reported heroin as their greatest drug threat. And just last week, Governor Charlie Baker signed legislation mak-

ing Massachusetts the first state to pass a statewide cap on first-time opioid prescriptions.

My question is, with the rising number of opioid deaths, what steps has DEA taken to collaborate with the state and local law enforcement agencies to reduce opioid overdoses and deaths?

Mr. MILIONE. Congressman, thank you for the question. Under the leadership of our Special Agent in Charge up there, Mike Ferguson, they have a great relationship with the U.S. Attorney's Office, and they have brought together all the different elements—state, Federal, local, working with the health community—to identify where the hot spots are, and then to do the community outreach piece, but then also to do the enforcement on the groups that are trafficking in those substances.

Mr. CARTWRIGHT. Okay. And, Director Botticelli, how is the Federal Government working to encourage and support innovative ideas by the states to combat the opioid epidemic?

Mr. BOTTICELLI. I think there are a number of ways that we are doing that. One, looking at funding opportunities to provide states with the opportunities to really create innovative strategies. One of the things that our office does is really look at how do we promote some of these innovative things that are happening at the state level. So whether that is law enforcement that are working to get people into treatment, or things like the 24/7 triage programs.

So part of what the Federal Government's response is is ensuring that states and locals have the resources they need to continue to implement programs that address these issues. Secretary Tennis in Pennsylvania I think has really demonstrated some really strong leadership in terms of the work that is happening here. I talk with the Secretary just about every day in terms of looking at what more the Federal Government can continue to do.

But I think the largest function that we have is making sure that states and locals get the resources they need to continue to develop and show leadership on this issue.

Mr. CARTWRIGHT. Well, amen to that, and I yield back, Mr. Chair.

Mr. MICA. I recognize Mr. Hice from Georgia.

Mr. HICE. Thank you, Mr. Chairman.

The CDC in Georgia has a report that Georgia alone has seen a 10 percent increase in overdose deaths. I am sure you have seen that in the last couple of years. To me, this is especially alarming just for the fact that high school students are using painkiller medication at alarming rates which makes them 40 times more vulnerable to use heroin.

The DEA said that heroin is currently available in larger quantities, that it is used by a larger number of people, and that it is causing an increasing number of overdose deaths. Is that correct?

Mr. MILIONE. Yes, sir.

Mr. HICE. I want to focus on where this stuff is coming from. So, Mr. Milione, let me start with you. From your testimony regarding the DEA's new 360 Strategy, which you referred to a little while ago, it sounds to me like the DEA is going to focus less on the Mexico-based organizations that are trafficking heroin and focus more on the street gangs that are distributing heroin. Is that a correct assessment?

Mr. MILIONE. Congressman, it actually is not. We are more nuanced than that. We are never going to go away from our core mission of working up the chain to the cartel leaders in Mexico. So the 360 focuses on the link point, the link point that bridges the violent distribution cells domestically that are affecting the communities, and also the cartels that are flooding the country with the heroin. So it absolutely is not one or the other. It is a comprehensive approach.

Mr. HICE. So is there a greater emphasis, though, on the distribution side of things now?

Mr. MILIONE. I wouldn't say there was necessarily a greater emphasis. It is a shift of focus so that we can do everything we can to get the violent distribution cells under control and give the communities back their communities.

Mr. HICE. Is it fair to say from your assessment that our interdiction efforts with the cartels have failed, or at least not been as successful as we had hoped?

Mr. MILIONE. Congressman, I wouldn't characterize it as a failure. Interdiction is one part of it, but what we are focused on at the DEA is going after the actual individuals that are selling the powder, that are pushing it, the infrastructure, the corrupting influence, the money. Those are the things we are focused on. Interdiction is one piece of that.

Mr. HICE. All right. Sounds to me like you were just then saying that the emphasis is going to be on the distribution side of things.

Mr. MILIONE. No, I don't believe I said that it was just going to be on the distribution. It was going to be on —

Mr. HICE. I didn't say "just," but the emphasis.

Mr. MILIONE. There is going to be an emphasis on the distribution, and also on the supply side.

Mr. HICE. Okay. You mentioned a while ago—and I will just shake my head with all of this, because we have been into this war on drugs forever, and it is getting worse. We are not making any headway on this. You mentioned just a while ago that we have a great relationship with the Mexican government and that that relationship—the reality is that heroin is coming across the border more now than it ever has. What good is a great relationship if we are not addressing the problem? At some point, this thing is getting worse and worse and worse, and we are throwing more and more money to it all the time. It frankly doesn't appear to me as though anything is happening to stop the problem that would go to the point of what you said a while ago, that we are addressing this aggressively.

Mr. MILIONE. Congressman, as somebody who has served for 20 years and has seen the sacrifices that the brave men and women of the DEA do every day, and dangerous situations in the country, and also in the foreign arena, we are doing everything we can to deal with this very, very difficult and complicated problem. We are working to reduce demand, but we also have to go after the organizations that are flooding our country.

So the war on drugs is not necessarily a phrase that we would use. We do criminal investigations in highly dangerous, sophisticated cartels operating —

Mr. HICE. Well, I take my hat off to those agents who are out there in the field, and I am not in any way belittling them. But for us to come in here and somehow try to give a picture that we are aggressively dealing with the problem when in reality it is getting worse and worse is putting forth a false image.

Mr. MILIONE. I would have to disagree with the false image.

Mr. HICE. Well, you can disagree all you want. The fact is the problem is getting worse. You yourself have admitted that.

Mr. MILIONE. Congressman, I don't disagree that it is a difficult problem and that there are parts of it that are getting worse, but I am not painting a picture that is inaccurate when I say that we are aggressively doing everything that we can, at tremendous sacrifice.

Mr. HICE. So how many criminals have been arrested and prosecuted under DEA's Rolling Thunder program?

Mr. MILIONE. I can't give you the number of arrests. I can tell you that there are 448 investigations in 125 cities around the country.

Mr. HICE. But you don't know how many arrests?

Mr. MILIONE. I would have to get back to you with any specific statistics.

Mr. HICE. Please get back to me.

Mr. Chairman, I see my time has expired.

Mr. MICA. I thank the gentleman.

The gentleman from California, Mr. DeSaulnier, you are recognized.

Mr. DESAULNIER. Thank you, Mr. Chairman.

First of all, I appreciate the panel. I think all of us have stories about constituents who have been affected by this, and the frustration I think of some of my colleagues at our inability as a country to deal with the drug problem, no matter what we have tried.

I would like to ask a couple of questions on the opiate side. I have one constituent who came to me and made me aware of her personal situation where her son was going to school at the University of Arizona and drove to Los Angeles with some other students to actually go to a doctor in Los Angeles and then overdosed. This doctor was just recently convicted, multiple convictions in Los Angeles.

I have another constituent who went out to walk to a Baskin and Robbins on a Sunday afternoon, and one of his two kids was killed right in front of him when a woman who had been abusing opioids and drinking came across. So all of us have those stories, unfortunately.

One of the things we were able to do in California—and Mr. Lieu and I were part of this in the legislature—was update our prescription monitoring system. So my question is really around electronic health records. I would talk to doctors and they would say, well, electronic health records are right around the corner. Doctor shopping will be a thing of the past. We worked with the Attorney General in California, and that process is in effect now, but we are just waiting to see how effective that is.

So, Mr. Botticelli, maybe you could tell us—and one of the frustrating things, of course, is when you have this patchwork of different states doing different things, it seems to me that it would

be fairly efficient for the Federal Government to provide the infrastructure for a nationwide electronic monitoring system so that the Department of Justice in all 50 states and the Federal Department of Justice would have red flags so that they would see if a doctor, like the doctor in Los Angeles, is abusing his or her privileges, or if a client is doctor shopping.

Mr. Botticelli?

Mr. BOTTICELLI. Prescription drug monitoring programs have been part of our main emphasis since the beginning of this epidemic, and I think to your point, we are seeing a tremendous amount of success. When we started we had only 20 states that had effective prescription drug monitoring programs, and now we have 49 states that do that. We actually thought it was more prudent, because we had so many states that already had an existing program, to really look at the state level.

But to your point, I think what we are trying to focus on next is interstate data sharing so that states can talk to one another, and interoperability with electronic health records, because that is the next phase of—we want to be responsive to physicians in terms of the burden of workload and look at how do we get timely information to them by supporting that. So we have been working with HHS and others. This is an important priority for governors as well, so we have been talking to the National Governors Association in terms of what states can do.

But this has really been one of the more effective tools that we have seen, but we also need physicians to use them. So part of this is, again, I think we are very interested in states that have passed not only mandatory education but, like Massachusetts just did, checking the prescription drug monitoring program not only at first dispensing but at every dispensing —

Mr. DESAULNIER. So it is mandatory.

Mr. BOTTICELLI. So they are only as good as when people use them.

Mr. DESAULNIER. And, Ms. Enomoto, maybe you could talk to this. In Northern California we have a lot of Kaiser clients. So there you have a closed system where there is still a problem, so there is a financial aspect to this. For them, if they were able to use electronic records both for the cost and efficient use of the system, but also to protect the clients from being either over-prescribed or clients taking advantage of the system, how far away are we from having a real strong electronic monitoring system that can do both?

Ms. ENOMOTO. You know, I think we are seeing in some states already great progress. So in 2012, SAMHSA had the opportunity to issue grants for the enhancement of prescription drug monitoring programs that focused on both the interoperability with EHR as well as interstate interoperability. In those grants, during the period of the grant, we got six out of the nine states that were able to achieve that level of interoperability, and then post-grant we have two more states who are now online with their MOUs so that they should be able to start exchanging information with their EHRs very soon. So out of a relatively small investment, partnering with CDC, partnering with the Office of the National

Coordinator and ONDCP, we were able to get eight out of nine states to achieve that level of interoperability.

Mr. DESAULNIER. And lastly, the statistics always come to mind. The U.S. has about 5 percent of the world's population, but we use over 80 percent of the opiates. How much of this is the criminal aspect of it, Mr. Botticelli?

Mr. BOTTICELLI. I would actually say very little. Again, I think this has been a concerted effort by the pharmaceutical companies to falsely promote those medications. In 2013, we prescribed enough prescription pain medication to give every adult American a bottle of pain pills, and I think that is why the CDC guidelines become so important, looking at not having opioid therapy as a first-line defense for chronic pain, really supporting when you do start with opioids for some people who do need them, starting with the smallest, the lowest dosage and the smallest possible amount, because I really do believe that we have made progress in many areas, and I don't believe that we have made enough progress in really implementing safe opioid prescribing behavior.

Mr. DESAULNIER. Thank you.

Thank you, Mr. Chairman.

Mr. MICA. Thank you.

Let me recognize now Mr. Carter from Georgia.

Mr. CARTER. Thank you, Mr. Chairman. And thank all of you for being here.

I have been kind of in and out. I apologize. I had three committee meetings at one time, at the same time. But I want to associate myself, first of all, with all the comments that have been made about marijuana being a gateway drug and leading to drug abuse. I could not feel more adamantly about that, so I just want to make sure everyone understands that.

For those of you who don't know, I am a pharmacist, not practicing anymore. The only pharmacist in Congress. I have over 35 years of experience, and a lot of experience with opioids as a dispenser. I am very blessed that I have never taken any drugs, never had that. I am human and I have weaknesses, but that is not one of them, and I feel very strongly about that.

I want to start with you, Mr. Milione. This is very uncomfortable, but I will tell you that almost a year ago, a little over a year ago, in fact, in Tampa, a judge ruled against the actions of the DEA when you raided a compounding pharmacy. You destroyed the medication and completely shut down the pharmacy without any real cause. This was Westchase Pharmacy in Florida. Are you familiar with that situation?

Mr. MILIONE. I am not.

Mr. CARTER. You are not? Well, you need to be because, let me tell you, this is not a shining example that you want to point toward. This is an example where one of the supervisors that you oversee conducted a raid and at the time had no experience in diversion investigation, hadn't read the DEA handbook, yet raided a compounding pharmacy with tactical gear and guns, shut down the business, seized hundreds of thousands of dollars of medicine, and improperly stored them, therefore rendering them useless, all because the DEA misinterpreted and failed to follow their own laws.

This is, as the judge said, preposterous, and this is not going to be accepted.

Now, look, I support the DEA. I don't like anybody in health care who is not practicing by the best of standards. We have bad pharmacies out there, we have bad pharmacists, we have bad doctors. Dr. Wen, there are bad doctors out there. You can't paint with a broad brush. There are bad actors in every profession. But this kind of action, this kind is totally unacceptable, Mr. Milione, especially when we have someone coming to your pharmacy bearing guns. That is unacceptable. So I hope you will look at that. It is Westchase Pharmacy. I hope you will research that and understand that.

I want to ask you, Dr. Wen especially, we have talked about opioids being used as the entry-level drug for pain control. One of the problems that I see here—and, Mr. Botticelli, you and I have worked together before. You know I sponsored the legislation in the Georgia State Senate to set up the PDMP for Georgia. But one of the problems I see is with the FDA taking a lot of the products off of the market.

Now, specifically I want to talk about propoxyphene. You know, propoxyphene was on the market for years and years. I can't imagine how much I dispensed in my career. But I will tell you, when they took it off, what did it do? It led people to opioids. That is the only choice the doctors had. What do you do now? You have ibuprofen and acetaminophen. That is where you want to start.

Well, let me tell you, as a practicing pharmacist I can tell you, you try to get a patient to take something that is available without a prescription, you are not going to be able to convince them that it is going to work. You have to have a prescription for it. That is just the way it is. No, it is not right, but I will try as hard as I can, and I can't convince them of that.

And just like the propoxyphene, don't give me that white one, only the pink one works, that is the only one that works. That is what you are dealing with.

But one of the problems, I think, has been the FDA taking—and I know that propoxyphene had its problems. I am not trying to question that. But what I am trying to point out is that we need more entry-level drugs, something in-between the opioids and ibuprofen and acetaminophen. That would be better. The CDC guidelines that have come out, the prescribing guidelines for doctors, I think that is very, very helpful. It needs to be enforced more. It needs to have some kind of teeth in it.

I am running out of time here because I want to get into so many things.

Another problem is mail-order pharmacies sending these gigantic containers of opioids to the doorsteps of people, leaving them on the doorsteps for them to be—who knows what is going to happen to them. You get a 90-day supply. I have people bringing them now to the drugstore my wife now owns. They bring into those drugstores all the time giant containers of opioids. That needs to be suppressed, Mr. Milione. The DEA needs to do something about that. That is ridiculous and something that we need to address as well.

The last thing I want to talk about is 21st Century Cures and the locking provision. Listen, I am a big proponent of 21st Century Cures. I think it is some of the best legislation we have passed here since I have been in Congress, and I support it, and I voted for it. However, that locking provision is very dangerous and I think it needs to be looked at. You have a relationship between pharmacies and patients, between doctors and patients. When you get into a locking provision, it is going to be very, very difficult, because you need pharmacists. You need pharmacists to participate in this and help us to curb this problem because it is—let me tell you, I have seen it ruin families, I have seen it ruin lives, I have seen it ruin careers, and it is worse than can even be imagined at this point.

Mr. Chairman, I know I have gone over, and I apologize. Thank you.

Mr. MICA. Thank you.

The gentleman from Virginia, Mr. Connolly.

Mr. CONNOLLY. Thank you, Mr. Chairman.

I will say, Mr. Mica and I had a series of hearings in the previous Congress on U.S. drug policy that included marijuana, and it forced me to reexamine some things I thought I knew or believed about our drug policy with respect to marijuana. But what is disturbing to me, if there is a gateway drug to heroin, it is opioid prescription drug addiction far more than marijuana, and that is why this hearing is so timely. It is affecting every community we represent here in this body. It is not a rural phenomenon or an urban phenomenon or a suburban phenomenon.

Well, let me ask you, Mr. Botticelli, how did we get to this point? I mean, I don't want any doctor to leave a patient in pain. Serious pain is a terrible affliction, and first you do no harm. But how do we draw that line between pain management and just an unbelievable avalanche of prescriptions for opioids that has now led to an epidemic of addiction in America? With, presumably, the best of intentions originally.

Mr. BOTTICELLI. I agree, and I think when you look at the roots of this epidemic and what are the significant drivers, yes, there are other issues going on. It is really about the over-prescribing of these very addictive pain medications that we have.

Mr. CONNOLLY. But why? How did we get there? Doctors aren't stupid people.

Mr. BOTTICELLI. Well, I think that doctors were given a significant amount of misinformation from pharmaceutical companies, and even from the medical professions themselves, that these were not addictive medications. So that was really the start of this, that despite scant scientific evidence, there was this full court press to basically educate physicians, saying that these medications were not very addictive, and at the same time we had what I think is a very noble and should be a noble goal, that we have to do a better job at pain treatment in the United States, that there are a lot of people who have significant pain and who need it.

So I think you had this confluence in terms of really a full court press to treat pain—the VA even talked about pain as the fifth vital sign—and little education on the part of these prescribers about how addictive these substances were, about how to identify people. So physicians in the United States get very little training

on appropriate pain prescribing. I think there was a GAO study that showed veterinarians actually get more training on pain prescribing, and physicians get little to no training on substance use issues.

So I think it was this kind of mixture of a whole set of factors that really drove up addiction and overdose in the United States, and now we have that compounded by heroin and fentanyl availability.

Mr. CONNOLLY. Dr. Wen, what is effective treatment? I mean, what is the system for recognizing somebody has a problem and we need to get them treatment? What is efficacious treatment in trying to turn this around early before it moves on to, say, heroin or something worse?

Dr. WEN. It is often said that medicine is an art and not completely a science because even something like pain is subjective. What is a pain for you is not the same for somebody else. So that is why doctors do need discretion about how to treat each individual patient based on their symptoms and who they are, also recognizing that it is not just about medications. We also have to do physical therapy and counseling and education that sometimes pain is okay. We don't have to treat everything with a pill.

So we very much agree with the increase in the use of PDMPs, recognizing that some PDMPs are very cumbersome to use. If I am seeing 40 patients in eight hours, I can't be spending an hour of that time figuring out how to get into every patient's PDMP.

Mr. CONNOLLY. Got it, but we are running out of time. So what is efficacious treatment? What do you recommend in the Baltimore Health Department?

Dr. WEN. We recommend, first of all, judicious use of pain medication so that we are not —

Mr. CONNOLLY. I get that. I am talking about treatment. We have a problem; what is the treatment? What is efficacious? What have we learned? Because, look, we are policymakers up here. We want to solve a problem. We get that part. But if we have gotten to the point where we have an addictive problem but we are trying to prevent that person from going on to the heroin part, what works? What, in your experience, works by way of intervention?

Dr. WEN. One thing, recognizing that addiction is a disease, and therefore we have to get people into addiction treatment, which is medication-assisted treatment, psychosocial counseling, and wrap-around services. We know that the World Health Organization shows for \$1 invested in treatment, that saves \$12 for society, and that is something we should invest in.

Mr. CONNOLLY. Thank you very much.

Thank you, Mr. Chairman, and thank you for the hearings you and I held. They were quite informative —

Mr. MICA. I believe the only ones in Congress, and we got criticized for them.

Government Operations, he was my ranking member, and then years ago with the ranking member here.

Mr. CONNOLLY. Thank you again, and thank you to the panel.

Mr. MICA. The gentleman from Wisconsin, Mr. Grothman.

Mr. GROTHMAN. I will yield my first minute to Mr. Carter.

Mr. CARTER. I thank the gentleman for yielding.

I would be remiss if I did not mention next week in Atlanta we are having the National Prescription Drug Abuse and Heroin Summit. Representative Hal Rogers from Kentucky, who has been a champion for this, is a co-chair of that. I hope that you will be there. I hope that my colleagues will be there. This is an opportunity to learn more about prescription drug abuse. It is a great, great summit, and I encourage everyone to attend. Thank you.

I thank the gentleman for yielding.

Mr. GROTHMAN. Anytime.

Okay, now I have a question. One of the things that bothers me is the legal prescription of opiates. I had two minor health things in my life in the last two years that I had earlier in my life. Both times, the medical professionals were willing to give opiates, like a month's worth of opiates, for something that had no business under any circumstances prescribing opiates, and they wouldn't have five years ago.

I guess I will start with Mr. Botticelli, but anybody else can chime in here. What can we do to stop, in these basic things—I would say what they were, but I don't want to embarrass the medical professionals. They were par for the course. I mean, one of the things is we are not going to reimburse for Medicaid, we are not going to reimburse for Medicare, we are not going to reimburse anything else the Federal Government is kicking in for these sorts of problems, no matter how much pain you claim you have, because people never used to have it. Or we could perhaps say even for CMS. We are just not going to reimburse across the board. And if we are going to reimburse, it is for three days, none of this month's prescription stuff.

Is that something that could be done? I don't think we can give the medical professionals a lot of wiggle room here because they have shown in the past they abuse that wiggle room.

Mr. BOTTICELLI. I think there are a number of things that we can be doing. I think, one, you are right, there are opportunities to work with not only CMS but private insurance as well with that.

Mr. GROTHMAN. Why don't we do it?

Mr. BOTTICELLI. CMS actually sent out a letter to state Medicaid directors this summer to really look at putting in place prescribing protocols around that. I also think that we really need to continue to focus on mandatory prescriber education. I am not a big fan of government mandates around that, but I do think, again, that we really need to educate the medical profession about safe and effective opioid prescribing.

Mr. GROTHMAN. All you need—I don't mean to cut you off. All you need is a little common sense. I mean, if we have that many people in the medical field that lacking in common sense, we have a bigger problem than lack of education.

Mr. BOTTICELLI. I don't think it is a matter of common sense. I think it was a matter of the medical profession, very well meaning to the largest extent, who were given misinformation on the lack of addictive properties of these drugs, and it was really a full court press to more appropriately treat pain with a prescribing community that gets little to no training on appropriate pain prescribing.

Mr. GROTHMAN. Well, 90 percent of the people on average in Wisconsin know this is all screwed up. I can't believe that the medical

professionals need training on this, but okay, if you say they need training.

Now I want to come around to the penalty thing, Mr. Milione. I got here late, didn't hear your name. It seems to me that the penalties for people who sell heroin is not as high as it should be, or they are not going to prison as long as possible. One of the problems I have is a lot of this is local stuff, it is not a Federal issue. But I assume we do arrest people. The Federal Government arrests people who possess heroin, at least enough that you can assume that they are dealing in that drug.

Do we arrest people for that? And if we do, what is the recommended sentence?

Mr. MILIONE. Congressman, at the DEA at the Federal level and in our task forces, we are not focused at all on users or simple possession.

Mr. GROTHMAN. I am not saying possession. If you get somebody with enough heroin, which isn't very much, that you know it can't be for personal consumption, you know they are going to be selling for somebody, what do you do with that person?

Mr. MILIONE. I can't really give you a quick answer like that. It depends on the investigation and obviously in conjunction with the Federal prosecutors we work with, the state prosecutors. They look at the conduct, and then ultimately a judge decides what that sentence is going to be based upon the guidance that the judge gets. That is the clearest answer I can give you. It is not a very clear answer.

Mr. GROTHMAN. It is a very muddy answer, yes.

Mr. MILIONE. Yes, but it is the world we live in.

Mr. GROTHMAN. Okay. I will give you one more quick question, then I will hang around here to see whether the Chairman eventually can call on me again if I wait long enough.

What do they do in other countries on this? I toured another country 10 years ago and I asked about a drug problem, and they told me the criminal penalty for these severe drugs was shockingly high. I won't say what it was because it might have been wrong, shockingly high.

What do they do in other countries to make sure they don't have this big opiate abuse, say in Southeast Asia in some of these countries where they don't want to have a penalty, so they hand out?

Mr. BOTTICELLI. It is interesting that you say that. I actually just returned from—there is a U.N. group of my colleagues from around the world in terms of looking at the global approach to drug policy, and I think that there is an emerging consensus with the vast majority of the countries that we need to continue to focus on an enhanced public health response, that while law enforcement plays a key role for some of our major traffickers, that we need to look at and continue to explore alternatives to incarceration.

So I think that there is a kind of consensus among countries —

Mr. GROTHMAN. I don't mean to cut you off. I am well past my time, and because I am past my time, I would like it if you would answer my question, okay? I know that there are a lot of people out there who like this public health response, okay? I am under the impression that we put people in prison for a reason, okay?

Other countries have very large penalties and much less of an opiate problem. Could you tell me what their penalties are?

Mr. BOTTICELLI. Well, I think they probably have less of an opiate problem because in many parts of the world most people actually don't have access to medications at all. So it is not a function that they have criminal penalties.

Mr. GROTHMAN. No, you are wrong. But just tell me what they are because these are countries that are fairly advanced, and they don't have an opiate problem, and part of it is the penalties are pretty dramatic. Do you know what these penalties are, say in places in Southeast Asia?

Mr. BOTTICELLI. I don't, but I can tell you that Southeast Asia considers labor camps part of their treatment regimen. So I wouldn't necessarily equate drug policy around there as it relates to their drug problem.

Mr. MICA. Thank you. I think in Singapore they also execute them.

Mr. Lieu from California, you are recognized.

Mr. LIEU. Thank you, Mr. Chairman.

Mr. Botticelli, thank you for your public service. I have a few questions for you. Let me begin by saying that the current heroin and opiate epidemic has some similarities to the crack epidemic of the 1980s. Unfortunately, our response back then was to increase prison sentences. I am pleased to see we are taking a different approach this time, and America is finally starting to realize that drug addiction is primarily a disease.

One of the most noticeable differences between the crack epidemic and the opioid epidemic is that the crack epidemic mostly affected poor communities of color, but the face of the opioid epidemic is very different. According to a study published in Journal of the American Medical Association, nearly 90 percent of the people who tried heroin for the first time in the past decade are white. Does that statistic sound largely correct to you, sir?

Mr. BOTTICELLI. It does.

Mr. LIEU. I have an article here in the New York Times titled, "In Heroin Crisis, White Families Seek Gentler War on Drugs." In that article you are quoted as saying, "Because of demographics, the people affected are more white, more middle class. These are parents who are empowered. They know how to call a legislator. They know how to get angry with their insurance company. They know how to advocate. They have been so instrumental in changing the conversation." You said that, correct?

Mr. BOTTICELLI. Correct.

Mr. LIEU. So I believe that it is important that we need to address these issues among the white middle class, but I want to make sure also that our resources are directed across the country regardless of socioeconomic or race status. My question to you is how to ensure that Federal resources are applied fairly and match the unique issues facing individual communities.

Mr. BOTTICELLI. Thank you for your comment. It is a really important issue to me and to you and Congressman Cummings. I have been doing this work for the better part of my life, and I am glad that in this country we are finally at a point where we have acknowledged the disproportionate impact on people of color and

poor folk in terms of this issue, and I am glad we are at a different place. I am glad that we have now a huge political movement that is happening with people around the country to call for a different response.

I completely agree. I think that we have to make sure that the policies that were implemented, that the programs that were implemented are targeted at those communities that have the most pressing need, and that when we talk about things like criminal justice reform, we are talking about criminal justice reform for everybody, regardless of color, as it relates to this, that our human response to this epidemic needs to be a human response for everybody and not just for the 90 percent of white people who are affected by this issue.

I am glad we have learned a lot over the past 40 years in response to failed drug policies in the past. I am glad we are at the place where we are finally acknowledging that this is a disease and that we can't make our jails and prisons our de facto treatment programs for anybody.

So I feel a tremendous responsibility in terms of making sure that we use this moment in time where there is broad acknowledgement of the fact that this is a disease and that we can't arrest and incarcerate, that we implement those policies and programs for everybody.

Mr. LIEU. Thank you for that answer.

Mr. Chairman, I would like to enter for the record the New York Times article, "In Heroin Crisis, White Families Seek Gentler War on Drugs."

Mr. MICA. Without objection, so ordered.

Mr. LIEU. There have been anecdotal stories today that marijuana is a gateway drug. Are you familiar with an article in Time magazine that says, "Marijuana as a Gateway Drug, the Myth That Will Not Die"? Have you read that article?

Mr. BOTTICELLI. I don't know if I read that.

Mr. LIEU. So let me quote from it. It says, "Scientists long ago abandoned the idea that marijuana causes users to try other drugs. As far back as 1999, in a report commissioned by Congress to look at the possible dangers of medical marijuana, the Institute of Medicine of the National Academy of Sciences wrote there is no conclusive evidence that the drug effects of marijuana are causally linked to subsequent abuse of other illicit drugs."

Now, it is true there is a correlation, and this article and the study explains that underage drinking of alcohol also has a correlation, that those that actually use typically precedes marijuana, and that marijuana is not the most common and is rarely the first gateway illicit drug use. And then this article goes on to say why there might be a correlation, and one simple reason is that people who are extremely interested in altering their consciousness are likely to want to try more than one way of doing it. So if you are a true music fan, you probably won't stick to listening to just one band. That doesn't make lullabies a gateway to the Grateful Dead. It means people who really like music probably like many different songs and groups.

So isn't it correct that there is no scientific evidence that marijuana is a causal link to illicit drug use?

Mr. BOTTICELLI. I think the evidence is pretty clear that early use of alcohol, tobacco and marijuana, often used together, significantly increases the probability that someone will develop a more significant addictive disorder later in their life, and I think that the more younger people use, the more that those chances grow.

I also think that the music analogy is kind of inaccurate in this situation because early substance use actually affects brain development, not just affects people's taste, and it actually affects people's brain development and predisposes people for more significant vulnerabilities later in their life.

Mr. LIEU. Thank you. My time is up. I will send you the article on that issue also.

Mr. Chairman, if I could enter into the record the Time magazine article that says "Marijuana as a Gateway Drug, the Myth That Will Not Die."

Mr. MICA. Without objection, so ordered.

Mr. MICA. The gentle lady from New Mexico, Ms. Lujan Grisham.

Ms. LUJAN GRISHAM. Thank you, Mr. Chairman.

I have no doubt that we will continue in Congress, and localities and cities and states will continue the debate about gateway drugs. Certainly, I participated in many of those discussions about alcohol, which is really the foundation in terms of creating an environment where you put yourself more at risk, particularly adolescents and adolescent drinking. I come from a state, unfortunately, that has some of the highest drug abuse rates and the highest overdose rates in the country.

Mr. Botticelli, I appreciate very much you raising the issue in your testimony and talking about there is now a very direct and specific correlation between the number of prescriptions that have gone up and the number of prescription drug issues, which we are trying to deal with today. And I would hope that Congress undertakes an effort, when we are combating the opioid problem, that we look at drug issues in general, drug policy in general, and certainly continue to debate and work on criminal justice reform so that we are focusing on both prevention and effective treatment, which is really the way to get at it.

I also want to say I appreciate the panel and members' questions. I am in a state that just passed legislation that would make naloxone available to far more than just the medical providers and prescribers, that we want it to be in the jails, we want first responders, and first responders to include family members in close proximity so that we can prevent overdose deaths. In a state that has a Republican House and a Democratic Senate, there was great bipartisan effort to recognize if we can prevent an overdose death, let's do that, but now let's not minimize everything else.

So finally, potentially a question, and maybe either Director or Dr. Wen. This is a very complex set of problems, and that doesn't mean that we should walk away from it, and I could probably get into a debate with you right here about good-faith dispensing and how that can be a benefit, and how it will also limit access. One of the realities about over-prescribing isn't just that the sellers, the manufacturers of these drugs have done such a great job, now it

is cheap, so insurance companies are more than happy to make sure that that is right there.

But if you can't get back to your physician, you are in the hospital or in the ER and you waited 27 hours to be seen, they need to make sure that whatever prescription they are giving you is going to tide you over. The issue is that you have lots of these patients who have other family members who then have access to the excess medication, and I am struck by the number of now large pharmacies that are thinking about making sure that they have kiosks and opportunities for you to get rid of those drugs safely and get them out of the hands potentially of guests and kids and families and grandkids, which is clearly part of the epidemic here.

Given all of these complexities, I really want to talk about the behavioral health correlation, too, where we aren't treating—there really isn't mental health parity. In my state, we now have no behavioral health infrastructure, and I should admit to you that I think that is partially the fault of this Administration through CMS and HHS. So there is zero treatment available. We have some of the highest heroin overdose rates. In Mora County, it has been the highest. One in 500 is going to die of a heroin overdose. It is huge, and it is not new. It is decades old.

What are we doing to really create policy that recognizes that behavioral health, that dual diagnosis and self-medicating is really also part of this larger problem here?

Mr. BOTTICELLI. I will start, and then I am sure that other folks on the panel can do that. So, I think there are a number of things from a large policy perspective that have happened. One is the Affordable Care Act, and one of the dramatic things, why 2 in 10 people get —

Ms. LUJAN GRISHAM. I am really going to just caution you. The Affordable Care Act is the reason this Administration has said that it was okay to cancel 100 percent of all the behavioral health providers in my state. So in that example it doesn't quite work, although I am a fan of general access, make no mistake. But you should know that about New Mexico.

Mr. BOTTICELLI. Well, I will just say that part of the reason that people are not able to access care is the fact that they don't have affordable coverage. We know that from data. The Affordable Care Act says a couple of things; one, that mental health and substance abuse disorder benefits have to be a part of any marketplace plan. That is huge, because there has always been a lack of coverage.

The second thing that it does, to your point, is basically say to insurance companies you can't discriminate in the provision of —

Ms. LUJAN GRISHAM. How are we enforcing that? Because I will tell you that access is still a giant issue in my state and so many others. So we recognize it in policy, but what are we doing—and there are only 10 seconds left—to actually make sure it is occurring? And given that now Medicaid is largely a managed care environment, we are going to debate fee-for-service and managed care ad nauseam, I am sure, in further health care reform environments. But the reality is, if the insurance companies aren't really making it available, then you really don't have access in spite of coverage; correct?

Mr. BOTTICELLI. I agree, and I should say I hear that a lot in my travels around the country, and I think that the Federal Government can do more work around enforcing parity, but states can play a key role, and the state insurance commissioners can play a pivotal role in this. Providers play a key role in making sure that complaints get to state insurance commissioners about this. So we all have a role to play in terms of enforcing parity and ensuring that we are about to finalize Medicaid managed care rules as it relates to parity.

So I would agree that we each have a role to play in terms of parity enforcement.

Ms. LUJAN GRISHAM. I am well above my time. Thank you, Mr. Chairman, for your flexibility and patience.

Mr. MICA. Thank you for staying and participating.

The gentleman from South Carolina, Mr. Gowdy.

Mr. GOWDY. Thank you, Mr. Chairman.

Agent Milione—am I pronouncing that correctly?

Mr. MILIONE. Yes, that is correct.

Mr. GOWDY. Agent, I want to talk to you in a second about drug court. But before we get to drug court, would you agree that there are some who traffic in narcotics who themselves are not users?

Mr. MILIONE. I would agree.

Mr. GOWDY. So drug court is not going to be much help for us or for them because they are not addicts, they don't use. So let's go with those who are using drugs. I think you would also agree with me that folks who use drugs commit robberies and burglaries and domestic violence and a host of crimes that we consider to have an element of violence. Would you agree with that?

Mr. MILIONE. Certainly, that contributes to an element of violence, yes.

Mr. GOWDY. All right. So you have drug dealers who don't use, and then you have drug addicts who are not engaged in Title 21 crimes.

Mr. MILIONE. That is correct.

Mr. GOWDY. All right. There are different models for drug courts. Some are diversion programs where you just divert out of the criminal justice system altogether. Some you plead guilty and your sentence is drug court. We had a dickens of a time in South Carolina in getting criminal defense attorneys to plead their clients to drug court even though in the eyes of everyone it is better for their client, who happened to be an addict. It is tougher than probation, so the criminal defense attorneys had no interest in that.

So how do we devise a plan where you get drug court even if your criminal defense attorney doesn't want you to have it?

Mr. MILIONE. Congressman, I don't know that I am actually the right person to answer that since at the Federal level we are working at a level where we are going to take in the Federal system, and drug courts aren't an option. That would be more the state and local level with some of our state task forces. So I really wouldn't be in the best position to answer that question.

Mr. GOWDY. Well, before I go to Mr. Botticelli, I want to ask you something that might be in your wheelhouse, and that would be diversion. Do you have a background in diversion, Agent Milione?

Mr. MILIONE. Yes, yes, yes.

Mr. GOWDY. All right. Back in the old days, the standard was if physicians prescribe drugs outside the course of a medical practice, a professional medical practice, they actually could be prosecuted themselves.

Mr. MILIONE. That is correct.

Mr. GOWDY. There was a dip, it looked like to me, in the number of cases that DEA was pursuing from a diversion standpoint. Was that just an optical illusion, or at some point the DEA decided to interact more with the pharmaceutical companies and less with the physicians who were actually prescribing the medicine?

Mr. MILIONE. I need to know if you are speaking about criminal cases. I am not aware of any dip on criminal or civil cases. But then there is also the administrative actions, potentially revoking the registrant's registration. I am not aware—if you are talking about criminal, I am not aware that there was a dip in any criminal numbers as far as the criminal prosecutions.

Mr. GOWDY. Would you check that for me?

Mr. MILIONE. Be happy to.

Mr. GOWDY. All right, because —

Mr. MILIONE. What span were you speaking to?

Mr. GOWDY. Well, I have been gone since 2010.

Mr. MILIONE. Okay.

Mr. GOWDY. I know that we did DEA diversion cases and we prosecuted doctors, and then it just seemed to me that the focus shifted over to pharmaceutical companies.

Mr. MILIONE. I can tell you from a policy perspective, and also from what we are doing, it has never been a conscious shift. We have aggressively gone after, where appropriate, again a small percentage of the overall number of DEA registrants. But I will certainly look at those numbers and get back to you on that.

Mr. GOWDY. All right. I know it is hard to prosecute doctors, but when you are prescribing medicine without even doing an examination, without even so much as checking blood pressure, you are just running a pill mill. I think, with all due respect to my friends on the other side, prison might be the right place for those doctors.

Mr. Botticelli, what kind of drug court can you devise where criminal defense attorneys do not advise their clients against their overall better health to opt for probation instead of drug court?

Mr. BOTTICELLI. I am not familiar with that. I would be happy to work with you.

Mr. GOWDY. Have you met any criminal defense attorneys? Are you familiar with them?

Mr. BOTTICELLI. No, I am. Actually, there has been huge support across the board as it relates to our drug courts.

Mr. GOWDY. I am sure there is, if it is a diversion court. I am quite certain that there is huge support for that. I am not talking about diversion where you have no record and you actually don't face any consequences. I am talking about pleading guilty and your punishment is drug court as opposed to probation, with probation being much easier than drug court.

Mr. BOTTICELLI. There are many drug courts that operate under that model, right? So it is very interesting to me, and again, it has gotten wide support among many folks in the criminal justice world. So if there are particular folks you would like us to work

with in terms of doing some more education around drug courts, what they can do with the various models, we work very closely with the National Association of Drug Court Professionals to do levels of training and outreach and I would be happy to work with you.

Mr. GOWDY. I am out of time. Mr. Chairman, could I ask one more question?

Mr. MICA. Yes.

Mr. GOWDY. Let's assume that you plead guilty to armed robbery and your sentence is drug court. How many lapses do you think are appropriate before the actual sentence imposed is carried out?

Mr. BOTTICELLI. I would have to go back and see what the guidelines look like. I would assume that that probably gets interpreted different ways by different judges —

Mr. GOWDY. I was asking you.

Mr. BOTTICELLI. I actually don't know that in terms of if there is specific guidance around —

Mr. GOWDY. I am talking about best practices. I mean, obviously, for the first offense, the first relapse, it doesn't make any sense, but the hundredth doesn't make any sense either.

Mr. BOTTICELLI. No. I would have to look at the National Association of Drug Court Professionals. It does put out best practice guidance, and I don't know explicitly what that —

Mr. GOWDY. Would you do that for me so we can have an idea what is fair?

Mr. BOTTICELLI. Absolutely. But to your point, I think there is an acknowledgement that many people with substance use disorders do relapse, and we need to have a good response in terms of that. You are right, people need to be held accountable for their actions as well, so it is a real balance between recognizing relapse and still holding people accountable. But I would be happy to —

Mr. GOWDY. I will tell you what I will do, then. In honor of you, I will acknowledge that there are relapses. And in partial honor of me, the next time you have a chance to talk to criminal defense attorneys, you tell them that it is overall in their clients' best interest to get off drugs, not to get onto probation, which is much easier to navigate than drug court. In the short term it might inure to their clients' benefit. In the long run, it does not.

Mr. BOTTICELLI. Okay, happy to do that.

Mr. GOWDY. Thank you.

Mr. MICA. To conclude, we will do a quick round of summary questions.

Mr. Cummings?

Mr. CUMMINGS. Dr. Wen, one of the things that is so disturbing to me is there are certain areas in Baltimore where people are getting methadone treatment, and when you see the number of people whose lives have been destroyed, and we see the masses of them—and I would say to the gentleman from South Carolina, would invite you, Mr. Gowdy, I would invite you at some point to come with me to Baltimore. When you see the masses of people who are using, it is painfully painful, I am telling you. I agree that there are those who are selling drugs who are not using. I agree with you that there are folks who are going out there and committing a lot of

crime. As a matter of fact, probably most of the crime in Baltimore has something to do with drugs in one way or another.

But there is also a group of people who are truly addicted, and they are dying at 78 a day. That is major stuff. So I would invite you. I think when you see it like that—because the Chairman came with me to Baltimore and saw what I am talking about. In some kind of way, we have to get to that, and I think there are a lot of different remedies to try to address these things, but I am definitely not one that wants to be soft on people who are going around and selling death, and I have said that many times. But at the same time, we have a lot of people who truly are addicted.

Dr. Wen, where do you—and the gentleman from South Carolina made some good points—where do you draw the line and say, okay, I have these addicts, but these addicts, some of them are committing crimes. And what do you think of the methadone treatment? Because a lot of people question whether you are just keeping people continuing to be addicted to a substance. Do you follow me?

Dr. WEN. Thank you very much, Congressman Cummings. So the first issue is that we know in Baltimore that there are 20,000 people who use heroin, and many more who are addicted to other drugs, and most of the drug arrests that are happening—there are 73,000 arrests that happen in our city every year. The majority of the arrests that happen are for individuals for only selling drugs to feed their own habit.

What they need is not incarceration. What they need is drug treatment, and that is what we have to provide, and we have to make sure they get treatment while they are incarcerated. If they are incarcerated, they have to get treatment in jail as well.

Mr. CUMMINGS. Can you pause there for one second? One thing a lot of people don't know about heroin is you can be addicted to heroin for 30 or 40 years. Am I right?

Dr. WEN. Yes.

Mr. CUMMINGS. And still function. Is that right?

Dr. WEN. Yes. There are some individuals who are very high functioning who are in all walks of life, all professions, while they are addicted to a variety of drugs, including alcohol as well.

To your point about treatment, I am a doctor and a scientist and I have to use the evidence, and evidence shows that medication-assisted treatment, including methadone and buprenorphine, are the first line, they are the standard of care when it comes to opioid addiction. We also agree, though, that we need to have increased treatment, including with buprenorphine, which can be given in an office-based setting. That will also help us to reduce the stigma around addiction.

And, Congressman Cummings, I want to thank you also for your leadership in Baltimore City. We hope that there will be additional funding directed to our cities of greatest need, areas of greatest need. We are the ones on the front lines, we are the ones who are innovating, and we are the ones who need the most resources, rather than have the peanut butter spread evenly across all areas.

Mr. CUMMINGS. You know, naloxone, the idea that we were getting a 10-pack for \$190 back in 2014, and then they increased it to \$400—is that right?—have you seen any movement? I know that various states and our attorney general has been trying to work

out something where we can get that cost back down. Have you seen any movement in that area?

Dr. WEN. We have not. We have not in Baltimore City. Last year we were fortunate to receive a generous donation from a pharmaceutical company to assist us for over 8,000 units of naloxone, but we can't depend forever on the generosity, on the donations from companies. We have to have this medication, which is a generic medication that is on the World Health Organization's list of essential medications, available to everyone so that we can save lives.

Mr. CUMMINGS. Again, I want to thank all of you for being here today. We do have a lot to do. It is a very serious problem, and we are going to have to try to hit it from a lot of angles. As Chairman Mica said, years ago he and I—you were the Chairman—the chairman and ranking member of a subcommittee called the Drug Subcommittee did a lot of work, and we are going to have to do even more. So, I thank all of you.

Mr. MICA. Let's see. Mr. Grothman?

Mr. GROTHMAN. Sure. I will give you two quick questions.

First of all, drunk driving is a big problem in our society, and when we arrest somebody for drunk driving, some people are alcoholics and have an addiction to alcohol, and a lot of people are just irresponsible people, social pressure, whatever, got a drunk driving ticket. I have only met two people in my life who have used heroin. They both were in the criminal justice system. Both felt they were not addicted.

Percentage-wise, give me a stab at it. Of the people who are arrested with heroin possession or whatever, what percentage are addicts, and what percentage are just people who are social pressure or whatever, want to feel good for the day, are using heroin? What percentage do you think need treatment, and what percentage are people who are just like the person who gets a drunk driving ticket because they are just irresponsible? Could a couple of you give me your guess?

Mr. BOTTICELLI. I will take a stab at it and take a look at it. I would assume that the rates of non-addictive heroin use are incredibly low just because it is a very powerfully addictive drug.

Mr. GROTHMAN. Each one of you just give me a percentage. I don't have a lot of time. What percentage of people who are arrested for heroin are like the two people that I talked to who didn't crave it, didn't need it, one did it for social reasons and one was going through a depression at that time? What percentage are addicted and what percentage are just using it because my buddy is using it and it is cool?

Mr. BOTTICELLI. I would say probably 5 percent of people who are using marijuana have no addiction to it, but that would be —

Mr. GROTHMAN. You mean heroin?

Mr. BOTTICELLI. Heroin. I am sorry.

Mr. GROTHMAN. Only 5 percent are addicted.

The next gentleman?

Mr. MILIONE. I can't give you a percentage. That is not how we encounter—we don't encounter individuals that way based on the work that we do at the DEA. So I can't give you a percentage.

Mr. GROTHMAN. Okay. Ms. Enomoto?

Ms. ENOMOTO. What we can give you is data from our National Survey on Drug Use and Health, which just surveys people about how many people have used heroin the last month or in the last year, and then how many of those people actually meet criteria for disorder, and I would imagine you would find fairly parallel realities. We don't do screening on arrest. We don't have the time to do diagnostic evaluations on everyone who is arrested for possession, so we don't have those data available.

Mr. GROTHMAN. Do you have an opinion?

Ms. ENOMOTO. No, but I am happy to get you those data, the data that we do have.

Mr. GROTHMAN. Anybody up there have an opinion? Anyone else have an opinion on the percentage that are addicted and the percentage that are just using?

Dr. WEN. I can give you my perspective as a practicing physician, and also experience in Baltimore, which is that the vast majority—we are talking well over 90 percent—will be individuals who have an addiction. Heroin comes from opium, and it is one of the most addictive substances in the world.

Mr. GROTHMAN. Okay.

Ms. JACOBS. I don't have the answer. I can tell you that out of the 2,000 people that come through our jail that acknowledge they are using heroin, all of them have an addiction. Now, the reality is that they are acknowledging it because they know they are going to go through withdrawal.

But, you know, I think that there is some information that we could obtain through some databases dealing with people that have been prescribed opioids and how many of them have become addicted. I don't really think —

Mr. GROTHMAN. I am out of time. I will cut you off because I want to ask one more question.

Okay, so maybe the two people I have met who have actually used heroin and got caught, when they say they were not craving it at all, maybe they are an aberration.

Okay, the next question I have, just one example. If I break my arm, just a simple break, do you think under any circumstances, given that they never prescribed it 15 years ago, under any circumstances—what percentage of the time do you think a doctor should prescribe opiates for a broken arm?

Dr. WEN. A broken arm is extremely painful, and if somebody had come to the ER with a broken arm, I would give them even IV medications, including for opioids. So it does make sense that this is a reasonable use for opioids.

Mr. GROTHMAN. Does anybody else think in all cases for a broken arm you should be prescribing opiates? For how long? Say for over a week? What percent think if you have a broken arm you should prescribe opiates, give a prescription for at least a week?

Mr. BOTTICELLI. I can tell you what the CDC guidelines recommend in those kinds of situations. Obviously, that is a decision that needs to be made between the patient and the doctor. There should be a conversation to do it. But the CDC guidelines say the lowest possible dose and the shortest possible duration.

Mr. GROTHMAN. So would you, if you were the doctor, give a prescription for at least a week?

You know, politicians are known for not giving straight answers, not you guys. But okay, go ahead.

Anybody else have a stab at this? Is it responsible to give a prescription for opiates for at least a week if I crack my arm here?

Ms. JACOBS. Sir, if I could take a stab at this?

Mr. GROTHMAN. Sure.

Ms. JACOBS. I am not a doctor. I am a mother of four children. One of my children has had multiple broken bones in sports. One of them had three torn ACLs and meniscus tears, so they have all gone through a lot of surgery. Each time they have been given opioids, and each time I would say it was probably for about a week. In all cases they were warned—I was warned about what to look for in case of addiction. In every case, they were not on opioids for more than 48 hours. We took them off in 48 hours. So I can tell you that as severe as those injuries were, we weaned them off.

I had a severely broken bone in both of my arms. I was off of painkillers in three days and never on opioids. So I hope that answers your question. I think anything more than that really needs to be carefully looked at.

Mr. GROTHMAN. Now, are you a mental health professional? I'm sorry, are you a health professional?

Ms. JACOBS. Am I? No. I am a mom of four kids. I think I probably know a whole lot of things.

Mr. GROTHMAN. No wonder you have so much common sense.

Ms. JACOBS. I could be a mental health professional by the time I raise four children.

Mr. GROTHMAN. Good. We got one commonsense answer out of the five, and it was the person who is not a mental health professional—not a health professional.

Thank you very much.

Mr. MICA. I thank the gentleman.

Mr. Gowdy?

Mr. GOWDY. Thank you, Mr. Chairman.

I want to thank all of our panelists, and I want to thank my friend from Maryland for his gracious invitation, which I will take him up on. I would love to go see what is happening in Baltimore. I expect, Mr. Chairman, that it is, at least on a larger scale, similar to what was happening in my own home town, which is why I started a drug court in 2000, and in addition to that drug court we started a drug court for expectant mothers who were using controlled substances during the course of their pregnancy, because I do believe getting them off drugs is infinitely preferable to incarceration in non-violent cases.

I would also say this, Mr. Chairman, and to my friend from Maryland, there is no joy like going to a graduation ceremony for those who have concluded drug court successfully. I have had folks that I prosecuted stop me in the grocery store to show me the certificate from their graduation, and they were prouder of that than anything you or I could have ever accomplished in our careers. I used to counsel folks who were still going to need prison, so I would be a little reluctant to close all the prisons as we open up drug courts.

But the gentleman from Maryland is right. I would say about half the crime we saw for 16 years, drugs and/or alcohol were at

the root of that. There was one addict in particular, Mr. Chairman, who took a hammer to the older couple that lived next to him and beat them. They were in bed, asleep, in the middle of the night, and he broke in to rob them, and he beat them with a hammer where they were unrecognizable as humans. That was the pathologist's description, not mine. And then he raped the female victim post-mortem. He was an addict.

But we are going to need to hang onto those prisons, Mr. Chairman, in addition to the drug courts, and I would be happy to go to Maryland with my friend to see the work that they are doing there, and I would invite him down to Spartanburg.

Drug courts can save people's lives and get them off. I just hope they get off before they do acts of violence against the innocent public, because the addicts sometimes leave a wake of violence and mayhem in the wake of their addiction.

With that, I would yield back.

Mr. CUMMINGS. Would the gentleman yield, please, just for one second?

Mr. GOWDY. Be happy to.

Mr. CUMMINGS. First of all, I want to thank you for agreeing to come to Baltimore. I agree to go to South Carolina, be happy to.

Just one thing, Mr. Chairman. I agree with you, we have very effective drug courts in Maryland, and I know what you are talking about. One of my first cases was a death penalty case, early in my career, where a young man hammered his grandmother to death, and he was on drugs. So I get it, I get it.

Like I said, I think there are different categories here of folks, and I swear, I just wish we could catch them early, like you said, because I have seen some really bad, bad stuff. So the thing is trying to figure out a balance here. And even when you figure out the balance, you are probably going to still find people falling through the cracks, but I guess we have to use our best science and best judgment.

But I thank the gentleman for yielding.

Mr. GOWDY. Yes, sir.

Mr. MICA. I thank the members for participating, and our witnesses.

I just have a couple of final things.

It is now 1 o'clock. We started this some three hours ago. Fifteen people in the United States have died from drug overdoses, three of them from heroin. Before the day is over, 120 Americans will die, 24 of them from heroin.

We have heard different things touted here today. Some people have said we just need to put more money into treatment. Treatment is essential, but treatment is at the end of the line.

You heard a couple of comments from the other side of the aisle today that we need to act before we go home at Easter and put more money into the heroin and drug overdose situation.

This is the remarks of Senator Grassley on the floor. "According to the Office of National Drug Control Policy, the appropriations act passed in December provided more than \$400 million in funding specifically to address the opioid epidemic. This is an increase of \$100 million over the previous year." That is a 25 percent increase, okay? None of that money, when he said that just a few

months ago, has been spent yet. All of that money is available today. Is that right? Or most of it? Tell me. Most of that money is available today, and you would think we were going out of here not providing money—25 percent increase.

I want this in the record, and then let's put in the record too the record of how much was asked for, how much was appropriated, how much money was taken from interdiction and law enforcement and put into treatment, okay? These are just the facts. We don't want to deal with the facts, but we are going to put this also in the record so you can see that, again, there is money there.

And I want a report. I want a report, I am telling you, this week, of how much money is spent, and I want that in the record, okay Mr. Botticelli? And then I want something from you, too, Ms. Director of our Mental Health and Substance Abuse office. I want to see how much money is pending, and I want it in the record, and I want it in my office by Friday close of business, because I know the money is there. It hasn't even been distributed.

So we are not going to play these games. I want the facts there, and we need to stop this stuff at our border. It is coming in, and I just showed—my mayor I think also cited it. It is coming in by the boatload across the borders.

I have one question, too. I talked about El Chapo. The biggest drugs are coming across the border like it was some kind of a vacation holiday. I was told, speaking of weapons which are used in most drug offenses, most of the murders are—in Baltimore, they are killing people in drugs. In Orlando, we are killing them—we kill them at the mall, we kill them in our streets, in our great communities, our poor communities. We are killing them. Most of them are gun deaths, and they are related to drug trafficking, aren't they, Mr. Milione?

Mr. MILIONE. Yes —

Mr. MICA. Yes, and a lot of those are illegal weapons. Now I am told—I just got this this morning—El Chapo, who is coming back and forth, also one of the weapons he had was traced to the Fast and Furious. So it was a weapon that was supplied by the United States Government, and the principal drug trafficker who is trafficking across the border like a holiday visit, he had one of the Fast and Furious. Are you aware of that?

Mr. MILIONE. I am aware from the press reports.

Mr. MICA. Okay. Can you confirm that also for the committee?

Mr. MILIONE. I wouldn't be in the best position to do that. It would be another agency. I will take it back to the Department.

Mr. MICA. All right. Well, I want you to check on it for me and let me know, okay?

And I am very pleased with the people out there, but I met with some of your people, and the prosecutions are not what they should be. You know, you go to Singapore and they do not have a treatment program. I want to put you out of business, Ms. Wen, all the treatment programs. I want to put them out of business because our kids and our adults should not have to go to treatment. But we are allowing this crap to come into the United States. It is offensive.

We are killing tens of thousands, folks, and anything else, people would be outraged. Where are you? Just Say No, and saying Just

Say Maybe, there are consequences, or Just Say Okay makes a difference to our young people and what is happening.

You can tell I can get a little hot, the Italian comes out of me, but I have seen them. I have seen them dying in the streets of Baltimore, and I see them now dying again in my community, and we need to do something about it, and that supply has to be cut off. Then I can put Ms. Wen and others out of business. We won't have to be treating people. We won't have the scourge on our streets.

There being no further business before this committee of the House, this hearing is adjourned.

Thank you, witnesses.

[Whereupon, at 1:10 p.m., the committee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

News / Opinion / Op-Eds

The effects of opioid overprescription are evident in the emergency room

By Emily, Connor Narciso

MARCH 19, 2016

It's a Monday night in a Baltimore emergency room. An unkempt, middle-aged man is complaining of wrist pain. "I came in a week ago," he says. "I broke my right wrist." Records indicate it was actually two days ago. Now his left wrist hurts too, he complains, and he's out of pain meds. In 48 hours, he has evidently consumed his entire prescription of 30 Oxycodone.

Behind him, more Baltimoreans are in pain. "It's my knee," claims the next man. "It's been hurting for years, but it's been worse the last few months." An obese woman has arrived following a motor vehicle accident. "Well, actually, the car was parked," she explains. "Another car bumped into my car in the parking lot." She says her neck pain is a 14 out of 10. Another patient has a chronic back injury. He's out of meds, and he can't wait until Friday, when his refill is due. These are considered "emergencies."

The waiting room is full tonight. People fidget in their chairs. Some sleep. Most wear blank expressions. They've done this before. Some know the providers by name. "A true addict will wait as long as it takes to get a prescription," remarks a doctor. Some of tonight's patients will wait 14 hours to be seen by a provider. This is not exceptional. Last year, investigative journalists at ProPublica measured the average time, for each state, that patients spent in the E.R. before being sent home. Despite its world-class facilities, no state had longer wait times than Maryland.

Although the amount and severity of actual pain afflicting Americans has remained unchanged over the years, the amount of opioids prescribed and sold in the U.S. has quadrupled since 1999. Here, we are exceptional: With only 5 percent of the world's population, we are consuming over 80 percent of the world's painkillers.

This week, the CDC released long-awaited federal prescription guidelines — guidance the medical community would have benefited from well over a decade ago. The non binding recommendations discourage doctors from prescribing painkillers for chronic conditions such as backaches, neck pain and migraines.

Prescription of opioids had been traditionally limited to cancer pain and comfort measures, but in the mid-'90s drug companies began marketing these pills as the solution to a new plethora of ailments. In their efforts to expand the market, producers understated and willfully ignored the powerfully

addictive properties of their drugs. The promotion of OxyContin by Purdue Pharma was the most aggressive marketing of a schedule II drug ever undertaken by a pharmaceutical company. The Sackler family, which owns Stamford, Conn.-based Purdue Pharma, achieved a place on Forbes' 2015 list of America's wealthiest families. The Sacklers — the richest newcomers to the list — are worth an estimated \$14 billion.

By now, the damage of opioid over-prescription is indisputable. The largely hidden plague of heroin in America has surpassed the crack epidemic in size and scope, and it's largely driven by the explosion in opioid prescriptions: Once a patient is hooked, he or she often turns to the street drug, which can be easier and less expensive to acquire. Nationwide, heroin deaths have more than tripled since 2010. According to the federal government, heroin addiction rates in Baltimore are the highest of any major city in the country, with the number of users estimated to range from 19,000 to 60,000 plus.

Back at the Baltimore emergency room, the staff works to medically clear a 39-year-old Baltimore native for detox. You could tell that she was once a beautiful young woman. Today, she appears weathered, exhausted, and deeply depressed. Heroin has taken over her life. Overdoses can be serious and complicated affairs, and they are only getting more common. Spurred by prescription opioids, the Drug Enforcement Administration reported last year that drug overdoses overtook auto accidents nationwide for the first time in 2013, and are now the leading cause of death for Americans aged 44 and younger.

It's hard to find any individuals or institutions that aren't paying a price for this epidemic, in one form or another. Families have been torn apart. Thousands lose their lives every year. Taxpayers are footing the bill for federal and state treatment funds. And as any staff member will point out, patients with legitimate medical emergencies are suffering every day from the congestion in the E.R.

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In Heroin Crisis, White Families Seek Gentler War on Drugs

By KATHARINE Q. SEELYE OCT. 30, 2015

NEWTON, N.H. — When Courtney Griffin was using heroin, she lied, disappeared, and stole from her parents to support her \$400-a-day habit. Her family paid her debts, never filed a police report and kept her addiction secret — until she was found dead last year of an overdose.

At Courtney's funeral, they decided to acknowledge the reality that redefined their lives: Their bright, beautiful daughter, just 20, who played the French horn in high school and dreamed of living in Hawaii, had been kicked out of the Marines for drugs. Eventually, she overdosed at her boyfriend's grandmother's house, where she died alone.

"When I was a kid, junkies were the worst," Doug Griffin, 63, Courtney's father, recalled in their comfortable home here in southeastern New Hampshire. "I used to have an office in New York City. I saw them."

Noting that "junkies" is a word he would never use now, he said that these days, "they're working right next to you and you don't even know it. They're in my daughter's bedroom — they are my daughter."

When the nation's long-running war against drugs was defined by the crack epidemic and based in poor, predominantly black urban areas, the public response was defined by zero tolerance and stiff prison sentences. But today's heroin crisis is different. While heroin use has climbed among all demographic groups, it has skyrocketed among whites; nearly 90 percent of those who tried heroin for the first time in the last decade were white.

And the growing army of families of those lost to heroin — many of them in the suburbs and small towns — are now using their influence, anger and grief to cushion the country's approach to drugs, from altering the language around addiction to prodding government to treat it not as a crime, but as a disease.

"Because the demographic of people affected are more white, more middle class, these are parents who are empowered," said Michael Botticelli, director of the White House Office of National Drug Control Policy, better known as the nation's drug czar. "They know how to call a legislator, they know how to get angry with their insurance company, they know how to advocate. They have been so instrumental in changing the conversation."

Mr. Botticelli, a recovering alcoholic who has been sober for 26 years, speaks to some of these parents regularly.

Their efforts also include lobbying statehouses, holding rallies and starting nonprofit organizations, making these mothers and fathers part of a growing backlash against the harsh tactics of traditional drug enforcement. These days, in rare bipartisan or even nonpartisan agreement, punishment is out and compassion is in.

The presidential candidates of both parties are now talking about the drug epidemic, with Hillary Rodham Clinton hosting forums on the issue as Jeb Bush and Carly Fiorina tell their own stories of loss while calling for more care and empathy.

Last week, President Obama traveled to West Virginia, a mostly white state with high levels of overdoses, to discuss his \$133 million proposal to expand access for drug treatment and prevention programs. The Justice Department is also preparing to release roughly 6,000 inmates from federal prisons as part of an effort to roll back the severe penalties issued to nonviolent drug dealers in decades past.

And in one of the most striking shifts in this new era, some local police departments have stopped punishing many heroin users. In Gloucester, Mass., those who walk into the police station and ask for help, even if they are carrying drugs or needles, are no longer arrested. Instead, they are diverted to treatment, despite questions about the police departments' unilateral authority to do so. It is an approach being replicated by three dozen other police departments around the country.

"How these policies evolve in the first place, and the connection with race, seems very stark," said Marc Mauer, executive director of the Sentencing Project, which examines racial issues in the criminal justice system.

Still, he and other experts said, a broad consensus seems to be emerging: The drug problem will not be solved by arrests alone, but rather by treatment.

Parents like the Griffins say that while they recognize the racial shift in heroin use, politicians and law enforcement are responding in this new way because "they realized what they were doing wasn't working."

"They're paying more attention because people are screaming about it," Mr. Griffin said. "I work with 100 people every day — parents, people in recovery, addicts — who are invading the statehouse, doing everything we can to make as much noise as we can to try to save these kids."

An Epidemic's New Terrain

Heroin's spread into the suburbs and small towns grew out of an earlier wave of addiction to prescription painkillers; together the two trends are ravaging the country.

Deaths from heroin rose to 8,260 in 2013, quadrupling since 2000 and aggravating what some were already calling the worst drug overdose epidemic in United States history.

Over all, drug overdoses now cause more deaths than car crashes, with opioids like OxyContin and other pain medications killing 44 people a day.

Here in New England, the epidemic has grabbed officials by the lapels.

The old industrial cities, quiet small towns and rural outposts are seeing a near-daily parade of drug summit meetings, task forces, vigils against heroin, pronouncements from lawmakers and news media reports on the heroin crisis.

New Hampshire is typical of the hardest-hit states. Last year, 325 people here died of opioid overdoses, a 68 percent increase from 2013. Potentially hundreds more deaths were averted by emergency medical workers, who last year administered naloxone, a medication that reverses the effects of opioid overdoses, in more than 1,900 cases.

Adding to the anxiety among parents, the state also ranks second to last, ahead only of Texas, in access to treatment programs; New Hampshire has about 100,000 people in need of treatment, state officials say, but the state's publicly financed system can serve just 4 percent of them.

Since New Hampshire holds the first-in-the-nation presidential primary, residents have repeatedly raised the issue of heroin with the 2016 candidates.

Mrs. Clinton still recalls her surprise that the first question she was asked in April, at her first open meeting in New Hampshire as a candidate, was not about the economy or health care, but heroin. Last month, she laid out a \$10 billion plan to combat and treat drug addiction over the next decade.

She has also led discussions on the topic around the country, including packed forums like the one in Laconia, N.H., where hundreds of politically engaged, mostly white middle-class men and women, stayed for two hours in a sweltering meeting hall to talk and listen. One woman told of the difficulties of getting her son into a good treatment program, and said he eventually took his own life. Another told Mrs. Clinton of the searing pain of losing her beloved son to heroin.

Many of the 15 Republican candidates for president have heard similar stories, and they are sharing their own.

"I have some personal experience with this as a dad, and it is the most heartbreaking thing in the world to have to go through," Jeb Bush, the former governor of Florida, said at a town hall-style meeting in Merrimack, N.H., in August. His daughter, Noelle, was jailed twice while in rehab, for being caught with prescription pills and accused of having crack cocaine.

Carly Fiorina, the former chief executive of Hewlett-Packard, tells audiences that she and her husband "buried a child to addiction." And Gov. Chris Christie of New Jersey released an ad here in New Hampshire declaring, "We need to be pro-life for the 16-year-old drug addict who's laying on the floor of the county jail."

Some black scholars said they welcomed the shift, while expressing frustration that earlier calls by African-Americans for a more empathetic approach were largely ignored.

"This new turn to a more compassionate view of those addicted to heroin is welcome," said Kimberlé Williams Crenshaw, who specializes in racial issues at Columbia and U.C.L.A. law schools. "But," she added, "one cannot help notice that had this compassion existed for African-Americans caught up in addiction and the behaviors it produces, the devastating impact of mass incarceration upon entire communities would never have happened."

Now, all the political engagement around heroin has helped create what Timothy Rourke, the chairman of the New Hampshire Governor's Commission on Alcohol and Drug Abuse, says is an impetus for change, not unlike the confluence of events that finally produced a response to the AIDS epidemic. "You have a lot of people dying, it's no longer just 'those people,'" he said. "You have people with lived experience demanding better treatment, and you have really good data."

A More Forgiving Approach

Among recent bills passed by the New Hampshire legislature in response is one that gives friends and family access to naloxone, the anti-overdose medication. Mr. Griffin, a few months after his daughter died, was among those testifying for the bill. It was set to pass in May but would not take effect until January 2016 — until Mr. Griffin warned lawmakers that too many lives could be lost in that six-month gap. At his urging, the bill was amended to take effect as soon as it was signed into law. It went into effect June 2.

Other parents like him have successfully lobbied for similar measures across the country. Almost all states now have laws or pilot programs making it easier for emergency medical workers or family and friends to obtain naloxone. And 32 states have passed "good Samaritan" laws that protect people from prosecution, at least for low-level offenses, if they call 911 to report an overdose. A generation ago when civil rights activists denounced as racist the push to punish crack-cocaine crimes, largely involving blacks, far more severely than powder-cocaine crimes, involving whites, political figures of both parties defended those policies as necessary to control violent crime.

But today, with heroin ravaging largely white communities in the Northeast and Midwest, and with violent crime largely down, the mood is more forgiving.

"Both the image and reality is that this is a white and often middle-class problem," said Mr. Mauer of the Sentencing Project. "And appropriately so, we're having a much broader conversation about prevention and treatment, and trying to be constructive in responding to this problem. This is good. I don't think we should lock up white kids to show we're being equal."

So officers like Eric Adams, a white former undercover narcotics detective in Laconia, are finding new ways to respond. He is deployed full time now by the Police Department to reach out to people who have overdosed and help them get treatment.

"The way I look at addiction now is completely different," Mr. Adams said. "I can't tell you what changed inside of me, but these are people and they have a purpose in life and we can't as law enforcement look at them any other way. They are committing crimes to feed their addiction, plain and simple. They need help."

Often working with the police, rather than against them, parents are driving these kinds of individual conversions.

Their efforts include attempts to recast addiction in a less stigmatizing light — many parents along with treatment providers are avoiding words like "addict" or "junkie" and instead using terms that convey a chronic illness, like "substance use disorder."

Parents are involved in many ways. To further raise awareness, Jim Hood, 63, of Westport, Conn., who lost his son, Austin, 20, to heroin three years ago, and Greg Williams, 31, of Danbury, Conn., who is in long-term recovery from substance abuse, organized the Oct. 4 "Unite to Face Addiction" rally in Washington. Featuring musicians like Sheryl Crow, it brought together more than 750 groups that are now collaborating to create a national organization, Facing Addiction, devoted to fighting the disease of addiction on the scale of the American Cancer Society and the American Heart Association.

"With heart disease or cancer, you know what to do, who to call, where to go," Mr. Hood said. "With addiction, you just feel like you're out in the Wild West."

Ginger Katz of Norwalk, Conn., has equally lofty goals. After her son, Ian, 20, died of a heroin overdose in 1996, she founded the Courage to Speak Foundation to try to end the silence surrounding addiction, and she has developed a drug-prevention curriculum for schools.

For Doug and Pam Griffin Courtney is still their focus; her pastel bedroom is as she left it, with the schedules of meetings of Narcotics Anonymous taped to what she called her "recovery wall."

"We've pretty much given up what used to be our life," Mr. Griffin said.

But in addition to grieving and testifying at hearings and forums, the Griffins take calls day and night from parents across the country who have read their story and want to offer an encouraging word or ask for advice. They are establishing a sober house, named after Courtney. And they

host a potluck dinner and church service once a month on Sunday nights at the First Baptist Church in nearby Plaistow, where they held their daughter's funeral, for people with addictions and their families.

At last month's service, more than 75 people filled the pews, including the family of Christopher Honor, who was Courtney's boyfriend. He was also addicted to heroin. Last month, almost a year after her death, Chris, 22, died of an overdose — the 23rd overdose and third fatal one this year in Plaistow, a town of 8,000 people.

Chris's mother, Amanda Jordan, 40, wanted to attend the Sunday night service last month, but it was just two weeks after she had buried Chris, and she worried it might be too soon to go back to that church, where Chris's funeral was held. She sometimes thinks Chris is still alive, and at his funeral she was convinced he was still breathing.

She was afraid she would fall apart, but she and other family members decided to go anyway. During the service, her son Brett, 18, became so overwhelmed with emotion that he had to leave, rushing down the center aisle for the outside. Ms. Jordan ran after him. Then a family friend, Shane Manning, ran after both of them. Outside, they all clutched one another and sobbed.

"I'm a mess," Ms. Jordan said after coming back inside and kneeling in front of a picture of Chris. In addition to yearning for her son, she had been worried that the Griffins blamed her for Courtney's death. But at the church, they welcomed her. In their shared pain, the families spoke and embraced.


Ms. Jordan, one of the more recent involuntary members of this club of shattered parents, said that someday, when she is better able to function, she "absolutely" wants to work with the Griffins to "help New Hampshire realize there's a huge problem." Right now, though, she just wants to hunt down the person who sold Chris his fatal dose. "These dealers aren't just selling it," she said. "They're murdering people."


Correction: October 30, 2015

Because of an editing error, an earlier version of this article erroneously included one drug among the prescription opioids contributing to 44 deaths each day from overdoses. While OxyContin is a prescription opioid, heroin is not.

A version of this article appears in print on October 31, 2015, on page A1 of the New York edition with the headline: White Families Seek a Gentler War on Heroin.

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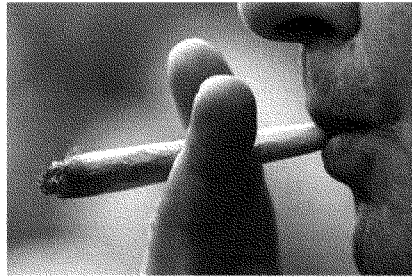
DRUGS

Marijuana as a Gateway Drug: The Myth That Will Not Die

By Maia Szalavitz @maiasz Oct. 29, 2010

Of all the arguments that have been used to demonize marijuana, few have been more powerful than that of the “gateway effect”: the notion that while marijuana itself may not be especially dangerous, it ineluctably leads to harder drugs like heroin and cocaine. Even Nick Kristof — in a column favoring marijuana legalization — alluded to it this week in the *New York Times*. In what is known as the “to be sure” paragraph, where op-ed writers cite the arguments of opponents, he wrote:

I have no illusions about drugs. One of my childhood friends in Yamhill, Ore., pretty much squandered his life by dabbling with marijuana in ninth grade and then moving on to stronger stuff. And yes, there's some risk that legalization would make such dabbling more common.



Sean Gallup/Getty Images

The idea that marijuana may be the first step in a longer career of drug use seems plausible at first: when addicts tell their histories, many begin with a story about marijuana. And there's a strong correlation between marijuana use and other drug use: a person who smokes marijuana is more than 104 times more likely to use cocaine than a person who never tries pot, according to the National Institute on Drug Abuse. (**More on Time.com:** 7 Tips for California: How to Make Legalizing Marijuana Smart)

The problem here is that correlation isn't cause. Hell's Angels motorcycle gang members are probably more 104 times more likely to have ridden a bicycle as a kid than those who don't become Hell's Angels, but that doesn't mean that riding a two-wheeler is a “gateway” to joining a motorcycle gang. It simply means that most people ride bikes and the kind of people who don't are highly unlikely to ever ride a motorcycle.

Scientists long ago abandoned the idea that marijuana causes users to try other drugs: as far back as 1999, in a report commissioned by Congress to look at the possible dangers of medical marijuana, the Institute of Medicine of the National Academy of Sciences wrote:

Patterns in progression of drug use from adolescence to adulthood are strikingly regular. Because it is the most widely used illicit drug, marijuana is predictably the first illicit drug most people encounter. Not surprisingly, most users of other illicit drugs have used marijuana first. In fact, most drug users begin with alcohol and nicotine before marijuana — usually before they are of legal age.

In the sense that marijuana use typically precedes rather than follows initiation of other illicit drug use, it is indeed a “gateway” drug. But because underage smoking and alcohol use typically precede marijuana use, marijuana is not the most common, and is rarely the first, “gateway” to illicit drug use. There is no conclusive evidence that the drug effects of marijuana are causally linked to the subsequent abuse of other illicit drugs.

Since then, numerous other studies have failed to support the gateway idea. Every year, the federal government funds two huge surveys on drug use in the population. Over and over they find that the number of people who try marijuana dwarfs that for cocaine or heroin. For example, in 2009, 2.3 million people reported trying pot — compared with 617,000 who tried cocaine and 180,000 who tried heroin. (**More on Time.com:** See photos of cannabis conventions)

So what accounts for the massive correlation between marijuana use and use of other drugs? One key factor is taste. People who are extremely interested in altering their consciousness are likely to want to try more than one way of doing it. If you are a true music fan, you probably won’t stick to listening to just one band or even a single genre — this doesn’t make lullabies a gateway to the Grateful Dead, it means that people who really like music probably like many different songs and groups.

Second is marijuana’s illegality: you aren’t likely to be able to find a heroin dealer if you can’t even score weed. Compared with pot dealers, sellers of hard drugs tend to be even less trusting of customers they don’t know, in part because they face greater penalties. But if you’ve proved yourself by regularly purchasing marijuana, dealers will happily introduce to you to their harder product lines if you express interest, or help you find a friend of theirs who can.

Holland began liberalizing its marijuana laws in part to close this particular gateway — and indeed now the country has slightly fewer young pot-smokers who move on to harder drugs compared with other nations, including the U.S. A 2010 Rand Institute report titled “What Can We Learn from the Dutch Cannabis Coffeeshop Experience?” found that there was “some evidence” for a “weakened gateway” in The Netherlands, and concluded that the data “clearly challenge any claim that the Dutch have strengthened the gateway to hard drug use.” (**More on Time.com:** Is Marijuana Addictive? It Depends How You Define Addiction)

Of course, that’s not the gateway argument favored by supporters of our current drug policy — but it is the one supported by science.



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

SEP 20 2016

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Louis J. Milione, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on March 22, 2016, at a hearing entitled "America's Heroin and Opioid Abuse Epidemic." We hope that this information is of assistance to the Committee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

A handwritten signature in dark ink, appearing to read "P. Kadzik", is written over a light blue horizontal line.

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Elijah Cummings
Ranking Member

U.S. Department of Justice
 Questions for the Record
 Committee on Oversight and Government Reform
 U.S. House of Representatives
 Hearing on "America's Heroin and Opioid Abuse Epidemic"
 March 22, 2016

Questions posed by Chairman Jason Chaffetz

1. Opioid addiction rates were high for many years before heroin overdose rapidly increased. What other factors may be responsible for the explosion of heroin deaths since 2010?

Response:

There are numerous factors contributing to the increase in overdose deaths involving opioids since 2010. A major factor is the introduction of non-pharmaceutical fentanyl and fentanyl analogues that are either mixed with heroin or sold as heroin substitutes. It should be noted that the majority of the fentanyl that the Drug Enforcement Administration (DEA) seizes is clandestinely produced and not diverted from legitimate DEA registrants (manufacturers, distributors, hospitals, or pharmacies). Fentanyl is a schedule II controlled substance that is extremely powerful and is significantly more potent than heroin. We believe the rationale for this is to increase the user perception of euphoria. Fentanyl is a synthetic opioid and the cost to produce a kilogram of fentanyl is very inexpensive when compared to heroin. Law enforcement has seen a surge in the amount of fentanyl submitted to crime labs throughout the United States. The National Forensic Laboratory Information System (NFLIS) database maintained by DEA collects drug seizure information from over 300 state and local crime laboratories across the United States. Nationally, in 2010, there were only 641 reports of fentanyl. That number increased to more than 13,000 reports in 2015.

In an effort to appeal to those who are misusing prescription opioids, drug traffickers are manufacturing counterfeit tablets to resemble the appearance of brand name and generic pharmaceutical pain relievers comprised of fentanyl and other anesthetics. A user who is new to or unfamiliar with using opioids would typically use a relatively low dose of either pharmaceutical hydrocodone or oxycodone, so the introduction of a potent, unknown dose of fentanyl in a counterfeit tablet creates a potential for significant overdose risk. Significant overdoses and deaths as a result of counterfeit opioid medications were recently seen in the Sacramento, California region in April 2016.

Deaths from fentanyl are also occurring in cocaine users and in some places cocaine and fentanyl combinations are increasingly a cause of death.¹ In some cases cocaine is being seized in

¹ Peterson AB, Gladden RM, Delcher C, Spies E, Garcia-Williams A, Wang Y, Halpin J, Zibbell J, McCarty CL, DeFiore-Hymer J, DiOrio M, Goldberger BA. Increases in Fentanyl-Related Overdose Deaths - Florida and Ohio, 2013-2015. MMWR Morb Mortal Wkly Rep. 2016 Aug 26;65(33):844-9. doi: 10.15585/mmwr.mm6533a3.

combination with fentanyl.² To the extent that cocaine users without a history of opioid use unwittingly take fentanyl believing it to be cocaine, they are likely to be even more vulnerable to its effects because they lack tolerance for such a powerful opioid and are unlikely to be carrying naloxone, which does not reverse cocaine overdoses.

2. What challenges or benefits do you see in extending access to naloxone and associated training to law enforcement professionals and other first responders?

Response:

The benefits of having first responders and law enforcement properly trained in administering naloxone are readily apparent. This life saving drug is extremely effective in stopping overdoses that may lead to death, thereby protecting the public. Equally important, naloxone should be readily available to law enforcement and first responders who are accidentally exposed to fentanyl or heroin. Through proper training, naloxone has the potential to save members of the public, law enforcement personnel, and first responders.

Initial challenges present themselves in the areas of cost and properly training first responders to administer naloxone. It is important that law enforcement is adequately trained to administer naloxone as there are other potential medical factors that may need to be handled for someone coming out of an overdose.

An often unseen problem exists as to the lack of follow up care to those persons with substance use disorders who have been revived after receiving naloxone. Anecdotally, first responders have reported administering naloxone to the same person on different days. In other words, naloxone will be administered to revive an overdose victim. That same overdose victim could be treated in the hospital and released, only to overdose and be revived by naloxone again. In general there is limited reporting of naloxone administration and so it is not clear how frequently this problem occurs. One factor that may be at issue in this type of scenario is the combination of potent opioids with fentanyl in a community that has limited resources for substance use disorder treatment. We believe the solution to this problem is to grow treatment resources and facilitate transport for medical care after reversal. Further, it is important to support hospital programs that link patients to treatment prior to overdose, if possible, through better identification of people with an opioid use disorder, and certainly after an overdose is encountered and treated in an emergency room setting.

**3. What more can be done to control improper prescribing through the internet?
Please describe successes and ongoing challenges in prosecuting these operations.**

² J Anal Toxicol. 2014 Oct;38(8):592-8. doi: 10.1093/jat/bku086. A series of forensic toxicology and drug seizure cases involving illicit fentanyl alone and in combination with heroin, cocaine or heroin and cocaine. Marinetti LJ1, Ehlers BJ2.

Response:

Internet drug sales fall into one of two categories: those that involve DEA registrants (i.e., physicians/pharmacies); and those that do not involve DEA registrants (i.e., clandestine sources). Investigations involving the improper prescribing of pharmaceuticals through the Internet have decreased significantly since the passage of the Ryan Haight Online Consumer Protection Act in 2008 (Pub. L. 110-425). Although DEA currently has some investigations that involve practitioners dispensing pharmaceuticals through the Internet, DEA has far more clandestine website investigations.

DEA has seen a dramatic increase in the distribution of counterfeit pharmaceuticals. Investigations have disclosed that counterfeit drugs are being manufactured by individuals who purchase bulk supplies of counterfeit pharmaceuticals, heroin, fentanyl, and/or other synthetic designer drugs, eventually pressing the chemicals into pill form. Investigations have established that China (followed by India and Pakistan) is the primary supplier of counterfeit pharmaceuticals/synthetics and pill pressing machines.

An example of a recent successful Internet investigation is "Operation Cookie Drop," through DEA's Special Operations Division. The DEA – Dallas Field Division (DFD) investigated a Southwest Asian transnational criminal organization (TCO) that illegally imported between 500,000 and 1,000,000 counterfeit controlled substances (schedule II, III, and IV pharmaceuticals) into the United States every month for over three years. The pills were then sold on the Internet to U.S. citizens who believed they were purchasing legitimate pharmaceuticals, but in reality were purchasing counterfeit controlled substances. The investigation resulted in eight arrests, including a high-level Pakistani distributor at John F. Kennedy International Airport while entering the United States. This defendant was prosecuted in the Eastern District of Texas, convicted, and sentenced to 20 years federal imprisonment.

Emerging technologies, such as the Dark Web, Tor Networks, and other encrypted communication technologies, pose a significant threat to law enforcement efforts. Law enforcement's ability to lawfully intercept these electronic data communications is extremely limited. Many of the clandestine websites are purposely hosted on servers in countries where the United States lacks a mutual legal assistance treaty (MLAT). In addition, TCOs utilize encrypted e-mail services that also thwart traditional methods of gathering intelligence and evidence. As previously stated, investigations show that China is the largest supplier of counterfeit pharmaceuticals and synthetic precursors, many of which are legal and/or not considered a threat in China. China recently has increased cooperative and investigative efforts with DEA and taken significant steps to better regulate dangerous chemicals and substance; however, China continues to face challenges in its enforcement efforts.

In summary, drug traffickers and most criminal organizations worldwide are increasingly taking advantage of Internet technology to communicate anonymously, expand into new markets, launder drug proceeds, and build alliances with other illicit organizations.

4. How commonly do drug traffickers rely on commercial delivery services and what can be done to prevent their use?

Response:

Utilizing commercial delivery services appears to be a growing trend with traditional Mexican and Latin American TCOs, Asian TCOs that specialize in synthetic drugs (such as so-called “bath salts” or fentanyl), and domestic/local trafficking organizations and distributors. Each type of trafficking organization abuses commercial delivery services and the U.S. Postal Service (USPS), but the benefits to each type of organization differ, and thus they should be viewed as different threat groups.

For example, Asian synthetic TCOs typically use the cover of international trade between the United States and China to abuse the commercial delivery system. Synthetic substances such as fentanyl can be so potent that, for example, one kilogram of fentanyl is enough to produce approximately one million counterfeit oxycodone pills in the United States. If a TCO subdivides one kilogram of fentanyl down into smaller packages, it means that a single TCO can ship dozens, or even hundreds, of small packages a day from China to the United States, and it will be almost impossible for U.S. Customs and Border Protection (CBP) to inspect and stop all U.S. bound packages.

DEA works very closely with CBP, the U.S. Postal Inspection Service, and the private sector to target suspect packages. DEA also enjoys a close working relationship with commercial courier services, which enables the rapid sharing of information when a tactical intelligence situation arises. DEA also works closely with its Chinese counterparts and the Chinese government to identify targets in China, recommend substances for scheduling in China, and recommend regulatory changes in China that could assist in international law enforcement efforts. In fact, last fall China took action to control over 100 chemicals used by drug traffickers to supply dangerous narcotics to the United States.

An additional challenge in this area is that law enforcement agencies, including CBP, lack the authority to seize non-controlled synthetic designer drugs, also known as new psychoactive substances (NPS). Legislatively scheduling a large number of NPS would allow for many of these substances to be seized at the U.S. border or from smoke shops, convenience stores and “head shops.” Legislative scheduling of substances would also be a deterrent for those that are selling these substances online. Additionally, this type of action may reduce the number of substances that are being moved via commercial delivery services.

5. What successes and resistant obstacles are being encountered, if any, in prosecuting medical professionals who improperly prescribe opioids and heroin distributors?

Response:

Investigating and prosecuting medical professionals who are operating outside the scope of acceptable medical practice is essential to addressing the prescription opioid epidemic as well as

the surging use of heroin. DEA has criminal, civil, and administrative authorities to address these issues, and does so primarily through its DEA's Diversion Units and Tactical Diversion Squads address the issue of DEA registrants who are violating the Controlled Substances Act.

As numerous DEA investigations have demonstrated, prescribers who prescribe pharmaceutical controlled substances without a legitimate medical purpose or outside the usual course of professional practice, pharmacies that dispense illegitimate prescriptions, and supply chain wholesalers and manufacturers that fail to provide effective controls and procedures to guard against diversion, facilitate illicit access to opioids at the expense of public health and safety. It has been reported by the Substance Abuse and Mental Health Administration (SAMHSA) that approximately 80% of recent heroin initiates have a history of nonmedical use of prescription opioids. It is also reported that opioid addiction is typically chronic, associated with high rates of morbidity and mortality, and can require life-long treatment. Therefore, in order to reduce the number of people who are addicted to opioids, it is critical to prevent new cases from developing, particularly in people who are predisposed to chronic use disorders and who may turn to heroin because it is widely available and cheaper than pharmaceutical controlled substances.

DEA has conducted a number of successful operations against registrants who are operating outside the scope of usual professional practice, not adhering to the corresponding liability when dispensing, and/or not providing effective controls to guard against diversion. The first major operation conducted was "Operation Pill Nation," an Organized Crime Drug Enforcement Task Forces (OCDETF) investigation. Operation Pill Nation took place from 2010 through 2011 in South Florida to address rogue pain clinics. During this operation more than 300 undercover purchases took place from over 60 doctors and 40 "pill mill" pain clinics. Subsequent regional investigations have taken place in Houston, Texas, and most recently in 2015 through OCDETF's "Operation Pilluted," which investigated rogue pain clinics across four states and resulted in 25 DEA registrants being arrested and 62 DEA registrations surrendered. DEA has had success in additional investigations throughout the United States. Investigations into DEA registrants can be very challenging because they are labor and resource intensive. Additionally, educating prosecutors on the nature of these types of investigations is necessary because they are different than investigations that involve traditional illicit drugs. Nonetheless, DEA is fully committed to pursuing these investigations and cases as part of its efforts to address the opioid abuse epidemic.

It is also important to note that when providers are disciplined by state medical boards, these actions are usually "complaint driven." Patients with opioid use disorders who are receiving prescriptions for opioid-based medication are unlikely to complain about their prescribers for said activity. Proactive use of prescription drug monitoring programs databases (PDMPs) by state licensing boards and coroners could help identify lethal providers to remediate them sooner. Many states need to change their PDMP laws to allow such access.³

³ Hoffmann, Diane E., and Tarzian, Anita J., Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards, *Journal of Law, Medicine & Ethics*, 31 (2003): 21-40.

6. What additional investigation and prosecution techniques would be useful in targeting the drug supply chain?

Response:

DEA strongly supports the implementation and use of PDMPs, which are valuable tools for components of the drug supply chain, such as prescribers and pharmacists, as well as law enforcement agencies, to identify, detect, and prevent nonmedical prescription drug use and diversion. PDMPs are typically state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access to the data, as well as the medications captured, varies according to state law. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMPs and encourages the use of these programs by medical professionals to intervene and refer to treatment individuals with opioid use disorders and in detecting and preventing doctor shopping and other diversion. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users) and 34 participate in a program which facilitates the transfer of PDMP data across state lines to authorized users.

While PDMPs are valuable tools, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interoperability remains a challenge, as many drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous pain clinics and physicians.

It is important to note that DEA and our federal partners are working to address the interoperability problems in state PDMPs. Several federal entities, including SAMHSA, the Office of National Drug Control Policy (ONDCP), and the Department of Justice's Bureau of Justice Assistance (BJA) are supporting efforts to improve interoperability between PDMPs through grants and other assistance. DEA also understands that the Centers for Disease Control and Prevention supports work in 16 states to enhance and maximize PDMPs as public health and clinical tools in its Prevention for States program. Further, the Alliance of States with Prescription Drug Monitoring Programs, Brandeis University's PDMP Center of Excellence, and the Indian Health Service are also partnering to improve interoperability between IHS, its pharmacies, and PDMPs. Additionally, the National Association of Boards of Pharmacy (NABP) hosts NABP Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of PDMP data across state lines to authorized users. The program allows users of participating PDMPs to securely exchange prescription data between certain states. Currently, PDMPs in 34 states are participating in the program, but to what extent they share data with other states depends on their state laws.

7. What special enforcement challenges, if any, are posed by fentanyl?

Response:

Fentanyl and its analogs are incredibly potent synthetic opiates. Fentanyl is significantly more potent than morphine and heroin; can be deployed through inhalation, injection, ingestion, or via transdermal delivery; and is inexpensive to produce by chemical manufacturers in other nations. DEA investigations indicate that a kilogram of fentanyl, which can be diluted into one million pills sold in the US for \$1-\$3 per pill, can be purchased for as little as \$3,000 in China.

The potency of fentanyl means that small quantities can be diluted into the same number of doses as a much larger quantity of a similar drug, such as heroin. Smaller quantities are by nature more challenging for law enforcement to detect, and criminals take advantage of this. Fentanyl can easily be disguised as an industrial chemical powder and shipped internationally, which hinders Customs detection. TCOs can traffic a few kilograms of fentanyl across the border, which once in the United States can be diluted into the same number of doses that many tens or hundreds of kilograms of heroin would produce.

Fentanyl, acetyl fentanyl, and other emerging fentanyl analogues are mainly produced in China, available for purchase on the Internet, and shipped directly to distributors in the United States, Canada, and Mexico via commercial parcel post. These substances can pose significant challenges to law enforcement. Distributors use tablet machines to press fentanyl and its analogs into precise replicas of legitimate prescription drugs making it extremely difficult for law enforcement and the unsuspecting user to identify the counterfeit pills as fentanyl.

Officer safety is a significant concern when dealing with fentanyl-related crime. Already, a number of United States, Chinese, Mexican, and Canadian law enforcement officers have needed life-saving interventions after accidental exposure to fentanyl. Officers are putting themselves at a great personal risk when handling fentanyl because fentanyl is most often a white powder that resembles cocaine or heroin. The result is that officers may not be aware of the substance they are dealing with and thus may not take the additional, appropriate safety measures that are required when handling such a dangerous and potent substance like fentanyl.

As noted above, accidental exposure to fentanyl and its analogues through the skin or inhalation of airborne powder poses health risks to public health workers, first responders, and law enforcement personnel. While the current number of overdoses resulting from accidental exposures is low, there is a potential for more widespread exposure as fentanyl to occur as availability and seizures increase. This makes it critical to outfit law enforcement and other personnel with naloxone as well as equipment to properly process and transport substances suspected of containing fentanyl or its analogues a priority.

“Fentanyl Mills” require a Level A Clandestine Laboratory Team response to enter, neutralize, and process the fentanyl mill. Entry is often high risk due to suspects being exposed to fentanyl during processing and handling fentanyl for distribution. Non-drug evidence found at the scene is often contaminated and is difficult to process for evidentiary purposes. Clandestine Laboratory Team member’s equipment must be decontaminated upon departure from the fentanyl mill and ultimately destroyed.

Questions posed by Representative Trey Gowdy

- 8. Please provide data on federal drug prosecutions since 2010, and detail regarding the number of prosecutions against:**
- a. Doctors or other medical professionals (diversions);**
 - b. Pharmaceutical companies; and**
 - c. Other actors.**

Response:

According to its records, DEA has recorded 225 prosecutions and convictions of Medical Doctors and Doctors of Osteopathic Medicine since 2010. Of those, 155 were prosecuted in federal court and 70 in state court.

In addition to criminal charges that can be brought against DEA registrants, DEA can also take action to revoke or deny a registrant's authority to handle controlled substances through an administrative action called an Order to Show Cause (OTSC) and/or an Immediate Suspension Order (ISO). From 2010 through 2015, DEA issued 413 OTSC and/or ISOs against practitioners. During this time frame, DEA also issued 134 OTSC and/or ISOs against pharmacies, distributors, and manufacturers of controlled substances.

Questions posed by Representative Jody B. Hice

- 9. How many criminals have been arrested and prosecuted on DEA's rolling thunder program?**

Response:

As of April 29, 2016, DEA's Special Operations Division, DEA's Office of Global Enforcement, and OCDETF have 3,863 combined state and federal arrests through "Project Rolling Thunder." The DEA does not have the number of prosecutions for these arrests. The prosecution data is maintained by the corresponding jurisdictions in which they were charged.

Questions for Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services
Administration

Questions from Chairman Jason Chaffetz
Committee on Oversight and Government Reform

March 22, 2016, Hearing: "America's Heroin and Opioid Abuse Epidemic"

1. Please briefly summarize SAMHSA's view on what is known and unknown about the effectiveness of current treatments for opioid and heroin addiction and how their effectiveness varies, if at all, based on drug, duration of addiction, treatment characteristics (residential/non-residential/duration) and provider characteristics. What are the top research priorities from the treatment perspective?

Response: The aggregate evidence shows that methadone, buprenorphine, and naltrexone all reduce opioid use, opioid use disorder-related symptoms, risk of infectious disease, and crime.¹ Methadone and buprenorphine reduce mortality, and patients on methadone or buprenorphine are also more likely to remain in treatment when compared to patients not receiving medication.^{2,3} The scientific evidence supports long term maintenance with these medicines in the context of behavioral treatment, including talk therapy and recovery support, rather than short term detoxification programs aimed at abstinence. Relapse rates are high when tapering off of these medications, and abstinence orientations popular in many treatment programs do not facilitate patients' long term, stable recovery.¹ Mortality due to relapse in persons not retained in treatment is high.⁴

Access to one of the three approved medications for the treatment of opioid use disorder is the single characteristic of treatment most strongly associated with success. To facilitate the expansion of access to effective, evidence-based medication-assisted treatment (MAT), additional research is needed to evaluate the outcomes of each of these medications compared to one another rather than placebo. This will allow patients to be matched to the specific form of MAT most likely to assure an optimal outcome. Research is also needed in the clinical translation and implementation of MAT in different health care settings and by different providers. Such work could help overcome real and perceived barriers related to induction onto MAT, compliance monitoring, and patient safety.

The National Institute on Drug Abuse (NIDA) is conducting three comparative effectiveness trials will provide comparative effectiveness data for extended release naltrexone and opioid agonist therapy for treatment of vulnerable youth, HIV positive opioid users and opioid use disorder broadly. NIDA also has a robust implementation science portfolio including a services planning research project in the Appalachian Region to address adverse health consequences associated with increased opioid injection drug use.

The Office of the Assistant Secretary for Planning and Evaluation is also supporting research that may contribute to these research priorities by analyzing the extent to which opioid use disorder treatment is reimbursed by private sector health plans and what treatment services are generally provided.

The American Society of Addiction Medicine (2013). Advancing Access to Addiction Medications.

² Mattick, R.P., Breen, C., Kimber, J., and Davoli, M. (2009). *Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. In Cochrane Database of Systematic Reviews, The Cochrane Collaboration, ed. (Chichester, UK: John Wiley & Sons, Ltd).*

³ Mattick, R.P., Breen, C., Kimber, J., and Davoli, M. (2014). *Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst. Rev. 2, CD002207.*

⁴ Kakko, J., Svanborg, K. D., Kreek, M. J. & Heilig, M. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trial. *The Lancet* 361, 662–668 (2003).

2. To what extent has access to treatment for mental health and substance abuse disorders increased among persons covered by health insurance over recent years, particularly since passage of the Affordable Care Act, which required that insurance plans offer equitable access to coverage for such treatments?

Response: The emerging evidence is that access, affordability, and coverage is improving for individuals with mental health and substance use conditions. Early research indicates that Medicaid expansion, Centers for Medicare & Medicaid Services (CMS) demonstration opportunities, section 2703 of the Affordable Care Act (CMS Health Homes), the Mental Health Parity and Addiction Equity Act (MHPAEA), parity protections in the commercial market, and dependent coverage requirements are leading to more individuals getting the services they need. In addition, SAMHSA has conducted and supported a variety of related studies over the past year related to the Affordable Care Act. Below is a selection of findings with citations.

A. There is emerging literature on the impact of the Affordable Care Act's dependent coverage provision on young adults, where the consensus is that access to health insurance has increased utilization and lowered costs for health services, according to one study. It found that young adults with behavioral health disorders generally were less likely to have high levels of out-of-pocket costs as a share of their total health care spending after the Affordable Care Act's expansion of dependent coverage.¹

¹ Mir M. Ali, Ph.D., Jie Chen, Ph.D., Ryan Mutter, Ph.D., Priscilla Novak, M.S., Karoline Mortensen, Ph.D., *The ACA's Dependent Coverage Expansion and Out-of-*

B. If all states expanded Medicaid to include the Medicaid and private insurance expansions under the Affordable Care Act:

- There are approximately 2.3 million individuals with a mental illness or substance abuse disorder who have incomes suggesting they would be eligible for health insurance coverage if their states chose to expand Medicaid.²
- States that choose to expand Medicaid may achieve significant budget savings. Four Medicaid expansion states saved an average of 15.2 percent of their state general fund behavioral health budgets. That average percentage could amount to between \$8 million and \$122 million in annual savings for individual states that have yet to expand.³

C. Another 2015 study found differences in the prevalence of receiving mental health treatment between low-income uninsured nonelderly adults with serious mental illness (SMI) who are eligible for Medicaid under the Affordable Care Act and their existing Medicaid counterparts. It suggested that the prevalence of receiving mental health treatment among new Medicaid enrollees with SMI would significantly increase in the 28 states that had expanded Medicaid.⁴

D. Another paper examines whether health insurance expansion may result in an increase in substance use disorder (SUD) treatment utilization as a result of the Affordable Care Act.⁵

- The analysis finds that over 80% of individuals with substance use disorder receive no treatment and 97% do not perceive a need for treatment.
- When they do receive treatment, they are more likely to receive mental health treatment.
- Having Medicaid or private insurance is associated with a higher likelihood of receiving SUD treatment, but only when individuals perceive a need for it.

Pocket Spending by Young Adults With Behavioral Health Conditions

² <https://aspe.hhs.gov/sites/default/files/pdf/190506/BHMedicaidExpansion.pdf>

³ <https://aspe.hhs.gov/sites/default/files/pdf/190506/BHMedicaidExpansion.pdf>

⁴ Han, B., Gfroerer, J., Kuramoto, S. J., Ali, M., Woodward, A. M., & Teich, J. (2015). Medicaid Expansion Under the Affordable Care Act: Potential Changes in Receipt of Mental Health Treatment Among Low-Income Nonelderly Adults With Serious Mental Illness. *American Journal of Public Health*, (0), e1-e8.

⁵ Ali, M. M., Teich, J. L., & Mutter, R. (2015). The Role of Perceived Need and Health Insurance in Substance Use Treatment: Implications for the Affordable Care Act. *Journal of Substance Abuse Treatment*, 54, 14-20.

E. Finally, research shows that behavioral health treatment utilization has trended upward, while some cost barriers have diminished.⁶

- Insurance coverage among young adults aged 19 to 26 has trended upward since the extension of dependent care coverage by the Affordable Care Act.
- Mental health service utilization has shown a similar upward trend, with more young adults reporting that they are receiving mental health treatment.
- Cost barriers associated with mental health service or substance use treatment have fallen in the wake of the dependent care expansion and MHPAEA bringing parity to the market.
- Payment for treatment has shifted away from public sources in this age range, with private insurance becoming a more prevalent source of payment.

SAMHSA continues to make significant investments in new analytics capacities, existing data, and survey systems to help identify the effects of the Affordable Care Act and MHPAEA laws. These efforts should help in identifying the effects of the Affordable Care Act and MHPAEA on individuals with mental or substance use disorders and how to better ensure they get the services they may need.

3. The Final Report of the National Heroin Task Force, submitted in response to congressional mandate, recommended "applying a continuum of care approach to the problem of opioid abuse disorder." It also recommended "implementing screening, assessment, and linkage to treatment." Are there any data on how often this is currently occurring?

Response: SAMHSA has implemented primary care screening, brief intervention, and referral to treatment (SBIRT) in 30 different states and tribal entities over the past 13 years. All the grantees have screened for the full array of alcohol and other drug misuse and abuse. This includes screening for heroin and other illegal opioids as well as prescription opioids. When screening results indicate a need for specialty treatment these programs have referred or linked the patient to professional substance use disorder treatment when the patient concurred with the recommendation.

Although SAMHSA does not collect universal prevalence data regarding screening, since the SAMHSA SBIRT program began in 2003, we do have evidence that the integration of screening and brief intervention has expanded well beyond the trauma and emergency rooms into health centers, clinics, and other behavioral health locations. The American College of Surgeons has instituted a requirement that their level 1 and 2 trauma centers be required to screen for alcohol. In addition, the American Academy of Pediatrics now endorses screening and brief intervention for adolescents. Both of these actions have led to further acceptance of screening and

⁶ Maclellan, Chandler. (2015). *The CBHSQ Report. Trends in Insurance Coverage And Treatment Utilization By Young Adults*. Retrieved from <http://www.samhsa.gov/data/sites/default/files/SR-1887/SR-1887.htm>

brief intervention throughout behavioral health.

In addition, since 2008, SAMHSA has funded 117 SBIRT Training grants to universities across the country to train the next generation of health care providers in the aspects of SBIRT. Though originally directed at medical residents solely, the grants have expanded their training opportunities to include medical students, physicians' assistants, nurses, social workers, counselors, dentists, pharmacists, and psychologists. To date, more than 22,000 medical residents and other behavioral health providers have been trained. All of these programs provide some training on the nature of opioid screening, intervention, and referral to specialty treatment. It should also be noted that the most recent funding opportunity announcements for both the SBIRT state and training grantees have included enhanced requirements to specifically refer eligible patients to medication assisted treatment (MAT). As these are newly implemented awards, SAMHSA does not yet have results of this enhanced focus on MAT.

SAMHSA appreciates the recommendations of the National Heroin Task Force, and SAMHSA grants encourage the use of the continuum of care approach in all programs, including those that focus on opioid use disorders. For instance, Targeted Capacity Expansion: Medication Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA) grantees are required to provide an array of MAT services, including integrated care, counselling, behavioral therapies, and other clinical services to help clients achieve and maintain abstinence. The new buprenorphine regulation also emphasizes that MAT should include a comprehensive and integrated treatment program that reflects the continuum of care approach.

4. Given that buprenorphine and methadone both have some addictive potential, what does SAMHSA regard as the safest way to expand access to medication assisted treatment?

Response: Across HHS, SAMHSA and our sister agencies are working to expand education on the most effective opioid prescribing practices in this country, which includes prescriptions as part of MAT. On March 15, 2016, the Centers for Disease Control and Prevention (CDC) issued the Guideline for Prescribing Opioids for Chronic Pain. Developed in consultation with SAMHSA, the Guideline offers information on medication selection, dosage, duration, and when and how to reassess progress and discontinue medication if needed. The guideline is crucial new tool to improve prescription practices and help expand MAT while reducing diversion of needed MAT drugs.

In addition to focusing on preventing diversion of these drugs when prescribed as MAT, SAMHSA efforts are also focused on educating providers on best prescribing practices for the treatment of pain. The safest way to expand access to MAT is to assure patients receive individualized therapy with the most appropriate pharmacotherapy and in the most appropriate treatment setting to support their recovery. To accomplish this, all approved forms of MAT need to be available and

provided by well trained and adequately supported providers in a non-punitive treatment setting. Buprenorphine and methadone are both opioids and thus have abuse potential. The treatment systems currently in existence are designed to minimize diversion and misuse of these medications. These systems can be expanded within current and proposed regulations to help address the need for increased access to treatment.

5. What is known about the effectiveness of naloxone in reviving addicts who have overdosed in the presence of fentanyl-laced heroin (versus other types)? Does it work as well in these cases?

Response: Fentanyl is fast acting and has extremely high affinity for the opioid receptor. Because of these properties, respiratory depression and death can happen much more quickly with fentanyl. This is in stark contrast to overdose with many other opioids, where respiratory depression happens slowly and death may take hours. As a result, in cases of fentanyl overdose naloxone must be available and administered immediately. At the time of this hearing, SAMHSA is aware of one published case report of fentanyl overdose reversal with intranasal naloxone.

6. With so many new people, including former opioid abusers, trying heroin for the first time each month, where should preventive efforts be focused? How effective are existing primary or secondary prevention efforts?

Response: Prevention of opioid addiction starts at the source, which is often a prescription. As mentioned above, SAMHSA assisted CDC in developing guidelines to improve opioid prescribing practices, titled the “Guideline for Prescribing Opioids for Chronic Pain.” Dissemination and adoption of these best practices is an important step toward preventing opioid misuse, which can lead to first-time heroin use.

In terms of evidence-based prevention efforts, education about the dangers of opioid misuse and overprescribing opioid pain killers is paramount. The first step is educating the public and prescribers about overprescribing and drug interactions, and developing outreach strategies to engage community stakeholders and their constituents about the opioid overdose crisis and its effects. Additionally, developing a community-based strategy for the education, distribution and administration of Naloxone beyond traditional emergency personnel, such as agencies and organizations working with prison and jail populations and offender reentry programs, healthcare providers, harm reduction groups, pharmacies, community health centers, and families is essential. The effectiveness of preventing prescription drug abuse is corroborated by a study led by Richard Spoth of Iowa State University, which demonstrates that even brief intervention programs staged during adolescence can dramatically reduce the long-term rates of prescription drug abuse. That research is available at: <https://www.nih.gov/news-events/nih-research-matters/youth-interventions-lower-prescription-drug-abuse>.

Questions for Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Questions from Representative John L. Mica
Committee on Oversight and Government Reform

March 22, 2016, Hearing: "America's Heroin and Opioid Abuse Epidemic"

1. Please provide the 2015 data on heroin overdose deaths and usage as soon as they are available.

Response: The latest National Survey on Drug Use and Health (NSDUH) data will be available in September. SAMHSA is happy to provide that information when it becomes available.

2. Please provide the amounts of funds appropriated to programs under your purview to address the opioid epidemic and the increase in such amounts over the previous fiscal year (2015). Please also provide the amounts of these funds awaiting obligation, obligated, and expended.

Response: The table below provides a breakdown of current and anticipated funding for FY 2016 opioid-related funding. The table shows the funding enacted for FY 2016, the amount of funding above the FY 2015 enacted level, the funding that will be obligated by March 31, 2016 (end of the 2nd quarter of the fiscal year), and the date funds should be fully obligated for each program. It is important to note that FY 2016 appropriations were enacted on December 18, 2015, and that most of the funds are being awarded through grants. Due to the nature of programs, funding for grants is typically awarded in the fourth quarter of the fiscal year.

Substance Abuse and Mental Health Services Administration	FY2016 Enacted Level	FY2016 Enacted Level +/- FY2015	Obligations Or Expenditures through March 31, 2016	Anticipated Date when funds will be fully obligated
Strategic Prevention Framework for Prescription Drugs (SPF Rx)	\$10,000,000	\$10,000,000	0	9/30/2016
Medication-Assisted Treatment for Prescription Drugs and Opioid Addiction (MAT-PDOA)	\$25,000,000	\$13,000,000	0	9/30/2016
Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths (PDO)	\$12,000,000	\$12,000,000	0	9/30/2016

Questions for Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human
Services

Questions from Representative Michael R. Turner
Committee on Oversight and Government Reform
March 22, 2016, Hearing: "America's Heroin and Opioid Abuse Epidemic"

1. Your agency, by rule, could eliminate the restriction that prevents SAMHSA funds from being used to assist people with substance abuse disorders while they are incarcerated. Why hasn't SAMHSA done so?

Response: There are two restrictions that prevent SAMHSA from funding substance use disorder treatment within prison facilities. First, section 1931(a)(3) of the Public Health Service Act restricts SAMHSA from providing Substance Abuse Prevention and Treatment block grant funds "for the purpose of providing treatment services in penal and correctional institutions of the State." The statute further provides that "the State will not expend more than an amount equal to the amount expended for such purposes by the State from the grant made under section 1912A for the State for the fiscal year 1991." Together, these provisions restrict SAMHSA from funding substance use disorder treatment services in penal institutions beyond any expenditures already in place by States in FY 1991 under section 1912(a). This statutory restriction cannot be overturned by rule, and covers all of SAMHSA's block grant funds, which comprise the bulk of SAMHSA's funding for substance use disorder treatment.

The second restriction of SAMHSA funds from being used for substance use treatment services within correctional facilities is based on a policy decision reached between SAMHSA and the Bureau of Justice Assistance (BJA) in the Office of Justice Programs, DOJ in 1995. This decision was based on a number of factors:

- Congress passed the Violent Crime Control and Law Enforcement Act of 1994 that created the Residential Substance Abuse Treatment Program for State Prisoners (RSAT) in BJA; this was a major formula grant program for all states to expand substance use treatment for prisoners in correctional facilities, both prisons and jails.
- Both SAMHSA and BJA were Federal agencies receiving funding for substance use treatment services for people involved in the criminal justice system, and there was concern about duplicating federal efforts and a desire to increase federal efficiencies by targeting existing grant resources;
- BJA was receiving substantial congressional funding for a number of corrections-based treatment programming, beginning with the RSAT program for

individuals in correctional institutions while SAMHSA justice-treatment grant funding was at a low level.

- There was concern expressed at the State level about SAMHSA's limited substance use treatment funds being used for correctional populations when it was not sufficient to cover those individuals in the community who were not involved in the justice system.

SAMHSA and BJA agreed to leverage their substance use treatment budgets and prevent duplication by focusing on grant program coordination and specific targeting of funds. For example, federal grant programs to fund Treatment Drug Courts were bifurcated but still integrated such that BJA grant funding paid for the planning, implementation and administration and management of these courts while SAMHSA grant funds paid for substance use treatment and recovery supports. With regard to institutional corrections, the same strategy was used: BJA through its large grant programs for correctional populations provided funds for substance use treatment in correctional institutions while SAMHSA focused its limited funding resources on the community corrections populations such as parolees and probationers.

Later, when limited congressional funds were provided, SAMHSA created its Offender Reentry Programs (ORP), grant programs designed to provide funding for the transition from correctional facilities to the community, including screening, assessment, release and transition planning and linkages with community-based treatment programs. The policy decision restricts SAMHSA funding from being used to support substance use treatment services to incarcerated individuals (which are often provided by BJA and State budgets) but allows for ancillary support for transition services.

Congress has provided grant funding for a number of BJA correctional treatment programs during several Administrations since 1995 including: RSAT, the Serious and Violent Offender Reentry Initiative, the President's Reentry Initiative, and the Second Chance Act to name a few. States may also use the BJA Byrne Justice Assistance Grants for correctional treatment services.

SAMHSA's congressional funding has stipulated the majority of its criminal justice grant funds go to "drug courts." For example, the FY 2016 budget level of \$78 million for criminal justice grant programs contains language requiring SAMHSA to expend \$60 million for drug court treatment services. Within remaining funding, SAMHSA has continued its correctional reentry programs through the ORP grant program.

There have been a number of GAO reports that have praised SAMHSA and BJA for their innovative way of leveraging grant resources for the justice-involved populations while increasing efficiencies and reducing funding duplication. Given the limited funding levels for corrections-related grant programming at SAMHSA and the investment the Congress has made through the numerous BJA corrections-related grant programs, the focus on effective transition from the institution to the community aims to balance both priorities.

Questions for Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Questions from Representative Glenn Grothman
Committee on Oversight and Government Reform

March 22, 2016, Hearing: "America's Heroin and Opioid Abuse Epidemic"

1. What is the likelihood that a person found in possession of heroin is heroin-dependent?

Please provide any relevant data from the National Survey on Drug Use and Health (NSDUH).

Response: NSDUH does not collect data on whether respondents are in actual possession of the drugs they report they have used. In 2014, the most recent NSDUH data available, the rate of past-year heroin dependence among people aged 12 or older was 0.2 percent. That corresponds to approximately 539,000 people nationwide.

Questions for Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Questions from Representative Tammy Duckworth
Committee on Oversight and Government Reform

March 22, 2016, Hearing: "America's Heroin and Opioid Abuse Epidemic"

In my home state of Illinois, The Department of Public Health reported 1,652 overdose deaths across the state in 2014 - a 29% increase since 2010. These are alarming statistics. Many cities, some in Illinois, now equip first responders with this easily administered drug through an intranasal version or in an auto-injector similar to an Epi-Pen. I am proud that Illinois has led the charge on the distribution of naloxone through community programs. For instance, since 2010, Illinois has passed statewide laws to expand naloxone access. In my home district, the DuPage County Health Department has trained 1,200 police officers and reported 34 overdose reversals in 2014 alone. While I'm glad that Illinois has been on the forefront of effective treatment programs, much more needs to be done on a Federal level to address this epidemic.

1. Mr. Enomoto, HHS published the "Opioid Overdose Prevention Toolkit" this year. Can you tell me, how important is naloxone in prevention of overdose deaths?

Response: The overdose prevention toolkit is an essential resource for community stakeholders, emergency personnel and physicians to better understand the scope of the opioid epidemic and how best to confront it. According to the CDC, U.S. overdose deaths involving prescription opioid analgesics increased to about 19,000 deaths in 2014; more than three times the number in 2001.

Naloxone is the FDA approved drug that reverses the potentially fatal respiratory depression caused by opioid overdose. That's why SAMHSA proposed the Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths, for which Congress appropriated \$12 million in FY 2016. New in FY 2016, these grants will help states identify communities of high need and to provide education, training, and resources necessary to tailor the overdose kits to meet their specific needs. The grant funds can be used for purchasing naloxone, equipping first responders with naloxone, and providing training on other overdose death prevention strategies, supporting education on these strategies, and providing materials to assemble and disseminate overdose kits. This grant program aligns with Secretary Burwell's Opioid Initiative, which includes the expanded use of naloxone to treat opioid overdoses as well as opioid prescribing practices and the expanded use of medication- assisted treatment to reduce opioid use disorders and overdose.

2. Beyond first responders, who should have access to naloxone?


Response: SAMHSA supports a community-based strategy for the education, distribution

and administration of naloxone beyond traditional emergency personnel, such as to agencies and organizations working with prison and jail populations and offender reentry programs, healthcare providers, harm reduction groups, pharmacies, and community health centers. Individuals at risk of overdose, their friends, and families need to have naloxone on hand and be trained to use it. In addition, health care providers with patients who are at high-risk of an opioid overdose including pain management clinics, opioid treatment programs, and addiction treatment providers should prescribe or furnish naloxone directly to their patient populations. Naloxone is a prescription medicine. Many states have created the ability for patients to access this medicine without first visiting a prescriber, effectively making naloxone available like a non-prescribed product by using a standing order or collaborative practice arrangement between prescribers and pharmacists. Access to naloxone via this route is especially important for users who are unable to enter treatment or bystanders wishing to help out a loved one.

3. Please address the biggest impediments to achieving widely available and accessible naloxone for individuals who need it, such as cost or barriers to access.

Response: Cost imposes a substantial barrier for overdose prevention programs, especially localized community programs. Distribution of naloxone also poses a substantial challenge, particularly in rural areas. Barriers to access also include the need for a prescription to obtain naloxone in some states, and whether naloxone is sufficiently available to first responders, including law enforcement. Community awareness of the existence and effectiveness of naloxone is also a barrier to naloxone access. Bias and misinformation hinder efforts to expand the availability of naloxone, and also prevent many individuals from seeking medication-assisted treatment to definitively address one of the root causes of overdose, addiction.

MAY 11 2016

<p>CITY OF BALTIMORE</p> <p>STEPHANIE RAWLINGS-BLAKE, Mayor</p>		<p>HEALTH DEPARTMENT Leana S. Wen, M.D., M.Sc., FAAEM Commissioner of Health 1001 E. Fayette St. Baltimore, MD 21202 health.baltimorecity.gov Tel: 410-396-4398</p>
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May 3, 2016

TO: Members of the House Committee on Oversight and Government Reform

FROM: Dr. Leana Wen, Baltimore City Health Commissioner

RE: America's Heroin and Opioid Abuse Epidemic, Questions for the Record

1. Can you tell us about the trainings and outreach your office does with regard to the use and administration of naloxone?

Thank you for your interest in our efforts to combat the opioid epidemic. The first pillar of Baltimore's opioid overdose prevention campaign is expanding access to naloxone. Our naloxone education efforts are extensive. In 2015, we trained over 8,000 people to use this life saving drug: in jails, public housing, street corners and bus shelters. We are committed to training not only individuals who use drugs, but also their family and friends, police officers and other first responders, and anyone who wishes to learn how to save a life. Our approach to trainings and outreach is multi-faceted:

- Since 2003, Baltimore City has been training drug users on using naloxone through our Staying Alive Program. We were one of the first jurisdictions to require naloxone training as part of court-mandated time in Drug Treatment Court. We have trained federal, state, and city legislators so that they can not only save lives, but also serve as ambassadors and champions to their constituents.
- We use up-to-date epidemiological data to target our training to "hotspots," taking naloxone directly into the most at-risk communities and putting it in the hands of those most in need. We began hot-spotting in 2015, when we saw that 39 people died from overdose due to the opioid Fentanyl between January and March of 2015. Fentanyl is many times stronger than heroin, and individuals using heroin were not aware that it had been laced with Fentanyl. This data led us to target our messaging so that we could save the lives of those who were at immediate risk.
- As of October 1, 2015, I have the authority to write blanket prescriptions for naloxone for all 620,000 residents in Baltimore City under a "Standing Order" which was approved by the Maryland State Legislature. This is one of the single largest efforts in the country to achieve city-wide naloxone distribution. A Standing Order means that someone can receive a short training from a Health Department employee or volunteer (which can be done in less than five minutes) and immediately receive a prescription for naloxone, in my name, without having seen me personally as their doctor. In order to train even more

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people in the use of Naloxone, we have launched an online platform that now allows residents to get trained online and receive a prescription for Naloxone in just ten minutes. This online platform, the first-of-its-kind around the country and the world, is the next step to reducing barriers to naloxone. In Baltimore we believe that naloxone should be part of everyone's medicine cabinet and everyone's First Aid kit.

- Already, our naloxone outreach and trainings are changing the way our frontline officials approach addiction treatment, with a focus on assessment and action. In addition to training paramedics, we have also trained police officers. The initial trainings were met with resistance from the officers who were hesitant to apply medical interventions that some did not see as part of their job description. However, in the first month of carrying naloxone, four police officers used naloxone to save the lives of four citizens. This past fall, I attended a training where I asked the officers what they would look for if they were called to the scene for an overdose. In the past, I would have received answers about looking for drug paraphernalia and other evidence. This time, officers answered that their job was to find out what drugs the person might have taken, to call 911 and administer naloxone, because their duty is to save a life. By no means is naloxone training the panacea for repairing police and community relations. However, it is one step in the right direction as we make clear that addiction is a disease and overdose can be deadly. We are changing the conversation so that all of our partners can join in encouraging prevention, education, and treatment.
- We successfully advocated for Good Samaritan legislation, which expanded protections for those who assist in the event of an overdose, and malpractice protection for doctors who prescribe naloxone.
- Our state Medicaid program has agreed to set the co-pay for naloxone at \$1. While we still struggle with the pricing for naloxone, this has allowed us to provide prescriptions to patients and others at a greatly reduced cost. We have to get naloxone into the hands of everyone who can save a life – which we believe is each and every one of us.

2. Dr. Wen, how do we increase accessibility of naloxone?

Naloxone should be part of everyone's medicine cabinet. To increase accessibility of this life saving drug, we need to take a multi-faceted approach to both training and providing access to every person that wants naloxone.

- Because of the risk of addiction and overdose with opioids, it is crucial for us to require co-prescribing of naloxone for any individual taking opioids or at risk for opioid overdose. Hospitals keep naloxone on hand if patients receive too much intravenous morphine or fentanyl. Patients must also receive a prescription for naloxone if they are to be discharged with opioid medications that can result in overdose. Naloxone should also be prescribed to every individual in substance use disorder treatment.
- The federal government should remove barriers that prohibit easy access to naloxone by making it available as an over the counter medication that is covered by both private and public insurance. Naloxone is a safe, easily administered drug with no potential for

abuse. Major pharmacies across the country like CVS are already selling Naloxone without prescriptions in a number of states. Making naloxone available over the counter would significantly increase access to the drug.

- Congress can monitor and regulate the price of naloxone. Naloxone is part of the World Health Organization's (WHO) list of essential medications. Over the last two years, the price of naloxone has dramatically increased. The cost of naloxone skyrocketing means that we can only save a fraction of the lives we were able to before. This is particularly problematic for cities and counties that must purchase naloxone for use by paramedics, police officers, and other front-line workers. Naloxone should be affordable and directly available to local jurisdictions with the greatest need.

3. Please address the biggest impediments to achieving widely available and accessible naloxone for individuals who need it, such as cost or barriers to access.

While naloxone is being recognized as a key tool in the fight against the opioid epidemic, there are still significant barriers that we must address if we want Naloxone to be a part of every person's medicine cabinet. These barriers include:

- Cost. Over the last two years, the price of naloxone has dramatically increased. In Baltimore, the cost per dose of naloxone has tripled—meaning that we can only save one-third of the lives we could have saved. This is particularly problematic for cities and counties that must purchase naloxone for use by paramedics, police officers, and other front-line workers. Manufacturers have claimed that this price increase is related to increased demand. However, it is unclear why the cost of a generic medication that is available for much lower costs in other countries will be suddenly so expensive. These challenges are not unique to Baltimore, and Congress can help overcome this obstacle by calling for an investigation into the price increase, and monitoring and regulating the price of naloxone.
- Stigma. Some people have the misconception that providing naloxone will only encourage a drug user to continue using, by providing a safety net. This dangerous myth is not based on science but on stigma. Would we ever say to someone whose throat is closing from an allergic reaction that they shouldn't get epinephrine because it might encourage them to eat peanuts or shellfish? An Epi-Pen saves lives; so does naloxone, and it should be just as readily available. Our mantra is that we must save a life today in order for there to be a better tomorrow.

This is why we have been at the forefront of changing public perception of addiction so those in need are not ashamed to seek treatment. In Baltimore, we have launched a public education campaign "DontDie.org" to educate citizens that addiction is a chronic disease and to encourage individuals to seek treatment. This was launched with bus ads, billboard ads, a new website, and a targeted door-to-door outreach campaign in churches and with our neighborhood leaders. We have also launched a concerted effort to target prevention among our teens and youth entitled "BMore in Control." Many local jurisdictions, like Baltimore City, have launched public education campaigns. There is much more

education that must be done in order to encourage people with addiction to seek treatment and to disband stigmas that are leading many communities to avoid providing treatment altogether. Local jurisdictions are limited by funding constraints. Launching a national stigma-reduction and opioid-awareness campaign will provide the spotlight this critical issue requires. Such a campaign would be an important step in changing how our country looks at addiction, from a moral failing to a curable disease. With such a shift people start to view Naloxone in the same way that they view life-saving drugs like epinephrine.

- Treatment. We know that providing access to Naloxone and stopping overdose is only the first step in addressing addiction. If we do not increase access to quality treatment options we are merely treading water, waiting for the person who has overdosed to use drugs and overdose again. The evidence is clear: addiction treatment requires a combination of medication-assisted treatment, psychosocial support, and wrap-around services including supportive housing. All of these must be in place for individuals suffering from addiction to recover, and they must be available at the time the individual is seeking these services—the same as for any medical condition.

My full written testimony outlines the specific steps we have taken in Baltimore to increase access to on-demand treatment, however to truly address this issue we will need the help of the federal government. Most critical is the need for direct funding for jurisdictions with the highest need. While States have traditionally received block grants from the federal government, local jurisdictions are the closest to the ground in service delivery, and understand the needs of residents the best.

