

EXAMINING THE GROWING PROBLEMS OF PRESCRIPTION DRUG AND HEROIN ABUSE

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED THIRTEENTH CONGRESS

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EXAMINING THE GROWING PROBLEMS OF PRESCRIPTION DRUG AND HEROIN ABUSE

TUESDAY, APRIL 29, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, Hon. Michael Burgess (vice chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Blackburn, Gingrey, Scalise, Harper, Gardner, Griffith, Johnson, Long, Ellmers, DeGette, Braley, Lujan, Schakowsky, Castor, Welch, Yarmuth, Green and Waxman (ex officio).

Staff present: Carl Anderson, Counsel, Oversight; Karen Christian, Chief Counsel, Oversight; Brittany Havens, Legislative Clerk; Sean Hayes, Deputy Chief Counsel, Oversight and Investigations; Tom Wilbur, Digital Media Advisor; Phil Barnett, Democratic Staff Director; Brian Cohen, Democratic Staff Director, Oversight and Investigations, Senior Policy Advisor; Kiren Gopal, Democratic Counsel; Hannah Green, Democratic Staff Assistant; Anne Morris Reid, Democratic Senior Professional Staff Member; and Stephen Salsbury, Democratic Investigator.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Good morning. I now convene the hearing of the Subcommittee on Oversight and Investigations, entitled Examining the Growing Problems of Prescription Drug and Heroin Abuse.

Just a brief housekeeping detail for those of you who were expecting to see Dr. Murphy here in the chair, he was called away back to his district for a family issue, so you are stuck with me, as the saying goes, but we will get through this together.

On the issue of prescription drug and heroin abuse, these are separate and distinct problems, but unfortunately, they do share a common endpoint; addiction, abuse, overdose, and death. As we know, the abuse of prescription drugs, and illegal drugs such as heroin, have plagued our nation for decades, however, over the last several months, there have been increasing reports that prescription drug and heroin abuse in communities around the country continues to grow. Sadly, those reports indicate that overdose deaths as a result of prescription drug and heroin abuse are also on the rise. Families have lost sons and daughters, mothers and fathers to this addiction.

Data from the federal agencies charged with addressing drug abuse paint a startling picture of the severity of the public health crisis. Prescription drug abuse kills more than 16,000 people a year. From 2007 to 2012, heroin use rose by almost 80 percent in this country, and 3,000 people die each year from heroin overdoses. The United States Attorney General, Eric Holder, declared recently that heroin abuse constitutes “an urgent and growing public health crisis.”

Certainly, there is a law enforcement aspect to solving this problem, and stopping the bad actors who illegally distribute prescription drugs or traffic heroin, but the other part of the equation is treating the addiction, the addiction to prescription drugs and heroin, and preventing deaths. The answer to a burgeoning heroin epidemic, as the Administration has called it, is not to wage war on all opiates. To address a complex issue, the solution cannot be simple.

The purpose of today’s hearing is to examine the federal response, including the public health response, to prescription drug and heroin abuse. Our oversight has revealed that this is a complex problem. Those who abuse drugs also have, often, an underlying mental illness. Treating their addiction means that the underlying mental illness must be successfully diagnosed and treated. As the testimony of Mr. Botticelli states, the substance abuse is a progressive disease. Those who suffer from addiction often start at a young age with alcohol, maybe marijuana, move on to other drugs like opiates. In examining opiate abuse, we must also consider the factors that lead people to abuse, and what we are doing to address those factors.

Many Americans also suffer from chronic and debilitating pain. It is important to remember that the millions of individuals who safely use opiate narcotics under the guidance of their physicians, pain that we hope a loved one would never have to suffer is involved. As Dr. Volkow of NIH recognizes in her testimony, we need to recognize the special character of prescription drug abuse. On the one hand, we have a growing prescription drug and opiate addiction. On the other, we have a very real need for these drugs to treat chronic pain, treat acute pain, and alleviate suffering where it exists, especially in patients with chronic conditions who are suffering from illnesses like cancer. These drugs are safe when used as directed. It is their improper use that leads to abuse, overdose, and death.

Over recent years, we have heard a great deal about doctor shopping, about pill mills, and about the efforts of the prescription drug monitoring plans to address these problems. We need to ensure that doctors and pharmacists have the tools at their disposal to adequately fill their role with ensuring appropriate prescribing, but addicts also get these drugs through illegal channels, such as rogue Internet pharmacies, off the street, and obtaining them through family members who may have an outdated prescription. Although some question whether federal efforts to crackdown and prevent prescription drug abuse have contributed to the recent rise in heroin abuse, and whether this should have been anticipated, there is no question that both are on the rise, and as a consequence, we have a responsibility to recognize and solve that problem. While

most prescription drug abusers do not go on to abuse heroin, there is data from the White House Office of National Drug Control Policy, and the Substance Abuse and Mental Health Services Administration, that indicates over 80 percent of people who started using heroin in 2008 to 2010 had previously abused prescription drugs.

The Federal Government is devoting resources to drug control programs. Some would say significant resources; over \$25 billion annually, of which about \$10 billion goes towards drug abuse prevention and treatment programs across 19 different federal agencies. We will ask today's witnesses to identify the specific policies, the programs, the initiatives that have been the most effective in combatting prescription drug and heroin abuse, and which have not. With 19 agencies having a hand in over 70 drug control programs, we need to know what is working and what is not. What can we do better?

Is oversight by the federal agencies also an important issue as significant funding is block granted to the states for their treatment programs?

Testifying before us today are representatives of five of the agencies with lead roles in addressing opiate abuse. Mr. Michael Botticelli, the Acting Director of the White House Office of National Drug Control Policy; Mr. Daniel Sosin of the Centers for Disease Control and Prevention; Dr. Nora Volkow of the National Institute on Drug Abuse; Dr. Westley Clark of the Substance Abuse and Mental Health Services Administration; and Mr. Joseph Rannazzisi of the Drug Enforcement Agency.

This is a prestigious panel, and we are very grateful for your presence here today. We certainly look forward to your testimony. [The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Good morning. I now convene this hearing of the Subcommittee on Oversight and Investigations entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

These are separate and distinct problems with a common end point; abuse, overdose, and death.

As we know, the abuse of prescription drugs and illegal drugs such as heroin have plagued our nation for decades. However, over the last several months, there have been increasing reports that prescription drug and heroin abuse in communities around the country continue to grow. Sadly, those reports indicate that overdose deaths as a result of prescription drug and heroin abuse are also on the rise. Families have lost sons and daughters and fathers and mothers to this addiction.

Data from the federal agencies charged with addressing drug abuse paint a startling picture of the severity of this public health crisis. Prescription drug abuse kills more than 16,000 people a year. From 2007 to 2012, heroin use rose by 79 percent in this country and 3,000 people die each year from heroin overdoses.

U.S. Attorney General Eric H. Holder declared recently that heroin abuse constitutes "an urgent and growing public health crisis." Certainly, there is a law enforcement aspect to solving this problem and stopping the bad actors who illegally distribute prescription drugs or traffic heroin. But the other part of the equation is treating addiction to prescription drugs and heroin—and preventing deaths. The answer to a burgeoning heroin epidemic, as the administration has called it, is not to wage a war on all opioids. To address a complex issue, the solution will not be simple.

The purpose of today's hearing is to examine the federal response, including the public health response, to prescription drug and heroin abuse. Our oversight has revealed that this is a complex problem. Those who abuse drugs often have an underlying mental illness. Treating their addiction means that the underlying mental illness must be successfully diagnosed and treated.

As the testimony of Mr. Botticelli, states, substance abuse is a “progressive disease.” Those who suffer from addiction often start at a young age, with alcohol and marijuana, and then move to other drugs like opioids. In examining opioid abuse, we must also consider the factors that lead people to abuse—and what we are doing to address them.

Many Americans also suffer from chronic and debilitating pain. It is important to remember the millions of individuals who safely use opioids under the guidance of their physicians, pain that we all hope us or a loved one would never suffer.

As Dr. Volkow of NIH recognizes in her testimony, we need to recognize the “special character” of prescription drug abuse. On one hand, we have growing prescription drug and opiate addiction; on the other, we have the very real need for these drugs to treat chronic pain and alleviate suffering, especially in patients with conditions like cancer. These drugs are safe when used as directed—it is their improper use that leads to abuse and overdose.

Over recent years, we have heard a great deal about doctor shopping, pill mills, and the efforts of Prescription Drug Monitoring Plans to address these problems. We need to ensure that doctors and pharmacists have the tools at their disposal to adequately fill their role in ensuring appropriate prescribing. But addicts also get these drugs through illegal channels, such as rogue Internet pharmacies, off the street, and obtaining them through family and friends. Although some question whether federal efforts to crackdown or prevent prescription drug abuse have contributed to the recent rise in heroin abuse, and whether this should have been anticipated, there is no question that both are on the rise and we have a responsibility to examine this issue fully.

While most prescription drug abusers do not go on to abuse heroin, there is data from the White House Office of National Drug Control Policy (ONDCP) and the Substance Abuse and Mental Health Services Administration (SAMHSA) that indicates 81 percent of people who started using heroin in 2008 to 2010 had previously abused prescription drugs.

The federal government is devoting significant resources to drug control programs—over \$25 billion annually, of which about \$10 billion goes toward drug abuse prevention and treatment programs across 19 federal agencies. We will ask today’s witnesses to identify the specific policies, programs, and initiatives have been most effective in combatting prescription drug and heroin abuse—and which have not. With 19 agencies having a hand in over 70 drug control programs—is this working? What can we do better? Oversight by the federal agencies is also an important issue, as significant funding is block granted to states for treatment programs.

Testifying before us today are representatives of the five agencies with lead roles in addressing opiate abuse: Mr. Michael Botticelli, Acting Director of the White House Office of National Drug Control Policy; Dr. Daniel Sosin of the Centers for Disease Control and Prevention; Dr. Nora Volkow of the National Institute on Drug Abuse; Dr. H. Westley Clark of the Substance Abuse and Mental Health Services Administration (SAMHSA); and Mr. Joseph Rannazzisi of the Drug Enforcement Agency. This is a prestigious panel, and I thank you for being here today. We look forward to your testimony.

Mr. BURGESS. I would now like to recognize for 5 minutes for the purposes of an opening statement the ranking member, Ms. DeGette from Colorado.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Burgess, and we are glad to have you presiding today.

Prescription drug and heroin abuse is a public health crisis and it is growing every day. In many communities across the country, we are seeing an epidemic of opioid overdose deaths. I am interested in learning from the panel about what more we can do to prevent the abuse of these drugs, and also to save lives.

The non-medical use of opioids has escalated in recent years. In 2011, hospitals tallied nearly ½ million emergency room visits related to these medications. The number of these visits nearly tri-

pled over a 7-year period. The link between prescription opioid use and heroin abuse is also deeply troubling, and as the Chairman noted, only a small percentage of people who use pain relievers go on to abuse heroin, but the opposite is not true. The vast majority of those who abuse heroin previously abused prescription drugs.

While far more people continue to abuse prescription drugs, the number of individuals who reported heroin nearly doubled between 2007 and 2012. There is also evidence to suggest that people who abuse prescription drugs move on to heroin as pain relievers become less available or too costly. A 2012 study in the *New England Journal of Medicine* found heroin use rose dramatically after the introduction of an abuse deterrent form of Oxycontin.

The use of drugs that ultimately lead to addiction and abuse often begins innocently. The majority of people who illegally use a prescription drug get that drug from a friend or a family member often, and sometimes the drug has been stolen, but at other times, a parent may even give the drug to a child, unaware of the risks. We must educate patients on the dangers of abuse of these drugs, as well as the need to properly store and dispose of them. If we can reduce inappropriate access to drugs, we can also reduce the incidence of their abuse. We must change the public perception of the prescription opioids. We face the inaccurate perception that just because a drug is legal, it is somehow less harmless, less addictive and less risky. Providers should also be better educated on the use and potential abuse of these drugs, so they can be more effective in recognizing problems of abuse, and, in turn, more effective in educating and treating the patients. Studies show that even brief interventions by healthcare providers can be successful in reducing or eliminating substance abuse by patients who began abusing prescription opioids but have not yet become addicted to them.

When prescribed appropriately, these medicines provide much-needed relief, and many patients have had their suffering reduced by opioid pain killers. However, a patient with an acute short-term pain may be able to find relief from a less addictive pain killer. Prescription drug abuse is a public health problem, and it is not just a law enforcement problem. Reducing this abuse will require a multifaceted approach, and partnership among federal, state and local agencies. Every state should effectively use prescription drug monitoring programs. These databases help states identify and address drug diversion, so they should be as robust and effective as possible. States should be able to share information with due regard for privacy expectations. Information should be added to the databases regularly, including by encouraging prescribers and pharmacists to use the databases. When used, they can help doctors and public health authorities prevent and respond to the potential devastating effects of prescription drug abuse.

I am interested in learning from our witnesses today about the effects of this medication assisted treatment that we are hearing about, and also whether we have the resources to meet the demand for these treatment programs. I am also interested in learning about the state of research into new medications with lower abuse potential, and how we can expand access to overdose interventions like naloxone.

Prescription opioid and heroin abuse, as you said, Mr. Chairman, is a serious public health threat. I look forward to hearing from all of the witnesses, and to working with all of my colleagues on both sides of the aisle to ensure that Congress plays a vital role in protecting families from the growing danger of these drugs.

And I yield back the balance of my time.

Mr. BURGESS. The gentlelady yields back.

The Chair now recognizes the gentlelady from Tennessee 5 minutes for purposes of an opening statement please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. And I know we are all cheering for Congressman Murphy and his daughter, as they are about to welcome that new baby into their family. What an exciting, exciting time. I can only tell you the joys of being a grandparent are marvelous. It is a big part of my day.

Well, I thank you for the attention that we are putting on this issue. Prescription drug and heroin abuse are epidemic in our country, and I think you can tell by what is being said in this room this morning; it is an issue that our committee is concerned about, and I applaud the efforts of the committee to take a very thoughtful approach and process as how we move forward. It is clear that we need to understand the factors that have contributed to the rise in prescription drug and heroin abuse. We need to understand which prevention, treatment, and law enforcement efforts are the most effective in reducing the abuse of prescription drugs and heroin.

On the other side of this issue are the millions of Americans who have legitimate need for prescription medication for the control of pain, reduction of anxiety, and the overall improvement of their lives. These medications must be available to them. H.R.4069, the Ensuring Patient Access and Effective Drug Enforcement Act of 2013, that is a Bill by Representative Marino and I, it will establish a combatting prescription drug abuse working group. This group will include members from the DEA, FDA, ONDCP, State Attorney Generals, patient groups, pharmacists, industry, healthcare providers and others. Within one year of enactment, the working group shall provide, they must do this, provide recommendations to Congress on initiatives to reduce prescription drug diversion and abuse. We think this is the right approach.

We welcome each of our witnesses. We look forward to hearing your testimony and to the discussion.

And with that, Mr. Chairman, I yield back my time, or to anyone who is seeking time.

Mr. BURGESS. Seeing no one seeking time, the gentlelady yields back.

The Chair now recognizes the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement please.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman, for holding this important hearing today.

We are here to discuss the epidemic of opioid abuse. The numbers are stark. Each year, approximately 17,000 people die from prescription opioid overdoses, and 3,000 die from heroin overdoses.

For far too long, prescription opiate pain relievers were prescribed too easily, without enough attention paid to the potential risks, and a large number of people became addicted. Some of those who became addicted to prescription opiates eventually moved on to heroin because that is a cheaper alternative, offering the same high.

Fortunately, there are steps that we can take to fight this problem. I appreciate our witnesses being here today to discuss their efforts to educate the public and providers about the dangers of abusing these drugs. We will also hear how we can change prescribing practices, monitor the use of opiates, effectively treat those who are addicted, and investigate and prosecute those involved in diverting and trafficking these drugs.

Our five witnesses, Mr. Rannazzisi from the DEA; Mr. Botticelli from ONDCP; Dr. Sosin from CDC; Dr. Volkow from NIH; and Dr. Clark from SAMHSA, represent an all-star panel of experts, and we are delighted that you are here.

There are many reasons to be thankful for the launch of the Affordable Care Act. Let me repeat that. There are many reasons to be thankful for the launch of the Affordable Care Act. One that is often overlooked is the help the law offers to individuals addicted to prescription opiates and heroin. The lack of insurance and the high cost of treatment could present an insurmountable barrier to receiving the help they need. The Affordable Care Act addresses this problem by expanding insurance coverage, and requiring all policies to cover the costs of substance abuse services. This will mean that millions of individuals with addiction disorders will have access to the tools they need to help break their addictions. We need to build upon this hopeful step, and increase our efforts to combat this epidemic.

Mr. Chairman, at this point, I wish to yield the balance of my time to Mr. Welch from Vermont.

Mr. WELCH. I thank the member from California for yielding, and I thank the committee for having this hearing, but I want to give some credit to Governor Peter Shumlin of Vermont. He did something extremely unusual. He dedicated his entire State of the State Address to this single problem, and that was a bold decision for two reasons. One, most of the time, the State of the State is a laundry list of objectives and hopes. This got very specific about one topic. But second, in taking this on, he made public what people knew was real, but didn't want to acknowledge. And what we have seen in Vermont as a result of that was that we are facing what is a terrible problem that creates enormous anxiety for the folks that are in the grip of this addiction, but their families. And before we began talking about this, it was restricted to our law enforcement folks and our mental health folks who were dealing with

these isolated individuals as though they were the only ones in the world that faced this incredible challenge. And what Governor Shumlin did is he brought it out in the open, and that was in large part because in his travels around, and governors do get around, he was talking to our law enforcement people, like Chief Taylor in Saint Albans, like Chief Baker in Rutland, and they were dealing on the street with kids that they knew and with adults that they knew who had jobs, but had this horrible addiction, and they had to deal with it. And what our police kept saying, who have frontline responsibilities, you cannot arrest your way out of this. And there is a distinction that they make between the dealers who came from out of state and started inflicting our kids and others with this opiate addiction, throw the book at them, forget about them, but a lot of the kids who are in the grip, they are our kids, they have a future, they have a challenge. And what has happened in our communities with the leadership of our police and our mental health people and our mayors, like Liz Gamache in Saint Albans, and like Chris Louras in Rutland, is that by bringing this out into the open, it has helped us talk about this in concrete ways so that there is not only the treatment program, the Hub and Spoke Program, which I hope you might talk about, but it also is allowing parents and the community to see this as something where we all have to be engaged to provide some basis of support for these kids and adults who want not to be in the grip of this horrible opiate addiction.

So I thank you, the committee, for having this hearing, and making it a collective effort to try to bring our resources together to help people get whole. Thank you.

Mr. BURGESS. The gentleman yields back.

I would now like to introduce the witnesses on the panel for today's hearing. Mr. Michael Botticelli is the Acting Director of the Office of National Drug Control Policy in the Executive Office of the President; Dr. Daniel Sosin, who is the Acting Director of the National Center for Injury Prevention and Control at the Centers for Disease Prevention; Dr. Nora Volkow is the Director of the National Institute on Drug Abuse at the National Institute of Health; Dr. Westley Clark is the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration; and Mr. Joseph Rannazzisi is the Deputy Assistant Administrator in the Office of Diversion Control within the Drug Enforcement Agency at the United States Department of Justice.

I will now swear in the witnesses. As you are aware, this committee is holding an investigative hearing, and when doing so, has had the practice of taking testimony under oath. Do any of you have any objections to testifying under oath this morning? Seeing a negative response from the witnesses, the Chair then advises that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of our witnesses desire to be advised by counsel during testimony today? And negative response was received from the panel of witnesses. In that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. BURGESS. Let it be noted that the witnesses answered affirmatively. You are now under oath and subject to the penalties set forth in Title XVIII, Section 1001 of the United States Code.

We would now welcome a 5-minute summary of your written statements. We will start with Mr. Botticelli and move down the table.

STATEMENTS OF MICHAEL BOTTICELLI, ACTING DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT; DANIEL M. SOSIN, ACTING DIRECTOR, NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL, CENTERS FOR DISEASE CONTROL AND PREVENTION; NORA D. VOLKOW, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH; H. WESTLEY CLARK, DIRECTOR, CENTER FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION; AND JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT AGENCY, U.S. DEPARTMENT OF JUSTICE

STATEMENT OF MICHAEL BOTTICELLI

Mr. BOTTICELLI. Chairman Burgess, Ranking Member DeGette, and members of the subcommittee, I want to thank you for the opportunity to appear today to discuss the tremendous public health and safety issues surrounding the diversion and abuse of opioid drugs, including many prescription pain killers and heroin, in the United States.

I know that, given recent media attention to overdose deaths, there is a heightened public interest in the threat of opioid drug use, but this is something many communities have been dealing with for a very long time, and it is a matter of great concern for this Administration.

According to the Centers for Disease Control and Prevention, drug overdose deaths, primarily driven by prescription opioids, now surpass homicides and traffic crashes in the number of injury deaths in America. In 2010, the latest year for which nationwide data are available, approximately 100 Americans died on average from overdose every day. Prescription analgesics were involved in almost 17,000 of those deaths that year, and heroin was involved in about 3,000, and more recent data posted by several states indicates that deaths from heroin continued to increase.

While heroin use remains relatively low in the United States as compared to other drugs, there has been a troubling increase in the number of people using heroin in recent years, from 373,000 past-year users in 2007 to 669,000 in 2012.

It is clear that we cannot arrest our way out of the drug problem. Science has shown us that drug addiction is a disease of the brain, a disease that can be prevented, treated, and from which one can recover. We know that substance use disorders, including those driven by opioids, are a progressive disease. Many people who develop a substance use disorder begin using at a young age, and often start with alcohol, tobacco and/or marijuana. We know that as an individual's abuse of prescription opioids becomes more fre-

quent or chronic, that person is more inclined to purchase the drugs from dealers or obtain prescriptions from multiple doctors, rather than simply getting it from a friend or relative for free or without asking. This progression of an opioid use disorder may lead an individual to pursue a lower cost alternative such as heroin.

With these circumstances in mind, we released the Obama Administration's inaugural National Drug Control Strategy in 2010, in which we set out a wide array of actions to expand public health interventions and criminal justice reforms to reduce drug use and its consequences in the United States. That strategy noted opioid overdoses as a growing national crisis, and set specific goals for reducing drug use, including heroin.

Three years ago, the Administration released the first comprehensive action plan to combat the prescription drug abuse epidemic. The Prescription Drug Abuse Prevention Plan strikes a balance between the need to prevent diversion and abuse, and the need to ensure legitimate access to prescription pain medications. The Plan expands on the National Drug Control Strategy, and brings together a variety of Federal, state, local, and tribal partners to support: 1) the expansion of state-based prescription drug monitoring programs; 2) more convenient and environmentally responsible disposal methods for removing expired or unneeded medication from the home; 3) education for patients and training of healthcare providers in the proper prescribing practices and treatment of substance use disorders; and 4) reducing the prevalence of pill mills and doctor shopping through enforcement efforts. This work has been paralleled by efforts to address heroin trafficking and use.

The Administration is also focusing on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions, increasing access to naloxone, an emergency overdose reversal medication, and working with states to promote Good Samaritan laws and other measures that can help save lives. Because police are often the first on scene of an overdose, the Administration strongly encourages local law enforcement agencies to train and equip their personnel with this lifesaving drug.

It is not enough, however, to save a life from an overdose. A smart public health approach requires us to catch the signs and symptoms of substance use early, before it develops into a chronic disorder. We have been encouraging the use of screening and brief intervention to catch risky substance use before it becomes an addiction, and since only 11 percent of those who needed substance use disorder treatment in 2012 actually received it, the Administration is dramatically expanding access to treatment. The Affordable Care Act and Federal parity law are extending access to substance use disorders and mental health benefits for an estimated 62 million Americans, helping to close the treatment gap and integrate substance use treatment into mainstream healthcare. This represents the largest expansion of treatment access in a generation and can help guide millions into successful recovery.

The standard of care for treating substance use disorders driven by heroin or prescription opioids involves the use of medication-assisted treatment, an approach to treating opioid addiction that uti-

lizes behavioral therapy along with FDA-approved medications, either methadone, buprenorphine, or naltrexone. Medication-assisted treatment has already helped thousands of people in long-term recovery, and I applaud the recent commentary by my HHS colleagues in the *New England Journal of Medicine* to expand the use of medications to treat opioid addiction and reduce overdose deaths.

There are some signs that our national efforts are working. The number of Americans 12 and older initiating the non-medical use of prescription opioids in the past year has decreased significantly since 2009. Additionally, according to the latest *Monitoring the Future* survey, the rate of past year use of Oxycontin or Vicodin among high school seniors in 2013 is at its lowest since 2002. And recent studies have shown that implementation of robust naloxone distribution programs and the expansion of medication-assisted treatment can reduce mortality and also be cost-effective.

However, continuing challenges with prescription opioids and the re-emergence of heroin use underscore the need for leadership at all levels of government. We will therefore continue to work with our Federal, state, tribal and community partners to continue to reduce and prevent the health and safety consequences of prescription opioids and heroin. Thank you for the opportunity to address the committee today.

[The prepared statement of Mr. Botticelli follows:]



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

**“Examining the Growing Problems of
Prescription Drug and Heroin Abuse”**

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

Tuesday, April 29, 2014
10:00 a.m.
2322 Rayburn House Office Building

Written Statement
of
Michael P. Botticelli
Acting Director
Office of National Drug Control Policy

Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for this opportunity to address the public health and safety issues surrounding the diversion and abuse of opioid drugs – including prescription painkillers and heroin - in the United States.

As you know, the Office of National Drug Control Policy (ONDCP) was established in 1988 by Congress with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, our office establishes policies, priorities, and objectives for the Nation's drug control programs. 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 moves beyond an outdated "war on drugs" approach and is guided by what experience, compassion, and science demonstrate about the true nature of drug use in America.

The considerable public health and safety consequences of opioid misuse and abuse underscore the need for action. Since the Administration's inaugural *2010 National Drug Control Strategy*, we have deployed a comprehensive and evidence-based strategy to address overdose deaths and opioid abuse. The Administration has significantly bolstered support for medication-assisted opioid treatment and overdose prevention, coordinated a government-wide response to the prescription drug abuse epidemic, and pursued action against criminal organizations trafficking in opioid drugs.

Trends and Consequences of Opioid Misuse and Abuse

The abuse of opioids – a category of drugs including heroin and prescription pain relievers like oxycodone and hydrocodone – is having a considerable impact on public health and safety in communities across the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 100 Americans on average died from overdose every day in 2010. Of the more than 38,300 overdose deaths in 2010, opioid pain relievers were involved in over 16,600, while heroin was involved in approximately 3,000. (See Figure.) Overall, drug overdose deaths now outnumber deaths from gunshot wounds (31,000) or motor vehicle (35,000) crashes in the United States.¹

As this Subcommittee knows, the diversion and abuse of prescription opioid medications have been of serious concern at the national, state, and local levels. Increases in substance abuse

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 2000-2010 on CDC WONDER Online Database. Extracted May 2013.

treatment admissions,² emergency department visits,³ and, most disturbingly, overdose deaths⁴ attributable to prescription drug abuse place enormous burdens upon communities across the country.

In 2012, approximately 4.9 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.⁵ This makes prescription pain reliever misuse more common than use of any type of illicit drug in the United States except for marijuana. By comparison, approximately 335,000 Americans reported past month use of heroin.⁶ Heroin use remains relatively low in the United States when compared to other drugs; however, there has been a troubling increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 669,000 in 2012.⁷ This trend comports with other indicators, including preliminary reporting from the National Institute on Drug Abuse’s Community Epidemiology Work Group, which finds that several U.S. cities, including Atlanta, Baltimore, Boston, Chicago, Cincinnati, Denver, Miami, Minneapolis, San Diego, Seattle, and St. Louis, indicate increases in heroin use. In addition, heroin remains at relatively stable but high levels in Detroit, New York City, and Philadelphia.⁸ The Drug Enforcement Administration (DEA) also reports an over 300 percent increase of heroin seizures at the Southwest border from 2008 to 2013.⁹

The use of these opioids translates into very real health consequences. In 2012 alone, approximately 2.1 million Americans met the diagnostic criteria for abuse or dependence on prescription pain relievers, while heroin accounted for approximately 467,000 people with past year abuse or dependence. Both of these figures represent significant increases from just a decade earlier.¹⁰

² Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) 2001-2011, National Admissions to Substance Abuse Treatment Services*. U.S. Department of Health and Human Services. [2013]. Extracted April 2013.

³ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

⁴ CDC, National Center for Health Statistics. Underlying Cause of Death 2000-2010 on CDC WONDER Online Database. Extracted October 2012.

⁵ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DETABS/NSDUH-DETABSsect1peTabs1to46-2012.htm#Tab1.1A>

⁶ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DETABS/NSDUH-DETABSsect1peTabs1to46-2012.htm#Tab1.1A>

⁷ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DETABS/NSDUH-DETABSsect7peTabs1to45-2012.htm#Tab7.2A>

⁸ National Institute on Drug Abuse. Highlights and Summaries from January 2014 Reports. Available: <http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cwg/highlights-summaries-january-2014-reports>

⁹ National Seizure System, El Paso Intelligence Center, extracted January 25, 2014.

¹⁰ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available:

Beyond the many lives taken by overdoses involving these medications, prescription opioids are also associated with significant consequences to our health care system. In 2011 alone, 1.2 million emergency department (ED) visits involved the non-medical use of all prescription drugs. Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class involved in these medical emergencies, accounting for approximately 488,000 visits alone. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just 7 years earlier in 2004 (173,000).¹¹ Among specific opioid drugs in 2011, oxycodone accounted for the largest share (31 percent) of ED visits; there were 100,000 more visits involving oxycodone in 2011 than in 2004, an increase of 263 percent.¹² While ED admissions involving heroin have remained relatively flat over the past several years, the drug was still involved in nearly 260,000 visits in 2011.¹³

Similar trends are reflected in the country's substance use disorder treatment system. Data show a nearly five-fold increase in treatment admissions for individuals primarily abusing prescription pain relievers, from 36,000 in 2001 to nearly 181,000 in 2011. Heroin treatment admissions remained flat over the same time period, but still account for 278,000 admissions in the United States.¹⁴

There has been considerable discussion around potential connections between the non-medical use of prescription opioids and heroin use. There is evidence to suggest that some users, specifically those with chronic opioid addictions, will substitute heroin for prescription opioids, since heroin is often cheaper than prescription drugs. While research into the potential nexus between these two types of opioids remains sparse, a recent report from the Substance Abuse and Mental Health Services Administration (SAMHSA) found that four out of five recent heroin initiates had previously used prescription pain relievers non-medically. However, only a very small proportion (3.6%) of those who had started using prescription drugs non-medically initiated heroin use in the following five-year period.¹⁵ This suggests that while most new heroin users have previously used prescription opioids non-medically, a very small portion of all non-medical prescription drug users transitions to heroin.

http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabsIto45-2012.htm#Tab7_40A

¹¹ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

¹² Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

¹³ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

¹⁴ Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment Admissions by Primary Substance of Abuse, According to Sex, Age Group, Race, and Ethnicity, United States [2001 through 2011 tables]*. U.S. Department of Health and Human Services. [2013]. Extracted April 2013.

¹⁵ Substance Abuse and Mental Health Services Administration. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Department of Health and Human Services. [August 2013]. Available: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

We also know that substance use disorders, including those driven by opioids, are a progressive disease. Most people who develop a substance use disorder begin using at a young age and often start with alcohol, tobacco, and/or marijuana. This is important when examining the progression of opioid use. We know from survey data that as an individual's abuse of prescription opioids becomes more frequent or chronic, that person is more inclined to purchase the drugs from dealers/the internet/prescriptions from multiple doctors, rather than simply getting them from a friend or relative for free/without asking.¹⁶ This progression of an opioid use disorder may lead an individual to pursue lower cost alternatives, such as heroin.

The Administration's Response

Since 2009, the Obama Administration has deployed a comprehensive and evidence-based strategy to address the threat posed by opioid drugs. Within 30 days of his confirmation, then-Director of National Drug Policy Kerlikowske declared combatting prescription drug abuse a top drug control priority for the Administration. Since then, the Administration has coordinated a Government-wide response to the prescription drug abuse epidemic, significantly bolstered support for medication-assisted opioid treatment and overdose prevention, and pursued action against criminal organizations trafficking in opioid drugs. 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 the abuse of prescription opioids and heroin.¹⁷

As I described earlier, prescription drugs represent the bulk of opioid abuse in America, and our response to this public health emergency focused not only on preventing the diversion and abuse of prescription drugs, but also decreasing the number of Americans dying from opioid overdose every day. In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan*,¹⁸ which created a national framework for reducing prescription drug diversion and abuse. This *Plan* built upon the goal identified in the *National Drug Control Strategy* to reduce drug-induced deaths by 15 percent by 2015 and augmented that goal with a distinct goal to reduce unintentional overdose deaths related to opioids by 15 percent within 5 years. 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 medications from the home, and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

The Administration has made considerable progress in all four areas of the *Plan*, including expanding available continuing education for prescribers. Managing patients' pain is a crucial area of clinical practice, but unfortunately, research indicates that health care practitioners receive little training on pain management, safe opioid prescribing, or recognizing and treating

¹⁶ Unpublished estimates from Substance Abuse and Mental Health Services Administration, *National Survey on Drug Use and Health*. 2009-2012, March 2014.

¹⁷ 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>

¹⁸ 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

substance use disorders.^{19,20} Several states, including Iowa,²¹ Kentucky,²² Massachusetts,²³ Ohio,²⁴ Tennessee,²⁵ and Utah,²⁶ have passed legislation mandating education for prescribers, and we strongly encourage other states to explore this as an option. At the Federal level, the *Plan* calls for amending Federal law to require practitioners (such as physicians, dentists, and others authorized to prescribe), who request DEA registration to prescribe controlled substances, to be trained on responsible opioid prescribing practices as a precondition of such registration. Currently, Department of Health and Human Services (HHS) is implementing education requirements for its agency health care personnel, including professionals serving tribal communities through the Indian Health Service (IHS), those working with underserved populations through the Health Resources and Services Administration, and personnel attending to biomedical research trial participants at the Clinical Center of the National Institutes of Health (NIH). Similar efforts are underway at the Bureau of Prisons, and education efforts are being planned at the Department of Defense (DOD) and the Department of Veterans Affairs (VA).

The Administration has also made free and low-cost training options available for prescribers and dispensers of opioid medications. SAMHSA provides such training. In addition, ONDCP worked with NIH's National Institute on Drug Abuse (NIDA) to develop two free, online training tools on safe prescribing for pain and on managing pain patients who abuse prescription opioids. Since their launch in late 2012, thousands of doctors, nurses, and pharmacists have completed these training modules, which are eligible for continuing medical education and continuing education credit. The Food and Drug Administration (FDA) now requires manufacturers of extended-release and long-acting (ER/LA) opioid pain relievers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy for these drugs. Through these innovative training programs, FDA expects to train at least 60 percent of the approximately 320,000 prescribers of these medications within the first four years of the program.²⁷

The FDA has also taken a number of steps to help safeguard access to opioid pain relievers while reducing risks of non-medical use and overdose. In September 2013, ONDCP

¹⁹ Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

²⁰ U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: <http://www.gao.gov/assets/590/587301.pdf>

²¹ Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available: http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

²² Kentucky Board of Medical Licensure. "House Bill 1." Commonwealth of Kentucky. [2012]. Available: <http://khtml.kv.gov/hb1/Pages/default.aspx>

²³ Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available:

<http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html>

²⁴ General Assembly of the State of Ohio. "129th General Assembly – Amended Substitute Senate Bill Number 83." [2012]. Available: http://www.legislature.state.oh.us/bills.cfm?ID=129_SB_83

²⁵ State of Tennessee. "Public Chapter No. 430 – Senate Bill 676." [April 18, 2013]. Available: <http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>

²⁶ Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act*, 58-37-6.5. State of Utah. [May 2012]. Available: <http://www.dopl.utah.gov/laws/58-37.pdf#page=24>

²⁷ Food and Drug Administration. "Questions and Answers: FDA approves a Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics." Department of Health and Human Services. [updated March 2013]. Available: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm#Q8>

joined the FDA to announce significant new measures to enhance the safe and appropriate use of ER/LA opioid analgesics.²⁸ FDA required class-wide labeling changes for these medications, including modifications to the products' indication for severe pain, warnings around use during pregnancy, as well as post-market research requirements. FDA also announced that manufacturers of ER/LA opioids must conduct further studies and clinical trials to better assess risks of misuse, addiction, overdose, and death. In April 2013, FDA approved updated labeling for reformulated OxyContin that describes the medication's abuse-deterrent properties, which are expected to make abuse via injection difficult and to reduce abuse via the intranasal route.²⁹ And in December 2013, after an extensive review of scientific literature and hundreds of public comments and several public meetings, FDA announced its recommendation that the DEA should reschedule hydrocodone combination products into Schedule II of the Controlled Substances Act, which requires more stringent standards for storage, record keeping, and prescribing. On February 27th, DEA issued a Proposed Notice of Public Rulemaking to begin the process of this rescheduling.

The Administration is also educating the general public around opioid abuse. The Drug-Free Communities (DFC) Support Program currently funds 643 community coalitions to work with local youth, parent, business, religious, civic, and other groups to help prevent youth substance use. Grants awarded through the DFC program are intended to support established community-based coalitions capable of effecting community-level change. All DFC-funded grantees are required to collect and report data on past 30-day use; perception of risk or harm of use; perception of parental disapproval of use; and perception of peer disapproval of use for four substances, including prescription drugs.

The second pillar of the Administration's *Plan* focuses on improving the operations and functionality of state-administered Prescription Drug Monitoring Programs (PDMPs) across the country. PDMP data can help prescribers and pharmacists identify patients who may be at-risk for substance use disorders, overdose, or other significant health consequences of misusing prescription opioids. State regulatory and law enforcement agencies may also use this information to identify and prevent unsafe prescribing, doctor-shopping (seeing multiple doctors to obtain prescriptions), and other methods of illegally diverting controlled substances. Aggregate data from PDMPs can also be used to track the impact of policy changes on prescribing rates. The Prescription Behavior Surveillance System, funded by CDC and FDA, is developing this surveillance capacity for PDMPs. Research also shows that PDMPs may have a role in reducing the rates of prescribing for opioid analgesics and that states whose PDMPs were administered by a state health department, rather than another government agency such as the bureau of narcotics or board of pharmacy, showed especially positive results.³⁰ In 2006, only 20 states had PDMPs. Today, 49 have laws authorizing PDMPs, and 48 states have operational

²⁸ Food and Drug Administration. "ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements – Letter to ER/LA opioid application holders." Department of Health and Human Services. [September 2013]. Available: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>

²⁹ "Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20–553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness." Federal Register 78:75 (April 18, 2013) p. 23273. Available: <http://www.gpo.gov/fdsys/pkg/FR-2013-04-18/pdf/2013-09092.pdf>

³⁰ 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.

programs. Building upon this progress, the HHS Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA are working with state governments and private sector technology experts to integrate PDMPs with health information technology (health IT) systems such as electronic health records. Health IT integration will enable authorized healthcare providers to access PDMP data quickly and easily at the point of care to support more informed clinical decision-making about prescribing or dispensing prescription opioids. To date, SAMHSA has provided funding to 16 states, and ONC has conducted 13 pilots focusing on integration with health IT systems. Integration with health IT systems also requires maintaining the privacy of the public health information in the PDMP as it transits within systems, since PDMP data in most states are held to the same privacy standard as all other health care information.

The Bureau of Justice Assistance (BJA) of the Department of Justice (DOJ) is also supporting expanded interstate sharing of PDMP data. PDMPs in 20 states can share data with other states' systems, and many PDMP administrators are working to better integrate these systems into other health IT programs. In February 2013, VA issued an Interim Final Rule authorizing VA physicians to access state PDMPs in accordance with state laws and to develop mechanisms to begin sharing VA prescribing data with state PDMPs. The interim rule became final on March 14, 2014.³¹ IHS clinics are now sharing data with state PDMPs in many states, and IHS is in the process of negotiating data-sharing with more states.³² As these systems continue to mature, PDMPs can enable health care providers and law enforcement agencies reduce and prevent the diversion and abuse of prescription opioids.

The third pillar of our *Plan* focuses on safely removing millions of pounds of expired and unwanted medications from circulation. Research shows that approximately 70 percent of recent initiates and occasional users misusing prescription pain relievers in the past year report getting them from a friend or relative the last time they abused them.³³ Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner.

Since September 2010, DEA has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold seven National Take-Back Days. Through these events, DEA has collected and safely disposed of more than 3.4 million pounds of unneeded or expired medications.³⁴ As part of the Secure and Responsible Drug Disposal Act of 2010, DEA has published proposed regulations that, once finalized, will expand the safe and effective disposal of prescription drugs nationwide. ONDCP will work with Federal, state, local, and tribal stakeholders to identify ways to establish disposal

³¹ Disclosures to Participate in State Prescription Drug Monitoring Programs, 78 Fed. Reg. 9589 (Feb. 11, 2013); 79 Fed. Reg. 14400 (Mar. 14, 2014).

³² Cynthia Gunderson, Prescription Drug Monitoring Programs & Indian Health Service, Barriers, Participation, and Future Initiatives, Presentation at Third Party Payer Meeting, December 2012. <http://www.pdmpexcellence.org/sites/all/pdfs/Gunderson.pdf>

³³ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2013]. Available: http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2_16

³⁴ Drug Enforcement Administration. "Americans Turn Out in Doves for DEA's Seventh National Prescription Drug Take-Back Day." Department of Justice. [November 6, 2013]. Available: <http://www.justice.gov/dea/divisions/hq/2013/hq110613.shtml>

programs in their communities upon completion of the rulemaking process. DEA sponsored its most recent Take Back Day on April 26th.

The *Plan's* fourth pillar focuses on improving law enforcement capabilities to reduce diversion of prescription opioids. Federal law enforcement is partnering with state and local agencies across the country to reduce pill mills and prosecute those responsible for improper or illegal prescribing practices. The National Methamphetamine and Pharmaceuticals Initiative (NMPI), funded through ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program, provides critical training on pharmaceutical crime investigations to law enforcement agencies across the country. Since 2009, NMPI has provided training in pharmaceutical crime investigations and prosecutions to over 26,000 law enforcement and criminal justice professionals. These efforts continue to disseminate critical knowledge to enforcement and prosecution professionals.

All of these efforts under the *Prescription Drug Abuse Prevention Plan* are intended to reduce the diversion, abuse, and health and safety consequences associated with prescription opioids. Given their substantial role in overall opioid abuse and their nexus with heroin use, the Administration has worked tirelessly to address the problem at the source and at an array of intervention points. This work has been paralleled by efforts to address heroin trafficking and abuse, as well as the larger opioid overdose problem facing this country.

In June 2012, ONDCP convened top officials from NIDA, CDC, and other leaders from HHS, DOJ, DOD, and VA to discuss the latest data regarding heroin trends in the United States and the Administration response. ONDCP directed Federal public health and safety officials to increase data sharing, identify trends in substitution between prescription opioid misuse and heroin use, and coordinate a timely and evidence-based response to any emerging trends in the use of opioids. This meeting also reinforced the existing overdose prevention and opioid use disorder treatment goals outlined in the *National Drug Control Strategy*.

The Administration is focusing on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions; increasing access to naloxone, an emergency opioid overdose reversal medication; and working with states to promote Good Samaritan laws and other measures that can help save lives. With the recent rise in overdose deaths across the country, it is increasingly important to prevent overdoses and make antidotes available.

The Administration is providing tools to local communities to empower them to save lives. In August 2013, SAMHSA released the *Opioid Overdose Prevention Toolkit*.³⁵ This toolkit provides communities and local governments with material to develop policies and practices to help prevent opioid-related overdoses and deaths. It contains information specifically for first responders, treatment providers, and those recovering from opioid overdose. This kit will enable state and community leaders to implement effective overdose prevention initiatives, saving lives and connecting people to the treatment they need.

³⁵ Substance Abuse and Mental Health Services Administration. Opioid Overdose Prevention Toolkit. Department of Health and Human Services. [August 2013]. Available: <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>

In addition, working closely with ONDCP, the American Society of Anesthesiologists (ASA) has created an informational card on recognizing and responding to an opioid overdose.³⁶ The ASA's "Opioid Overdose Resuscitation" card lists symptoms to look for when an opioid overdose is suspected, and details step-by-step instructions for assisting a person suspected of an overdose prior to the arrival of emergency medical personnel. The Administration is working with ASA and other key stakeholders to provide this card to those who may encounter and can intervene with victims of opioid overdoses.

The Administration continues to promote the use of naloxone, the emergency opioid overdose reversal medication, among those likely to encounter overdose victims. Profiled in the 2013 *National Drug Control Strategy*, the Police Department in Quincy, Massachusetts, has partnered with the State health department to train and equip police officers to resuscitate overdose victims using naloxone. The Department reports that since October 2010, officers in Quincy have administered naloxone in more than 220 overdose events, almost all of them resulting in successful overdose reversals.³⁷ The Police Department and Sheriff's Office in Lorain, Ohio, working with county public health and substance abuse leaders, started a similar pilot program in October 2013, and officers have already reversed approximately 20 overdoses.³⁸ In addition, the New York/New Jersey HIDTA, a grant program funded by ONDCP, provided funding for a pilot program in a New York City Police Department precinct on Staten Island to train and equip police officers with naloxone. Other major jurisdictions are exploring naloxone programs as well. Boston Mayor Marty Walsh announced on February 11th that Boston police and firefighters will be equipped with naloxone,³⁹ and Vermont Governor Peter Shumlin recently announced that the Vermont State Police will have a similar training program for officers.⁴⁰

The Administration is also working with health care leaders to identify and promote other promising naloxone distribution models. For example, a joint program with the University of Rhode Island's College of Pharmacy, the Rhode Island Pharmacy Foundation, the State Board of Pharmacy, and Walgreens, has created a continuing education program and collaborative practice agreement that allows pharmacists to initiate naloxone therapy for patients who may be at risk for an opioid overdose.⁴¹ A DOD-led program, Operation Opioid Safe at Fort Bragg, North Carolina, educates patients about the risks and abuse issues surrounding long-term use of prescription opioids and distributes naloxone to high-risk patients.⁴²

³⁶ American Society of Anesthesiologists. "Opioid Overdose Resuscitation Card." [September 2013]. Available: <http://www.asahq.org/WhenSecondsCount/~media/For%20the%20Public%20Media/Patient%20Education/Opioid%20Overdose%20Card.pdf>

³⁷ Quincy (Massachusetts) Police Department Reporting

³⁸ Personal Communication, Lorain County (Ohio) Police Department

³⁹ Associated Press. "Boston mayor wants 1st responders to carry Narcan." Boston Herald. [February 11, 2014]. Available: http://bostonherald.com/news_opinion/local_coverage/2014/02/boston_mayor_wants_1st_responders_to_carry_narcan

⁴⁰ Krantz, L. "State Unveils Easier Access to Overdose-Reversing Drug." VTDigger.org. [March 3, 2014]. Available: <http://vtdigger.org/2014/03/03/state-unveils-easier-access-overdose-reversing-drug>

⁴¹ University of Rhode Island College of Pharmacy. "Opioids: Addiction, Overdose Prevention (Naloxone) And Patient Education." [November 2011]. Available: http://prescribetoprevent.org/wp-content/uploads/2012/11/naloxoneCEU_vUdRI_CE.pdf

⁴² Anthony Dragovich, M.D., Womack Army Medical Center, Fort Bragg, NC, personal communication, 2011, cited in Centers for Disease Control and Prevention. "Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010." MMWR 2012;61:101-105 [February 17, 2012]. Available: <http://www.cdc.gov/mmwr/pdf/wk/mm6106.pdf>

Seventeen states⁴³ and the District of Columbia have passed laws that have made it easier for medical professionals to prescribe and dispense naloxone, or for third party individuals to possess and administer the medication. They do this by limiting civil or criminal liability for prescribers or third parties, permitting prescribers to prescribe naloxone to third parties or via standing order, and removing liability for possession of naloxone without a prescription.

ONDCP is collaborating with state health and law enforcement officials to promote best practices and connect officials interested in starting their own naloxone programs. The odds of surviving an overdose, much like the odds of surviving a heart attack, depend on how quickly the victim receives treatment. At least 14 states⁴⁴ have passed Good Samaritan laws, which protect victims and witnesses who seek medical aid for an individual who is overdosing.⁴⁵ As these laws are implemented, the Administration will carefully monitor their effect on public health and public safety.

The Affordable Care Act and Federal parity laws are extending access to and parity for mental health and substance use disorder benefits for an estimated 62 million Americans. This will help integrate substance use treatment into mainstream health care.⁴⁶ This represents the largest expansion of treatment access in a generation and could help guide millions into successful recovery.

We are also seeking to ensure that the treatment people may receive for their opioid use is evidence-based and effective. Medication-assisted treatments for prescription drug and heroin abuse and dependence are effective treatment tools. Several FDA-approved medications, including methadone, buprenorphine, and naltrexone, are proven treatment tools, and are helping thousands of people in long-term recovery. Medication-assisted treatment may also help reduce deaths from opioid drugs; a study found that increased access to medication-assisted treatment in Baltimore, Maryland, was associated with a reduction in heroin deaths.⁴⁷ The Administration is committed to promoting medication-assisted treatment in treatment systems at the Federal, state, and local levels.

Reducing and preventing opioid diversion, abuse, overdose, and the array of public health and safety consequences requires collaboration with a broad range of stakeholders. The Administration has worked closely with a number of associations and groups, including the National Governors Association, the National Association of Attorneys General, the American Medical Association, the American Dental Association, the American College of Emergency

⁴³ States with Naloxone Laws: NM, NY, IL, WA, CA, RI, CT, MA, NC, OR, CO, VA, KY, MD, VT, NJ, OK, and DC

⁴⁴ States with Good Samaritan Overdose Laws: NM, WA, NY, CT, IL, CO, RI, FL, MA, CA, NC, NJ, VT, and DE

⁴⁵ The Network for Public Health Law. "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws." [updated January 2014]. Available: http://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf

⁴⁶ Berino, K., Rosa, P., Skopec, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief*. Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm)

⁴⁷ Schwartz, RP, Gryczynski, J, O'Grady, KE, Scharfstein, JM, Warren, G, Olsen, Y, Mitchell, SG, and Jaffe, JH. Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009 *Am J Public Health*. 2013;103:917–922.

Physicians, the National Safety Council, the National Conference of State Legislatures, the National Association of Boards of Pharmacy, the Association of State and Territorial Health Officials, state medical boards, and countless community groups in states, localities, and tribes across the country. All of these groups and the constituencies they represent have recognized the urgency of this national problem and are helping to bring about the changes we need to prevent more abuse, more arrests, and more deaths.

And there are some signs that these national efforts are working. The number of Americans 12 and older initiating the nonmedical use of prescription opioids in the past year has decreased significantly since 2009, from 2.2 million in that year to 1.9 million in 2012.⁴⁸ Additionally, according to the latest Monitoring the Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2013 is its lowest since 2002.⁴⁹

State actions are also taking effect. Innovative monitoring, enforcement strategies, and collaboration across Federal, state, and local law enforcement agencies and criminal justice leaders are helping many communities shut down illegal pain clinic operations. Florida is a great example of this success. According to DEA, 90 of the top 100 oxycodone purchasing physicians in the Nation were located in the State in 2010.⁵⁰ State leaders like Attorney General Pam Bondi and state legislators worked for passage of laws that stopped doctors operating at these pain clinics from being able to dispense controlled substances. These state actions, combined with a number of significant enforcement actions led by DEA, and state and local agencies, had an effect. By 2011, only 13 of the top 100 resided in Florida, and by the end of 2012, not one Florida doctor appeared on the top 100 list.^{51,52} These efforts have also helped dramatically reduce opioid overdose deaths in the state. According to the Florida Attorney General's office, state reporting shows that between 2005 and 2010, overdose deaths involving prescription drugs were increasing in Florida on average by 12 percent each year, with deaths involving oxycodone increasing an average of 35 percent each year.⁵³ Since the 2011 implementation of state enforcement, monitoring, and public health efforts to address the prescription opioid epidemic,

⁴⁸ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [September 2013]. Available: http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7pcTabsIto45-2012.htm#Tab7_36A

⁴⁹ The Monitoring the Future study, *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12*. University of Michigan. [December 2013]. Available: <http://www.monitoringthefuture.org/data/13data/13drfig8.pdf>

⁵⁰ Drug Enforcement Administration. (2013) Automation of Reports and Consolidated Orders System (ARCOS) Data. Retrieved: January 2013.

⁵¹ Drug Enforcement Administration. (2013) Automation of Reports and Consolidated Orders System (ARCOS) Data. Retrieved: January 2013.

⁵² Florida Office of the Attorney General. *Statewide Task Force on Prescription Drug Abuse & Newborns: 2014 Progress Report*. State of Florida. [2014]. Available: [http://myfloridalegal.com/webfiles.nsf/WF/IMEE-9GUS2X/\\$file/ProgressReportOnline.pdf](http://myfloridalegal.com/webfiles.nsf/WF/IMEE-9GUS2X/$file/ProgressReportOnline.pdf)

⁵³ Florida Office of the Attorney General. *Statewide Task Force on Prescription Drug Abuse & Newborns: 2014 Progress Report*. State of Florida. [2014]. Available: [http://myfloridalegal.com/webfiles.nsf/WF/IMEE-9GUS2X/\\$file/ProgressReportOnline.pdf](http://myfloridalegal.com/webfiles.nsf/WF/IMEE-9GUS2X/$file/ProgressReportOnline.pdf)

there has been a 23 percent decline in prescription drug overdose deaths, with a remarkable 52 percent decline in the number of oxycodone overdose deaths alone.⁵⁴

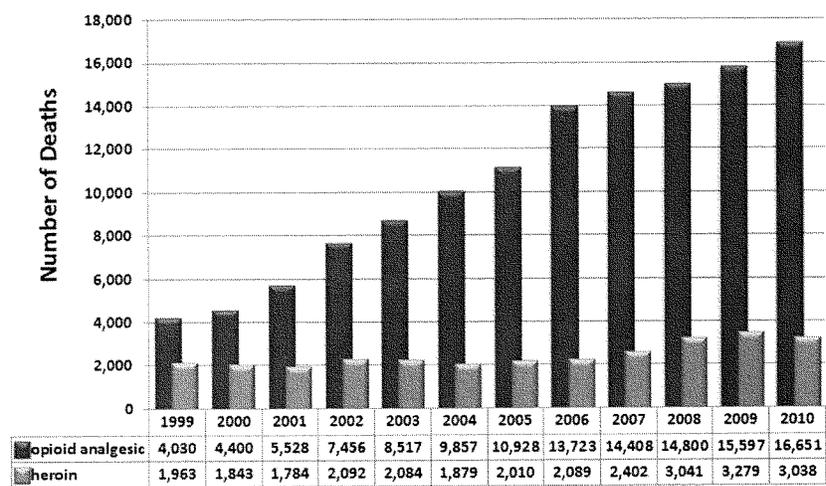
However, while all of these trends are promising, the national data cited earlier concerning increases in emergency department visits, treatment admissions, and overdoses involving opioids bring the task ahead of us into stark focus. Continuing challenges with prescription opioids, and concerns about a reemergence of heroin use, particularly among young adults, underscore the need for leadership at all levels of government.

Conclusion

We continue to work with our Federal, state, local, and tribal partners to continue to reduce and prevent the health and safety consequences of prescription opioid and heroin abuse. Together with all of you, we are committed partners, working to reduce the prevalence of substance use disorders through prevention, increasing access to treatment, and helping individuals recover from the disease of addiction. Thank you for the opportunity to testify here today, and for your ongoing commitment to this issue. I look forward to continuing to work with you on this pressing public health matter.

⁵⁴ Florida Department of Law Enforcement. (2013). Drugs Identified in Deceased Persons by Florida Medical Examiners: 2012 Report. September 2013. Retrieved from: <http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2e6fd4cb3c9f/MFC-Publications-and-Forms.aspx>

Figure. Drug Poisoning Death Rates Involving Opioid Analgesics and Heroin in the United States, 1999-2010



Source: CDC WONDER Online Mortality Database, extracted February 11, 2014

Mr. BURGESS. The gentleman yields back.
The Chair recognizes Dr. Sosin for the purposes of the 5-minute opening statement please.

STATEMENT OF DANIEL M. SOSIN

Dr. SOSIN. Good morning, Chairman Burgess, and members of the subcommittee. Thank you for the opportunity to testify about the public health issues related to prescription drug overdoses, and the Centers for Disease Control and Prevention's role in preventing them.

It is an honor to be with you today to talk about CDC's approach to prescription drug overdoses and the prevention of them.

Drug overdose death rates are higher than they have ever been, with prescription opioids being a key driver of this trend. More than 125,000 Americans have died from prescription opioid overdoses in the last decade. CDC has played an important role in raising the visibility of the health impact of prescription opioid overdoses, and helping to identify the role of increased inappropriate opioid prescribing in fueling this epidemic. Research also suggests that the growth in heroin use may be due in part to the increased addiction caused by the rise in prescribing of opioid pain relievers.

The doubling in heroin use in the past 6 years is a worrisome trend, and undoubtedly has a relationship to prescription opioids. Reducing inappropriate opioid prescribing is one of the approaches needed to keep people from becoming addicted to opioids, and prevent them from later transitioning to heroin.

Because of the complexity of these issues, the response demands engagement from a diverse group of federal, state and local partners. The partners at this table are all critical in the overall goal to reduce abuse and overdose of opioids while ensuring that patients with pain are safely and effectively treated.

As the nation's health protection agency, CDC is focused on upstream drivers of this epidemic, in this instance, the prescribing behaviors that created and continue to fuel this crisis. Our approach fits into three pillars that leverage CDC's unique expertise: One, improving data quality and use to monitor the trends and causes of the epidemic. Timely, drug-specific information on prescribing, and the health effects of prescription drugs is critical. We generate, use, and improve data to identify threats, assess local trends, and evaluate the impact of prevention measures. Two, strengthening state prevention efforts. States maintain prescription drug monitoring programs, or PDMPs. States regulate healthcare professionals and institutions, they monitor the problem through their health departments, and they run large public insurance programs, including Medicaid. CDC provides resources and technical assistance to states to implement interventions and evaluate and adapt their approach to have the most impact. And three, improving patient safety by supporting healthcare providers and systems with tools and data needed to respond effectively. For example, CDC is working to promote responsible opioid prescribing through guidelines and decision support tools.

While CDC has ongoing work in each of these areas, we are focusing this year on accelerating state prevention efforts. We will be

funding four to five state health departments for up to a total of \$2 million per year to implement and evaluate the strategies I just outlined.

The 2015 President's Budget includes a request for \$15.6 million in new funds to expand CDC's Core Violence and Injury Prevention Program, which is a state-based program addressing injury and violence prevention. This will allow us to include additional states with the high burden of prescription drug overdose, to prevent injuries and violence, and expand the investment of these programs on reducing prescription drug overdose.

In conclusion, prescription drug abuse and overdose is a serious public health problem in the United States. The burden of prescription drug abuse and overdose affects people of all walks of life, and many sectors of our economy. Addressing this complex problem requires a multifaceted approach and collaboration. CDC is committed to tracking and understanding the epidemic, supporting states working on the frontlines of this crisis, and rigorously evaluating what works to improve patient safety, prevent overdoses and save lives.

Thank you again for the opportunity to be here today.
[The prepared statement of Dr. Sosin follows:]



Testimony before the
Oversight and Investigations Subcommittee
Energy and Commerce Committee
U.S. House of Representatives

**Examining the Growing Problems of
Prescription Drug and Heroin Abuse**

Daniel Sosin, M.D., M.P.H., F.A.C.P.
Acting Director, National Center for Injury Prevention and
Control
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release upon Delivery
10:00am
April 29, 2014

Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee. Thank you for the opportunity to testify before you today about the public health issues related to prescription drug overdoses and CDC's role in the prevention of these overdoses.

My name is Dr. Daniel Sosin, and I am the Acting Director of the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC). In this role, I am responsible for the leadership and implementation of CDC's programs that prevent violence and injuries and reduce their consequences. It is a pleasure to be with you today to talk about CDC's approach to the prevention of prescription drug overdoses—a national epidemic. We are at an important moment for this public health challenge. As you will hear today, we know more now than ever before about the burden and who is at risk for prescription drug overdose. However, there is still much to learn to be able to completely address this epidemic. My testimony reviews the nature of the epidemic, how preventing prescription drug overdoses has the potential to prevent some heroin overdoses, and CDC's unique contribution to addressing this public health crisis.

The National Prescription Drug Overdose Epidemic

Drug overdose death rates have climbed sharply and steadily over the past decade and are higher now than they have ever been. Drug overdose death rates have climbed throughout the country, with some states like New Mexico, West Virginia and Kentucky being among the hardest hit.¹

Increases in prescribing opioid pain relievers – drugs like oxycodone, hydrocodone, methadone and fentanyl – are driving the dramatic increase in overdose deaths over the

¹ Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008, *Morbidity and Mortality Weekly Report*, November 4, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>.

last decade. Opioid pain reliever overdose deaths have quadrupled since 1999.² CDC has declared the problem of prescription drug abuse a public health epidemic and addressing it remains a key priority for the Agency.

The prescription drug overdose epidemic is driven by fundamental changes in the way healthcare providers prescribe opioid pain relievers. Beginning in the 1990s, providers started prescribing more opioid pain relievers in an effort to address what was, at that time, perceived to be a widespread problem of undertreated pain. As opioid pain reliever prescribing increased, overdose deaths increased simultaneously.³ Today, the supply of opioid pain relievers is larger than ever.⁴

As the nation's health protection agency, CDC has worked to identify the clear connection between increased inappropriate opioid prescribing and overdose deaths. Certainly, the Agency recognizes and supports the appropriate use of opioid pain relievers as a useful tool for clinicians in controlling certain types of pain, such as pain related to cancer diagnoses. But, we are concerned with and are working to address the inappropriate prescribing of these drugs—such as when they are prescribed at doses or for durations not clinically-indicated, in combination with other contraindicated drugs like sedative-hypnotics, or for conditions for which other remedies may be indicated.

In addition to the clear human toll of opioid abuse, it also is a tremendous strain on our country's healthcare system. One study estimated that people who abuse opioids generate over eight times the annual health care costs compared to people who do not abuse these drugs.⁵

² QuickStats: Number of Deaths From Poisoning,* Drug Poisoning,† and Drug Poisoning Involving Opioid Analgesics — United States, 1999–2010, *Morbidity and Mortality Weekly Report*, March 29, 2013, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6212a7.htm?s_cid=mm6212a7_e%20.

³ Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999–2008, *Morbidity and Mortality Weekly Report*, November 4, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>.

⁴ Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999–2008, *Morbidity and Mortality Weekly Report*, November 4, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>.

⁵ White AG, Birnbaum, HG, Mareva MN, et al. Direct Costs of Opioid Abuse in an Insured Population in the United States. *J Manag Care Pharm*. 11(6):469-479. 2005.

Prescription Opioid Abuse and Dependence Still Greater than Heroin Abuse and Dependence

One of the reasons we are gathered here today is our shared concern over reports that heroin use and overdoses are increasing. This is true; the number of persons meeting criteria for heroin abuse or dependence more than doubled from 2007 to 2012.^{6,7} Some states, cities, and counties from across the country have reported recent increases in heroin-related deaths, including Maryland, Kentucky, and New York City. This increase in deaths is alarming. However, opioid abuse/dependence is still approximately four times greater than heroin abuse/dependence. In 2012, more than two million people reported opioid abuse/dependence—approximately the population of Houston—compared to about 467,000 people reporting heroin use.⁸

For CDC, preventing prescription opioid abuse and misuse will help prevent some cases of heroin abuse. For example, some studies of people who use heroin show that many times prescription opioid abuse precedes heroin use. CDC's analysis has found that more than three out of four people who reported both past-year opioid abuse and heroin use said they used opioids non-medically—that is, without a prescription or for the feeling or experience the drugs cause—prior to heroin initiation.⁹ In addition, more than seven out of ten people who reported past-year heroin use also reported using opioids non-medically in the past year.¹⁰ From 2002 to 2011, first-time heroin use was 19 times higher among those reporting prior nonmedical opioid use than among those

⁶ Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). *Results from the 2007 National Survey on Drug Use and Health: National Findings* (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.

⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁸ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁹ Jones, C.M., Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002–2004 and 2008–2010. *Drug Alcohol Depend.* (2013).

¹⁰ Jones, C.M., Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002–2004 and 2008–2010. *Drug Alcohol Depend.* (2013).

who did not report using opioids non-medically.¹¹ In short, research suggests that a small portion of people, less than four percent of past year non-medically prescription opioid initiates, began using heroin within five years of prescription opioid initiation.

These findings suggest the need for additional strategies to reduce inappropriate opioid prescribing and use so that there are fewer people who become addicted. Reducing inappropriate opioid prescribing is one of the necessary approaches to prevent people from becoming addicted to opioids and keep them from later transitioning to heroin.

CDC Efforts to Reverse the Prescription Drug Overdose Epidemic

CDC is working to reverse the prescription drug overdose epidemic by focusing on three areas that are both central to the CDC mission and complementary to the work of our sister agencies like the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, the National Institute on Drug Abuse, the Department of Justice, and the Office of National Drug Control Policy. The first area of focus is on protecting the public's health by improving data quality and tracking trends to monitor actionable changes in the epidemic, including promoting the use of prescription drug monitoring program data for safer prescribing. Prescription drug monitoring programs, or PDMPs, are a promising tool to directly help prescribers reduce unwarranted prescribing. They also will allow CDC and states to better understand more quickly what populations are being prescribed these drugs to inform where and how to implement prevention strategies. The second area of focus is strengthening state efforts by scaling up effective public health interventions. Through our technical assistance and direct funding to be awarded later this year, CDC is helping states implement tailored, state-specific prevention strategies and evaluate their own policies and programs aimed at addressing the epidemic. Third, we are focused on improving patient safety by supplying health care providers with data, tools, and guidance for

¹¹ Muhuri PK, Gfroerer JC, Davies MC. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. SAMHSA CBHSQ Data Review. 2013. Available at <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf> (accessed April 23, 2014).

evidence-based decision making that improves population health, for instance by identifying effective insurer mechanisms for preventing over-prescribing of opioids. One example includes Patient Review and Restriction Programs (PRRs) where insurers direct patients whose claims are flagged for potential overutilization or abuse (such as a single patient receiving opioid prescriptions from multiple prescribers and/or pharmacies) to a single provider, pharmacy, or both. In 2012, CDC convened expert representatives from state Medicaid agencies, managed care organizations, and private insurers to share experiences using PRRs as one method to prevent prescription drug abuse, diversion and overdose.

In addition, the Fiscal Year 2015 President's Budget includes \$15.6 million in new funding to expand CDC's Core Violence and Injury Prevention Program (VIPP) to include additional states with high burdens of prescription drug overdose. The increased investment will equip more states to prevent injuries and violence, with the requirement that, each state that is funded selecting prescription drug overdose as one of the state's four injury-prevention focus areas. Sixteen of the currently-funded States through the Core VIPP have prioritized prescription drug overdose within the State public health department.

By applying these strategies, CDC is focusing on one of the "upstream" drivers of the epidemic—that is, the prescribing behaviors that created and continue to fuel this crisis—to impact this epidemic on a national scale and break the cycle of abuse, addiction, and overdose.

Conclusion

Prescription drug abuse and overdose is a serious public health issue in the United States. The burden of prescription drug abuse and overdose not only impacts individuals and families but communities, employers, the healthcare system, and public and private insurers. Addressing this complex problem requires a multi-faceted approach and collaboration between public health, clinical medicine, and public safety

at the federal, state, and local levels. CDC is committed to tracking and understanding the epidemic, supporting states working on the front lines of this crisis, and rigorously evaluating what works to prevent overdoses and save lives.

Thank you again for the opportunity to be here with you today and for your continued support of CDC's essential public health work.

Mr. BURGESS. Thank you. The gentleman yields back.
The Chair recognizes Dr. Volkow for 5 minutes for an opening statement. Thank you.

STATEMENT OF NORA D. VOLKOW

Dr. VOLKOW [continuing]. Is a component of the NIH to speak about the value of science in helping address the problem from the diversion and abuse of prescription opioid pain killers, and the related rising abuse of heroin. Opioids medications are the most effective intervention we currently have for management of severe pain. Unfortunately, these drugs not only inhibit pain sensors in the brain, but they also potently activate brain reward regions, which is why they are abused and they can cause addiction.

So we face the unique challenge of preventing their abuse, while safeguarding their value for managing severe pain, which, if untreated, is terribly debilitating.

It is estimated that 2.1 million Americans are addicted to opioid pain killers, which reflects, in part, the widespread availability of these drugs. Indeed, the number of yearly prescriptions for opioids has more than doubled over the past 20 years, from 76 million to 207 million prescriptions per year, during a period that in parallel saw a fourfold increase in death overdoses from prescription opioids.

Pain killers, like Oxycontin and Vicodin, affect the brain similarly to heroin. They interact with exactly the same opioid receptors. Their difference depends on the potency, that is, how strongly they activate those receptors, and how rapidly they do so. So as for heroin, they can produce euphoria, which some abusers of prescription medications intensify by taking higher doses, crushing the pills so that they can snort them or inject them, or taking them in combination with other drugs like alcohol and Benzodiazepines. These practices make opioids far more dangerous, not only because they are more addictive, but also because they increase the risk for respiratory depression, which is the main cause of death from overdoses.

Recent trends, as the other witnesses have mentioned, also indicate a rise in heroin abuse which currently affects more than 1/2 million Americans, and this rise is possibly driven in part by people switching from prescription opioids to heroin because it is cheaper and, in some instances, more available.

Heroin is dangerous not just because of its high addictiveness and the overdose risk that it poses, but also because it is frequently injected which increases the risk of diseases like HIV and Hepatitis C, predominantly from the use of contaminated injection material.

So what is NIDA doing about the problem? We are funding research in two major areas. One, research that will allow us to manage pain more effectively, research that will allow us to prevent deaths from overdoses from opioids, and that research will allow us to treat substance use disorders more effectively, including prescription medications.

As it relates to the safe management of pain, we still don't know enough about the risk for addiction among chronic pain patients, or about how pain mechanisms in the brain interact with prescrip-

tion opioids to influence their addictive potential, but ongoing research will help us clarify some of these issues.

So with respect to treatment, we are funding research to develop non-opioid-based analgesics that are non-addictive, opioid medications that have less risk for diversion and abuse, as given by different formulations, or different ways of administering them, and finally, non-medication strategies such as transcranial magnetic stimulation, or electrical brain stimulation for the management of pain.

Research related to preventing overdoses, making the effective opioid overdose antidote, naloxone, which is also very safe, more available, will help prevent many deaths. The FDA recently approved a handheld auto injector of naloxone that patients and others can use easily. NIDA is supporting the development of user-friendly naloxones in the form of nasal spray to be used by non-medical personnel or the overdose victim. Also, since many overdoses occur when no one is around or during sleep, NIDA is supporting the development of self-activated systems that initiate an emergency response when wireless sensors signal that an overdose is occurring.

As it relates to opioid addiction, methadone, buprenorphine and naltrexone have been shown to be effective in treating opioid addiction, and in preventing overdoses, but these medications are not being used widely. NIDA is working to overcome the barriers that interfere with their adoption. In parallel, research of new interventions such as vaccines for heroin will allow us to treat this problem in a different way and to prevent it. Additionally, we work with our partners, CDC, SAMHSA, ONDCP and ONC in implementing and evaluating evidence-based interventions.

Again, I want to thank you for recognizing the urgency of the problem posed by the abuse of prescription opioids, and for inviting NIDA to discuss how science can help address this problem.

[The prepared statement of Dr. Volkow follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Prescription Opioid and Heroin Abuse

**Witness appearing before the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

Nora D. Volkow, M.D.

Director, National Institute on Drug Abuse

April 29, 2014

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this important hearing and contribute what I believe will be useful insights into the growing and intertwined problems of prescription pain relievers and heroin abuse in this country.

Background

The abuse of and addiction to opioids such as heroin, morphine, and prescription pain relievers is a serious global problem that affects the health, social, and economic welfare of all societies. It is estimated that between 26.4 million and 36 million people abuse opioids worldwide,¹ with an estimated 2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin.² The consequences of this abuse have been devastating and are on the rise. For example, the number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999. There is also growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States.³

To address the complex problem of prescription opioid and heroin abuse in this country, we must recognize and consider the special character of this phenomenon, for we are asked not only to confront the negative and growing impact of opioid abuse on health and mortality, but also to preserve the fundamental role played by prescription opioid pain relievers in healing and reducing human suffering. That is, scientific insight must strike the right balance between providing maximum relief from suffering while minimizing associated risks and adverse effects.

¹ UNODC, World Drug Report 2012. <http://www.unodc.org/unodc/en/data-and-analysis/WDR-2012.html>

² Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

³ Pradip et al. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the US. Center for Behavioral Health Statistics and Quality Data Review. SAMHSA (2013) <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm>

Abuse of Prescription Opioids: Scope and Impact

Prescription opioids are one of the three main broad categories of medications that present abuse liability, the other two being stimulants and central nervous system (CNS) depressants.

Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies. These factors together have helped create the broad “environmental availability” of prescription medications in general and opioid analgesics in particular.

To illustrate this point, the total number of opioid pain relievers prescribed in the United States has skyrocketed in the past 25 years (Fig. 1).⁴ The number of prescriptions for opioids (like hydrocodone and oxycodone products) have escalated from around 76 million in 1991 to nearly 207 million in 2013, with the United States their biggest consumer globally, accounting for almost 100 percent of the world total for hydrocodone (e.g., Vicodin) and 81 percent for oxycodone (e.g., Percocet).⁵

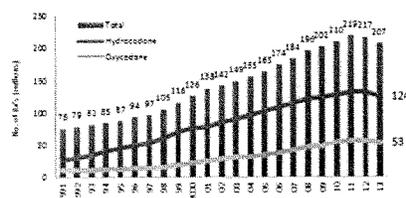


Figure 1. Opioid Prescriptions Dispensed by US Retail Pharmacies. IMS Health, Vector One: National, Years 1991-1996, Data Extracted 201. IMS Health, National Prescription Audit, Years 1997-2013, Data Extracted 2014.

This greater availability of opioid (and other) prescribed drugs has been accompanied by alarming increases in the negative consequences related to their abuse.⁶ For example, the estimated number of emergency department visits involving nonmedical use of opioid analgesics increased from 144,600 in 2004 to 305,900 in 2008;⁷ treatment admissions for primary abuse of opiates other than heroin increased from one percent of all admissions in 1997 to five percent in

⁴ IMS's National Prescription Audit (NPA) & Vector One®: National (VONA).

⁵ International Narcotics Control Board Report 2008.. United Nations Pubns. 2009, p. 20

⁶ To clarify our terminology here, when we say “prescription drug abuse” or “nonmedical use,” this includes use of medications without a prescription, use for purposes other than for what they were prescribed, or use simply for the experience or feeling the drug can cause.

⁷ Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network, 2007: national estimates of drug-related emergency department visits.

2007⁸; and overdose deaths due to prescription opioid pain relievers have more than tripled in the past 20 years, escalating to 16,651 deaths in the United States in 2010.⁹

In terms of abuse and mortality, opioids account for the greatest proportion of the prescription drug abuse problem. Deaths related to prescription opioids began rising in the early part of the 21st century. By 2002, death certificates listed opioid analgesic poisoning as a cause of death more commonly than heroin or cocaine.¹⁰

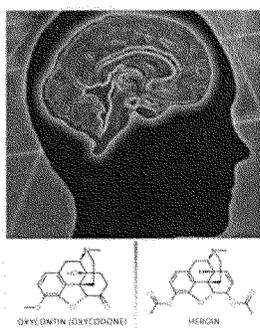


Figure 2.
Chemical similarity between Opioid
Prescriptions and Heroin

Because prescription opioids are similar to, and act on the same brain systems affected by, heroin and morphine (**Fig.2**), they present an intrinsic abuse and addiction liability, particularly if they are used for non-medical purposes. They are most dangerous and addictive when taken via methods that increase their euphoric effects (the “high”), such as crushing pills and then snorting or injecting the powder, or combining the pills with alcohol or other drugs. Also, some people taking them for their intended purpose risk dangerous adverse reactions by not taking them exactly as prescribed (e.g., taking more pills at once, or taking them more frequently or combining them with medications for which they are not being properly controlled);

and it is possible for a small number of people to become addicted even when they take them as prescribed, but the extent to which this happens currently is not known. It is estimated that more than 100 million people suffer from chronic pain in this country,¹¹ and for some of them, opioid therapy may be appropriate. The bulk of American patients who need relief from persistent, moderate-to-severe non-cancer pain have back pain conditions (approximately 38 million) or

⁸ Treatment Episode Data Set (TEDS) Highlights – 2007. National Admissions to Substance Abuse Treatment Services. SAMHSA

⁹ Mack, K.A. Drug-induced deaths - United States, 1999-2010. *MMWR Surveill Summ.* 2013 Nov 22;62 Suppl 3:161-3. CDC

¹⁰ Paulozzi et al. Increasing deaths from opioid analgesics in the United States *Pharmacoepidemiol. Drug Saf.*, 15 (2006), pp. 618–627

¹¹ Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. REPORT BRIEF JUNE 2011; Johannes et al. The prevalence of chronic pain in United States adults: results of an Internet-based survey. *J Pain.* 11(11):1230-9. (2010); Gallup-Healthways Well-Being Index.

osteoarthritis (approximately 17 million).¹² Even if a small percentage of this group develops substance use disorders (a subset of those already vulnerable to developing tolerance and/or clinically manageable physical dependence¹³), a large number of people could be affected. Scientists debate the appropriateness of chronic opioid use for these conditions in light of the fact that long-term studies demonstrating that the benefits outweigh the risks have not been conducted. In June 2012, NIH and FDA held a joint meeting on this topic,¹⁴ and now FDA is requiring companies who manufacture long-acting and extended-release opioid formulations to conduct post-marketing research on their safety.¹⁵

The Effects of Opioid Abuse on the Brain and Body. Opioids include drugs such as OxyContin and Vicodin that are mostly prescribed for the treatment of moderate to severe pain. They act by attaching to specific proteins called opioid receptors, which are found on nerve cells in the brain, spinal cord, gastrointestinal tract, and other organs in the body. When these drugs attach to their receptors, they reduce the perception of pain and can produce a sense of well-being; however, they can also produce drowsiness, mental confusion, nausea, and constipation.¹⁶ The effects of opioids are typically mediated by specific subtypes of opioid receptors (mu, delta, and kappa) that are activated by the body's own (endogenous) opioid chemicals (endorphins, enkephalins). With repeated administration of opioid drugs (prescription or heroin), the production of endogenous opioids is inhibited, which accounts in part for the discomfort that ensues when the drugs are discontinued (*i.e.*, withdrawal). Adaptations of the opioid receptors' signaling mechanism have also been shown to contribute to withdrawal symptoms.

Opioid medications can produce a sense of well-being and pleasure because these drugs affect brain regions involved in reward. People who abuse opioids may seek to intensify their

¹² De Leon Casada. Opioids for Chronic Pain: New Evidence, New Strategies, Safe Prescribing The American Journal of Medicine, 126(3s1):S3–S11. (2013).

¹³ American Academy of Pain Medicine; American Pain Society; American Society of Addiction Medicine. *Definitions Related to the Use of Opioids for the Treatment of Pain.* Glenview, IL, and Chevy Chase, MD: American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine: 2001

¹⁴ Assessment of Analgesic Treatment of Chronic Pain: A Scientific Workshop, linked to 4-24-2014 available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308363.pdf>

¹⁵ ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements (PDF - 136KB) Letter to ER/LA opioid application holders. Linked to 4-24-2014 Available at

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

¹⁶ Mattoo, S. Prevalence and correlates of epileptic seizure in substance-abusing subjects. *Psychiatry Clin Neurosci.* 63(4):580-2. (2009).

experience by taking the drug in ways other than those prescribed. For example, extended-release oxycodone is designed to release slowly and steadily into the bloodstream after being taken orally in a pill; this minimizes the euphoric effects. People who abuse pills may crush them to snort or inject which not only increases the euphoria but also increases the risk for serious medical complications, such as respiratory arrest, coma, and addiction. When people tamper with long-acting or extended-release medicines, which typically contain higher doses because they are intended for release over long periods, the results can be particularly dangerous, as all of the medicine can be released at one time. Tampering with extended release and using by nasal, smoked, or intravenous routes produces risk both from the higher dose and from the quicker onset.

Opioid pain relievers are sometimes diverted for nonmedical use by patients or their friends, or sold in the street. In 2012, over five percent of the U.S. population aged 12 years or older used opioid pain relievers non-medically.¹⁷ The public health consequences of opioid pain reliever abuse are broad and disturbing. For example, abuse of prescription pain relievers by pregnant women can result in a number of problems in newborns, referred to as neonatal abstinence syndrome (NAS), which increased by almost 300 percent in the United States between 2000 and 2009.¹⁸ This increase is driven in part by the high rate of opioid prescriptions being given to pregnant women. In the United States, an estimated 14.4 percent of pregnant women are prescribed an opioid during their pregnancy.¹⁹

Prescription opioid abuse is not only costly in economic terms (it has been estimated that the nonmedical use of opioid pain relievers costs insurance companies up to \$72.5 billion annually in health-care costs²⁰) but may also be partly responsible for the steady upward trend in poisoning mortality. In 2010, there were 13,652 unintentional deaths from opioid pain

¹⁷ SAMHSA: Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables

¹⁸ CDC. Vital signs. <http://m.cdc.gov/en/VitalSigns/prescription-painkiller-overdoses>

¹⁹ Bateman, B.T. et al. Patterns of Opioid Utilization in Pregnancy in a Large Cohort of Commercial Insurance Beneficiaries in the United States. *Anesthesiology*. in press (2014)

²⁰ Coalition Against Insurance Fraud. Prescription for peril: how insurance fraud finances theft and abuse of addictive prescription drugs. Washington, DC: Coalition Against Insurance Fraud; 2007. Available at <http://www.insurancefraud.org/downloads/drugDiversion.pdf>

reliever (82.8 percent of the 16,490 unintentional deaths from all prescription drugs),²¹ and there was a five-fold increase in treatment admissions for prescription pain relievers between 2001 and 2011 (from 35,648 to 180,708, respectively).²² In the same decade, there was a tripling of the prevalence of positive opioid tests among drivers who died within one hour of a crash.²³

A property of opioid drugs is their tendency, when used repeatedly over time, to induce *tolerance*. Tolerance occurs when the person no longer responds to the drug as strongly as he or she did at first, thus necessitating a higher dose to achieve the same effect. The establishment of tolerance hinges on the ability of abused opioids (e.g., OxyContin, morphine) to desensitize the brain's own natural opioid system, making it less responsive over time.²⁴ This tolerance contributes to the high risk of overdose during a relapse to opioid use after a period in recovery; users who do not realize they may have lost their tolerance during a period of abstinence may initially take the high dosage that they previously had used before quitting, a dosage that produces an overdose in the person who no longer has tolerance.²⁵ Another contributing factor to the risk of opioid-related morbidity and mortality is the combined use of benzodiazepines (BZDs) and/or other CNS depressants, even if these agents are used appropriately. Thus, patients with chronic pain who use opioid analgesics along with BZDs (and/or alcohol) are at higher risk for overdose. Unfortunately, there are few available practice guidelines for the combined use of CNS depressants and opioid analgesics; such cases warrant much closer scrutiny and monitoring.²⁶ Finally, it must be noted in this context that, although more men die from drug overdoses than women, the percentage increase in deaths seen

²¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012. Data are from the Multiple Cause of Death Files, 1999-2010, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

²² Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2001-2011. National Admissions to Substance Abuse Treatment Services*. BHSIS Series S-65, HHS Publication No. (SMA) 13-4772. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

²³ Brody and Li. *Am. J. Epidemiology*. 2014

²⁴ Williams, J. Regulation of μ -opioid receptors: desensitization, phosphorylation, internalization, and tolerance. *Pharmacol Rev.* 65(1):223-54. (2013).

²⁵ Möller et al. Acute drug-related mortality of people recently released from prisons. *Public Health.* 124(11):637-9. (2010); Buster et al. An increase in overdose mortality during the first 2 weeks after entering or re-entering methadone treatment in Amsterdam. *Addiction.* 97(8):993-1001. (2002).

²⁶ Paulozzi, L. Prescription drug overdoses: a review. *J Safety Res.* 43(4):283-9 (2012)

since 1999 is greater among women: Deaths from opioid pain relievers increased five-fold between 1999 and 2010 for women versus 3.6 times among men.²⁷

Relationship between Prescription Opioids and Heroin Abuse

The recent trend of a switch from prescription opioids to heroin seen in some communities in our country alerts us to the complex issues surrounding opioid addiction and the intrinsic difficulties

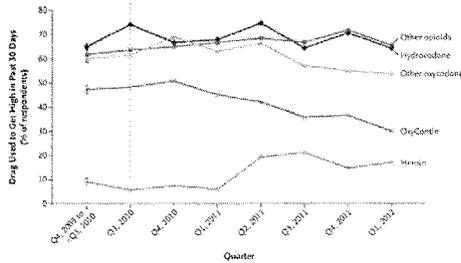


Figure 3. Growing evidence suggests that abusers of prescription opioids are shifting to heroin as prescription drugs become less available or harder to abuse. For example, a recent increase in heroin use accompanied a downward trend in Oxycodone abuse following the introduction of an abuse-deterrent formulation of that medication (dashed vertical line).⁴

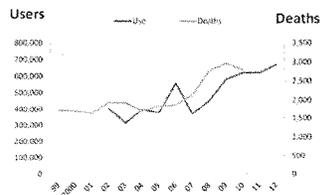
in addressing it through any single measure such as enhanced diversion control (Fig.3). Of particular concern has been the rise in new populations of heroin users, particularly young people.

The emergence of chemical tolerance toward prescribed opioids, perhaps combined in a smaller number of cases with an increasing difficulty in obtaining these medications illegally²⁸,

may in some instances explain the transition to abuse of heroin, which is cheaper and in some communities easier to obtain than prescription opioids.

The number of past-year heroin users in the United States nearly doubled between 2005 and 2012, from 380,000 to 670,000 (Fig. 4).²⁹ Heroin

Figure 4. Trend in prevalence of heroin use and Heroin related overdose death in the US (1999-2012)



²⁷ CDC. Vital signs: overdoses of prescription opioid pain relievers and other drugs among women--United States, 1999-2010. MMWR 62(26):537-42. (2013).

²⁸ Slevin and Ashburn. Primary care physician opinion survey on FDA opioid risk evaluation and mitigation strategies. J Opioid Manag. 2011 Mar-Apr;7(2):109-15.

Hooten and Bruce. Beliefs and attitudes about prescribing opioids among healthcare providers seeking continuing medical education. J Opioid Manag. 7(6):417-24.(2011).

²⁹ Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

abuse, like prescription opioid abuse, is dangerous both because of the drug's addictiveness and because of the high risk for overdosing. In the case of heroin, this danger is compounded by the lack of control over the purity of the drug injected and its possible contamination with other drugs (such as fentanyl, a very potent prescription opioid that is also abused by itself).³⁰ All of these factors increase the risk for overdosing, since the user can never be sure of the amount of the active drug (or drugs) being taken. In 2010, there were 2,789 fatal heroin overdoses, approximately a 50 percent increase over the relatively constant level seen during the early 2000s.³¹ What was once almost exclusively an urban problem is spreading to small towns and suburbs. In addition, the abuse of an opioid like heroin, which is typically injected intravenously, is also linked to the transmission of human immunodeficiency virus (HIV), hepatitis (especially Hepatitis C), sexually-transmitted infections, and other blood-borne diseases, mostly through the sharing of contaminated drug paraphernalia but also through the risky sexual behavior that drug abuse may engender.

NIDA Activities to Stem the Tide of Prescription Opioid and Heroin Abuse

NIDA first launched its prescription drug abuse public health initiative in 2001. Our evidence-based strategy calls for a comprehensive three-pronged approach consisting of (1) enhancing our understanding of pain and its management; (2) preventing overdose deaths; and (3) effectively treating opioid addiction.

Research on Pain and Next Generation Analgesics. Although opioid medications effectively treat acute pain and help relieve chronic pain for some patients,³² their addiction risk presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. Little is yet known about the risk for addiction among those being treated for chronic pain or about how basic pain mechanisms interact with prescription opioids to influence addiction potential. To better understand this, NIDA launched a research initiative on "Prescription Opioid Use and Abuse in the Treatment of Pain." This initiative encourages a

³⁰ SAMHSA advisory Bulletin 2/7/14 <http://www.samhsa.gov/newsroom/advisories/1402075426.aspx>.

³¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012. Data are from the Multiple Cause of Death Files, 1999-2010, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

³² Moore, A. et al. Expect analgesic failure; pursue analgesic success *BMJ*. 3;346 (2013).

multidisciplinary approach using both human and animal studies to examine factors (including pain itself) that predispose or protect against opioid abuse and addiction. Funded grants cover clinical neurobiology, genetics, molecular biology, prevention, treatment, and services research. This type of information will help develop screening and diagnostic tools that physicians can use to assess the potential for prescription drug abuse in their patients. Because opioid medications are prescribed for all ages and populations, NIDA is also encouraging research that assesses the effects of prescription opioid abuse by pregnant women, children, and adolescents, and how such abuse in these vulnerable populations might increase the lifetime risk of substance abuse and addiction.

Another important initiative pertains to the development of new approaches to treat pain. This includes research to identify new pain relievers with reduced abuse, tolerance, and dependence risk, as well as devising alternative delivery systems and formulations for existing drugs that minimize diversion and abuse (*e.g.*, by preventing tampering and/or releasing the drug over a longer period of time) and reduce the risk of overdose deaths. New compounds are being developed that exhibit novel properties as a result of their combined activity on two different opioid receptors (*i.e.*, mu and delta). Preclinical studies show that these compounds can induce strong analgesia but fail to produce tolerance or dependence. Researchers are also getting closer to developing a new generation of non-opioid-based medications for severe pain that would circumvent the brain reward pathways, thereby greatly reducing abuse potential. This includes compounds that work through a type of cannabinoid receptor found primarily in the peripheral nervous system. NIDA is also exploring the use of non-medication strategies for managing pain. An example is the use of “neurofeedback,” a novel modality of the general biofeedback approach, in which patients learn to regulate specific regions in their brains by getting feedback from real-time brain images. This technique has shown promising results for altering the perception of pain in healthy adults and chronic pain patients and could even evolve into a powerful psychotherapeutic intervention capable of rescuing the circuits and behaviors impaired by addiction.

Developing More Effective Means for Preventing Overdose Deaths. The opioid overdose antidote naloxone has reversed more than 10,000 overdose cases between 1996 and 2010,

according to CDC.³³ For many years, naloxone was available only in an injectable formulation and was generally only carried by medical emergency personnel. However, FDA has recently approved a new hand-held auto-injector of naloxone to reverse opioid overdose that is specifically designed to be given by family members or caregivers. In order to expand the options for effectively and rapidly counteracting the effects of an overdose, NIDA is also supporting the development of a naloxone nasal spray—a needle-free, unit-dose, ready-to-use opioid overdose antidote that can easily be used by an overdose victim, a companion, or a wider range of first responders (*e.g.*, police) in the event of an emergency.³⁴

Research on the Treatment of Opioid Addiction. Drug abuse treatment must address the brain changes mentioned earlier, both in the short and long term. When people addicted to opioids first quit, they undergo withdrawal symptoms, which may be severe (pain, diarrhea, nausea, vomiting, hypertension, tachycardia, seizures). Medications can be helpful in this detoxification stage, easing craving and other physical symptoms that can often trigger a relapse episode. However, this is just the first step in treatment. Medications have also become an essential component of an ongoing treatment plan, enabling opioid-addicted persons to regain control of their health and their lives.

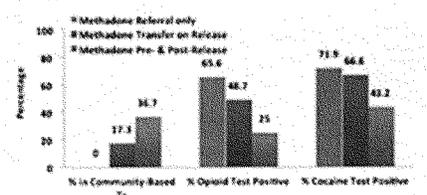
Agonist medications developed to treat opioid addiction work through the same receptors as the addictive drug but are safer and less likely to produce the harmful behaviors that characterize addiction, because the rate at which they enter and leave the brain is slower. The three classes that have been developed to date include (1) agonists, *e.g.*, methadone (Dolophine or Methadose), which activate opioid receptors; (2) partial agonists, *e.g.*, buprenorphine (Subutex, Suboxone), which also activate opioid receptors but produce a diminished response; and (3) antagonists, *e.g.*, naltrexone (Depade, Revia, Vivitrol), which block the receptor and interfere with the rewarding effects of opioids. Physicians can select from these options on the basis of a patient's specific medical needs and other factors. Research has shown methadone- and buprenorphine-containing medicines, when administered in the context of an addiction treatment

³³Community-Based Opioid Overdose Prevention Programs Providing Naloxone. United States, 2010. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. MMWR. Vol 61/No.6 February 17, 2012.

³⁴NIDA STTR Grantee: AntiOp, Inc., Daniel Wermerling, CEO.

program, can effectively maintain abstinence from other opioids and reduce harmful behaviors; we believe their gradual onset and long duration contribute to this ability to “stabilize” patient behavior.

Figure 5. Methadone Treatment Pre-and Post Release Increases Treatment Retention and Reduces drug use (Findings at 12 months Post-Release)



Scientific research has established that medication-assisted treatment of opioid addiction is associated with decreases in the number of overdoses from heroin abuse,³⁵ increases retention of patients in treatment and decreases drug use, infectious disease transmission, and criminal activity. For example, studies among criminal offenders, many of whom enter the prison system with drug abuse problems, showed that methadone treatment begun in prison and continued in the community upon release extended the time parolees remained in treatment, reduced further drug use, and produced a three-fold reduction in criminal activity (Fig. 5). Investment in medication-assisted treatment of opioid addiction also makes good economic sense. According to a 2005 published analysis that tracked methadone patients from age 18 to 60 and included such variables as heroin use, treatment for heroin use, criminal behavior, employment, and healthcare utilization, every dollar spent on methadone treatment yields \$38 in related economic benefits—seven times more than previously thought.³⁶

Buprenorphine is worth highlighting in this context for its pioneering contributions to addiction treatment. NIDA-supported basic and clinical research led to the development of this compound, which rigorous studies have shown to be effective, either alone or in combination with naloxone, in significantly reducing opiate drug abuse and cravings.

The arrival of buprenorphine represented a significant health services delivery innovation. FDA approved Subutex® (buprenorphine) and Suboxone® tablets (buprenorphine/naloxone formulation) in October 2002, making them the first medications to be eligible for prescribing under the Drug Addiction Treatment Act of 2000. Subutex contains only buprenorphine

³⁵ Schwartz, R.P. et al. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009. *Am J Public Health*. 103(5):917-22 (2013).

³⁶ Zarkin, G. Benefits and costs of methadone treatment: results from a lifetime simulation model. *Health Econ*. 14(11):1133-50 (2005).

hydrochloride. This formulation was developed as the initial product. The second medication, Suboxone, contains naloxone to guard against misuse (by initiating withdrawal if the formulation is injected). Subutex and Suboxone are less tightly controlled than methadone because they have a lower potential for abuse and are less dangerous in an overdose. As patients progress in their therapy, their doctor may write a prescription for a take-home supply of the medication. To date, of the nearly 872,615 potential providers registered with the Drug Enforcement Administration (DEA), 25,021 registered physicians are authorized to prescribe these two medications. The development of buprenorphine and its authorized use in physicians' offices gives opioid-addicted patients more medical options and extends the reach of addiction medication to remote populations.

Medication-assisted treatments remain grossly underutilized in many addiction treatment settings, where stigma and negative attitudes (based on the misconception that buprenorphine or methadone “substitute a new addiction for an old one”) persist among clinic staff and administrators. This leads to insufficient dosing or limitations on the duration of use of these medications (when they are used at all), which often leads to treatment failure and the perception that the drugs are ineffective, further reinforcing the negative attitudes toward their use.³⁷ Policy and regulatory barriers also can present obstacles.

Integrating Drug Treatment into Healthcare Settings

Medication-assisted treatment will be most effective when offered within the larger context of a high-quality delivery system that addresses opioid addiction not only with medication but also with behavioral interventions to support treatment participation and progress, infectious disease identification and treatment (especially HIV and HCV), screening and treatment of co-morbid psychiatric diseases, and overdose protection (naloxone). NIDA's research over the last two decades has provided us with evidence that a high quality treatment system to address opioid addiction must include all these components, yet there are currently very few systems in the

³⁷ Knudsen, H.K.; Abraham, A.J.; and Roman, P.M. Adoption and implementation of medications in addiction treatment programs. *J Addict Med* 2011; 5:21-27.

United States that provide this bundle of effective services.³⁸ Health care reform—with a focus on both expanding access to treatment and improving the quality of care—offers hope that we may be better able to integrate drug treatment into healthcare settings and offer comprehensive treatment services for opioid addiction. We also are examining ways to use health care reform and the focus on health promotion and wellness to pay for and deliver prevention interventions targeted at children, adolescents, young adults, and high-risk adult populations like those with chronic pain or returning veterans.

Prevention, Education, and Outreach

Because prescription drugs are safe and effective when used properly and are broadly marketed to the public, the notion that they are also harmful and addictive when abused can be a difficult one to convey. Thus, we need focused research to discover targeted communication strategies that effectively address this problem. Reaching this goal may be significantly more complex and nuanced than developing and deploying effective programs for the prevention of abuse of illegal drugs, but good prevention messages based on scientific evidence will be difficult to ignore.³⁹

Education is a critical component of any effort to curb the abuse of prescription medications and must target every segment of society, including doctors (**Fig.6**). NIDA is advancing addiction awareness, prevention, and treatment in primary care practices, including the diagnosis of prescription drug abuse, having established four Centers of Excellence for Physician Information. Intended to serve as national models, these Centers target physicians-in-

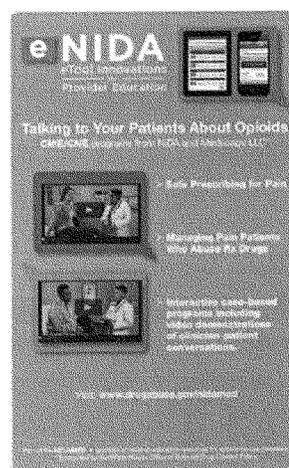


Figure 6. Medscape's Test-and -Teach is one example of NIDA's multiplatform approaches to enhance a physician's ability to properly manage pain while preventing the abuse of prescription opioids.

³⁸ National Institute on Drug Abuse. *Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition)*, NIH Publication No. 12-4180. Rockville, MD: National Institute on Drug Abuse, 2012. <http://www.drugabuse.gov/publications/principles-drug-addiction-treatment>

³⁹ Spoth et al. Longitudinal substance initiation outcomes for a universal preventive intervention combining family and school programs. *Psychology of Addictive Behaviors* 16(2):129–134, 2002.

training, including medical students and resident physicians in primary care specialties (*e.g.*, internal medicine, family practice, and pediatrics). NIDA has also developed, in partnership with the Office of National Drug Control Policy (ONDCP), two online continuing medical education courses on safe prescribing for pain and managing patients who abuse prescription opioids. To date, combined, these courses have been completed over 80,000 times. Additionally, NIDA is directly reaching out to teens with its PEERx initiative, an online education program that aims to discourage prescription drug abuse among teens,⁴⁰ by providing factual information about the harmful effects of prescription drug abuse on the brain and body.

NIDA will also continue its close collaborations with ONDCP, the Substance Abuse and Mental Health Services Administration (SAMHSA), and other Federal Agencies. It will also continue to work with professional associations with a strong interest in preserving public health. For example, NIDA recently sponsored a two-day meeting in conjunction with the American Medical Association and NIH Pain Consortium, where more than 500 medical professionals, scientific researchers, and interested members of the public had a chance to dialogue about the problems of prescription opioid abuse and to learn about new areas of research. In another important collaborative effort, NIDA, CDC, SAMHSA, and the Office of the National Coordinator for Health Information Technology reviewed eight clinical practice guidelines on the use of opioids to treat pain and developed a common set of provider actions and associated recommendations.⁴¹

Conclusion

We are seeing an increase in the number of people who are dying from overdoses, predominantly after abuse of prescribed opioid analgesics. This disturbing trend appears to be associated with a growing number of prescriptions in and diversion from the legal market.

We commend the Subcommittee for recognizing the serious and growing challenge posed by the abuse of prescription and non-prescription opioids in this country, a problem that is exceedingly complex. Indeed, prescription opioids, like other prescribed medications, do present health risks

⁴⁰ <http://teens.drugabuse.gov/peerx>.

⁴¹ CDC. Home and Recreational Safety. <http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html>

but they are also powerful clinical allies. Therefore, it is imperative that we strive to achieve a balanced approach to ensure that people suffering from chronic pain can get the relief they need while minimizing the potential for negative consequences. We support the development and implementation of multipronged, evidence-based strategies that minimize the intrinsic risks of opioid medications and make effective, long term treatments available.

Mr. BURGESS. The Chair thanks the doctor. The gentlelady yields back.

Chair recognizes Dr. Clark 5 minutes for the purposes of summary of your opening statement please. Your microphone, sir.

STATEMENT OF H. WESTLEY CLARK

Dr. CLARK. Thank you for inviting the Substance Abuse and Mental Health Services Administration to participate in this panel.

I echo the testimony of my colleagues regarding the importance of the topics of this hearing. I will focus on SAMHSA's programs and activities, but I want to point out that we work with our federal partners: with states, tribes and local communities. According to the National Survey on Drug Use and Health, which SAMHSA conducts, 4.9 million people reported non-medical use of pain relievers during the past month in 2012, 335,000 reported past month use of heroin, a figure that has more than doubled in 6 years. In 2012, more than 1.89 million people reported initiating non-medical use of pain relievers, and 156,000 reported initiating use of heroin. One challenge in combating the misuse of pain relievers is educating the public on dangers of sharing medications.

According to our national survey, 54 percent of those who obtained pain relievers for non-medical use in the past year received them from a friend or relative for free. Another 14.9 percent either bought them or took them from a friend or relative. Thus, we have both the public health problem intertwined with a cultural problem.

SAMHSA has several programs focused on educating the public, including the "Not Worth the Risk Even If It's Legal" campaign, which encourages parents to talk to their teens about preventing prescription drug abuse, our "Prevention of Prescription Abuse in the Workplace" effort supports programs for employers, employees, and their families. Our Partnership for Success grant includes prescription drug abuse prevention, as one of the capacity building activities in communities of high need. Our Screening, Brief Intervention and Referral to Treatment Program includes screening for illicit drugs, including heroin and other opioids. We have developed programs to help physicians maintain a balance between providing appropriate pain management, and minimizing the risk of pain medication misuse. Our expert medical residency program includes a module for prescription opioids for pain management and opioid misuse. Over 6,000 medical residents and over 13,700 non-residents have been trained nationally. Our physician clinical support system for Medication Assisted Treatment training is available via live in-person, live Online, and recorded modules, accessible at any time. SAMHSA funds a Prescribers' Clinical Support System for Opioid Therapies, a collaborative project led by the American Academy of Addiction Psychiatry, with six other leading medical societies. We will be funding a Providers' Clinical Support System on the Appropriate Use of Opioids in the Treatment of Pain and Opioid-related Addiction this fiscal year.

Last week's article in the New England Journal of Medicine, authored by HHS leadership, including Dr. Volkow and SAMHSA's administrator, describes the underutilization of vital medications

and addiction treatment services, and discusses ongoing efforts by major public health agencies to encourage their use.

Medication-assisted treatment includes three strategies: agonist therapy, which includes Methadone maintenance; partial agonist therapy, which includes buprenorphine; and antagonist therapy, which uses an extended release injectable naltrexone, or Vivitrol.

SAMHSA is responsible for overseeing the regulatory compliance of certified Opioid Treatment Programs which use methadone and/or buprenorphine for treatment of opioid addiction. We estimate that there are approximately 300,000 people receiving methadone maintenance. There are currently 26,000 physicians with a waiver to prescribe buprenorphine; of these, 7,700 are authorized to prescribe up to 100 patients. We estimate that there are 1.2 million people receiving buprenorphine.

SAMHSA also issued an advisory encouraging drug courts to utilize Vivitrol in their treatment programs. In August of 2013, we published the Opioid Overdose Tool Kit to educate families, first responders, individuals, prescribing providers, and community members about steps to take to prevent and treat opioid overdose, including the use of naloxone. When administered quickly and effectively, naloxone restores breathing to a victim in the throes of an opioid overdose. This can be used as a teachable moment to assess treatment need and refer the person to the appropriate resources. We inform states and jurisdictions that the Substance Abuse Prevention and Treatment Block Grant primary prevention set-aside funds may be utilized to support overdose prevention education and training. In addition, we notified jurisdictions that block grants, other than the primary prevention set-aside funds, may be used to purchase naloxone and the necessary materials to assemble overdose kits to cover the costs associated with the dissemination of such kits.

SAMHSA continues to focus on our mission of reducing the impact of substance abuse and mental illness on America's communities, and we thank the subcommittee chairman and members for convening this important hearing, and providing SAMHSA with the opportunity to address this very critical issue.

[The prepared statement of Dr. Clark follows:]



**Testimony Before the
House Energy and Commerce Oversight and Investigation Subcommittee
Hearing on
"Examining the Growing Problems of Prescription Drug and Heroin Abuse"
April 29, 2014**

Statement of H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM

Director, Center for Substance Abuse Treatment

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

Good morning Chairman Murphy, Ranking Member DeGette, and distinguished members of the Energy and Commerce Oversight and Investigation Subcommittee. My name is Dr. H. Westley Clark, and I am the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am pleased to address SAMHSA's role in preventing non-medical use of prescription opioids, and treating individuals who abuse or misuse prescription opioids and heroin.

SAMHSA's Role

SAMHSA was established in 1992 and is directed by the Congress to effectively target substance abuse and mental health services to the people most in need of them, and to translate research in these areas more effectively and more rapidly into the general health care system. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA strives to create awareness that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

SAMHSA serves as a national voice on mental health and mental illness, substance abuse, and behavioral health systems of care. It coordinates behavioral health surveillance to better understand the impact of substance abuse and mental illness on children, adults, and families, as well as the costs associated with treatment. SAMHSA helps to ensure dollars are invested in evidence-based and data-driven programs and initiatives that result in improved health and resilience.

SAMHSA applies strategic, data-driven solutions to field-driven priorities. To this end, SAMHSA helps states, territories, and tribes build and improve basic and proven practices and system capacity by encouraging innovation, supporting more efficient approaches, and incorporating research-based programs and best practices into funded programs so they can produce measureable results. In addition, SAMHSA's longstanding partnerships with other Federal agencies, Tribal governments, systems, national stakeholders, and the public have uniquely positioned SAMHSA to collaborate and coordinate across multiple program areas, collect best practices and develop expertise around behavioral health services, and, understand and respond to the full breadth of the behavioral health needs of children, individuals and families across the country.

Substance abuse, 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. SAMHSA works to focus the Nation's attention on these preventable and treatable problems.

The challenges of the non-medical use of prescription opioids as well as heroin abuse are complex issues that require epidemiological surveillance, distribution chain integrity,

interventions, prescriber education, access to effective treatment services, and further research. No organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical partners, public health administrators, 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, high school and college students, adults at high risk, older adults, and many others. Outreach to physicians as well as pharmacists needs to be complemented by education, screening, intervention, and treatment services for those misusing or abusing opioids.

SAMHSA's strategy to reduce the non-medical use of prescription opioids as well as heroin use and to assist individuals who misuse or abuse these drugs is in alignment with the Office of National Drug Control Policy's (ONDCP) four-part strategy: education for prescribers, patients, and the public; prescription monitoring; safe drug disposal; and effective enforcement. SAMHSA works across HHS through the Behavioral Health Coordinating Committee'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, the Centers for Medicare & Medicaid Services, the Office of the National Coordinator for Health Information Technology (ONC), the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Planning and Evaluation aimed at preventing and treating the non-medical use of prescription drugs. SAMHSA is also represented on the ONDCP Interagency Workgroup on Prescription Drug Abuse.

What the Current Data Show

According to the 2012 National Survey of Drug Use and Health (NSDUH), which SAMHSA conducts annually, 6.8 million people (aged 12 and older) reported nonmedical use of psychotherapeutics during the past month.¹ That equals 2.6 percent of the U.S. population. In addition, 335,000, or 0.1 percent of the population, reported past month use of heroin. Although the total number reporting heroin use is significantly lower than reported nonmedical use of psychotherapeutics, the numbers have been increasing fairly steadily since 2007 -- both for past month use, as well as past year use. In fact, past month heroin use has more than doubled in six years, going from 161,000 in 2007 to 335,000 in 2012.²

¹Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

²Id.



Preventing Opioid and Heroin Misuse and Abuse

SAMHSA prevention programs address opioid abuse. In fact, preventing and reducing the non-medical use of prescription drugs are specific goals of SAMHSA's Prevention of Substance Abuse and Mental Illness Strategic Initiative.

The Strategic Prevention Framework - Partnerships for Success (SPF-PFS) grant program, one of SAMHSA's prevention initiatives, requires grantees to build capacity in communities of high need to address one or both of two national priorities: underage drinking among persons aged 12-20 and prescription drug misuse and abuse among persons aged 12-25. Also, the Fiscal Year (FY) 2014 Request for Application for the SPF-PFS program alerts applicants that they can choose a third area of focus which may include preventing and reducing heroin abuse. In addition, the President's FY 2015 Budget proposes a new \$10 million initiative to combat the non-medical use of prescription drugs, "The Strategic Prevention Framework Rx," for the prevention of prescription drug misuse and abuse in high-priority age groups (including young- and middle-aged adults) through education and prevention. This new program is to be implemented in collaboration with the CDC's prescription drug abuse efforts.

SAMHSA also supports the "Not Worth the Risk, Even If It's Legal" education campaign, which encourages parents to talk to their teens about preventing prescription drug abuse. Another educational program, "Prevention of Prescription Abuse in the Workplace," is designed to support workplace-based prevention of misuse and abuse of prescription drugs for employers, employees, and their families.

In addition, SAMHSA recognizes the significant role of the states and jurisdictions in meeting the challenge of substance abuse. Therefore, SAMHSA has indicated to states and jurisdictions that Substance Abuse Prevention and Treatment Block Grant (SABG) primary set-aside funds may be utilized to support overdose prevention education and training.

Finally, SAMHSA's third National Prevention Week (May 18-24) is dedicated to increasing public awareness of substance abuse and mental health issues. The activities scheduled for May 20th are specifically dedicated to the prevention of prescription drug abuse and marijuana use.

Prescriber Education

The high degree of diversion of prescription medications is also of great concern. According to 2011-2012 NSDUH data, 69 percent of those who used pain relievers non-medically in the past year obtained them from a friend or relative.³ About 82 percent of those relatives or friends obtained their medications from one doctor.

A recent study using NSDUH data studied the different sources used by low-risk opioid users versus high-risk users. The lowest-use/lowest-risk group, which made up 63.9 percent of the sample group, obtained opioids from multiple sources. However, the highest-risk/highest-use group of opioid users was more likely to obtain opioids from a physician's prescription or from a drug dealer than were the other two user/risk groups.⁴ Therefore, education must be directed toward physicians and prescribers, as well as communities – and must address the cultural phenomena surrounding medication sharing.

SAMHSA has developed a series of medical education courses designed to help physicians provide appropriate pain management while minimizing the risk of pain medication abuse. Although these courses focus on pain medications, they teach skills that apply to all medications that can be abused. In addition, SAMHSA has partnered with Boston University School of Medicine and the Massachusetts Board of Medicine to develop a series of online courses on prescribing for pain. The courses are available 24/7 to any physician or other health care provider in any state, at no cost. More than 25,000 certificates of completion have been issued since the inception of this program. In a follow-up survey of the 2012 course, more than 76 percent of the respondents said they either have changed the way they practice or are in the process of making such changes as a result of what they learned. SAMHSA also offers live Continuing Medical Education courses in partnership with state health departments, medical societies, medical licensing boards, medical schools, and state Prescription Drug Monitoring Programs (PDMPs). In addition, SAMHSA has developed special courses for the Indian Health Service, community health centers, and U.S. military hospitals. More than nine thousand physicians and other health professionals have completed a live course offered at one of 50 sites in 28 states.

SAMHSA supports training in the use of buprenorphine for the treatment of opioid substance use disorders via the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT). Training is available via live in person, live on-line and recorded modules accessible at

³Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁴Jones, C.M., PharmD, MPH; Paulozzi, L.J., MD, MPH; Mack, K.A, PhD (3/4/2014), Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008-2011, *JAMA Internal Medicine*. Retrieved from <http://archinte.jamanetwork.com/> by a Health Services Research Library User on 03/21/2014

any time. This same support system provides a variety of training opportunities on more advanced topics related to medication assisted treatment with buprenorphine to physicians and other health professionals. An important feature of PCSS-MAT is the mentorship it provides for individuals entering the field of addiction treatment with buprenorphine.

SAMHSA also funds the Prescribers' Clinical Support System for Opioid Therapies (PCSS-O). PCSS-O is a collaborative project led by American Academy of Addiction Psychiatry with the six other leading medical societies. Program tools focus on the safe use of opioids in treatment of pain, including training on how to recognize non-medical, abuse, and dependence in those with pain. PCSS-O has also introduced an iPhone Application that brings together evidence-based resources that are currently available to clinicians in safe and effective use of these medications.

Prescription Drug Monitoring Programs

In 2011, SAMHSA initiated the Enhancing Access to PDMPs Project to improve access to PDMPs and to reduce prescription drug abuse, misuse and overdose in the United States. The project is funded by SAMHSA and managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. Pilot programs have tested new ways to integrate and provide clinicians access to PDMP data, including connecting through a Health Information Exchange (HIE) and looking at how data can be sent in near real-time from a pharmacy to the PDMP. The program also focuses on creating and disseminating messaging to PDMP stakeholders, especially prescribers and dispensers. The current phase of the project launched in October 2013 and focuses on bringing together PDMP and Health IT stakeholders to establish a standardized approach to retrieving prescription drug data from PDMPs and delivering that data to health IT systems for authorized health care providers to use to inform clinical decision-making.

SAMHSA's Cooperative Agreements for Electronic Health Record (EHR) and Prescription Drug Monitoring Program (PDMP) Data Integration and Interoperability Expansion awarded funds in FY 2013 to seven states to integrate their PDMPs into EHRs and other health information technology systems. The purpose is to increase the use of PDMPs by facilitating the secure and timely transmission of prescription drug information to prescribers, dispensers, and other entities. The major goals of the program are: (1) to improve the quality of prescription drug information available to healthcare providers by integrating PDMP data into existing technologies (e.g. EHRs, HIEs); and (2) support real-time access to prescription drug information by integrating PDMP data into existing clinical workflows. Additionally, for the first cohort grantees, they are required to strengthen state PDMPs by increasing interoperability between states.

Treatment of Individuals with Prescription Opioid and Heroin Addiction

The abuse and misuse of opioids is a complex issue. The challenge cannot be met unless those needing treatment receive it. However, according to the 2012 NSDUH, only 10.8 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received

treatment at a specialty facility.⁵ The challenge cannot be met unless those needing treatment receive it. However, according to the 2012 NSDUH, only 10.8 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received treatment at a specialty facility.⁶

Of all the barriers reported to receipt of treatment, the largest is the lack of recognition that treatment is needed. The 2012 NSDUH data show that 94.6 percent of those identified as needing treatment for dependence or abuse of an illicit drug did not receive that treatment because they did not feel they needed it.⁷ Another 3.7 percent felt they needed treatment but still did not seek it. And, even for those who seek treatment there are significant barriers. Foremost among those barriers are lack of health coverage and inability to pay for treatment— reported by NSDUH at 48.3 percent in 2012.⁸ These data, however, were collected before the Marketplaces established by the Affordable Care Act were opened and before most states that are choosing to expand Medicaid did so. Of those respondents who indicated they had not sought treatment, 17.4 percent were worried that treatment might have a negative effect on their jobs or might cause their neighbors or communities to have a negative opinion of them. Other barriers reported included not knowing where to go for treatment (8.9 percent), not having any or convenient transportation (8.2 percent), and not having the time (7.1 percent).⁹

SAMHSA's Treatment Episode Data Set tracks substance abuse treatment admissions and discharges at facilities that receive public funding. Of the 1.8 million admissions to treatment (aged 12 and older) reported by TEDS in 2011, 465,000 (or 25 percent) involved opioids as the primary substance of abuse.¹⁰ An additional 117,000 admissions involved opioids as the secondary or tertiary substance of abuse. Three and a half percent of those served by SAMHSA's substance abuse treatment grant programs report heroin as their primary substance of abuse at intake. Although this figure may appear low, heroin is the fourth most reported drug — after alcohol, marijuana, and cocaine. An estimated 7.7 percent report abuse of a wide range of psychotherapeutics, including benzodiazepines, Oxycontin/oxycodone, Percocet, morphine, barbiturates, etc. This number represents an increase in primary opioid admissions from 2001, when they represented 18 percent. Heroin represented 88 percent of all primary opioid admissions in 2001 but declined to 60 percent in 2011. Admissions for primary heroin abuse were fairly steady over this time period -- representing 16 percent of total admissions (aged 12 and older) in 2001 and 15 percent in 2011. However, an increase in primary heroin admissions has occurred between 2007 and 2011, following a previous decline. Primary admissions for other opioids (including pain relievers and misused methadone) increased from two percent in 2001 to 10 percent in 2011. Those admitted to treatment for injection heroin use reported that they had

⁷Id.

⁸Id.

⁹Id.

¹⁰Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2001-2011. National Admissions to Substance Abuse Treatment Services*. BHSIS Series S-65, HHS Publication No. (SMA) 13-4772. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

been using heroin an average of 9.9 years before first admission. As troubling as this figure is, it is actually down from 2001, when the average of years of use before treatment was twelve.

TEDS data also report that in 2011 a majority of admissions to treatment for heroin and other opioid use reported using an average of two substances. The most reported substances in addition to the primary opioid use were marijuana, alcohol, cocaine, and tranquilizers.¹¹ According to the NSDUH, in 2012, among the 17 million heavy drinkers aged 12 or older, 31 percent were current drug users. Twenty-three percent of past month cigarette smokers (aged 12 and older) reported current use of an illicit drug, and 40.7 percent of adults with past year substance use disorder had a co-occurring mental illness in 2012. However, of those 8.4 million adults with co-occurring substance use and mental health disorders, only 7.9 percent received both mental health care and specialty substance use treatment.¹²

For those addicted to opioids medication-assisted treatment (MAT) is an evidence-based method of treatment.¹³ However, TEDS reports that the inclusion of MAT in the management plan for primary heroin admissions declined from 36 percent in 2001 to 27 percent in 2011. This may be attributed to the availability of buprenorphine in the non-specialty treatment setting, from which TEDS data is not collected.

SAMHSA is responsible for overseeing the regulatory compliance of Opioid Treatment Programs (OTPs). OTPs must maintain certification with SAMHSA in order to operate. SAMHSA cooperates with state level and local agencies, the Drug Enforcement Administration and approved accrediting organizations to accomplish this. OTPs provide medication assisted treatment and counseling services for opioid use disorders using either methadone or buprenorphine. OTPs provide these medications directly to their respective patients. Currently there are 1,311 OTPs in operation.

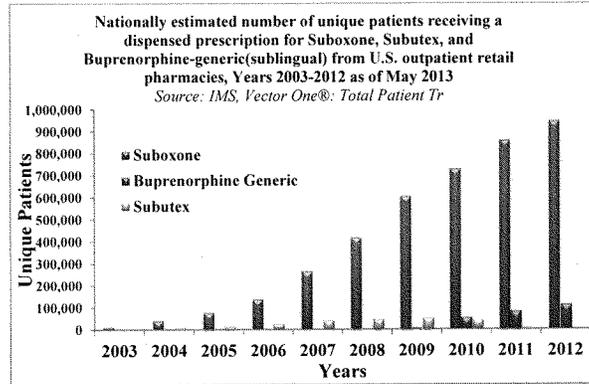
In accordance with Drug Addiction Treatment Act of 2000 (DATA 2000), physicians wishing to treat opioid use disorders with buprenorphine in a practice setting not subject to the regulations which apply to OTPs, such as a private practice or non-OTP treatment program, must request a waiver from SAMHSA. Initially physicians are restricted to treating a maximum of 30 patients at a time. After one year of experience with buprenorphine, physicians may choose to request SAMHSA increase their patient limit to 100. SAMHSA coordinates both of these steps with the DEA. There are currently 26,143 physicians with a waiver to prescribe buprenorphine for opioid dependence. Of these, 7,745 are authorized to treat up to 100 patients. By way of comparison there are currently more than 850,000 physicians registered with the DEA to prescribe controlled

¹¹ Id.

¹² Id.

¹³ 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.

substances who are also eligible to seek a waiver allowing them to treat opioid use disorders with buprenorphine in a practice setting not subject to the regulations which apply to OTPs. Nonetheless, the existing complement of waived physicians treated almost 900,000 patients with buprenorphine/naloxone combination medication in 2012.¹⁴



One program that has focused activities on clients with opioid addiction is SAMHSA's Pregnant and Postpartum Women's (PPW) initiative. SAMHSA encourages the PPW grantees to accept women with opioid addictions into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering medication-assisted treatment to their clients on-site while the women are closely monitored and provided the medication as clinically appropriate. This allows women to remain in treatment longer, resulting in healthier births.

In SAMHSA's criminal justice programs – including those in the re-entry program – grantees are allowed to use up to 20 percent of their grant awards for medication-assisted treatment, or MAT. SAMHSA's Screening, Brief Intervention and Referral to Treatment (SBIRT) program provides screening for illicit drugs, including heroin and other opioids (including prescription opioid medication abuse). To date, more than two million patients have received screening – with approximately 12 percent receiving a brief intervention, brief treatment, or referral to treatment. Realizing the importance of including behavioral health in medical school curricula, SAMHSA funds the SBIRT Medical Residency training programs. Each of the medical residency grant programs includes prescription opioids and/or pain management/treatment modules. To date, 6,141 medical residents and 13,686 nonresidents have been trained. Nonresidents include physician assistants, psychologists, social workers, and other health care professionals.

¹⁴ IMS, Vector One®: Total Patient Tr.

The President's FY 2015 Budget proposes an additional \$20 million for a new program, the "Primary Care and Addiction Services Integration" program, which will enable substance abuse treatment providers to offer a full array of both physical health and substance abuse services to clients.

Opioid Overdose Prevention

SAMHA has also developed tools to help educate first responders about naloxone. When administered quickly and effectively, 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 and equip their personnel with naloxone as a means of improving response. SAMHSA has communicated to SABG grantees that, at the state's discretion, block grant funds – other than primary prevention set-aside funds – may be used to support first-responder naloxone initiatives.

Also, SAMHSA recently published an Opioid Overdose Toolkit to educate individuals, families, first responders, prescribing providers, persons in recovery from substance abuse, and community members about steps to take to prevent opioid overdose and to treat overdoses (including the use of naloxone). The toolkit is available for download from the SAMHSA website. SAMHSA continues to promote the availability of the toolkit through various social media outlets to reach a wide range of populations.

On April 2, SAMHSA sent a letter to state agencies that administer the SABG to clarify that, at a State's discretion, SABG funds (other than primary prevention set-aside funds) may be utilized to purchase naloxone (Narcan®) and the necessary materials to assemble overdose kits and to cover the costs associated with the dissemination of such kits.

Finally, SAMHSA recently alerted the treatment community and the general public that since the beginning of the year a marked increase in deaths reportedly linked to the use of heroin contaminated with the drug fentanyl has been noted. Fentanyl is a form of opioid and when used in combination with heroin can rapidly cause respiratory depression that can lead to respiratory arrest and even death.

Conclusion

As I stated earlier in my testimony, prescription opioid and heroin abuse is a complex issue. It requires a concerted effort by many. SAMHSA's prevention and treatment strategies to address drug misuse and abuse are both targeted specifically to the drugs themselves and to programs that support prevention, intervention, and treatment of substance abuse disorders, which can have a significant long-term impact on this serious public health problem. Through these and other educational and public service activities, SAMHSA continues to focus on our mission of reducing the impact of substance abuse and mental illness on America's communities.

Thank you for this opportunity. I welcome any questions that you may have.

Mr. BURGESS. The gentleman yields back.

The Chair now recognizes Mr. Rannazzisi 5 minutes for the purposes of summarizing your testimony please, sir.

STATEMENT OF JOSEPH T. RANNAZZISI

Mr. RANNAZZISI. Thank you, Chairman Burgess, and distinguished members of the subcommittee. On behalf of DEA Administrator, Michele Leonhart, and the men and women of the Drug Enforcement Administration, I want to thank you for the opportunity to discuss today the relationship between prescription opioids and heroin, and how DEA is addressing the public health problem.

First, let me say that the present state of affairs is not a surprise. DEA has been concerned about the connection between the rising prescription opioid diversion and abuse problem, and rising heroin trafficking use for several years. The DEA believes that increased heroin use is driven by many factors, including the increase and the misuse and abuse of prescription opioids. The signs have been there for some time now.

Law enforcement agencies across the country have been reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opioids. Treatment providers report that opioid addicted individuals switch between prescription opioids and heroin, depending on price and availability. Non-medical prescription opioid use, particularly by teens and young adults, can easily lead to heroin use. Heroin traffickers know all this, and are relocating to areas where prescription drug abuse is on the rise.

To give you an example, we know that many teens and young adults first get their prescription opioids for free, from medicine cabinets or friends. Let us assume that a teenager gets hydrocodone, a Schedule III prescription opioid, and also the most prescribed drug in the United States, from a family medicine cabinet or friend. Once that free source runs out, it could cost as little as between \$5 and \$7 a tablet on the street, but then the teen will eventually need more opioid to get the same effect that he is trying to achieve. Black market sales for prescription drugs are typically 5 to 10 times their retail value. On the street, a Schedule II prescription opioid can cost anywhere from \$40 to \$80 per tablet, depending on the relative strength of the drug. These increasing costs make it difficult to continue purchasing, especially for teens and young adults who don't have steady sources of income. Given the high cost to maintain this high, the teenager turns to heroin at a street cost of generally \$10 a bag. The teenager gets a high similar to the one he got when he abused prescription drugs. It is just that easy.

Any long-term solution to reduce opioid abuse must include actions to address prescription drug diversion and misuse, while also educating the public about the dangers of non-medical use of pharmaceuticals, educating prescribers and pharmacists and treating those individuals who have moved from misuse and abuse to addiction.

The DEA currently operates 66 tactical diversion squads in 41 states, the District of Columbia and the Caribbean. These groups capitalize on combined law enforcement authorities of task force of-

ficers and DEA agents to conduct criminal investigations in the diversion of pharmaceutical drugs. The DEA regulates more than 1.5 million registrants. DEA diversion groups concentrate on the regulatory aspects of enforcing the Controlled Substances Act, utilizing increased compliance inspections. This oversight enables DEA to proactively educate registrants, and ensure that DEA registrants understand and comply with the law.

The tactical diversion squads and the diversion groups have brought their skills to bear on what was previously known as ground zero for prescription drug use, Florida-based Internet pharmacies and pain clinics. As the current pill mill threat is driven out of Florida and moves north and northwest, DEA will continue to target the threat with the tactical diversion groups' proven law enforcement skills, the diversion groups' regulatory expertise, and by educating registrants.

DEA and our law enforcement partners have aggressively targeted both prescription drug diversion and heroin trafficking. From 2001 to 2012, there has been a staggering increase in drug analysis of opioid pain medications, 275 percent for oxycodone, 197 percent for hydrocodone, and 334 percent for morphine. There has also been a significant increase in heroin cases. From 2008 to 2012, there was a 35 percent increase. If the data for the first half of 2013 remains constant, the increase from 2008 to 2013 would be approximately 51 percent.

The increase in heroin abuse and trafficking is a symptom of our country's appetite for prescription opioids that will eventually lead to abuse and addiction. It is a natural progression from the abuse of prescription opioids.

There is a dangerous misperception that abusing prescription drugs is safer than abusing heroin. Both abuse of prescription opioids and heroin can lead to addiction and death. Preventing the availability of pharmaceutical controlled substances to non-medical users, and educating practitioners, pharmacists, and the public about pharmaceutical diversion, trafficking and abuse are priorities at DEA. As such, DEA will continue to work in a cooperative effort with other federal, state, and local officials, law enforcement, professional organizations, and community groups to address this epidemic.

Thank you for your invitation to appear today, and I look forward to answering any questions that you may have. Thank you.

[The prepared statement of Mr. Rannazzisi follows:]



Department of Justice

STATEMENT OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

“EXAMINING THE GROWING PROBLEMS OF PRESCRIPTION DRUG AND HEROIN
ABUSE”

PRESENTED ON

APRIL 29, 2014

TESTIMONY OF DEPUTY ASSISTANT ADMINISTRATOR JOSEPH T. RANNAZZISI
OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
U.S. HOUSE OF REPRESENTATIVES
APRIL 29, 2014

INTRODUCTION

Chairman Murphy, Ranking Member DeGette, and distinguished Members of the Committee, on behalf of Drug Enforcement Administrator Michele M. Leonhart and the men and women of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the epidemic of pharmaceutical controlled substance abuse, specifically the relationship between prescription opioid diversion, misuse and abuse and heroin trafficking and use. DEA and other agencies have been concerned about the connection between prescription opioid diversion, misuse and abuse and rising heroin trafficking and use for several years.

According to the most recent National Survey on Drug Use and Health (NSDUH), there were 335,000 current heroin users in 2012, more than double the number in 2007 (161,000). The DEA believes the increased heroin use is driven by many factors, including an increase in the misuse (e.g., using more than medically indicated or using in a manner not medically indicated) and abuse (i.e., using in order to feel the psychoactive effects of the drug) of prescription psychotherapeutic drugs, specifically opioids. Increases in heroin purity and availability, the low street cost of heroin, expanded Mexican Drug Trafficking Organizations' involvement in the distribution of heroin, and the lack of public awareness of the risks of heroin use are also important contributing factors.

BACKGROUND

There has been some speculation that action to curb prescription drug diversion and non-medical use somehow "diverted" attention from the ongoing problem of heroin use and paved the way for abusers and traffickers to abandon prescription drugs in favor of heroin. However, the cycle of drug abuse is not that simple. To be sure, heroin use steadily increased as prescription drug abuse became an epidemic in this country. The problem of prescription drug abuse has increased exponentially in the last 15 years due to a combination of excessive prescribing, drug availability through friends and family, Internet trafficking, rogue pain clinics, 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—all of which fueled illicit access at the expense of public health and safety.

At the outset, it is important to note that the non-medical use of prescription opioids and heroin use can lead to addiction and death. We know that more than 16,000 people lost their lives in 2010 to overdoses involving prescription opioids. These deaths represent not just a statistic, but our family members, friends, neighbors and colleagues who join others who lost their lives to heroin as well as a myriad of other drugs.

The extent of the lives lost to illicit and licit drug overdoses must be put into context. Recently, the Centers for Disease Control and Prevention (CDC) reported its analysis revealing that 38,329 people died from a drug overdose in the United States in 2010.¹ Nearly 60 percent of those drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about three of every four pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.²

The cycle of abuse between licit and illicit opioids requires us to recognize that what these individuals and communities are facing is not a heroin *or* a prescription drug problem. It is an *addiction* problem. Heroin use and prescription drug abuse are both addictions that begin with use and are sustained and promoted through increased trafficking. This serious public health problem can be addressed by education, appropriate screening and treatment, recovery support, and enforcement. These initiatives can be effective regardless of whether the problem is fed by heroin or prescription drugs. The DEA supports all of these initiatives to address both prescription drug misuse and abuse and heroin use.

ABUSE OF PHARMACEUTICAL CONTROLLED SUBSTANCES

According to the 2012 NSDUH, 6.8 million people over the age of 12 used psychotherapeutic drugs for non-medical reasons during the past month. This was higher than the users reported in 2011, but similar to the number of users reported between 2005 and 2010. This represents 29 percent of illicit drug users and is second only to marijuana in terms of popularity. There are more current users of psychotherapeutic drugs for non-medical reasons than current users of cocaine, heroin, and hallucinogens combined.

¹ Drug Overdose in the United States: Fact Sheet. www.cdc.gov/homeandrecreational/safety/overdose/facts.html (accessed Marc. 18, 2014).

² Naloxone is an opiate antagonist that can rescue individuals who have overdosed on an opiate. Introduction of naloxone into the victim immediately reverses the affects of the opiate and can save a patient from the overdose. Naloxone is currently available as an injectable, however, police departments in several areas of the country such as Quincy, Massachusetts and Suffolk County, New York are using a nasal naloxone delivery method that is administered by police officers who are certified to carry and utilize the drug under established protocols. Police first responders generally arrive on the scene of an overdose well before emergency medical service personnel and in overdose situations, every second counts. The quicker that naloxone is administered the better chance for patient survival.

In 2012, 156,000 persons aged 12 or older used heroin for the first time within the previous 12 months, which was similar to estimates from 2007 to 2011. However, this was an increase from annual initiates during 2003 (92,000) and 2006 (90,000). Among recent initiates aged 12 to 49, the average age for first-time heroin use was 23.0 years, which was similar to the 2011 estimate (22.1 years).³ Notably, a special analysis by the NSDUH indicates that 81 percent of heroin initiates between the ages of 12 and 49 in 2008-2010 had previously used pain relievers non-medically.⁴

Non-medical prescription opioid use, particularly by teens and young adults, can easily lead to heroin use. Black-market sales for prescription controlled substances 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 III prescription drug and also the most prescribed drug in the country)⁵ can be purchased for as little as \$5 to \$7 per tablet. Stronger drugs like oxycodone combinations (e.g., Percocet, a schedule II drug) can be purchased for as little as \$7 to \$10 per tablet. Even stronger prescription drugs are sold for as much as \$80.00 per tablet or more in the case of the previous formulation of OxyContin 80 mg, and \$30.00 to \$40.00 per tablet for 30 mg oxycodone single entity immediate release or the 30 mg oxymorphone extended release. These increasing costs make it difficult, especially for teens and young adults, to purchase in order to support their addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Not surprisingly, some users of prescription opioids turn to heroin, a much cheaper opioid, generally \$10 per bag, which provides a similar “high” and keeps the drug seeker/abuser from experiencing painful withdrawal symptoms. This cycle has been repeatedly confirmed. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opioids.

Healthcare providers and the victims they treat are confirming this increase. According to some reporting by treatment providers, many individuals addicted to opioids will use whichever drug is cheaper and/or available to them at the time. Individuals addicted to opioids are anecdotally known to switch back and forth between prescription opioids and heroin, depending on

³ Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health.

⁴ Gfroerer, Joe and Muhuri, Pradip. Association between nonmedical pain reliever use and heroin initiation. Presentation at ONDCP Interagency Meeting on Heroin. June 28, 2012.

⁵ On February 27, 2014, DEA published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) 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 and as supported by the DEA’s own evaluation of relevant data. This NPRM proposes to impose the regulatory controls and sanctions applicable to schedule II substances on those who handle or propose to handle hydrocodone combination products. The NPRM is available on the DEA’s website, www.dea.usdoj.gov. Members of the public are invited to submit comments or request a hearing. Electronic comments must be submitted, or written comments postmarked, by 11:59 p.m. Eastern Time on April 27, 2014. Requests for hearings must be submitted by March 31, 2014.

price and availability. Abusers who have recently switched to heroin are at high risk for accidental overdose. Unlike with prescription drugs, heroin purity and dosage amounts vary, and heroin is often cut with other substances, all of which could cause individuals with less tolerance to higher potency opioids to accidentally overdose.

A HOLISTIC APPROACH TO NON-MEDICAL PRESCRIPTION DRUG USE, DIVERSION AND AVAILABILITY

Non-medical drug use cannot be addressed through law enforcement action alone. The Office of National Drug Control Policy's 2011 Prescription Drug Abuse Prevention Plan, a multi-pronged approach that includes education, tracking and monitoring, proper medicine disposal, and enforcement is a science-based and practical way to address this national epidemic.

Education

The DEA educates the registrant population, including pharmacy personnel, as well as parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the prescription drug diversion problem, and how to best address prescription drug diversion in communities throughout the United States.

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; to date, 34 separate PDACs have been held in 16 different states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. In addition, the DEA Office of Diversion Control routinely makes presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and non-medical use of pharmaceutical controlled substances.

DEA also established the Distributor Initiative Program in 2005 to educate registrants 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 CSA, as well as provides registrants with current trends and “red flags” that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer.

Monitoring

Prescription drug monitoring programs (PDMPs) are typically State-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMP programs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other forms of diversion. Currently, 48 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). Additionally, DEA makes its registrant database available to any state, without a fee, for use in their PDMP, or other state agency charged with investigating healthcare fraud or controlled substance diversion. 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.

Medication Disposal

Another factor that contributes to the increase of prescription drug diversion is the availability of these drugs in the household. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users, accidental ingestion, or illegal distribution for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for treatment. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to use these medications non-medically. Removing household medication that is unwanted or no longer needed is a key component to limiting the availability of and access to these drugs by children and drug seekers for non-medical purposes.

DEA has responded to this problem by coordinating, every six months, Nationwide Prescription Drug Take-Back Days with our Federal, state, local, and tribal law enforcement partners. Prescription drug take-back days are convenient opportunities for the public to safely dispose of unused, unwanted or expired medications. Since September 2010, DEA has held seven Nationwide Prescription Drug Take-Back Days. On October 26, 2013, the most recent Nationwide Take Back Day, 647,211 pounds (324 tons) of prescription medications were collected from members of the public. Collectively, the seven Nationwide Take Back Days have removed a total of 3.4 million pounds (1,733 tons) of medication from circulation. The eighth national take-back day is scheduled for April 26, 2014.

In addition, DEA is fully engaged in ensuring proper disposal of controlled substances and is developing a final rule implementing the Secure and Responsible Drug Disposal Act. The Act authorizes DEA to promulgate regulations allowing additional ways for Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner. DEA's goal is to implement the Secure and Responsible Drug Disposal Act of 2010 by expanding the options available to safely and securely collect pharmaceutical controlled substances from ultimate users for purposes of disposal, to include: take-back events, mail-back programs, and collection receptacle locations. With the final regulations on the horizon, the DEA hopes that all Americans will be able to remove unwanted controlled substances more readily from their households, thereby helping to reduce diversion and the public health concerns regarding these substances.

Enforcement

Over the past several years, DEA has uncovered two types of illegal schemes used to divert powerful and addictive controlled substance pharmaceuticals. Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into the illicit marketplace across the United States. Between 2005 and 2009, the diversion of millions of dosage units of schedule III hydrocodone products was facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing these sites. The *Ryan Haight Online Pharmacy Consumer Protection Act* that took effect in April 2009 responded to the explosion of domestic rogue internet pharmacy diversion. This law, combined with intensified law enforcement and regulatory actions, virtually eliminated domestic-based rogue internet pharmacies that were involved in internet distribution of prescription opioids.

As the number of domestic, Internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida.⁶ Instead of hydrocodone combination products, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a schedule II controlled substance that is just as dangerous as hydrocodone combination products when taken for a non- medical use. There was a sharp increase in pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties) in 2009. According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. They then would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and the Midwest.

⁶ In addition, the amount of heroin seized at the South West border increased over 300 percent from 2008 to 2013.

Not unexpectedly, increased diversion leads to increased enforcement activity. The National Forensic Laboratory Information System (NFLIS) collects results of drug chemistry analyses conducted by Federal, state, and local forensic laboratories across the country. As such, NFLIS can provide detailed analytical results of drugs seized by law enforcement, including trends in the diversion of pharmaceutical controlled substances into illegal markets. As of December 2013, 49 state laboratory systems, 96 local laboratory systems, and one territorial laboratory system were participating in NFLIS. In 2012, an estimated 1.6 million drug analysis records were reported to participating NFLIS state and local laboratories. The increase in opioid pain medication analyses conducted by NFLIS-reporting laboratories from 2001 to 2012 is staggering: 275 percent for oxycodone; 197 percent for hydrocodone; and 334 percent for morphine.

DEA intelligence reveals that heroin trafficking organizations are relocating to areas where non-medical use of prescription drugs on the rise. Correspondingly, NFLIS shows an increase in the heroin cases and reports⁷:

NFLIS Estimates						
	2008	2009	2010	2011	2012	Jan - Jun 2013
Heroin Reports	95,879	112,153	110,393	119,765	131,624	74,049
Heroin Cases	73,562	83,535	82,385	88,924	99,830	55,744
Total Reports	1,711,763	1,758,505	1,713,360	1,660,216	1,622,435	770,851
Total Cases	1,290,363	1,297,735	1,274,383	1,218,161	1,189,089	578,034
% Heroin Reports	5.60%	6.38%	6.44%	7.21%	8.11%	9.61%
% Heroin Cases	6.92%	7.95%	8.04%	9.24%	10.72%	12.25%

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 TDS’s from 37 to 66. With the expansion of TDS groups across the United States, the number of diversion-related criminal and administrative cases has increased significantly.

⁷ In NFLIS, a “case” is a law enforcement investigation; a “report” is an analysis of an exhibit pertaining to an investigation. There are typically many reports in a single case.

Enforcement: Diversion Groups

When the DEA was established in 1973, DEA regulated 480,000 registrants. Today, DEA regulates more than 1.5 million registrants. The expansion of the TDS groups has allowed Diversion Groups to concentrate on the regulatory aspects of enforcing the Controlled Substances Act. DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; importers; exporters; 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 Controlled Substances Act and its implementing regulations.

The TDS's and the Diversion Groups have brought their skills to bear on Florida-based pain clinics and as the pill mill threat is driven out of Florida and moves towards the north and northwest, DEA will continue to target the threat with the TDS groups' proven law enforcement skills, the Diversion Groups' regulatory expertise, and by educating registrants.

CONCLUSION

Non-medical prescription opioid use is a major factor contributing to the increase in heroin trafficking and use throughout the United States. Any long-term solution to reduce non-medical opioid use must include aggressive actions to address prescription drug diversion while educating the public about the dangers of the non-medical use of pharmaceuticals, educating practitioners on methods of diversion and trends of non-medical pharmaceutical use, and treating those individuals with substance use disorders. The increase in heroin use and non-medical prescription opioid use and trafficking leads to addiction. Preventing the availability of pharmaceutical controlled substances to non-medical users and educating practitioners and the public about pharmaceutical diversion, trafficking and abuse are priorities for the DEA. As such, DEA will continue to work in a cooperative effort with other Federal, state, local, and tribal officials, law enforcement, professional organizations, and community groups to address this epidemic. The DEA and our Federal, state, local, and tribal law enforcement and regulatory counterparts are attempting to control the diversion of prescription opioids into the illicit marketplace, as well as controlling the rise in heroin use. The increase in heroin use derives, in part, from the non-medical use of prescription opioids and the addiction made possible by abuse and availability. DEA and its partners will continue to address this epidemic through a holistic approach.

Mr. BURGESS. The gentleman yields back. I thank the gentleman for his testimony.

We will now hear from the members for questions, 5 minutes for each member.

I will begin.

Well, Mr. Rannazzisi, you just gave some rather startling statistics. Mr. Botticelli, you said in your testimony we can't arrest our way out of this problem. So let me just ask you, from a federal perspective, we have put a lot of money and a lot of effort on behalf of taxpayers into this, what is it about this that is not working?

Mr. Botticelli, we will start with you, and maybe we can just go down the line and just answer the question, how has this become the problem that it is?

Mr. BOTTICELLI. Sure. I think a number of my Federal panelists have articulated some of the problems, and I think, first and foremost, a lot of this issue is driven by the vast overprescribing of prescription pain medication. A recent report by the GAO showed that the vast majority of physicians get little to no training in substance use disorders and little to no training in safe opioid prescribing. And a part of our—

Mr. BURGESS. Let me stop you there because this is not a new problem. I mean this was a problem 40 years ago when I was in medical school, and I would disagree with the statement that we got no training, but OK, the training may not be adequate to the scope of the problem, but honestly, can we say that this is something that just happened to us, and we were completely unaware that this was an issue? I mean how could you possibly make a statement like that?

Mr. BOTTICELLI. I think part of what the balance has been, and I think it has been out of kilter, is that physicians, quite honestly, were pushed in terms of making sure that we adequately treated pain in the United States. And we absolutely need to make sure that we do that. I think we need to have a balanced strategy that understands the tremendous addiction potential of these drugs, the risky patients that we have before us in terms of who should be prescribed prescription medication, as well as monitoring those who are developing a problem.

So I do think that this is a balanced approach in terms of both making sure that we are adequately treating pain, but we are also not inadvertently creating a problem by overprescribing these medications to people who are developing a problem, or who are at risk.

Mr. BURGESS. I don't want to put words in his mouth, but Mr. Rannazzisi seemed to imply that we are overprescribing. Is that a fair assessment of your testimony?

Mr. RANNAZZISI. I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing. Actually, they are prescribing illegally, they are not overprescribing, they are illegally prescribing.

So, yes, if you are considering that overprescribing, yes.

Mr. BURGESS. Well, that is your job. You are law enforcement, so you get to close them down, right?

Mr. RANNAZZISI. And we are trying. They are overwhelming us with numbers.

Mr. BURGESS. All right, I do want everyone's response to that because in the interests of time and wanting to keep to the 5-minute interval, I am going to submit that in writing to each of you.

I want to bring up something because each—or several of you have brought it up, and that is the issue of making naloxone much more available. Maybe we should also be talking about making Ambu bags available for people who are going to overdose. I mean it is hard to know who is going to overdose, but, Mr. Botticelli, you brought it up, and I think, Dr. Sosin, you brought it up as well, but what is the issue here with making this available?

Mr. BOTTICELLI. I think that we have been tremendously heartened, both at the Federal level, as Dr. Volkow talked about, in terms of the approval of new delivery devices for doing that. One of the main areas that ONDCP has been working with our state partners is the passage of state legislation to look at naloxone distribution. And so I think we have now 17 states that have enacted naloxone distribution legislation, which I think has really been helpful here.

We have also been, quite honestly, working with many law enforcement agencies across the state—

Mr. BURGESS. Pardon me for a moment. It is a federally controlled substance, is it not? Naloxone?

Mr. BOTTICELLI. It is not a controlled substance, if I remember correctly.

Mr. BURGESS. OK. Is there a cost issue?

Mr. BOTTICELLI. There is a cost issue, and one of the things, Chairman, that you asked is what are the opportunities that we have in terms of looking at this, and again, I think it was really helpful that SAMHSA looked at how we might use existing Federal funds, but I think if there is an area that we can continue to explore together it is how we might enhance resources for many overdose prevention efforts.

One of the things that I have heard as I have traveled around the country is that having state legislation and having these devices is a great start, but many states and local areas are under-resourced in terms of implementing it.

Mr. BURGESS. Yes, and again, I may submit that in—for answer in writing as well, but, Dr. Volkow, let me just ask you. You mentioned in your testimony to address this problem, we have to recognize the special character of this phenomenon, and part of which is that opiates play a key role in relieving suffering. So as providers and policymakers, are we doing a good job of walking this line?

Dr. VOLKOW. Based on the numbers, I don't think we can say we are, and the reality is that in this country, we have both an under-treatment of pain and over-prescription of medications. These are not exclusive. And one of the issues that we have been faced with, and Mr. Botticelli had been discussing is, in 2000, when the Joint Committee for Accreditation of Hospital demanded that you treat pain, you see a steep increase in the number of prescriptions. So what you are doing in parallel, there has not been an increase in education in medical schools. So each 7 hours average in the

United States there is a diversity of opiate medications that are currently available, and there are many indications where actually patients are being given the opioids when it is not severe pain, and this, for example, is the case in many cases for young people with dentists that are prescribing the opiate medication, so there is a room for improvement on that education of providers.

The other issue too that we have not understood very much when we were—I mean certainly, when I was in medical school, they will tell you if you prescribe an opioid medication with someone that is suffering from pain, they are not going to become addicted. Now, we can come to recognize that it is not the case, that there are patients that are taking the medication as prescribed, and they can become addicted. So the issue is who are they, how do we recognize them so we can prevent that transition. And——

Mr. BURGESS. Well, and my time has expired. I will just offer the observation, 40 years ago, I was given the admonition by a professor in anesthesiology, this stuff is so good, don't even try it once. So clearly, it was known 40 years ago.

I recognize Mr. Welch for 5 minutes for questions please.

Mr. WELCH. OK, I want to thank the panel and the Chairman as well.

You know, in Vermont, as I mentioned in my opening statement, we are just trying to face this directly, which is, I think, a much better approach than denial, and it has engaged the community in some very effective ways. And it has developed—I think it has helped our providers develop what they call a Hub and Spoke System where there is an emphasis on medication, which really does seem to be helping some folks who are willing to be helped, and then some wraparound treatment services for people who can benefit by that. And a lot of our ability to do that is because we are getting some federal help. We get about \$6 million out of the Substance Abuse Prevention and Treatment Block Grant. That has been level funded. And my question really to Mr. Clark, can you explain the decision, I guess this is the Administration decision not to propose an increase in that program, given the intensity of the crisis. And I think with this discussion occurring all around the country, obviously, you are going to have many more states that are willing to roll up their sleeves and try to get engaged, which would suggest the resource need is there in order to help make this successful.

Dr. Clark?

Dr. CLARK. Mr. Welch, we are working very closely with state authorities, with organizations like NASADAD and NASMHPD to address these issues, but we also, as Mr. Botticelli pointed out, are approaching this from a comprehensive approach rather than simply using a single funding mechanism to address the issue. We need to keep in mind that we need multiple strategies to address this problem, and with those multiple strategies, we believe that we can make an impact. So relying, indeed, on the Affordable Care Act and other strategies, we can leverage the Block Grant Funding to target this.

We are also allowing jurisdictions to prioritize using our prevention efforts, as well as our treatment efforts. The problems that they are experiencing——

Mr. WELCH. All right.

Dr. CLARK [continuing]. In their respective jurisdictions—

Mr. WELCH. OK, thank you. No—but no more money. Money is tight, I get it.

And, Mr. Botticelli, your predecessor came up and had a great visit with us in Vermont. It was tremendous to have him there. And we have expanded the use of naloxone—how do you say that?

Mr. BOTTICELLI. Naloxone.

Mr. WELCH. Naloxone. Yes, and we have had some success with that. We have had a number of instances of it being used successfully just recently about 15 times.

But do you think that the FDA should consider making that an over-the-counter medication?

Mr. BOTTICELLI. Yes. So, first of all, like you, I really want to applaud you and Governor Shumlin in terms of calling significant attention to this issue. I spent the better part of my career in Massachusetts, and am very familiar with—

Mr. WELCH. Right.

Mr. BOTTICELLI [continuing]. The heroin issue that we have had in New England for a long, long time.

Our office, as part of our prescription drug abuse plan and overdose, has been looking for continued ways to expand the use of naloxone. Again, I think we are heartened by this delivery device. Our partners at NIDA are looking at and researching the expansion of and use of other ways. So we are having conversations with both Federal partners and, quite honestly, some external stakeholders who are really, really interested in terms of looking at how do we increase the—not only the availability of naloxone, but continue to promote easier to use and, quite honestly—

Mr. WELCH. OK.

Mr. BOTTICELLI [continuing]. Perhaps some cheaper versions of—

Mr. WELCH. Right.

Mr. BOTTICELLI [continuing]. Naloxone.

Mr. WELCH. I have time for one more question.

Dr. Volkow, I want to ask you about this issue with doctors and with patients. I have known close friends who have had serious medical issues and have been in a lot of pain, and once that line is crossed where they are getting the prescription medication, it almost seems like there is an undertow where the answer to the pain question always is essentially to get more medication and more powerful medication. And a patient in that moment is pretty vulnerable. And the doctor gets really persistent advocacy by the patient and sometimes the patient's family. You have got to do something. So how do we help the doctors deal with what, Dr. Burgess, of course, we have another doctor here, but how do they, there are a lot of doctors around here, but how do we—the doctors really have to be on the frontline, and it is very tough because they have a patient who is in pain, they have a family who is saying will you do something, but the something that is getting done in many cases is resulting in long-term problems.

Dr. VOLKOW. Yes, and you are touching on one of the hardest issues to deal with clinically: how do you manage severe chronic pain. What many people don't know is that the risk of suicide for

patients with chronic pain is double that of the general population, so it is extraordinarily debilitating. And the strongest medication we have are opioids. The problem with opioids, apart from addictiveness, is that you become tolerant very rapidly, and so that requires that you increase the dose. So chronically, and then you have to shift to something more potent, and that is exactly where the whole problem lies around. They are not ideal, but it is what we have, and it can relieve the patients in the moment that they need them.

The strategy is what other alternatives we can use other than just relying as—in opioids as the only alternative, and that is where research is ongoing to see—that is what I was mentioning in the whole area of brain neuroscience, the feasibility of devices that can actually be used potentially to handle and manage pain will be a breakthrough. You will rely less on medications. And I also think the aspect of we as a society have created the expectation that anything that is wrong with you should be treated with a medication. So zero tolerance for pain. And I think that as a culture, we need to revision that also.

Mr. WELCH. Thank you.

I yield back. Thank you very much.

Mr. GINGREY [presiding]. Thank you, Mr. Welch.

And I am sitting in, obviously, for Dr. Burgess. Let me just make a brief statement, and then I will ask my question.

As a physician of many years, I don't think that even back in the day we were given the proper training in regard to pain medication. Also I will say this, there has been a lot of emphasis over the past 10 years or so about advanced directives and the necessity for that, and, of course, the hospice programs that have developed and that sort of thing, but I don't hear hardly any discussion about patients given their wishes in regard to how they want their pain controlled in a terminal situation where there is no chance for recovery. I don't know that people really understand, and in many instances pain medication is started because the family members don't want their loved one to suffer. That is quite natural and appropriate, but before you know it, the patient has gone beyond the stage where they can say, look, I don't want to be totally zonked out at the time of my demise. So that is just, I guess, food for thought in a way.

I am going to ask my specific question, Mr. Rannazzisi. You said earlier in your testimony that the DEA is just getting overwhelmed by all these rogue pain clinics that are popping up everywhere. How is that happening? How do these places just pop up, as you put it, and why is it happening, why are you getting overwhelmed?

Mr. RANNAZZISI. Well, that is a great question, sir. It is not just DEA that is overwhelmed. Our state and local counterparts are overwhelmed. Think about this. Prior to the Ryan Haight Act, the Internet drug bill that was passed, there were, say, seven clinics—pain clinics in Broward County, in 2010 there were 142 clinics in Broward County. Now, if you look, when we moved our enforcement groups down there, and we moved 10 tactical diversion squads to work with our state and local counterparts, and we started knocking off these rogue pain clinics, they moved up into Georgia. If you looked at the 75 corridor, there were over 100 pain clinics.

ics going up that 75 corridor. Some of them were right off of the interstate. You just get off and get back on. Then they moved into Tennessee. Tennessee now has approximately 300 clinics.

Now, if you think that—state and local law enforcement and DEA doesn't have the capacity to go after every one of these clinics quickly, because these are legal drugs that they are peddling, and we have to establish that that doctor is prescribing outside the usual course of professional practice, and not for legitimate medical purposes. It takes time. These cases take time. So what they are doing is they are just counting on the fact that they are going to run the clinic that is not being hit by DEA. So we are all overwhelmed, everyone in law enforcement.

Mr. GINGREY. Yes, but what percentage would you say of these clinics are fraudulent?

Mr. RANNAZZISI. In Florida, the vast majority of them. In Georgia, I believe that the vast majority of those clinics that popped up were. There are good pain clinics, don't get me wrong. Every pain clinic is not bad.

Mr. GINGREY. Yes.

Mr. RANNAZZISI. But the pain clinics that we are looking at are absolutely atrocious. There is no medical care.

Mr. GINGREY. Yes.

Mr. RANNAZZISI. It is the modern-day crack house.

Mr. GINGREY. Thank you for that answer.

And any of you could answer this. Last year, GAO, the Government Accountability Office, found an overlap in 59 of the 76 programs it identified in the drug abuse and prevention area. What steps are any of your agencies taking to minimize overlap and more efficiently spend out taxpayer dollars? I mean you would think that we could get some efficiency here. Anybody?

Mr. BOTTICELLI. Sure, Chairman. Our office has looked at that report and has been working with our Federal partners to look at the breadth of our prevention programs, and to make sure that we are not, quite honestly, duplicating programs.

I do think that, however, if you talk to many, many people at the local level, they will tell you, however, that we don't have enough prevention, and I think you heard from many, many folks up here that while we may have programs that are addressing the same issue, they are reaching not the entirety of the population. So we really want to make sure that, one, that we are not kind of duplicating the programs that we have already—

Mr. GINGREY. Well, very important, I would think that you guys are talking to each other, of course. Others? I have a little time left, 2 seconds, 1 second. Wait a minute, I am the chair now, aren't I? I have 5 minutes left. Mr. Clark?

Dr. CLARK. Well, as—

Mr. GINGREY. Dr. Clark, excuse me.

Dr. CLARK. One of the things we are concerned about in the Administration is the issue of fragmentation, overlap, and duplication, and that we do work very closely with our federal partners to make sure that we minimize fragmentation, overlap, and duplication. And working under the assistance of ONDCP, we are able to address that.

As was pointed out, communities need multiple resources, and you find that sometimes you cannot completely eliminate some overlap because, indeed, the unique issues of individual communities require that there be some overlap, but we are very sensitive to both the GAO concerns and OMB's concerns about fragmentation, overlap, and duplication, and assiduously try to avoid that.

Mr. GINGREY. Thank you all. I thank the panel. My time has expired, and I yield 5 minutes now to Mr. Lujan.

Mr. LUJAN. Mr. Chairman, Doctor, thank you so very much for the time today, and I am glad to see that we are having this hearing. This is important. By the chairman and the committee staff acknowledging that this hearing needed to take place, I think we are acknowledging there is a problem across the country.

The question after this hearing today though is, are we going to sweep this under the rug again, or are we going to do something significant with recommendations that are going to come from experts?

This is a problem plaguing America. The case in New York brought more attention to what was happening with heroin abuse and overdoses, but we have been losing lives across the country for years. And what are we going to do? There are recommendations that have been put on the table by many experts. It has been studied over and over and over. There is a program from 2011 on the prescription drug side to reduce abuse significantly over 5 years, I will be asking the question where are we with that, but every life that is lost as a result of this is one life too many.

There are only so many parts of the world that are growing poppies. Do we not know, as the United States of America, where poppies are being grown and how they are migrating into the United States in the form of heroin and illegal substances? Seems to me we should. And what are we doing to stop that flow? That is very troubling.

Now, going back to the prescription drug side, there have been presentations that we have seen in New Mexico that have been put together by some people that I respect very much, that show a correlation with drug overdoses with increased prescriptions that are coming out, not just pain medication facilities that are popping up. And so one of the questions that I have is, is there data that is reported to any of you that you do analysis on, where there is a court—at least with the data that I have seen, there is—it is shown that there is a correlation between overdoses and increased prescriptions that are being administered, and what do we do with that data? Are we able to go in or is that an area where we don't have enough support now between the federal and the state partners? And I would ask anyone that would like to tackle that.

Dr. SOSIN. Thank you, Congressman Lujan.

You mentioned a New Mexico report. Dr. Paulozzi from CDC worked with scientists in New Mexico and health department staff there to analyze and demonstrate those relationships, and absolutely, there is a very tight relationship between the volume of opioid prescribing and opioid overdose deaths. That information does get used at a national level, and thinking about the areas to intervene, but also at the state and local level where it has to be, to better understand how the problems in each individual jurisdic-

tion, and the factors that are influencing the prescribing practices are being addressed there.

One of the ways that CDC in particular works is by trying to liberate data by working with state and local health departments to understand the context of prescribing, of health system data, and of mortality data, to put a better picture and understand the context within which overdose deaths are occurring and abuse is occurring, and then be able to target programs like through their PDMP's, like restriction programs, et cetera, that address those problems.

Dr. VOLKOW. If I may, first of all, I want to thank you for bringing up that issue because the way that I view it, this is an urgent issue and we cannot put it under the rug, under no conditions. And I feel passionate because I do get the parents coming to me and say when we went to wake up our child, it was dead, and we didn't even know that they were abusing opioids.

The other issue is that we do have the tools to actually address the problem of opioid prescription abuse and opioid deaths. We need to implement them. We have treatments that work for drug addiction that can decrease the number of overdoses, but also we need to address the problem that we have with chronic pain in this country. How many people suffer chronic pain in this country? Estimated IOM, 100 million. 100 million. There is the notion on that 100—that there is an increase in chronic pain, and that needs to be addressed. So from the healthcare perspective, we need to address it.

Mr. LUJAN. And, Dr. Volkow, as my time expires, there are some questions that I will be submitting in to the record, but I would welcome your response as well.

And, Mr. Chairman, I just wanted to share with you that there is a program in New Mexico that appears to be working with the distribution of Narcon, where there has been a reversal of more than 250 overdoses last year, where they are getting it into the hands of first responders and nurses. So it is not necessarily on the street, but it is with those that are responding to these accidents. And there may be a way for us to work on that with some ideas down the road.

Mr. Chairman, again, I share, before you return to the hearing, how much we appreciate that you are doing this and you have brought this hearing, but I certainly hope that there is more that will be done, and that this hearing won't be the last of hearings and conversations, and an approach that we can take as a Congress to work with our state partners to do something. This is a bad problem across the country, but it is also plaguing New Mexico. And I thank you for your attention to this, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentleman, and does also observe that further hearings are likely to be necessary, and as Mr. Welch pointed out, to hear from governors, and I would like to hear from some of our mayors because they are on the first lines of this battle.

The Chair now recognizes the gentlelady from North Carolina, Mrs. ELLMERS, 5 minutes for questions please.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you to our panel for being here today, addressing this very important issue.

I would like to start by asking a question of Mr. Botticelli and Dr. Volkow.

Understanding the path of addiction, there is, and I think you have both identified a genetic basis for that, one of the things I would like to know is, again, the progression. Is this something that starts with tobacco use, smoking, use of alcohol, drinking, and then how does it progress and how do you feel? And I will just start with you, Mr. Botticelli, and then have Dr. Volkow comment.

Mr. BOTTICELLI. I do have to acknowledge that just about everything that this field knows about this has come from the work of Dr. Volkow.

Clearly, we know that there is a genetic predisposition for many people in terms of family history of substance abuse, but we also know that there is, like many diseases, there are environmental factors that go into that issue.

We know that substance use disorders are a disease of early onset, so that many people who do develop, left untreated, left undiagnosed, develop a substance use disorder, largely because of starting alcohol, tobacco and/or marijuana use—

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. At a very young age. Clearly, there are some particular issues as it relates to the addiction potential of prescription drug medication—

Mrs. ELLMERS. Yes. Yes.

Mr. BOTTICELLI [continuing]. But the vast majority of people that, at least, I have talked to, and the data show that those folks who do have a significant opioid use disorder have started from a very young age. And if you saw the Philip Seymour Hoffman story, he actually started with alcohol abuse at a very young age. So we know that there are prevention and intervention opportunities that we can have along the way to really make sure that we are identifying people early in their disease progression, and then we are intervening in this issue.

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. The other piece that you talked about, and again, I think it still warrants further work, is what about the progression from prescription drug use to heroin addiction.

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. Clearly, we know that it is a progressive disease, and people, left untreated, will often progress to more significantly harmful use patterns, but we also know that price plays a role, as the DEA mentioned, in terms of the progression. So we know that there are multiple factors that really affect peoples' progression, not only in terms of overall development of a substance use disorder, but from prescription medication to heroin.

Mrs. ELLMERS. Yes. Yes. Dr. Volkow?

Dr. VOLKOW. Yes, and the questions you ask intrigue many scientists, and it is called—has led to the term of gateway—

Mrs. ELLMERS. Right.

Dr. VOLKOW [continuing]. Hypothesis because all of the epidemiological studies have repeated corroborated that most individuals that become addicted to illicit substances started with nicotine or alcohol, then transition into marijuana and then the other drugs.

So the question is that just because it is more accessible that you start with nicotine or alcohol—

Mrs. ELLMERS. Yes.

Dr. VOLKOW [continuing]. Or could it be that these drugs, including nicotine, alcohol, and marijuana, are changing your brain in such a way that it makes it more receptive to the addictiveness of drugs.

Mrs. ELLMERS. Yes.

Dr. VOLKOW. And there is data now from genetic studies and from studies in animals that suggest, at least for the case of nicotine and alcohol, and also marijuana, that it is changing the sensitivity of the brain reward sequence in a way that primes you—

Mrs. ELLMERS. Yes.

Dr. VOLKOW [continuing]. To the addictiveness of these other drugs. And in the case of prescription opioids, that is also what they are observing, that most of the individuals that end up addicted to prescription opioids had a history of nicotine addiction earlier, or had started abusing alcohol.

Mrs. ELLMERS. Yes. Thank you.

My last question is for Mr. Rannazzisi. Obviously, your agency is working with many other agencies on this issue, and I am going to ask you a question that really falls under the FDA, but from your opinion, in the work that you are doing, do you believe that some of the prescription drugs, the deterrent formulas such as, you know, for Oxycontin, some of the deterrent formulas, will that make a difference and is it feasible that if we take this approach, that that is going to help on the wide and broad scope that you have outlined if we are using these deterrent forms?

Mr. RANNAZZISI. Absolutely. The abuse deterrent formulations will make a difference. But those drugs will still be abused—

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Orally with a potentiator, like a muscle relaxer, or a Benzo, but in the end, it is going to stop them from crushing and snorting, or crushing and injecting.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. And we know that when you crush and inject, or crush and snort, you are raising the risk—

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Of overdose and death—

Mrs. ELLMERS. Yes. Yes.

Mr. RANNAZZISI [continuing]. Just in that method of delivery. So, yes, do I think it is important? Absolutely, it is important. Look at what happened with the Oxycontin product, when it went from the OC to OP, you could bang that tablet with a hammer and it is not going to break.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. It balls up in your nose when you try to snort it. It is crazy—

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. That, if you try to abuse that drug, but what do we see everybody doing? Immediately, they started moving to the Oxymorphone product—

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Or the immediate release Oxy 30s. OK, so they are adapting.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. If we could figure a way to get an abuse deterrent formulation across the board, then we are going to see some significant results—

Mrs. ELLMERS. Thank you.

Mr. RANNAZZISI [continuing]. Absolutely.

Mrs. ELLMERS. Thank you so much for your answers, and your insight on this issue.

And, Mr. Chairman, I yield back the remainder of my time.

Mr. BURGESS. Gentlelady yields back.

The gentleman from Kentucky, Mr. Yarmuth, recognized 5 minutes for your questions please.

Mr. YARMUTH. Thank you very much, Mr. Chairman. And I thank the panel as well for the testimony, and for what is obviously a very committed effort across the spectrum of government to deal with this problem. I am glad to know that, I shouldn't say glad, but it is somewhat reassuring to know that this is not just a Kentucky problem. Certainly, in my travels in my district and around the state, and talking with law enforcement and with mental health professionals, and everyone who is involved in this area, we have a huge problem in Kentucky. During the first 3 quarters of 2013 there were at least 170 Kentuckians who died from heroin overdoses, and that was 41 more people who had died the entire previous year, and is actually a 200-plus percent increase since 2011. So we have a problem that is there and growing.

And one of the young people who died was the nephew of a Kentucky state representative, Joni Jenkins, a good friend of mine and a great representative. Her nephew, Wes, they suspected, began with prescription drugs and then moved to heroin because of expense. He died in May of 2013. And she told her story in the Louisville Courier-Journal, and I would like to read one of the things she said because it prompts a question. She said, for an entire year, our family kept the addiction private. They were well aware of it, he had been in and out of treatment and they were working with him, but they kept it private so Wes would not suffer the social stigma of being a drug addict. I now know that there is a terrible shame attached to this illness, but we have to break through the silence to find a cure. And she said, I also know that I will search for answers the rest of my life for that.

Is this a problem that you have seen? You are nodding your head, Mr. Botticelli, so respond to that, that much of the the access to treatment or the willingness to treatment is deterred because of a social stigma?

Mr. BOTTICELLI. I have—and many of us have heard that story countless times from parents. Many of us were just in Atlanta with a conference sponsored by Chairman Rogers. And we hear that story repeatedly, and I think our collective efforts have really been to raise the visibility of ensuring that people know that addiction is a disease, and this is not about shame, this is not about guilt. We know that one of the reasons why people don't seek treatment, and why parents don't ask for help, is because of the shame and embarrassment that is related to that. And so part of what I think

all of our Federal partners are doing is how do we raise the understanding and visibility, and, quite honestly, the compassionate treatment of people with addiction—of addictive disorders into this work. And I think that we are seeing, quite honestly, a movement in terms of—like we did with other disorders that were shameful and stigmatized—

Mr. YARMUTH. Yes.

Mr. BOTTICELLI [continuing]. That we have to elevate the voice of parents and people in recovery so that we do know that hope is possible, and that it would be easier for them to come forward and ask for help, but unfortunately, we have heard that story way too many times from—

Mr. YARMUTH. Yes.

Mr. BOTTICELLI [continuing]. From parents and people who are affected.

Mr. YARMUTH. Have you come up with any great answers? I mean what can we do to help that just as individual members? We do span the country anyway.

Mr. BOTTICELLI. Yes. I think there are a couple of things that we are doing. A lot of our work at the Office of National Drug Control Policy, we actually established an Office of Recovery to really promote the fact—we are looking at the development of recovery support services, so that people in the community can see that recovery is possible. I think we have been promoting—those of us who are in recovery, talking very publicly about the fact that we are in recovery, because it shows to other people that this is not just about death and destruction, that there really is hope on the other side of this. So I think all of us play a role in terms of destigmatizing that.

Just having these hearings really shows the fact that we have leadership in this country who are concerned about this, and it is not a shame. This is not a moral choice, this is not a moral failing, this is about a disease, and we have to deal with it from a public health perspective.

Mr. YARMUTH. Yes.

Mr. BOTTICELLI. So I really appreciate your acknowledgement of that—those challenges.

Mr. YARMUTH. Well, it seems to me that much of this problem involves education. I assume that when these young people, or whether it is young or not, but predominantly young people begin on prescription drugs, they have no idea that this is the course that they could likely be on. And I don't know whether that is a school issue, a PTA issue, what it is, but it seems to me like information is one of the greatest avenues for combatting this problem.

Well, anyway, Mr. Chairman, I would request unanimous consent that this OpEd that I mentioned from Joni Jenkins be made a part of the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. YARMUTH. Thank you, and I yield back.

Mr. BURGESS. The gentleman yields back his time.

The Chair now recognizes the gentleman from Ohio, Mr. Johnson, 5 minutes for your questions please.

Mr. JOHNSON. Thank you, Mr. Chairman, and I really appreciate the opportunity to hear from the panel today on this very, very important issue.

You know, prescription drug and heroin abuse are very serious—is a very serious epidemic in Ohio, and parts of my district in eastern and southeastern Ohio are some of the worst hit.

In 2012, 5 Ohioans died every day from unintentional drug overdose with opioids, both prescription and heroin, as the driving factor. Attorney General Mike DeWine identified heroin as contributing to as many as 11 fatal overdoses a week. It is a major public health crisis. However, prescription opioids continue to be the lead contributor to fatal overdoses in the state. In 2012, for example, an average of 67 doses of opioids were dispensed for every Ohio resident.

Law makers, nonprofit organizations, medical, industry leaders, communities and parents across the state have been working to coordinate their response to this epidemic, but in a corner of Ohio that shares borders with 3 other states, communities are struggling to get drug abuse under control. Individuals identified as abusing in one state may cross state lines to escape detection and abuse in another. A nonintegrated system also makes it harder to identify prescribing providers and pill mills.

So for all of you on the panel, anyone that wants to try and respond to this, I realize that states are largely in charge of implementing their own prescription drug monitoring programs, but in multistate areas like I serve, the importance of working together to curb abuse cannot be emphasized enough. So what is being done at the federal level to encourage states to share information compiled by their respective PDMPs?

Mr. BOTTICELLI. Thank you, Congressman, and as you have articulated, both the establishment of vibrant prescription drug monitoring programs, and, quite honestly, the interstate interoperability of those programs, has been key for much of the work that we have been doing on the Federal level. So, we are happy that in 2006 we only had about 20 operable prescription drug monitoring programs in the United States, and now we have 48 that are operable, one in the process and unfortunately, one state that doesn't have a prescription drug monitoring program. And as part of this strategy, we have been working with the Bureau of Justice Assistance and the Boards of Pharmacy to really look at interstate operability so that those states that share a border can make sure that they are sharing data. So now we have 20 states that are able to share information across borders, and clearly, we have a goal of making sure that all of these programs share data among particularly neighboring states.

Mr. JOHNSON. Yes, I will share with you that, as a 30-year IT professional myself, I can tell you that architecture and data standardization, interface standards, those are very, very critical components. If you don't know where you are going, any road will get you there. And it is one thing to have a monitoring system, it is quite something else to have a monitoring system that adheres to standards so that it can be effectively used.

How do we make the nationwide PDMP system more effective, and what still needs to be done to fully achieve a fully-integrated network?

Dr. SOSIN. Congressman Johnson, thank you for your question. Clearly, the PDMP and the ability to achieve successful, effective PDMPs is critical to the law enforcement side, the public health side as well, the clinical side as well. And as Mr. Botticelli commented, we are making progress, meaning that we are better understanding the components of these PDMPs, and what it is that needs to be shared and how to share them. The work that you all are doing in raising visibility, that governors and mayors are doing, saying that this is an issue that they are going to address, also allows this opportunity to set the standards for what we need to share and how we will share that information across borders.

The CDC, working with the FDA and the Bureau of Justice Assistance, has been funding at Brandeis, the prescription behavioral surveillance system, which takes from 20 states the PDMP data they have, to better understand what these factors are that increase the success of PDMP's.

Mr. JOHNSON. Let me get to one more quick question. I have to move quickly.

How can we shift drug abuse prevention efforts from the collection of silo data like we are talking about, to a system in which this information isn't lost every time an individual realizes that they are being tracked, and takes evasive measures like leaving a health plan, for example, because not only do you have working across state lines, but an abuser that goes from one health plan to another can also hide. So how do we solve that problem?

Mr. BOTTICELLI. And some of my colleagues can add on to this, but part of what we have been really trying to focus on is make sure that we are treating and integrating substance use issues as part of mainstream healthcare, of really looking at things like making sure that people are getting screened and intervened as part of their overall health plan so that, you know, for a very, very long time, we have had two systems of care in the United States. We have had medical care over here and behavioral healthcare over here, and that we haven't necessarily really looked at how we make sure that we are treating substance use disorders as a medical condition.

So part of our goal is more thorough integration of mental health and substance use services within our primary care settings—

Mr. JOHNSON. Sure.

Mr. BOTTICELLI [continuing]. Because it is really important that we not see these as two separate issues.

Mr. JOHNSON. Yes.

Mr. Chairman, I have many, many more questions. Obviously, this is a complex and sensitive issue for many Americans, but I have run out of time so I yield back. Thank you.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back his time.

The Chair recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for your questions please.

Ms. CASTOR. Thank you, Mr. Chairman, and thank you to the panel very much.

This hearing is really hitting home for me today because yesterday I learned that the death of a friend last month was tied to her long-term opioid addiction. Her sister sent me an email, I got it just yesterday, and she committed suicide, and her sister said because of her long-term addiction. So she left a daughter and a husband and an entire family, and the sister is asking please do more. So I hope we can all come together to tackle this. It is causing so much pain for so many families.

And the State of Florida has really been at the heart of the problem. And still in Florida, they say that every 7 to 8—every—I can't believe it, 7 to 8 minutes, someone overdoses in the State of Florida. I am also hearing from my local hospitals. They have had to add rooms in the NICU units of hospitals because of babies being born addicted, and these babies typically will cost \$1 million to take care of, and they are in the hospital for a month. So we had better invest in prevention or else we are going to be spending a lot on the outside.

So, Mr. Rannazzisi, Florida—the general talking points are, well, Florida has improved. There was a huge law enforcement crackdown. We have adopted a prescription drug tracking system, the PDMP. The problem is that doctors are not using it. The last statistics I saw, only 3.5 percent of all prescriptions being written are being checked on that database.

What is your view right now in Florida? Have we made progress? What is left to do?

Mr. RANNAZZISI. I think under the leadership of Attorney General Bondi and law enforcement leaders down in Florida, yes, we have made progress, absolutely. The problem is, again, we are overwhelmed by the numbers. There are so many people down there in Florida. We actually have cases where Florida rogue pain clinic operators were funding clinics in northern states, so when when the heat is on them, they are going to move into another state.

I think that we are making progress, but again, it is going to take time. Now, the PDMP issue, I would love to see mandated PDMP use. The National Association of Boards of Pharmacy have gone out of their way to ensure that there is interoperability and interconnectivity between the PDMP's. I think they have 25 states that are already connected, and they have done a phenomenal job, but if no one is looking at that PDMP, or very few are looking at that PDMP, it is not going to help.

Ms. CASTOR. So do you agree that the local law enforcement efforts—what I see on the ground in my community, in the Tampa Bay area, we used to have these long lines with cars from out of state, people waiting outside in the alley for these pill mills to open up. You don't really see that anymore, but with these statistics on the rate of deaths from overdose, something else is happening. We are not really making a dent there. Has it shifted to the internet, are they going out of state, is it both? What is going on?

Mr. RANNAZZISI. I think they are moving to more rural areas where there is less law enforcement presence. I think the operators understand—I have a great video I would have loved to have shown you of a clinic, and what happens as soon as the clinic opens. I think that they are adapting. The clinic owners are adapting very well, and they are one step ahead of us right now, but in

the end, local law enforcement is doing a phenomenal job, and they are moving people out of the Tampa Bay area and out of the 3-county area, but it is still there——

Ms. CASTOR. Yes.

Mr. RANNAZZISI [continuing]. It is just moving to more rural areas where they can't address the problem as quickly.

Ms. CASTOR. So in this very sad e-mail from my friend that I got yesterday, she said she has read now about the FDA approval of Zohydro, pure Hydrocodone, non-tamper resistant, 10 times stronger than Vicodin, the Vicodin prescription opiate. I know that the Advisory Committee to FDA had some very serious concerns with this, yet it has been approved.

Dr. Volkow, could you give me your opinion on whether this drug should be readily available?

Dr. VOLKOW. Well, we clearly have a very large number of opioid medications, and we are overprescribing them. I wouldn't point my finger at one or the other. I do think that the feasibility of getting formulations that cannot be diverted is something that is very powerful, and the FDA should be commended because it came up—pharmaceuticals can come up with an indication for a medication that is deterrent proof, and that is incentivizing to the development of these types of medications.

Zohydro is Hydrocodone, it is slow delivery over 12 hours, and it actually does not have Acetaminophen, and because the way that you have—correctly which is Vicodin, the way that you have it is combined with Acetaminophen which produces liver toxicity, which led the FDA to consider if someone needs Hydrocodone, do you need to give them Acetaminophen, and it was in that context that they approved it——

Ms. CASTOR. And——

Dr. VOLKOW [continuing]. But——

Ms. CASTOR [continuing]. Could I ask, since my time is short, Mr. Botticelli, do you agree with the FDA's approval, or do you have concerns?

Mr. BOTTICELLI. I think the important point, and again, I don't think the FDA has their own process in terms of how they approve medications. I would agree that how we continue to make sure that we have abuse-deterrent formulations is really important. I also think that this really underscores the importance of prescribing, and training on prescribing, because I think the point is that we have many medications that are open for a potential to abuse, and we want to make sure that physicians and other prescribers really understand the risks associated with these drugs.

Ms. CASTOR. And, Mr. Rannazzisi, local law enforcement has expressed concern about this new drug on the street because it is so potent, and because it is likely, if a child takes it, it could death. What is your view?

Mr. RANNAZZISI. Yes, local law enforcement and DEA and our federal partners have all expressed. We all lived through the Oxycontin problem back in the '90's into the 2000's, and we just don't want history to repeat itself. Too many people passed from the abuse, circumventing that delivery system.

Mr. BURGESS. The gentlelady's——

Ms. CASTOR. And my——

Mr. BURGESS [continuing]. Time has expired.

The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions please.

Mr. GRIFFITH. Well, let me pick up there. You are concerned about this newer drug, and so my question is what do you all do, and I would ask it of all of you but I start with you, Mr. Rannazzisi.

Mr. RANNAZZISI. Rannazzisi.

Mr. GRIFFITH. Rannazzisi, thank you. And that would be, how do we do a better job of predicting where we are going to see spikes and abuse on drugs as they come forward, because some people say that we should have probably seen the increase in the prescription drug abuse of opioids and heroin?

Mr. RANNAZZISI. Well, we monitor the amount of drug going into a particular state through our ARCOS system, but in the end, what we generally see is the drug being abused in the Appalachian area of the country, and then it spreads out from there. So when we were looking at Oxycontin, for instance, the Oxycontin abuse epidemic started in that area, Kentucky, Tennessee, southern Ohio—

Mr. GRIFFITH. Southwest Virginia.

Mr. RANNAZZISI. Yes, southwest Virginia—well, yes, absolutely. And then spread out. And we believe that pattern is going to happen again with this new product. It is just a matter of time. We know that product is now in the pharmacies and being dispensed, so—

Mr. GRIFFITH. And, now, for the people that we—that you have identified, I think that one of the other speakers said abuse-deterrent formulations. Once we know somebody is abusing, I have always liked the lock-in, where you lock into a pharmacy and you lock into a doctor, because one of the problems in southwest Virginia that you mentioned a minute ago is, is that you can be in West Virginia, Tennessee, Kentucky and North Carolina all within—no matter where you are in southwest Virginia, within an hour or 2 hours, you can be in any one of those states because of the way the geography is, and you can go from one rural area to another.

So what are we doing on that? Are we looking at that as a possible means? Dr. Clark, if you want to answer, that is fine. I am just trying to find answers.

Dr. CLARK. Clearly, there is no simple answer, and your question is a very important one, and this committee is trying to address it. We are working with the Association of State and Territorial Health Offices, and the Federation of State Medical Boards, and the Boards of Pharmacy. We do collect surveillance data from our household survey and working with our colleagues in the CDC, so part of the issue is monitoring the movement of individuals, getting practitioners, whether they are pharmacists, nurse practitioners or physicians, to monitor what it is that they are doing. Getting people to access and actually use the PDMPs, and having interoperability, as was pointed out. So—and then involving community coalitions, because, as was pointed out from the representative from Florida, people know where the places are. And what we need to do is—

Mr. GRIFFITH. Sure.

Dr. CLARK [continuing]. To get community coalitions—

Mr. GRIFFITH. Well, that is why—

Dr. CLARK [continuing]. To carry that information.

Mr. GRIFFITH. That is kind of why I like the lock-in because then, you lock them into a doctor, into a pharmacy, if you know, now, I don't want to do that to folks who haven't been identified as having a problem, but once you know they have a problem, then that gives you a better handle on what they are doing if you lock them in and that is the only place they can go. Wouldn't you agree, and I need to hurry because I have other things I want to ask?

Dr. CLARK. That is one strategy that can be employed. So you want to make sure that if you do that, that they have access to the resources necessary to be in that—

Mr. GRIFFITH. Sure. And here is the dilemma that we have, because one of the things that the DEA is—has done, and we talked about this the last time you were here, is that they are asking the distributors to, you know, say, OK, don't sell so much to a pharmacy if that pharmacy looks like they are above the average, or if you see some sign that they may be abusing. And I told the story about what happened when I went to my local pharmacy, and there were two people in there who were both being told you have to come back next month, which was not a few—but a few days away, because we used up our allotment. And I intuited that maybe they only had 1 supplier, and then that supplier said, he's above average for other people who have more than 1 supplier. I went back and checked and that is exactly what is going on. He didn't know that was the problem, but I said, you only have one supplier, don't you? He said, yes, I use one distributor. And I think that is the problem.

So we have on the one hand, we want to lock out people who are abusing it. On the other hand, we want to make sure people who need it, get it. So I guess what I am saying in the second matter is, for the rural areas, it may be a problem because that is less law enforcement, and we recognize that, and why a lot of my region is in different HIDA designations. At the same time, you want to make sure people are getting the drugs they need, and if you are in a rural area, you are a small pharmacy, you may only be using one distributor. While the DEA doesn't have a quota, the distributor then is putting a quota on because, based on other pharmacies, that particular pharmacist or drugstore is ordering more drugs, but it is because they are only using the one supplier as opposed to using two or three.

How do we solve that problem? And I think Dr. Volkow wants in on this.

Dr. VOLKOW. Yes, I was smiling because the notion is we have situations where a patient cannot get their medication, and yet at the same time, the DEA has to collect this massive amount of pills that people are not using, which tells you we are overprescribing the number of pills that are necessary.

So coming back to the point that we have been discussing, we really need to educate the healthcare system on the optimal way of prescribing them, not just when they need them, but the number of tablets that you are given. I mean all of us have the idea, go to the dentist, 2 weeks of opioid prescriptions. I mean you need one

day. So it is the whole notion of educating the healthcare system, and educating the lay public, and making the responsibility too of—why do we need to provide so many pills. And the insurers can get involved into these type of solutions.

Dr. CLARK. And the lock-in approach works as part of a treatment plan—

Mr. GRIFFITH. That is right.

Dr. CLARK [continuing]. With someone who suffers from chronic pain, the practitioner develops a treatment plan, the patient agrees, and that actually benefits everyone.

Mr. GRIFFITH. Very good.

Mr. BURGESS. The—

Mr. GRIFFITH. I know my time—

Mr. BURGESS. The gentleman's time has expired. We will give an opportunity perhaps for a second round, but I wanted to go to Mr. Griffith because he has been waiting so long.

Mr. GRIFFITH. Absolutely.

Mr. SCALISE. Thank you for that, Mr. Chairman, and for our panelists for this important discussion. I know in my home parish of Jefferson, Louisiana, we have seen spikes in increase of drug-related deaths over the last few years, and each year it just seems to be going up higher. When I talk to my coroner in Jefferson, Gerry Cvitanovich, who works very closely in trying to, of course, they see the end result of it, but they also try to work on the front end in doing some of the education that Dr. Clark has talked about and others. They have seen that heroin is the one that seems to be popping up the most. I think last year, heroin deaths accounted for a majority of all the drug-related deaths, over 100 of those. And in my home parish of Jefferson, like I said, we are seeing this across the board.

One of the things they do work on is just trying to educate people in the community. And I know, Dr. Clark, you have talked about this in your testimony, and alluding to work with not just pharmacists but others.

What are the different things that you have been doing, and if you have had success on the education front, especially not just within the medical community, but within the targeted populations of those folks that might have the highest likelihood of being exposed to heroin?

Dr. CLARK. Again, one of the things, a comprehensive strategy becomes critical, and I talked with prevention, working with community coalitions, so that we have that message. We have already heard about the issue of chronic pain management, and people moving from the use of a prescription opioid to drugs like heroin.

So having good strategies for pain treatment, working with state health and territorial health officers, federation and state medical boards, nursing organizations, dental organizations and even veterinarians, because they, too, have access to prescription—

Mr. SCALISE. Right.

Dr. CLARK [continuing]. Opioids, we can address that end of the agenda, then—

Mr. SCALISE. Yes, I want Mr. Rannazzisi—

Dr. CLARK [continuing]. Probably—

Mr. SCALISE [continuing]. To answer this too because I know you talked about this in your testimony as well, so if you can touch on your experiences there.

Mr. RANNAZZISI. We never turn down the opportunity to go out and speak to professional organizations. We have a very good relationship, or a fine relationship with the National Association of Boards of Pharmacy, the individual pharmacist associations, and the medical associations. When they ask us, we will come out. The Pharmacist Diversion Awareness Conference, we go out and we have been to 14 states, and trained over 6,000 pharmacists in their corresponding responsibility, the trends and trafficking for pharmaceuticals, to make them aware of what is going on so they know how to deal with this when a bad prescription comes in and what they are supposed to do.

We have industry conferences. We bring industry in. October of last year, we brought the distributors in to talk about what we are seeing trendwise, and what they need to do as far as their legal obligations under the Act. We bring the manufacturers and importers in. In April or May of last year, we brought them in. And we do this on a regular basis to show the trends and trafficking. We are out there educating as much as possible because it is one of the pillars in the pharmaceutical initiative that the White House is pushing for.

Mr. SCALISE. One of the things when you talk to the people on the ground, our local, whether it is coroners, law enforcement, there are a lot of different federal programs out there, and I do want to touch on that GAO report because there are some concerning issues that they raised that have been touched on a little bit, but I want to get into a little bit more, but on that front, when you look at all the grants that are out there, I know in Louisiana, I think grants come in from five different departments through thirty different programs for some of these treatment programs. So there is a lot of overlap and duplication, but is there a better way maybe to block grant these, to put them together in a way that would be more flexible? And maybe, Dr. Clark, you can answer, are we giving states enough flexibility today and with the duplication can we do a better job and maybe consolidating those grants in a way that allow the states to do what they do best, without having to go through so many different processes, through so many different agencies, where you have this duplication?

Dr. CLARK. Well, clearly, we have to work with states and their discretion in how to prioritize what it is that they view as important epidemiologically in their jurisdiction. And so we have supported the use of block grant funds to the discretion of the states, and worked with both the individual state authorities and the national organizations associated with that.

We are also working with recovery-oriented organizations so that we have peers, people who are recovering from substance use disorders to help speak up and carry out the message, working with community coalitions and others because, indeed, they can tell a better story than professionals or regulators, et cetera. So—

Mr. SCALISE. OK, and—

Dr. CLARK [continuing]. The—

Mr. SCALISE [continuing]. And let me apologize, my time is about to go, I do want to at least ask for the record, if I can get this information on the GAO report, because it did identify, you have, what, 15 different federal agencies, 76 different federal programs that all have abuse prevention or treatment programs, and they also identified overlap of 59 of the 76 programs. And so I think Dr. Gingrey had earlier asked Mr. Botticelli and Dr. Clark to talk about what your agencies are doing to address that overlap, those problems that were identified in the GAO report.

If, Dr. Sosin, I am sorry, Dr. Volkow and Mr. Rannazzisi can also get me their information to—just to show what you all are doing to try to address the overlap problems that were raised in that GAO report.

And with that, I will—

Mr. BURGESS. Well, the gentleman's time has expired. I think that information will be generally interesting to the committee, so if the committee staff will provide that information to the committee.

Mr. SCALISE. Would you all be OK with getting that to the committee? Thank you.

Mr. BURGESS. And the Chair would recognize the gentleman from Texas, Mr. Green, 5 minutes for your questions please.

Mr. GREEN. Thank you, Mr. Chairman. And I thank the O&I Committee for having this hearing.

Prescription drug abuse is a real growing and public health threat that must be addressed. The consequences of abuse and addiction to opioids such as prescription pain relievers and heroin has a devastating effect on our communities. We need a comprehensive solution that protects public health, preserves patient access to the needed therapies, and improved access to treatment.

Last week, an article was published in the New England Journal of Medicine discussing the Department of Health and Human Services' efforts to address the prescription opioid overdose epidemic, including improving access to the addiction treatment services.

Dr. Volkow, you were one of the authors of this article, and, Dr. Clark and Dr. Sosin, the heads of your respective agencies also authored this article. The article makes clear that the treatment of addiction to prescription drugs and other opioids with proven approaches like Methadone and other medication assisted therapy is of crucial importance. It describes the importance of the Affordable Care Act in increasing access to care for many Americans, including those who are struggling with addiction disorders.

Dr. Volkow, can you elaborate on how the ACA builds on the Mental Health Parity and Addiction Equity Act, and improve on insurance coverage for people who are addicted to prescription drugs, heroin or other substances?

Dr. VOLKOW. Yes, the problem is that, as I mentioned in my testimony, is that less than $\frac{1}{3}$ of patients that require, that could benefit from opioid medications, are getting them for the treatment of their addiction. And these reflect, among other things, the fact that many of the people that are addicted to drugs do not have an insurance, and rely on the state funding to get their treatment. And as a result of that, we have removed the healthcare system for a position there—where they could not just act in preventing substance

use disorders, but on treating them. The healthcare act, by providing insurance to those that currently don't have it, will give them the opportunity to be treated in the healthcare system for substance use disorders, as well as, in those instances where the addiction has not occurred, for the healthcare system to intervene in prevention. So that is why it is so important.

Mr. GREEN. Dr. Clark, do you agree with that?

Dr. CLARK. Indeed. When people who present for treatment can't get treatment, are asked why they couldn't get treatment, the largest reason is cost and access to treatment.

Mr. GREEN. OK, thank you. I understand the ACA provision creates an optional Medicaid state plan, benefit for states to establish health homes for the coordination of beneficiaries with chronic conditions, has also supported some states in their effort to address the drug abuse.

Dr. Clark, can you elaborate on how the Health Home Program is beneficial in tackling the problem of abuse?

Dr. CLARK. Well, we have actually, with regard to opioids, we have got several jurisdictions that are looking at health homes as a way of dealing with opioids. So in Vermont, one jurisdiction, I think, Rhode Island, I will have to clarify that, is also taking that approach. Comprehensive services being offered where a person's care is adequately monitored offers us an opportunity to reduce some of the complexities associated with opioid misuse.

Mr. GREEN. Thank you. It is clear from the comments the Affordable Care Act makes it possible for many people with substance use disorders, whether it is addiction to prescription drugs, heroin, or other substances, to access the treatment they so desperately need.

Mr. Chairman, I know we have had our differences over the Affordable Care Act, but I would hope we all share the goal of providing more robust treatment to those who are working to overcome this addiction.

And I yield back my time.

Mr. BURGESS [presiding]. The gentleman yields back. Our discussion with the Affordable Care Act will continue at a later date.

Mr. GREEN. I am sure it will.

Mr. BURGESS. We have now I think heard from all members who wanted to ask a question. I would ask unanimous consent that a follow-up question be allowed for those of us who remain.

Mr. GREEN. I don't have any problem with that. I can't stay, but—

Mr. BURGESS. Very well, but I wanted to get that unanimous consent agreed to before you left, so it is not just on my shoulders.

Mr. GREEN. I trust the Chairman.

Mr. BURGESS. Mr. Griffith, I interrupted you before. Would you like to follow up on your line of questioning?

Mr. GRIFFITH. Well, I would just like to give an opportunity, Mr.—

Mr. RANNAZZISI. Rannazzisi.

Mr. GRIFFITH [continuing]. Rannazzisi.

Mr. RANNAZZISI. Yes.

Mr. GRIFFITH. Thank you. I am sorry I have such a hard time with that this morning. But Mr. Rannazzisi was about to comment

on the dilemma that we have with the small rural pharmacists, or pharmacy, that has one distributor.

Mr. RANNAZZISI. Yes, and I want to thank you for clarifying that DEA has not set a quota downstream for the distributors.

The distributors are working through their issues regarding due diligence to determine if there is a problem pharmacy or if it is not a problem pharmacy. I think that the rural pharmacies present a specific problem because they do need to get medication to their patients, and they need that downstream supply. We are hoping that the distributors are on site, looking at their operations before they completely cut off the distributor, or limit the pharmacy, but again, that is a business practice and, unfortunately, I have no control over their business practices.

Mr. GRIFFITH. Well, and I would just say it is because of the concerns and I am sure some memos have been put out by the DEA, we are all trying to do the right thing, that has caused the distributor to be concerned, and maybe if there could be some acknowledgement from the DEA to the distributors, hey, keep an eye out if it is rogue, but if it is just you are looking at, you know, this pharmacy is more than another pharmacy, find out if they have just one distributor because that makes a huge difference in whether or not they are truly distributing more of the opioids than somebody else. And if you all could do that, that would be greatly appreciated.

Mr. BURGESS. The gentleman yields back. I thank the gentleman for his follow-up.

Dr. Volkow, you made a statement that was really fairly provocative a few moments ago, and I just wanted to follow up on it a little bit with you when you were discussing the effect of nicotine, alcohol on developing—I guess you were talking about developing brains and then you added the—with the addition of marijuana, and I ask you not to say anything about the rightness or wrongness of the public policy, but as you know, this nation is right now engaged in a significant experiment where some states have legalized marijuana. Are you all studying that and the effect of this decriminalization in some states? Are we prepared for what might happen next?

Dr. VOLKOW. Yes, definitely. I know, unfortunately, it is one of those experimental situations that is happening, whether we like it or not. So what we have done is provided, identified the grantees, the researchers, in those communities where there has been legalization for recreational or medical purposes to actually give them supplemental money so that they can look at the consequences of these changes in policy, in the education of systems, in accidents, in emergency room admissions, in productivity in the workforce. We need to have evidence that can then—hopefully can guide policy, as opposed to doing policy in darkness on the beliefs of people, and what—since you brought up the issue, to one of the things that is also a concern as discussing the prescription, people are using prescriptions because they feel that are prescribed by physicians, they cannot be so harmful.

The notion that marijuana has so-called medical purposes is also changing the perception of this drug cannot be so harmful if it has medicinal properties. And the whole perception of risk is changing,

which, again, has opened the willingness of young people to take marijuana and to consume it regularly.

Mr. BURGESS. Well, I do hope that you are monitoring the situation, since society has provided you the experimental situation. I also hope that you are preparing to deal with what the downstream effects are from this rather bold social experiment that some of the states are undertaking right now. And I hope that is more than just sending more money to those states. I hope that it is something that you are—that oversight is happening at your level, that there will be a national monitoring of this.

Dr. VOLKOW. The way that we oversee research protocol is very, very rigorous. If the scientist is not producing or the methodology is not adequate, we do not fund them.

Mr. BURGESS. Just speaking of downstream effects, there is also the issue, and it has been brought up several times this morning, and any of you feel free to comment on this, the issue of, of course, the device by which the drug is administered, and then the possibility for exposure to Hepatitis B or C, or HIV. From a public health perspective, are we preparing ourselves for any differences in the incidence of these illnesses as a consequence of the delivery device?

Mr. BOTTICELLI. I will start on that. One of the main concerns of HHS has been, obviously, the increase in viral hepatitis and hepatitis C among the very young cohort of injection drug users. So we have been working in concert with the Health and Human Services who has put forth actually an action plan to diminish viral hepatitis, and clearly, there is a lot of overlap in terms of the issues that we are talking about here. So this is obviously a significant public health concern, so we want to make sure that we are dealing with this in a concerted way.

Mr. BURGESS. Yes, and, of course, the good news right now is Hepatitis C is one of those things that looks very well like there may be a cure that is not just on the horizon but is here. The only problem is it is very expensive. And my differences with Mr. Green over the Affordable Care Act aside, ultimately though, someone has to pay for that, so I hope we are doing the necessary—I hope we are monitoring and doing the necessary preventive things to keep that in check, and to prevent the disease, rather than just simply now being able to cure it with a very expensive therapy that, thankfully, is available.

Mr. Botticelli, did you have some additional observations on the issue of the states that are legalizing marijuana?

Mr. BOTTICELLI. I do, and what I wanted you to know is that in addition to the additional NIDA grants that are out there, our office has actually convened a group of Federal partners to look at the eight criteria that the Department of Justice has laid out for Colorado and Washington, and are really committed to gathering data on the Federal, state and local level, looking at what is the impact in terms of legalization in Colorado and Washington have on both the public health and public safety consequences that we have. So in addition to some of the public health-related work that Dr. Volkow has funded, we are also looking at what are the public safety consequences, things like increase in drugged driving, interstate transportation of marijuana from Colorado to other states. So

our office has really been committed in terms of ensuring that we have good public health and public safety data to monitor what is happening in Colorado and Washington.

Mr. BURGESS. And, Mr. Rannazzisi, I would assume that your agency is participating in that as well?

Mr. RANNAZZISI. It still is a Schedule I controlled substance. We are still doing investigations concerning marijuana downstream.

Mr. BURGESS. And are you monitoring the downstream effects in neighboring states, in the incidences—as Mr. Botticelli talked about, the incidence of driving while impaired, the incidence of even just crime, are you compiling those statistics so they will be available to policymakers in subsequent hearings?

Mr. RANNAZZISI. We are talking to our state and local counterparts in all of the surrounding states, and we are gathering information. I don't know how all-inclusive that information is because, quite frankly—some of the state and locals are not keeping that type of information, but we are keeping tabs with our state and locals on what is going on within their states.

Mr. BURGESS. Very well.

Mr. GRIFFITH. Mr. Chairman.

Mr. BURGESS. Yes, the Chair recognizes the gentleman from Virginia.

Mr. GRIFFITH. I would be remiss, since we have taken on marijuana, not to mention that I have just introduced a Bill to legalize the use of marijuana in medicinal circumstances, akin to the Virginia plan that was passed in 1979, that requires a doctor's prescription, thus, changing the scheduling. The Bill actually calls for the changing of the scheduling. The DEA is in a tough spot. Some of these states are doing it, but it is still a Schedule I, which means that the DEA has a hard time collecting the data that you just asked for without stumbling across felons that they are not prosecuting. So they are in a catch 22. I think it is much better to have doctors and pharmacists, and the regular system working, because then you get real data for your scientists to look at and see if it is effective, as they designed it to be.

So the Bill doesn't go as far as Colorado or Washington might want it, or the Crazy California Plan as I often call it, but it allows real doctors with real pharmacists and real distributors, controlled by and under the laws of the United States, to use true marijuana if it can be used in a real way medicinally.

Mr. BURGESS. Very good. The gentleman yields back.

I am all for giving doctors more power.

That actually concludes all of the questions that we have from members. I neglected to mention at the start of the hearing, ask unanimous consent that members' written opening statements be introduced into the record. Without objection, the documents will be entered into the record.

In conclusion, I would like to thank all of our witnesses. I will thank the member that have participated in today's hearing. I will remind members they have 10 business days to submit questions for the record, and I will ask the witnesses to all agree to respond promptly to the questions submitted in writing.

With that, the subcommittee is adjourned. Thank you for your attendance today.

[Whereupon, at 12:06 p.m., the subcommittee was adjourned.]
 [Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Three months ago, the country was shocked and saddened by the death of actor Philip Seymour Hoffman. Like many who battle addiction, Mr. Hoffman struggled to stay clean as he alternated between pain pills and heroin. His story is far too common. Opiate addiction surrounds us—from cities, rural towns, and affluent suburbs—and it breaks our heart to see so many families torn apart by abuse of drugs that are both legal and illegal.

My own district has suffered terribly from opiate overdoses. Last year, more than 90 people in Westmoreland County lost their lives to prescription drug and heroin abuse. That was four times the number of overdose deaths in the county compared to a decade ago. Allegheny County saw more than 20 deaths linked to fentanyl-laced heroin this past January.

Heroin-related deaths have increased 400 percent in Cleveland. Vermont Governor Peter Shumlin dedicated his entire annual “State of the State” address to what he called the “fullblown heroin crisis” facing his state. Kentucky, West Virginia, New Mexico, and other states are also experiencing rising rates of prescription drug overdoses and heroin abuse.

Here’s the awful truth about this public health crisis: prescription painkillers are involved in more overdose deaths than cocaine and heroin combined. Prescription drug abuse kills more than 16,000 people a year.

While most prescription drug abusers do not go on to abuse heroin, data from the White House Office of National Drug Control Policy (ONDCP) and the Substance Abuse and Mental Health Services Administration (SAMHSA) indicates that 81 percent of people who started using heroin in 2008 to 2010 had previously abused prescription drugs.

As authorities have cracked down on access to legal pain killers in the last five years, heroin use has risen by an astonishing 79 percent.

Certainly, there is a law enforcement aspect to solving this problem and stopping the bad actors who illegally distribute prescription drugs or traffic heroin. But the other part of the equation is treating addiction to prescription drugs and heroin—and preventing deaths.

The purpose of today’s hearing is to examine the federal public health response to prescription drug and heroin abuse. Our oversight has revealed that this is a complex problem. For example, 40 percent of those who abuse drugs have an underlying mental illness. Treating their addiction successfully necessarily means that the underlying mental illness must be successfully diagnosed and treated.

But just as when someone has a mental illness, those who are battling addiction are unlikely to get effective treatment, too. More than 90 percent of persons with a substance abuse disorder won’t get medical care. And of those who are enough to access care, 90 percent of them will not get evidence-based treatment.

There are effective treatments available, but too often the substance abuse debate is divided between those who adhere to the abstinence or 12-step model, and those who promote medical assistance therapies. These groups must come together and find a solution because thousands of lives are at stake.

As the testimony of Mr. Botticelli, the Acting Director of the Office of National Drug Control Policy, states, substance abuse is a “progressive disease.” Those who suffer from addiction often start at a young age, with alcohol and marijuana, and then move to other drugs like opioids. In examining opioid abuse, we must also consider the factors that lead people to abuse—and how federal programs are addressing them.

Prescribing practices are an issue. Roughly 20% of prescribers prescribe 80% of all prescription painkillers. Those suffering from chronic and debilitating pain need access to opiates, but we also need to make sure those individuals who develop an addiction are referred to treatment. Right now, too many states lack a robust prescription drug monitoring program that would help physicians and emergency rooms keep tabs on patients receiving powerful opiates.

Educating doctors and pharmacies about appropriate prescribing will address one part of the problem—but addicts also get these drugs through illegal channels, such as rogue Internet pharmacies, off the street, and even from the medicine cabinets of family members and friends.

The federal government is devoting significant resources to drug control programs—over \$25 billion annually, of which about \$10 billion goes toward drug abuse prevention and treatment programs across 19 federal agencies. With 19 agencies

having a hand in over 70 drug control programs, we have to ask, 'is our current approach working and what can we do better?' Oversight by the federal agencies is also an important issue, as significant funding is block granted to states for treatment programs. How are you confident that we are funding treatments with the best chances of success in preventing and treating opiate abuse?

The Courier-Journal (Louisville, Kentucky)

April 1, 2014 Tuesday
METRO Edition

Senate must pass bills to fight tragedy of drug addiction

BYLINE: By, Joni Jenkins

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I grew up in southwest Jefferson County and was fortunate to have the support, love and care of two great parents and four grandparents. We were taught right from wrong and we are passing those ideals to the next generations of nieces and nephews.

So, when I received a call from my brother in June 2012 saying, "Wes is addicted to heroin," my family's world skidded to a stop.

Wes, my 22-year-old nephew, was the funny, sunny baby of the family. A natural athlete, popular in school, defender against bullies, Wes was just special. When he was 5 years old, I stretched my arms out as far as I could and said, "I love you this much," and he replied, "I love you 10 percent more than you love me." He was a great kid and was becoming a great man.

Wes addicted to heroin? No way.

As a legislator, I thought I was very familiar with drug addiction; one of the very first bills I passed was the certification of drug and alcohol counselors. I had attended countless meetings on the pervasive problem of addiction in Kentucky and that year in Frankfort we addressed the proliferation of meth labs and illegal pain pill clinics through tougher laws.

So later, when law enforcement warned us about the exploding increase in heroin - a cheap alternative to the opiate prescription drugs that had become harder to buy - I was skeptical. Heroin, I thought, was so '70s.

But we were face to face with the grip heroin had on our beloved Wes, and we struggled to understand how it happened.

We believe Wes' addictive tendencies began with a prescription pain medication given after oral surgery. At the time, he worked the twilight shift at UPS and some of his co-workers were abusing opiate prescription drugs. We think Wes missed the "high" he got from the prescribed pain meds, so when his co-workers sent him - while on the clock - to purchase drugs for them and their supervisor, the perfect storm swept him up.

There were few real signs something was happening except that Wes, a legendary saver of money, began running through cash like crazy. Later we found out that when he ran low on money, his supplier introduced him to a cheaper high - heroin.

For months and months, Wes was in and out of treatment: The Healing Place, 12-step programs, The Morton Center. He would detox and stay clean for a while but the addiction would return and the cycle would repeat itself.

In the fall of 2012, he seemed to have kicked it. He was working, talking about returning to Spalding University for his business degree, and was fine at Christmas.

I thought we had made it out of the darkness. But on Easter Sunday, my brother called and said Wes was back at The Healing Place detoxing. Again, he began nightly group counseling with his parents and had individual counseling. Again, it seemed like he was back on the road to recovery.

I spent time with him during this period and I told him I loved him and would do anything to help him.

The last time I saw Wes was on Saturday, May 25, 2013. He and his dad had come over to mow my lawn while I worked in my vegetable garden. We talked about school, babies and zucchini. Wes said he wanted to make fried zucchini like he did as a kid with his older brother. Later I took a plant to his house just for him and his text to me was, "I'm excited. Thank you!"

At 4 a.m. on Tuesday, May 28, my brother called from the hospital and said Wes had overdosed and died.

Why am I sharing this private and still so painful story?

For an entire year, our family kept it private so Wes would not suffer the social stigma of being a drug addict.

I know now that there is terrible shame attached to this illness, but we have to break through the silence to find a cure. I also know that I will search for answers the rest of my life and will focus on what we can do as a state, as a community, to invest in treatment and prevention.

This session, I sponsored two bills relating to addiction treatment.

HB 240 gives greater power to family members seeking involuntary treatment by adding the definition of "incapacitated by alcohol and/or drug abuse" to the statutes. Opiate use changes brain chemistry and abusers cannot make rational decisions about their health and the risk factors. This legislation lets family members speak for them. HB240 passed the House of Representatives by a vote of 94-0.

HB 16 would help Kentucky drug and alcohol counselors assist more troubled citizens by moving their classification from certification to licensure. This change will allow licensed mental health professionals to be reimbursed by Medicaid and private insurance to comply with national changes in Medicaid and private coverage. HB16 passed the House 87-8.

HB240 and HB16 still await action in the Kentucky Senate. I rarely plead for help on legislative initiatives but I have learned through Wes' tragic death that few families are immune to the ravages of addiction and more resources are desperately needed.

Without public support, these two important bills will not become law. Worse, more Kentucky families will endure terrible loss, pain and suffering such as my family has since that phone call on May 28.

Please call your state senator at (800) 372-7181 and ask that they enact HB16 and HB240 into law.

Much like your loved one, our Wes was an amazing young person with limitless potential and we miss him every day. Your calls could help save countless lives and families caught in the agonizing grip of addiction.

Joni Jenkins represents Kentucky House District 44.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115
Majority (2021) 225-2927
Minority (2021) 225-3841

May 21, 2014

Mr. Michael Botticelli
Acting Director
Office of National Drug Control Policy
Executive Office of the President
750 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Botticelli:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 29, 2014, to testify at the hearing entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

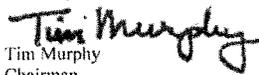
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, June 4, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
MICHAEL P. BOTTICELLI
ACTING DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING APRIL 29, 2014, HEARING ENTITLED,
"EXAMINING THE GROWING PROBLEM OF PRESCRIPTION DRUG
AND HEROIN ABUSE"
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Michael C. Burgess

- 1. Do you feel co-prescribing naloxone injectors or a naloxone injection kit with opioids would be of any use in dealing with such a large number overdoses?**

ANSWER:

Naloxone is unlikely to be the solution for every opioid overdose. For example, some people may overdose without another person available to rescue them. In addition, there are challenges with making naloxone available for use population-wide, including its being available by prescription only and the lack of immunity protections (Good Samaritan laws) in some jurisdictions for persons aiding those in the midst of an overdose. Nonetheless, even if naloxone prevents only a small percentage of overdoses, it will still benefit a large number of the more than 16,000 individuals annually who die from prescription opioid overdose. Co-prescription theoretically could benefit some people who are prescribed or dispensed prescription opioids. In considering this practice, it is important to remember that overdoses occur in a variety of populations, including but not limited to people with active substance use disorders and people under medical care for pain treatment or addiction treatment who may or may not intentionally misuse their medicines. Certain factors may put people at increased risk for opioid overdose, and thus naloxone also could be of relative benefit for them; for example, those:

- on a high dose of opioids;
- who take methadone for pain;
- with certain physical problems that affect breathing, such as sleep apnea;
- who drink alcohol or take other medicines that may interact with opioids (e.g., anti-anxiety medicines); or
- who misuse or abuse their medication intentionally.

During an overdose, naloxone administration by a family member or loved one who administers the drug as prescribed to a patient could prevent death. The Food and Drug Administration recently approved a naloxone auto-injector that can be used by third parties without medical backgrounds. Prescription of naloxone also could be valuable in many at-risk individuals who do not have current opioid prescriptions. Groups who could benefit include people in treatment for substance use

disorders with a history of opioid misuse or opioid use disorders not receiving opioid replacement medication, and other vulnerable groups, such as re-entry populations who have lost tolerance for opioids after a period of incarceration. Theoretically, prescribers could conduct an overdose risk assessment to determine the potential utility of providing naloxone; however, patients may deny having risk factors related to misuse.

The Obama Administration has long supported expanded access to naloxone by first responders, including law enforcement, to prevent deaths from opioid overdose. In many jurisdictions, policy changes to support overdose reversal by patients or their loved ones, such as immunity for those who call emergency services, will be necessary to facilitate these efforts. To raise awareness of the benefits of naloxone, Acting Director of National Drug Control Policy Michael Botticelli participated in the Food and Drug Administration's announcement of a new naloxone auto-injector formulation and also in a webinar to help elevate the issue of naloxone use within the emergency physician community.

The Honorable Jan Schakowsky

1. **What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of pop up clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and pop up clinics, so I am interested in seeing what they are doing to help us combat the crisis.**

ANSWER:

The Office of National Drug Control Policy (ONDCP) is aware that industry has participated in the following activities to combat the prescription drug abuse crisis, such as:

- Drug development for:
 - tamper-resistant formulations;
 - abuse-deterrent formulations;
 - medicines to treat substance use disorders; and
 - medicines and delivery devices to reverse overdose.
- Funding and conducting post-marketing studies required by the Food and Drug Administration (FDA) to assess the known serious risk of misuse, abuse, addiction, hyperalgesia, overdose and death associated with the long-term use of extended-release/long-acting (ER/LA) opioid analgesics;
- Financial sponsorship of the prescriber continuing medical education (CME) programs required under the FDA Risk Evaluation and Mitigation Strategy (REMS) for ER/LA opioid analgesics. These are CME programs funded by unrestricted grants from the pharmaceutical companies to accredited CME organizations that independently develop content for CME. The content for the programs is based on an educational blueprint developed by FDA.
- The National Association of Boards of Pharmacy's PMP Interconnect, which facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users has received funding from the pharmaceutical industry.

2. **What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?**

ANSWER:

ONDCP does not have access to information concerning new opioids currently under development. This is proprietary information of the companies developing these drugs. However, we do know that after a steady escalation in the number of opioid prescriptions in the past 25 years,¹ for the first time the number of opioid prescriptions did not grow significantly from 2011 to 2012 and actually dropped from 2012 to 2013.² The impact this market shift will have on prescription drug abuse is difficult to ascertain. However, given the extensive activity that has

¹ IMS's National Prescription Audit (NPA) & Vector One ®: National (VONA).

² Opioid prescriptions down, but not as much as some expected By John Fauber of the Journal Sentinel Feb. 26, 2014 <http://www.jsonline.com/watchdog/opioid-prescriptions-down-but-not-as-much-as-some-expected-b9921037221-247409631.html> (See sidebar graphic. Data analysis performed by Elbert Chu of MedPage Today.).

gone on in prescription drug abuse prevention policy at the Federal, national and state levels, newly-introduced opioids will be monitored more closely by industry, stakeholder groups, and Federal partners such as the FDA. It seems unlikely that widespread unchecked overprescribing of these new opioid drugs will occur.

Given the increased knowledge we have about the effects of opioid drugs and the extent of the prescription drug abuse epidemic, Federal agencies are, to the extent possible, using de-identified aggregated information from state prescription drug monitoring programs (PDMPs) to determine the extent of utilization of newly approved pharmaceuticals tracked in PDMPs. Depending on state law, PDMPs may be capable of alerting or serving as a resource to public health and public safety officials if prescribing trends appear concerning. However, there are challenges with respect to directly connecting prescribing rates to outcomes. For example, with few exceptions, PDMPs lack the ability to provide up-to-date data that could quickly provide information to connect negative prescription drug consequences to new drug approvals. States and Federal partners at the Department of Health and Human Services are actively working on ways to improve PDMP data accessibility and utilization for monitoring in real-time. FDA also has access to a number of databases that permit the agency to monitor prescribing and adverse drug events. In the event that FDA notices an emerging problem, it has means of recourse, such as modifying the REMS for that drug or class of drugs or requiring enhanced prescriber education activities.

Another complication is that mortality (overdose) data are delayed due to the complexities of establishing cause of death and then collecting and aggregating data from multiple jurisdictions that use different methods of data collection and analysis. Major data collection programs that were previously used for monitoring the criminal justice population (e.g., the Arrestee Drug Abuse Monitoring program) or used emergency department presentations (e.g., the Drug Abuse Warning Network) have been discontinued.

- 3. Are most of the prescription opioid drugs that are abused Schedule II drugs?
Which drugs are Schedule III? Are there more drugs that can/should be moved to
Schedule II?**

ANSWER:

The national data collection systems on drug abuse to which ONDCP has access, for example, the National Survey on Drug Use and Health and the Monitoring the Future survey, currently do not collect information regarding each of the scheduled drugs distinctly; thus, we cannot accurately categorize prescription drugs that are being abused by their schedule under the Controlled Substances Act (CSA). Questions in the current Federal surveys would need to be modified.

According to IMS Health, a company that provides healthcare information for consumers, drug companies, and government, the most commonly dispensed types of opioid-containing prescriptions in 2012, the last year for which data are available, were: hydrocodone combination products which are Schedule III (number one of all prescriptions dispensed, and all of which are included in Schedule II as of October 6, 2014, following a DEA final rule rescheduling

hydrocodone combination products to Schedule II³); tramadol (number 21 of all prescriptions dispensed in 2012 and recently controlled in Schedule IV⁴); and oxycodone products (number 22 of all prescriptions dispensed in 2012 and in Schedule II).⁵ With the rescheduling of hydrocodone combination products to Schedule II, arguably the vast majority of the most commonly dispensed opioid drugs will be in Schedule II. Tramadol was controlled in Schedule IV because its abuse potential is comparable to the schedule IV controlled substance propoxyphene and is lower than comparative drugs and products in Schedule III. We defer to DEA in regard to making scheduling determinations.

With the implementation of the final rule rescheduling of hydrocodone products as of October 6, 2014, the current opioids listed in CSA Schedule III include the following:⁶

SUBSTANCE ⁷	OTHER NAMES
Buprenorphine	Buprenex, Temgesic, Subutex, Suboxone Bunavail
“Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid.”	Codeine with papaverine or noscapine
“Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.”	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
“Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.”	Synalgos-DC, Compal
“Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one	N/A

³ Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49661 (Aug. 22, 2014).

⁴ Schedules of Controlled Substances: Placement of Tramadol into Schedule IV. 79 Fed. Reg. 37623 (Jul. 2, 2014).

⁵ For top 25 medicines by dispensed prescriptions (U.S.), see: http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/2012_U.S/Top_25_Medicines_Dispensed_Prescriptions_U.S..pdf Available at linked to 6-15-2014.

⁶ Controlled Substances - by CSA Schedule – available at http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf linked to 6-15-2014

⁷ Substances were characterized as presented in 21 CFR §1308.13 – Schedule III.

SUBSTANCE ⁷	OTHER NAMES
or more active, nonnarcotic ingredients in recognized therapeutic amounts.”	
“Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.”	Paregoric, other combination products
“Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.”	N/A
Nalorphine	Nalline

4. According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?

ANSWER:

A combination of approaches is needed to reduce the overall supply of prescription drugs in circulation. In addition to the *National Drug Control Strategy's* emphases on prevention and early intervention, the Obama Administration's Prescription Drug Abuse Prevention Plan (Plan) has a four-prong approach to addressing the prescription drug abuse epidemic:

- **Education.** A crucial first step in tackling the problem of prescription drug abuse is to educate parents, youth, and patients about the dangers of abusing prescription drugs, while requiring prescribers to receive education on the appropriate and safe use and proper storage and disposal of prescription drugs.
- **Monitoring.** Implement PDMPs in every state and enhance PDMPs to enable data sharing across state lines and maximize their use by healthcare providers.
- **Proper Medication Disposal.** Develop convenient and environmentally responsible prescription drug disposal programs to decrease the supply of unused prescription drugs in the home.
- **Enforcement.** Provide law enforcement with the tools necessary to eliminate improper prescribing practices and stop pill mills.

The data from the National Survey on Drug Use and Health, to which Dr. Clark refers, shows that approximately 70 percent of individuals misusing prescription pain relievers in the past year

report getting them from a friend or relative the last time they abused them.⁸ Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner, which reduces their availability for misuse.

Since September 2010, DEA has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold nine National Take-Back Days. Through these events, DEA has collected and safely disposed of 4.8 million pounds of unneeded or expired medications.⁹ As part of the Secure and Responsible Drug Disposal Act of 2010, DEA has published a Final Rule that will expand the safe and effective disposal of prescription drugs nationwide. ONDCP will work with Federal, state, local, and tribal stakeholders to identify ways to establish disposal programs in their communities upon completion of the rulemaking process.

However, the best way to prevent access to unneeded or expired medications from being misused is if they were not excessively prescribed in the first place. A recent evaluation of NSDUH data indicates that prescribers are a source of prescription drugs for chronic nonmedical users of prescription drugs.¹⁰ It is thus imperative to address prescriber behavior. The education prong of the Plan emphasizes mandatory prescriber education on responsible opioid prescribing practices. With proper education, it is hoped that excess amounts of opioid drugs are not provided to patients in the first place.

In addition, ONDCP manages the Drug-Free Communities (DFC) Support Program with its administrative partner, the Substance Abuse and Mental Health Services Administration. The DFC Program is a Federal grant program that provides funding to community-based coalitions that organize to prevent youth substance use. The philosophy behind the DFC Program is that local drug problems require local solutions, and community coalitions are the best vehicle for creating community change. The broad availability of prescription drugs and misperceptions about their dangers is an alarming combination. DFC-funded coalitions are expected to work with youth, parents, schools, law enforcement, business professionals, media, local, state and tribal government, and other community members to identify and address local youth substance use problems and create sustainable community-level change. Through the use of environmental prevention strategies, DFC coalitions use comprehensive approaches to address prescription drug abuse such as raising awareness for prescribers, parents, and youth; organizing prescription drug take back events; and developing systems for safe disposal of prescription drugs. The DFC Program recently modified its four core measures to include prescription drug abuse. This modification was necessary due to the fact that DFC grantees have identified prescription drug abuse as a priority for their coalitions.

Further examples of DFC activities to address prescription drug abuse include:

⁸ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2013]. Available:

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2.16>

⁹ Drug Enforcement Administration. "DEA'S National Prescription Drug Take-Back Days Meet a Growing Need for Americans." Department of Justice. [May 8, 2014]. Available: <http://www.justice.gov/dea/divisions/hq/2014/hq050814.shtml>.

¹⁰ Jones, CM, Paulozzi, LJ, and Mack, KA. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use United States, 2008-2011. *JAMA Intern Med.* 2014 May;174(5):802-3. Available at: <http://archinte.jamanetwork.com/article.aspx?articleid=1840031>.

- Law enforcement take-back events, specifically designated days for mass collections to decrease access to unused, expired, or unwanted prescription drugs in homes;
- Drop-off boxes, permanent locations for prescription drug drop-off, at law enforcement locations in order to encourage proper disposal;
- Law enforcement partnerships to educate community members, raise awareness, offer support at coalition events, and house drop-off boxes for public use;
- Public service announcements and media campaigns, such as newspaper and radio advertisements, to inform community members about take-back events, drop-off boxes, and to provide information about prescription drug abuse in general;
- Partnering with doctors to supply them with prescription pads that have prescription drug misuse information written on them, put brochures in waiting rooms, be a non-controlled substance prescription drug drop-off site, make changes in drug prescription practices, and encourage involvement in efforts to prevent “doctor shopping”;
- Partnering with pharmacies and pharmacists to house a prescription drug drop-off box and provide information on safe drug usage, storage, and disposal; and
- Specifically reaching out to senior citizens to educate them on the risks associated with prescription drug use and provide them with resources.

The Honorable Ben Ray Lujan

1. As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me about what your office is doing to address the challenges of rural districts like New Mexico.

ANSWER:

The Office of National Drug Control Policy (ONDCP) agrees that rural communities across the Nation face tremendous challenges in accessing mental health and substance use disorder services.¹¹ In many of these communities, there is a shortage of mental health and substance use disorder professionals, and the infrastructure that supports these services are nonexistent.¹² Stressful life events along with mental health and substance use disorders are among the risk factors for suicide in rural communities.¹³ These factors highlight the importance of improving rural communities' behavioral health care service delivery systems and treatment centers and for developing treatment centers where they do not presently exist. The Department of Agriculture's (USDA) Community Facilities direct loan program provides loans to assist service providers in building bricks and mortar facilities.

Enhancing and/or developing behavioral health care service delivery systems is particularly important, as two key changes have occurred in the landscape of the delivery of healthcare affecting rural communities. The first is the implementation of the Affordable Care Act (ACA); with full implementation in 2014, more people will have access to behavioral health care. The second is the passage of the Mental Health Parity and Addiction Equity Act, which requires insurers that cover substance use disorders to cover this treatment no more restrictively than medical or surgical treatments. As part of the Administration's ongoing commitment to help individuals experiencing mental health problems, the President's *Now is the Time* initiative allocates \$130 million to improve access to mental health services. In addition, the USDA will invest \$50 million in the construction, expansion or improvement of mental health facilities over the next 3 years through the Community Facilities direct loan program. ONDCP is working closely with the USDA to assist rural community providers, associations, and key stakeholders in understanding the availability and requirements of the USDA Community Facilities direct loan program for the construction, expansion, or equipping of rural mental health and substance use disorder facilities.

Furthermore, rural communities may be able to receive some services related to substance use treatment using telemedicine, a system created to provide certain services to individuals, particularly those in remote locations, using computer-based or telecommunications technology.

¹¹ See Benavides-Vaello, S.; Strode A.; and Sheeran, B.C. (2013). Using Technology in the delivery of mental health and substance abuse treatment in rural communities: a review. *Journal Behavioral Health Services and Research* 40 (1) doi: 10.1007/s11414-012-9299-6.

¹² Bird, D.; Dempsey, P.; and Hartley, D. *Addressing mental health workforce needs in underserved rural areas: Accomplishments and challenges*. Edmund S. Muskie School of Public Service, Maine Rural Health Research Center, 2001.

¹³ National Institute of Mental Health. *Suicide Facts*. Suicide Research Consortium, 1997.

For instance, in some rural areas, Medicare Part B covers certain services like office visits and consultations that are provided using an interactive two-way telecommunications system (with real-time audio and video) by a doctor or certain other health care professional who is not at a patient's location. Such services are covered in rural areas when they take place in a doctor's office, hospital, critical access hospital, rural health clinic, federally qualified health center, hospital-based dialysis facility, skilled nursing facility or community mental health center.¹⁴ Medicaid may also provide reimbursement for certain telemedicine services for qualifying individuals; however, the Federal Medicaid statute does not recognize telemedicine as a distinct service, so states determine which services their Medicaid systems will reimburse.¹⁵

Telemedicine has been used, for example, to augment evaluation processes for substance use disorders if a qualified professional is not employed on site, to conduct psychiatric diagnostic interview examinations, and to facilitate teleconference therapy sessions. One specific example of telemedicine implementation is the provision of mental health treatment to children in remote Alaskan villages via video teleconference from providers located in facilities hundreds of miles away.¹⁶ Rural communities are interested in telemedicine for the access to services it provides at comparable costs to face-to-face sessions. Advanced encryption and other security measures allow telemedicine services to meet Health Insurance Portability and Accounting Act requirements for confidentiality.

2. **Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse: The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public? Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs? The need to expand access to Naloxone to the public as prescription drug abuse continues to rise? A lack of funding for implementation of proven strategies? The need for legislation?**

ANSWER:

ONDCP has not ranked substance abuse prevention, risk mitigation activities, or treatment access-related activities in terms of prioritization. All three kinds of activities are necessary parts of a comprehensive effort to prevent:

- Initiation of prescription drug misuse;
- New cases of opioid use disorders;

¹⁴ See the Centers for Medicare and Medicaid Services web site relating to Medicare coverage at: <http://www.medicare.gov/coverage/telehealth.html>

¹⁵ See the Centers for Medicare and Medicaid Services web site relating to Medicaid reimbursement at: <http://www.medicare.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html>.

¹⁶ Benderly, B.L. "Conference Explores High-Tech Treatments" (2005). *SAMHSA News*. Vol. 13 (1). Available at: http://www.samhsa.gov/SAMHSA_News/VolumeXIII_1/jan_feb_2005.pdf

- Hospitalization and overdose deaths in both experienced and inexperienced users and those receiving chronic opioid therapy for legitimate reasons (e.g., methadone for pain);
- Initiation of heroin or prescription drug use by routes of administration that present additional health or safety risks (i.e., smoking or injecting); and
- Acquiring blood-borne and injection-related infectious diseases such as HIV and hepatitis C.

If ultimately the aim is to prevent new users, prescriber education is essential to train prescribers on ways to prescribe safely and in ways that minimize risk of diversion. This would include not prescribing when opioids are contraindicated or when evidence indicates no benefit. However, given that opioid prescribing for pain and substance use disorder treatment are currently a routine part of medical practice and given that this practice exposes some patients to risk of overdose even in some cases when medicines are used as directed, risk mitigation efforts, such as naloxone use by first responders and caregivers, are also essential. Finally, the extent of the prescription drug misuse and diversion problem in certain parts of our country is so severe, and the treatment capacity and workforce are so inadequate, that many people with a chronic substance use disorder face many more years of risk from opioid use disorders, in some cases incorporating the use of heroin and/or injecting, even after they recognize the need to seek treatment. This is not to say that users themselves are the problem. Many became involved with prescription drugs believing them to be safer than non-prescription drugs – even if not taken in accordance with the prescription or label. Some believed this because they were prescribed these medicines by their own doctors and later began to misuse them.

- 3. Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin – and other illicit drugs – has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its “Prescription Drug Abuse Prevention Plan” with the goal to reduce non-medical use of prescription drugs by 15% in 5 years. What is the progress of this initiative? Is there evidence that this plan is having an impact? Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?**

ANSWER:

The Administration’s Prescription Drug Abuse Prevention Plan (Plan) was released in 2011. As the most recent drug overdose mortality data available is for the year 2011, we cannot yet tell what impact the Plan is having on mortality. However, some elements of the Plan show signs of progress. For example, in regard to expanding use of prescription drug monitoring programs (PDMPs), at the beginning of the Administration, only 20 states had PDMPs in place. There are now 49 states with legislation authorizing PDMPs, and almost all have active PDMPs. We now have more evidence that using PDMPs affects prescription drug misuse. For example, in Tennessee, where as of January 2013 prescribers were mandated to use the State’s PDMP and review it for each new controlled substance prescription, there was a 47 percent reduction in doctor shopping from its peak in the Third Quarter of 2011 to the end of the Fourth Quarter of

2013.¹⁷ Additionally, looking at the recommendations in the Plan concerning expanded disposal, the Drug Enforcement Administration has issued final regulations to implement the Secure and Responsible Drug Disposal Act of 2010. Concerning the Plan's education recommendations, the Food and Drug Administration has implemented some elements of the plan concerning prescriber and public education through its Risk Evaluation and Mitigation Strategy for extended release/long acting opioids, which makes available free or low-cost prescriber education continuing education modules and patient information.

ONDCP has been working with Federal agencies to encourage implementation of mandatory prescriber education among Federal employee prescribers. We have had some successes. For example, prescribers at the Clinical Center at the National Institutes of Health and a majority of prescribers at the Federal Bureau of Prisons (BOP), the U.S. Coast Guard and the U.S. Air Force have received continuing education training on safe prescribing. Other branches of the military have training programs in operation and are encouraging their staff to complete them. In addition, ONDCP provided funding to the National Institute on Drug Abuse to develop continuing medical education (CME) courses on managing patients who use opioid pain relievers, with nearly 100,000 clinicians taking the courses for credit since they launched in late 2012. It has also been accessed by another 170,000 clinicians who have viewed the information online.

Regarding the correlation between heroin and prescription drug use, both heroin and prescription opioids activate μ (mu) opioid receptors in the brain's reward centers. Recent studies show that individuals who react positively to the rewarding effects of prescription opioids, particularly those who need larger doses to achieve the same effects (a normal consequence of ongoing use), may view heroin as a low-cost alternative to prescription opioids.¹⁸ Research shows that chronic users, specifically those with 100 days or more of past year opioid misuse, are more likely to initiate heroin use.¹⁹ Recent analyses by the Substance Abuse and Mental Health Services Administration (SAMHSA) also show that while most heroin users have a history of prescription opioid misuse, the percentage of non-medical prescription opioid users who initiate heroin use is relatively small (just four percent of people who had initiated prescription opioid abuse initiated heroin use within five years).²⁰ It is thus reasonable to surmise that heroin use would eventually drop if prescription drug misuse were curtailed by preventing initiation of prescription drug misuse and by providing treatment to those who are already dependent. However, given the large number of chronic prescription drug users, heroin use likely will climb as long as heroin remains readily available and relatively inexpensive, and people who need treatment for their opioid use disorders continue

¹⁷ Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2014 Report to the 108th Tennessee General Assembly, February 1, 2014. Page 5. http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf

¹⁸ "Every never I ever said came true": transitions from opioid pills to heroin injecting. Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D. *Int J Drug Policy*. 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19. PMID: 24238956

¹⁹ Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010. *Drug Alcohol Depend*. 2013 Sep 1;132(1-2):95-100. doi: 10.1016/j.drugalcdep.2013.01.007. Epub 2013 Feb 12. PMID: 23410617

²⁰ Muhuri, PK, Gfroerer, JC, and Davies, MC. CBHSQ Data Review: Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States Substance Abuse and Mental Health Services Administration, August 2013. Available at: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

to face challenges to obtaining treatment, including cost-prohibitive treatment options and waitlists for public treatment.

4. **You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further there is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types programs in New Mexico?**

ANSWER:

The Administration's *National Drug Control Strategy* calls for all people with substance use disorders who become involved in the criminal justice system to have access to evidence-based treatment and recovery support, including treatment for people who are incarcerated.

ONDCP is working with state and local law enforcement, judges, correction officials, and criminal justice policymakers to address the substance use disorders that are often intertwined with criminal behavior. Through these interactions, we have advised on the importance of connecting justice-involved people with health care coverage through the ACA. As states and localities are undergoing significant reform, ONDCP encourages them to invest the savings into treatment and recovery support.

In addition, with ONDCP support, the National Association of Drug Court Professionals is developing a program for practitioners on the appropriate evidence-based interventions applicable at each stage of the criminal justice system.

Our Department of Justice partners at the BOP and the Bureau of Justice Assistance (BJA) have been working to expand access and incorporate additional modalities of care through BOP's Residential Drug Abuse Program (RDAP) and BJA's Residential Substance Abuse Treatment Program. Currently, BOP reports that all people in Federal prisons who have a history of a substance use disorder and meet the admission criteria are able to take part in the RDAP program. For those who do not meet the admission criteria for RDAP, there are alternative programs, such as drug abuse education and Non-Residential Drug Abuse Treatment, to help the participants make better decisions after release.

BOP conducted a pilot project on the feasibility and efficacy of providing access to medication-assisted treatment (MAT) as a maintenance treatment within the prisons and of connecting patients with MAT providers in the community after release. Based on the results of this pilot, BOP decided to implement an MAT program for individuals with opioid use disorders.

The Attorney General's announcement²¹ that Residential Reentry Centers—or halfway houses—must provide evidence-based treatment for substance use disorders will also help

²¹ See <http://www.justice.gov/opa/pr/2014/March/14-ag-301.html>.

people transitioning back to their communities. As you note, people with substance use disorders need assistance to access care after a period of incarceration to begin or maintain their recovery.

The ACA will help to expand access to services related to substance use disorders. This is a significant change to the way services for substance use disorders have been delivered, which historically has been through a separate delivery system only for the most chronic patients. Under ACA, the Medicaid expansion population – those living at 133 percent of the poverty level (\$14,404 for an individual or \$29,327 for a family of four in 2009), including single adult males without dependents – is likely to include a significant number of individuals in need of services for substance use disorders. Thus, full implementation of the ACA gives many more Americans in need of substance use treatment an opportunity to be treated.

These services will augment the prevention and treatment services that are made available through the support of the Substance Abuse Prevention and Treatment Block Grant (SAPTBG). Even after implementation of the ACA, there will continue to be a need for the services supported through the SAPTBG. Drug prevention is a state and local effort, and the SAPTBG represents the only large Federal mechanism that supports these efforts. As the ACA is fully implemented there are many substance use disorder services that will not be covered by insurance plans, which can then be supported through the SAPTBG. While New Mexico reviews its individual substance use disorder treatment services infrastructure – with an emphasis on building treatment capacity – the SAPTBG is necessary to support both supportive services such as case management which may not be covered as well as those who are not insured or underinsured.

5. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to – so that there is greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?

ANSWER:

ONDCP has two discretionary grant programs, the Drug-Free Communities (DFC) Support Program and the High Intensity Drug Trafficking Areas (HIDTA) Program.

The DFC Program provides grants to local drug-free community coalitions through a competitive peer review process. ONDCP and its administrative partner, SAMHSA, post a Request for Applications (RFA) each year in January. All DFC applications are jointly screened by ONDCP and SAMHSA to determine whether each applicant meets all the DFC Program's statutory eligibility requirements.

Applications submitted by eligible coalitions that meet all requirements are then scored through a peer review process according to the evaluation criteria described in the RFA. Once peer review is complete, the applications are scored using a composite of the scores given by the three reviewers. Grant awards are issued based on these scores. For a list of the DFC statutory eligibility requirements please visit: <http://www.whitehouse.gov/ondcp/information-for->

potential-applicants.

The HIDTA Program provides assistance to Federal, state, local, and tribal law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. There are currently 28 HIDTAs, which include approximately 16 percent of all counties in the United States and 60 percent of the U.S. population. HIDTA-designated counties are located in 47 states, as well as in Puerto Rico, the U.S. Virgin Islands, and the District of Columbia.

At the local level, the HIDTAs are directed and guided by Executive Boards composed of an equal number of regional Federal and non-Federal (state, local, and tribal) law enforcement leaders. ONDCP funds and manages the National HIDTA Program. In some years, discretionary funds are available directly to the regional HIDTAs to support activities in their designated area. To learn more about which regional HIDTAs may be engaged in activities in your area, visit <http://www.whitehouse.gov/ondcp>.

If there are questions about ONDCP's discretionary grant programs, individuals should contact Helen Hernandez, the DFC Administrator, at (202) 395-6665 or Michael Gottlieb, the National HIDTA Director, at (202) 395-6752. Congressional inquiries on these programs should be made to ONDCP's Office of Legislative Affairs at (202) 395-6602.

6. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?

ANSWER:

Substance use has significant negative consequences for Americans and the U.S. economy. In 2007, the use of illicit substances was estimated to have cost the United States \$197 billion due to lost productivity, health care, and crime.²² Substance use negatively affects academic achievement²³ and absenteeism,²⁴ making for a less well-prepared workforce. Substance abuse, however, is not a problem confined to the poor; it affects people at all income levels, although the relationship between income and substance abuse is complex. Data from the National Survey on Drug Use and Health indicate that those adults 18 and older who are unemployed or working part-time are more likely to be current users of illicit drugs than those working full-time.²⁵ On the other hand, research by Galea et al. suggests that neighborhood income and income distribution may play more important roles in determining population substance use than

²² National Drug Intelligence Center. 2010. *National Threat Assessment: The Economic Impact of Illicit Drug Use on American Society*. Department of Justice, Washington, DC.

²³ Substance Abuse and Mental Health Services Administration. The NSDUH Report: Academic Performance and Substance Use among Students Aged 12 to 17: 2002, 2003, and 2004. Department of Health and Human Services, 2006.

²⁴ Bass, AR et al. 1996. Employee drug use, demographic characteristics, work reactions, and absenteeism. *J. Occup. Health Psychol.* Jan; 1(1):02-99.

²⁵ Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*. NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

individual income. Their research found that those neighborhoods with both the highest income and the highest income maldistribution had the highest prevalence of use of alcohol and marijuana.²⁶

ONDCP is not aware of any specific studies that have examined the relationship between economic development and substance use prevention.

²⁶ Galea, S; Ahern, J; Tracy, M; and Vlahov, D. 2007. Neighborhood income and income distribution and the use of cigarettes, alcohol, and marijuana. *Am. J. Prev. Med.* 32(6 Suppl):S195-S202.

Attachment 2 – Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Michael C. Burgess

- 1. The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?**

ANSWER:

Placing sufficient resources and evidence-based strategies behind our efforts will lead to further progress in reducing substance use. Recent data show some increase in drug use, particularly marijuana use;²⁷ however, the rate of illicit drug use among Americans 12 and older is approximately lower by a third from its peak in the late 1970s,²⁸ cocaine production in Colombia has dropped to its lowest levels since 1994,²⁹ and alternatives to incarceration are being used to divert non-violent drug offenders into treatment instead of jail. Previous national efforts to reduce smoking, drunk driving, and other public health issues have shown that sustained and balanced approaches can significantly improve public health and safety. The Administration's *National Drug Control Strategy (Strategy)* provides a roadmap to decrease drug use and its consequences.

In 2010, the Office of National Drug Control Policy (ONDCP) launched the Obama Administration's inaugural *Strategy*, emphasizing community-based drug prevention, integrating evidence-based interventions and treatment into the healthcare system, promoting innovations in the criminal justice system to decrease recidivism, and forging and maintaining strong international partnerships to disrupt drug trafficking organizations. 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 moves beyond an outdated "war on drugs" approach and is guided by what experience, compassion, and science demonstrate about the true nature of drug use in America.

Prevention is an essential component of this new public health approach and has become one of the highest national drug policy priorities of the Administration. We know prevention works. Recent research has shown that each dollar invested in a proven school-based prevention

²⁷ Substance Abuse and Mental Health Services Administration. Results from the 2012 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2013] Available: <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect7peTabs1to45-2012.htm#Tab7.44B>

²⁸ Substance Abuse and Mental Health Services Administration. Unpublished estimate from the National Household Survey on Drug Abuse and the National Survey on Drug Use and Health

²⁹ Department of State, Bureau of International Narcotics and Law Enforcement Affairs. 2013 International Narcotics Control Strategy Report [March 2013] Available: <http://www.state.gov/j/inl/rls/nrcrpt/2013/vol1/index.htm>

program can reduce costs related to substance use by as much as \$18.³⁰ Under this Administration, Federal funding for public health approaches to drug policy have increased every year. In fact, the portion of the budget requested for drug treatment and prevention efforts (43 percent) has grown to its highest level in over 12 years.

As part of the *Strategy*, we proposed a number of five-year goals to reduce the prevalence of drug use in America. We have made some progress in advancing these goals. For instance, there is evidence to suggest that the Nation is achieving the goals to reduce use of illicit drugs (except marijuana) by youth and young adults, reducing the number of chronic users of cocaine and methamphetamine, and reducing the prevalence of drugged driving. However, other goals, such as reducing drug-induced deaths and drug-related morbidity, have proven more problematic. The emergence of the prescription drug abuse epidemic since the beginning of this century and the uptick in heroin use, along with the rise of new synthetic cannabinoids and cathinones, demonstrates that the effort to combat substance use requires a long-term commitment and the need to adapt to address substances as they emerge or re-emerge.

ONDCP is encouraged by reduced rates of drug use when law enforcement is supported by both robust programs that provide prevention messages, particularly to youth, and evidence-based drug treatment for those with substance use disorders. Through the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, more individuals with substance use disorders will have access to care through private or Government-provided health insurance.

While the Federal Government has sustained its investment in research and development of youth drug prevention programs, we look forward to working closely with Congress to fully fund promising interventions that are part of the Administration's budget request, such as the Department of Education's requested investment for School Climate Transformation Grants and related technical assistance to help schools train their teachers and other school staff to implement evidence-base strategies to improve school climate. A key aspect of this multi-tiered approach is that it provides differing levels of support and interventions to students based on their needs.

We also endorse the sustained and distinct support to the states for substance abuse prevention and treatment that is made through the Substance Abuse and Mental Health Services Administration's Substance Abuse Prevention and Treatment Block Grant Program.

Another essential component of the *Strategy* is ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program. The HIDTA program coordinates and assists Federal, state, local and tribal law enforcement agencies at the local level to address regional drug threats to the purpose of reducing drug trafficking and drug production in the United States. The 28 regional HIDTAs share their information and their task forces do case and subject deconfliction.

In 2012, the most recent year for which complete data is available, HIDTA reports indicate there were 733 initiatives in the 28 HIDTAs distributed among the following categories: intelligence, enforcement, interdiction, prosecution, support, prevent, treatment, and management. These

³⁰ Miller, T., Hendrie, D. (2009). Substance abuse prevention dollars and cents: a cost-benefit analysis. DHHS Pub. No. (SMA) 07-4298. Rockville, MD: Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration

initiatives were staffed by 7,399 Federal agents and analysts; 15,915 state, local, and tribal officers and analysts; and other representatives, such as the U.S. Attorneys, District Attorneys, and prevention specialists. Each of the initiatives has established goals and objectives that are in line with the *Strategy*. In 2012, HIDTA initiatives identified 8,864 Drug Trafficking Organizations (DTOs) operating in their areas of responsibility and reported disrupting or dismantling 3,030. Over 60 percent of the disrupted or dismantled DTOs were determined to be part of multi-state or international operations. In the process, HIDTA initiatives removed significant quantities of drugs from the market and seized over \$800 million in cash and \$1.1 billion in non-cash assets from drug traffickers (\$1.9 billion total). This law enforcement effort is significant.

Prevention and treatment initiatives continue to be an integral part of the HIDTA program. The HIDTA members work with community-based coalitions and adhere to evidence-based prevention practices, such as community mobilization and organizational change.

2. What is the cost of a single dose of Naloxone? Is the cost of Naloxone a barrier to making the antidote more readily available?

ANSWER:

According to a recent editorial, prices for naloxone vary from \$8.00 for an injectable vial (although two vials may be needed to treat overdose of more long-acting, potent drugs) to \$50.00 for a nasal kit.³¹ EVZIO, the hand-held auto-injector formulation of naloxone that was recently approved by the FDA, is available at a retail price of around \$600.00 per kit as of October 14, 2014.³² The cost of naloxone may be a barrier to purchase by the uninsured or some insured people with little disposable income who cannot afford the copayment. However, we are already seeing more state and local governments commit to making it more readily available to first responders. In an effort to prevent fatal and non-fatal opioid overdoses, the Department of Veterans Affairs (VA) recommends implementing Opioid Overdose Education and Naloxone Distribution to at-risk Veterans. Naloxone kits for intramuscular and intranasal administration and the naloxone auto-injector for intramuscular/subcutaneous administration are all listed on the VA National Formulary. VA's Consolidated Mail Outpatient Pharmacy (CMOP) is now dispensing the intramuscular and intranasal naloxone kits prepared by CMOP and several opioid overdose reversals have been reported.

³¹ <http://jama.jamanetwork.com/article.aspx?articleID=1829642>

³² See retail pricing information for EVZIO at the GoodRx.com website: <http://m.goodrx.com/evzio>.

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May 21, 2014

Dr. Daniel M. Sosin
Acting Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Sosin:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 29, 2014, to testify at the hearing entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, June 4, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Questions for the Record for
Dr. Daniel Sosin, Acting Director of the National Center for Injury Prevention and Control
From
“Examining the Growing Problems of Prescription Drug and Heroin Abuse”
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
April 29, 2014

Attachment 1—Additional Questions for the Record
The Honorable Michael C. Burgess

1. I am told that abuse and misuse of medicines is flat or slightly declining. What are the recent statistics over the last few years on non-medical use of prescription drugs? And since the government sites statistics that 70% of those who use medicines non-medically are getting them from family or friends, what is causing the flattening or decline?

Answer: The rate of past month nonmedical use of prescription drugs among young adults aged 18 to 25 in 2012 was 5.3 percent – similar to rates in 2010 and 2011, but significantly lower than the rate from 2009 (6.4 percent), according to the Substance Abuse and Mental Health Services Administration’s (SAMHSA’s) 2012 National Survey on Drug Use and Health (NSDUH).

Overall, nonmedical use of psychotherapeutic drugs among people age 12 years and up has ranged from 19.9 percent to 20.9 percent during 2002-2012, according to the NSDUH. For prescription pain relievers, the percentage has ranged from 12.6 percent to 14.2 percent during this time period. These percentages did not change significantly from 2010 to 2012. However, relatively flat rates of nonmedical use among *all* nonmedical users masks a sharp increase in opioid abuse by a small number of “heavy users.”

The percentage of people using pain relievers nonmedically 200 or more days a year—the “heavy users”—increased 75 percent from 2002-2003 to 2009-2010.¹ These are the users whose nonmedical use is more likely to be considered “abuse” and who account for a disproportionate share of overdoses. While the overall rate of nonmedical use of opioids has not grown substantially over the last decade, the smaller subset of high-risk “heavy users” has increased sharply. CDC has not yet examined use rates for these “heavy users” for 2011 and 2012, and future research will indicate whether the sharp growth in this group has continued.

¹ Jones CM. Frequency of Prescription Pain Reliever Nonmedical Use: 2002-2003 and 2009-2010. JAMA Intern Med. 2012;172(16):1265-1267.

The Honorable Jan Schakowsky

1. **What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of pop up clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and pop up clinics, so I am interested in seeing what they are doing to help us combat the crisis.**

Answer: While CDC is not aware of the pharmaceutical industry's efforts to address pop up clinics, CDC is aware of some steps the pharmaceutical industry has taken to address prescription drug abuse. These include reformulating two opioid products in an effort to make them abuse-resistant, funding of the Researched Abuse, Diversion and Addiction-Related Surveillance system, and offering voluntary education programs for health care providers.

2. **What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?**

Answer: New opioid drugs are being introduced to market, and FDA oversees the process for the approval of new drugs. CDC defers to FDA's regulatory authority regarding new opioid drugs entering the market.

CDC's work to prevent prescription drug overdoses addresses the impacts of both new and existing controlled substances on the public's health. CDC monitors and tracks prescribing data using IMS Health data, which helps to understand prescribing trends for different types of opioid pain relievers. CDC's efforts to improve prescribing practices of these drugs for all patients (*e.g.*, volume of pills prescribed and recommended dosage) and to strengthen prescription drug monitoring programs as a tool to promote safer prescribing also address the prescribing of newer opioid drugs. These surveillance and prevention programs are designed to address the risks posed by all opioid pain relievers, whether they are long-established opioids like methadone or recently approved medications.

3. **Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?**

Answer: Most of the nonmedical use or overdose death cases involving opioids are related to Schedule II drugs such as oxycodone, morphine, oxymorphone, fentanyl, and methadone. Drug products containing limited amounts of hydrocodone in combination with other active ingredients currently are Schedule III and account for 135 million prescriptions per year, roughly half of all opioid prescriptions. HHS recently recommended to DEA that hydrocodone combination products be moved to Schedule II. On February 27, 2014, DEA published a Notice of Proposed Rulemaking proposing to reschedule hydrocodone combination products to Schedule II.

4. **According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?**

Answer: The data cited by Dr. Clark indicate that excess opioid pain reliever pills are diverted to nonmedical users who may misuse or abuse the drugs. A recent CDC analysis of these data (gathered from SAMHSA's NSDUH) further demonstrate the role that prescribing plays in nonmedical use. The study found that the opioid source for nonmedical users varies significantly depending on the frequency of nonmedical use. For instance, the highest-use, highest risk nonmedical users (*i.e.*, those who reported nonmedical opioid use more than 200 days a year) reported that the last time they used, they were more likely to obtain their opioids from doctors' prescriptions than any from other source.² Heavy users also account for a disproportionate fraction of all opioid overdoses compared with light users.³

The primary insight CDC gained from the NSDUH data is the key role of prescribing. Whether a nonmedical user obtains an opioid from a friend or family member or directly from a physician, virtually all the drugs originate from a health care provider's prescription. Efforts to promote safe prescribing (*e.g.*, prescriber education programs), effective prescription drug monitoring programs that can give doctors critical information about their patients' histories, patient review and restriction programs that can protect high risk patients, or pain clinic laws to shut down rogue prescribers) are critical to addressing the inappropriate prescribing at the root of the epidemic.

² Jones CM, Paulozzi LJ, Mack KA. Sources of Prescription Opioid Pain Relievers by Frequency of Past-Year Nonmedical Use: United States, 2008-2011. *JAMA Intern Med.* 2014;174(5):802-803.

³ Paulozzi LJ, Zhang K, Jones CM, Mack KA. Risk of Adverse Health Outcomes with Increasing Duration and Regularity of Opioid Therapy. *Journal of the American Board of Family Medicine.* May-June 2014; 27(3) 329-38.

The Honorable Ben Ray Lujan

1. **As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me what your office is doing to address the challenges of rural districts like New Mexico?**

Answer: The prescription drug overdose epidemic has impacted some rural communities where limited resources and poverty can make prevention difficult. CDC recognizes the needs of these communities and has designed initiatives to ensure that states, including those with many rural communities, can compete for the assistance and support they need to advance prevention.

For example, CDC's new Funding Opportunity Announcement (FOA), Prevention Boost, is an initiative to accelerate PDO prevention in states through direct support to state health departments. The initiative targets funding to states that have both a high burden of prescription drug overdoses and have demonstrated readiness and capacity to achieve impact. Under the FOA's evaluation criteria, applications from states with the highest drug overdose burden will be weighted somewhat more favorably than states with a lower burden to ensure that prevention dollars go towards achieving the maximum impact. Similarly, the initiative in the President's Fiscal Year (FY) 2015 Budget proposes increased funding of \$15.6 million to support additional states with a high prescription drug overdose death burden to ensure those states have the maximum opportunity to receive support to reduce prescription drug overdose deaths through the existing Core Violence and Injury Prevention Program (Core VIPP).

2. **Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse:**

- **The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public?**

Answer: DEA leads the effort to increase public awareness and promote drug take back events. Safe disposal is one part of a much larger effort to address prescription drug abuse and overdoses.

- **Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs?**

Answer: Access to substance abuse treatment is a crucial part of helping those already dependent on and addicted to opioid pain relievers. It is crucial that providers in both primary and specialty care settings become trained in medication-assisted treatment (MAT), an approach that uses FDA-approved pharmacological treatments such as methadone, Naltrexone (Vivitrol) Buprenorphine Buprenorphine/Naloxone. MAT should be offered in combination with psychosocial treatments, for patients with opioid use disorders. Equally important, use of these medications should be covered as part of a comprehensive approach to treating prescription and illicit substance use disorders.

On April 24, 2014, a commentary on MAT jointly written by the directors of CDC, SAMHSA, the Centers for Medicare & Medicaid Services (CMS), and NIDA, was published in the *New England Journal of Medicine*.⁴ As noted in that article, the three types of MAT—methadone, buprenorphine, and naltrexone—are underutilized. Of the 2.5 million Americans 12 years of age or older who abused or were dependent on opioids in 2012 (according to the National Survey on Drug Use and Health conducted by SAMHSA), fewer than one million received MAT. The article also cites a recent report from the American Society of Addiction Medicine describing public and private insurance coverage for MATs that highlights several policy-related obstacles, such as limits on MAT dosages, annual or lifetime medication limits, initial authorization and reauthorization requirements, poor counseling coverage, and other barriers.⁵

CDC is working with states to implement comprehensive strategies for overdose prevention that include MAT, as well as enhanced surveillance of prescriptions and clinical practices. Through CDC's existing Core-VIPP-funded states, 16 out of the 20 funded have highlighted prescription drug abuse as a statewide prevention priority. CDC is also establishing statewide norms to provide better tools for the medical community in making prescription decisions. Prevention efforts that focus on changing behaviors that have led to the problem are crucial to reducing prescription drug abuse and overdose, so that the need for treatment will be also be reduced.

- **The need to expand access to naloxone to the public as prescription drug abuse continues to rise?**

Answer: Naloxone is a promising and useful tool to reverse opioid overdose deaths, and it is a piece of a broad approach to reverse this epidemic. CDC's primary focus is to address the underlying causes of the epidemic so last resort necessities like naloxone are not necessary.

- **A lack of funding for implementation of proven strategies?**

Answer: States need support to identify and implement effective strategies for prevention of prescription drug overdoses. Supporting states to expand effective prevention measures—especially those aimed at changing the prescribing behaviors that drive the epidemic—is a central tenet of CDC's strategy to preventing prescription drug overdoses. The President's FY 2015 Budget is designed to meet this important prevention need. Both would provide direct, targeted assistance to states to help implement, expand, and evaluate key prescription drug and overdose prevention interventions.

- **The need for legislation?**

Answer: States have broad authority to regulate the prescribing and dispensing of prescription drugs and do so in a variety of ways. Some states interventions have shown promising results, as highlighted below.

⁴ Volkow ND, Frieden TR, Hyde PS, Cha S. Medication-Assisted Therapies -- Tackling the Opioid-Overdose Epidemic. *NEJM*. April 23, 2014. Available at URL: <http://www.nejm.org/doi/full/10.1056/NEJMp1402780>.

⁵ ASAM. Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. 2013. Available at URL: <http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>.

Prescription Drug Monitoring Programs (PDMPs) are state-run databases that track controlled substance prescribing and dispensing. PDMPs have tremendous potential to inform prescribers about patient histories, identify troubling patterns, and provide key information about the epidemic. However, PDMPs vary considerably between states (*e.g.*, some PDMPs are real-time while others have a long delay). Some states now have statutes mandating that prescribers of controlled substances use the state PDMP. Approximately 14 states mandate prescribers to use the PDMP in certain circumstances. Initial examinations of the impacts of these mandated use laws are promising. For example, in New York state, according to an initial analysis by the PDMP Center of Excellence at Brandeis University, in the first full quarter following the PDMP use mandate:

- The number of prescriptions for all opioids decreased 9.53 percent.
- Patients receiving opioids from multiple sources (*i.e.*, when individuals saw five prescribers/five pharmacies over three months, also called “doctor shopping”) decreased by 74.8 percent.
- The number of prescriptions for buprenorphine—a drug used to treat opioid dependence—increased 14.6 percent.

These initial results suggest that the increased use of the PDMP may prevent high risk behaviors, reduce overprescribing, and help get assistance to people at risk for opioid abuse and overdose.

Some states have also enacted and are enforcing laws to prevent doctor shopping and the operation of rogue pain clinics or “pill mills,” and other laws to reduce opioid painkiller diversion and abuse while safeguarding legitimate access to pain management services. Some states are also enacting “immunity” laws that provide limited immunity for people seeking medical attention during an overdose, laws that increase access to Naloxone (a medication that can reverse opioid overdoses), and laws or policies that increase access to medication-assisted treatment for opioid dependence. Some of these laws have significant promise. For instance, while further evaluation is needed, some initial reports show that after Florida passed a pill mill law, it saw a subsequent drop in oxycodone overdose deaths.

3. **Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin—and other illicit drugs—has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its “Prescription Drug Abuse Prevention Plan” with the goal to reduce non-medical use of prescription drugs by 15% in 5 years.**

- **What is the progress of this initiative? Is there evidence that this plan is having an impact?**

Answer: The White House Office of National Drug Control Policy’s (ONDCP’s) Prescription Drug Abuse Prevention plan was instrumental in calling attention to this epidemic and helping to coordinate the efforts of Federal agencies to advance prevention. In the plan, CDC was charged as the lead agency for the following actions: developing clinical guidelines on opioid prescribing with the American College of Emergency Physician (ACEP) and advancing epidemiological studies on patterns of opioid abuse. CDC completed the joint development of ACEP clinical guidelines on opioid prescribing in 2012.⁶ CDC continues to advance epidemiological studies on prescription drug use and abuse. For instance, a new surveillance system is in development—called the Prescription

⁶ <http://www.acep.org/Content.aspx?id=88136>.

Behavior Surveillance System—that uses de-identified data from multiple state PDMPs to create an innovative and timely new way to monitor prescribing trends and patterns. This summer CDC will release Vital Signs, a major scientific release that will examine opioid prescribing rates in all 50 states using IMS Health data. These, and other studies, are in addition to our routine analyses of drug overdose mortality data.

CDC defers to ONDCP about specific progress on other parts of the Prescription Drug Abuse Prevention Plan.

- **Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?**

Answer: The number of persons meeting the criteria for heroin dependence or abuse more than doubled from 2007 to 2012. In 2012, more than two million people reported opioid abuse/dependence compared to about 467,000 people reporting dependence on or abuse of heroin.⁷ While prescription opioid abuse and overdose rates remain far above heroin rates, the heroin increases are concerning.

Studies of people who use heroin show one consistent fact: in most cases, heroin use follows prescription opioid use. More than three out of four people who reported both past-year opioid misuse and heroin use said they used opioids non-medically—that is, without a prescription or for the feeling the drugs cause—prior to heroin initiation. The increased prescribing of opioid pain relievers appears to have increased opioid dependence and addiction and driven demand for heroin.

It is too early to tell how reductions in prescription drug abuse and overdose will impact heroin use and overdose rates. Based on the trends identified above, reducing overprescribing of opioids may reduce the number of people who initiate on heroin. HHS will continue to rigorously monitor both prescription drug and heroin trends and evaluate ways to prevent opioid addiction and abuse.

4. **You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further this is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types of programs in New Mexico?**

Answer: CDC does not have any current plans to expand treatment access in prison and jail facilities as this is outside of the purview of our mission. CDC is working with states to implement comprehensive strategies for overdose prevention that include medication-assisted therapies, as well as enhanced surveillance of prescriptions and clinical practices.

⁷ SAMHSA. Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings. Table 7.3 <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm>.

5. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to—so that there is a greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?

Answer: CDC posts Funding Opportunity Announcements on the website www.grants.gov. The website is the best resource for identifying available CDC funding. Additionally, the National Center for Injury Prevention and Control at CDC maintains a listserv which announces funding opportunities to state and national partners and communicates critical budget updates related to injury prevention and control. Individuals and organizations may e-mail CDC's Injury Center at injurycenter@cdc.gov with direct questions or to request to be added to the Injury Center listserv.

6. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?

Answer: Many studies have identified people at lower income/education levels or enrolled in Medicaid to be at a higher risk for drug abuse and its consequences, such as fatal overdoses. For example, in Washington State, the Medicaid population had a 5.7 times greater risk of dying from an opioid overdose than the non-Medicaid population.⁸ CDC is not aware of any studies identifying strategies linking economic development with substance abuse prevention or treatment.

⁸ Coolen P, Best S, Lima A, Sabel J, Paulozzi L. Overdose deaths involving prescription opioids among Medicaid enrollees— Washington, 2004–2007. MMWR 2009;58(42):1171–1175.

Attachment 2—Member Requests for the Record

The Honorable Michael C. Burgess

1. **The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?**

Answer: The prescription drug overdose epidemic is a complicated public health problem that requires action from multiple sectors. Unlike previous drug abuse epidemics, the drugs driving the increase in overdose deaths can be traced primarily to prescribing practices, which required a new approach to prevention. Investments to date in prevention, treatment, and law enforcement have been important in getting to where we are today. For instance, in 2005 less than half of states had a prescription drug monitoring program; today, 49 states have one. Advances like these are laying an important foundation for reversing the epidemic.

But, there is more that can be done. In particular, the high rates of opioid prescribing that have marked the steady increase in overdose deaths over the last fifteen years need to be addressed. CDC's approach to the epidemic focuses on "upstream" prevention—that is, the prescribing and patient behaviors that drive prescription opioid abuse, addiction, and overdose. CDC's strategy for prescription drug overdose prevention is three-fold: (1) improving the tracking and monitoring of prescribing and overdose trends; (2) supplying health care providers with data, tools, and guidance for evidence-based decision making that improves population health; and (3) strengthening state efforts by scaling up effective public health interventions. Continued progress in these areas, as well as advances in law enforcement (*e.g.*, implementation of pain clinic laws) and substance abuse treatment access for those already addicted to opioids are important steps to continue work to reduce prescription drug overdoses.

Collaboration between and amongst Federal agencies is essential to prescription drug overdose prevention activities. For example, CDC is developing the prescription behavioral surveillance system. This is an early warning surveillance and evaluation tool using data from multiple state PDMPs. With this new tool, states can spot patterns that they could never have seen using only their own PDMPs. This project is an example of interagency collaboration. CDC is partnering with FDA—who is supporting the project to improve prescriber education—and the Bureau of Justice Assistance—who administers the Harold Rogers Prescription Drug Monitoring Program—to bring the agencies' unique strengths together.

2. **What is the cost of a single dose of naloxone? Is the cost of naloxone a barrier to making the antidote more readily available?**

Answer: According to a recent (non-CDC) study, programs traditionally pay approximately \$6 per dose, \$15 per kit of injectable naloxone, and \$30 per kit of intranasal naloxone.⁹ Most programs dispense injectable naloxone. CDC has not conducted any studies regarding the cost of naloxone as a barrier to making it more readily available.

⁹ Coffin PO, Sullivan SD. Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal. *Ann Intern Med.* 2013;158:1-9.

The Honorable Steve Scalise

1. **According to the GAO report, there are 15 federal agencies and 76 abuse prevention or treatment programs. The GAO report identified overlap in 59 of the 76 programs. Please discuss what your agency is doing to address that overlap and the problems addressed in the GAO report.**

Answer: While CDC does not administer any of the 76 programs listed in the 2013 GAO report, CDC believes close coordination with other Federal agencies, including SAMHSA, CMS, FDA, ONDCP, HHS' Office of the National Coordinator for Health Information Technology (ONC), NIDA, and the Department of Justice, is key to CDC's approach to fighting the prescription drug abuse epidemic. One example of this interagency collaboration is the work with SAMHSA to advance PDMP Integration with electronic health records (EHRs). Under this initiative, SAMHSA funded a program to help integrate PDMPs into EHR systems to make PDMPs easy to use in doctors' day-to-day practices. CDC is leading the evaluation of these efforts, leveraging our expertise in program evaluation to make sure that other states and health systems can learn from this initiative's experience.

CDC also participates in the HHS Behavioral Health Coordinating Committee (BHCC) to align CDC's work with the efforts of other Federal agencies within HHS. The coordination at the BHCC level is supported by extensive networks of communication and collaboration from staff level researchers at CDC and other agencies to regular communications between agency leadership on this priority topic. CDC is also engaged with ONDCP in advancing multiple items in the Prescription Drug Abuse Prevention Plan and National Drug Control Strategy.

Finally, CDC works to avoid unnecessary overlap and duplication by leveraging CDC's particular expertise in addressing this epidemic. As the Nation's public health agency, CDC has experience working with state health departments to monitor health trends and advance data-driven, evidence-based prevention and evaluation. This unique niche is reflected in the President's FY 2015 Budget initiative, leveraging the state health departments and state injury prevention programs to address the key driver of the epidemic—inappropriate opioid prescribing. This "upstream" focus on prescribing practices complements the work of other agencies, like SAMHSA's emphasis on substance abuse treatment, NIDA's biomedical research on addiction and treatment, and ONC's work on health information technology systems.

FRED LIPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
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May 21, 2014

Dr. Nora D. Volkow
Director
National Institute on Drug Abuse
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Volkow:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 29, 2014, to testify at the hearing entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

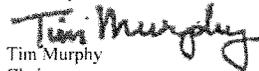
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, June 4, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

**Questions for the Record for
Nora D. Volkow, M.D., Director, National Institute on Drug Abuse
From
“Prescription Opioid and Heroin Abuse”
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
April 29, 2014**

The Honorable Jan Schakowsky

1. What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of pop-up clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and pop-up clinics, so I am interested in seeing what they are doing to help us combat the crisis.

2. What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?

Answer to #s 1 and 2: These issues are outside the scope of the mission of the National Institute on Drug Abuse (NIDA).

3. Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?

Answer: According to the Substance Abuse and Mental Health Service Administration’s (SAMHSA’s) Drug Abuse Warning Network (DAWN), which captures hospital emergency department visits, there were over 150,000 oxycodone-related and 80,000 hydrocodone-related emergency room (ER) visits in 2011. Most of the prescription opioids captured by DAWN were schedule II drugs, such as oxycodone or oxycodone in combination, hydromorphone, fentanyl, and methadone. The rest of the commonly abused opioid drugs fall mostly under schedule III, such as, hydrocodone, buprenorphine, and codeine in combination (refer to table, below).

All controlled-substance medications must be scheduled based on procedures outlined in the Controlled Substances Act. Decisions about rescheduling specific medications should only be made after a thorough review of available data. The Food and Drug Administration (FDA) is the lead agency within HHS for drug-scheduling decisions, and NIDA provides assistance on data interpretation on request.

Drug	Schedule
Fentanyl/combinations	II
Hydromorphone/combinations	II
Meperidine/combinations	II

Methadone	II
Oxycodone/combinations	II
Oxymorphone	II
Codeine/combinations	II/III
Morphine/combinations	II/III
Opium/combinations	II/III/V
Propoxyphene/combinations (no longer available in the U.S.)	II/IV
Buprenorphine/combinations	III
Hydrocodone/combinations	II/III

4. According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?

Answer: Based on existing research and in accord with the Office of National Drug Control Policy's 2011 *Prescription Drug Abuse Prevention Plan*, NIDA recommends a multipronged approach to reducing diversion of opioid medications while also ensuring that they remain available to people with severe/chronic pain. That approach involves:

- *Research to identify new pain relievers with reduced abuse, tolerance, and dependence risk as well as working with industry and government to devise alternative delivery systems and drug formulations that minimize diversion and prevent overdose deaths.* To address this need, NIDA has recently partnered with the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) to assist Signature Therapeutics, a small biopharmaceutical company, in advancing the development of an abuse-deterrent pain medication based on an inactive, pro-drug formulation. The pro-drug is composed of extended-release oxycodone that is inactive until it reaches the digestive system, where specific enzymes cleave the pro-drug, releasing the opioid therapy. This approach would significantly decrease the possibility that the medication could be abused via non-oral routes (e.g., injection or inhalation). Additionally, through funding provided through the American Recovery and Reinvestment Act (ARRA), NIDA supported the development of Probuphine, a diversion-resistant buprenorphine implant that allows continuous medication delivery for 6 months to treat opioid addiction. Once implanted in the doctor's office, the opioid can no longer be diverted. Currently, Probuphine, developed by Titan Pharmaceuticals, is undergoing further clinical testing in preparation for a revised New Drug Application (NDA) with FDA.

- Epidemiological studies to identify patterns, trends, and motivations for prescription drug abuse in order to create more effective prevention strategies.*
 To this end, NIDA continues to support a diverse prescription drug abuse research portfolio including epidemiological studies of the patterns, trends, and motivations underlying prescription drug abuse; research to better understand the factors that predispose someone to become addicted to prescription pain relievers and what can be done to prevent it among those at risk; studies of the effectiveness and impact of prescription drug monitoring programs and patient-provider agreements; and the development and testing of treatments (both pharmacological and behavioral) and prevention interventions to reduce prescription drug abuse and prevent overdoses. NIDA has recently entered into an agreement with Lightlake Therapeutics to conduct the dosing studies needed to obtain FDA approval for an intranasal formulation of the opioid antagonist naloxone to rapidly reverse opioid overdose and prevent deaths. The intranasal naloxone formulation would provide an additional tool alongside the naloxone auto-injector (Evzio) for expanding access to this life-saving medication.
- Collaborating with Federal partners and other stakeholders to develop programs to reduce unintended access to or abuse of these medications, as well as create educational materials to improve safe use and opioid prescribing practices and inform the public about the dangers associated with non-medical use of these medications.* Prescription opioid abuse cannot be entirely eliminated without a collective understanding of the harms associated with unintended use and the role that each party plays in perpetuating this abuse. One in six parents (16 percent) believes that abusing prescription drugs is safer than abusing street drugs, and one in four teens (27 percent) share this belief.¹ NIDA has partnered with Medscape Education, with funding from the White House Office of National Drug Control Policy, to develop two online continuing medical education (CME) courses on Safe Prescribing for Pain and Managing Pain Patients Who Abuse Prescription Drugs (87,000 have completed these CMEs to date).² These courses provide practical guidance for physicians and other clinicians in screening pain patients for substance use disorder risk factors *before* prescribing, and in identifying patients who are abusing their medications without losing sight of addressing pain treatment. NIDA is also reaching out to teens with its PEERx initiative,³ providing factual information about the harmful effects of prescription drug abuse on the brain and body. In addition, NIDA coordinates efforts on behalf of the entire NIH community to dispose of unused and unwanted pharmaceutical substances through the DEA-sponsored National Prescription Drug Take-Back Day events. These

¹ MetLife Foundation and the Partnership at Drugfree.org. 2012 *partnership Attitude Tracking Study: Teens and Parents*. (2013, April 23). Available at: <http://www.drugfree.org/wp-content/uploads/2013/04/PATS-2012-FULL-REPORT2.pdf>

² <http://www.drugabuse.gov/opioid-pain-management-cmesces>

³ <http://teens.drugabuse.gov/peerx>

events aim to provide safe, convenient, and responsible means for disposing of prescription drugs while also educating the general public about the potential for abuse of medications. As of April 26, 2014, this program has been credited with the collection and removal of over 2,123 tons of unused medications from circulation.

The Honorable Ben Ray Lujan

1. As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me about what your office is doing to address the challenges of rural districts like New Mexico.

Answer: These issues are largely outside of NIDA's mission and scope. However, NIDA's web-based physician education and teen prevention initiatives are as accessible in rural areas as in urban ones. Two online CME courses on Safe Prescribing for Pain and Managing Pain Patients Who Abuse Prescription Drugs guide clinicians in screening pain patients for substance use disorder risk factors and in identifying patients who are abusing their medications.⁴ NIDA also reaches out to teens with its PEERx initiative,⁵ providing factual information about the harmful effects of prescription drug abuse on the brain and body.

2. Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse: The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public? Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs? The need to expand access to Naloxone to the public as prescription drug abuse continues to rise? A lack of funding for implementation of proven strategies? The need for legislation?

Answer: Decreasing prescription drug abuse and overdoses is indeed a multifaceted challenge, and all the factors listed in the question are important contributors to the complex problem, and there are additional ones. For example, the Centers for Disease Control and Prevention considers a key driver to the problem to be inappropriate prescribing. The NIDA Director and staff have commented upon these issues extensively in some recent articles, although it would be scientifically unsound to rank them in order of importance.⁶ However, another key driver of the overdose epidemic that is not mentioned often enough is *underlying substance use disorders*. It follows that expanding access to addiction treatment services is an essential component of a comprehensive response to this problem.

⁴ <http://www.drugabuse.gov/opioid-pain-management-cmesces>

⁵ <http://teens.drugabuse.gov/peerx>

⁶ Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted Therapies – Tackling the Opioid-Overdose Epidemic. *N Engl J Med*. 2014 April 23. Compton W.M.; Volkow N.D.; Throckmorton D.C.; Lurie P. Expanded access to opioid overdose intervention: research, practice, and policy needs. *Ann Intern Med*. 2013 Jan 1;158(1): 65-6. Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SR. Characteristics of opioid prescriptions in 2009. *JAMA*. 2011 April6;305(13):1299-301.

As is the case with other chronic diseases, such as diabetes or hypertension, which require management for life, effective treatment and functional recovery is possible. In the case of opioid addiction, healthcare providers have three types of medication-assisted therapies (MATs) to treat patients: methadone, buprenorphine, and naltrexone. Yet, these effective medications are markedly underutilized. Out of an estimated 2.5 million people age 12 or older in the United States who abused or were dependent on opioids in 2012 (2.1 million involved prescription opioids), fewer than one million received MAT.

3. Over the last several decades, even as enforcement and imprisonment rates have increased, the street price for heroin—and other illicit drugs—has decreased, leading to proliferation of this drug in virtually every state. In 2011, the ONDCP released its “Prescription Drug Abuse Prevention Plan” with the goal to reduce non-medical use of prescription drugs by 15% in 5 years. What is the progress of this initiative? Is there evidence that this plan is having an impact? Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?

Answer: These issues are largely outside of NIDA’s mission and scope. However, to the extent that prescription opioid abuse is a precursor to heroin abuse, NIDA expects that prevention efforts, which reduce the onset of prescription drug abuse, should be useful at reducing heroin use as well. However, the onset of heroin addiction is multifaceted and will require direct approaches as well. As outlined by HHS leadership, expanded access to effective treatments for opioid addiction is a key approach that addresses both prescription-type opioid addiction as well as heroin addiction.⁷

4. You can’t talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn’t have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further there is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types of programs in New Mexico?

Answer: NIDA grasps the importance of this issue and funds a broad portfolio of research addressing drug abuse in the context of the justice system, including:

- The Juvenile Justice Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS);
- Criminal Justice Drug Abuse Treatment Studies (CJ-DATS); and
- Seek, Test, and Treat: Addressing HIV in the Criminal Justice System.

⁷Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted Therapies – Tackling the Opioid-Overdose Epidemic. *N Engl J Med*. 2014 April 23.

NIDA's JJ-TRIALS is worth highlighting in this context. Launched in 2013, JJ-TRIALS is a seven-site cooperative research program designed to identify and test strategies for improving the delivery of evidence-based substance abuse and HIV prevention and treatment services for justice-involved youth. Numerous evidence-based screening, assessment, prevention, and treatment programs target substance use and HIV risk behaviors in this high-need population, yet these services rarely reach these youth. This study will help identify strategies for improving the implementation of evidence-based services in the juvenile justice system ensuring that every justice-involved youth has access to evidence-based services.

In addition, NIDA has produced a book, *Principles of Drug Abuse Treatment for Criminal Justice Populations*, which distills three decades of research on effectively addressing substance use disorders while an individual is in the criminal justice system.⁸ It has been one of the most popular NIDA publications and provides information to treatment providers, program administrators, criminal justice professionals, and policymakers on what research has demonstrated are effective interventions and practices for this population. The research underlying these principles has indicated drug use and drug related crime can be reduced.

We also have a three-site study looking at the use of different medications to facilitate transition of jail inmates into the community and prevent relapse to opioid use. New Mexico is one of the sites participating in that study, which is led by David Farabee from the University of California, Los Angeles.

NIDA has both an historical and ongoing commitment to research partnerships with criminal justice partners to develop more effective strategies to simultaneously reduce drug use and related health consequences, while reducing recidivism and improving public safety. NIDA has partnered with the Bureau of Prisons (BOP) on a research study that recently ended to determine effective strategies for increasing access to medications used to treat opioid addiction. For example, BOP staff have indicated a strong interest in expanding access to medications, and it is NIDA's understanding that they will be conducting a pilot program where MAT for opioid disorder would be initiated prior to release and continued in the community.

5. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to—so that there is greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?

Answer: Information on NIH funding opportunity announcements (FOAs) can be found online at <http://grants.nih.gov/grants/oe.htm>. Information on NIDA FOAs can be found at <http://www.drugabuse.gov/funding>.

6. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance use have been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?

⁸ <http://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations>

Answer: Epidemiological study after epidemiological study has shown that poverty has an enormous and long-lasting negative influence on the health of an individual— not only as it pertains to substance abuse and addiction risk but also as it relates to other major health problems such as obesity, stress, and cardiovascular disease as well. Indeed, research has shown that poverty and economic inequality are major risk factors for the development of problem behaviors.⁹ The problem is even more disturbing and devastating than it may seem, as research has shown that some of the negative health impacts of poverty may be passed on to later generations.¹⁰ Research also shows that the relationship between poverty and substance use may be bidirectional, as early substance use is a strong predictor of lower life achievement. For example, high levels of cannabis use are related to poorer educational outcomes, lower income, greater welfare dependence and unemployment, and lower relationship and life satisfaction.¹¹

We are not aware of specific studies designed to rigorously measure the impact of a drug abuse prevention program on sustainable economic development. One NIDA-funded observational study has demonstrated that increasing family income may lead to improvements in health, including reduced onset of substance use disorders in youth.¹²

⁹ Biglan A, Cody C. Integrating the Human Sciences to Evolve Effective Policies. *J Econ Behav Organ.* 2013 Jun 1;90(Suppl):S152-S162.

¹⁰ Bygren LO. Intergenerational health responses to adverse and enriched environments. *Annu Rev public Health.* 2013;34:49-60.

¹¹ Fergusson DM, Boden JM. Cannabis use and later life outcome. *Addiction.* 2008 Jun;103(6):969-76s.

¹² Costello Ej, Erkanli A, Copeland W, Angold A. Association of family income supplements in adolescence and development of psychiatric and substance use disorders in adulthood among an American Indian population. *JAMA* 2010;303:1954-1960.

The Honorable Michael C. Burgess

1. The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?

Answer: The ready availability and inappropriate prescribing of opioid pain relievers are important drivers of the problem, as are the failure to adopt and implement effective evidence-based treatment for opioid use disorders within the healthcare system. Evidence shows that when properly used, MAT using methadone, buprenorphine, or naltrexone can improve social functioning and reduce overdose deaths, in addition to reducing risk of transmitting infectious diseases like HIV and reducing criminal activities, but despite this, they remain severely underutilized.¹³ Out of an estimated 2.5 million people age 12 or older in the United States who abused or were dependent on opioids in 2012 (2.1 million involving prescription opioids)¹⁴, less than one million received MAT. MATs have been adopted in fewer than half of private sector treatment programs, and in programs that offer MATs, only 34.4 percent of their patients actually receive these treatments.¹⁵ Several intertwined factors contribute to this lack of MAT adoption and implementation, including:

- *Continued segregation of the opioid treatment system.* Unlike other medical conditions, addiction is typically treated within specialty care treatment settings, including methadone programs and other specialty addiction treatment programs that provide highly variable quality of care and may lack expertise in administering medications. This segregation means treatment remains highly stigmatized—and that stigma carries over into primary care, where physicians don’t want to treat drug addicts.
- *A lack of access to physicians in treatment programs.* Many treatment programs do not have physicians on staff, and this has been identified as a major barrier to the adoption of MAT in those programs.
- *Misunderstandings about MAT.* Even in programs that do have physicians on staff and that have adopted MAT, including programs whose sole job is to administer medication for opioid addiction, there is a widespread belief that maintenance treatment with buprenorphine or methadone “merely substitute a new addiction for an old one.” Consequently, patients may not receive a sufficient dose, for long enough duration (leading to treatment failure, which reinforces perception that MAT is not effective), and may expel patients for relapse.

¹³ Bart G. Maintenance medication for opiate addiction: the foundation of recovery. *J Addict Dis.* 2012;31:207-225.

¹⁴ Substance Abuse and Mental Health Services Administration. *Results from the 2012 national Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

¹⁵ Knudsen, H.R.; Abraham, A.J.; and Roman, P.M. Adoption and implementation of medications in addiction treatment programs. *J Addict Med* 2011; 5:21-27.

- *Policy and regulatory barriers.* Insurance coverage for MAT is limited, and both public and private insurers have utilization management policies such as dosage limits, lifetime or annual medication limits, difficult initial and reauthorization prescription processes, minimal coverage for counseling, and “fail first” criteria requiring that other therapies be attempted before MAT.¹⁶

2. What is the cost of a single dose of Naloxone? Is the cost of Naloxone a barrier to making the antidote more readily available?

Answer: NIDA has no role in the determination of the cost of naloxone. A search on the Web shows that a major medical supply company, Henry Schein, sells a 10-pack of prefilled naloxone syringes for \$275, which puts the price of a single dose at \$27.50. A DC needle exchange program, The Bread Line, gets it discounted from that supplier for \$79.16 for a 10-pack (*i.e.*, \$7.92/dose) but distributes the syringes for free. Some insurance plans, including Medicaid and Medicare in some states, provide reimbursement for naloxone.

Cost is not the main barrier to wider availability of naloxone. The major obstacles are: (1) mode of delivery (currently, only by injection); (2) prescribing laws in most states that limit a medication’s availability to the user him/herself or healthcare providers, but not to other emergency responders or laypeople who may be in a better position to use it in the event of a crisis; and relatedly; and (3) naloxone’s current status as a prescription-only medication.

- The first obstacle is being met through development of delivery systems that make naloxone easier to deliver by non-medical personnel and bystanders to an overdose. Recently, FDA approved an auto-injector formulation that is easier to use than a typical syringe, and NIDA is funding research to develop an intranasal formulation that would considerably simplify its delivery even by friends or family members of a person in crisis. Traditional syringes fitted with atomizers to deliver the drug intranasally are already being used in pilot overdose education and naloxone distribution programs, although intranasal delivery of a formulation intended for intravenous use is not ideal and may carry health risks. Such programs have been shown to reduce opioid overdose deaths and not to increase opioid use.¹⁷
- The second obstacle is laws limiting prescriptions to the person intended to receive the drug (in this case, the opioid user at risk of overdosing) and not third parties who may be better positioned to administer it. Recognizing that emergency medical personnel often arrive on the scene of an overdose too late, some states have passed laws allowing for wider prescription of naloxone to family members and friends of opioid-addicted persons as well as distribution to a wider array of emergency personnel, such as police and

¹⁶ American Society of Addiction Medicine. Advancing Access to Addiction Medications. Available at <http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>.

¹⁷ Doe-Simkins, M.; Quinn, E.; Xuan, Z; Sorensen-Alawad, A; Hackman, H.; Ozonoff, A.; and Walley, A.Y. Overdose rescues by trained and untrained participants and change in opioid use among substance-using participants in overdose education and naloxone distribution programs: A retrospective cohort study. *BMC Public Health* 2014, 14:297: <http://www.biomedcentral.com/147-2458/14/297>.

firefighters (many of these states have also passed “Good Samaritan” laws that protect bystanders who summon or deliver emergency aid).

- The prescription-only status of naloxone is the major limitation on its availability. Since the drug presents few dangers and has no abuse liability, some public health experts have suggested that naloxone’s access can be expanded by making it available over the counter.

The Honorable Steve Scalise

1. According to the GAO report, there are 15 federal agencies and 76 abuse prevention or treatment programs. The GAO report identified overlap in 59 of the 76 programs. Please discuss what your agency is doing to address that overlap and the problems addressed in the GAO report.

Answer: NIDA's mission is to support and carry out research designed to establish the evidence base that would serve as the platform used by other agencies to launch effective prevention and treatment programs. Once our Agency disseminates the results of its research, the way those results are implemented will be defined by each service provider. NIDA is not a purveyor of drug abuse prevention and treatment programs; thus, the nature and contents of its portfolio in this area are not really the subjects of this particular GAO report. That said, identifying places where redundancies can be prevented to increase efficiency is a worthy and important goal at every level of the Federal Government.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

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May 21, 2014

Dr. H. Westley Clark
Director
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Dear Dr. Clark:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 29, 2014, to testify at the hearing entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

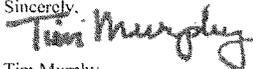
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, June 4, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Dr. H. Westley Clark, SAMHSA, Center for Substance Abuse Treatment
 Responses to Questions for the Record
 Committee on Energy and Commerce, Subcommittee on Oversight and Investigations
 April 29, 2014
 "Examining the Growing Problems of Prescription Drug and Heroin Abuse"

The Honorable Tim Murphy:

Q1. Two weeks ago SAMHSA posted to its website a report titled "SAMHSA's Einstein Expert Panel Medication-Assisted Treatment and the Criminal Justice System: Proceedings from the October 6- 7, 2011 Expert Meeting." Based on the date (October 2011), it is evident that it took over 2 ½ years for this report to be made available to the public. We are also aware of important practice guidelines on the use of the non-addictive, non-narcotic opioid blocker, extended-release naltrexone that has been held up nearly as long. What can be done to accelerate the pace with which important guidance and related documents are released to the professional community? Is there anything that we can do to assist you?

A1. SAMHSA subject matter experts on Medication-Assisted Treatment have many channels through which they can communicate critical information to key stakeholders including the professional community, such as "Dear Colleague" letters, virtual meetings, newsletters, technical assistance webinars and conference calls, blog posts, website updates, and curriculum development and outreach through continuing education channels such as WebMD, and dissemination of information via our grantees and partner organizations. All of these efforts have been utilized to ensure that the professional community has information related to the best ways to prevent and treat prescription opioid and heroin abuse. Depending on the nature of the content in question, high levels of clearance and oversight may be required when producing a product for the community. SAMHSA maintains a schedule of products undergoing review and is taking several steps to streamline the review of our products so that critical information reaches key stakeholders as quickly as possible.

Q2. SAMHSA has regulatory authority for the 1,300 "opioid treatment programs" or "OTPs" in the United States today. We know from NIDA-funded studies that when these patients stop taking their opioid replacement medications (methadone or buprenorphine) the vast majority will relapse back to illicit opioid use. We also know that the majority of patients in OTPs will in fact drop out of treatment within a matter of months (in the case of buprenorphine) or years (in the case of methadone). In other words, despite the good intentions of treatment providers and policy-makers, opioid dependent individuals are relapsing to illicit opioid use. Given that most individuals on opioid replacement therapy return to illicit opioid use when they stop taking their replacement opioids, and given that the vast majority of patients in OTPs will drop out of treatment, what can SAMHSA [do] to encourage OTPs to employ relapse prevention medications, such as opioid antagonists, and other approaches, designed to establish long-term abstinence? In other words, what is the "exit strategy"?

A2. The reasons for withdrawal from opioid agonist therapy are varied. For example, it has been demonstrated that patients on 60mg or more of methadone are more likely to be in treatment at the end of one year.¹ Also,

¹ Yan-ping Bao. A Meta-Analysis of Retention in Methadone Maintenance by Dose and Dosing Strategy. Am J Drug Alcohol Abuse. 2009;35(1):28-33.

inability to pay prompts a number of patients to leave treatment since many programs currently operate on a cash only basis and do not accept third party reimbursement. However, with implementation of the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, this barrier will be significantly decreased, as more individuals gain access to substance abuse treatment, including medication assisted treatment, through their health insurance.

It should be noted that relapse is not unique to treating substance use disorders; it occurs in the course of treating other chronic public health conditions such as diabetes and high blood pressure. Relapse prevention in treating opioid misuse is a core component of currently provided behavioral interventions. OTPs are also beginning to provide naloxone to reduce the chance of fatal overdose should relapse occur in OTPs. SAMHSA also solicits input from OTP providers regarding barriers to more comprehensive treatment including a wider variety of pharmacotherapies, pre-treatment and aftercare services. Through the Agency's long-standing relationships with the American Association for the Treatment of Opioid Dependence and other groups, SAMHSA maintains an effective communication channel regarding OTP issues and challenges.

Bringing medicines to patients has been used effectively in many low-resource settings where compliance is essential (*e.g.*, drug resistant TB regimens use directly observed therapy administered when necessary so patients never miss a dose).

Transition from opioid-agonist therapy to extended-release injectable naltrexone requires anywhere from three to 10 days of complete opioid abstinence. Many patients cannot accomplish this in the community even after a period of successful opioid agonist therapy and with ongoing support from their program. In some cases, state licensing requirements limit OTPs to opioid-agonist therapy with the result that patients must be discharged upon completing titration from methadone or buprenorphine making transitioning them to antagonist therapy impossible.

Because it is not a controlled substance, any prescriber could offer extended-release naltrexone. Patients leaving detoxification and residential treatment programs or being released from detention are ideal candidates for therapy with extended-release injectable naltrexone. This suggests an important role for the criminal justice system in increasing access to extended-release injectable naltrexone.

Q3. We understand that there are three medications approved by the FDA for the treatment of opioid dependence: methadone, buprenorphine and extended-release naltrexone. SAMHSA's website promotes referrals to methadone treatment providers and buprenorphine treatment providers through provider locators - but there is no SAMHSA provider locator for the one medication that is not a controlled substance (extended release naltrexone). Please help us understand why SAMHSA only promotes referrals through its two Provider Locators to methadone providers and buprenorphine providers, and not the other medication - especially when it is the only one that isn't a drug of abuse?

A3. Questions on naltrexone services were included in the 2013 National Survey of Substance Abuse Treatment Services (N-SSATS), which supplies information used in SAMHSA's Behavioral Health Treatment Services Locator.² On May 16, 2014, a new version of the Locator was released that includes substance abuse treatment facilities that offer oral naltrexone and Vivitrol, as well as methadone and buprenorphine.

² <http://findtreatment.samhsa.gov>

The Honorable Jan Schakowsky

- Q1. What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of pop-up clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and pop-up clinics, so I am interested in seeing what they are doing to help us combat the crisis.**
- Q2. What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market? Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?**

A1/A2. The Food and Drug Administration (FDA), not SAMHSA, regulates drugs manufactured by pharmaceutical companies. SAMHSA has worked with FDA on implementation of the Food and Drug Administration Amendments Act of 2007 that provided FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) of manufacturers to help ensure that the benefits of a drug or biological product outweigh its risks. FDA may also require a manufacturer to conduct post-marketing studies designed to assess the risks of a drug. REMS may also require education for prescribers to help ensure the benefit outweighs the risk of a medication. For example, prescriber training is required as part of the REMS for extended-release and long-acting opioids.

SAMHSA continues to participate in various workgroups, such as the HHS Behavioral Health Coordinating Committee's Prescription Drug Abuse Subcommittee, with FDA and other agencies regarding these and other issues surrounding prescription drug abuse.

According to SAMHSA's 2011 Drug Abuse Warning Network (DAWN) data, 1,244,872 Emergency Department (ED) visits involved nonmedical use of prescription medicines, over-the-counter drugs, or other types of pharmaceuticals (Table 18 in the paper). This represents about a quarter (24.6 percent) of all drug-related ED visits and about half (50.5 percent) of ED visits for drug abuse or misuse. Over half (53.0 percent) of medical emergencies seen in the ED resulting from nonmedical use of pharmaceuticals involved multiple drugs. Such visits will appear multiple times in the table (*e.g.*, a visit involving both methadone and tramadol will appear twice in this table). About one in five (17.6 percent) of ED visits involving nonmedical use of pharmaceuticals also involved alcohol. There were 366,181 ED visits which included narcotic pain relievers, with the majority involving CIIIs, particularly oxycodone products, however, hydrocodone products were the second most abuse opioid in the DAWN report accounting for about half of the oxycodone products incidence.³ SAMHSA will continue to track misuse of prescription opioid drugs and report on specific categories of these drugs where possible. The drugs in the DAWN report that are Schedule III include buprenorphine products, codeine products, and hydrocodone products (which is being rescheduled to CII). As for what drugs can/should be moved to Schedule II, we defer to FDA and DEA in regard to making scheduling recommendations.

- Q3. According to your testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?**
- A3. The large number of pain relievers used non-medically that are obtained from a friend or relative presents both a public health and a cultural problem. There is a perception that because pain relievers are legally prescribed that they are safe. Therefore, part of the effort to combat this trend needs to be focused on education. Toward that goal, SAMHSA has developed several programs focused on educating the public --

³ <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.1> accessed 9/5/14.

including the “Not Worth the Risk, Even If It’s Legal” campaign, and the “Prevention of Prescription Abuse in the Workplace” effort, both of which were mentioned in SAMHSA’s testimony. Also, for the past several years, SAMHSA participated in the Drug Enforcement Administration’s (DEA) Federal Agency Pharmaceutical Take-Back Days. These events, held in conjunction with the DEA’s national take-back days, provide federal agencies with the opportunity to collect unwanted, unused, and/or expired prescription drugs. Furthermore, SAMHSA’s participation in this effort helps to educate its staff members about the dangers of prescription drug misuse and abuse and broader promotion of the DEA’s national effort to improve public health.

SAMHSA’s Strategic Prevention Framework Partnerships for Success grant program (SPF-PFS), encourages grantees to target prescription drug misuse and abuse among persons aged 12 to 25. Funded states implement a combination of programs designed to reduce availability and access to prescription drugs for non-medical use. Funded strategies include education programs for families about the dangers of prescription drug interactions, educating consumers and prescribers about the dangers of high-risk prescribing, and implementing prescription drug take-back programs throughout targeted communities.

It is also important to take an “upstream” approach in identifying persons misusing opioids. To this end, SAMHSA continues to support the development and implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT). SBIRT is a public health approach to the delivery of early intervention and treatment services for people with substance use disorders and those at risk of developing these disorders.

Finally, it is also important to educate physicians who prescribe these medications to better recognize the potential for misuse and abuse. Through SAMHSA’s SBIRT Medical Residency program and the Physician’s Clinical Support Systems, physicians and clinicians are receiving the information and training needed to help them educate their patients and monitor potential abuse.

The Honorable Ben Ray Lujan

Q1. As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me about what your office is doing to address the challenges of rural districts like New Mexico.

A1. In FY 2013, SAMHSA provided New Mexico with Substance Abuse Prevention and Treatment Block Grant (SABG) funds in the amount of \$8,437,153, and discretionary grants which total \$39,485,588. In FY 2014, the New Mexico Human Services Department, Behavioral Health Services Division will receive an increase in the SABG. SABG funds can be used to provide substance abuse prevention and treatment services in rural communities. In fact, 63 percent of SABG grantees, including the state of New Mexico, indicate that they plan to use SABG primary prevention set-aside funds to target rural communities in FY 2014. SAMHSA informed states and jurisdictions that Substance Abuse Prevention and Treatment Block Grant primary set-aside funds may be utilized to support overdose prevention education and training consistent with legislation. In addition, SAMHSA has notified jurisdictions that block grants – other than primary prevention set-aside funds – may be used to purchase naloxone and the necessary materials to assemble overdose kits and to cover the costs associated with the dissemination of such kits.

SAMHSA has a number of discretionary grant programs which address the unique challenges of rural districts, many of which are active within New Mexico. A number of SAMHSA's Drug Free Communities grantees serve rural New Mexico communities, including the Rio Arriba County Coalition services in Espanola, NM, a rural area with a population of 12,000; and the Taos CARES Health Council services in Taos County, NM, a rural area with a population of 35,000.

New Mexico has also received a SAMHSA Access to Recovery (ATR) grant for 10 years. From the current grant, New Mexico has received \$13 million and has served over 9,000 individuals with treatment and recovery support services. Through the New Mexico ATR program there are currently 165 New Mexico faith based and secular substance abuse treatment and recovery support providers serving individuals across the state. Current efforts are focused on the state's three largest population centers of Bernalillo County, Santa Fe County and Dona Ana County, the rural counties of Otero and Curry, and in the tribal communities of Five Sandoval Indian Pueblos, Inc. Follow-up data collected on program participants indicate 80 percent abstinence from alcohol and drugs at six months.

In FY 2013, New Mexico was awarded a second SBIRT state grant. This 5-year grant is designed to introduce screening, brief intervention and referral to treatment into rural and underserved areas of New Mexico. It is designed to identify early stages of substance misuse and intervene or refer individuals to the appropriate treatment regimen. It is also designed to enhance the utility of health information technology (HIT) into the system to help sustain these services into the era in which electronic health records will be essential for billing. In the future HIT and electronic health records/billing and coding may mean the difference between prosperity or cessation of services in individual clinic or organization settings.

In particular, SAMHSA's Center for the Application of Prevention Technologies (CAPT) is a national substance abuse prevention training and technical assistance center. The CAPT Southwest Resource Team (RT) provides training and technical assistance to SAMHSA-funded grantees in the state of New Mexico on successfully implementing SAMHSA's Strategic Prevention Framework, a five-step planning process that guides the selection, implementation, and evaluation of evidence-based, culturally appropriate substance abuse prevention activities. Within the scope of this contract, the CAPT Southwest RT has provided technical assistance to New Mexico communities in Grant County, Dona Ana County, Luna County, Lea County, and McKinley County. Specifically, the CAPT has reviewed and provided feedback on community needs assessments, readiness and capacity assessments, and strategic plans to help ensure that rural communities select prevention interventions that are most appropriate to the community and most

effective in addressing prescription drug abuse. In the upcoming months, the CAPT will provide training and technical assistance to the state on building the capacity of rural communities to identify and implement effective prevention strategies, such as implementing media campaigns in rural areas to address prescription drug abuse.

Under SAMHSA's Strategic Prevention Framework - Partnerships for Success II cooperative agreement, the state of New Mexico has funded high need, low capacity rural communities which are seeking to address the priorities of non-medical use of prescription drugs and underage drinking.

Q2. Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse: The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public? Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs? The need to expand access to Naloxone to the public as prescription drug abuse continues to rise? A lack of funding for implementation of proven strategies? The need for legislation?

A2. As stated, the challenge of achieving the goal of reducing prescription drug abuse and overdoses is a complex one that is best approached with activities and programs that focus on prevention, education, and treatment (including early intervention). SAMHSA seeks to weave these approaches, when appropriate, into discretionary grant programs such as the previously described SPF PFS, which implements a combination of strategies designed to reduce availability and access to prescription drugs for non-medical use. Funded strategies include education programs for families about the dangers of prescription drug and opioid interactions, educating consumers and prescribers about the dangers of high-risk prescribing, ensuring proper training of first responders, and implementing prescription drug take-back programs throughout targeted high need communities.

Additionally, recognizing the increase in overdose deaths and lack of funding for expanding access to Naloxone, SAMHSA sent guidance to all Substance Abuse Prevention and Treatment Block Grant (SABG) grantees on April 2, 2014. This guidance stated that SABG primary prevention set-aside funds could be used to support overdose prevention education and training, and SABG funds other than primary prevention set-aside funds could be used to purchase Naloxone and the necessary materials to assemble overdose kits and to cover the costs associated with the dissemination of such kits.

The Affordable Care Act and Mental Health Parity and Addiction Equity Act will expand coverage for substance use disorder treatment, capacity -- particularly for medication-assisted treatment. The most significant barrier is the pervasive misapprehension among health care providers that substance use disorders and related problems are not within their responsibility to address, not within their skills to address, or not treatable.⁴ This stems in large part from the lack of training on substance use disorders as an integral part of the prevention, identification and management of the health of the individual or the public. For this reason, SAMHSA funds the SBIRT Medical Residency program, which integrates substance abuse treatment into residency programs, as well as a series of medical education courses designed to help physicians provide appropriate pain management while minimizing the risk of pain medication abuse.

⁴ Cape, G., Hannah, A. and Sellman, D. (2006), A longitudinal evaluation of medical student knowledge, skills and attitudes to alcohol and drugs. *Addiction*, 101: 841–849. doi: 10.1111/j.1360-0443.2006.01476.x. Saitz, R., Friedmann, P. D., Sullivan, L. M., Winter, M. R., Lloyd-Travaglini, C., Moskowitz, M. A. and Samet, J. H. (2002), Professional Satisfaction Experienced When Caring for Substance-abusing Patients. *Journal of General Internal Medicine*, 17: 373–376. doi: 10.1046/j.1525-1497.2002.10520.x

Q3. Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin – and other illicit drugs – has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its "Prescription Drug Abuse Prevention Plan" with the goal to reduce non-medical use of prescription drugs by 15% in 5 years. What is the progress of this initiative? Is there evidence that this plan is having an impact? Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?

A3. SAMHSA fully supports the Office of National Drug Control Policy's (ONDCP) four-part strategy and is actively engaged, with other federal agencies, in reaching the goals of that policy. SAMHSA recognizes the significance of the impact on society and its citizens of heroin use and prescription drug abuse. Research supports the perspective that opioid addiction is a medical disorder that can be treated effectively with medications. Medication-assisted treatment (MAT) for opioid addiction has been effective in facilitating recovery from opioid addiction for many patients. Recognizing that MAT may be an important part of a comprehensive treatment plan, SAMHSA allows Criminal Justice grantees to use up to 20 percent of their funding for appropriate medication (e.g., methadone, injectable naltrexone, non-injectable naltrexone, disulfiram, acamprosate calcium, and buprenorphine).

There is continued discussion regarding the relationship between the misuse of pain medication and heroin. SAMHSA pooled the data from the National Survey on Drug Use and Health (NSDUH) for the years 2002 through 2011 regarding this issue. The study finds that past year heroin use is 19 times higher among those who reported prior nonmedical use of pain relievers than among those who did not (0.39 percent vs. 0.02 percent). The study also found that the incidence rate for nonmedical use of pain relievers was almost two times higher among those who reported prior heroin use than among those who did not (2.8 percent vs. 1.6 percent).⁵ Given this data, the Administration's efforts to address and prevent prescription opioid misuse and abuse may also prevent individuals from using heroin as well.

Scarcity of prescription analgesics will drive up the price, making heroin the more affordable option. According to SAMHSA's Treatment Episode Data Set (TEDS) 2012 treatment admissions for heroin increased 16% between 2010 and 2012. According to the National Association for State Alcohol and Drug Abuse Directors (NASADAD) a majority of states report that heroin use and heroin overdose have been rising over the past two years.⁶

Q4. You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact or expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further there is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types programs in New Mexico?

A4. SAMHSA recognizes the need for substance abuse treatment for an offender population with high incidence of substance abuse dependence and co-occurring mental health disorders. SAMHSA's substance abuse treatment criminal justice portfolio currently includes 215 grants, serving approximately 20,000 individuals in the criminal and juvenile justice system as of this date. Programs include drug courts, re-entry programs and jail diversion programs, totaling \$75 million in FY 2014 funds. SAMHSA expects to fund approximately 75

⁵ Murhuri, PK, Gfroerer, J, Davies, MC (August 2012), Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, *CBHSQ Data Review*, <http://samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm>

⁶ <http://www.samhsa.gov/data/2k13/TEDS2011/TEDS2011INTOC.htm>

<http://nasadad.org/wp-content/uploads/2014/05/NASADAD-Prescription-Drug-and-Heroin-Abuse-Inquiry-Full-Report-Final.pdf>

additional Drug Court grants this fiscal year. Funding for approximately 30 of these grants is possible due to the FY 2014 \$10 million increase in Drug Court funding by the Congress.

SAMHSA also published a Request for Application for the Grants to Expand Substance Abuse Treatment Capacity in Adult Tribal Healing to Wellness Courts and Juvenile Courts. The program will fund up to 14 grants. SAMHSA received applications for this program from two New Mexico applicants and the applications are being reviewed for possible funding for up to 3 years, beginning in September 2014.

Currently, the Bernalillo County Metropolitan Court in Albuquerque has a jointly funded BJA/SAMHSA Adult Treatment Drug Court grant. This grant was funded on September 30, 2013 for up to three years. The Court is using the funds to enhance their adult DWI/Drug Court and Mental Health Court and assist nonviolent offenders with successful rehabilitation from the use of drugs and/or alcohol and/or mental health issues. The program has set a goal of serving 220 clients each year for a total of 660 clients over the lifetime of the program. Currently the program has exceeded its intake client target numbers and is well over 100% and is doing well with their six month follow-up rate also. The programs interventions are: implementation of the RANT risk screening tool; implementing gender-specific trauma and other recovery support services; expanding community linkages and providing culturally-competent services to Native American participants; and expanding community supervision by adding community supervision officers.

SAMHSA and the Office of Juvenile Justice and Delinquency Prevention in the U.S. Department of Justice have worked together over the past 6 years to fund newer models of juvenile justice programs such as the "Reclaiming Futures" model. This model is designed to help change the current approach to juvenile justice – treatment linkages. A key component of the model is coordinated individualized response for each juvenile (initial screening and assessment for substance abuse problems using reputable tools), services coordination, and community directed engagement.

SAMHSA also funds the GAINS Center for Behavioral Health and Justice Transformation, a resource and technical assistance center for state planning and coordination among the mental health, substance abuse, and criminal justice systems. The Center focuses on the application of science to services and the documentation and promotion of evidence-based and promising practices in program development.

Q5. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to-so that there is greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?

A2. SAMHSA annually publishes Requests for Applications (RFA) for its discretionary grant funds on the SAMHSA website.⁷ Each RFA contains all the information needed to apply for a grant, *e.g.*, eligibility, estimated award amount, estimated number of awards as well as contact information for program issue and grants management/budget issues.

Constituents can also sign up for e-mail updates from SAMHSA⁸ that provide information on available grants and contracts and new information on topics that are relevant to the full spectrum of the behavioral health field.

Finally, SAMHSA has regional administrators in each of the ten public health regions. Mr. Michael Duffy serves as the Regional Administrator for Region VI which includes New Mexico. Mr. Duffy serves as a tremendous resource for citizens in your district to reach out to for information partnership with SAMHSA.

⁷ www.samhsa.gov/grants

⁸ <http://bit.ly/subscribeSAMHSA>

Q6. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?

- A6. It is evident that social determinants, such as poverty, education, employment, age, social class, etc., have a dramatic impact on peoples' physical and behavioral health. According to the 2012 NSDUH, adults aged 18 and older who graduated from college or university had a lower rate of substance dependence or abuse than those who did not graduate from high school (7.2 percent vs. 10.3 percent). A higher percentage of unemployed adults were classified with dependence or abuse than were full-time employed adults (16.9 percent vs. 9.1 percent). An analysis of 2006-2008 NSDUH data of individuals aged 12 or older living in poverty reported that 12.3 percent (3.7 million persons) were classified as being in need of substance use treatment in the past year.

Existing research and data suggest that common or *shared* risk and protective factors throughout life impact both substance abuse and mental health outcomes. Examples of shared risk factors include poor grades/achievement and family history of substance use disorders. Examples of shared protective factors include parental support and bonding as well as participation in social activities. Understanding these factors is critical to designing substance abuse prevention interventions to help individuals develop the intentions and skills to act in a healthy manner as well as focusing on the creation of environments that support healthy behavior. The most effective prevention interventions are those that incorporate both these approaches. Practitioners can use these interventions to target their prevention efforts to meet the needs of sub-populations that may be at increased risk of developing substance abuse and related behavioral health problems.

SAMHSA's substance abuse treatment grant programs report outcome measures based on the social determinants, including social connectedness, employment, housing, and criminal justice involvement. Overall, these data demonstrate the connectivity of increasing quality of life with decreased substance abuse. SAMHSA's Office of Behavioral Health Equity (OBHE) was established in accordance with section 10334 of the Affordable Care Act. Launched in 2012, OBHE coordinates SAMHSA efforts to reduce behavioral health (mental health and substance abuse) disparities for diverse racial and ethnic and lesbian, gay, bisexual and transgender (LGBT) populations. OBHE's efforts are geared to promote health equity for all racial and ethnic and LGBT populations, and support populations vulnerable to behavioral health disparities.

OBHE is organized around five key strategies: data, communication, policy, quality practice and workforce development and customer service/technical assistance. OBHE seeks to impact SAMHSA policy and initiatives by:

- Creating a more strategic focus on racial, ethnic and LGBT populations in SAMHSA investments;
- Using a data-informed quality improvement approach to address racial and ethnic disparities in SAMHSA programs;
- Promoting behavioral health equity at a national level;
- Increasing awareness and access to information regarding behavioral disparities and strategies to promote health equity;
- Ensuring that SAMHSA policy, funding initiatives and collaborations include emphasis on decreasing disparities;
- Implementing innovative, cost-effective training strategies to a diverse workforce;
- Serving as a trusted broker of behavioral health disparity and equity information.

Dr. H. Westley Clark, SAMHSA, Center for Substance Abuse Treatment
Responses to Member Requests for the Record
Committee on Energy and Commerce, Subcommittee on Oversight and Investigations
April 29, 2014
“Examining the Growing Problems of Prescription Drug and Heroin Abuse”

The Honorable Michael C. Burgess

Q1. The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment, and law enforcement. What is it about the current system that is not working?

A1. One of the biggest challenges is the lack of health coverage that includes payment for substance abuse treatment. According to 2012 NSDUH data, 38 percent of individuals seeking treatment for substance use/abuse did not receive it because they lacked health coverage and could not afford it. Another 10 percent had health coverage that did not cover substance use treatment. With the implementation of the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, this barrier will be significantly decreased, as more individuals gain access to substance abuse treatment through their health care insurance.

In addition, more research is needed to develop best practices around prescription drug misuse and abuse. As an evolving issue, efforts to prevent prescription drug and opioid misuse and abuse require our continued attention. Through the efforts of SAMHSA’s Partnership for Success grantees and Substance Abuse Prevention and Treatment Block Grant recipients, SAMHSA continues to collect relevant data to ensure programs targeting prescription drugs are evidence-based. In addition to efforts being conducted at SAMHSA, the National Institute on Drug Abuse continues to work collaboratively with SAMHSA and other agencies to bring new information to the field.

Q2. What is the cost of a single dose of Naloxone? Is the cost of Naloxone a barrier to making the antidote more readily available?

A2. The cost of naloxone has been estimated to be approximately \$6 per dose or \$25 to \$40 if packaged with the necessary supplies for use. Scarcity and lack of competition in the manufacture of naloxone has also led to price increases in recent years and, consequently, the cost may be a barrier to some individuals without insurance coverage. In the aggregate, the cost born by some states with a great need for wide availability may become prohibitive.⁹ The price for the new autoinjector product has not been released by Kaleo but it is expected to be more costly. However it lasts 2 years, is certified to be able to withstand difficult environments such as temperature extremes and requires little training other than learning to recognize the signs of an overdose. Where insurance covers this product cost should not be a barrier.

⁹ Coffin PO, Sullivan SD. Cost effectiveness of distributing naloxone to heroin users for lay overdose reversal. *Ann Int Med.* 2013;158:1–9. Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 13-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
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2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (269) 225-2992
Minority (269) 226-3841

May 21, 2014

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Agency
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

Dear Mr. Rannazzisi:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 29, 2014, to testify at the hearing entitled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

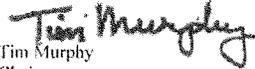
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, June 4, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

February 26, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Oversight and Investigations, on April 29, 2014, at a hearing entitled, "Examining the Growing Problems of Prescription Drug and Heroin Abuse." 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 black ink, appearing to read "Peter J. Kadzik".

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Frank Pallone, Jr.
Ranking Member

**Questions for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice**

**Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
"Examining the Growing Problems of Prescription Drug and Heroin Abuse"
April 29, 2014**

Questions Posed by the Honorable Michael C. Burgess

- 1. Based on the available data, it appears that abuse of Immediate Release (IR) opioids involves the same risks as abuse of Extended Release (ER) opioids and is causing similarly large numbers of abuse and misuse problems. It is my understanding that FDA has treated them differently in terms of labeling, warnings, and REMS. Shouldn't IR and ER opioids be treated the same so that prescribers and patients receive the same important warnings about all opioids?**

Response:

This matter is not within the Drug Enforcement Administration's (DEA) jurisdiction. DEA respectfully defers to the Department of Health and Human Services (HHS).

Questions Posed by the Honorable Jan Schakowsky

1. **What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of popup clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and popup clinics, so I am interested in seeing what they are doing to help us combat the crisis.**

Response:

DEA regulations require non-practitioners such as wholesale distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). Further, all DEA registrants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). One factor relevant to compliance with the security requirements is the “adequacy of the registrant’s . . . system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.” 21 C.F.R. § 1301.71(b)(14).

In recent years, DEA has steadily increased the frequency of compliance inspections of specific categories of registrants, such as manufacturers (including bulk manufacturers), distributors, pharmacies, and certain practitioners. This renewed focus on oversight has enabled DEA to take a more proactive approach to educating registrants and ensuring that they understand and comply with the Controlled Substances Act (CSA) and its implementing regulations. DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with Federal laws and regulations. Each inspection entails close communication between DEA and the registrant to educate the registrant about proper procedures and to ensure corrective action is taken to comply with the law. These inspections typically result in remediation or continued compliance, and no further action is taken. DEA conducts compliance inspections of registered distributors every two years.

DEA’s Distributor Initiative Program was implemented in late 2005 and was designed to educate wholesale distributors that were supplying diversion schemes such as rogue Internet pharmacies and, more recently, rogue pain clinics and rogue pharmacies. The goal of the program is to cut off the source of supply to these or other schemes through effective due diligence and monitoring for suspicious orders. As stated above, wholesale distributors are required to design and operate a system that would disclose suspicious orders to the registrant and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA provides registrants with information such as “red flags,” trending information, and data analysis that they should be aware of prior to distributing controlled substances. Factors that should generally be considered include, but are not limited to: the type of drug(s) ordered (e.g., the breadth and schedule of controlled substances ordered), orders of unusual size, orders that deviate from a normal pattern, frequency of orders, and the percent of controlled and non-controlled substances ordered.

- 2. What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?**

Response:

This matter is not within DEA's jurisdiction. DEA respectfully defers to the Department of Health and Human Services (HHS).

- 3. Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?**

Response:

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. § 812. The five schedules are categorized by potential for abuse, medical usefulness, and the potential for producing physical dependence and psychological dependence, and each schedule imposes a varying degree of controls and penalties. As a class of substances, prescription opioids generally have a high potential for abuse and this abuse is characterized by severe psychological or physical dependence. In addition to the schedule II substances, a few opioids and opioid formulations are placed under schedules III and IV. The determination of the appropriate schedule is done on a case-by-case basis with special consideration given to the scheduling recommendation provided by HHS.

The initial schedules of controlled substances established by Congress are found at 21 U.S.C. § 812(c), and the current list of all scheduled substances is published at 21 C.F.R. § 1308 and 21 U.S.C. § 812(a). In recent scheduling actions, DEA has placed a number of opioids under the CSA, including tapentadol in schedule II and tramadol in schedule IV. Additionally, on August 22, 2014, DEA after evaluating all available data, finalized the rescheduling of hydrocodone combination products from schedule III to schedule II. DEA will continue to monitor and collect information to evaluate drug scheduling and initiate actions to protect public health and safety, as appropriate.

The majority of prescription opioid drugs are placed under schedule II in the CSA. This placement is based on the drug or substance's relative potential for abuse. The findings required for placing a drug or other substance in schedule II are as follows: (a) it has a high potential for abuse; (b) it has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and (c) abuse of the drug or other substance may lead to severe psychological or physical dependence.

Please see the table below for a brief explanation of the schedules of controlled substances:

Schedule I	A) The drug or other substance has a high potential for abuse. B) The drug or other substance does not currently have an accepted medical use for treatment in the United States. C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
Schedule II	A) The drug or other substance has a high potential for abuse. B) The drug or other substances has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.
Schedule III	A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
Schedule IV	A) The drug or other substance has low potential for abuse relative to the drugs or other substances in schedule III. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drug or other substances in schedule III.
Schedule V	A) The drug or other substance has low potential for abuse relative to the drugs or other substances in schedule IV. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 812 (b)(1), (2), (3), (4), and (5).

- 4. According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?**

Response:

The Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- 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. Each one-day PDAC is held on a Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. At this time, there are 16 proposed PDACs in eight states for FY 2015.
- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided 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. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Orders System (ARCOS) reporting, import/export permits, and import/export declarations were

- discussed. Approximately 370 people attended, representing more than 200 registrants.
- The Distributor Conference was held on October 22, 2013, and this conference provided an overview of Federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. Approximately 220 people attended, representing more than 130 registrants.
 - To better assist DEA registrants with their understanding of the CSA and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via the DEA website:
 - Chemical Handler's Manual
 - Pharmacist's Manual
 - Practitioner's Manual

Additionally, as noted in the response to Question 1, above, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors that 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.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.¹ However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.² The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior

¹ This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in schedule II.

² The Brandeis University PDMP Center of Excellence, retrieved 12/18/14
<http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>.

year).³ While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse 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; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.⁴

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over \$87 million from FY 2002 to FY 2014, including \$7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

³ Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

⁴ The Brandeis University PDMP Center of Excellence, retrieved 12/18/14
<http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>.

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled Substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately \$16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other

entities violate the law. For example, in March 2013, UPS agreed to a \$40 million settlement with the Department of Justice for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, \$34 million in seized assets, and forfeiture orders totaling \$51 million.

In 2012, DEA pursued administrative actions against two CVS pharmacy stores in Florida, where these two registrants violated provisions of the CSA and committed acts that are inconsistent with the public interest by dispensing controlled substances to customers under circumstances indicating that the drugs were being diverted from legitimate channels, misused, or abused, and by failing to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). In October 2012, the DEA Administrator issued a final order revoking the registrants' certificates of registration and denying any pending applications for renewal, stating that the misconduct was both egregious and of extended duration, and undoubtedly caused extensive harm to the public interest. During 2013, DEA, together with the United States Attorneys' Offices for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an \$11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay \$80 million in civil penalties for the actions by their distribution center and six pharmacies in Florida, which resulted in the diversion of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of FY 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. As of September 30, 2014, there was only one Florida physician in the top 100 purchasers of oxycodone, as Florida law no longer allows practitioners to dispense schedule II and schedule III controlled substances, with the exception of some very limited circumstances (e.g., practitioners may dispense to patients who: are under hospice care; have undergone a surgical procedure, and a 14-day supply may be dispensed; are an inmate in a prison; or are a participant in an approved clinical trial). The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

Questions Posed by the Honorable Ben Ray Lujan

- 1. As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me about what your office is doing to address the challenges of rural districts like New Mexico.**

Response:

The Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas.

In 2014, ONDCP awarded funds to the Southwest Border HIDTA-New Mexico Region for the Rio Arriba Community Empowerment (RACE) Project. Project RACE is a prevention initiative targeting the rates of drug overdose, student graduation, delinquency, and crime in Rio Arriba County. This project advances the National Drug Control Strategy prevention priorities by strengthening local efforts to prevent drug use in SMART (State, Metropolitan Area, Rural, Tribal) communities.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- 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. Each one-day PDAC is held on a Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states, two of which were held in Albuquerque, NM on March 2-3, 2013, with a total of 284 attendees. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. There are 16 proposed PDACs in eight states for FY 2015.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.⁵ However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.⁶ The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior year).⁷ While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse 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; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers.

⁵ This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in schedule II.

⁶ The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 <http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>.

⁷ Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states, including New Mexico, have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.⁸

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over \$87 million from FY 2002 to FY 2014, including \$7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the Controlled Substance Act (CSA) provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

⁸ The Brandeis University PDMP Center of Excellence, retrieved 12/18/14
<http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. One such TDS is located in Albuquerque, New Mexico. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

The Albuquerque District Office (ADO) Diversion Group and TDS traditionally covered the entire State of New Mexico, a significant task for a relatively small group of Diversion Investigators, DEA Special Agents, and Task Force Officers. In October 2013, recognizing the need to increase resource allocation in the State of New Mexico, DEA's El Paso Division (EPD) placed the southern portion of New Mexico under a regulatory and enforcement group based in the EPD. This move allowed an additional group of Diversion Investigators and Special Agents to focus on the southern New Mexico counties of Catron, Lincoln, Chavez, Grant, Sierra, Otero, Eddy, Lea, Luna, Dona Ana, and Hidalgo.

The ADO has developed a close relationship with regulatory, law enforcement, and prosecutorial counterparts at all levels of government in New Mexico. This has allowed the ADO to effectively use its resources and leverage the power of state government to help target the prescription drug epidemic.

The Diversion Groups and the TDS Groups based in Albuquerque and El Paso are regulatory and enforcement oriented, and are not traditionally focused on prevention, treatment, and rehabilitation, other than to work in a regulatory capacity of licensing narcotic treatment

programs. In 2014, the ADO and the United States Attorney's Office began working on a comprehensive program of cooperation based on a heroin and opioid epidemic community action plan first implemented in Northeast Ohio. Although law enforcement's role is limited, a new paradigm of cooperation between law enforcement, treatment facilities, medical boards, legislators, hospital administrators, and prescription drug manufacturers is being created.

Initiated by the United States Attorney's Office, the first H.O.P.E. (Heroin, Opioid, Prescription Drug and Education) conference will take place at a future date in 2015. The unique aspect of the overall strategy is not to develop new working groups, but rather to incorporate established treatment, counseling, law enforcement, rural community working groups, and legislative entities in a spirit of communication. The ADO Assistant Special Agent in Charge (ASAC) was asked to co-chair the law enforcement panel of this conference with an Assistant United States Attorney.

The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the nation's principal enforcer of drug laws.

- 2. Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse: The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public? Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs? The need to expand access to Naloxone to the public as prescription drug abuse continues to rise? A lack of funding for implementation of proven strategies? The need for legislation?**

Response:

DEA agrees that prescription drug abuse and overdoses are a complex problem with no simple solution. All of the factors you mention may play a part in decreasing prescription drug abuse and overdoses. To the extent that a need for additional legislation is identified, the Department would appreciate the opportunity to work with you, your staff, and the Committee. Please see the response to question 1, above, for further information regarding these issues.

Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin-and other illicit drugs has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its "Prescription Drug Abuse Prevention Plan with the goal to reduce non-medical use of prescription drugs by 15% in 5 years. What is the progress of this initiative? Is there evidence that this plan is having an impact? Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?

Response:

DEA respectfully defers to ONDCP on this matter.

3. **You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further there is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types programs in New Mexico?**

Response:

The Bureau of Prisons (BOP) places strong emphasis on preparing inmates for reentry. Excellent substance abuse programming is one of BOP's most significant endeavors toward this goal. Drug abuse education and substance abuse treatment are available in each of BOP's 121 institutions. There are also a total of 89 Residential Drug Abuse Programs (RDAP), which have been proven effective at reducing recidivism and relapse, and decreasing institution misconduct. These highly interactive programs have been designed using the most recent and effective evidence based practices. The addition of new programs in FY 2013 and FY 2014 has increased drug treatment capacity in BOP considerably.

Specifically, BOP has RDAP, Nonresidential Drug Abuse Treatment, and Drug Education. Drug Education is a psychoeducational course to encourage offenders with a history of drug use to review the choices they have made, including their choice to use drugs and the consequences of their choices. Inmates must review how those choices have affected them physically, socially, and psychologically. Drug abuse education takes the offender through the cycle of drug use and crime, and offers compelling evidence of how continued drug use can lead to a further criminality and related consequences. Drug abuse education is designed to motivate appropriate offenders to participate in nonresidential or residential drug abuse treatment, as needed.

The Nonresidential Drug Abuse Treatment program is designed as therapy groups to include a variety of clinical activities organized to treat complex psychological and behavioral problems. The activities are unified through the use of Cognitive Behavioral Therapy (CBT), which was selected as the theoretical model because of its proven effectiveness with the inmate population. A good percentage of inmates in BOP struggled with drugs, alcohol, and dysfunctional lifestyles before incarceration.

The RDAP provides nine to twelve months of intensive drug abuse treatment to inmates diagnosed with a drug use disorder. The RDAP targets behaviors that; reduce antisocial peer associations; promote positive relationships; increase self-control, self-management, and problem solving skills; end drug use; and replace lying and aggression with pro-social alternatives. This is an excellent treatment program and prepares inmates for their reentry into

society. BOP staff take great pride in operating clinically effective programs so that inmates do not persist in their drug use. For non-violent offenders, successful completion of RDAP, to include transitional treatment while in a Residential Reentry Center (halfway house), includes an early release incentive of up to one year off the term of incarceration. Thus, RDAP not only helps return inmates to their communities as law-abiding citizens, but also helps with institution crowding. Currently, inmates completing RDAP are receiving an average of 10.4 months off their sentences.

In coordination with the National Institute on Drug Abuse, BOP conducted a rigorous three-year outcome study of the RDAP. The study revealed that male participants were 16 percent less likely to recidivate and 15 percent less likely to relapse than similarly-situated inmates who do not participate in residential drug abuse treatment for up to three years after release. The analysis also found that female inmates who participate in RDAP are 18 percent less likely to recidivate than similarly situated female inmates who do not participate in treatment. This study demonstrates that BOP's RDAP makes a positive difference in the lives of inmates and improves public safety.

While BOP does not have a federal prison in New Mexico, federal offenders from all 50 states, to include New Mexico, are referred and receive treatment in federal facilities. There are three institutions in Arizona providing various drug treatment programs to include RDAP. The Arizona institutions include the Federal Prison Camp and the Federal Correctional Institution in Phoenix, and the Federal Correctional Institution in Safford. There is also a federal prison on the Texas/New Mexico border, Federal Correctional Institution El Paso, offering RDAP and other drug programs described above.

- 4. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to so that there is greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?**

Response:

This matter is not within DEA's jurisdiction, as DEA does not have grant authority. The Office of Justice Programs, the Office of Community Oriented Policing Services, and the Office on Violence Against Women are the primary grant-making components of the Department.

- 5. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?**

Response:

DEA does not have any data regarding pairing economic development with initiatives to reduce and treat substance abuse as those matters fall outside of DEA's jurisdiction and expertise.

Attachment 2**Member Requests for the Record**

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

Questions Posed by the Honorable Michael C. Burgess

- 1. The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?**

Response:

DEA agrees that prescription drug abuse and overdoses are complex problems with no simple solution. In order to better address prescription abuse, the Office of National Drug Control Policy (ONDCP) developed the Prescription Drug Abuse Prevention Plan, which expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all of these areas.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- 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. Each one-day PDAC is held on a Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. At this time, there are 16 proposed PDACs in eight states for FY 2015.
- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided 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. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Orders System (ARCOS) reporting, import/export permits, and import/export declarations were discussed. Approximately 370 people attended, representing more than 200 registrants.
- The Distributor Conference was held on October 22, 2013, and this conference provided an overview of Federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. Approximately 220 people attended, representing more than 130 registrants.
- To better assist DEA registrants with their understanding of the Controlled Substance Act (CSA) and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via DEA the website:
 - Chemical Handler's Manual
 - Pharmacist's Manual
 - Practitioner's Manual

Additionally, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors that 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.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.⁹ However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.¹⁰ The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior year).¹¹ While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse 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; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers. This issue will become less of a hurdle as states continue to enroll in the National Association of Boards of Pharmacy Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of prescription monitoring program data across state lines to authorized users. As of December 31, 2014, PMPs in 27 states are enrolled in the program.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June, 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.¹²

The Department has supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over \$87 million from FY 2002 to FY 2014, including \$7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze

⁹ This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in schedule II.

¹⁰ The Brandeis University PDMP Center of Excellence, retrieved 12/18/14
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¹¹ Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

¹² The Brandeis University PDMP Center of Excellence, retrieved 12/18/14
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controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessioned pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately \$16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other entities violate the law. For example, in March 2013, UPS agreed to a \$40 million settlement with the Department of Justice for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, \$34 million in seized assets, and forfeiture orders totaling \$51 million.

In 2012, DEA pursued administrative actions against two CVS pharmacy stores in Florida, where these two registrants violated provisions of the CSA and committed acts that are inconsistent with the public interest, by dispensing controlled substances to customers under circumstances indicating that the drugs were diverted from legitimate channels, misused, or abused, and by failing to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). In October 2012, the DEA Administrator issued a final order revoking the registrants' certificates of registration and denying any pending applications for renewal, stating that the misconduct was both egregious and for an extended duration, and undoubtedly caused extensive harm to the public interest. During 2013, DEA, together with the United States Attorneys' Offices for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an \$11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay \$80 million in civil penalties for the actions by their distribution center and six pharmacies in Florida, which resulted in the diversion

of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of FY 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. As of September 30, 2014, there was only one Florida physician in the top 100 purchasers of oxycodone, as Florida law no longer allows practitioners to dispense schedule II and schedule III controlled substances, with the exception of some very limited circumstances (e.g., practitioners may dispense to patients who: are under hospice care; have undergone a surgical procedure, and a 14-day supply may be dispensed; are an inmate in a prison; are a participant in an approved clinical trial). The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

2. What is the cost of a single dose of Naloxone? Is the cost of Naloxone a barrier to making the antidote more readily available?

Response:

DEA does not have data or information responsive to this question as it falls outside of DEA's jurisdiction.

Questions Posed by the Honorable Steve Scalise

- 1. According to the GAO report, there are 15 federal agencies and 76 abuse prevention or treatment programs. The GAO report identified overlap in 59 of the 76 programs. Please discuss what your agency is doing to address that overlap and the problems addressed in the GAO report.**

Response:

DEA does not have data or information responsive to this question as it falls outside of DEA's jurisdiction.

