

**EXAMINING LEGISLATIVE PROPOSALS TO COMBAT  
OUR NATION'S DRUG ABUSE CRISIS**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON HEALTH  
OF THE  
COMMITTEE ON ENERGY AND  
COMMERCE  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED FOURTEENTH CONGRESS  
FIRST SESSION

OCTOBER 8 & 20, 2015

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**EXAMINING LEGISLATIVE PROPOSALS TO  
COMBAT OUR NATION'S DRUG ABUSE CRI-  
SIS—DAY 1**

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**THURSDAY, OCTOBER 8, 2015**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON HEALTH,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:16 a.m., in room 2322 Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Lance, Bilirakis, Bucshon, Brooks, Green, Engel, Butterfield, Sarbanes, Matsui, Luján, and Kennedy.

Also present: Representative Tonko.

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Karen Christian, General Counsel; Noelle Clemente, Press Secretary; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Chris Sarley, Policy Coordinator, Environment and the Economy; Adrianna Simonelli, Legislative Associate, Health; Sam Spector, Counsel, Oversight and Investigations; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Eric Flamm, Democratic FDA Detailee; Waverly Gordon, Democratic Professional Staff Member; Tiffany Guarascio, Democratic Deputy Staff Director and Chief Health Advisor; Una Lee, Democratic Chief Oversight Counsel; Samantha Satchell, Democratic Policy Analyst; and Kimberlee Trzeciak, Democratic Health Policy Advisor.

**OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA**

Mr. PITTS. The subcommittee will come to order. I believe the clock is a little slow, so we will get started.

And I want to start by mentioning we have a couple of distinguished alumni in the audience of this committee. Phil Gingrey, who was a member of our subcommittee, welcome. A very distinguished member, Mary Bono Mack, is here. Where is Mary? She often raised this issue with me. So welcome. We appreciate all of your interest and input as well.

The Chair will recognize himself for an opening statement. Today's hearing will consider a number of proposals intended to ad-

dress various aspects of our nation's drug abuse crisis. The Oversight and Investigations Subcommittee has held five hearings examining this public health epidemic and current efforts underway to combat prescription drug abuse. It is clear that, despite these efforts, the epidemic has continued to grow exponentially.

Today is a good opportunity to better understand what Congress can do to help. I appreciate the administration witnesses being here and working with us on these complicated issues. I also look forward to the testimony of outside experts on these various bills in the near future. Prescription drug abuse does not discriminate: it is not limited by geography, income, or age. According to the National Institute on Drug Abuse, one in five Americans has used prescription drugs for nonmedical reasons.

In 2011, the Substance Abuse and Mental Health Services Administration published a National Survey on Drug Use and Health and found that 1.7 million 12-to-25-year-olds abused prescription drugs for the first time, which amounts to more than 4,500 new initiates per day. These startling statistics should concern all of us. Unfortunately, only about 10 percent of people with substance abuse disorders will get any form of medical care. There are many of our constituents and their families that still need help, and I applaud my colleagues for working on legislation with that goal in mind.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today's hearing will consider a number of proposals intended to address various aspects of our Nation's drug abuse crisis. The Oversight and Investigations subcommittee has held five hearings examining this public health epidemic and current efforts underway to combat prescription drug abuse. It is clear that despite these efforts, the epidemic has continued to grow exponentially.

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These startling statistics should concern all of us.

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I will now yield to the distinguished gentleman from Indiana, Dr. Bucshon.

Mr. PITTS. I now yield to the distinguished gentleman from Indiana, Dr. Bucshon.

Mr. BUCSHON. Thank you, Mr. Chairman. Congressman Womack and I introduced H.R. 2872 as a starting point that will eventually result in legislation that helps reverse the heroin and opioid epidemic. Over 100 years ago, Congress first began legislating opioid addiction treatment policies, and since that time, Congress has had to come together and pass such legislation time and time again.

Given the worsening epidemic, it is time for Congress to act once more.

H.R. 2872 is not a final product. To that end, Congressman Womack, Congressman Tonko, and I held the first Opioid Addiction Treatment Workgroup composed of the leading opioid addiction professional associations and other stakeholders to discuss our legislation. Our objective is to refine this legislation to become a bill that all the key stakeholders support.

We can only reverse the opioid epidemic by effectively treating the underlying cause, and part of that underlying cause is our Federal Government's public health response to addiction. Clearly, what we are currently doing is not working well enough, and change is needed. We will need to treat addiction as the medical disease that it is, and confront the very real issues that prevent a person from receiving individualized care specific to his or her circumstances.

We need to understand what the data is telling us, and we shouldn't allow the status quo to prevent a legitimate deliberation over what is the best path forward for addressing a crisis that is touching all of our communities. These are the challenges that we must overcome.

[H.R. 2872 has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF14/20151008/104047/BILLS-1142872ih.pdf>.]

Mr. BUCSHON. At this point, I also ask unanimous consent to submit for the record a statement from the American Association for the Treatment of Opioid Dependence.

Mr. PITTS. Without objection, so ordered.

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

Mr. BUCSHON. Thank you, Mr. Chairman. I yield back.

Mr. PITTS. And I would like to ask unanimous consent to submit the following document for the record: a letter from the American Medical Association. Without objection, so ordered.

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

Mr. PITTS. The Chair now recognizes the ranking member, Mr. Green, 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. GENE GREEN, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Good morning, and thank each of you for being here today. As we know, the Centers for Disease Control and Prevention declared our nation's prescription drug abuse crisis an epidemic. In 2013, drug overdose was the leading cause of injury death in the United States. This is a battle we have waged for more than 100 years. When Congress first passed laws to confront the problems of heroin and opioid addiction, we once again face the challenges of controlling and combating this menace that is ravaging communities across the country.

In the past few years, overdose deaths involving opioids increased fourfold and the number of heroin use has almost doubled. Cases of HIV and hepatitis C are on the rise. Despite universal recognition of the problem, our current efforts are not enough to meet the challenges of the crisis. The drivers of the problem are complex

and there is no single silver-bullet solution. It is critical that we approach this challenge through a public health lens.

Experts have documented serious impediments to widespread access to treatment, including a shortage of substance abuse providers, social and cultural stigmas, and lack of health coverage for such services. Current research suggests that a combination of medication-assisted treatment and behavioral treatment such as counseling and support services are the most effective way to treat opioid addiction.

In 2013, medication-assisted treatments were available in only 9 percent of substance abuse treatment facilities. For example, in 2012, 96 percent of States and the District of Columbia had opioid abuse dependence rates higher than their buprenorphine treatment capacity rates. Thirty-eight States reported that at least 75 percent of the opioid treatment programs, also known as methadone clinics, were operating at a greater-than-80-percent capacity.

Today, we are here to examine seven legislative proposals aimed at combating our nation's drug abuse epidemic. They build upon the hearings this committee has held and represent various approaches to improving prevention and treatment. Each is a product of thoughtful consideration and dedication from their sponsors, and I thank my colleagues for their efforts and the chairman for having this hearing. It is critical that we give law enforcement, health providers, and communities enhanced tools to address this epidemic. We need more resources and a coordinated effort to ensure the evidence-based treatment is available and diversion is stymied. The statistics are staggering. The need for action is clear. Again, thank you for being here.

[The prepared statement of Mr. Green follows:]

#### PREPARED STATEMENT OF HON. GENE GREEN

Good morning and thank you all for being here today.

As we know, the Centers for Disease Control and Prevention declared our nation's prescription drug abuses crisis an "epidemic."

In 2013, drug overdose was the leading cause of injury death in the United States. This is a battle we have waged for more than 100 years, when Congress first passed laws to confront the problems of heroin and opioid addiction.

We are once again faced with the challenges of controlling and combatting this menace that is ravaging communities across the country.

In the past few years, overdose deaths involving opioids increased four-fold, and the number of heroin users almost doubled.

Cases of HIV and Hepatitis C are on the rise.

Despite universal recognition of the problem, our current efforts are not enough to meet the challenges of this crisis.

The drivers of the problem are complex, and there is no single silver bullet solution.

It is critical that we approach this challenge through a public health lens.

Experts have documented serious impediments to widespread access to treatment, including a shortage of substance abuse providers, social and cultural stigmas, and lack of health coverage for such services.

Current research suggests that a combination of medication assisted treatment and behavioral treatments—such as counseling and support services—are the most effective way to treat opioid addiction.

Yet, in 2013, medication assisted treatments were available in only 9 percent of substance abuse treatment facilities.

We know there is a gap in the availability these treatments.

For example, in 2012, 96 percent of States and the District of Columbia had opioid abuse dependence rates higher than their buprenorphine treatment capacity rates.

Thirty-eight States reported that at least 75 percent of the Opioid Treatment Programs, also known as methadone clinics, were operating at greater than 80 percent capacity.

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It is critical that we give law enforcement, health care providers, and communities enhanced tools to address this epidemic.

We need more resources and a coordinated effort to ensure that evidence-based treatment is available, and diversion is stymied.

The statistics are staggering. The need for action is clear.

Again, I thank you all for being here today and look forward to examining the legislative proposals before this subcommittee.

I yield the remainder of my time to my colleague from Maryland, Representative Sarbanes, the sponsor of the Co-Prescribing to Reduce Overdoses Act.

Mr. GREEN. And I would like to yield 1 minute to Congressman Luján.

Mr. LUJÁN. Thank you, Mr. Chairman and Ranking Member, for scheduling this incredibly important hearing on a crisis that is plaguing our nation. This crisis touches everyone, from dense urban cities to rural States like New Mexico, for getting access to health services can often be a challenge. Most recent data from New Mexico's health department puts the accidental drug overdose rate at 24.3 per 100,000. That is more than double the national average. In two of the counties in my district, the overdose rate is more than five times the national average.

Too many people are being forgotten and too many people are suffering. That is why I have introduced the Improving Treatment for Pregnant and Postpartum Women Act to strengthen efforts to ensure that some of our most vulnerable get the care they need. I want to thank my colleagues, Representative Matsui, Tonko, Clark, and Cardenas, for joining me in introducing this bill, and I look forward to today's discussion and getting this done. Mr. Chairman, the thoughtfulness behind all of this legislation is so important, and I just hope that we can get this done. Thank you, Mr. Chairman. I yield back.

[The bill introduced by Mr. Luján has been retained in committee files and also is available at <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104047>.]

Mr. GREEN. Mr. Chairman, I yield another minute to Congresswoman Matsui.

Ms. MATSUI. Thank you very much. Thank you, Mr. Chairman, for holding this hearing today on such an important topic. There is a growing prescription drug epidemic plaguing this country that we can no longer ignore. Prescription drugs are the second-most abused category of drugs among young people, and sadly, these painkillers often serve as a gateway to cheaper street drugs like heroin.

The abuse of both prescription painkillers and heroin is devastating families and undermining public health and safety in our communities. In order to address this epidemic, we need to engage the full range of players, including patients, providers, parents, and

manufacturers, as they all can and should play a critical role in curbing the abuse of prescription drugs.

Addressing this crisis should be a priority, and I am pleased that this committee is holding a hearing on this important issue. I look forward to hearing from other witnesses as we consider strategies for addressing this epidemic. Thank you, and I yield back.

Mr. GREEN. Mr. Chairman, I yield the remainder of my time to Congressman Sarbanes, if he would like to make a very brief statement.

Mr. SARBANES. It will be brief indeed. Thank you for yielding. One of the bills we are going to be talking about or I will be referring to is the Co-Prescribing to Reduce Overdoses Act. This would allow for co-prescribing of naloxone when physicians are prescribing opioids in cases where the patient is at high risk for overdose, and it would allow for a demonstration project to support certain facilities in exploring this opportunity, training physicians on it, who in turn can train patients on how to self-administer this lifesaving drug. We have an epidemic across the country. Certainly, Baltimore, Maryland, is experiencing this, and we look forward to testimony today on topics of this kind. And I yield back. Thank you.

[The bill introduced by Mr. Sarbanes has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF14/20151008/104047/BILLS-114pih-Co-PrescribingtoReduceOverdosesActof2015.pdf>.]

Mr. GREEN. Mr. Chairman, I would also like ask to place into the record a statement by the Drug Policy Alliance.

Mr. PITTS. Without objection, so ordered.

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

Mr. PITTS. The gentleman yields back. And now the Chair recognizes the gentlelady from Indiana, Mrs. Brooks, who is filling in for the chair of the committee.

**OPENING STATEMENT OF HON. SUSAN W. BROOKS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA**

Mrs. BROOKS. Thank you, Mr. Chairman. I would like to thank the committee for bringing attention once again to this important topic. Sadly, Indiana is leading the country but not in a way we would like. Unfortunately, according to our State Public Health Commissioner, Dr. Adams, Indiana is one of 13 States where the prescribers write enough prescriptions that every citizen in our State has a paying prescription.

Unsuspecting addicts get hooked on opioids, but oftentimes, they switch to heroin, not only for the high but because now it is less expensive, and it is actually easier to get. And heroin on our streets is cheaper, stronger, and thanks to the synthetic add-ins, more unpredictable in its results than in the past. From '99 to 2009 Indiana health officials have seen a 500-percent increase in the rate of drug overdose death, and in fact, overdose deaths now surpassed motor vehicle-related deaths in our State.

And it is not just the overdoses, but in this past year, as this committee has already heard, Indiana has seen a drastic spike in hepatitis C and HIV due to opioid and heroin infusions, with the

most recent figure at 183 confirmed cases of HIV in one small rural county alone.

Now, we have held lots of roundtable discussions with providers and with prescribers and with law enforcement, but tragically, it is the families of the addicts and of those who have died who have become the real experts in this field. The consistent thread in the debate is that 80 percent of heroin use starts with prescription for pain meds, and many prescribers are unaware they may be a major part of the problem.

So there is no silver bullet to fix it, but that is why I am very pleased that Congressman Kennedy and I have introduced H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015. Yes, it is a comprehensive approach to solving the problem. It incorporates law enforcement, medical providers, educators, and first responders.

I am thankful to my colleagues for participating in today's hearing and I look over to working with them in the coming weeks to advocate not only for passage of this bill, but the many thoughtful solutions being proposed by this committee. I yield back.

[H.R. 2805 has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF14/20151008/104047/BILLS-1142805ih.pdf>.]

Mr. PITTS. The Chair thanks the gentlelady. And now the Chair recognizes the gentleman from Massachusetts, Mr. Kennedy, filling in for the ranking member of the full committee.

**OPENING STATEMENT OF HON. JOSEPH P. KENNEDY, III, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS**

Mr. KENNEDY. Thank you, Mr. Chairman. I appreciate the opportunity. And I want to thank the witnesses for coming to testify today, and for your extraordinary dedication to these issues and your service to our country.

The other day, I asked some of my constituents to tell me about their experience with opiate abuse and drug addiction, whether it was their own personal struggle or the battle of a loved one. Their responses were heartbreaking: a grandmother who lost her 25-year-old grandson over the summer, a father whose 56-year-old son battled mental illness late in life and eventually fell victim to cocaine addiction, a young woman who just lost her cousin to an overdose 2 weeks ago, a mother whose son was denied entrance into a treatment program last month because he was already in detox after overdosing. So she gave him the money he needed to buy drugs and test positive. The themes of each story were unique, but every constituent ended their message the same way, by calling on Congress to act.

Many of the bills we are considering today will help us began to answer those calls, including one I was proud to introduce with my colleague, Congresswoman Brooks, earlier this year. Chairman Pitts and Ranking Member Green, thank you for your continued commitment to this issue. I look forward to listening to the conversation today and discussing some bipartisan solutions.

I would like to yield the balance of my time to Representative Tonko.

Mr. TONKO. And I thank the gentleman for yielding. I am pleased that we are holding this legislative hearing today on bills that aim to ease the burden of our nation's growing opioid epidemic. I am here today in support of the Recovery Enhancement for Addiction Treatment Act, also known as the TREAT Act, on which I joined with my fellow upstate New Yorkers, Representatives Higgins, Katko, and Hanna, to introduce.

This legislation would lift the current caps in place on the number of patients that doctors can serve while prescribing buprenorphine, a medication-assisted treatment for opioid addiction. Under current laws, if every opioid treatment program and DATA 2000-waivered physician treated the maximum number of patients, that would still be roughly 1 million opioid-addicted individuals unable to secure treatment.

The hope with this bill is that we can lessen this gap between individuals seeking treatment and our inadequate treatment capacity. While this legislation is not a cure-all and we still need to examine measures to ensure the highest quality care, I believe the TREAT Act will go far in helping to alleviate our acute treatment capacity issues and put more people on the path to recovery. I urge our committee to take swift action on this bill so that we can turn the tide on this epidemic. And with that, I thank you and yield back to Representative Kennedy.

Mr. KENNEDY. Unless there is another member of the minority that wants time, I yield back.

Mr. PITTS. The Chair thanks the gentleman. That concludes the opening statements. As usual, all written opening statements of the members will be made a part of the record as well. We have two panels for this hearing. We are going to take one today, the second, the week of October 20 when we come back from break. But I would like to thank our first panel here today, and I will introduce them in the order of their testimony.

First, we have Mr. Michael Botticelli, Director of the National Drug Control Policy, Executive Office of the President; secondly, Dr. Richard Frank, Assistant Secretary for Planning and Evaluation, Health and Human Services; and finally, Mr. Jack Riley, Deputy Administrator, Drug Enforcement Administration.

Thank you very much for coming today. Your written testimony will be made part of the record. You will be each given 5 minutes to summarize. We have a series of three little lights. Green will be on for 4 minutes, yellow a minute, and at minute number 5 the red will come on. We ask you to wrap it up if you could, and then we will go to questions and answers. So thank you very much for coming. And, Mr. Botticelli, you are recognized for 5 minutes for your summary.

**STATEMENTS OF MICHAEL P. BOTTICELLI, DIRECTOR, NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT; RICHARD FRANK, PH.D., ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JACK RILEY, ACTING DEPUTY ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION**

**STATEMENT OF MICHAEL P. BOTTICELLI**

Mr. BOTTICELLI. Thank you, Chairman Pitts, Ranking Member Green, and members of the subcommittee, for the opportunity to appear here today to discuss the administration's response to the epidemic of opioid abuse, particularly the rise in nonmedical prescription opioid and heroin use, overdose deaths, and the use of new psychoactive substances.

The Office of National Drug Control Policy produces the National Drug Control Strategy, which is the administration's primary blueprint for drug policy. This strategy treats our nation's substance use problems as a public health issue, not just a criminal justice issue.

Using ONDCP role as the coordinator of Federal drug control agencies, in 2011 our administration released a plan to address the sharp rise in prescription drug misuse. This plan contains items categorized in four areas: education of prescriber and patients, increased prescription drug monitoring programs, proper medication disposal, and law enforcement efforts.

The administration has also convened at Congress' urgency an interagency Heroin Task Force co-chaired by ONDCP and the Department of Justice to more closely examine our strategies as it relates to heroin use in the United States. The task force will release its strategic plan later this year.

There has been a stark increase in the number of people using heroin over recent years and the number of overdose deaths involving heroin. As communities and law enforcement struggle with an increasing number of overdose deaths, heroin use, and increased heroin trafficking, it is important to note that plentiful access to opioid drugs via medical prescribing and easy access to diverted opioids for nonmedical use is feeding our opioid drug use epidemic.

Even though data indicate that over 95 percent of prescription opioid users do not initiate heroin use, four out of five new heroin users have experience as nonmedical prescription drug users. Given this interrelationship, the public health response to heroin use must be part of the response to nonmedical prescription opioid use.

A further complicating factor in addressing this epidemic is law enforcement reporting of heroin that is laced with fentanyl, an opioid drug that is estimated to be 100 times more potent than heroin. This increased potency has resulted in more overdose deaths in many parts of the country.

We have seen overdose deaths from prescription opioid level off, but unfortunately, this is coupled with a dramatic 39 percent increase in heroin-involved overdose deaths in 1 year, from 2012 to 2013. To address the overdose death issue, we are working to increase access to naloxone for first responders and individuals close

to those with an opioid drug use disorder, and to promote Good Samaritan laws so witnesses to an overdose will take steps to help save lives.

First responders nationwide are rising to this challenge of addressing the increase in opioid use in overdose deaths, but the medical establishment also needs to increase access to treatment for individuals with opioid use disorders before they become chronic or result in other public health consequences such as infectious diseases or neonatal abstinence syndrome.

Given that little to no time in graduate medical education programs is devoted to the identification or treatment of substance use disorders and given that very few physicians have availed themselves of voluntary training options, our administration continues to press for mandatory prescriber education tied to controlled substance licensure.

Evidence shows that medication-assisted treatment with FDA-approved medications, when combined with behavioral therapies and other recovery supports, has shown to be the most effective treatment for opioid use disorders. Our administration continues to pursue a wide variety of ways to increase access to these lifesaving medications. But since some of these products are subject to diversion, it is essential that this expansion be done in a way that promotes high-quality care and minimizes the opportunity for diversion.

It is also important to continue our efforts to educate the public about the risks and consequences of nonmedical prescription opioid and heroin use and the availability of options for treatment for opioid use disorders to help improve and save lives. To help with all of these efforts, the administration's fiscal year 2016 budget proposal includes \$133 million in new funding to reduce opioid misuse, abuse, and overdose deaths.

Lastly, a few comments about the use of new psychoactive substances, or NPS. The administration's activities to reduce the use, availability of NPS include data collection, research, prevention, treatment, domestic and foreign law enforcement actions, and international cooperation to reduce the manufacture and distribution of these serious life-endangering substances.

The health risks of NPS can be significant, including serious injury and even death. The contents and effects of synthetic cannabinoids and synthetic cathinones are unpredictable due to a costly changing variety of chemical compounds used in manufacturing processes that are devoid of quality control and regulatory oversight. These substances also contain toxic impurity byproducts, and the potency can vary significantly from batch to batch.

In conclusion, this administration will continue our work with Congress and our Federal, State, and local partners on public health and public safety issues resulting from the epidemic of the nonmedical prescription opioid and heroin use, as well as new psychoactive substances.

Thank you.

[The prepared statement of Mr. Botticelli follows:]



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

**“Examining Legislative Proposals to Combat  
our Nation’s Drug Abuse Crisis”**

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

Thursday, October 8, 2015  
10:15 a.m.  
2322 Rayburn House Office Building

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

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

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

At ONDCP, we are charged with producing the *National Drug Control Strategy* (*Strategy*), the Administration's primary blueprint for drug policy, along with a national drug control budget. The *Strategy* is a 21<sup>st</sup> century plan that outlines a series of evidence-based reforms that treat our Nation's drug problem as a public health challenge, not just a criminal justice issue. It is guided by what science, experience, and compassion demonstrate about the true nature of drug use in America.

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

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

This statement focuses largely on the Administration's interventions to address opioid drug misuse, as well as those of our Federal, state and local partners, including professional associations that are involved with opioid prescribing or the prevention and treatment of opioid misuse. It will also discuss Federal efforts to reduce use and availability of new psychoactive substances.

### Trends and Consequences in Opioid Use

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

The Nation is making some progress in addressing prescription opioid misuse. In 2014, more than 4.3 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month, and in 2013 there were 4.5 million such reporting users, in contrast to rates as high as 5.3 million in 2009.<sup>4</sup> The number of Americans 12 and older initiating the nonmedical use of prescription pain relievers in the past year has decreased since 2009, from 2.2 million in that year to 1.4 million in 2014.<sup>5</sup> Additionally, according to the latest Monitoring the Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2014 is its lowest since 2002.<sup>6</sup> Despite these developments, nonmedical prescription pain reliever use is more common than use of any category of illicit drug in the United States except for marijuana.

Approximately 435,000 Americans reported past month use of heroin in 2014.<sup>7</sup> Heroin use remains relatively low in the United States when compared to other drugs; however, the increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 914,000 in 2014 – and the high rate of overdose deaths are troubling.<sup>8</sup> These figures likely undercount the number of users, as national household surveys do not track all heroin-using populations, such as homeless users.

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

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

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

<sup>4</sup> Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DeTTab2014/NSDUH-DeTTab2014.htm#tab7-3a>

<sup>5</sup> Substance Abuse and Mental Health Services Administration. Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2015] Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DeTTab2014/NSDUH-DeTTab2014.htm#tab4-5b>

<sup>6</sup> The Monitoring the Future study. *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12*. University of Michigan. [December 2014]. Available: <http://www.monitoringthefuture.org/data/14data/14drrig11.pdf>

<sup>7</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *National Survey on Drug Use and Health, 2013 and 2014: Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014*.

<sup>8</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *National Survey on Drug Use and Health, 2013 and 2014: Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014*.

Similar trends concerning growth in heroin use are reflected in the country's substance use disorder treatment system. Data show a more than tripling in the past 10 years of treatment admissions for individuals primarily seeking treatment for substance use disorder, from 53,000 in 2003 to 170,000 in 2012. Heroin treatment admissions remained flat over the same time period, yet accounted for 285,451 primary admissions in 2012.<sup>9</sup> Although all states have not yet reported specialty treatment admission data for 2013 and 2014, the states that have reported show a rise in the number of people seeking treatment for heroin use.<sup>10</sup>

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

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

When used chronically by pregnant women, both prescription opioids and heroin can cause withdrawal symptoms in newborns upon birth, and if these opioids are withdrawn during pregnancy, fetal harm may result. The Administration continues to focus on vulnerable populations affected by opioids, including pregnant women and their newborns. From 2000 to 2009 the number of infants displaying symptoms of drug withdrawal after birth, known as neonatal abstinence syndrome (NAS), increased approximately threefold nationwide.<sup>13</sup> Newborns with NAS have more complicated and longer initial hospitalizations than other newborns.<sup>14</sup> Newly published data shows the problem increased 40 percent from 2009 to 2012.<sup>15</sup>

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

[http://www.samhsa.gov/data/sites/default/files/2002\\_2012\\_TEDS\\_National/2002\\_2012\\_Treatment\\_Episode\\_Data\\_Set\\_National\\_Tables.htm](http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_Treatment_Episode_Data_Set_National_Tables.htm)

<sup>10</sup> Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment extracted 6/2/2015* <http://www.dasis.samhsa.gov/web/newmapv1.htm>

<sup>11</sup> Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available:

<http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

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

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

<sup>14</sup> Patrick, S., Schumacher, R.E., Benneyworth, B.D., Krans, E.E., McAllister, J.M., & Davis, M.M. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. *Journal of the American Medical Association*, 307(18): 1934-40. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22546608>

<sup>15</sup> Patrick, S.W., Davis, M.M., Lehman, C.U., Cooper, W.O. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012. *Journal of Perinatology* (2015): 1-6 online publication, April 30, 2015; doi:10.1038/jp.2015.36

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

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

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

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

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

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

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

<sup>18</sup> Drug Enforcement Administration, *Updated Results from DEA's Largest-Ever Global Synthetic Drug Takedown Yesterday*, June 2013. Available: <http://www.justice.gov/dea/divisions/qa/2013/qa062613.shtml>

<sup>19</sup> *Id.*

### The Administration's Response

President Obama's inaugural *National Drug Control Strategy*, released in May 2010, labeled opioid overdose a "growing national crisis" and laid out specific actions and goals for reducing nonmedical prescription opioid and heroin use.<sup>20</sup> In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*,<sup>21</sup> which created a national framework for reducing prescription drug diversion and misuse. The *Plan* focuses on: improving education for patients and healthcare providers; supporting the expansion of state-based prescription drug monitoring programs; developing more convenient and environmentally responsible disposal methods to remove unused and unneeded medications from the home; and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

Since graduate medical education programs may not necessarily provide a comprehensive focus on identification or treatment of substance use disorders, and since the opioid drug epidemic is connected to overprescribing of prescription opioid drugs in the United States, the first pillar of the *Plan* focuses on ensuring that prescribers are better educated on the dangers of misuse and abuse of prescription drugs. Much progress has been made in expanding available continuing education for prescribers. At least ten states (Connecticut,<sup>22</sup> Delaware,<sup>23</sup> Iowa,<sup>24</sup> Kentucky,<sup>25</sup> Massachusetts,<sup>26</sup> Nevada,<sup>27</sup> New Mexico,<sup>28</sup> Tennessee,<sup>29</sup> Utah,<sup>30</sup> and West Virginia<sup>31</sup>) have passed legislation mandating education for prescribers.

Additionally, the Administration has developed and made available free and low-cost training options for prescribers and dispensers of opioid medications via several sources, including the Substance Abuse and Mental Health Service Administration (SAMHSA) and NIH's National Institute on Drug Abuse (NIDA). Also, the Food and Drug Administration (FDA) now requires manufacturers of extended-release and long-acting opioid pain relievers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy (REMS) for these drugs.

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

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

<sup>20</sup> Office of National Drug Control Policy, *2010 National Drug Control Strategy*. Executive Office of the President. [2010]. Available: <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf#page=49>

<sup>21</sup> Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: [http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx\\_abuse\\_plan.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf)

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

<sup>23</sup> 24 DEL. CODE ANN. § 3.1.1, available at

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

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

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

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

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

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

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

<sup>30</sup> UTAH ADMIN. CODE r. 58-37-6.5 (2012), available at [http://le.utah.gov/xcode/Title58/Chapter37/58-37-S6.5.html?v=C58-37-S6.5\\_1800010118000101](http://le.utah.gov/xcode/Title58/Chapter37/58-37-S6.5.html?v=C58-37-S6.5_1800010118000101)

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

substance use disorder, the second area of the Administration's *Plan* focuses on improving the operations and functionality of state-administered prescription drug monitoring programs (PDMP). PDMPs can help prescribers and pharmacists identify patients who may be at risk for substance use disorders, overdose, or other significant health consequences of misusing prescription opioids. State regulatory and law enforcement agencies may also use this information to identify and prevent unsafe prescribing, doctor shopping, and other methods of diverting controlled substances. Research also shows that PDMPs may have a role in reducing the rates of prescribing for opioid analgesics.<sup>32</sup>

In 2006, only 20 states had PDMPs. Today, the District of Columbia has a law authorizing a PDMP, and 49 states have operational programs.<sup>33</sup> Kentucky<sup>34</sup>, New Jersey,<sup>35</sup> New Mexico<sup>36</sup>, New York<sup>37</sup>, Oklahoma<sup>38</sup>, and Tennessee<sup>39</sup> all require their prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances. In Tennessee, where the requirement to check the PDMP went into effect in 2013, there was a drop in the number of high-utilizing patients of opioid pain relievers compared to 2011.<sup>40</sup>

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

In FY 2014, BJA made 15 site-based awards for states to enhance a PDMP program or implement a strategy that addresses non-medical prescription drug use and diversion within their communities. Since inception of the grant program in FY 2002, grants have been awarded to 49 states and 1 U.S. territory. In recent years, the grant program has been expanded to include tribal participation, and gave support to states and localities to expand collaborative efforts between public health and public safety professionals.

<sup>32</sup> Brady, JE, Wunsch, H, Dimaggio, C, Lang, BH, Giglio, J, and Li, G. Prescription drug monitoring and dispensing of prescription opioids. *Public Health Reports* 2014, 129 (2): 139-47. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904893/pdf/ahr129000139.pdf>

<sup>33</sup> National Alliance of Model State Drug Laws. (2014). Status of State Prescription Drug Monitoring Programs (PDMPs). Retrieved from <http://www.namsdl.org/librarv/16666FCC-65BE-F4BB-A2BBAD44E1RC7031/>.

<sup>34</sup> Kentucky 201 KAR 9:260. 2012. Available at <http://www.lrc.ky.gov/kar/2011/009/260.htm>

<sup>35</sup> P.L. 2015, c.74 (N.J. 2015), available at [http://www.nileg.state.nj.us/2014/Bills/AL15/74\\_PDF](http://www.nileg.state.nj.us/2014/Bills/AL15/74_PDF)

<sup>36</sup> New Mexico Register. 16.12.9.9. November 15, 2012. Available at [http://www.nmcpr.state.nm.us/new-mexico-register/prev\\_issues/prev\\_issuesxxiii/xxiii21/16.12.9amend](http://www.nmcpr.state.nm.us/new-mexico-register/prev_issues/prev_issuesxxiii/xxiii21/16.12.9amend)

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

<sup>38</sup> Oklahoma 3251. 2010. Available at [http://www.oklegislature.gov/cf\\_pdf/2009-10%20FLR/hflr/13/2009-10%20FLR/hf13251%20hflr.pdf](http://www.oklegislature.gov/cf_pdf/2009-10%20FLR/hflr/13/2009-10%20FLR/hf13251%20hflr.pdf)

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

<sup>40</sup> Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2014 Report to the 108th Tennessee General Assembly, February 1, 2014. Page 5. Available at [http://health.tn.gov/statistics/Legislative\\_Reports\\_PDF/CSMD\\_AnnualReport\\_2014.pdf](http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf) Linked to 9-04-2014

In addition, the President's FY 2016 Budget request includes a total of \$65 million (an increase of \$45 million) to expand the CDC's *Prescription Drug Overdose Prevention for States* program to all 50 states. This program provides grants to states to help implement tailored, state-based prevention strategies such as maximizing PDMPs, enhancing public insurer mechanisms to prevent overdoses, and evaluating state policies and programs aimed at addressing the opioid epidemic.

Research shows that approximately 66 percent of past-year nonmedical users of prescription pain relievers report getting them from a friend or relative the last time they used them, and approximately 84 percent of the time, that friend or relative obtained the pain relievers from one doctor.<sup>41</sup> Therefore, the third area of the *Plan* focuses on safely removing millions of pounds of expired and unneeded controlled substances from circulation. Since September 2010, the Drug Enforcement Administration (DEA) has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold 10 National Prescription Take-Back Days, most recently on September 26. At the first 9 events, DEA collected and safely disposed of more than 4.8 million pounds of unneeded or expired medications.<sup>42</sup> In addition, DEA published a Final Rule for the Disposal of Controlled Substances, which took effect October 9, 2014.<sup>43</sup> These new regulations expand the options available to securely and safely dispose of unneeded prescription medications. ONDCP and DEA have engaged with Federal, state, and local agencies, and other stakeholders to increase awareness and educate the public about the new rule.

The final part of the *Plan* focuses on improving law enforcement capabilities to reduce the diversion of prescription opioids. Federal law enforcement, including our partners at DEA, are working with state and local agencies across the country to reduce pill mills, prosecute those responsible for illegal prescribing practices, and make it harder for unscrupulous registrants to remain in business. In May 2015, the Administration held its inaugural meeting of the Congressionally-mandated interagency Heroin Task Force, which is co-chaired by ONDCP and DOJ. The Task Force includes Federal agency experts from law enforcement, medicine, public health and education. At the end of 2015, the Task Force will produce a report focused on evidence-based public health and public safety models to reduce the health and safety consequences of opioid use and the supply and demand of opioids.

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

<sup>41</sup> Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2014]. Available: [http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm#2\\_16](http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm#2_16)

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

<sup>43</sup> Disposal of Controlled Substances, 79 Fed. Reg. 53519 (Sep. 9, 2014). Available: <https://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances>

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

The Administration continues to promote the use of naloxone by those likely to encounter overdose victims, especially first responders and caregivers. The Administration's FY 2016 Budget requests \$12 million in grants to be issued by SAMHSA to states to purchase naloxone, equip first responders in high-risk communities, and provide education and the necessary materials to assemble overdose kits, as well as cover expenses incurred from dissemination efforts. Prior to 2012, just six states had any laws which expanded access to naloxone or limited criminal liability for persons that took steps to assist an overdose victim. As of May 2015, 36 states<sup>47</sup> and the District of Columbia have passed laws that offer criminal and/or civil liability protections to lay persons or first responders who administer naloxone. Twenty-five states<sup>48</sup> have passed laws that offer criminal and/or civil liability protections for prescribing or distributing naloxone. Thirty-four states<sup>49</sup> have passed laws allowing naloxone distribution to third-parties or first responders via direct prescription or standing order. And 25 states<sup>50</sup> and the District of Columbia have passed laws which prevent arrest, charge, or prosecution for possession of a controlled substance or paraphernalia if a person seeks emergency assistance for someone who is experiencing an opioid induced overdose.

The expansion of treatment services for persons with opioid and other substance use disorders has been a key focus of the Administration. The Affordable Care Act and Federal parity laws are extending access to mental health benefits and substance use disorder services for an estimated 62 million Americans.<sup>51</sup> This represents the largest expansion of treatment access in a generation, and could help guide millions into successful recovery.

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

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

<sup>46</sup> <http://www.va.gov/opa/40cs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf>

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

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

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

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

<sup>51</sup> Berino, K., Rosa, P., Skopec, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief*. Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at [http://aspe.hhs.gov/health/reports/2013/mental/rb\\_mental.cfm](http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm))

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

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

#### **Improvements in Treatment**

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

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

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

overdose mortalities<sup>53</sup> and individuals' risks for blood-borne infections like HIV and hepatitis.<sup>54</sup> Yet too many people are not connected to this care. In 2013, only 9 percent (1,282) of treatment facilities provided treatment with methadone and/or buprenorphine.<sup>55</sup> There is a significant need for medical professionals who can provide MAT in primary care and integrated health care settings. To help address this need, Secretary Burwell recently announced that HHS will engage in rulemaking related to the prescribing of buprenorphine to expand access to opioid dependence treatment. It is important that any expansion of such prescribing be accompanied by a range of therapy services and recovery supports.

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

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

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

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

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

<sup>55</sup> SAMHSA. *National Survey of Substance Abuse Treatment Services (N-SSATS): 2013 – Data on Substance Abuse Treatment Facilities* (September 2014). Retrieved from [http://www.samhsa.gov/data/sites/default/files/2013\\_N-SSATS\\_National\\_Survey\\_of\\_Substance\\_Abuse\\_Treatment\\_Services/2013\\_N-SSATS\\_National\\_Survey\\_of\\_Substance\\_Abuse\\_Treatment\\_Services.pdf](http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf).

<sup>56</sup> Personal communication (email) from Robert Hill (DEA).

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

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

#### **Addressing NPS**

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

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

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

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

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

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

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

**Conclusion**

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

Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Frank, 5 minutes for your summary.

**STATEMENT OF RICHARD FRANK**

Dr. FRANK. Thank you, Chairman Pitts, Ranking Member Green, and members of the subcommittee. I appreciate the opportunity to speak with you about addressing the misuse and abuse of opioids.

We at HHS share your sense of urgency to take action to end this epidemic. Secretary Burwell has made halting the opiate epidemic a top priority.

The numbers on the epidemic are stark. In 2014, more than 10 million people reported nonmedical use of prescription opioids, and nearly a million reported use of heroin. Moreover, it is estimated that more than 2 million people have an opioid use disorder. These disorders tear apart families, increase crime, and kill too many of our neighbors.

When Secretary Burwell arrived at HHS a little over a year ago, she directed our senior leadership to develop and implement an initiative to address the opioid problem. She insisted that it be department-wide, focused, and evidence-based so as to produce maximum impact. That effort resulted in the strategy that consists of three elements: first, improving prescribing practices for opioid pain medications; second, expanding the use of medication-assisted treatment for opioid use disorder; and third, expanding the use and distribution of naloxone to reverse overdoses.

In the time I have with you today, I want to focus on our efforts to expand the use of medication-assisted treatment, or MAT. MAT is a treatment that combines medication, behavioral interventions, recovery support services, and careful patient monitoring. There are three FDA-approved medications used in MAT: methadone, buprenorphine, and naltrexone. MAT, using each one of these, has been shown to be effective in clinical trials and in public health interventions. It is in fact the most effective approach to treating opioid use disorders. Yet MAT is woefully underused. Provision of MAT faces unique barriers in part because methadone and buprenorphine are controlled substances.

In addition, stringent medical management techniques are used to control utilization, and in the case of buprenorphine, the number of opioid use disorder patients a certified physician can treat is limited to 100 at any one time.

Our approach to expanding the use of MAT is guided by, first of all, the recognized need to expand the use of MAT; two, the fact that effective use of MAT means delivering the full package of services: pharmaceuticals, counseling, recovery supports, and monitoring for a patient's adherence; and third, that the capacity be expanded in a way that minimizes the risk of drug diversion. This approach is supported by the American Society of Addiction Medicine's recent guidelines on appropriate use of MAT.

Given these guardrails, I want to share with you the steps we are taking to expand MAT that we believe have much in common with proposed legislation that has already been mentioned today such as the TREAT Act.

Following Secretary Burwell's recent announcement, we are engaging in rulemaking related to expanding access to

buprenorphine-based MAT. Our Health Resources and Services Administration, or HRSA, recently announced a competition for \$100 million to expand the use of MAT in community health centers. SAMHSA recently awarded \$11 million per year for 3 years to 11 States across the Nation to increase MAT, and is proposing an additional 25.1 million for this purpose to go to 22 States for fiscal year 2016.

CMS recently issued a letter to State Medicaid Directors describing opportunities and authorities that States can use to provide a continuum of care to beneficiaries suffering from substance use disorder, including opioid use disorder.

We are also exploring ways to expand education and training for providers in the treatment of opioid use disorders. We are committed to tracking and evaluating our efforts, that we make the best use of public resources, and in the end, we will measure our success by the impact we have on families, people, and communities touched by the opioid crisis.

Thank you.

[The prepared statement of Dr. Frank follows:]

**Testimony of Dr. Richard Frank  
Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services  
For Delivery October 8, 2015**

Chairman Pitts and Ranking Member Green, thank you for this opportunity to talk with you about addressing the misuse and abuse of opioids. The President has made addressing this important public health issue a priority and we at HHS share this commitment to doing what it takes to turn this public health crisis around. Secretary Burwell has made addressing the opioid crisis a top priority; she is keenly aware of the toll it is taking on communities across the Nation.

The terrible consequences of opioid misuse and abuse have no regard for demographic, economic or geographic distinctions: they affect us all. At HHS, we are encouraged by the momentum building in communities and across party lines on both sides of the Capitol and in state and local governments to take action to halt the crisis and save lives.

The data on the crisis are stark. In 2014, over 10 million people reported nonmedical use of prescription opioids and nearly one million reported heroin use. Further, more than two million people have an opioid-use disorder.<sup>1</sup> This disrupts families, creates disability and produces criminal activity. This costs American society in money and lost human potential. Most alarming, thousands of families are losing loved ones to opioid overdoses and many more struggle to overcome the shame and social consequences of opioid use disorder.

When Secretary Burwell arrived at HHS, a little over a year ago, one of the first things she did was direct our senior leadership team to develop and carry out an initiative to address opioid

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<sup>1</sup> Jones CM et al. National and State Treatment Need and Capacity for Opioid-Agonist Medication Assisted Treatment. Am J Public Health. 2015

misuse and abuse. She insisted that we identify targeted, strategic investments to promote evidence based solutions and partner with states, communities and the Congress to find common ground. She also asked us to track our progress and evaluate our work as we go, so that we can know what's working and make midcourse corrections if our efforts aren't having the intended outcomes. Based on a review of the evidence and clinical science, our plan focuses on the actions that existing evidence suggests would produce the most impact on three specific areas: (1) improving opioid analgesic prescribing practices; (2) expanding the use of medication-assisted treatment and recovery services for individuals with an opioid-use disorder; and (3) expanding the use and distribution of naloxone.<sup>2</sup>

We are taking important steps on all three fronts:

- First, on the prescribing issue, as part of the Centers for Disease Control and Prevention (CDC)'s Prescription Drug Overdose: Prevention for States program, HHS has invested \$20 million in Fiscal Year (FY) 2015 to stand up comprehensive, multi-sector prevention programs in 16 states to combat the prescription drug overdose epidemic on multiple fronts, including improving state prescription drug monitoring programs (PDMPs), enhancing insurer and health system practices, and reaching the hardest hit communities. This builds on previous work of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of the National Coordinator for Health Information Technology (ONC). The President's FY 2016 Budget includes \$68 million to expand CDC's program to all 50 states and \$10 million for a related SAMHSA initiative.

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<sup>2</sup> The evidence we uncovered showed that utilization of PDMPs and prescribing guidelines change prescribing behavior, that naloxone in the hands of first responders reduces overdose death and that MAT is effective in treating opioid use disorder. For more background information, please refer to the ASPE Issue Brief, [Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths](http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths), <http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths>.

The FY 2016 Budget also includes \$5.6 million to support CDC's efforts to address the troubling rise in overdose deaths from illicit opioids such as heroin and \$5.0 million to expand electronic death-reporting to provide faster, better-quality data on deaths of public health importance, including Prescription Drug Overdose deaths.

- Also, related to prescribing, in January, just a few months from now, the CDC, in partnership with the National Institute on Drug Abuse (NIDA), SAMHSA, ONC, and the Food and Drug Administration (FDA), and the Office of National Drug Control Policy, will release suggested guidelines for providers on safer, more effective use of opioids to treat chronic pain outside of end-of-life care.
- Regarding the distribution of naloxone, the National Institute on Drug Abuse (NIDA) is supporting a number of research trials exploring the efficacy of prescribing take-home naloxone and FDA is supporting the development of new opioid overdose treatments by using its expedited review programs. In addition, the Health Resources and Services Administration (HRSA) is awarding \$1.8 million in grants to support rural communities in reducing opioid overdose and death. And, the President's FY 2016 Budget includes \$12 million for SAMHSA to fund "Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths," which will provide states with funds to purchase and distribute naloxone.
- In July, we released a \$100 million funding opportunity to expand substance abuse treatment, including medication-assisted treatment (MAT) for opioid misuse and abuse, at community health centers. I will go into greater detail on MAT later in this statement.

HHS believes that addressing this problem is an area of common ground and there are a number of bills introduced in the Congress that touch on some of the same issues. While the

Administration does not have a formal position on any of the bills discussed below, we look forward to working with the Committee on these proposals and welcome the opportunity to provide technical assistance to you and your staff on these topics. For example, one of the bills we are discussing today, the Heroin and Prescription Opioids Abuse Prevention, Education and Enforcement Act (H.R. 2805), touches upon the themes of provider education, bolstering PDMPs, and increasing access to naloxone to prevent overdose death. The Overdose Prevention Act (S. 1654), and Stop Overdose Stat Act (H.R. 2850), focus on increasing access to naloxone and improving surveillance and research. Several bills address the need for better training for providers to safely prescribe opioids; the Administration supports mandatory training as part of the National Drug Control Strategy. In addition, earlier this year, the National All Schedules Prescription Electronic Reporting Reauthorization Act (H.R. 1725), and the Protecting Our Infants Act (H.R. 1462), were passed by this Committee and then the full House of Representatives.

In the remaining time I have with you today I would like to describe our efforts related to improving access to high quality treatment for the estimated more than two million people with opioid use disorders. We have effective treatments for opioid use disorders. MAT is the combination of medication supported by behavioral interventions and recovery support services, as well as careful patient monitoring that has been shown by the best science to reduce cravings for opioids and morbidity. MAT also prevents relapse to unwanted drug use and has been shown to reduce risk behaviors associated with the transmission of HIV.<sup>3</sup> Yet, despite the established

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<sup>3</sup> Kresina TF, Lubran R. Improving Public Health Through Access to and Utilization of Medication Assisted Treatment. *International Journal of Environmental Research and Public Health*. 2011;8(10):4102-4117. doi:10.3390/ijerph8104102.

clinical and cost-effectiveness of this therapy, MAT is underutilized. Fewer than half of those diagnosed with opioid use disorders receive MAT.<sup>4</sup> We are committed to changing that.

MAT for opioid use disorders can make use of one of three types of FDA-approved medications, including those containing: buprenorphine, methadone, and injectable long-acting naltrexone. Depending on the medication used, MAT may be delivered in different treatment settings. Provision of MAT faces unique barriers to patient access including the application of stringent medical management techniques like prior-authorization requirements and time-in-treatment limitations.<sup>5</sup>

Furthermore, in the case of office-based buprenorphine, that only physicians can prescribe, the number of opioid use disorder patients a physician can treat is limited to no more than 100 at any one time.<sup>6</sup> Additionally, methadone can be dispensed for substance-use disorder only in Federally-regulated opioid-treatment programs, which often are subject to local zoning regulations that prevent them from opening in many communities. Injectable, long-acting naltrexone requires complete abstinence for 7-10 days prior to administration. All of these factors complicate expanding access to MAT.

Our approach to expanding use of MAT is guided by: (1) the recognized need to expand the use of MAT; (2) the fact that effective use of MAT means delivering the full package of pharmaceuticals, counseling, recovery support, and monitoring of patient adherence with treatment; and (3) the goal that capacity be expanded in a way that minimizes the risks of drug

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<sup>4</sup> Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies: tackling the opioid-overdose epidemic. *N Engl J Med*. 2014;370(22):2063-2066.

<sup>5</sup> We are examining these issues in the context of parity implementation.

<sup>6</sup> It is well known that methadone, which is also used to treat addiction, faces stringent conditions regarding providers permitted to dispense and conditions of use.

diversion.<sup>7</sup> This approach is supported by national clinical guidelines including SAMHSA's Treatment Improvement Protocols and the American Society of Addiction Medicine's recently issued guidelines on the appropriate use of MAT in treating opioid use disorders.<sup>8</sup> These guidelines include recommendations regarding the proper diagnosis, withdrawal-management, and treatment protocols for the use of MAT in treating opioid-use disorders. Moreover, the guidelines include steps physicians should take to reduce the chance of buprenorphine diversion, including frequent office visits, urine drug-testing, and recall visits for pill counts.

I want to share with you the steps we are taking to expand our capacity to deliver MAT, which touch on similar issues as certain proposed bills, such as the TREAT Act (H.R. 2536), currently under consideration in the Congress. As with the other proposals under consideration, we look forward to working with the Committee on this topic and providing additional technical assistance as needed.

Just a few weeks ago, at her 50 State convening on the opioid crisis, Secretary Burwell announced that we will be engaging in rulemaking to address buprenorphine prescribing as enumerated in the Federal Drug Addiction Treatment Act of 2000, as amended. Under current regulations, physicians certified to prescribe buprenorphine for MAT are allowed to prescribe up to 30 patients initially, and then after one year can request authorization to prescribe up to a

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<sup>7</sup> According to the National Forensic Laboratory Information System data (DEA), buprenorphine is the 4<sup>th</sup> most commonly diverted prescription opioid. However, recent studies have indicated that motivations for buprenorphine diversion differ from those associated with other prescription opioids. For example, according to a 2013 study published in the journal, *Addictive Behaviors*, nearly 75% of participants reporting use of street-obtained buprenorphine, reported using the drug to manage withdrawal symptoms (as opposed to getting intoxicated).

<sup>8</sup> Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. <http://www.asam.org/docs/default-source/default-document-library/asam-national-practice-guideline-supplement1b630f9472bc604ca5b7ff000030b21a.pdf?sfvrsn=0>

maximum of 100 patients. This cap on prescribing limits the ability of some physicians to prescribe to patients with opioid-use disorders. Secretary Burwell is using other tools to encourage broader adoption of MAT in primary care settings, particularly in underserved areas. HRSA has recently announced a competition for \$100 million to expand the use of MAT in community health centers nationwide, and SAMHSA recently awarded \$11 million to eleven states across the Nation to increase access to comprehensive medication-assisted treatment for opioid use disorders and has requested \$25.1 million to expand to 22 states in FY 2016.

Additionally, we are working with states to help them improve the delivery of treatment for substance use disorders. The Centers for Medicare Medicaid Services (CMS) issued a letter to State Medicaid Directors (SMD) this past July describing opportunities and Federal authorities that states can use to provide a continuum of care for beneficiaries with substance use disorders including opioid addiction. CMS also recently launched the Innovation Accelerator Program (IAP) to support states in improving their delivery systems with technical assistance at varied levels of intensity. The first phase of this IAP initiative is focused on helping states transform substance use disorder treatment services including by taking advantage of the new opportunities to pay for a continuum of care for substance use disorders outlined in the recent SMD letter. There are two platforms of technical assistance available to states through the IAP initiative on substance use disorder. The first, called the High Intensity Learning Collaborative, is geared for states that committed to work intensively on designing and implementing SUD delivery system reforms. The second, called the Targeted Learning Opportunities, is geared to states that want peer-based learning series on successful SUD delivery reforms but are not ready to commit to immediate program changes. The seven states participating in the High Intensity Learning Collaborative and receiving strategic support are Washington, Louisiana, Texas, Michigan,

Minnesota, Kentucky and Pennsylvania. So far, 46 states (including the District of Columbia) have participated in the Targeted Learning Opportunities. We are also exploring ways to expand provider understanding of opioid use disorders and ways they can engage in treating them. The Federal Government is committed to providing clinicians with the state of the art in education on the treatment of pain and addiction and in providing screening and clinical decision support tools to facilitate integration of that knowledge into clinical practice. To date, over 60,000 physicians, nurses, and other health care professionals have successfully completed a continuing medical education module developed by NIDA with support from ONDCP managing pain patients who use drugs, and over 50,000 successfully completed a module concerning safe prescribing for pain.

And while clinician engagement is key to improving access to opioid use disorder treatment, HHS recognizes the need to ensure that the care being delivered is of the highest quality and consistent across delivery systems. To that end, HHS and its partners in the quality improvement field are promoting widespread adoption of existing substance use disorder screening and treatment intervention measures as well as refining or developing new provider performance measures. This effort is intended both to assess the quality of care being delivered and to incentivize broader adoption of effective substance use disorder treatment.

Secretary Burwell is doing all she can to get the word out that we need an “all hands” solution to the opioid crisis. I mentioned a while ago the 50 State convening. At this meeting, just a couple of weeks ago, Secretary Burwell hosted representatives from all the states and the District of Columbia to share best practices and discuss solutions to reverse the opioid crisis. The meeting was very well received and added even more energy and support to our efforts to collaborate

with partners in the states to improve opioid prescribing practices, increase access to naloxone and expand the use of MAT.

There is some progress to report. Forty-one states plus the District of Columbia have adopted laws that facilitate the prescribing and/or distribution of naloxone, and, as mentioned, hundreds of community health centers and other community-based programs are poised to receive over \$100 million in Federal support for the delivery of addiction treatment, including medication-assisted treatment for opioid use disorders. We are starting to see progress in certain states as well. Florida, Kentucky, Washington State, and Oregon have seen declines in prescription opioid prescribing and opioid-related health outcomes after working across sectors to implement comprehensive policies and programs. These are notable markers of progress but do not suggest that victory is yet in sight.

As you can see, we are fighting this battle on many fronts. We will continue to work with many partners – states, the addiction-treatment community, specialists, general practitioners, private-sector partners, public safety, and state legislators. And of course we are very interested in continuing to work with the Congress to secure funding for the Secretary's Opioid Initiative included in the President's FY 2016 Budget and to provide technical assistance on legislation addressing the priority impact areas we have identified. The Secretary continually reminds us that among our most important partners are people suffering with addiction, people in recovery and the people who love them. At its heart, this is an issue that affects families and communities and we will measure the success of our initiative by the impact it has on them.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Mr. Riley, 5 minutes for your opening statement.

#### **STATEMENT OF JACK RILEY**

Mr. RILEY. Chairman Upton, Chairman Pitts, Ranking Member Pallone, Ranking Member Green, and members of the subcommittee, I want to thank you for this opportunity to testify this morning about our nation's most pervasive drug issues: the continuing opioid epidemic and the rise of synthetic drugs.

DEA's single mission is enforcing the Controlled Substances Act, and we are honored to work closely with our counterparts, including those in education, enforcement, research, recovery field, as well as partners in the supply chain.

Sadly, today, 120 Americans will die as a result of drug overdose. Heroin and prescription drugs cause over half of those fatalities. Accordingly, DEA views the opioid addiction epidemic as the number one drug threat to our country.

I spent my entire career in law enforcement. Having been an agent with the DEA for over 30 years, I have to tell you I have never seen it this bad. Prescription drug abuse has increased tremendously in the last 15 years. The abuse of prescription drugs and resulting addiction has fueled a spike in the use of heroin. In fact, four out of five new heroin users have misused prescription painkillers.

Increases in heroin purity, its low cost on the streets, the expanding role of violent Mexican organized crime groups, and the toxic business relationship with violent urban street gangs has also played a significant role in the resurgence of heroin. DEA is addressing this evolving threat by targeting the highest-level traffickers and the vicious organizations they run.

I have personally spent the bulk of my career chasing the man I consider to be the most dangerous heroin dealer in the world, El Chapo Guzman. He and his Sinaloa Cartel clearly dominate the U.S. heroin market, as the map I have brought with me today depicts.

Just as we cannot separate violence from drugs, we cannot separate controlled prescription drug abuse from heroin. As a result, DEA established highly effective tactical diversion squads, 66 in total, to target the critical nexus between the diversion of prescription drugs and heroin. DEA has also addressed the threat posed by the drugs that are in our medicine cabinets through our National Take-Back, the latest one being just 2 weeks ago. We have removed over 5-1/2 million pounds of unused and unwanted drugs. However, DEA drug disposal is still a problem to us and we can't solve it on our own.

DEA promulgated a regulation last year to allow the drug supply chain to become authorized collectors. At present, we have 500 registrants. It is simply not enough. This is one important way in which we can step up as partners in our effort to curb prescription drug abuse.

Lastly, I want to address the growing synthetic issue that we are facing. Some of these designer drugs are referred to as synthetic THC and marketed with similar effects. Nothing could be further from the truth. Last year, there was a 229-percent spike in calls

to Poison Control Centers for synthetics. The physical reaction to even one use of a synthetic drug varies widely, and in some cases, has resulted in death.

DEA has identified literally hundreds of synthetic drugs that have been encountered during Federal, State, and local law enforcement operations. Manufactured in overseas laboratories, these drugs are unregulated, have no medical use, and are not tested for safety. This means that those who misuse these products—most likely teens and adolescents—are really unwittingly allowing themselves to become guinea pigs.

Law enforcement has been encountering these substances more and more. According to the National Forensic Laboratory Information System, substances identified as synthetic cannabinoids by Federal, State, and local forensic laboratories have increased from 52 reports in 2009 to over 49,000 reports just last year.

DEA has made several enforcement operations targeting this problem, including Operation Log Jam, Project Synergy I and II, which have collectively resulted in 377 arrests and over \$80 million in cash seized, and literally tons of synthetic drugs taken off our streets. These operations demonstrate the scope of the problem, but I believe they are really just the tip of the iceberg.

I want to thank you for your partnership. DEA and I look forward to continuing to work with this subcommittee and Congress on these important issues.

[The prepared statement of Mr. Riley follows:]



# Department of Justice

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STATEMENT OF

JACK RILEY  
ACTING DEPUTY ADMINISTRATOR  
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE  
HEALTH SUBCOMMITTEE  
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

EXAMINING LEGISLATIVE PROPOSALS TO COMBAT OUR  
NATION'S DRUG ABUSE CRISIS

PRESENTED

OCTOBER 8, 2015

**Statement of Jack Riley  
Acting Deputy Administrator  
Drug Enforcement Administration  
Before the  
Committee on Energy and Commerce  
Subcommittee on Health  
United States House of Representatives  
October 8, 2015**

**INTRODUCTION**

Chairman Pitts, Ranking Member Green, and Members of the Subcommittee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss our Nation's two most pervasive drug issues of the day, specifically the epidemic opioid abuse and threat posed by dangerous synthetic drugs.

Drug overdoses are the leading cause of injury-related death here in the United States, eclipsing deaths from motor vehicle crashes.<sup>1</sup> There were over 43,000 overdose deaths in 2013, or approximately 120 per day, over half of which involved either a prescription opioid or heroin. These are our family members, friends, neighbors, and colleagues.

According to the 2014 National Survey on Drug Use and Health (NSDUH), 6.5 million people over the age of 12 used psychotherapeutic drugs for non-medical reasons during the past month. This represents 24 percent of the 27 million current illicit drug users and is second only to marijuana (22.2 million users) in terms of usage. There are more current users of psychotherapeutic drugs (i.e., pain relievers, tranquilizers, stimulants, and sedatives) for non-medical reasons than current users of cocaine, heroin, and hallucinogens combined.<sup>2</sup>

Approximately 435,000 Americans reported past month use of heroin in 2014.<sup>3</sup> Heroin use remains relatively low in the United States when compared to other drugs; however, the increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 914,000 in 2014 – is troubling.<sup>4</sup>

The misuse of controlled opioid prescription drugs (CPD) and the growing use of heroin are being reported in the United States in unprecedented numbers. According to the United Nations' body which monitors treaty compliance, the International Narcotics Control Board

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

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

<sup>3</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2013 and 2014. Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014.

<sup>4</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2013 and 2014. Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014.

(INCB), the United States consumes 78 percent of the world's oxycodone and 99 percent of the world's hydrocodone<sup>5</sup>, despite having only 5 percent of the world's population.

#### CONTROLLED PRESCRIPTION DRUGS (CPDs)

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

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the “street” cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)<sup>6</sup> can be purchased for \$5 to \$7 per tablet. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for \$7 to \$10 per tablet. Even stronger prescription drugs are sold for as much as \$1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost \$30 to \$40 per tablet. These increasing costs make it difficult to purchase in order to support the addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Data from NSDUH show that chronic and frequent users are more likely than recent initiates to buy opioid drugs from a dealer.<sup>7</sup> Not surprisingly, a small number of people who use prescription opioids non-medically turn to heroin, a much cheaper opioid, generally \$10 per bag, which provides a similar “high” and keeps some individuals with opioid use disorders from experiencing painful withdrawal symptoms. This cycle has been repeatedly observed by law enforcement agencies. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began using prescription opioids non-medically.<sup>8</sup>

Healthcare providers, as well as nonmedical users of CPDs are confirming this increase. According to some reporting by treatment providers, many individuals with serious opioid use disorders will use whichever drug is cheaper and/or available to them at the time.<sup>9</sup> Individuals with opioid use disorders who have 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

<sup>5</sup> International Narcotics Control Board. March, 2015. “Report 2014: Estimated World Requirements for 2015 – Statistics for 2013,” available at [www.incb.org](http://www.incb.org).

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

<sup>7</sup> SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2012-2013. Unpublished special tabulations (March 2015).

<sup>8</sup> U.S. Department of Justice, Drug Enforcement Administration, 2015 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2015, available at:

[http://www.dea.gov/divisions/hq/2015/hq052215\\_National\\_Heroin\\_Threat\\_Assessment\\_Summary.pdf](http://www.dea.gov/divisions/hq/2015/hq052215_National_Heroin_Threat_Assessment_Summary.pdf).

<sup>9</sup> U.S. Department of Justice, Drug Enforcement Administration, 2014 National Drug Threat Assessment Summary, November, 2014.

with other substances (e.g. fentanyl), all of which could cause individuals with lower tolerance to higher potency opioids to accidentally overdose.<sup>10</sup>

Some CPD users become dependent on opioid medications originally prescribed for a legitimate medical purpose.<sup>11</sup> A Substance Abuse and Mental Health Services Administration (SAMHSA) study found that four out of five recent new heroin users had previously used prescription pain relievers non-medically, although a very small proportion (3.6%) of those initiated heroin use in the following five-year period.<sup>12</sup> The reasons an individual may shift from one opiate to another vary, but today's heroin is higher in purity, less expensive, and often easier to obtain than illegal CPDs. Higher purity allows heroin to be smoked or snorted, thereby circumventing a barrier to entry (needle use) and avoiding the stigma associated with injection. However, many who smoke or snort are vulnerable to eventually injecting. Heroin users today tend to be younger, more affluent, and more ethnically and geographically diverse than ever before.<sup>13</sup>

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

#### **DEA RESPONSE TO THE NONMEDICAL USE OF CPDS**

Nonmedical drug use cannot be addressed through law enforcement action alone. The Office of National Drug Control Policy's (ONDCP) 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 of the Drug Supply Chain:*

DEA provides education and guidance to registrants, professional associations, and industry organizations on current pharmaceutical diversion and nonmedical use, new and existing programs, policies, legislation, and regulations. In fiscal year 2014, DEA conducted

<sup>10</sup> Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, *Int J Drug Policy*, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: *Int J Drug Policy*, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi: 10.1016/j.drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D, "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, *Int J Drug Policy*, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

<sup>11</sup> Pain, 2015 Apr; 156(4):569-76, doi: 10.1097/01.j.pain.0000460357.01998.fl, Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Vowles KE1, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN.

<sup>12</sup> Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Department of Health and Human Services, and [August 2013], available at: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>.

<sup>13</sup> Cicero, T., Ellis, M., Surratt, H, Kurtz, S. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, July, 2014.

over 150 such events and additionally through the first two quarters of fiscal year 2015 DEA has conducted 90 outreach and public education events, including:

DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conferences address pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of these conferences is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. DEA hosted 16 PDACs in eight states, with 2,197 attendees, and an additional 16 PDACs in eight states were scheduled for FY 2015. Since DEA began hosting PDACs in 2011 we have trained a total of 9,218 pharmacy professionals.

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

DEA also established its Distributor Initiative Program in 2005 to educate this registrant population on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA educates distributors about their obligations under the Controlled Substances Act (CSA), as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious, 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. The Distributor Conference was recently held on April 15-16, 2015, and consisted of approximately 220 industry leaders from over 130 companies.

#### *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, 49 states have an operational PDMP (meaning collecting

data from dispensers and reporting information from the database to authorized users). 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.

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge, as many drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous pain clinics and physicians. The National Association of Boards of Pharmacy (NABP) hosts NABP Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of PDMP data across state lines to authorized users. The program allows users of participating PMPs to securely exchange prescription data between certain states. Currently, PMPs in 30 states are participating in the program.

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. As of June 2014, only 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.<sup>14</sup> DEA encourages all practitioners and pharmacists to use their state PDMP program.

#### *Medication Disposal*

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues its national attention on the issue of nonmedical use of prescription drugs and related substance use disorders (SUDs), promotes awareness that one source of these drugs is often the home medicine cabinet, as 50.5% of persons aged 12 or older who used pain relievers non-medically in the past year got the pain relievers from a friend or relative for free<sup>15</sup>, and provides a safe and legal method for the public to dispose of unused or expired CPDs.

Since 2010 DEA has simultaneously held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on September 26, 2015. As a result of all ten National Take Back Days, the DEA, in conjunction with its state, local, and tribal law

<sup>14</sup> PDMP Center of Excellence, Brandeis University. <http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps>, retrieved September 30, 2015.

<sup>15</sup> Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health, Table 6.47B, Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older, by Age Group: Percentages, Annual Averages Based on 2011-2012 and 2013-2014.

enforcement partners, has removed a total of 5.53 million pounds (2,762 tons) of medications from circulation.

*Enforcement: Tactical Diversion Squads*

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

Between March 2011 and March 2014, DEA increased the number of operational TDSs from 37 to 66. Case initiations increased from 691 in 2005 to 1,727 in 2014, while arrests increased from 105 in 2005 to 2,418 in 2014.

*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 CSA. DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; importers; exporters; and narcotic treatment programs. This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the CSA and its implementing regulations.

**HEROIN AVAILABILITY TO THE U.S. MARKET**

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

DEA has also seen a 50 percent increase in poppy cultivation in Mexico primarily in the State of Guerrero and the Mexican “Golden Triangle” which includes the states of Chihuahua, Sinaloa, and Durango. The increased cultivation results in a corresponding increase in heroin

production and trafficking from Mexico to the United States, and impacts both of our nations, by supporting the escalation of heroin use in the United States, as well as the instability and violence growing throughout areas in Mexico.

The majority of Mexican and Colombian heroin bound for the United States is smuggled into the United States via the SWB, and heroin seizures at the border have more than doubled, from 846 kilograms in 2009 to 2,196 kilograms in 2013.<sup>16</sup> During this time, the average seizure also increased from 2.9 kilograms to 3.8 kilograms. The distribution cells and the Mexican and South American traffickers who supply them are the main sources of heroin in the United States today. The threat of these organizations is magnified by the high level of violence associated with their attempts to control and expand drug distribution operations.

DEA has become increasingly alarmed over the addition of fentanyl into heroin sold on the streets as well as the use of fentanyl analogues such as acetyl fentanyl. One of the most potent Schedule II narcotics which is 25 to 40 times more potent than heroin,<sup>17</sup> fentanyl presents a serious increased risk of overdose death for a heroin user. In addition, this drug can be absorbed by the skin or inhaled, which makes it particularly dangerous for law enforcement officials who encounter the substance during the course of an enforcement operation. On March 18, 2015, DEA issued a nationwide alert to all U.S. law enforcement officials about the dangers of fentanyl and fentanyl analogues and related compounds. In addition, due to a recent spike in overdose deaths related to the use of acetyl fentanyl, on July 17, 2015, DEA used its emergency scheduling authority to place acetyl fentanyl in Schedule I of the CSA.

#### **DEA RESPONSE TO THE HEROIN THREAT**

##### *Anti-Heroin Task Force Program*

As directed by Congress, the Department of Justice has joined with ONDCP to convene an interagency task force to confront the growing use, abuse, and trafficking of heroin in America. DEA and more than 28 Federal agencies and their components are actively participating in this initiative. The task force expects to have a strategic plan for the President and Congress by the end of 2015.

##### *International Enforcement: Sensitive Investigative Units*

Funds requested for International Drug Enforcement Priorities will be used to support and expand a key element of DEA's international efforts: the Sensitive Investigative Unit (SIU) program. DEA's SIU program, nine of which are in the Western Hemisphere, helps build effective and vetted host nation units capable of conducting complex investigations targeting major TCOs. DEA currently mentors and supports 13 SIUs, which are staffed by over 900

<sup>16</sup> Drug Enforcement Administration, Unclassified Summary, 2014 National Drug Threat Assessment, Pg. 10, available at: <http://www.dea.gov/resource-center/dir-ndta-unclass.pdf>.

<sup>17</sup> Centers for Disease Control, Emergency Response Safety and Health Database, FENTANYL: Incapacitating Agent, [http://www.cdc.gov/niosh/ershdb/emergencyresponsecard\\_29750022.html](http://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750022.html), accessed March 19, 2015; U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Drug & Chemical Evaluation Section, Fentanyl, March 2015.

foreign counterparts. The success of this program has unquestionably enhanced DEA's ability to fight drug trafficking on a global scale.

*International Enforcement: Bilateral Investigations Units*

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

### **SYNTHETIC DESIGNER DRUGS**

In addition to the existing heroin abuse and nonmedical CPD use threats, new psychoactive substances (NPS), or synthetic designer drugs, represent the most recent area of concern for DEA. Synthetic designer drugs are dangerous chemical compounds with no known legitimate medical or industrial use and are not approved by the Food and Drug Administration for human consumption. These compounds pose a great danger to the public, especially children and teenagers, because they are perceived as "legal" alternatives to the illicit drugs they intend to mimic. The two most common categories of these synthetic drugs are synthetic cannabinoids and synthetic cathinones.

Synthetic cannabinoids (sometimes sold under brand names such as K2 or Spice) continue to be drugs of considerable concern. These depressant/hallucinogenic drugs are primarily sourced from China. Synthetic cannabinoid substances are typically prepared for packaging in the U.S., and marketed over the Internet, or supplied to retail distributors before being sold to the public at retail stores (e.g., "head shops," convenience stores, gas stations, and liquor stores). Laws governing the legality of the substances vary widely between states, and the chemical components are frequently altered, making it difficult for the DEA to schedule the substances.

Synthetic cathinone substances fall under the phenethylamine class of stimulant/hallucinogenic drugs, and are marketed as "bath salts" or "glass cleaner," among other street names. These substances are often labeled "not intended for human consumption" as a false means to defend against the Government's utilization of the federal Controlled Substance Analogue Enforcement Act. Synthetic cathinones are also widely available on the illicit street market, oftentimes being mixed with other drugs such as MDMA.

### **CURRENT CHALLENGES**

*Traffickers Adapting to the Law*

Even though several NPS compounds have been controlled or banned through temporary scheduling or by legislative or administrative scheduling (per 21 USC 811 and 812), entrepreneurs procure new synthetic cannabinoid compounds with relative ease. Clandestine chemists can easily continue to provide retailers with "legal" products by developing/synthesizing new synthetic cannabinoid products that are not controlled. In fact, when DEA takes an action to temporarily schedule a substance, retailers begin selling new

versions of their products with new unregulated compounds in them. In addition, these same retailers are provided with spurious chemical analyses that purport to document that the new product line did not contain any controlled substance.

Over the past several years, DEA has identified hundreds of designer drugs from eight different structural classes, the vast majority of which are manufactured in China. There are a seemingly infinite number of possible new chemical compounds that are on the horizon. Manufacturers and distributors will continue to stay one step ahead of any state or Federal drug-specific banning or control action by introducing/repackaging new cannabinoid products that are not controlled.

There is also a large financial incentive that continues to drive the wholesale and retail distribution of these products. Information that DEA has obtained through the course of its investigations demonstrate that a \$1,500 purchase of a bulk synthetic drug can generate as much as \$250,000 of revenue at the retail level. It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for manufacturers, distributors, and retailers to seek/find substitute products that are not yet controlled or banned by Federal or state action.

#### *Prosecutions Pursuant to the Analogue Act*

A designer drug may or may not be a “controlled substance analogue” pursuant to the CSA. Even if a particular substance is widely regarded as a “controlled substance analogue” under the CSA, each criminal prosecution must establish that fact anew. The primary challenge to preventing the distribution and abuse of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is not automatically subject to control. In Analogue Act prosecutions, the Government must establish that the substance involved is a “controlled substance analogue” as defined by the CSA; accordingly, each prosecution is a new case even if the same substance is involved. Prosecutors must also prove that the substance was intended for human consumption.

In addition, without establishment and inclusion of specific sentencing equivalencies in the U.S. Sentencing Guidelines, prosecutors are required to produce evidence addressing the factors identified in the relevant guidelines. This typically results in prosecutors calling two expert witnesses to testify at every sentencing hearing to demonstrate that the substances in question fall within guideline definitions, a time consuming, resource intensive, and inefficient process. Different courts have reached very different results for the same substance which has resulted in disparate sentences for similarly situated offenders.

The above considerations, along with the increasing volume and endless variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Controlled Substance Analogue Enforcement Act ineffective by itself as a tool to prevent diversion and abuse of designer drugs. The Synthetic Drug Abuse Prevention Act (SDAPA) approach to control specific, known, synthetic substances in some instances by description of chemical characteristics, was a swift and aggressive contribution to the overall effort to combat

the designer drug threat.<sup>18</sup> DEA will continue to identify ways to better combat the designer drug threat.

## **DEA RESPONSE TO THE THREAT OF SYNTHETIC DRUGS**

### *Scheduling by Administrative Rulemaking: Temporary Control*

By their nature, designer drugs are non-controlled substances. They can be controlled under the CSA either by Congress or by DEA through its administrative rulemaking authority. DEA may also temporarily place a substance into Schedule I of the CSA for a maximum of three years if such action is necessary to avoid imminent hazard to the public safety, it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. § 812), and if there is no exemption or approval in effect under 21 U.S.C. § 355 for the substance.

DEA has utilized its regulatory authority to place many synthetic cannabinoids and synthetic stimulants into the CSA pursuant to its temporary scheduling authority. Once a substance is temporarily controlled, DEA moves towards permanent control by requesting a scientific and medical evaluation from the Department of Health and Human Services (HHS), and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since March 2011, DEA has temporarily controlled 32 synthetic designer drug substances, and 8 of these substances were subsequently controlled on a permanent basis. Seven of these 8 substances were permanently controlled by Congress through legislation, and DEA permanently controlled 1 of the 8 substances, methylone, through DEA's administrative authority. Twenty-four substances remain controlled on a temporary basis, and DEA has formally requested HHS to conduct a scientific and medical review and provide a scheduling recommendation for 20 of the 24 substances. DEA will continue working with the National Institute on Drug Abuse to collect information critical to the evaluation of a number of synthetic designer drug substances for consideration for both temporary and permanent scheduling.

### *Enforcement Operations*

DEA's Operation Log Jam was initiated in 2011 and culminated in a nationwide takedown on July 25, 2012. This DEA Special Operations Division Operation resulted in multiple Organized Crime Drug Enforcement Task Forces (OCDETF) Operations throughout the U.S., including those in 25 federal districts. This operation was coordinated by DEA in cooperation with U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI), the Federal Bureau of Investigations (FBI), U.S. Customs and Border Protection (CBP), and the Internal Revenue Service (IRS). The goals of this operation included the targeting of manufacturers, wholesale distributors, and retail distributors of designer drug products, the development of information on foreign based sources of supply, raising public awareness of the dangers associated with the use of these drugs and the development of leads for a Phase II initiative (Operation Synergy).

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<sup>18</sup> S. 3190 (112<sup>th</sup> Congress). The SDAPA was introduced on May 16, 2012, but was not enacted.

Operation Log Jam resulted in 100 arrests; the execution of 300 search warrants and 80 consent searches, and the identification of 38 manufacturing sites. Law enforcement seized 196 kilograms of raw synthetic cathinones, 722 kilograms of raw synthetic cannabinoids, 167,187 packets of synthetic cathinones ready for distribution, 4,852,099 packets of synthetic cannabinoids ready for distribution, 4,766 kilograms of plant material treated with synthetic cannabinoids ready to be packaged, 21,933 kilograms of untreated plant material, over \$45,000,000 in U.S. Currency and bank accounts, 88 vehicles, 77 firearms, additional assets valued at \$5,688,500, and 1,096 gallons of acetone.

The information and evidence obtained during Operation Log Jam led investigators to initiate Project Synergy, the second phase of a national cooperative effort in combating the synthetic designer drug distribution, which also resulted in multiple OCEDEF operations, in at least 13 federal districts. Project Synergy began in December 2012 and culminated in a nationwide take down on June 26, 2013 conducted by the DEA, HSI, FBI, CBP, and the IRS as well as domestic law enforcement departments in 45 states. This operation also included some of our international partners with joint operations being conducted with Australia, New Zealand, Canada, and Barbados.

As part of Project Synergy, the DEA conducted an enforcement operation in June 2013 in the Houston, Texas, area on a synthetic cannabinoid wholesale distributor who was selling AM-2201 and XLR11. During this operation, law enforcement seized enough synthetic cannabinoid products to gross approximately \$21,000,000 in revenue at the retail level.

Project Synergy involved many investigations that culminated on June 26, 2013, and included 234 arrests, 416 search warrants and 68 consent searches that led to the seizure of 305 kilograms of raw synthetic cathinones; 1,278 kilograms of raw synthetic cannabinoids; 10,263 packets of synthetic cathinones and cannabinoids; 959 kilograms of treated plant material ready to be packaged; \$53,201,595 in currency and assets, 132 vehicles and 141 weapons.

The second phase of Project Synergy culminated in May 2014 and involved law enforcement action in 29 states. More than 150 individuals were arrested and federal, state and local law enforcement authorities seized hundreds of thousands of individually packaged, ready to sell synthetic drugs as well as hundreds of kilograms of raw synthetic products to make thousands more. More than \$20 million in cash and assets were seized.

More recently, the DEA coordinated Operation Spice in partnership with the OCEDEF New York Strike Force and multiple other law enforcement agencies in New York City in September. This massive takedown targeted the local sale of dangerous designer synthetic drugs manufactured in China. The scheme, which operated in all five boroughs of New York City, allegedly involved the unlawful importation of at least 100 kilograms of illegal synthetic compounds, an amount sufficient to produce approximately 1,300 kilograms of dried product, or approximately 260,000 retail packets. As part the operation, five processing facilities were searched, as well as warehouses used to process, store, and distribute the drugs. In addition, over 80 stores and bodegas around New York City were searched. Over two million packets of synthetic drugs were seized. These packets were ready for street distribution, were concealed in over 100 laundry bags, and were ready for delivery.

**CONCLUSION**

The supply of heroin entering the United States feeds the increasing user demand for opioids which has been spurred, in part, by the rise of nonmedical prescription opioid use and the large numbers of people with active substance use disorders, many of whom have not yet been engaged by the treatment system. It is likely that this demand will continue to be met by ongoing diversion of prescription opioids and Mexican-based TCOs who are pushing to expand their profits. DEA will continue to address this threat by attacking the crime and violence perpetrated by the Mexican-based TCOs which have brought tremendous harm to our communities. Additionally, DEA's Office of Diversion Control will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. The Anti-Heroin Task Force will develop a comprehensive strategy that will combine education; law enforcement; treatment and recovery; and a coordinated community response. Further, DEA is constantly monitoring the emergence of NPS, and we have identified hundreds of compounds. We look forward to continuing to work with Congress to find legislative solutions needed to address the threat posed by synthetic drugs.

Mr. PITTS. The Chair thanks the gentleman. That concludes the opening statements of the witnesses. We will now begin questioning. I will recognize myself for 5 minutes for that purpose. Dr. Frank, and then Mr. Botticelli, in your view, what are the most significant obstacles at the present time preventing more individuals with opioid use disorders from receiving the most effective treatments?

Dr. FRANK. I think there are several factors. I think supply of treatment is certainly one important factor. The second one is stigma and the shame that comes from seeking treatment, the attitude of friend to neighbors. And then third, I think we are still working on our payment and coverage arrangements as we implement our parity legislation, and as we move towards expanding our parity regulations.

Mr. PITTS. Mr. Botticelli?

Mr. BOTTICELLI. As you indicated, only about 20 percent of people who have substance use disorder get care and treatment, and the factors that are often cited in those surveys, as Dr. Frank alluded to, is, one, insurance status. And we know that either not having insurance, or not having insurance that appropriately covers a spectrum of substance use disorder services is particularly challenging.

As he also talked about, stigma plays a role. We know that in national data, and I hear it time and time again reflected in people's stories, that it keeps them from asking for help, or delaying their care.

And the third aspect, particularly as it relates to opioid use disorders, as we have been discussing here, is the really dramatic underutilization of medication-assisted therapies not only in our treatment programs but in our correctional facilities. We know we have many parts of the country that don't have a dedicated treatment program, and looking at, and I think particularly, the Secretary's initiative, focusing on increasing access to community health centers—becomes particularly important. So we know that not having dedicated treatment in a local community is really, really important.

Mr. PITTS. Would the two of you expand on that, on the role that you think medication-assisted therapy should play?

Mr. BOTTICELLI. I will start and—

Mr. PITTS. Yes, go ahead.

Mr. BOTTICELLI [continuing]. Have Doctor— again, I think there is common agreement and that all of the studies are really very crystal clear that, by far, people with opioid use disorders do better on medication-assisted treatment when done in a high-quality way that includes other behavioral therapies and supports, bar none. So we know that not only do people do better, they don't die, they don't get infectious disease as it relates to it. And part of our efforts on the administration level, both at ONDCP in conjunction with HHS, is to ensure that people have adequate access.

In addition to grants and other activities, we have also been strengthening our Federal contracting language to ensure that those programs that get Federal dollars that support treatment include the entire spectrum of FDA-approved medications for opioid use disorders.

Mr. PITTS. Dr. Frank, do you want to add to that?

Dr. FRANK. The one point I would add to that is that it is not only important that we have people out there able to conduct medication-assisted treatment, but they have to do it in a way that is evidence-based, that is, having all of the components in place, the counseling, the recovery supports, the patient monitoring. You need the whole package for it to work. But clearly, when you have that, it is the most effective treatment out there.

Mr. PITTS. Thank you. Mr. Riley, I appreciate DEA's willingness to work with the committee to ensure that veterinarians can travel with and administer pain medication to their animal patients. Athletic team physicians also have an inherently mobile practice, yet as was the case with the vets, the statute prohibits them from administering appropriate medication to their patients outside of their physical office. Will you commit to working with the committee and Chairman Sessions on a responsible solution to this important issue?

Mr. RILEY. Well, yes, sir, we will and we are. This is a difficult balancing act, in terms of making sure that the supply is there to legitimate patients given by legitimate caregivers, but we also want to make sure that the ability of diversion in these situations are as limited as much. So I look forward to working with the committee, and I know we already are.

Mr. PITTS. Thank you. I also appreciate DEA's efforts to combat the recent influx of incredibly dangerous synthetic drugs hitting communities across the country, yet I understand that due to no fault of your own, the criminals are a step or two ahead of you. Can you explain how Congressman Dent's bill would help in this regard?

Mr. RILEY. Well, first of all, I want to say thank you to the leadership in this issue because it really is an issue for us. As I look across the country today, what keeps me up at night is clearly the heroin issue, the opioid addiction issue, various organized crime groups. But second that is the growth of synthetic drugs primarily targeting our young people. I personally witnessed this where people have lost their lives. So from a cop's point of view, sir, and that is what I am, anything that could help us as a tool to make sure we can move quicker, we would welcome. And again, we are going to work with the committee to get it done.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. Current research suggests that the most effective treatment to combat opioid addiction is a combination of medication and counseling. Methadone, which was approved nearly 50 years ago, is a synthetic opioid. Methadone is also a DEA Schedule II drug. Director Botticelli, could you talk a little bit about the evidence base regarding methadone and how it impacts patients' retention and treatment, transmission of infectious disease, and other health outcomes?

Mr. BOTTICELLI. So methadone is one of the most highly evaluated treatments for opioid use disorders. It has been around for over 50 years. And so not only have we seen kind of remarkable results in terms of treatment engagement and retention, and reduction in infectious disease but also reduction in criminal behav-

ior, increase in full-time employment. It is one of the highly effective medications that we have as it relates to opioid use disorders.

I think the bright spot that we do have with the opioid use epidemic is a growing armamentarium of highly effective medications, and when done in a quality way, methadone treatment programs wrap not only medication but look at addressing other medical conditions but also ensure that people have access to behavioral therapies and other recovery supports.

Mr. GREEN. OK. Dr. Frank, what are the advantages and disadvantages of using methadone to treat opioid addiction?

Dr. FRANK. Thank you for the question. As Director Botticelli said, first and foremost, it is extraordinarily effective, and that is a huge advantage. It is administered in a highly structured environment that provides testing, support, and therefore has a very low probability of diversion. Now, this structured setting is there because of the way methadone is metabolized, and careful attention to dosing is necessary early in the treatment because of the increased risk of mortality. And a disadvantage is that methadone is particularly prone to stigma.

Mr. GREEN. OK. Another drug used for opioid addiction is buprenorphine. This drug is a synthetic opioid and a DEA Schedule III drug. Buprenorphine can be prescribed by physicians who receive a DATA waiver. They are only permitted to treat a maximum of 100 patients at a given time. Dr. Frank, can you talk about the evidence base for buprenorphine and its impact on overdoses and other health outcomes?

Dr. FRANK. Yes, thank you. There have been 16 clinical trials on buprenorphine. It is impossible to pronounce, isn't it?

Mr. GREEN. Oh, it is very, although we are learning.

Dr. FRANK. Buprenorphine—

Mr. GREEN. People who think Members of Congress can't learn are so off.

Dr. FRANK. So there have been 16 trials of buprenorphine-based medication-assisted treatment. They consistently show strong effectiveness in treatment retention and reduced illicit opioid use. They also show improved maternal and fetal outcomes in pregnancy, relative to placebo trials, and they also have some mortality benefits. So they also have been highly effective.

Mr. GREEN. I understand that an injectable drug called Vivitrol also has been approved by FDA to treat opioid addiction. Vivitrol is an opioid antagonist, meaning it blocks opioid receptors. It is neither a narcotic nor a DEA-scheduled drug. Director Botticelli or Dr. Frank, can you comment on the evidence base regarding the use of Vivitrol in the treatment of opioid addiction?

Mr. BOTTICELLI. Once again, there is significant study to show that injectable naltrexone is highly effective in terms of dealing with opioid addiction. I think the premise here is we have three really highly effective medications that are underutilized. But it is also, I think, important to understand that, as in any disease, you want as many highly effective medications as possible, to make sure that we are matching the right treatment with the right person, and that if one fails, you have another option to be able to use for people. So, you know, again, I think our approach is to ensure

that people have access to all of the three FDA medications that we have.

Mr. GREEN. Is there a problem with diversion of either of those drugs? Because I know you said earlier in the testimony that methadone wasn't a diversion on these two drugs?

Mr. BOTTICELLI. You know, clearly, and I think it would be disingenuous to say that there is not a diversion issue, particularly with buprenorphine. However, what we see when it is done in a high-quality way, when it is done with sufficient patient monitoring, that it is particularly effective in terms of the work that we see.

Mr. GREEN. OK. Mr. Chairman, finally, buprenorphine, I think I can get that done.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions.

Mr. BUCSHON. Thanks, Mr. Chairman. As background, I was a practicing cardiovascular surgeon for 15 years, and my wife is an anesthesiologist so I have a little bit of experience prescribing and seeing patients on these medications. And now I kind of get my medical knowledge through my wife, and as an anesthesiologist, when patients come to surgery these days, it is amazing the number of people who are already on prescription narcotics for a variety of reasons, it is just striking, as well as others like benzodiazepines. But we are addressing the opioids today.

The other thing is this does go across socioeconomic class; it goes across ages. For example, the number one prescribed medication under Medicare Part D is a prescription opioid pain medicine. That is seniors. So this is really a problem we need to address, and it really is something that I am really happy that we have chosen to have this hearing, amongst many others today and in the past and future.

But enhanced provider education is another priority for reversing the current epidemic—as a provider, I can say that that is true—by really reducing inappropriate prescriptions of opioids. So what steps should be taken to strengthen prescriber training and primary care, outpatient opioid treatment, and methadone clinics for the use of non-opioid methods of managing pain, and also non-opioid things like Vivitrol and other medicines in the recovery of opioid addiction? Mr. Botticelli, you can start that.

Mr. BOTTICELLI. Maybe I will start, and I will let Dr. Frank talk about HHS efforts in this domain. As the Congresswoman from Indiana pointed out, a 2012 study by the CDC showed that we are prescribing enough pain medication in the United States, not just in Indiana, to give every adult American 75 pain pills. And while we clearly want to make sure that pain is treated in the United States, when you look back over the past 10 years, all of the morbidity and mortality is directly correlated to the increase in prescribing. So we know that giving people good education is important. That is why we continue to pursue mandatory prescriber education. And I will yield to Dr. Frank to talk about HHS efforts in those domains.

Dr. FRANK. Let me mention four things that we think are important. First is continue bringing prescription drug monitoring programs into the clinical world so that we can track prescribing pat-

terns as part of routine medical practice and can do so across States and across settings. That is one thing.

Second thing is we are in the process of developing guidelines for prescribing, particularly for non-cancer pain. And we have accelerated that effort and should be putting those guidelines out early next year. We have just had a set of public meetings where we have rolled out some initial ideas and gotten public feedback on it.

Third is we are engaging with a variety of medical societies and specialty groups to find ways and to partner with them to up the amount of training that is done within each of their organizations. And then finally, for the second year in a row, we have brought together the 50 States to compare best practices for helping to improve prescribing and monitoring of prescriptions.

Mr. BUCSHON. And I think that is really important. I can tell you in my own medical training in medical school and honestly 7 years of residency, I never had a specific month or week even directed at how to manage pain, and that is a person who is a surgeon. So we really learn how to manage pain almost on the go, so to speak, and I think addressing that issue probably with accrediting agencies that accredit medical school training or residency training is another avenue.

But I can tell you, as a physician, it takes months or maybe even years to understand how to manage pain, whether that is nonsurgical, whether that is related to injury, and top that off with managing people that already have significant issues with using prescription medication and trying to manage their pain, that we clearly need to address training, probably all the way back to medical school moving forward, and that may take us a generation to fix. So I yield back. Thank you.

Mr. PITTS. The Chair thanks the gentleman, and now the Chair recognizes the gentleman from North Carolina, Judge Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you very much, Chairman Pitts, and thank the witnesses for your testimony today. Let's see. Where do I start? All of you are right. All of my colleagues are right. All of the witnesses are right. We have a crisis in this country, and it is preventable, in my opinion. And so it is therefore incumbent upon all of us to address the opiate epidemic that has claimed too many, too many victims in my district and in your districts and all across the country.

Opiate addiction doesn't discriminate. It does not discriminate. Black, white, rich, or poor, anyone can succumb to opiate addiction. And that presents a very difficult challenge to finding ways to curb the epidemic. My home State of North Carolina has seen a 300-percent death increase due to opiate poisoning since 1999. Our emergency officials where I live in Wilson, North Carolina, respond to overdose calls every other day on average. In March, police in the city of Greenville, North Carolina, responded to six heroin overdoses in a single day.

This is real. It is a real problem which reaches each and every community in our country from the most urban to the most rural and across every demographic. There is much that we can and should do in response to this significant problem. Recently, I received a letter from our attorney general, Mr. Roy Cooper, and 37

other State Attorneys General urging Members to support legislation to assist with recovery from opiate addiction. One of the provisions important to my State included in that legislation is funding to increase access to naloxone for first responders. This drug is a lifesaving treatment which can counteract some of the damages of narcotic overdoses.

And so I appreciate the convening of this hearing to consider some of the policy options to combat this dangerous national epidemic. While some of these pieces of legislation are steps in the right direction, we must consider increasing access to naloxone—and I may be pronouncing that wrong—for law enforcement.

It is also clear that we cannot do this alone. The private sector is a key stakeholder and is stepping up to the plate. From abuse-deterrent formulations to injectable and implantable treatments, the future of medicine can help reduce prescription drug abuse and diversion.

But let me underscore the urgency of doing it now. From 2001 to 2013 there was a threefold increase in deaths from opiates, and the doctors in the room, I appreciate you helping to put a spotlight on this problem. There has been a threefold increase in deaths from opiates. These are our nation's mothers and fathers and sisters and brothers. This is a crisis. To Director Botticelli, thank you for your testimony. Are abuse-deterrent formulations having an impact here in the United States?

Mr. BOTTICELLI. One of the areas that we continue to evaluate is how abuse-deterrent formulations will diminish people's use. I think we are continuing to work with FDA to look at the evaluation strategies. But clearly, we know that this is a prime strategy that we have been putting forth in our Prescription Drug Abuse Plan to really look at the impact that abuse-deterrent formulations will continue to play in reducing prescription drug use issues.

I think as you discussed that abuse-deterrent formulations are one part of a larger strategy that we have to employ in terms of dealing with this issue. Clearly, we don't want people just switching from one drug to another. We want to use that as an opportunity to get people into care and treatment. So this is obviously a prime part of our strategy, an important part of our strategy, but it has to be linked to other things to ensure that people get interventions and get good, high-quality care.

Mr. BUTTERFIELD. While I have your attention, let me talk about manufacturers just for a moment. Can you describe whether we should be doing more to encourage opiate manufacturers to convert their medicines to abuse-deterrent formulations?

Mr. BOTTICELLI. And I probably can't speak as eloquently as the FDA can on this issue, but clearly, they have signaled their strong preference for approving abuse-deterrent formulations as part of their overall goal and work that they are doing. And again, it has been clearly part of our overall prescription drug abuse strategy to continue to promote abuse-deterrent formulations.

Mr. BUTTERFIELD. Thank you. Now, I will go to my far right. And we don't use that word, do we? All right. Go to the right. All right. Deputy Administrator Riley, as a representative from an area which has withstood some of the strongest storms in our nation's history, I am concerned. I am interested in the Medical Controlled

Substances Transportation Act of 2015. I know you recognize that. Can you describe whether this legislation would increase access of potentially lifesaving treatments to those in need in federally declared disaster areas?

Mr. RILEY. Well, clearly, in situations unfortunately the Carolinas are going through now—

Mr. BUTTERFIELD. Yes.

Mr. RILEY [continuing]. It is an important aspect. While I don't know the specifics of the bill, I can tell you that we are working with the committee on this. We recognize this is an issue that really needs attention, and I give you my word we are going to come to some agreement here. We can work it out.

Mr. BUTTERFIELD. Mr. Chairman, you have been very patient with me. Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you so much. I appreciate it. Thanks for your testimony, panel. I have a question for Mr. Riley. Recently, as many of you discussed in your testimonies, heroin deaths have been increasing across the country at an alarming rate, unfortunately. Both Pinellas and Hillsborough Counties in Florida, which I represent—I represent a portion of both of those counties—they have seen heroin deaths rise in some cases by more than 700 percent over the course of a year. Unbelievable. Mr. Riley, what can we do to best address not only how to control the supply side of prescription drug abuse, but also address the demand issue so that this population doesn't turn to illicit drugs?

Mr. RILEY. Thank you for the question, sir. Well, I think you hit it on the head. While I have been in law enforcement for 30 years, I do recognize we cannot arrest our way out of this. This is an issue that can be found in every corner of this country in cities large and small, rural and urban. And we have got to get everybody's help, from law enforcement to policymakers, to educators, faith-based organizations, clearly treatment, and the registrants that handle prescription drugs. So it is an educational fight as much as it is I think a law enforcement fight.

Now, on the law enforcement side, I also have to tell you we have never seen organized crime—and I will use the Sinaloa Cartel. We have never seen in my 30 years a criminal entity so well financed, vicious, and willing to do anything to make a buck. What keeps me up at night, sir, is the growing relationship between American street gangs, urban street gangs, and the toxic business relationship that they have formed with Mexican organized crime. That in itself I think has fostered the spread of heroin across the country.

Today's heroin is not what it was 5 years ago. It is cheaper, it is more pure, it can be smoked and snorted. So it has really attracted a completely different user base. So everybody in this room plays a role in our success, and that is why I applaud this committee for even bringing this up.

But I can tell you DEA around the world, working with our partners, it is the number one priority. One of the things that we are doing better, sir, that we haven't done before, is we are communicating. The bad guys for years have counted on the cops not sharing information, not sharing intelligence information. We are doing

that better now than we have ever done it, even with our foreign counterparts.

I have spent quite a bit of time on the border and also in Mexico. I have to tell you we have never seen the exchange of information with the Mexican law enforcement authorities as good as it is. Our ability to share information and for them to share information back for domestic cases is at an all-time high. So I am optimistic on the law enforcement front that we are moving forward. But clearly, everybody has a piece of this.

Mr. BILIRAKIS. Thank you. That is good to know. Mr. Botticelli, you mentioned a steep rise in the number of babies born with neonatal abstinence syndrome. Counties within my district were found to be suffering from some of the highest number of babies born addicted to opiates in the country. What do you see as the greatest obstacle to ensuring access to services, and how can these challenges be addressed?

Mr. BOTTICELLI. So, again, this is, I think, an opportunity for us to work with Congress on additional issues, particularly the Protecting Our Infants Act that was passed in the House, and I think it is a really great opportunity to expand our efforts.

So clearly we, you know, as you have indicated, have seen a dramatic increase in the rise of pregnant women and neonatal abstinence among babies who are born here in the United States. You know, obviously, our overall efforts to focus on reducing prescription drug misuse and heroin use play a big role, but also making sure that pregnant women have good access to care and treatment, we have effective medications, again, for the use in this and that moms have particularly good access to a wide variety of treatment services. So this becomes really important for us to look at this.

We also want to ensure that we are not putting additional stigma on pregnant women in terms of their ability to seek care, and we hear that time and again. Dr. Frank talked about the role that stigma plays, but that is particularly true with pregnant women, and we don't want to do anything to further enhance that, particularly among pregnant women in terms of their ability to seek care.

Mr. BILIRAKIS. Thank you, sir. Would you be willing to come to my district and participate in a roundtable on this particular issue?

Mr. BOTTICELLI. Absolutely. I—

Mr. BILIRAKIS. I am in the Tampa Bay area.

Mr. BOTTICELLI. Great. I would be happy to do that. I have had the opportunity, as I have traveled, to talk and visit many neonatal intensive care units, had the opportunity to talk to practitioners. I think we have further work to do, and this is where we are looking forward to working with Congress on making sure that we have good standardized protocols for the treatment of pregnant women, that we have good surveillance. And so again, I think this is another area where administration priorities and congressional priorities are aligned.

Mr. BILIRAKIS. Absolutely. Thank you very much. I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from New Mexico, Mr. Luján, 5 minutes for questions.

Mr. LUJÁN. Thank you very much, Mr. Chairman. I appreciate this important hearing today. And, Mr. Chairman, my questions began with Dr. Frank. Looking specifically at the legislation that I have introduced, Assistant Secretary Frank, to see what we can do in, especially rural States like New Mexico, where it is hard to get to some of these areas and families are being separated because of the challenges of substance abuse, which is compounded by these distances and healthcare shortages, what are we doing to ensure that those in need of help are getting it? How do we make sure people don't have to wait 3 months to be able to get access to this care? And how do we make sure that rural communities are not left behind?

Dr. FRANK. Thank you for that question. As you probably know, Secretary Burwell, being from a rural area herself in West Virginia, where the opioid abuse and mortality rates are very high, is extraordinarily sensitive to these issues. And one of the things that is behind our new grant program putting \$100 million into community health centers to increase access to buprenorphine is to actually get more services, more people trained into the areas of high need and low availability. And so that is a major thrust of what we are doing there.

The other is to sort of revisit our rulemaking on access to buprenorphine and other medication-assisted treatments so that we can increase the number of doctors, potentially increase the physician capacity to treat opioid use disorder.

Mr. LUJÁN. And, Dr. Frank, can you quickly touch on the importance of how we should consider giving States flexibility when it comes to treatment programs? There is a program in a little community in my district in Espanola called Inside Out that talks about the length of time that it takes to get treatment. And many judges in New Mexico are requiring 6-month treatment programs. There aren't very many 6-month treatment programs, and the only ones available are if you get incarcerated. So we are spending money to put someone in jail and not putting that money into treatment for these individuals that are addicts.

Dr. FRANK. Yes, thank you for that question. Actually, I have been there, and I think that it is important. And in fact, the reason that we are using grant mechanisms is in part to allow us to kind of match the interventions and match the strategies to the local needs, and in particular, making sure that the patient is at the center of what we do, and their circumstances kind of dictate the way we put the treatment in place.

Mr. LUJÁN. Inside Out also makes the important point, as we have talked about, naloxone or Narcan, that — what can we do to make sure that that is readily available? It is about the safest substance, as we talk about these treatments, that someone can take. Is there a push or can Congress do something to make that available over-the-counter, as opposed to not being a prescription mechanism? Because of some of these addicts, you know, when there is an emergency or an issue, you have to go try to get a prescription. They need it then and now to save their lives. What are your thoughts, sir?

Mr. BOTTICELLI. As you indicated, increasing access to naloxone by anyone who is in a position to reverse an overdose has been a

particularly important priority for us. We have been working with law enforcement across the country, have really been heartened to do that. We have been significantly heartened by the number of States, including New Mexico, that have passed naloxone distribution efforts.

We are continuing to support, and will in the President's fiscal year 2016 budget, a naloxone purchase. SAMHSA sent out a letter to States saying that some of the existing grant structures can be used to support naloxone purchase. So that will continue to be a priority for us to look at how we increase the capacity for naloxone and look at supporting grant programs to look at increased naloxone purchase.

Mr. LUJÁN. And, Mr. Riley, I am trying to do the math here. Everything that I read suggest that 90 percent of the poppies in the world are grown in Afghanistan, or the opioids are produced in Afghanistan. So that leaves 10 percent for the rest of the world, and it is grown in lots of places. Ninety percent of the heroin coming to the United States is attributed to Colombia and Mexico, with 50 percent going to one cartel. So am I to understand that with less than 10 percent production, or a fraction of that production, Mexico and Colombia are growing their own poppies that lead to 90 percent of heroin that is coming to the United States? Or is there opium coming from Afghanistan to Mexico and to Colombia that is making its way to the United States? And if that is the case, how do we stop it?

Mr. RILEY. Well, I can tell you that the majority of the opium and heroin produced in the Afghanistan theater is destined for China, Russia, and Europe. We see as little as 5 percent in the United States. But clearly, between the Colombians' criminal organizations and the Mexican criminal organizations, they control virtually all of the heroin available across our country.

And what are we doing to ensure that—I go back to the cooperation that we have, sharing intelligence information, making sure that we work on organizations. For us to be successful, we have to stop the street level, which leads to violence, but at the same time, we have to ensure that we follow those cases wherever they take us, whether it is into Central/South America, working with our counterparts overseas, our agents on the ground to stop it at the source, and at the same time, to go after the reason they are in business, and clearly that is the profit. And that is just as important a part of what we are doing. So are we getting better? I certainly feel we are, but as I said before, this is a marathon, not a sprint. We are in it for the long haul, but we need everybody's help.

Mr. PITTS. The gentleman yields back. The Chair recognizes the gentlelady, Mrs. Brooks, from Indiana, 5 minutes for questions.

Mrs. BROOKS. Thank you, Mr. Chairman. And thank you all for your work on this issue. Mr. Botticelli, as I mentioned in my opening and as you also talked about, we have an issue with respect to the prescribing practices beginning with medical school education, or not just with med schools because it is not just physicians who are prescribers, there are a whole category of healthcare providers who are prescribers.

In ONDCP's 2011 report 4 years ago, it was epidemic, responding to America's prescription drug crisis, and one of the issues in that

report was that we were going to encourage medical and health professional schools to continue expanding their continuing education programs to include instruction on measuring pain and prescribing to treat it. What efforts have been made since 2011, if not before, with our medical education schools? Because I talked to our med school in Indiana just a couple of months ago and still yet less than 5 hours, if even 3 hours, of education is dedicated to those who are prescribing. What is the resistance? Why are our medical education providers, not just for physicians, but for nurses and for nurse practitioners and others, what is the resistance, and why haven't we gotten that done?

Mr. BOTTICELLI. There are two issues that you and Dr. Bucshon have articulated, and I think one is getting to the root cause about how do we make sure that healthcare providers, not just physicians but nurses, have embedded in their training programs good information on substance use disorders and safe prescribing? We have actually been working with the American Board of Addiction Medicine and all of the specialty medical societies and the AMA, as well as the deans of medical schools to look at embedding good medical education as part of—

Mrs. BROOKS. OK.

Mr. BOTTICELLI [continuing]. Their curriculum.

Mrs. BROOKS. Excuse me for interrupting, but why hasn't it been done yet, when we have known for now a number of years this has been a problem? You all identified it at least in 2011, if not before. What is their resistance in embedding it in their curriculum this academic year? Why isn't it there yet?

And what do we need to do with our State medical associations, with the medical school associations, and so forth, what do we need to do to get it embedded in education initially? Healthcare providers don't want to be helping cause the problem, but yet when they give a 30-day prescription for a pain med after a minor procedure when you might need 4 to 6 or 7 days—I don't know, I'm no doctor—why do we give 30 days of prescription? Why are the med schools resistant?

Mr. BOTTICELLI. Having been doing this for quite a while, I think there has been just an overall hesitancy and resistance to think about substance use disorders as part of someone's overall health conditions, and not seeing the impact of what we are seeing. You know, when we look at referrals to treatment, only 7 percent of referrals to treatment are coming from our healthcare providers. And I think we will continue to pursue opportunities not just to embed medical education but look at the testing requirements of those medical educations to make sure that we are having competencies as part of medical examinations.

And this is why I think, you know, being into this epidemic why we have been calling at least for mandatory education. We have seen States—about 10 States have passed medical education laws as it relates to pain prescribing, and we are seeing some remarkable results.

Mrs. BROOKS. Excellent. Could you please provide us with the list of which 10 States have done that? Because that is something that I would like to explore further.

Mr. BOTTICELLI. Happy to do that.

Mrs. BROOKS. Mr. Riley, I want to thank you for your many decades of service with the DEA. I am a former U.S. attorney from 2001 to 2007. Crack cocaine was the epidemic of the day in the '80s, '90s, and early 2000s, but it has obviously shifted. And I am curious, because the synthetic drugs that are coming into this country, you said in your written testimony, is primarily from China. And while we have this unprecedented—I am curious about the unprecedented cooperation with Mexico. Really? I would like to know a little bit more about why is it so much better now than it was 5 years ago? And how is China cooperating with us with respect to synthetics?

Mr. RILEY. Thank you, ma'am. In terms of China, we are beginning to make inroads there. It has been a tough road. Many of the synthetic drugs that are seized here are very difficult to origin, and that is by design. But we have made inroads. We have had several high-level meetings with the Chinese on this issue, dating back, I think, several years ago. So this is an ongoing dialogue.

Part of our issue there, as it has been in Mexico, is to make sure both the Mexican authorities and the Chinese authorities understand the damage that it is doing in the United States. In terms of our Mexican partnerships, I was the agent in charge of El Paso in the mid-2000s when Juarez was aflame, thousands of drug-related homicides.

We have really developed a working relationship with part of the Mexican authorities, not all of them, unfortunately. But we have developed a working relationship that is based off trust, that is based off productivity, and I think they understand the importance that they can play, in both their own country and around the world. Our extraditions continue to be strong. Just a couple of weeks ago we were able to pull out two very high-level targets that, I got to tell you, 5 years ago I don't think they would have even consider doing it.

So it is an ongoing process, ma'am. It is what keeps me up at night. I am really 35 years old, but this is what it has done to me. And I give you my word, around the world, our guys 24/7 are on it, because it truly is the new face of organized crime.

Mrs. BROOKS. Mr. Chairman, before I yield back, I just want to commend the agents of the DEA who I have worked with for quite some time, and they do remarkable work. There just aren't enough of them, and I don't think we give them all the tools they need. And with that, I yield back.

Mr. PITTS. The Chair thanks the gentlelady, and now recognizes the gentleman from Massachusetts, Mr. Kennedy, 5 minutes for questions.

Mr. KENNEDY. Thank you, Mr. Chairman. Mr. Riley, a couple of questions to start with. Mrs. Brooks and Mr. Luján touched a little bit on the origins of the opium trade and heroin trade internationally, and I was wondering if you could quantify, to the best of your ability, the total dollar figure, if you will, between the U.S. and Mexico for heroin.

Mr. RILEY. Well, that is very difficult to do, but I can tell you it is in the billions.

Mr. KENNEDY. Order of magnitude? Just so — and I don't mean to pin you down too much, but a billion, 10 billion, 100 billion?

Mr. RILEY. Definitely close to 50 billion. And I quantify that by saying just in Chicago, where I was the agent in charge and heroin has exploded in the last several years, it was billions of dollars when we really drilled down on it. And I think that is what is really important. And if you look at New England in particular, you are seeing this spread of violent organized crime, urban, in terms of street gangs, and their ability to interface almost as unwitting contractors with Mexican organized crime to put heroin on the street, to make it available and obviously causing violence. I mean, the way these organizations regulate themselves, sir, is with the barrel of a gun. And I think it has caused tremendous damage across the country.

Mr. KENNEDY. And, Mr. Riley, thank you, and thank you for your service. I want to touch on two other things. I just commend you briefly for bringing back, first off, the take-back days, and one day back on April 26 of 2014 Massachusetts residents alone, in a single day, dropped off nearly 23,000 pounds of drugs. And I believe nationally the figure was 390 tons in a single day. I think they are a tremendous asset for our country, and I appreciate you bringing them back.

I also want to thank you for your work with New England around the HIDTA designation, the high-intensity drug trafficking area. It has helped with critical resources for law enforcement in the region, and I want to thank you and commend you for that.

Mr. Frank, I wanted to touch base with you a little bit if I can somewhat briefly, my apologies. There are three FDA-approved medications for treatment of opioid dependence: methadone, buprenorphine, and naltrexone. I am interested in learning a little bit more from you about methadone, if you will. So could you describe a little bit about how methadone is used to treat individuals with opiate dependence?

Dr. FRANK. So methadone is a very powerful drug. It is a controlled substance. It is provided in a very controlled setting, so-called OTP, opioid treatment programs, that are very comprehensive. They provide the dose in person on the day. They provide counseling, they provide drug testing, they provide patient monitoring. And I think I said earlier that the reason that this is done is because the dosing and the management of methadone, particularly at the beginning of a treatment episode, must be done very carefully or risk mortality.

Mr. KENNEDY. And there are special restrictions on the ability to prescribe methadone?

Dr. FRANK. Yes, there is.

Mr. KENNEDY. And what are they, briefly, if you can?

Dr. FRANK. They have to be done within those programs, those certified programs.

Mr. KENNEDY. And are those requirements applied to treatment of individuals with opiate dependence with naltrexone or buprenorphine, or is the regulatory schema different?

Dr. FRANK. Yes, the regulatory schemes are quite different. The naltrexone sort of operates under the rules of DATA 2000 and — did I say naltrexone? I meant buprenorphine. And naltrexone is not a controlled substance, and so it can be prescribed by any physician.

Mr. KENNEDY. And is there a medical rationale to separate the way that those drugs are actually regulated?

Dr. FRANK. I think there is. As I said, I think there are unique risks, in, particularly, the early stages of methadone treatment. Buprenorphine, as we have noted, is a drug that is a controlled substance, and there is diversion of that drug. And because naltrexone is not a controlled substance, it can be more broadly prescribed. So I think there is a logic to it.

Mr. KENNEDY. So if I could squeeze one last question in here, do you think — does that separation of that different regulatory environment make sense, or do you think bringing it all together and putting it under one — basically abolishing the stovepipe regulations there makes sense, or is there rationale for keeping them separate?

Dr. FRANK. I think that even if you brought them together, you would see many of the same restrictions in place. I think that what we are trying to do is to particularly focus on buprenorphine right now, because I think that is an opportunity we have to rethink those rules so that we can expand access to MAT.

Mr. KENNEDY. Thank you very much, sir.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The Chair thanks the gentleman. Because Dr. Murphy is chairing a hearing downstairs, Mr. Guthrie is yielding him his 5 minutes. Dr. Murphy, you are recognized.

Mr. MURPHY. Thank you, Mr. Chairman. I appreciate that. I wanted to be here because, although downstairs we are having a hearing on Volkswagen and devices put in cars that affect emissions testing, this is a life-and-death matter, so I wanted to be here.

The first thing I wanted to ask, Mr. Chairman, I ask unanimous consent that this letter, signed by multiple members of the Energy and Commerce Committee, be submitted into the record. It was sent today to HHS and calls for a comprehensive review and additional rules on buprenorphine providers before HHS unilaterally lifts the DATA provider cap.

Mr. PITTS. Without objection, so ordered.

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

Mr. MURPHY. Thank you.

Now, I just want to make sure none of you are physicians, none of you are people who are involved in the treatment of people with addiction disorders. Am I correct?

Mr. BOTTICELLI. [Nonverbal response.]

Dr. FRANK. [Nonverbal response.]

Mr. RILEY. [Nonverbal response.]

Mr. MURPHY. OK. But you are involved with policymaking on these issues, correct?

Mr. BOTTICELLI. [Nonverbal response.]

Dr. FRANK. [Nonverbal response.]

Mr. RILEY. [Nonverbal response.]

Mr. MURPHY. OK. I am a psychologist. I have dealt with people with addiction disorders. And I want to start off by saying one of the problems we have in this country is that money that is sent to States that is being used for mental health funding for block grants and substance abuse block grants are not allowed to be used

together. The serious problem that comes with that is many people with substance abuse disorders also have mental health disorders,, and yet we create a barrier there.

Now, we are talking about increasing the number of prescriptions a physician can write. Dr. Frank, do you know how many—so we are talking about someone going from like 30 or so a month, a week, a day? What is it? Up to—

Dr. FRANK. Thirty patients at any one time.

Mr. MURPHY. Up to 100, and they can potentially go beyond that. Do you see a maximum with that?

Dr. FRANK. Right now, there is a limit to 100 after a year.

Mr. MURPHY. Right, but after that, they are looking to do more, to lift that cap, right?

Mr. FRANK. We are in the process of sort of reviewing the best way to expand access, and we are going to do it very cautiously.

Mr. MURPHY. I understand that. To what number?

Dr. FRANK. We don't have a number yet.

Mr. MURPHY. OK. Now, throughout this process — and you recognize that buprenorphine is the third-most diverted drug. That is people get it and they sell it, and they make money and then they will go out and buy heroin or something else. What attention is being given to make sure that doesn't happen?

Dr. FRANK. That is exactly why we are taking a careful approach, because of that concern. But let me give you an additional concern. So we want to expand access. We are concerned that too often you don't get the full package of services, the counseling, the supports, and in the testing and monitoring, and so we want to make sure that the evidence-based package is in place and that the risks of diversion are minimized. And so what we are trying to do is to collect evidence about where are the places, and under what conditions are you most likely to be able to significantly expand capacity while minimizing the risks of diversion, and maximizing the probability that evidence-based treatment will be provided.

Mr. MURPHY. So let me ask about some of those. How much time do you think the average amount of time is that one of the physicians who is prescribing will actually be face to face with a patient?

Dr. FRANK. I think that—

Mr. MURPHY. Well, let me put it this way: Is that something that will be assessed?

Dr. FRANK. Yes. Well, we want to consider sort of what it takes and what are the environments that get you combination of treatments, so that means you have to have the counseling, you have to have the—

Mr. MURPHY. Right. Well, let me go into just a couple things. I talked to one clinic and they said the average amount of time physicians may spend actually discussing and prescribing is about one and a half minutes. Now, during that amount of time, you have to assess those very things. Is this a diversion issue? Is the person in recovery? Are they seeing a counselor or therapist? Are they really engaged in treatment?

And also then in many of these cases the person who is perhaps the addictions counselor does not even communicate with the physician, except maybe to write a note in the chart in treatment. Or they may have someone there in some places where it is a nurse

or someone sitting in the waiting room, and while people are there waiting for their prescription, they have a chat and they write that down as group therapy. You are aware that some of these things take place. Knowing you, I would assume you would be as distressed as anyone to say that is not tolerable, that is not treatment. And such people not only should not have expanded prescription privileges, they should have zero.

Dr. FRANK. I completely share your concerns, but even more importantly, Secretary Burwell shares those concerns.

Mr. MURPHY. Yes, she does.

Dr. FRANK. And she has emphasized sort of a careful approach to make sure that both the evidence-based treatment and the risk of diversion are addressed carefully.

Mr. MURPHY. One more final thing in my final seconds here, I know Secretary Burwell is dedicated to this, too, but I am also concerned that the amount of training that these physicians get, deal with addictions, is minimal. Very few of them are actually addictions counselors, addiction trainers, and many times other people there have minimal training.

In my area of southwestern Pennsylvania I have heard proctologists, plastic surgeons, pediatricians, and others who do not have extensive board certification in these things. I think it is a dangerous issue for something that is growing as a deadly issue in America. And I hope we can continue our conversation. I want to work with you on this, but we are all concerned that just expanding the number of prescriptions can be written without total assurances of other things is a dangerous issue. Thank you. And I yield back.

Dr. FRANK. And we thank you for your support and agree.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. SARBANES. Thank you, Mr. Chairman. I want to thank all of you for being here today. I have introduced the Co-Prescribing to Reduce Overdoses Act, which would create a demonstration project to encourage co-prescribing opioid overdose reversal drugs like naloxone.

So let me talk a little bit about the need first, which you all are very familiar with. Over 100 Americans every day are dying from preventable drug overdose, and that kind of fatality is now the leading cause, the leading cause of accidental death in the country. In 2013, more than 16,000 people died due to prescription opioids overdose, and an additional 8,000 died from heroin overdose. In Maryland, we are having the same experience. We had 192 heroin overdoses in the City of Baltimore, in Anne Arundel County, which I also represent. There were 49 fatal overdoses from opioids, and that was part of 360 overdoses overall that occurred.

So this is an epidemic. There is no question about it. And we have to put real resources behind it. We have to put it behind workable and strategic solutions that we can identify. I will mention that, today, the State of Maryland released a \$680,000 grant from the U.S. Department of Justice to help address this epidemic in our State.

Let me talk about naloxone now. It is a drug that safely and effectively reverses both opioid and heroin-induced overdoses if administered in time. It has been used by nonmedical personnel with only minimal training for over 15 years and has been proven to reduce lower overdose mortality by almost 50 percent. More people need access to lifesaving medication, obviously.

And while efforts to distribute naloxone to first responders and community organizations are important, and we have talked about that today, it is critical that we also take a more proactive approach. One idea, one part of that proactive approach is the idea of co-prescribing naloxone to patients who are taking opioids and are at high risk of overdose. And this is supported by the American Society of Addiction Medicine, the American Medical Association, the Veterans Health Administration.

The bill that I have introduced, the Co-Prescribing to Reduce Overdoses Act, would create a demonstration project for federally qualified health centers, opioid treatment centers, and other providers to encourage co-prescribing naloxone. Funds could be used for training to purchase opioid overdose reversal drugs, to offset copays, and to conduct community outreach and raise awareness to connect patients who have experienced a drug overdose with appropriate treatment, and track individuals that are participating in the program. And all grant recipients, of course, would be required to evaluate the outcomes of the program.

A second program would allow States or local health departments to develop guidelines on co-prescribing opioid overdose reversal drugs like naloxone. So there is no question that opioid overdose is a public health epidemic. I believe strongly that increased access to naloxone, particularly this co-prescribing opportunity to patients at high risk of overdose, is a key element of any approach to successfully decrease prescription drug and heroin overdoses.

I would like to get the thoughts of the three members of the panel, certainly Mr. Botticelli and Dr. Frank, on this question of whether co-prescribing naloxone is an effective strategy that we should try to encourage and support going forward.

Mr. BOTTICELLI. Thank you for your leadership on this issue. I don't think we could agree with you more in terms of the opportunities that we have for supporting co-prescribing in a wide variety of settings, and particularly for people who are at highest risk.

We share your goals. We have actually continued to take action to support co-prescribing. We have hosted webinars with the American College of Emergency Rooms Physicians to support co-prescribing. We continue to work with our treatment programs to encourage co-prescribing. So this is, I think, a particularly important area for people who are at high risk.

Our overall policy goals are to ensure that anyone who is at high risk for an overdose also has access to naloxone. It has been truly remarkable in terms of its ability to save lives and actually motivate many people to go seek care and treatment. So we would love to continue to work on that to look at that legislation.

Mr. SARBANES. Dr. Frank, I have 15 seconds if you have a comment. Yes.

Dr. FRANK. Yes. I obviously am not going to say what he said, but there are some things that you need to do to go along with co-

prescribing and other measures to really expand supply here, and one of them is making sure that we have user-friendly versions of naloxone so that non-medically trained people can administer it. Two, I think we need to make sure that once somebody gets naloxone, they get the treatment. Just recovering and walking away isn't the right thing to do. We have to get them to see—

Mr. SARBANES. No, it is the first step is what you are saying.

Dr. FRANK. It is the first step, and it is an important first step—

Mr. SARBANES. Yes.

Dr. FRANK [continuing]. But we would like to complement that with links to treatment.

Mr. SARBANES. Great. Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman. The Chair recognizes Mr. Lance, 5 minutes for questions.

Mr. LANCE. Thank you, and good morning to the panel. And, Mr. Riley, did you say you are 35 years old? Is that what you said?

Mr. RILEY. Yes.

Mr. LANCE. Yes, I am 35 as well, but what keeps me up at night is leadership elections. You discussed challenges in carrying out a criminal prosecution pursuant to the Federal Analogue Act. It is my understanding that there is a very high burden of proof to establish that a compound is in fact a controlled substance analogue. Could you please elaborate on that standard and what changes can be made to the Analogue Act that would make it more effective as a tool in combating the spread of synthetic drugs?

Mr. RILEY. Well, first of all, just the mere amount of these synthetic drugs that we are encountering is mind-boggling, and our ability to test those through our scientific arm and get an identifier on them sometimes is very prolonged. So what we are doing now is we are really trying to look at how can we be effective? What is the best possible way that we can move this process along? But I have got to be honest with you. We are not one step behind the bad guys, we are three steps behind the bad guys.

Mr. LANCE. Thank you. Is there anyone else on the distinguished panel who would like to comment on this?

Mr. BOTTICELLI. I completely agree. I think it has been a challenge from both a prevention standpoint and a scientific standpoint to stay ahead of the chemical tweaks that manufacturers make to do that. I think that opportunities to lower the burden of proof around scheduling, around these analogues are important. I think despite Congress and States' best attempts to deal with this issue, that look at expediting the scheduling and thinking about the criteria with which we schedule those drugs is particularly important.

Mr. LANCE. Thank you. Director Botticelli, as you mentioned in your testimony, New Jersey, where I live, is one of a handful of States that requires greater use by prescribers of the State's Prescription Drug Monitoring Program. Specifically, Governor Christie recently signed into law a requirement for prescribers to check the program and patients returned for a second resale on a prescription opiate. What is your office doing to ensure that both State officials and prescribers are able to utilize effectively their Prescription Drug Monitoring Programs?

Mr. BOTTICELLI. So I will start, and I know that this is an important initiative for the Secretary, too, so there is more action.

Mr. LANCE. Certainly.

Mr. BOTTICELLI. When this administration started, we had 20 PDMP programs, 20 States. Today, I am happy to report that we have 49 States that have Prescription Drug Monitoring Programs. We continue to focus opportunities on increasing the interstate operability so that we can share information across State lines but also increase the utility and usability of these programs. And I will defer to Dr. Frank on that.

But one of the things that I think we are seeing promising practice, and particularly in States that require some level of mandatory check of their Prescription Drug Monitoring Program, we are seeing a decrease—in Florida, we saw a significant decrease in overdose deaths, and we have seen a significant decrease in doctor-shopping, people going from one doctor to another to get their medications when we have good, robust Prescription Drug Monitoring Programs.

Mr. LANCE. Thank you. Dr. Frank?

Dr. FRANK. Thank you. This here, we are investing \$20 million in State grants really to focus on improving Prescription Drug Monitoring Programs in the States. We have a proposal in for 2016 to put in 45 million in order to bring it to all 50 States. And we are hoping to build off the progress of some very successful pilots in addition that have integrated Prescription Drug Monitoring Programs in clinical health information technology.

Mr. LANCE. Thank you very much. And, Mr. Chairman, I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from New York, Mr. Engel, 5 minutes for questions.

Mr. ENGEL. Thank you, Mr. Chairman. You know, gentlemen, first of all, thank you all for excellent testimony. Really, all of you have just been terrific. And, you know, through my perch on the Foreign Affairs Committee when I was chairman of what we called the Western Hemisphere Committee, which dealt with Latin America, and we did a lot of work involving the drug trade in Mexico and some of the other places. And we fund money for treatment programs and we fund a lot of money to go after the bad guys, but so much of the consumption comes from us that I have always felt that we didn't do enough in terms of education, and in terms of that side of it rather than going after the bad guys after they have done it.

And the one thing that is stark for me is that there are so many people in this country that use drugs. I mean it is just mind-boggling. And young people, because when you are young, you think you are going to live forever and you think nothing is going to happen to you and so you are more likely to experiment, but this is an epidemic. I mean, this is just beyond the pale. You know, I don't make judgments on anybody, but I just know that we can't continue like this. I mean, we have got to do a better job of educating people and letting them understand that this is a life-ruining situation.

And you have really driven the point home, all three of you, about it. I mean I have some other questions to ask, but in general,

I think, you know, if you could expand on that because it is really just shocking, the extent of the abuse. And so not only are we keeping these criminal enterprises going, but we are destroying lives of American citizens.

Mr. BOTTICELLI. I will start. Thank you, Congressman, for your comments. I think, yes, what you have described is the entire approach, the Obama administration's view of drug policy that, while supply reduction and law enforcement has a big role to play, that we need and will continue to pay more attention to prevention, treatment, and recovery efforts for people here in the United States. If you look at our entire drug control budget, we are actually spending now more on those public health strategies than we have had during the entire time of our office, so this is particularly important.

I will say, however, that I think our heroin situation is a good example between the nexus of supply and demand, that because of the purity levels, because of the price, because of the widespread availability of heroin that we have, it really does combine both a public health and public safety approach. And I have really been heartened, as I travel around the country, to see law enforcement and police wanting to partner with public health to really come up with holistic strategies, knowing that arrest and incarceration are really ineffective in dealing with this issue.

Mr. ENGEL. You know, every time I see a young person smoke a cigarette, a regular cigarette, I think to myself, you know, why are they doing this? Because we have evidence now that we didn't have maybe when I was a kid that regular smoke just is terrible for your health. And you think, well, why would a young person do that? We are not getting through. And of course when you take it a notch up and you are talking about heroin or prescription drugs, it is that much worse. So we are failing as a society, and it is just shocking.

So let me ask you, Dr. Frank. The bill proposed by Congresswoman Brooks and Congressman Kennedy tasks an interagency coalition with developing best prescribing practices, and it is certainly needed. My district — New York's Lower Hudson Valley contains a portion of my district, and according to the New York State Office of Alcoholism and Substance Abuse Services, the number of New Yorkers admitted to hospitals on account of heroin skyrocketed 136 percent between 2004 and 2013, and in 2013 alone, nearly 90,000 New Yorkers were admitted to hospitals for heroin and prescription opioid. This is shocking. It is absolutely, absolutely shocking.

So given how varied the populations affected by this epidemic are, how would you, Dr. Frank, suggest that we ensure that any best practices created as a result of this bill or other bills will suit physicians and patients from contrasting backgrounds? You know, I worry about a one-size-fits-all approach. Do we need to tailor best practices to different populations?

Dr. FRANK. Thanks for that question. Our approach is very much aimed at two things. One is matching policies to context, locally, but also matching patients to actual treatments, and we want to do both. And so, for example, just a couple weeks ago we had a 50-State convening where we brought all the States together, all 50

States and the District of Columbia together, to talk about how to share best practices.

And what we did is we had breakout sessions where we had regional breakouts, so in fact people who bordered one another could talk about sort of common approaches that met their particular circumstances. Likewise, we try to have a full armamentarium of treatments available so that we can match patients and their circumstances in the best possible way, and our mechanism for doing this is largely grant support through the States.

Mr. ENGEL. Thank you. Thank you all. And, Mr. Riley, thank you for all you do.

Mr. PITTS. The Chair thanks the gentleman. The gentleman yields back. Without objection, the Chair recognizes Mr. Tonko, a member of the full committee, who wishes to ask questions for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. As I mentioned in my opening statement, access to effective addiction treatment is the biggest obstacle we face today in preventing more deaths in this epidemic. We know that nearly 80 percent of persons with an opioid addiction do not receive treatment. While the reasons for these gaps are multifaceted, it is clear that capacity in our current treatment system play some role.

A study published recently in the American Journal for Public Health estimated a gap between treatment need and treatment capacity between 1.3 and 1.4 million individuals in the year 2012. This is why I joined with my colleagues in introducing the TREAT Act, which would raise the arbitrary cap on buprenorphine prescribing for certain providers and allow physician assistants and nurse practitioners the ability to be waived providers.

As such, I was very encouraged by Secretary Burwell's announcement to start the rulemaking process to address opioid addiction and specifically addressed treatment hurdles such as the DATA 2000 caps. Dr. Frank, what is the expected time line and process for this rulemaking change?

Dr. FRANK. You are not going to like this answer, but we are going to move as fast as we can. But I can guarantee you that this is extraordinarily high on my office's agenda and the Secretary's agenda, and literally, we are meeting every week to kind of get this pushed through.

Mr. TONKO. Thank you. And, Director Botticelli, we have heard a number of concerns expressed today over the diversion of buprenorphine. Is that the most commonly diverted opioid?

Mr. BOTTICELLI. I will defer to my DEA partners on this in terms of diversion. I would suspect that probably pharmaceutical opioids are far more diverted than—

Mr. TONKO. Pharmaceutical?

Mr. BOTTICELLI [continuing]. Buprenorphine diversion.

Mr. TONKO. OK. And what actions does the administration recommend to address that diversion?

Mr. BOTTICELLI. Part of, I think, what we need to look at—and I have to be careful not to get ahead of the HHS rulemaking authority here—but I think that looking at how we can continue to support access to buprenorphine and other medications but also being mindful of ensuring quality treatment and minimizing diver-

sion become really important. And I think you have heard a willingness on the part of the administration to work with Congress on how do we strike that balance as we move forward, thinking about how many people who can prescribe, what is the quality care setting that we can do it. I have seen models across this country where we have been able to expand the number of people who get access to medications through a wide variety of, I think, really innovative State practice. And I think we can use some of that thinking and some of that guidance to help with the process about how we go forward.

Mr. TONKO. Let me ask you, Director Botticelli, why do you think we make it so much harder for individuals to get the treatments that help them recover than the drugs that get people addicted in the first place?

Mr. BOTTICELLI. I think there is a wide variety of — you know, both as a person in recovery and as someone who has been doing this for a long time, I think stigma plays a huge role. And I think, quite honestly, that we had viewed people with addictive disorders and their families as less deserving of care, and I think for a long time public policy has reflected that. And I think now with the opioid epidemic I think we are finally understanding some of the long-standing issues that we have had in this country as it relates to how we have treated people with addictive disorders. I think that is why our jails and prisons, quite honestly, unfortunately, our de facto treatment programs, that we viewed people with addictive behaviors as morally flawed or bad people. And I don't think we have seen them as deserving as a response, as people with a disease.

Mr. TONKO. Well, I think all of you gave powerful testimony, and it reminds us that we need to see addiction as a disease. And until we do, we won't get the results we require. And finally, Director, does the administration support mandatory prescriber education on pain management and substance use, prior to an individual being able to prescribe controlled substances?

Mr. BOTTICELLI. We do and we look forward to working with Congress in terms of how we might make that happen.

Mr. TONKO. And there are things that Congress can do to help with that effort?

Mr. BOTTICELLI. Absolutely.

Mr. TONKO. And you will direct us?

Mr. BOTTICELLI. And we look forward to working with you on that.

Mr. TONKO. Absolutely. I thank you all again for your testimony. It, I think, was very instructive. And with that, Mr. Chair, I will yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman. That concludes the questioning of members present. We have had members going in and out all morning because we have another hearing on Energy and Commerce being conducted downstairs, so I apologize for that.

But I want to thank the first panel of witnesses. This is a very important issue and we look forward to working with each of you as we proceed on the legislation. And we will have some follow-up questions, so we will send those to you in writing. We ask that you please respond promptly. I remind members that they have 10

business days to submit questions for the record. Members should submit their questions by the close of business on Thursday, October 22. I have a U.C. request, a statement for the record, on behalf of the Opioid Treatment Program Consortium. Without objection, so ordered.

Mr. PITTS. The subcommittee will stand in recess until the week of October 20, when we will convene our second panel on this issue. The subcommittee stands in recess.

[Whereupon, at 12:02 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

#### PREPARED STATEMENT OF HON. FRED UPTON

Today we will discuss several important bipartisan legislative proposals aimed at addressing the drug abuse crisis that is sadly unfolding in communities in my home State of Michigan as well as across the country. These bills and this hearing build upon the solid foundation laid by the Oversight and Investigations Subcommittee, which has held several hearings and meetings and heard from two dozen witnesses, including from the Federal Government, our partners in the States, and a wide range of health professionals and addiction specialists. They spoke about the root causes as well as the consequences of our nation's complex and growing opioid epidemic and about potential solutions.

In addition to the O&I hearings, many of my colleagues on both sides of the aisle have participated in numerous discussions back home with impacted constituents and local leaders about the devastating effects this public health crisis is having on our communities. In August I participated in an event in St. Joe, Michigan, with various local leaders to discuss the devastating effects of prescription drug and heroin abuse that was gripping our community.

There were 13 suspected overdoses in Kalamazoo in the first quarter of 2013, up from 9 in the first quarter of 2012. Opiate-related overdoses have recently become the number one cause of injury related death in Michigan and nationwide. This sad reality has hit hard at home in Kalamazoo County. In 2008, we lost Amy Bousfield, 18 years old and a graduate of Portage Central High School. In 2012, Marissa King died at 21 years old. She began using heroin in 2009, despite having lost two friends to the drug, including Amy Bousfield. This crisis does not discriminate between large and small, rural and urban, rich and poor. Now it is time to take what we have learned and begin making changes to help.

We have learned that while addiction is not easy to treat, it is treatable, and we need to rise to this challenge for the sake of the American family. Mr. Botticelli sitting before the committee today is an example that this disease is beatable. He is a champion of the patient community. We thank you for your continued efforts.

I commend those of you who have worked diligently on the legislation being discussed today and I look forward to continuing to learn about and work on these various bills. As we move forward, we must harmonize our efforts with the efforts already underway at the Federal and State levels, in order to take constructive and effective action, and I am committed to doing just that.

#### PREPARED STATEMENT OF HON. JOE BARTON

Mr. Chairman, I am pleased that we will be marking up H.R. 8, the North American Energy Security and Infrastructure Act of 2015, H.R. 3242, the Child Nicotine Poisoning Prevention Act and reconciliation recommendations today.

The reconciliation recommendations include three important parts. Section one repeals the Prevention and Public Health Fund, often referred to as the "Obamacare slush fund", which will result in a savings of \$12.7 billion over 10 years. Section two prevents Federal Medicaid dollars from going to private entities that perform abortions, such as Planned Parenthood, for 1 year. Section three redirects these Medicaid dollars to Community Health Centers. We all support funding for quality and widely accessible women's health centers, and I believe this reconciliation recommendation will ensure women have access to care while protecting the unborn.

I am pro-life because I believe that all life is precious and should be respected and I back that up with my vote. As a lawmaker, I have a constitutional and moral obligation to protect those who do not have the power to protect themselves. I will continue to fight in Congress for the unborn.

In addition, I am glad that we are marking up HR 8 as well. As the chairman of the Conference on the 2005 Energy Bill, I appreciate all the hard work it has taken to get to this point. While I may not agree with every provision, I know that getting into conference is the only path to the President's desk. I hope that all my colleagues on both sides of the aisle feel that creating sound energy policy is in the best interest of our country and will support this process moving forward.

#### PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Mr. Chairman, for calling today's hearing. I want to start by sharing a story from one of my constituents from Old Bridge, New Jersey. She has already lost one son to the drug abuse crisis and she is fighting to save her remaining son's life as he suffers from his own opiate dependence. Her younger son overdosed at the age of 21 and her older son—who was struggling with addiction when his brother died—continues that struggle.

No mother should have to endure this tragedy—having grieved the loss of one son and being overwhelmed with worry that she could lose another to the opiate epidemic. I know such stories are not unique to New Jersey or my District. Unfortunately, most of us have heard similar stories from constituents, family members, or friends. Each day we are losing 44 people in the U.S. from overdose of prescription painkillers. We must take action to combat this epidemic.

That is why I am pleased that we are holding this hearing on several bills to combat this drug abuse crisis. I strongly support efforts to expand access to substance abuse treatment services, increase access to overdose reversal medication, improve provider education, and increase public awareness of the problems of substance abuse.

That is why I support H.R. 2536, H.R. 2805, H.R. 3680, H.R. 3691, and I would like to thank Representatives Tonko, Kennedy, Sarbanes, and Luján for their leadership on this issue. I briefly want to mention that I have concerns with the remaining substance abuse treatment bill—H.R. 2872, the Opioid Addiction Treatment Modernization Act. While I support the goal of expanding access to all FDA-approved medications for the treatment of opiate dependence and I support efforts to increase provider education and training generally—I believe we must pursue those goals in a way that does not undermine our efforts to expand access to substance abuse treatment services. I don't think H.R. 2872 strikes the right balance and, as a result, could harm access to care.

There are also another two bills we will discuss today. H.R. 3537, which would place a number of synthetic drug substances on Schedule I of the Controlled Substances Act. Use of synthetic drugs has led to numerous overdoses and deaths, primarily among young adults. More must be done to eliminate the availability of these substances, and enable DEA to take appropriate enforcement action as H.R. 3537 strives to do. I am concerned, however, about whether the broad list of chemicals in the bill might include chemicals that can have legitimate research uses for developing important medical therapies.

The other bill, H.R. 3014, would allow registered physicians to transport controlled substances away from their registered practice locations to other locations, such as team physicians traveling to a game out of State, or physicians responding to a disaster in a neighboring State. I hope to work with stakeholders to ensure that the proper safeguards are in place to address this problem and maintain access to drugs for patients only when needed.

I look forward to hearing from all of our witnesses, and continuing the conversation about how to address the issue of substance abuse moving forward.

[H.R. 2536, H.R. 3014, and H.R. 3537 have been retained in committee files and also are available at <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104047>.]



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American Association for the Treatment of Opioid Dependence, Inc.

**Statement for Committee on Energy and Commerce  
United States House of Representatives  
October 8, 2015**

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**Recommendations on Increasing Access to Effective Treatment for Opioid  
Addiction from the American Association for the Treatment of Opioid  
Addiction (AATOD)**

My name is Mark Parrino, and I am writing on behalf of the American Association for the Treatment of Opioid Dependence (AATOD), which represents 1,000 Opioid Treatment Programs throughout the United States, treating 340,000 patients on any given day. These are the treatment programs that treat opioid addiction under certification through the Substance Abuse and Mental Health Services Administration. All of these programs must comply with SAMHSA's operating requirements, which were promulgated during 2001. All of the Opioid Treatment Programs (OTPs) must also comply with the Drug Enforcement Administration's security requirements. Finally, all of the OTPs are regulated by the State Opioid Treatment Authorities, which have different, and at times more stringent, standards of regulation.

The Committee and its representatives understand that our country is experiencing a public health crisis of untreated opioid addiction. It is useful to reference a recent article on this topic, which was published in the *New England Journal of Medicine* on January 15, 2015, "Trends in Opioid Analgesic Use and Mortality in the United States". Dr. Richard Dart is the lead author in this article, which made the following point: "Whatever the measure, the past few decades have been characterized by increasing use and diversion of prescription drugs, including opioid medications, in the United States. An estimated 25 million people initiated non-medical use of pain relievers between 2002 and 2011."

As the Committee knows, there have been a number of national reports from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC), documenting the increase in the use of prescription opioids. SAMHSA has also documented the fact that 80% of new heroin addicted individuals report using prescription opioids as a gateway drug.

**Need for Public Education**

One of AATOD's primary recommendations, which has been made to the representatives at the Department of Health and Human Services and other federal agencies which have jurisdiction in this area, is the need to provide a meaningful and clear public education campaign for Americans, underscoring the dangers of opioid abuse and addiction. There has been a loss of intergenerational knowledge given the fact that people do not understand how

they can get into trouble when abusing prescription opioids. Additionally, Americans need to understand that heroin use is not a safe alternative when they do not have access to prescription opioids. We recommend that the Department of Health and Human Services (HHS), in conjunction with its agencies, work with the White House Office of National Drug Control Policy in developing these clear messages to the American public. This would need to be a sustained campaign, since it took years for the American people to get to the current place of prescription and heroin abuse.

AATOD supports a number of the elements in Congressman Bucshon's legislation, especially in providing guidance to medical practitioners who work under the aegis of the Drug Abuse Treatment Act of 2000. Such practices need to provide greater education to their patients about the available medications to treat their illness.

#### **Recommended Policy Initiatives**

At the present time, 49 states have either enacted or implemented statewide Prescription Drug Monitoring Programs (PDMPs). These programs need to be utilized by physicians in general practice in addition to dentists and substance abuse treatment providers. It is understood that not all of these PDMPs are easy to use and should also be utilized by other clinical/administrative support personnel in a medical practitioner's office. Ultimately, medical practitioners must utilize these databases as a method of treating their patients with a greater margin of safety. Increasing such utilization of PDMPs will help in better treating individuals who are abusing opioids. However, it is part of a solution, not the only solution.

#### **The Use of Medications to Treat Chronic Opioid Addiction**

There are three federally approved medications to treat chronic opioid addiction in the United States: methadone, buprenorphine, and Vivitrol/Naltrexone. It is recommended that all three medications be used in conjunction with other clinical support services, including counseling. Methadone is primarily offered through OTPs, while buprenorphine is primarily offered through DATA 2000 practices. Injectable Naltrexone products may be used in any medical setting including OBOTs and OTPs.

The National Institutes on Drug Abuse (NIDA) has funded numerous studies in support of the use of these medications in treating chronic opioid addiction. There are guidelines for the use of such medications through the Treatment Improvement Protocol series, published by SAMHSA, in addition to recently released guidelines for the use of medications in treating opioid addiction through the American Society of Addiction Medicine. Physicians need to be trained in how such medications are used and when opioid addicted people would benefit from each of the three medications, as stated above.

### **Opioid Overdose Prevention Toolkits**

AATOD agrees with the recommendations of ONDCP and HHS in increasing the utilization of opioid overdose prevention toolkits. We have already seen the benefits of widespread availability through emergency responders and police forces in different cities of the United States. The key recommendation is to ensure that individuals who receive such overdose prevention toolkits get access to emergency room care once they have been revived. The Vermont Hub and Spoke model provides even more support in how such treatment is coordinated once the individual is saved, brought to an emergency room, and then referred to treatment through the available resources.

### **Recommendations to Increase Access to Medication Assisted Treatment for Opioid Addiction**

Congress passed the Drug Abuse Treatment Act of 2000 and subsequently amended it so that physicians who are DATA 2000 waived could treat up to 100 patients per practice. It is understood that a few congressional offices and HHS are considering how to increase access to such care under the aegis of DATA 2000. For the record, our Association has opposed the elimination of this patient limit as proposed by the TREAT Act.

- Before federal agencies and congressional offices proceed with recommendations to increase access to such treatment options, there needs to be a better understanding of what treatment is offered through DATA 2000 practices at the present time.
- If there is going to be any consideration in adjusting this patient number, there should be clear conditions placed on practices that wish to treat a greater number of patients. Illustratively, physicians should be offering counseling services and conducting toxicology profiles on patients to better guide success in treatment.
- Such practitioners also need to be accessing PDMP databases before and during the patient's care.
- The practitioner needs to assess the patient for their clinical needs, which may include counseling and other ancillary support services to treat comorbidities such as infectious diseases (Hepatitis C) or psychiatric comorbidity (depression, anxiety).
- Patient outcomes need to be followed as a method of better understanding the success of such treatment interventions. In this case, physicians need to be able to provide information about the length of time a patient remains in treatment and relapse rates.

### **Increasing Access to the Use of Medications in Opioid Treatment Programs**

At the present time, SAMHSA has certified approximately 1,300 OTPs, which operate in 49 states. Approximately 350,000 patients are treated through these OTPs at any given point in time. AATOD has identified the lack of Medicaid reimbursement for OTP services as a major impediment in 17 states in this country. AATOD has also learned that utilization of such services increases by a factor of 25% when Medicaid reimbursement is available. Accordingly, AATOD is working with a number of policy partners to address this impediment.

If the experience of OTPs provides any guidance to Congress and this Committee in its deliberations, the following illustration provides an important reference. OTPs expanded quickly in the late 1960s without any operating requirements. Congress passed legislation that created a regulatory oversight structure for these OTPs in 1972. The House Select Committee on Narcotics Abuse and Control directed the United States General Accounting Office to develop a report on Methadone Maintenance Treatment. This report was published in March 1990 "Methadone Maintenance – Some Treatment Programs are Not Effective; Greater Federal Oversight Needed". SAMHSA published its first Treatment Improvement Protocol in 1993 "State Methadone Treatment Guidelines" as a method of responding to the recommendations of the GAO report. The FDA asked the Institute of Medicine to evaluate the federal regulation of methadone treatment. The IOM released its findings in 1995, laying the foundation for the FDA to end its oversight of the OTPs and transition the oversight to SAMHSA. This was finalized in 2001. SAMHSA also published more detailed guidelines for OTPs in 2007 and these were revised during March 2015. The point in citing these references is to advise Congress that it took these interventions to improve the quality and practices of OTPs.

#### **Conclusion**

In summary, AATOD is pleased to work with members of Congress on the best methods of increasing access to treatment for opioid addiction and in educating America about the dangers of opioid abuse. This will take a sustained and coordinated effort so that federal policy and legislation need to be based on evidence and what is known to be effective. We have learned a great deal over the past 50 years of the most effective methods of treating opioid addiction. It is clear that our nation got into this problem in major part as a result of the improper and unsupervised prescribing of opioids for pain management. The way out is not to provide a different medication without appropriate supervision and the provision of essential services, which must be used in support of opioid addicted individuals. This explains our opposition to the element of the TREAT Act which completely eliminates the existing 100 patient restriction. Additionally, we are asking Congress to expand access to OTPs through Medicaid and Medicare to remove the existing impediments as stated above. We look forward to working with the House and other members of the legislature as these issues move forward.

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October 7, 2015

The Honorable Charlie Dent  
United States House of Representatives  
2211 Rayburn House Office Building  
Washington, DC 20515

Dear Representative Dent:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our support for your legislation, H.R. 3537, the "Synthetic Drug Control Act of 2015." This bill would close a gap in current law by regulating new synthetic drugs and thereby allowing prosecutors to bring more successful cases against the producers and distributors of these dangerous substances.

Although Congress passed AMA-supported legislation in 2012 that placed 26 synthetic drugs (including K2, Spice, and so-called "bath salts") in Schedule I under the Controlled Substances Act, drug traffickers have devised ways to circumvent federal drug laws by slightly altering the chemical structure of their products and designing new synthetic drugs that mimic the effects of controlled substances. These new products, referred to as "controlled substance analogues," are currently unregulated and are frequently marketed to young people. Since passage of the 2012 legislation, the Drug Enforcement Administration has identified over 250 new synthetic drug compounds in the United States. Under current law, the Federal Analogue Act provides that any chemical "substantially similar" to a controlled substance listed in Schedule I or II of the Controlled Substances Act is to be treated legally as though it were also listed in that schedule. However, it is very difficult to prosecute under the Federal Analogue Act because the courts have maintained a very high bar for the interpretation of "substantially similar."

By amending the Federal Analogue Act to strike "substantially" from the analogue definition and allow for a substance to be treated as an analogue if it is chemically similar or produces a similar effect on the nervous system, your bill would make it easier for law enforcement to pursue the producers and distributors of these dangerous and often deadly substances. We applaud your leadership in introducing this legislation, and look forward to working with you to advance this important bill to protect the public, especially our young people, from the dangers of these synthetic drugs.

S

James L. Madara, MD

October 7, 2015

The Honorable Fred Upton  
Chairman  
House Committee on Energy and Commerce  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Frank Pallone  
Ranking Member  
House Committee on Energy and Commerce  
United States House of Representatives  
Washington, D.C. 20515

Dear Chairman Upton and Ranking Member Pallone:

The Drug Policy Alliance (DPA) appreciates the opportunity to provide this letter for the record of today's hearing, "Examining Legislative Proposals to Combat our Nation's Drug Abuse" and the following bills that are being considered during today's hearing:

- H.R. 3537, the Synthetic Drug Control Act of 2015
- H.R. 2536, the Recovery Enhancement for Addiction Treatment Act
- H.R. 2872, the Opioid Addiction Treatment Modernization Act
- H.R. \_\_\_\_, the Co-Prescribing to Reduce Overdoses Act of 2015
- H.R. \_\_\_\_, the Improving Treatment for Pregnant and Postpartum Women Act of 2015
- H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015
- H.R. 3014, the Medical Controlled Substances Transportation Act of 2015

DPA advocates for new drug policies that are grounded in science, compassion, health and human rights, with a core mission to reduce the harms associated with drug use and drug prohibition. DPA views drug use as a health issue best managed by health and treatment practitioners and supported by policies that expand access to treatment, harm reduction and prevention services. DPA accordingly opposes policies that rely on the criminal justice system to address drug use and we work to eliminate draconian drug sentencing laws that fuel mass incarceration.

#### H.R. 3537 – the Synthetic Drug Control Act of 2015

DPA opposes this legislation. Synthetic drugs have already been harshly criminalized at the federal level through a combination of temporary scheduling as well as passage by Congress of the Synthetic Drug Abuse Prevention Act of 2012. Despite these prohibitions, however, there is no indication that laws criminalizing synthetic compounds have contributed to decreasing the already low rates of use.



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Czech Republic Vaclav Havel  
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### ***Mandatory Sentencing***

H.R. 3537 proposes to permanently place more than 200 synthetic compounds on Schedule I. Doing so will expand the use of federal mandatory sentencing and expand the criminalization of individuals for drug law violations. The legislation would authorize federal prosecutors to seek up to 20 years for individuals convicted of intent to distribute, distribution, importation or manufacturing of certain synthetic drugs. Individuals with certain aggravating circumstances could face a mandatory minimum sentence of 20 years to life imprisonment.

Under this proposal there are no specified quantity thresholds that would trigger mandatory minimum sentences if death or serious bodily injury results from the use of such substance. The person does not have to have the intent to distribute the drug nor the intent to injure or harm the recipient. *Any quantity* of a synthetic drug or chemical compound listed in this legislation could be treated as sufficient cause for the imposition of a mandatory minimum or otherwise lengthy sentence under the Controlled Substances Act. Should this legislation become law, more people would be subjected to a criminal record, subjecting a person to years of debilitating stigma and a large number of destructive collateral consequences including denied job opportunities, and barriers to professional licensing, public assistance, education loans, participation in public elections and other integral ways to be a productive member of society.

Criminalization can also exacerbate health risks from using drugs, by pushing risky behavior underground where people who need help the most are the least likely to get it. “Spice,” “bath salts,” and a slew of new emerging chemicals can be acquired through online retailers, many based in foreign countries – a threat that will not be removed if these products are prohibited in the United States. Moreover, the use of scarce government funds to enforce, prosecute, and incarcerate people who use these substances would put further strain on criminal justice resources. Expanding drug prohibition to include new synthetic drugs will result in significantly more wasteful drug war spending without decreasing rates of distribution or use.

### ***Scientific Research***

DPA is also very concerned about the chilling effect that listing the delineated synthetic compounds under Schedule I could have on research exploring the potential that these new substances might have for medical, scientific or industrial purposes. The additional hurdles that a researcher would need to overcome in order to work with and study the delineated synthetic substances placed on Schedule I by this legislation, combined with the novel nature of these synthetic substances, may mean that certain uses for these substances may go undiscovered. This legislation will subject researchers to burdensome bureaucratic red tape to study the delineated synthetic compounds that does not exist today. Scientists from university research centers have warned Congress in the past that placement of synthetic compounds into Schedule I could impede research exploring treatments for a range of diseases and disorders. Given that little is known about these synthetic substances, and some may not even be present in the United States, it does not make sense to hinder research on the potentially beneficial aspects of these compounds as well as their safety (or danger) for consumption.

### *Analogues*

DPA is very concerned that the proposed revision to the analogue definition will unnecessarily and unfairly ensnare new people in the criminal justice system with no chances of actually decreasing rates of use. Whereas it was previously required that an analogue's chemical structure must be *substantially* similar to a controlled substance *and* actually have a *substantially* similar effect *or* have been intended by the person to have a *substantially* similar effect, H.R. 3537 only requires that one of these three conditions be met and that the chemical structure, effect, or intended effect of the analogue need only be *similar* to a controlled substance. This is a "substantially" lower burden which will unnecessarily and unfairly ensnare new people in the criminal justice system with no chances of actually decreasing rates of use.

As just one example of the myriad problems that could result from requiring only one of the three conditions to be met, there could be an analogue which is *not* chemically similar to a controlled substance and which does *not* produce any stimulant, depressant, or hallucinogenic effect on the central nervous system similar to a controlled substance but which remains criminalized because someone *intended* for the analogue to have that effect. This result flies in the face of common sense, the basic understanding of what "analogue" means, and the purpose of the law. An "analogue" which is not chemically similar to a controlled substance and which does not produce similar effects on the nervous system is not an analogue, but, with this legislation, will be punished as such.

With respect to the removal of the word "substantially," Congress has also removed any ability a person has to understand and determine whether their conduct is lawful or unlawful – a basic attribute and tenant of criminal law. The Court in *McFadden v. United States* recently held that there is a "mental state requirement" to be convicted of distributing an analogue. This knowledge requirement can be established in two ways: 1) by evidence that a defendant knew that the substance he was distributing is controlled under the CSA or Analogue Act, regardless of whether he knew the substance's identity; or 2) by evidence that the defendant knew the specific analogue he was distributing, even if he did not know its legal status as a controlled substance analogue. The current Act is attempting to eviscerate the latter manner of proving knowledge as it no longer requires that the analogue be "substantially" similar in chemical structure and pharmacological effect, rendering the potential defendant clueless as to whether he is, in fact, breaking the law.

### *Recommendation*

DPA recommends that the Committee consider an alternative approach to dealing with synthetic drug use; one that implements a comprehensive drug education program coupled with legislation that commissions a task force to study and determine how best to regulate synthetic substances.

Comprehensive drug education is working for tobacco, a far more harmful drug that has contributed to more deaths than alcohol and illicit drugs combined. As a result of education initiatives and marketing restrictions, tobacco use has declined. Age controls,<sup>1</sup> product-labeling requirements,<sup>2</sup> as well as marketing,<sup>3</sup> branding<sup>4</sup> and retail display<sup>5</sup> restrictions are proven to reduce youth access to tobacco products and

impulse tobacco purchases among adults.<sup>6</sup> These kinds of strategies, combined with prevention and education programs, have resulted in a massive reduction of tobacco use.<sup>7</sup>

Both youth and adults would be better served by education programs to dissuade synthetic drug use, and a proactive effort by Congress and the states to fund studies and evaluations that give the public, lawmakers, and health authorities a better understanding of the health risks of synthetic drugs – as well as a better grasp on how to proactively reduce availability of these products to minors through market regulation.

There are other potential approaches to regulating synthetic drug use other than outright prohibition and criminalization. In July 2013, New Zealand’s parliament enacted a historic new law that created an FDA-like process for approving synthetic drugs if their relative safety can be demonstrated. While the outlines of the law are unique to New Zealand, it is one example of a different approach to a public health issue. Congress should task a commission with evaluating different approaches, including a New Zealand-style model, to the regulation of synthetic drugs and to thereafter make appropriate recommendations to Congress. Finally, demand for synthetic cannabinoids and other new psychoactive substances could drop if people could get legal and regulated access to marijuana. The vast majority of synthetic cannabinoids likely would not exist today if not for the prohibition of marijuana itself.

We urge the Committee to keep in mind our view that concern regarding synthetic drugs has largely driven by sensationalized media reports rather than facts. Indeed, according to the federally funded *Monitoring the Future* survey, use of synthetic cathinones (e.g., “bath salts,” “flakka,” etc.) among teens remains “very low.”<sup>8</sup> A 2015 national study found that only 1.1 percent of high school seniors reported using “bath salts” in the past year.<sup>9</sup> Rates of synthetic cannabinoids (e.g., “K2,” “Spice,” “synthetic marijuana,” etc.) among youth also remains low.<sup>10</sup> Notably, only 0.5% of non-marijuana users reported use of synthetic cannabinoids.<sup>11</sup> Federal arrests for distribution similarly confirm that demand for synthetics is minimal. According to the United States Sentencing Commission, in FY2014, only 4.5% (N=81) of offenders were convicted of distribution of synthetic cannabinoids.<sup>12</sup> These statistics do not support the notion that synthetic drug prevalence has reached the alarming levels depicted in media reports and from law enforcement officials. DPA certainly does not agree with the approach taken in H.R. 3537 to dealing with synthetic drug compounds.

#### **H.R. 2536, the Recovery Enhancement for Addiction Treatment (TREAT) Act**

The Drug Policy Alliance supports this legislation. There is broad consensus among experts that an individual struggling with opioid dependence should have access to the full spectrum of behavioral, pharmacological, and psychosocial treatments. However, nearly 80 percent of people experiencing opioid dependence do not receive treatment because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.<sup>13</sup> Expanding access to drug treatment is a key strategy to reducing demand for opioid analgesics and heroin. Effective treatment modalities should be available to people at all stages of the recovery spectrum.

It is critical that people experiencing dependence to opioid analgesics or heroin can enroll in medication assisted treatment. Scientific research has established that medication assisted treatment increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.<sup>14</sup> Medication assisted treatments are cost effective<sup>15</sup> and have been proven equally effective in treating heroin or prescription-type opioid dependence.<sup>16</sup> Opioid dependent individuals should have access to affordable, judgment-free, individualized counseling and pharmacological replacement therapies such as methadone and buprenorphine. Under medication assisted treatment, doctors prescribe one or more pharmaceutical drugs to people with drug-related problems to eliminate or reduce their problematic use of drugs and improve their mental and physical well-being.

At present, the FDA has approved only three medications for the treatment of opioid dependence.<sup>17</sup> Methadone is one of the most widely studied medicines and is employed effectively around the world to treat opioid dependence. Methadone therapy is widely regarded as the most effective treatment for heroin addiction.<sup>18</sup> Methadone and other medication assisted therapies lead to better health and social outcomes than any other treatment modality.<sup>19</sup> The Centers for Disease Control and Prevention,<sup>20</sup> the Institute of Medicine<sup>21</sup> of the National Institutes of Health,<sup>22</sup> the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services,<sup>23</sup> the National Institute on Drug Abuse (NIDA),<sup>24</sup> the World Health Organization,<sup>25</sup> and over four decades of government-funded, peer-reviewed medical research<sup>26</sup> have unequivocally and repeatedly proven that medication assisted therapies are the most effective treatments for opioid dependence.<sup>27</sup> Yet, extensive federal and state regulations and restrictions stand in the way of providing methadone and buprenorphine treatment services to patients.<sup>28</sup> The Drug Policy Alliance supports expansion of access to buprenorphine and accordingly supports passage of the TREAT Act.

#### **H.R. 2872, the Opioid Addiction Treatment Modernization Act**

DPA opposes this legislation, which we interpret to impose numerous new prerequisites on health practitioners that want to become certified to deliver medication assisted treatment (MAT) and already face numerous hurdles to carry out their duties:

- Annually submit to the HHS Secretary a notification of intent to dispense MAT medications;
- Training every two years for practitioners prescribing and dispensing MAT medications;
- Submit certification that practitioner will provide directly or by referral all drugs approved by the FDA for the treatment of opioid addiction including opioid maintenance, detoxification and overdose reversal and relapse prevention, and counseling and other services;
- Maintain a “diversion control plan”;
- Requires at least eight hours of opiate-dependent patient training at least every two years; and

- Requires practitioners to obtain from patients under their care a signed acknowledgment that the patient will be subjected to medication adherence and monitored among other stipulations.

DPA is concerned that these new requirements could have a chilling effect on the delivery of MAT. Medication assisted treatment is so difficult to obtain as it is, and difficult for physicians to gain certification and practice with so much red tape. These new requirements would be in addition to significant hurdles that health practitioners who want to deliver medication assisted treatment services must currently overcome. Health practitioners who are currently delivering methadone maintenance, for example, already must contend with numerous federal and state laws and regulations that have a stigmatizing chilling effect on the delivery of service and morale of practitioners who provide these services which in turn adversely impacts patients in need. In addition to methadone maintenance, H.R. 2872 seems to put more restrictions on buprenorphine treatment, the opposite direction of where we want to go to incentivize health practitioners to prescribe buprenorphine and patients to have access to it. DPA also questions whether the “Inspection Authority” as proposed is necessary.

**H.R. \_\_\_\_, the Improving Treatment for Pregnant and Postpartum Women Act of 2015**

DPA supports this legislation as we interpret it to enhance treatment capacity for pregnant and postpartum women. Treatment programs often fail to meet the needs of populations that have historically confronted barriers to accessing treatment, such as women, people of color, lesbian, gay, bisexual and transgendered (LGBT) individuals, and rural populations. Women face unique obstacles to recovery, ranging from being the primary caretaker of their children to having been physically, emotionally or sexually abused. Yet, a 2013 U.S. government study found that only 32 percent of treatment facilities in the U.S. have unique programs for women, and only 13 percent have special programs for pregnant or postpartum women.<sup>29</sup> There is a strong need for expanded access to treatment for women, including daycare, transportation and other indirect treatment services that improve the likelihood that women succeed in treatment.

**H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015**

DPA has several concerns about this legislation, as well as specific recommendations for improvement, all of which are outlined as follows.

***Reauthorization of Byrne-JAG Program***

DPA urges the Committee to strike this section from H.R. 2805. DPA opposes the reauthorization of the Byrne-JAG Program. Historically, Byrne Grants have been used primarily to finance drug task forces, which have a record of racially disproportionate low-level drug arrests and increased local and state costs with no measurable impact on public safety.<sup>30</sup> This troubled history led to the near elimination of the program in the mid-2000s. Through task forces, Byrne Grants

bring large numbers of people into the criminal justice system for low-level drug violations, but provide no subsidy for the resulting court proceedings or incarceration costs. In California, for example, it is estimated that every Byrne Grant dollar spent on arrests generates roughly \$10 in new costs to local and state governments – none of which is covered by Byrne Grants.

Task forces typically combine local, state and federal law enforcement officers who, in theory, collaborate to take down large-scale drug dealers and crime organizations and seize large quantities of drugs. In reality, however, there is little oversight of drug task forces, who they arrest and what assets they seize. A 2009 Department of Justice evaluation found that “Not only were data insufficient to estimate what task forces accomplished, data were inadequate to even tell what the task forces did as routine work.”<sup>31</sup> Task forces typically measure their own success in terms of numbers – not types – of arrests.<sup>32</sup> Thus, the programs unintentionally reward low-level arrests, rather than resource-intensive higher-level ones. Task forces may also focus within certain geographies, exacerbating racially disparate drug arrest rates. Although drug task forces routinely tout their “successes,” they have failed to make drugs less available or the public more safe. Similarly, DPA does not accept the logic that reauthorization of Byrne-JAG is pivotal to the elimination of heroin and diverted opioid trafficking.

#### *Expansion of Federal Funding for PDMPs*

DPA urges the Committee to strike this section from H.R. 2805. The Drug Policy Alliance opposes federal funding for prescription drug monitoring programs (PDMPs) designed for use by law enforcement to target patients and prescribing physicians. PDMPs can be a valuable health promotion tool. The use of PDMPs by physicians can enhance their ability to make informed decisions about pain management for patients and prevent overprescribing or medication errors. However, PDMP data should not be available for fishing expeditions by law enforcement. However, most states have passed laws implementing the use of PDMPs as a tool to monitor prescription sales of controlled substances.<sup>33</sup> Law enforcement in many states are given varying levels of authority in each state to monitor PDMPs and launch investigations against health practitioners and patients based upon evidence that, in a law enforcement agency’s view, a physician is writing too many prescriptions for opioid analgesics, or a patient is engaging in “doctor shopping.” Prescribing practices by physicians who specialize in pain management and treat patients with chronic pain are often scrutinized by law enforcement for running “pill mills.” In turn, law enforcement agencies routinely use PDMP sourced data to raid and shut down clinics that treat chronic pain patients and prosecute physicians for “overprescribing” as well as patients for doctor shopping. Yet, evidence is underwhelming that PDMPs have any impact on overdose rates or unsanctioned use of opioid analgesics.<sup>34</sup> In fact, federal survey data indicates that the vast majority of people engaged in unsanctioned use of prescription drugs are not obtaining them from a physician or from engaging in doctor shopping. 53 percent of people who engaged in unsanctioned use of prescription drugs in the past year obtained them for free from friends and family; 15 percent bought or took them from a friend or relative.<sup>35</sup>

Law enforcement agencies should not be empowered to decide when a physician has prescribed too much or a patient is being prescribed too many. Too often the assumption is made that a physician is prescribing too much pain medication, an assumption that is often fostered by law enforcement officials and echoed by lawmakers. Prosecuting prescribers believed to be overprescribing certain medications can lead to stigma against patients using those medications, as well as reduced access to certain medications that physicians may be reluctant to prescribe out of fear of law enforcement investigation.<sup>36</sup> Medical boards and the scientific community should determine what constitutes overprescribing by physicians, and physicians should be permitted to make decisions about pain management for patients. Pain remains one of the most severely undertreated conditions in the U.S. today.<sup>37</sup> As the general population in the United States trends older,<sup>38</sup> and more people are surviving illnesses and undergoing surgical operations, demand for prescription opioid analgesics will likely increase.<sup>39</sup>

Supply-side strategies do not address the underlying behavioral and physical health needs of people experiencing opioid dependence. Tragically, heavy emphasis on supply-side strategies can inadvertently worsen drug misuse in a community if demand-side strategies are not given equal emphasis. Case in point, as law enforcement agencies and lawmakers have stepped up restrictions on opioid analgesic prescribing, evidence suggests that opioid-dependent people who can no longer afford or find diverted medication on the illicit market or a health practitioner willing to prescribe it, are switching to heroin.<sup>40</sup> From a public health and safety standpoint, heroin use is much riskier than unsanctioned opioid medication use.<sup>41</sup> Whereas pharmaceutical opioids generally deliver a reliable and stable dose, people who turn to the illicit market to obtain and use heroin face a greater overdose risk.<sup>42</sup> Evidence indicates that a growing number of individuals who have been using opioid analgesics are substituting heroin, and that dependence on opioid analgesic medications is a strong risk factor for heroin dependence.<sup>43</sup>

#### *Naloxone Demonstration Programs*

Naloxone (Narcan) is a low-cost medication available by prescription and is the first line of treatment for paramedics and emergency room physicians who encounter an opioid overdose victim.<sup>44</sup> Naloxone takes as little as two minutes to start working, and provides additional time to obtain necessary medical assistance during an overdose. Evidence suggest that prompt administration of naloxone and provision of emergency care by a bystander can reduce health complications and attendant health care costs to government and private insurers.<sup>45</sup> DPA supports efforts to expand access to naloxone both inside and outside conventional medical settings. There is an enormous, unmet need for affordable access to lifesaving naloxone in communities hit hard by heroin and opioid misuse. DPA supports legislation that expands access to naloxone into community-based settings, as “**the Co-Prescribing to Reduce Overdoses Act of 2015**,” also before the Committee, proposes to do.

The section of H.R. 2805 authorizing naloxone demonstration programs for first responders is also an important first step to expanding the utilization of naloxone to combat opioid overdoses. However, we urge the Committee to expand the definition of “first responder” to ensure that properly trained individuals prescribed naloxone and trained on its use by a government or community agency are also eligible for

participation in these demonstration programs. Often, the true first responders to an overdose are friends, family members and other bystanders equipped with naloxone and trained in its use by a government or community agency. In these scenarios, trained bystanders at the scene of an overdose are often best positioned to reverse the opioid overdose and stabilize the victim until paramedics arrive. Every second counts in a life threatening opioid overdose situation. First responders can be many miles away from the scene of an overdose, especially in rural areas.

Government and community agencies that equip citizens with naloxone, train on its proper use and provide linkages to treatment and other services deserve to be included as eligible recipients of demonstration program funds under this section. A recent CDC report credits these overdose prevention services provided by government and community agencies with training more than 150,000 potential bystanders who successfully reversed more than 26,000 overdoses using naloxone.<sup>46</sup> The administration of naloxone at the scene of an overdose by a citizen properly trained in its use deserves to be studied and evaluated, as they would through participation in these demonstration grants, as an effective way to prevent opioid overdose fatalities – especially in situations where first responders are not summoned to the scene or are many minutes away from being able to intervene.

#### ***“Drug-Free” Media Campaign***

The Drug Policy Alliance is concerned about the proposed “Drug-Free Media Campaign” in this bill. The proposed media campaign would be established by ONDCP in coordination with the HHS Secretary and the Attorney General. ONDCP is the wrong government agency to administer a drug awareness media campaign. The last time ONDCP managed a drug awareness media campaign, studies showed that its over-the-top ads designed to deter young people from using marijuana actually had the opposite effect. Evaluations of ONDCP’s media campaigns were so abysmal that Congress eliminated funding for the program – citing their ineffectiveness and waste of tax dollars.

ONDCP has a long track record of ignoring scientific evidence and best practices when it comes to how to communicate to young people and the general public about the health effects of drug use. After all, ONDCP has traditionally served as a political and policy making office, not a hub for scientific evaluation or strict application of science in its drug policies. Accordingly, ONDCP is poorly equipped to develop objective public awareness messaging for the media.

The public deserves accurate, honest information about the health risks of heroin and opioid misuse, including tips on how to reduce health related harm from its use and an effective, objective, science-based drug awareness campaign. DPA urges the Committee to transfer ownership of this media campaign to the Secretary of Health and Human Services. The media campaign should not be framed as a “drug-free” campaign or referred to it as such. Messaging espousing the myth of a “drug-free America” turns off many young people and others who should otherwise hear the campaign’s important health messages. Most importantly, the Committee should specify that the substance of the media campaign be grounded in the latest available scientific evidence and public health research.

**H.R. 3014, the Medical Controlled Substances Transportation Act of 2015**

Currently prescriptions for controlled substances must be written from locations that are registered in advance with the DEA, and can only be stored and dispensed from locations where prior authority has been granted. Thus, transportation by a physician to an unregistered location causes physicians to be in technical violation of federal law.

The Drug Policy Alliance supports the intention of the legislation to provide statutory relief to health practitioners who wish to transport controlled substances. However, we are concerned that the proposed 72 hour limit provided to transport controlled substances and the reporting requirements could ensnare health practitioners in legal troubles. We are concerned about the requirement for physicians to notify DEA before transporting substances and that the DEA may not have the proper mechanisms and oversight in place to properly record registrations that in turn could place physicians in legal jeopardy because of bureaucratic errors. We are also concerned that physicians could get into legal trouble for circumstances – including emergency circumstances - that result in the transportation of medications beyond the 72 hour transportation limit. DPA recommends that the timeframe be eliminated or extended significantly and that the legislation account for emergency circumstances.

**Conclusion**

The Drug Policy Alliance urges the Committee to confront drug use as a health issue, rather than a criminal justice issue and develop policies and programs accordingly. The federal government has spent billions of dollars on counterproductive supply-side strategies. Laws criminalizing synthetic compounds will only further exacerbate harms of failed drug policies and may impede scientific research. The Committee should prioritize the elimination of federal roadblocks to accessible and affordable medication assisted treatment and facilitate the expansion of policy and programmatic solutions that address core issues that drive substance use.

Thank you for considering our views.

Respectfully Submitted,



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Drug Policy Alliance

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<sup>1</sup> Federal law prohibits the sale of tobacco to anyone under 18. 21 C.F.R. § 1140.14 2009. (setting this standard and mandating age confirmation with a photo ID). Some states have raised their own minimum

age to 19 or even 21. Hawaii Revised Statutes § 709-908 (banning the sale of tobacco in Hawaii to anyone under 21 effective in 2016).

<sup>2</sup> Since 1970, health warnings have been mandated on cigarette packages. These requirements, which were strengthened by Congress in 1984 and in 2009, require the conspicuous placement of such phrases as “Cigarettes cause cancer,” “Smoking can kill you,” and “Tobacco smoke can harm your children” as well as images depicting the harm caused by cigarette smoking. Public Health Cigarette Smoking Act, U.S. Code 15 (1969), § 1333(a) (listing the complete labeling requirements).

<sup>3</sup> Cigarette advertising has been banned on radio and television since 1971. Public Health Cigarette Smoking Act, U.S. Code (1969), § 1335 (making such advertisements unlawful “on any medium of electronic communication subject to the jurisdiction” of the FCC). Cigarette advertisements in lawful mediums such as magazines must contain the same type of warning labels required on cigarette packaging. Federal Cigarette Labeling and Advertising Act, U.S. Code 15 (1965), § 1333(b) (listing the warning label requirements for advertisements).

<sup>4</sup> Legislation in 2009 restricted the ability of tobacco companies to label products as “light,” “mild,” or “low” to limited circumstances. Family Smoking Prevention and Tobacco Control Act, U.S. Code 21(2009), § 387(k) (denying the ability to use these and similar adjectives without prior approval from the FDA).

<sup>5</sup> While there are no direct federal regulations of retail displays, states have passed their own regulations. New York Public Health Law §1399-cc(7) (mandating that tobacco products be placed behind the counter of a store or within a locked case).

<sup>6</sup> Janine Paynter, “Point of Sale Tobacco Displays and Smoking among 14-15 Year Olds In New Zealand,” *Tobacco Control* 18(4): 268 (2009) (presenting the results of a cross-sectional study which concludes that display restrictions for tobacco products reduce use rate among teens); M. O’Hegarty et al., “Reactions of Young Adult Smokers to Warning Labels on Cigarette Packages,” *American Journal of Preventative Medicine* 30(6): 467 (2006) (showing that smokers report that conspicuous warning labels reduce smoking and increase a desire to quit); Ron Borland, “Tobacco Health Warnings and Smoking-Related Cognitions and Behaviors,” *Addiction* 92(11): 1435 (1997) (concluding that health warnings on cigarette packages are effective at reducing cigarette smoking).

<sup>7</sup> When warning labels were first mandated on cigarette packaging in 1965, the national rate of smoking among adults was 42.4%. Today, that rate has fallen to 19%. Use rates among youth have fallen over this period as well. “Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965-2011,” CDC, last modified Nov. 14, 2013) [http://www.cdc.gov/tobacco/data\\_statistics/tables/trends/cig\\_smoking/](http://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/).

<sup>8</sup> D. Johnston et al., *Monitoring the Future, national survey results on drug use, 1975–2012: Volume I, Secondary school students* (Ann Arbor: Institute for Social Research, The University of Michigan, 2013).

<sup>9</sup> Joseph J. Palamar, “Bath salt use among a nationally representative sample of high school seniors in the United States,” *The American Journal on Addictions* (2015).

<sup>10</sup> Joseph J. Palamar and Patricia Acosta, “Synthetic cannabinoid use in a nationally representative sample of US high school seniors,” *Drug and Alcohol Dependence* 149(2015); Johnston et al., *Monitoring the Future* (2015).

<sup>11</sup> *Id.*

<sup>12</sup> United States Sentencing Commission, 2014 Sourcebook of Federal Sentencing Statistics, Drug Cases, Figure K. <http://www.ussc.gov/sites/default/files/pdf/research-and-publications/annual-reports-and-sourcebooks/2014/FigureK.pdf>

<sup>13</sup> C.L. Arfken, et al., “Expanding Treatment Capacity for Opioid Dependence with Buprenorphine: National Surveys of Physicians,” *Journal of Substance Abuse Treatment* 96, 39 (2010).

<sup>14</sup> National Institute on Drug Abuse, “Medication-Assisted Treatment for Opioid Addiction,” NIDA Topics in Brief (April 2012), [https://www.drugabuse.gov/sites/default/files/tib\\_mat\\_opioid.pdf](https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf).

<sup>15</sup> The American Society of Addiction Medications, “Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment, Part II: Economic Evaluation of Pharmacotherapies for the Treatment of Opioid Disorders;” (Chevy Chase, MD, ASAM: 2013), 8, 65- 91, [http://www.asam.org/docs/default-source/advocacy/aaam\\_implications-for-opioid-addiction-treatment\\_final](http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final); M. Connock, et al., “Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation,” *Health Technology Assessment* 11, 9 (2007): 1-192.

<sup>16</sup> C. Banta-Green, et al., “Retention in Methadone Maintenance Drug Treatment for Prescription-Type Opioid Primary Users Compared to Heroin Users,” *Addiction* 104 (2009): 775-783.

<sup>17</sup> Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid dependence for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both Federal and state regulation. Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced

synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid dependence. Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol™. See: American Society of Addiction Medicine, *Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment* (2013), [http://www.asam.org/docs/default-source/advocacy/aaam\\_implications-for-opioidaddiction-treatment\\_final](http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioidaddiction-treatment_final)

<sup>18</sup> The National Institutes of Health has explicitly recognized methadone is the most successful treatment to date for opioid dependence, and recommended a reduction in the unnecessary regulation of methadone maintenance therapy and other medication assisted treatment programs. National Institutes of Health, "Effective Medical Treatment of Opiate Addiction," NIH Consensus Statement 15, 6 (1997), 4, <http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf>; and National Institute on Drug Abuse (NIDA) "Research Report: Heroin Abuse and Addiction," (Revised 2005), <http://www.drugabuse.gov/ResearchReports/heroin/heroin.html>; and National Institute on Drug Abuse, "Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research-Based Guide," (National Institutes of Health, 2006), 5, 22, [https://www.drugabuse.gov/sites/default/files/txcriminaljustice\\_0.pdf](https://www.drugabuse.gov/sites/default/files/txcriminaljustice_0.pdf); and D.A. Fiellin, et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial," *JAMA* 286 (2001):1764-1765; and J.C. Ball and A. Ross, *The Effectiveness of Methadone Maintenance Treatment* (New York: Springer-Verlag, 1991); and Y.I. Hser, et al., "A 33-Year Follow-Up of Narcotics Addicts," *Archives of General Psychiatry* 58 (2001): 503-508; and J. Ward, W. Hal, and R.P. Mattick, "Role of Maintenance Treatment in Opioid Dependence," *The Lancet* 353 (1999): 221-226; and D.M. Novick and H. Joseph, "Medical Maintenance: The Treatment of Chronic Opiate Dependence in General Medical Practice," *Journal of Substance Abuse Treatment* 8 (1991): 233-239; and Centers for Disease Control and Prevention, "Methadone Maintenance Treatment," February 2002, accessed June 4, 2015, <http://www.cdc.gov/idu/facts/Methadone.htm>; and M. Connock, et al., "Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation," *Health Technology Assessment* 11, 9 (2007); Center for Substance Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (Tip) Series 43* (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005); World Health Organization, *Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention* (United Nations Office on Drugs and Crime, 2004), [http://www.unodc.org/docs/treatment/Brochure\\_E.pdf](http://www.unodc.org/docs/treatment/Brochure_E.pdf); and R.P. Mattick, et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence," *Cochrane Database System Review*, 3 (2009).

<sup>19</sup> N.D. Volkow, et al., "Medication-Assisted Therapies —Tackling the Opioid-Overdose Epidemic," *New England Journal of Medicine* 370, 22 (2014): 63; and R.P. Mattick, et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy For Opioid Dependence," *Cochrane Database System Review* 3 (2009).

<sup>20</sup> Centers for Disease Control and Prevention, "Methadone Maintenance Treatment," February 2002, <http://www.cdc.gov/idu/facts/MethadoneFin.pdf>.

<sup>21</sup> R.A. Rettig and A. Yarmolinsky, eds., *Federal Regulation of Methadone Treatment* (Washington, D.C.: National Academy Press, 1995), [http://www.nap.edu/catalog.php?record\\_id=4899](http://www.nap.edu/catalog.php?record_id=4899).

<sup>22</sup> National Institutes of Health, "Effective Medical Treatment of Opiate Addiction," NIH Consensus Statement 15, 6 (1997), 4, <http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf>.

<sup>23</sup> Center for Substance Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005), [http://buprenorphine.samhsa.gov/tip43\\_curriculum.pdf](http://buprenorphine.samhsa.gov/tip43_curriculum.pdf).

<sup>24</sup> National Institute on Drug Abuse, "Research Report: Heroin Abuse and Addiction," Revised 2005, accessed June 4, 2015, <http://www.drugabuse.gov/ResearchReports/heroin/heroin.html>; NIDA International Program. *Methadone Research Web Guide* (Bethesda, National Institute on Drug Abuse: 2007); and National Institute on Drug Abuse, "Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research-Based Guide," (National Institutes of Health, 2006), 5, 22, [https://www.drugabuse.gov/sites/default/files/txcriminaljustice\\_0.pdf](https://www.drugabuse.gov/sites/default/files/txcriminaljustice_0.pdf).

<sup>25</sup> World Health Organization, *Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention* (United Nations Office on Drugs and Crime, 2004), [http://www.unodc.org/docs/treatment/Brochure\\_E.pdf](http://www.unodc.org/docs/treatment/Brochure_E.pdf).

<sup>26</sup> D.A. Fiellin, et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial." *JAMA* 286 (2001):1764-1765; and J.C. Ball and A. Ross, *The Effectiveness of Methadone Maintenance Treatment* (New York: Springer-Verlag, 1991); and Y.I. Hser, et al., "A 33-year follow-up of narcotics addicts." *Archives of General Psychiatry* 58 (2001): 503 508; and J. Ward, W. Hal, and R.P. Mattick, "Role of Maintenance Treatment in Opioid Dependence," *The Lancet* 353 (1999): 221-226; and D.M.

Novick and H. Joseph, "Medical Maintenance: The Treatment of Chronic Opiate Dependence in General Medical Practice," *Journal of Substance Abuse Treatment* 8 (1991): 233-239.

<sup>27</sup> Centers for Disease Control and Prevention, "Methadone Maintenance Treatment," 2002, accessed June 4, 2015, <http://www.cdc.gov/od/oc/substance/Methadone.htm>; National Institutes of Health, Effective Medical Treatment of Opiate Addiction, NIH Consensus Statement 15 (1997); Center for Substance Abuse Treatment, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP) Series 43, DHHS (SMA) 05-4048, (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005); World Health Organization (WHO), Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention: Position Paper, (Geneva, Switzerland, World Health Organization, United Nations Office on Drugs and Crime, UNAIDS, 2004), [http://www.unodc.org/docs/treatment/Brochure\\_E.pdf](http://www.unodc.org/docs/treatment/Brochure_E.pdf); DA Fiellin, M O'Connor, M Chawarski, et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial," *Journal of the American Medical Association* 286 (2001):1764-1765; JC Ball and A. Ross, "The Effectiveness of Methadone Maintenance Treatment," New York: Springer-Verlag (1991); Hser Y-I, V. Hoffman, C.E. Grella, M.D. Anglin, "A 33-year Follow-up of Narcotics addicts," *Archives of General Psychiatry* 58 (2001): 503-508; Jeff Ward, Wayne Hall, Richard P Mattick, "Role of Maintenance Treatment in Opioid Dependence," *Lancet* 353 (1999): 221-226; DM Novick, and H. Joseph. "Medical Maintenance: The Treatment of Chronic Opiate Dependence in General Medical Practice," *Journal of Substance Abuse Treatment* 8 (1991): 233-239.; For more information, see Drug Policy Alliance, About Methadone and Buprenorphine: Revised Second Edition (New York: Drug Policy Alliance, 2006), <http://www.drugpolicy.org/docUploads/aboutmethadone.pdf>.

<sup>28</sup> Although federal law prohibits methadone from being prescribed in an office-based setting, federal law allows physicians to become eligible to prescribe buprenorphine (Suboxone™) for the treatment of opioid dependence. Physicians that meet certain qualifications can become eligible to apply for a special waiver which allows them to treat opioid dependence with buprenorphine in an office-based setting. However federal law arbitrarily caps the number of opioid patients a physician can treat with buprenorphine at any one time to 30 through the first year following certification, expandable to 100 patients thereafter. Evidence also suggests that particular patients, namely low income, non-white patients, are less likely to access buprenorphine than more affluent white patients. See: Drug Addiction Treatment Act of 2000, Public Law 106-310.; H.B. Hansen, et al., "Variation in Use of Buprenorphine and Methadone Treatment by Racial, Ethnic, and Income Characteristics of Residential Social Areas in New York City," *Journal of Behavioral Health Services & Research* 40, 3 (2013): 367-77; and H.K. Knudsen, et al., "Early Adoption of Buprenorphine in Substance Abuse Treatment Centers: Data from the Private and Public Sectors," *Journal of Substance Abuse Treatment* 30, 4 (2006): 363-73; and A. Stanton, et al., "Expanding Treatment of Opioid Dependence: Initial Physician and Patient Experiences with the Adoption of Buprenorphine," American Society of Addiction Medicine presentation (March 2006), [http://www.buprenorphine.samhsa.gov/ASAM\\_06\\_Final\\_Results.pdf](http://www.buprenorphine.samhsa.gov/ASAM_06_Final_Results.pdf); and J.D. Baxter, et al., "Factors Associated with Medicaid Patients' Access to Buprenorphine Treatment," *Journal of Substance Abuse Treatment* 41, 1 (2011):88-96.

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<sup>32</sup> California Emergency Management Agency, 2009 Annual/Ongoing JAG Allocation Plan, Program Summaries. Ettner et al., "Benefit-Cost in the California Treatment Outcome Project."

<sup>33</sup> <http://www.astho.org/Programs/Prevention/Injury-and-ViolencePrevention/Materials/Prescription-Drug-Overdose/>; Katherine Addleman, "Undertreated pain festers in our anti-opiate culture," *National Review of Medicine* 1 (30 August 2004); Maia Szalavitz, "Report: Chronic, Undertreated Pain Affects 116 Million Americans," *Time*, June 29, 2011, <http://healthland.time.com/2011/06/29/report-chronic-undertreated-pain-affects-116-million-americans/>; Human Rights Watch, Global State of Pain Treatment: Access to Medicines and Palliative Care (New York, NY: HRW, 2011) 5-10, 16-17, <http://www.hrw.org/sites/default/files/reports/hhr0511W.pdf>; NB King, V Fraser, "Untreated Pain, Narcotics Regulation, and Global Health Ideologies," *PLoS Medicine* 10.4 (2013), <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001411>; Institute of Medicine, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, (Washington, DC: National Academies Press, 2011), [http://img.medscape.com/pi/features/pain/IOM\\_RelievingPainAmerica\\_June2011pdf.pdf](http://img.medscape.com/pi/features/pain/IOM_RelievingPainAmerica_June2011pdf.pdf); US Census Bureau, The Next Four Decades: The Older Population in the United States: 2010 to 2050, Population Estimates and Predictions, (Washington DC: US Census Bureau, 2011), 1-16.; Institute of Medicine of

the National Academies, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (Washington D.C., The National Academies Press, 2011), 8, 62-64, 81.

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<sup>35</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2013 National Survey on Drug Use and Health: Summary of National Findings, (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014), 31-32, <http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHHTML2013/Web/NSDUHresults2013.htm>.

<sup>36</sup> Lisa N Sacco, Erin Bagalman and Kristin Finklea, Prescription Drug Monitoring Programs, (Washington: Congressional Research Service, 2014), 1-23, <http://www.fas.org/spp/crs/misc/R42593.pdf>.

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<sup>38</sup> US Census Bureau, *The Next Four Decades: The Older Population in the United States: 2010 to 2050, Population Estimates and Predictions*, (Washington DC: US Census Bureau, 2011), 1-16.

<sup>39</sup> Institute of Medicine of the National Academies, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (Washington D.C., The National Academies Press, 2011), 8, 62-64, 81.

<sup>40</sup> Holly Hedegaard, Li-Hui Chen, Margaret Warner, “Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012,” (Hyattsville, MD: Centers for Disease Control and Prevention, 2014), 1-5; Michelle Peavy et al., “‘‘Hooked on’’ Prescription-Type Opiates Prior to Using Heroin: Results from a Survey of Syringe Exchange Clients,” *Journal of Psychoactive Drugs* 44, no. 3 (2012); R. A. Pollini et al., “Problematic Use of Prescription-Type Opioids Prior to Heroin Use among Young Heroin Injectors,” *Substance Abuse Rehabilitation* 2. 1 (2011); A. Goodnough & K Zezima, “Drug is Harder to Abuse, but Users Persevere,” *New York Times*, June 15, 2011, <http://www.nytimes.com/2011/06/16/health/16oxy.html>; George Jay Unick, Daniel Rosenblum, Sarah Mars, Daniel Ciccarone, “Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin- and Opioid-related Overdoses, 1993-2009,” *Plos One* (2013), doi: 10.1371/journal.pone.0054496; Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, “Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States,” *Substance Abuse and Mental Health Services Administration*, (Rockville, MD, Center for Behavioral Health Statistics and Quality, 2013), 1-17, <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>; Theodore J. Cicero, Matthew S. Ellis, and Hilary L. Surratt, “Effect of Abuse-Deterrent Formulation of Oxycontin,” *New England Journal of Medicine* 367. 2 (2012): 187-189; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2003*, (Washington DC: DOJ, 2003), 1-3, <http://www.justice.gov/archive/ndic/pubs3/3300/pharm.htm>; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, (Washington DC: DOJ, 2011): 37, <http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf>.

<sup>41</sup> Heroin is more potent, readily available, and a cheaper alternative to prescription opioids. Today, a dose of high-grade heroin is available for about the price of a six-pack of beer. See: Theodore J. Cicero, Matthew S. Ellis, Hilary L. Surratt, SP Kurtz, “The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years,” *JAMA Psychiatry* 71 (2014):821-826.; United Nations Office on Drugs and Crime, *World Drug Report 2014*, (New York: UN, 2014), 30, [http://www.unodc.org/documents/wdr2014/World\\_Drug\\_Report\\_2014\\_web.pdf](http://www.unodc.org/documents/wdr2014/World_Drug_Report_2014_web.pdf) (assuming purchase in the US of an IV dose of 10 mg – would be between \$3-5 on average in US).

<sup>42</sup> Factors that contribute to a greater overdose risk include taking new batches of street heroin, buying from a new source selling a stronger drug, or from the presence of adulterants that increase the potency of heroin. See: A Weil, *From Chocolate to Morphine*, (New York: Houghton Mifflin Company, 1998), 161-163.; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, "Nonpharmaceutical Fentanyl-Related Deaths – Multiple States, April 2005–March 2007" *Morbidity and Mortality Weekly Report* 57.29 (July 2008): 793-796, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm>.; Substance Abuse and Mental Health Services Administration (SAMHSA), "Advisory to Treatment Community on The Danger of Heroin Contaminated with Fentanyl and What Can be Done to Save Lives," February 07, 2014, <http://www.samhsa.gov/newsroom/press-announcements/201402071000>; Don Sapatkin, "Deadly drug mix: Fentanyl Makes a Comeback," *Philly.com*, August 24, 2014, [http://articles.philly.com/2014-08-24/news/53143422\\_1\\_illicit-fentanyl-overdoses-heroin](http://articles.philly.com/2014-08-24/news/53143422_1_illicit-fentanyl-overdoses-heroin).; Coffin, P.O., S. Galea, J. Ahern, A.C. Leon, D. Vlahov, and K. Tardiff, "Opiates, Cocaine and Alcohol Combinations in Accidental Drug Overdose Deaths in New York City, 1990-98." *Addiction* 98 (2003): 739-47.

<sup>43</sup> Evidence suggests that the switch from using opioid analgesics to using heroin is particularly prevalent for individuals who are using opioid analgesics without a prescription. However, available evidence does not support the notion that individuals who use opioid analgesics will progress to using heroin for the purpose of experiencing a more potent drug alone. See: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Demographic and Substance Use Trends Among Heroin Users — United States, 2002–2013," *Morbidity and Mortality Weekly Report*, 64(26) (2015): 719-725,

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?\\_s\\_cid=mm6426a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?_s_cid=mm6426a3_w); NIDA Report Series, "Heroin," NIH publication number 15-0165, 3 (November 2014, rev.); TJ Cicero, MS Ellis, HL Surratt, "Effect of Abuse-deterrent Formulation of OxyContin," *New England Journal Medicine* 367.2 (2012):187–189; National Institute on Drug Abuse, *Epidemiologic Trends in Drug Abuse*, in *Proceedings of the Community Epidemiology Work Group*, (Bethesda, MD: NIDA, 2012); Amy Pavuk, "Rx for Danger: Oxycodone Crackdown Drives Addicts to Other Drugs," *Orlando Sentinel*, July 28, 2012, [http://articles.orlandosentinel.com/2012-07-28/health/oxycodonedrug-shift-dilaudid-20120728\\_1\\_oxycodone-prescription-drugs-dilaudid-pills](http://articles.orlandosentinel.com/2012-07-28/health/oxycodonedrug-shift-dilaudid-20120728_1_oxycodone-prescription-drugs-dilaudid-pills).; Theodore J. Cicero, Matthew S. Ellis, Hilary L. Surratt, Steven P. Kurtz, "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 years," *JAMA Psychiatry* 71 (2014): 821-6.)

<sup>44</sup> Naloxone is an opioid antagonist that blocks the brain cell receptors activated by heroin and other opioids, temporarily restoring normal breathing within two to three minutes of administration. First approved by the FDA in 1971, naloxone is effective at reversing opioid overdoses precipitated by the use of heroin, oxycodone (OxyContin™), hydrocodone (Vicodin™), percocet, methadone, fentanyl and other opioids. Naloxone's only effects are to reverse respiratory failure resulting from an opioid overdose and to cause uncomfortable withdrawal symptoms in the dependent user. It has no pharmacological effect if administered to a person who has not taken opioids and has no potential for abuse. It is impossible to overdose on naloxone. See: United Nations Office on Drugs and Crime, *Opioid Overdose: Preventing And Reducing Opioid Overdose Mortality*, (New York: United Nations, 2013), 7, <https://www.unodc.org/docs/treatment/overdose.pdf>.

<sup>45</sup> Phillip O. Coffin and Sean D. Sullivan, "Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal," *Annals of Internal Medicine* 158, (2013), 1057.

<sup>46</sup> See U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014," *Morbidity and Mortality Weekly Report* 64(23); (2012), 631-635.

**Congress of the United States**  
**Washington, DC 20515**

October 7, 2015

The Honorable Sylvia Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, D.C. 20201

Dear Secretary Burwell,

As you know, there is a rapidly growing opioid abuse epidemic in our nation and the need for comprehensive treatment has never been greater. Data from SAMHSA's 2013 National Survey on Drug Use and Health shows that 1.9 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines in 2013 and 517,000 suffered from a heroin use disorder. The number of unintentional overdose deaths from prescription opioids has soared in recent years, more than quadrupling since 1999.

Despite the increasingly high rate of opioid abuse and significant need for treatment, existing evidence-based comprehensive treatment strategies that move people from opioid maintenance and into full recovery are highly underutilized. Some have called for relaxing federal law to allow physicians in *Drug Addiction Treatment Act of 2000* (DATA 2000) practices, which are not required to use or offer comprehensive services, to increase the number of patients they see as a means to increase access to opioid addiction treatment. However, we know very little about the DATA 2000 waived practices, how many patients are in them, what treatment services they receive, how long they stay in treatment, and how often they use illicit opioids or divert the buprenorphine that is prescribed to them. Moreover, an HHS study which appeared in the *American Journal of Public Health* found that nationally only half DATA-waived physicians are listed on the buprenorphine treatment locator. This suggests that DATA 2000 physicians who can see more patients are not actively seeking to do so.

The evidence makes clear that prescription drugs alone is not the answer. Prescription drugs help to stabilize the patient, but they do not sufficiently ensure treatment effectiveness and success. If you are considering increasing the DATA 2000 patient limit, we strongly encourage you to better study and understand the quality and effectiveness of the treatment these practices provide. As such, we ask that you measure:

- The number of patients in treatment within each DATA 2000 practice relative to its cap;
- The percentage of practices providing counseling on-site and the corresponding number of patients in each practice who utilize those services;
- The percentage of physicians referring patients for counseling off-site and the corresponding number of patients in each practice who utilize those services;
- The percentage of practices providing toxicology testing to guide therapeutic dosing and decision making;
- The percentage of toxicology tests for illicit opioids that are positive;
- The percentage of other illicit drug use in DATA 2000 practices;

The Honorable Sylvia Burwell  
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 Page 2

- The percentage of patients in DATA 2000 practices that are divert their buprenorphine (for resale or other illicit use). The dropout rates in DATA 2000 practices. What percent of DATA-waivered practices;
- The relapse rate after drop out of DATA 2000 practices;
- The extent to which DATA 2000 practices successfully wean patients off of buprenorphine and on to opioid antagonist medication and relapse prevention counseling;
- What percentage of patients are enrolled in multiple DATA 2000 practices (that is, filling prescriptions from multiple practices);
- What percentage of patients are taking their prescriptions for buprenorphine to multiple pharmacies, and
- The dosing regimens for buprenorphine in DATA 2000 practices, and its association with buprenorphine diversion.

Further, to ensure that patients seeking care at DATA 2000 practices receive the type of care that has proven to be most-effective; we ask that you adopt the following MAT-based reforms at these practices:

- Inform patients of their treatment options and the availability of non-addictive FDA-approved treatments and counseling;
- Review all FDA-approved treatments options, and obtain informed consent to treatment selected;
- Report to HHS on patient length of treatment stay, dropout rates, and drug use in past 30 days prior to discharge;
- Report on the average buprenorphine prescription length (e.g., one week, 30 days, etc.);
- Conduct a minimum amount of counseling per patient, per month;
- Employ prescription drug diversion control strategies;
- Perform drug testing to make sure patients are taking their prescribed medications, are not using illicit drugs, and to guide treatment decisions (e.g., increase or decrease intensity);
- Use Prescription Drug Monitoring Programs to ensure patients are not getting opiates elsewhere;
- Provide each patient with a comprehensive ASAM Patient Placement Assessment;
- Develop individualized treatment plans based on their assessment, including relapse and overdose prevention;
- Monitor the patient's response to treatment, using toxicology tests and patient self-report, and make changes to the patient's treatment plan, when indicated by lack of treatment response, treatment failure, or the patient's desire to become opioid-free;
- Implement an active medication diversion control plan, including medication checks.

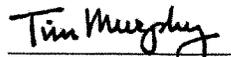
We do not believe that simply allowing DATA 2000 physicians the ability, whether acted upon or not, to prescribe more opiates to patients by increasing the patient cap is a solution. Doing so runs the risk of allowing more physicians to prescribe more opioids, without providing patients with the comprehensive and coordinated care necessary for effective treatment as described by HHS' own treatment guidelines in TIP 40. We agree strongly that there is a need for more quality treatment, which includes a full range of treatment options, including support for becoming opioid-free with the help of detoxification and relapse prevention medication assisted treatment. Only by safely reducing

The Honorable Sylvia Burwell  
October 7, 2015  
Page 3

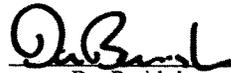
the number of people who are using opioids inappropriately will we reverse the current epidemic. We further ask that you work closely with the Congress before any action is taken in this area.

Thank you for your consideration.

Sincerely,

  
Tim Murphy  
Member of Congress

  
Lou Barletta  
Member of Congress

  
Dan Benishek  
Member of Congress

  
Steve Chabot  
Member of Congress

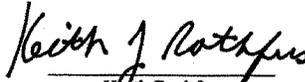
  
Daniel M. Donovan Jr.  
Member of Congress

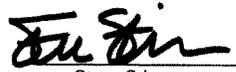
  
Frank C. Guinta  
Member of Congress

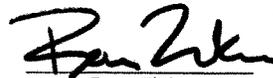
  
Richard Hanna  
Member of Congress

  
Richard Hudson  
Member of Congress

  
David B. McKinley  
Member of Congress

  
Keith Rothfus  
Member of Congress

  
Steve Stivers  
Member of Congress

  
Ryan Zinke  
Member of Congress

The Honorable Sylvia Burwell  
October 7, 2015  
Page 4

A handwritten signature in black ink, reading "Cathy McMorris Rodgers". The signature is written in a cursive style with a large initial "C" and a long, sweeping underline.

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Cathy McMorris Rodgers  
Member of Congress

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2027  
Minority (202) 225-3641

November 24, 2015

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

Dear Mr. Botticelli:

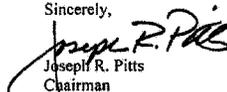
Thank you for appearing before the Subcommittee on Health on October 8, 2015, to testify at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis."

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.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 8, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [graham.pittman@mail.house.gov](mailto:graham.pittman@mail.house.gov).

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

Sincerely,

  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
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2125 RAYBURN HOUSE OFFICE BUILDING  
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Majority (202) 225-2927  
Minority (202) 225-3641

November 24, 2015

Dr. Richard Frank  
Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Dr. Frank:

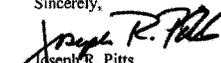
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

**Dr. Richard Frank**  
**Assistant Secretary for Planning and Evaluation**  
**U.S. Department of Health and Human Services**  
**"Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis"**  
**Committee on Energy and Commerce, Subcommittee on Health**  
**U.S. House of Representatives**  
**October 8, 2015**

Attachment — Additional Questions for the Record

The Honorable Representative Joseph R. Pitts

**1. Dr. Frank, a number of questions at the hearing focused on the Department's announcement related to the current DATA 2000 patient caps.**

- a. Can you please explain the factors that will be considered in determining how to raise these caps while limiting the potential for diversion?**

**Response:** Rulemaking related to DATA 2000 is one piece of the Department's strategy to expand access to medication-assisted treatment (MAT) for the treatment of opioid use disorder, and we are considering several options to help achieve this goal. Medicines containing buprenorphine that can be administered in office based settings as part of MAT have the potential to reach more patients than methadone, which can only be delivered by a certified, accredited opioid treatment program (OTP). We are therefore looking at factors related to the delivery of high-quality MAT and those that are consistent with the lowest risk of diversion.

- b. How will differences in various settings at which buprenorphine can be prescribed and/or administered be considered? Are you considering expanding the type of settings at which buprenorphine can be prescribed and/or administered? If so, how?**

**Response:** Buprenorphine can currently be prescribed in primary care and other office based settings once a physician receives a DATA 2000 waiver. In the first year, physicians can treat up to 30 patients. After the first year, physicians can request approval to prescribe to up to 100 patients. All considerations, including different treatment settings, are being examined according to their impacts on access to treatment, quality of care, and the risks of diversion. This includes all elements of evidence-based MAT.

- c. How will differences in certain types of patients or products be considered when determining whether and how to change the current limitations?**

**Response:** All considerations, including certain patient types or products, are being examined according to their impacts on access to treatment, quality of care, and the risks of diversion. We are committed to ensuring that the medication is delivered in accordance with the best clinical science, which includes supportive services such as counseling and toxicology screening. We recognize that innovative products may reduce risks of diversion and will consider these within

the context of our activities. HHS continues to support research to improve MAT technologies. For example, the National Institute on Drug Abuse (NIDA) has partnered with pharmaceutical companies to develop an implantable version of buprenorphine that provides continuous medication delivery (up to six months) and has the potential to address concerns about treatment adherence and drug diversion.

2. **Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives, should CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids? How could CMS most efficiently develop and advance such quality metrics? How might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?**
3. **CMS is in a position to impact the prescription drug abuse crisis more significantly, using a variety of levers at its disposal. In addition to curbing the risk of abuse in Part D, CMS could also take steps to reduce the overuse of opioids by Medicare providers in the surgical setting. There is a growing number of alternatives to opioids, often referred to as multimodal analgesia, that manage pain in the acute care setting without using more addictive opioids. According to the American Society of Anesthesiologists Task Force on Acute Pain Management, there is strong support for the use of such alternatives to minimize the unnecessary use of opioids (Anesthesiology, 2012).**
  - a. **Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives; wouldn't you agree that CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids?**
  - b. **How could CMS most efficiently develop and advance such quality metrics?**
  - c. **Do you agree that this is a reasonable goal and if so, how might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?**

**Response to #s 2 and 3:** CMS currently is exploring the potential development of quality measures related to the use of opioids. Such measures could be used under the Medicare Hospital Inpatient Quality Reporting program or the new Merit-based Incentive Payment System for physicians and other professionals. An expert working group is being convened to provide input on development of measures evaluating opioid overuse. Before measures are added to the programs referenced above, input from other stakeholder groups will be sought.

Providing clinicians with the education and tools they need to make informed prescribing decisions for opioids is a primary focus of HHS's Opioid Initiative. This includes efforts to improve opioid analgesic prescribing across practice settings, including the surgical setting. CMS, in both the Medicare and Medicaid programs, is undertaking a number of activities to help support HHS's goal of improving opioid prescribing. Under the Medicaid program, a number of Informational Bulletins have been released to provide guidance to state Medicaid plans about evidence-based strategies they can use to improve the appropriate use of medications based on

the best available science. In 2014, CMS released the Information Bulletin on Medication Assisted Treatment for Substance Use Disorders which provided the most recent scientific data on MAT, including MAT for opioid use disorders. The Information Bulletin also provided information of innovative ways states are working to expand access to MAT. CMS is now developing an Informational Bulletin that will provide best practices Medicaid programs are employing to ensure the appropriate use of opioid analgesics for pain management within the context of the full complement of pain treatment modalities.

Under the Medicaid program, a number of Informational Bulletins have been released to provide guidance to state Medicaid plans about evidence-based strategies they can use to improve the appropriate use of medications based on the best available science. In 2014, CMS released the Information Bulletin on MAT for Substance Use Disorders which provided the most recent scientific data on MAT, including MAT for opioid use disorders. The Information Bulletin also provided information of innovative ways states are working to expand access to MAT. CMS is now developing an Informational Bulletin that will provide the best practices Medicaid programs are employing to ensure the appropriate use of opioid analgesics for pain management within the context of the full complement of pain treatment modalities.

In Medicare Part D, CMS launched the Overutilization Monitoring System (OMS) in 2013. The OMS reviews opioid utilization patterns among Part D patients to identify potential opioid overutilizers (“outliers”) based on pre-specified criteria. Once outliers are identified, Part D plan sponsors take steps both to identify the appropriateness of utilization among these patients and then to curb utilization that is determined to be outside of good clinical practice. During the most recent review cycle, from January 2015 to July 2015, the number of opioid outliers reported by the OMS decreased by 3,364, or 19 percent, from 19,632 to 15,998.

In addition to efforts at CMS, other HHS agencies are engaged in work that will guide quality pain management across clinical practice settings. For example, the Centers for Disease Control and Prevention (CDC) is developing guidelines for opioid prescribing for chronic pain outside the setting of active cancer treatment, palliative care, or end-of-life care. To ensure effective implementation of these guidelines, the Office of the National Coordinator for Health Information Technology (ONC) will build upon this work by exploring opportunities to convert guidelines into standardized, sharable, health IT-enabled clinical decision support interventions. In addition, the National Institutes of Health is leading the development of a National Pain Strategy which is expected to be released early in 2016. This Strategy will examine a number of issues related to the current state-of-the-science of pain treatment and opportunities that exist to expand the use of multimodal, multidisciplinary pain care.

**4. Should patients addicted to opioids receive treatment based on their individual clinical needs? How does HHS intend to incorporate this principal into its recently proposed rule?**

**Response:** Studies have shown that the most effective treatments for opioid use disorders are those that include a medication approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorders in combination with comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. There are three medications approved by the FDA for MAT: buprenorphine, methadone, and extended

release injectable naltrexone, and each has different characteristics and indications with advantages and disadvantages for different types of patients. Our goal is to ensure that patients have the opportunity to receive high-quality, patient-centered evidence-based treatment that meets their needs.

Our undertaking of rule-making related to buprenorphine is only one component of our comprehensive strategy which targets the expanded use of all medications approved to treat opioid use disorders. Expanding access to all forms of MAT will help us meet our goal of helping patients access the evidence-based treatment that is most appropriate for their clinical situation. Taking these steps will help to ensure that clinicians and patients can work together to decide the best treatment that will meet their needs.

**5. Dr. Frank, should patients be able to choose from among all FDA-approved medications for opioid use disorder in any given treatment setting? Is that currently possible – why or why not?**

**Response:** HHS's goal is for patients to have access to all types of MAT, but given current law, it is not possible to do this in all treatment settings. We want to expand access to MAT in a way that allows patients the maximum opportunity to choose the right treatment for their clinical circumstances within the regulatory framework that currently exists for each type of medication assisted treatment. Each type has different characteristics with advantages and disadvantages for different types of patients. Currently, the only setting in which all three types of MAT approved for the treatment of opioid use disorder can be provided is in a certified, accredited opioid treatment program (OTP), because it is the only setting in which methadone can be dispensed for the treatment of opioid use disorder. OTPs can also dispense buprenorphine and extended release naltrexone if they choose. Buprenorphine can be administered in an office based setting after a physician takes the required steps to become DATA 2000 waived for prescribing. These same physicians could prescribe extended release naltrexone to appropriately selected patients.

Since naltrexone is a non-narcotic opioid antagonist with no potential for non-medical use, it can be prescribed for the treatment of opioid use disorder by any health care provider who is licensed to prescribe medications. However, naltrexone must still be administered in an evidence-based fashion much like methadone and buprenorphine, in conjunction with services such as toxicology screenings and counseling. Additionally, naltrexone requires 7-10 days of complete opioid withdrawal before treatment can begin and may not be suitable for all patients.

**6. How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?**

**Response:** Prescription Drug Monitoring Programs (PDMPs) are among the most promising tools to curb non-medical use of prescription opioids and inappropriate prescribing practices. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially misusing medications. Additionally, PDMPs provide a mechanism for identifying potentially problematic prescribing practices. PDMPs are managed by each individual state and are subject to individual states' laws and regulations.

Building off the infrastructure of the Prevention Boost and Core Violence and Injury Prevention programs, CDC received an increase of \$20 million in Fiscal Year (FY) 2015 to launch the Prescription Drug Overdose Prevention for States program, which will expand state-level interventions in states with high burdens of prescription drug overdose morbidity and mortality, including enhancements to PDMPs (i.e., improving access, expanding proactive reporting of inappropriate prescribing patterns, shortening the PDMP reporting interval). The President's FY 2016 Budget proposes an additional \$45 million to expand that program to all 50 states and Washington, DC.

In addition to the CDC funding for states, the Substance Abuse and Mental Health Services Administration (SAMHSA) and ONC have funded work in states to advance integration of PDMP data with electronic health records, to develop standards for data sharing, and to expand interstate data sharing of PDMP information. Increasing reporting regularity, widening delegate access, and improving interoperability across state borders are all ways in which states have made and continue to make progress and improve upon their PDMPs and increase their use.

**7. IOM recommended creation of a national strategy to transform how pain is assessed, understood and treated. Dr. Frank, has HHS made any progress on this front?**

**Response:** Yes, in response to the IOM recommendation, HHS created the Interagency Pain Research Coordinating Committee (IPRCC). The IPRCC has engaged with a broad range of experts and stakeholders to develop the National Pain Strategy. While an exact publication date has not yet been determined, we anticipate that it will be released in 2016.

**8. Improving professional education about opioid prescribing and appropriate pain management is critical. What is the government doing to improve provider education across the spectrum of disciplines and throughout the continuum of undergraduate, graduate and continuing health profession training?**

**Response:** Providing health care providers with the education and tools they need to prescribe opioids appropriately is a central component of the HHS Opioid Initiative. We are taking actions across the spectrum of health professional education and practice in this area. For example, the National Institutes of Health has funded 11 health professional schools as designated Centers of Excellence in Pain Education (CoEPEs). The CoEPEs will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to enhance and improve how health care professionals are taught about pain and its treatment.

To improve clinical decision-making to reduce inappropriate opioid prescribing, CDC is developing guidelines for opioid prescribing for chronic pain among patients who are not in active cancer treatment, palliative care, or end-of-life care. To ensure effective implementation of these guidelines, ONC will build upon this work by exploring opportunities to convert guidelines into standardized, sharable, health IT-enabled clinical decision support interventions. The guidelines are scheduled to be released in 2016.

In addition, multiple HHS agencies provide continuing education programs on appropriate opioid prescribing to practicing clinicians. FDA's Risk Evaluation and Mitigation Strategy for

Extended-Release/Long-Acting Opioid Analgesics requires manufacturers of these products to make available continuing education programs, based on an educational blueprint developed by FDA, available at no or nominal cost to providers. Both the National Institute on Drug Abuse through its NIDAMED program SAMHSA through its Providers' Clinical Support System for Opioids offer educational programs for health professionals on opioid prescribing.

**The Honorable Representative Tim Murphy**

**1. On September 17, Secretary Burwell announced that HHS would be revising the regulations related to buprenorphine dispensing in the physician office setting to “safely and effectively increase access.”**

**a. What is the timeframe you anticipate for this action and how, if at all, are you engaging with stakeholders to inform this process?**

**Response:** HHS is working as expeditiously as possible to publish a Notice of Proposed Rule Making (NPRM) for public comment. Prior to and since the Secretary’s announcement in September, we regularly have met with a diverse group of stakeholders on this issue to exchange facts and information. While we are unable to discuss specific provisions at this time because the rulemaking is ongoing, we are thoughtfully weighing all stakeholder opinions and input. Additionally, there will be a formal public comment period once the NPRM is released. This will allow stakeholders to review and provide input on the proposed regulation before it is finalized.

**b. Throughout this process, what attention is being given to the threat of drug diversion associated with the higher levels of supply envisioned?**

**Response:** HHS is keenly aware of the potential for buprenorphine diversion. As we consider various options during the rulemaking process, we are carefully weighing the risks of diversion and the need to ensure that buprenorphine is delivered in a high-quality manner in accordance with the best clinical practices, which includes supportive services such as counseling and toxicology screening.

**c. How can an effective drug diversion control plan assist in reducing the incidence of diversion? What are its limitations?**

**Response:** Monitoring for diversion is an essential responsibility of physicians engaged in prescribing buprenorphine for opioid use disorder. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use recently released by the American Society of Addiction Medicine states:

“Clinicians should take steps to reduce the chance of diversion. . . Strategies to reduce the potential of diversion include: frequent office visits, urine drug testing including testing for buprenorphine and metabolites, observed dosing, and recall visits for pill counts. Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely.”

**d. How does the Secretary’s initiative account for extended engagement and monitoring of patents by medical and addiction professionals?**

**Response:** The goals of the Secretary’s Initiative are to reduce prescription opioid and heroin dependence, overdose and death. With respect to patients receiving treatment for opioid use disorders, our goal is to ensure that patients receive high-quality evidence-based care. Studies

have shown that the most effective way to manage opioid use disorders is through use of a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. Implicit in this treatment is an ongoing partnership and engagement between patients and their treating health care providers. Substance use disorders are chronic relapsing conditions that require continuous engagement of providers and patients.

**2. How do federal privacy rules surrounding the sharing of patient alcohol and substance abuse data – such as 42 CFR Part 2 – frequently obstruct communication between healthcare providers or even among state agencies? What, if anything, can be done about this?**

**Response:** Privacy protections found at 42 CFR Part 2 limit the sharing of data that might identify a person as a substance use disorder treatment patient in certain settings. These protections prohibit the disclosure of patient identifying information without consent, unless an exception applies. These protections limit the sharing of data among members of the care team in some cases, and do not permit exchange of data among various state agencies. SAMHSA is currently working on an NPRM to revise 42 CFR Part 2 regulations. The revisions under consideration would continue to uphold privacy protections, while allowing for the exchange of data within certain entities such as like accountable care organizations for treatment purposes.

**3. How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?**

**Response:** Prescription Drug Monitoring Programs (PDMPs) are among the most promising clinical tools to curb non-medical use of prescription opioid and inappropriate prescribing practices. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially misusing medications. Additionally, PDMPs provide a mechanism for identifying potentially problematic prescribing practices. PDMP evaluations have detected positive changes in prescribing patterns, decreased use of multiple providers and pharmacies, and decreased substance use disorder treatment admissions. PDMPs are managed by each individual state and are subject to individual states' laws and regulations.

In FY 2015, CDC received an increase of \$20 million to launch the Prescription Drug Overdose Prevention for States Program, which expanded state-level interventions focusing on improving prescribing to prevent overdose, including enhancements to PDMPs. The President's FY 2016 Budget proposes an additional \$45 million to expand that program to all 50 states and Washington, DC.

In addition to the CDC funding for states, SAMHSA and ONC have funded work in states to advance integration of PDMP data with electronic health records, to develop standards for data sharing, and to expand interstate data sharing of PDMP information. Increasing reporting regularity, widening delegate access, and improving interoperability across state borders are all ways in which states have made and continue to make progress and improve upon their PDMPs and increase their use.

**The Honorable Representative Gus Bilirakis**

- 1. Dr. Frank, how will HHS ensure that patients receive comprehensive, effective treatment if the patient caps are raised without requiring physicians at DATA 2000 clinics to have the capacity to provide other services, such as counseling and patient monitoring?**

**Response:** Our goal is to ensure that patients receiving buprenorphine-based medication assisted treatment receive highest quality care. Studies have shown that the most effective way to manage opioid use disorders is through use of a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. As the rulemaking process is currently underway, I cannot provide details on specific provisions, but all considerations are being carefully weighed with the risks of diversion and ensuring that the medication is delivered in accordance with the best clinical science, which includes supportive services such as counseling and toxicology screening.

- 2. Are there regulations in place to ensure that buprenorphine provided at these clinics is not diverted?**

**Response:** Buprenorphine is a schedule III controlled substance under the Controlled Substances Act (CSA). The same requirements in the CSA intended to reduce diversion that apply to other schedule III drugs, also apply to buprenorphine. In addition, buprenorphine-based MAT is governed by the Drug Addiction Treatment Act of 2000 (DATA), an amendment to the Controlled Substances Act (CSA). Under this law, physicians may treat up to 30 patients at a time in the first year and then file a request to treat up to 100 patients at a time. The patient prescribing limits were established, in part, to prevent diversion of the medication.

In addition, monitoring for diversion is an essential responsibility of physicians engaged in prescribing buprenorphine for opioid use disorder. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use recently released by the American Society of Addiction Medicine states:

“Clinicians should take steps to reduce the chance of diversion... Strategies to reduce the potential of diversion include: frequent office visits, urine drug testing including testing for buprenorphine and metabolites, observed dosing, and recall visits for pill counts. Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely.”

- 3. Patients suffering from opioid addiction not only need treatment using prescription drugs, but also need comprehensive support services like counseling and patient monitoring. It is my understanding that under the DATA 2000 law, clinics are not required to offer any of these services. Since you spoke of the importance of medication-assisted treatment, which includes other therapy services, why shouldn't DATA 2000 clinics be required to adopt these patient-centered practices if they wish to raise patient caps?**

**Response:** Waivers under DATA 2000 are issued to individual physicians as opposed to practices. The best clinical science on MAT indicates that it must be delivered in conjunction with a comprehensive set of supportive psychosocial services. All considerations — including the ability to provide other therapy services such as counseling and toxicology screening — are being carefully weighed during the proposed rulemaking process to ensure that the medication is delivered in accordance with the best clinical science while minimizing the risks of diversion.

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3941

November 24, 2015

Mr. Jack Riley  
Deputy Administrator  
Drug Enforcement Administration  
U.S. Department of Justice  
8701 Morrisette Drive  
Springfield, VA 22152

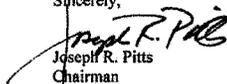
Dear Mr. Riley:

Thank you for appearing before the Subcommittee on Health on October 8, 2015, to testify at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis."

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.

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

Sincerely,  
  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

**EXAMINING LEGISLATIVE PROPOSALS TO  
COMBAT OUR NATION'S DRUG ABUSE CRI-  
SIS—DAY 2**

**TUESDAY, OCTOBER 20, 2015**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON HEALTH,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 4:00 p.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Blackburn, Bucshon, Brooks, Sarbanes, and Pallone (ex officio).

Also present: Representative Tonko.

Staff present: Clay Alspach, Chief Counsel, Health; Sean Bonyun, Communications Director; Leighton Brown, Press Assistant; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Chris Sarley, Policy Coordinator, Environment and the Economy; Adrianna Simonelli, Legislative Associate, Health; Sam Spector, Counsel, Oversight and Investigations; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Jeff Carroll, Democratic Staff Director; Eric Flamm, Democratic FDA Detailee; Tiffany Guarascio, Democratic Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Democratic Policy Analyst; and Kimberlee Trzeciak, Democratic Healthy Policy Advisor.

Mr. PITTS. Ladies and gentlemen, if you can take your seats, the subcommittee will come order.

We are reconvening this hearing. We had the first panel a week ago, couple weeks ago, and this will be the second panel. So welcome back.

For those of you just joining us today, today is the second day of our hearing to examine legislative proposals to combat our Nation's drug abuse crisis. On the first day of the hearing, which took place on October 8, we heard testimony from a panel of Federal witnesses representing DEA, HHS, and the Executive Office of the President. Today, we will hear from a number of distinguished doctors with a wide variety of expertise.

On our panel today we have—and I will introduce them in the order of their presenting their testimony—first, Dr. Paul Halverson, Dean, Indiana University's Richard M. Fairbanks School of Public Health.

Welcome.

Secondly, Dr. Chapman Sledge, Chief Medical Officer, Cumberland Heights.

Welcome.

Third, Dr. Robert Corey Waller, Chair of the American Society of Addiction Medicine's Legislative Advocacy Committee.

Welcome.

Then, Dr. Kenneth Katz, Department of Emergency Medicine, Section of Medical Toxicology, Lehigh Valley Health Network.

Welcome.

And I don't see Dr. Allen Anderson yet, President of the American Orthopaedic Society for Sports Medicine.

So thank you for coming. Your written testimony will be made a part of the record. You will each have 5 minutes to summarize your testimony, and after opening statements we will do the questioning.

So, Dr. Halverson, you are recognized for 5 minutes for your summary.

**STATEMENTS OF PAUL K. HALVERSON, PH.D., DEAN, RICHARD M. FAIRBANKS SCHOOL OF PUBLIC HEALTH, INDIANA UNIVERSITY; CHAPMAN SLEDGE, M.D., CHIEF MEDICAL OFFICER, CUMBERLAND HEIGHTS FOUNDATION; ROBERT COREY WALLER, M.D., CHAIR, LEGISLATIVE ADVOCACY COMMITTEE, AMERICAN SOCIETY OF ADDICTION MEDICINE; KENNETH D. KATZ, M.D., SECTION OF MEDICAL TOXICOLOGY, DEPARTMENT OF EMERGENCY MEDICINE, LEHIGH VALLEY HEALTH NETWORK; AND ALLEN F. ANDERSON, M.D., PRESIDENT, AMERICAN ORTHOPAEDIC SOCIETY FOR SPORTS MEDICINE**

**STATEMENT OF PAUL K. HALVERSON**

Dr. HALVERSON. Thank you, Mr. Chairman.

Chairman Pitts, Ranking Member Green, Representative Brooks, thank you for the opportunity to testify today.

I come before you today as both the founding dean of the Indiana University Richard M. Fairbanks School of Public Health at IUPUI as well as the former State health officer of Arkansas to discuss a very important and far-reaching public health issue: the heroin and prescription drug abuse epidemics and the deleterious effects which we are experiencing across the country and in my home State of Indiana.

We know addiction is a tragedy not for the addicted person alone but also for families, employers, and entire communities. Addiction is often at the root of myriad social, physical, mental, and public health problems. It harms all in its path, even the most innocent among us.

Newborns who have been exposed to opioids in utero are often born with a condition called neonatal abstinence syndrome. In the last 15 years, the number of affected babies is five times higher, mirroring the surge in opioid abuse over the same time period.

The financial costs of drug addiction for health care, criminal justice, and education are staggering. In my State of Indiana alone, the costs are estimated at over \$7.3 billion annually. Hospital charges for babies born with NAS were over \$1.5 billion nationally in 2013.

Opioid abuse is particularly pernicious because it is often a precursor to heroin use. SAMHSA found that nearly four out of five new heroin users took nonmedical prescription pain medication before taking up heroin.

The end result: People are dying. CDC notes that 44 people die each day in our country from an overdose of pain medication. Na-

tionally, heroin-related deaths have escalated over 39 percent between 2012 and 2013. And although mortality rates are up in many States in the country, Indiana is one of only four States where the rate of overdose deaths has quadrupled in 14 years.

Indiana made the national news this past spring with its public health crisis related to opioid abuse. Scott County, a population of less than 25,000 people, had an unprecedented outbreak of HIV related to needle sharing among intravenous drug users injecting prescription opioids. To date, the number of new confirmed cases of HIV for 2015 exceeds 180 people. This number is particularly alarming since the entire southeastern region of Indiana has never had more than five new cases annually prior to this year.

In addition, significant cuts in already chronically underfunded public health infrastructure nationwide make communities even more vulnerable and frequently leaves them without important public health services, such as education on how to protect themselves against life-threatening diseases and access to confidential HIV testing and treatment, among other important services like epidemiology and outbreak investigation capacity. Indiana's public health system is particularly vulnerable, with our overall health ranking at 41 and our funding of public health services at 47 out of the 50 States.

Between 2009 and 2013, this small, rural county led the entire State in both drug overdose deaths and nonfatal emergency department visits due to opioid overdose. It is also important to point out that there are numerous counties in Indiana and, frankly, throughout the country that are strikingly similar by virtue of their social and demographic characteristics as well as the fragile public health system capacity that exists.

We are grateful to colleagues from the CDC for assisting our State health department, under the leadership of Dr. Jerome Adams, as they responded to and supported local public health and community leaders; and to Governor Pence for recently establishing an executive branch task force to focus State government agencies on the system issues surrounding substance abuse.

In addition, our attorney general's longstanding Prescription Drug Task Force has been focused on the coordination and oversight of Indiana's prescription drug monitoring program, and its insight has been instrumental in developing legislative and policy-level recommendations.

Lastly, I would like to acknowledge the support that the Richard M. Fairbanks School of Public Health has provided, primarily through the leadership of Dr. Joan Duwve, who has tirelessly led and supported these efforts in our State.

In spite of these important State efforts, though, additional national legislative efforts are needed. We are grateful to Representative Brooks and other members of the committee for shedding light on the very serious problems with opioid abuse and heroin use, which are becoming more pervasive with each passing day. It is clear we need to effectively attack these problems from a system perspective to prevent further destruction of our public's health.

I applaud your efforts, and I am grateful for your dedication in addressing this important public health issue.

Thank you, sir.

[The prepared statement of Dr. Halverson follows:]



**Testimony to the U.S. House of Representatives' Committee on Energy and Commerce**

**Paul K. Halverson**

**Founding Dean**

**Indiana University Richard M. Fairbanks School of Public Health**

**Indianapolis, Indiana**

**October 20, 2015**

**SUMMARY**

- Prescription opioid abuse is a rapidly escalating public health issue across the country. Opioid abuse leads to many health problems including heroin use, drug overdose and death.
- Indiana's mortality rate from drug overdose, at 14.4 per 100,000, has quadrupled since 1999, according to a report by Trust for America's Health.
- Opioid abuse is the cause of an HIV outbreak in a small rural county in Indiana. As of June, the county of 25,000 had 169 confirmed cases in 2015. Prior to this year, there have never been more than 5 cases for the entire southeastern district of the state (12 counties).
- Infants exposed to opioids in utero often experience Neonatal Abstinence Syndrome at birth. They experience irritability, feeding and digestive issues, and respiratory distress. Their hospitalizations are complicated and costly.
- Addiction is a challenging public health problem, due to the lack of consensus about the cause of the problem, i.e., biological/genetic vs. lack of character and will power.
- Although many people who use illegal drugs and become addicted are prosecuted and sentenced to jail, drug abuse continues to grow. We cannot incarcerate our way out of the problem. New approaches are needed.

**Testimony to the U.S. House of Representatives' Committee on Energy and Commerce**

**Paul K. Halverson**

**Founding Dean**

**Indiana University Richard M. Fairbanks School of Public Health**

**Indianapolis, Indiana**

**October 20, 2015**

I'm before you today to discuss a very important and far reaching public health issue, the heroin and prescription drug abuse epidemics, and their deleterious effects, that we're experiencing across the country and in my home state of Indiana.

We know that addiction is not a tragedy for the addicted person alone. It is a tragedy for individuals, families and entire communities. The effects are cumulative, and contribute significantly to costly social, physical, mental, and public health problems. Addiction contributes to teenage pregnancy, harms unborn babies, fuels domestic violence and child abuse and contributes to the spread of sexually transmitted diseases. It leads to missed work, problems holding a job and sometimes to homelessness. Addiction is a major cause of motor vehicle crashes, crime, gun violence, homicide and suicide. As if the public health and social costs are not enough, the financial costs of drug addiction to our state alone, for health care, criminal justice, education and more, are estimated at \$7.3 billion annually.

Opioid abuse is particularly pernicious because it can be the precursor to heroin use. A study from the Substance Abuse and Mental Health Services Administration found that nearly 4 out of every 5 new heroin users took non-medical prescription pain medication before taking up heroin.

The end result is that people are dying. Forty-four people die each day in our country from an overdose of pain medication, according to the Centers for Disease Control and Prevention. Nationally heroin-related deaths have escalated from 5,300 to more than 8,200 between 2012 and 2013, a 39% increase.

In Indiana, we have the 17th highest drug overdose mortality rate in the United States, 14.4 per 100,000 people, according to a report from Trust for America's Health (TFAH). The majority of these deaths were from prescription drugs. Since 1999, when the rate was 3.2 per 100,000, our mortality rate has quadrupled. Although mortality rates are up in many states in the country, Indiana is one of only 4 states where the rate quadrupled in 14 years. The TFAH report also states that Indiana had only five out of 10 possible indicators for promising strategies to help curb prescription drug abuse. Nationally, 28 states and Washington, D.C. scored six or less, placing us squarely in the bottom half of states.

Indiana made the national news this past summer with its public health crisis related to opioid abuse. Scott County, with a population of less than 25,000 people, had an unprecedented outbreak of HIV related to needle sharing among intravenous drug users who were injecting a prescription opioid. As of June 2015, there were 169 confirmed cases in the county. The entire southeastern region of Indiana has never had more than 5 cases annually prior to this year. Significant cuts in an already chronically underfunded public health infrastructure have hit communities hard, and left them without important public health services such as education on how to protect themselves against life threatening diseases and confidential HIV testing and treatment. As a result, this small county led the entire state in both drug overdose deaths in 2009-2013 (42.66/100,000) and non-fatal emergency department visits due to opioid overdose in (75.28/100,000) in 2009-2013.

Neonatal Abstinence Syndrome (NAS) is another serious crisis unfolding throughout the country. NAS appears in newborns who have been exposed to opiates in utero. The symptoms include increased irritability, hypertonia (spasticity), tremors, feeding intolerance, vomiting, watery stools, seizures and respiratory distress. NAS infants are likely to have significantly longer, more complicated and very expensive hospitalizations at birth. The incidence of NAS has *quintupled* between 2000 (1.20/1,000) and 2012 (5.8/1,000) and mirrors the surge in opioid abuse over the same time period. The percentage of NAS infants covered by Medicaid has risen from 68.7% in 2000 to 81.5% in 2013. Hospital charges for NAS infants in 2013 were estimated at \$1.5 billion, placing a significant burden on governmental budgets and the health care system.

Opioid abuse and heroin use indeed have serious consequences for the country, not only in terms of morbidity and mortality, but in the fraying of the social fabric of our communities. Individual attitudes and political responses to illegal drug consumption combine to make substance abuse one of the toughest of all public health challenges. It is often a primary focus for discussions about social values. The bottom line is that we don't have consensus on whether substance abuse is a biological or genetic disease or a matter of personal choice. People sometimes assume incorrectly that drug abusers don't have strong moral principles or willpower. They believe users can stop taking drugs simply by changing their behavior. In reality, drug addiction is a complicated disease, and recovery takes more than good intentions or willpower. Because drugs change the brain in ways that foster compulsive drug abuse, quitting is extremely difficult even for those who desperately want to do so.

By the same token, substance abuse is often a lightning rod in the criminal justice system. However, we have learned that we can't incarcerate our way out of this problem. We already have prisons full of people debilitated by substance abuse problems, and yet still the problem grows. We have to find a new approach.

For all these complex and costly reasons, we are grateful to Representative Brooks for shedding light on the very serious problems of opioid abuse and heroin use, which are becoming more pervasive with each passing day. It is clear we need to effectively attack these problems and prevent further destruction of our public's health due to opioid abuse.

Sources:

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Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Sledge for 5 minutes for your summary.

#### STATEMENT OF CHAPMAN SLEDGE

Dr. SLEDGE. Thank you, Mr. Chairman. I want to thank this committee for holding this important hearing on legislative solutions to combat the worsening drug crisis in our country. Like all of us, I am deeply concerned as to what I see happening in regards to the opioid epidemic in particular, and I am grateful to have this opportunity to share my thoughts and experience.

I am chief medical officer of Cumberland Heights, a private, not-for-profit addiction treatment center on the banks of the Cumberland River in Nashville, Tennessee. I previously served as medical director of addiction treatment services at Pine Grove Behavioral Health in Hattiesburg, Mississippi, and have been practicing addiction medicine for over 26 years.

I am certified by the American Board of Addiction Medicine. I am a fellow of American Society of Addiction Medicine, and, from 2005 to 2009, I represented Mississippi, Alabama, Florida, Tennessee, and Kentucky on the board of directors of ASAM and served as secretary of the organization until 2011.

Cumberland Heights has a 50-year tradition of treating addiction. We provide treatment to adult men and women as well as adolescents. Most of our patients are working-class and insurance-dependent, but we treat a fair number of patients with resources to self-pay, and we treat a fair number of patients dependent upon scholarships to provide their treatment.

A watershed moment in my career as an addiction medicine specialist came around 2006 on a Saturday morning. I was making rounds on a detox unit with 25 beds, and I realized that every single one of those patients had a diagnosis of opioid dependence, and that was new to me. Some of those patients had other diagnoses, as well, but every single one of them had a diagnosis of opioid dependence. And, in fact, every single one of those patients was dependent upon prescription opioids.

Our most common diagnosis at Cumberland Heights of the 1,500 admissions per year has been opioid dependence, particularly in young adults. Tennessee leads the Nation in prescriptions for opioids per capita. And heroin addiction has become more and more prevalent as access to prescription opioids becomes limited through less abusable formulations, monitoring of controlled substance prescription databases, as well as education.

The Tennessean, Nashville's local newspaper, ran a cover story on the opioid epidemic last month. To quote, "At least 1,263 Tennesseans died last year from opioid overdose, up 97 deaths from 2003—a staggering statistic that points to growing abuse despite an array of measures to stem addiction. More people died in 2014 from opioid overdose in Tennessee than by car accidents or gunshots."

My expertise is based in direct patient care; I am an expert in what my patients disclose to me face-to-face in my office. Almost all of our patients admitted to Cumberland Heights for treatment of opioid dependence have some experience with buprenorphine, either by prescription or by buying the medication off the street.

Over the years, I have been amazed at stories of diversion and abuse of buprenorphine among patients presenting to Cumberland Heights for treatment.

Buprenorphine is sometimes used under the tongue, as it is designed. It can be used intranasally or even injected. Motivations for illicit use of buprenorphine include to get high as well as to treat withdrawal. Of course, some patients with buprenorphine diversion and abuse take it with the motivation to stop using other opioids.

A typical 8-milligram dose of buprenorphine costs \$20 in middle Tennessee when obtained illicitly and, in east Tennessee, as much as \$40 per 8-milligram dose. The street value supports my observation as to the level of diversion and abuse of buprenorphine. In fact, buprenorphine has been identified as the third-most-diverted medication in the U.S. by the DEA.

At a 2008 meeting of the American Society of Addiction Medicine's Medical Scientific Conference in Miami, I was asked by a colleague if I use buprenorphine to treat opioid dependence. I replied that we utilize buprenorphine to detox from opioids. He remarked that he had never seen a patient recover without buprenorphine, and I told him that I had recovered from opioid dependence without buprenorphine. He said, "Yes, but you weren't using intravenously." He appeared incredulous when I told him that I had recovered from IV opioid addiction without buprenorphine or methadone.

I cringe when an addiction medicine treatment provider makes a recommendation based on his or her personal experience in treatment and recovery; that is not what I am saying. But my experience indicates that there are multiple paths to recovery. There is no one-size-fits-all.

At Cumberland Heights, we promote abstinence after detox, we provide psychosocial treatment, and we use a long-acting opioid blocker, Vivitrol, as well as incorporation of a spiritual basis of recovery through 12-step facilitation. We completely understand that addiction is a chronic illness, and ongoing recovery requires ongoing treatment. No one is claiming that detox from opioids alone will result in recovery.

And I thank you for the opportunity to speak.

[The prepared statement of Dr. Sledge follows:]

Statement

Of Chapman Sledge, MD

Chief Medical Officer

Cumberland Heights Foundation

Nashville, Tennessee

to the

United States House of Representatives

Committee on Energy & Commerce

Subcommittee on Health

Re: "Examining Legislative Proposals to Combat our  
Nation's Drug Abuse Crisis."

October 20, 2015

### Summary

The following is a summary of my statement:

- An overview of my background and qualifications to testify
- A brief description of Cumberland Heights, the addiction treatment facility where I serve as Chief Medical Officer
- The opioid problem in Nashville, Tennessee
- The challenges and process of abstinence from opioids
- The course of opioid detoxification and treatment
- Support for the H.R. 2872: The Opioid Addiction Treatment Modernization Act
- Support for H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015

I want to thank the Committee for holding this important hearing on legislative solutions to combat the worsening drug crisis that has swept across our country. Like all of us, I am deeply concerned about what I see happening with regard to the opioid epidemic, in particular, and I am grateful to have this opportunity to share with you my observations and thoughts.

I am Chief Medical Officer of Cumberland Heights, a private not-for-profit addiction treatment center on the banks of the Cumberland River in Nashville, TN. I previously served as Medical Director of Addiction Treatment Services at Pine Grove Behavioral Health in Hattiesburg, MS. I am certified by the American Board of Addiction Medicine, and I am a Fellow of the American Society of Addiction Medicine. I represented Mississippi, Alabama, Florida, Tennessee, and Kentucky on the Board of Directors of the American Society of Addiction Medicine from 2005 until 2009, and served as Secretary of ASAM from 2009 until 2011.

Cumberland Heights will celebrate its fiftieth anniversary of treating addiction in 2016. We provide addiction treatment to men and women, both adults and adolescents. Though most of our patients are working class and insurance dependent, we also treat a fair number of patients with the resources to pay for treatment out of pocket, and we treat a number of patients dependent upon scholarships to fund their treatment.

A watershed moment in my career as an Addiction Medicine physician came around 2006. On a Saturday morning I was making rounds on our twenty-five bed detox unit. At the end of the day, I realized that every one of the twenty-five patients had a diagnosis of Opioid Dependence. Some of those patients had other substance use disorders as well, but every single patient had a diagnosis of Opioid Dependence. Every one of those patients was dependent upon

prescription opioids. Over the years I have seen our most commonly occurring diagnosis shift from Alcohol Dependence to Opioid Dependence. Of the more than 1,500 admissions to Cumberland Heights in the past year, the most common diagnosis is Opioid Dependence, particularly in young adult patients. Heroin addiction has become more and more prevalent as access to prescription opioids becomes more limited through less abusable formulations, monitoring of controlled substance prescription databases, and education.

My expertise is based in direct patient care. I am an expert in what my patients disclose to me, face to face, in my office.

In 2008, at the ASAM Medical Scientific Conference in Miami, I was asked by a colleague if I used Buprenorphine to treat Opioid Dependence. I replied that we utilized Buprenorphine to detox from Opioids. He remarked that he had never seen a patient recover without Buprenorphine. I told him that I had recovered from Opioid Dependence without Buprenorphine. He said, "Yes, but you weren't using intravenously". He appeared incredulous when I told him that indeed recovered from IV Opioid Addiction without Opioid Agonist Therapy. I am appalled when an addiction treatment provider makes recommendation based on his or her personal experience in treatment; that is not what I am saying. My experience is that there are multiple paths to recovery; there is no one size fits all approach.

Over the years, I have been amazed at the stories of diversion and abuse of Buprenorphine among patients presenting to Cumberland Heights for treatment. Buprenorphine may be used sublingually as designed, used intranasally, or injected. Motivations include "to get high" as well as to treat withdrawal. Of course, some patients with Buprenorphine diversion and abuse take it with the motivation to get off other opioids.

A typical 8 mg dose of Buprenorphine costs \$20 in Middle Tennessee, and as much as \$40 per 8 mg dose in East Tennessee. The street value supports the level of diversion and abuse. In fact, Buprenorphine has been identified as the third most diverted medication in the United States by the DEA.

My attraction to Cumberland Heights was the ability of the organization to honor tradition while maintaining an innovative approach to treatment. Rarely are patients naïve to Buprenorphine treatment when they present to Cumberland Heights for evaluation. Often, Opioid Dependent patients have failed Buprenorphine or Methadone treatment. During the course of evaluation, the patient identifies a desire to be free of opioids. We have developed a bit of a niche in the local addiction treatment community by using pharmacotherapy to support abstinence from opioids while provided psychosocial treatment to promote ongoing recovery. The most effective technique is residential treatment, detox from opioids, and initiation of long acting naltrexone through injection. We completely understand that addiction is a chronic medical illness, and ongoing recovery requires ongoing treatment. Upon discharge from residential treatment, patients are referred for ongoing psychosocial treatment as well as ongoing administration for extended release naltrexone, Vivitrol.

I am very enthusiastic about two of the bills that are currently under consideration.

The first is the bill that was introduced by Dr. Larry Bucshon and Congressman Womack, titled "H.R. 2872: The Opioid Addiction Treatment Modernization Act." This bill would require that doctors who obtain certification to prescribe buprenorphine be trained on the use of all FDA-approved treatments for opioid addiction; and they would be required to offer directly, or by referral, all treatment options, based on the individualized needs and preferences of the patient.

Likewise, I like that the bill would require that buprenorphine practices conduct drug screens to ensure patients are actually taking their medication, and not just selling them on the street. Another important provision of this bill is the requirement that these practices maintain diversion control plans. Simply giving opioid dependent individuals a 30-day supply of buprenorphine to take home with them is a prescription for disaster. I am not at all opposed to buprenorphine treatment, but I am opposed to poor and irresponsible treatment. HR 2872 would ensure that individualized, professional treatment is offered based on the needs of the patient, including the option to get off of all opioids.

I understand that HHS is planning on lifting the cap on buprenorphine practices. I do not see how we are ever going to end this opioid epidemic by simply increasing the amount of opioids being prescribed. Quality care and treatment options for patients should be priority number one, not the advancement of the current one-size-fits-all approach that is dominating today's treatment landscape. It is in this context that lifting of the caps should be considered.

There has been a lot of misinformation spread about how liberal access to buprenorphine in Baltimore, or in France, reversed the number of heroin overdoses. However, the data paints a different picture. Heroin overdose rates in Baltimore are at an all-time high, and the numbers of opioid overdoses in France are increasing steadily too.

Lastly, I also want to applaud Congresswoman Brooks and Congressman Kennedy for introducing "H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015." This bill calls for the formation of a "Pain Management Best Practices Inter-Agency Task Force" to develop recommendations for appropriate training in pain management; and a plan for disseminating the Task Force recommendations. In addition, it

would strengthen prescription drug monitoring programs so that providers can access for the early identification of patients at risk for addiction in order to initiate appropriate interventions.

Our country has to try and eliminate the irresponsible prescribing of opioids, and I support efforts at helping people get off of opioids whenever possible. These two bills do that and for that reason I hope you will give them your thoughtful consideration.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Waller, 5 minutes for your opening statement.

**STATEMENT OF ROBERT COREY WALLER**

Dr. WALLER. Thank you, Chairman Pitts and Ranking Member Green. Thank you very much for inviting me to participate in this important hearing. I am grateful to you and the other members of the subcommittee for your leadership in addressing the epidemic of opioid addiction currently ravaging our country.

My name is Dr. Corey Waller, and I am the chair of the Legislative Action Committee of the American Society of Addiction Medicine, also known as ASAM. This testimony is offered on behalf of ASAM, myself as a practicing addiction specialist physician, and my patients who are unable to speak before this committee themselves.

I am board-certified in both addiction medicine and emergency medicine. I am the medical staff chief of pain medicine to the Spectrum Health Hospital System as well as the substance use disorder medical director at a regional community mental health organization based in Grand Rapids, Michigan.

My testimony today will focus on the following three facts: Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, and social manifestations; addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions; and we have published guidelines that detail best practices for the use of these medications.

There are significant barriers to access to these effective medications, resulting in a significant addiction treatment gap in our country. This is, without question, a chronic neurobiological disorder that starts with a genetic risk, is informed by the environment, and is solidified by the culture surrounding it. Not unlike diabetes or hypertension, we can effectively manage the disease, but stopping that treatment prematurely costs us lives.

We are here today to provide recommendations on how best to respond to the epidemic of prescription opioid and heroin misuse, addiction, and related overdose deaths. According to the Centers for Disease Control, we have reached epidemic levels in our country. We have all seen the data and heard the shocking statistics, but what is not said or heard enough is that the 2.3 million people who need treatment for opioid addiction have a chronic disease of the brain. While we need to prevent other Americans from developing addiction, these 2.3 million people need treatment now.

There are currently three medications that are FDA-approved to treat opioid addiction: methadone, which has been used in highly regulated opioid treatment programs since the 1960s; buprenorphine, which has been used since 2002 by physicians who complete a special training in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber.

All of these medications have proven to be clinically effective. A 2013 review of the scientific literature found substantial, broad, and conclusive evidence for the effectiveness of all three medications and for methadone in particular. Notably, the literature on ef-

ficacy of these medications is not new. There are now eight large-scale, rigorously conducted reviews of the literature on these medications since the early 1980s. All FDA medications have been shown to reduce mortality.

Finally, we have a clear and comprehensive guideline for how to use these medications effectively in the clinical care of persons with addiction. However, despite the strong, evidence-based use of these medications and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Less than 30 percent of treatment programs offer medications, and less than half of eligible patients in those programs receive medications. Indeed, a study published just last week in the *Journal of the American Medical Association* found that 80 percent of Americans with opioid addiction don't receive treatment.

This treatment gap is attributable to many factors, some more complex than others. Research has demonstrated significant access barriers to methadone, including waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at an OTP daily.

DATA 2000 was intended to expand access to addiction treatment across geographies and populations by integrating it into the general medical setting. In recent months, my practice has had to turn away patients due to the 100-patient limit for buprenorphine, and this includes pregnant patients as well as the children of my friends, and has resulted in at least 2 overdose deaths that we can track.

If I am out of town or unavailable, my physician assistants are unable to see patients who need an urgent intake due to the restrictions on PAs and nurse practitioners writing for buprenorphine, which exists even if they are under the guidance of a physician who is board-certified in addiction.

It is important to note that the entire purpose of DATA 2000 was to make opioid treatment available outside an OTP, in traditional physician's offices, both to increase access in areas where OTPs may be physically inaccessible and to reduce the stigma and patient burden associated with visiting an OTP for treatment on a daily basis.

Still, because diversion and quality of care remain legitimate concerns, ASAM has proposed a gradual and limited lifting of the DATA 2000 limits. By coupling a lifting of the patient limit with increased training requirements and accountability for those physicians treating large numbers of patients, we feel we can expand access while also ensuring a certain quality of care.

Still, this single strategy should be just one part of a broader Federal effort to ensure safe prescribing of opioids for pain, alternative pain therapy options, and early identification and treatment of addiction.

Pain and addiction education should be required curriculum in medical school and encouraged as continuing medical education throughout a physician's career. Communities should have the resources to educate their citizens about these issues and the outreach and surveillance resources necessary to better understand the unique issues and needs.

Thank you again for the opportunity to present here today. ASAM and myself look forward to a continued collaboration on this and other addiction-related issues.

[The prepared statement of Dr. Waller follows:]



# ASAM

The Voice of Addiction Medicine  
American Society of Addiction Medicine

Testimony of Robert Corey Waller, MD, MS  
Before the Energy and Commerce Committee Subcommittee on Health  
October 20, 2015

## Executive Summary

My name is Dr. Corey Waller, and I'm the Chair of the Legislative Advocacy Committee of the American Society of Addiction Medicine (ASAM), which represents more than 3,700 of our nation's addiction specialist physicians and other clinicians.

My testimony today will focus on the following facts:

1. Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.
2. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

Opioid addiction is taking a devastating toll on our families, friends and neighbors across the country, but there is hope when patients can access effective treatment services. ASAM is honored today to offer its thoughts and expertise on how we can close the treatment gap, improve the quality of care, and ultimately save lives.

**Written Statement**

Chairman Pitts and Ranking Member Green, thank you very much for inviting me to participate in this important hearing. I'm grateful to you and the other Members of the Subcommittee for your leadership in addressing the epidemic of opioid addiction currently ravaging our country.

My name is Dr. Corey Waller, and I am the Chair of the Legislative Advocacy Committee of the American Society of Addiction Medicine, also known as ASAM. This testimony is offered on behalf of ASAM, myself as a practicing addiction specialist physician, and my patients, who are unable to speak before this committee themselves. I am board certified in both addiction medicine and emergency medicine, and I'm the Medical Director of the Spectrum Health Medical Group Center for Integrative Medicine, the Medical Staff Chief of Pain Medicine to the Spectrum Health Hospital System, as well as Substance Use Disorder Medical Director at Lakeshore Regional Partners in Grand Rapids, MI.

Established in 1954, ASAM is a national medical specialty society of more than 3,700 physicians and allied health professionals, including a growing number of nurse practitioners and physician assistants. Its mission is to increase access to and improve the quality of addiction treatment; to educate physicians, other health care providers and the public; to support research and prevention; and to promote the appropriate role of the physician in the care of patients with addictive disorders.

My testimony today will focus on the following three facts:

1. Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.

2. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

### **Addiction is a Chronic Brain Disease**

We're here today to provide recommendations on how best to respond to the epidemic of prescription opioid and heroin misuse, addiction and related overdose deaths, which, according to the Centers for Disease Control (CDC), have reached epidemic levels in our country. We've all seen the data and heard the shocking statistics. But what's not said or heard enough is that the 2.3 million people who need treatment for opioid addiction have a chronic disease of the brain. While we need to prevent other Americans from developing addiction, these 2.3 million people need treatment.

Like other chronic diseases, such as hypertension and diabetes, addiction is the result of a combination of biological (genetic) and environmental factors. Rather than affecting the circulatory or endocrine system, however, addiction affects areas of the brain involved in reward, motivation and memory, and leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, cravings, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction

often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

Also like other chronic diseases, addiction can be treated, but it requires long-term management. Historically, we've treated addiction in this country acutely, expecting patients to recover after relatively short stints in detox or rehabilitation programs. Unfortunately, this model of care isn't working, and it's putting patients at heightened risk for overdose when they return to their communities with a reduced opioid tolerance.

Instead, these patients need ongoing chronic disease management, the goal of which is to reduce morbidity and mortality related to their disease, improve functioning, and use the lowest dose of medication possible. Rather than considering whether or not a patient still needs medication to manage his or her illness, we should be looking for treatment outcomes like reduced incidence of infectious disease, increased employment, housing stability, and reduced involvement with the criminal justice system, among other indicators of a return to physical, mental, social and spiritual health.

#### **Addiction Involving Opioid Use Can Be Treated Successfully**

These outcomes are not unattainable for a person suffering from opioid addiction. Indeed, addiction involving opioid use can be treated successfully with a combination of medication and psychosocial services.

There are currently three medications that are FDA-approved to treat opioid addiction: methadone, which has been used in highly regulated opioid treatment programs since the 1960s; buprenorphine, which has been used since 2002 by physicians who complete a special

training in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber.

All of these medications have proven to be clinically effective. A 2013 review of the scientific literature found substantial, broad and conclusive evidence for the effectiveness of all three medications, and for methadone in particular.<sup>1</sup> Notably, the literature on the efficacy of these medications is not new - there are now eight large-scale, rigorously conducted, reviews of the literature on these medications since the early 1980's. In particular, treatment with methadone has been shown to reduce opioid use, criminal justice involvement, drug-related deaths, unemployment and HIV risk behavior. Several studies of office-based treatment with buprenorphine have found it improves treatment engagement; reduces cravings, illicit opioid use, and mortality; and improves psychosocial outcomes. While there were comparatively fewer studies of naltrexone available at the time of the review, the available research did suggest that it is safe, generally well tolerated and results in immediate and complete blockade of opioid receptors and thus discontinuation of self-administered opioids. Additional research is needed to determine whether early experience with extended-release injectable naltrexone, which suggests greater retention in treatment, reduced craving, and lower opioid use, will result in greater patient willingness to continue the monthly injections and the protection from opioid relapse afforded by those injections. It's important to note, as we consider how to expand access to these medications, that naltrexone cannot be administered to pregnant women; only methadone and buprenorphine are safe to use with expectant mothers.

Finally, we have clear and comprehensive guidelines for how to use these medications effectively in the clinical care of persons with addiction. ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* was developed to promote evidence-based clinical treatment of opioid use disorder and to assist physicians in the

decision-making process for prescribing pharmacotherapies to patients with opioid use disorder. It's the first guideline to address all the FDA-approved medications available to treat addiction involving opioid use and opioid overdose - methadone, buprenorphine, naltrexone and naloxone. The guideline offers specific clinical recommendations on the assessment and diagnosis of opioid use disorder, treatment options, managing withdrawal, initiating treatment and switching between medications, psychosocial treatment, and special considerations for populations such as pregnant women, adolescents, and persons involved in the criminal justice system.<sup>2</sup>

**There are Significant Barriers to Access these Medications Leading to a Major Treatment Gap**

However, despite the strong evidence base for the use of these medications and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Less than 30% of treatment programs offer medications and less than half of eligible patients in those programs receive medications.<sup>3</sup> Indeed, a study published just last week in the Journal of the American Medical Association found that 80% of Americans with opioid addiction don't receive treatment.<sup>4</sup>

This treatment gap is attributable to many factors, some more complex than others. Research has demonstrated significant access barriers to methadone, including waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the OTP daily.

The Drug Addiction Treatment Act of 2000 (DATA 2000) was intended to expand access to addiction treatment across geographies and populations by integrating it into the general

medical setting. However, there are also barriers to accessing buprenorphine, including provider willingness and limited insurance coverage. Particularly among specialists like myself and other physicians with advanced training in the treatment of addiction, the limit on the number of patients an individual physician can treat with buprenorphine is a significant barrier to access. ASAM surveyed its members regarding their buprenorphine prescribing practices, in 2013. The results illustrate the difficulties even addiction medicine specialists are having in meeting patient demand. Over 90% of respondents reported having a DEA waiver to prescribe buprenorphine to at least 30 patients with three quarters of those prescribing buprenorphine certified to treat up to 100 patients. However, nearly half reported patient demand in excess of 100 individuals.

In recent months my practice has had to turn away many patients due to the 100 patient limit for buprenorphine. This includes pregnant patients as well as the children of my friends and has resulted in at least 2 overdose deaths. If I am out of town or unavailable, my Physician Assistants are unable to see the patients who need an urgent intake, due to the restrictions on PAs and NPs writing for buprenorphine, which exists even if they are under the guidance of a physician who is board certified in Addiction.

It's important to note that the entire purpose of DATA 2000 was to make opioid addiction treatment available outside OTP settings in traditional physicians' offices, both to increase access in areas where OTPs may be physically inaccessible and to reduce the stigma and patient burden associated with visiting an OTP for treatment on a daily basis. Federal regulation of OTPs is significant, as is state oversight of these facilities. For example, these facilities are required to employ counselors and must be accredited by the Joint Commission or CARF. Regulating individual physician practices in such a manner would undoubtedly overburden smaller practices and drive individual physicians away from offering addiction treatment

services, reducing the already-limited addiction treatment workforce and exacerbating the treatment gap.

This is not to say that the quality of office-based buprenorphine treatment services available is of uniformly high quality. We recognize that diversion of buprenorphine is a problem in many areas and agree that it's a concern. Moreover, due to lack of insurance coverage or lack of qualified providers, some patients don't receive high quality psychosocial support in addition to their medication. That's why our recommendations to lift the patient limits under DATA 2000 include required training on diversion control techniques such as call-backs, pill counts and urine drug screens, as well as comprehensive education on psychosocial supports.

While increased diversion is often cited as a chief concern related to raising the patient limit, research suggests that the relationship between treatment access and diversion is an inverse relationship, meaning greater access may even reduce diversion. Highlighting this is a study out of the University of Kentucky that found an inability to access treatment was a risk factor for using diverted buprenorphine.<sup>5</sup> This finding aligns with what many addiction treatment providers know from experience: when patients cannot access treatment, either due to wait lists or lack of insurance, they may purchase diverted buprenorphine to self-medicate. Additionally, some patients will share their prescription with loved ones who cannot access treatment or sell part of their prescription to cover the expense of the office visit for their addiction treatment if their insurance coverage does not pay for (or does not pay adequately for) the physician's services or the cost of the medication.

Still, because diversion and quality of care remain legitimate concerns, ASAM has proposed a gradual and limited lifting of the DATA 2000 limits. Our recommendations would allow specialists and physicians with additional training to treat up to 500 patients, while being subject

to quality checks by SAMHSA (See Attachment 1). Specifically, ASAM proposes that either Congress or the Secretary of the Department of Health and Human Services (HHS) increase the limit as follows:

- Over a two-year phase-in, increase the limit for prescribing physicians to 250 patients in year 1 and 500 patients in year 2. Prescribers seeking an increase in patient limit must satisfy additional addiction treatment training requirements approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) that covers prescribing, counseling, treatment planning, drug testing, pill recall, etc. This training would be in addition to the buprenorphine certification requirement currently required to qualify for the 30/100 patient prescribing limit.
- Prescribing physicians who are expert in treating addiction as evidenced by board certification by ABAM in addiction medicine or the American Board of Psychiatry and Neurology (ABPN) in addiction psychiatry shall not be required to obtain the additional training, including training on diversion control techniques and psychosocial interventions.
- Additionally, we recommend there be a follow up study on the impact of increasing the limit on diversion rates and treatment access. Specifically, after year 2 of the increased prescribing limit, HHS, in consultation with the Drug Enforcement Administration (DEA), and CDC, should determine what impact, if any, the increase in access to opioid addiction medications has had on: decreasing deaths due to opioid overdose; decreasing diversion rates; and improving patient access to the Food and Drug Administration (FDA)-approved opioid addiction pharmacotherapies.

By coupling a lifting of the patient limit with increased training requirements and accountability for those physicians treating large numbers of patients, we feel we can expand access while also ensuring a certain quality of care. Still, this single strategy should be just one part of broader federal efforts to ensure safe prescribing of opioids for pain, alternate pain therapy options and early identification of and treatment for addiction.

Pain and addiction education should be required curriculum in medical school and encouraged as continuing medical education throughout a physician's career. Communities should have the resources to educate their citizens about these issues and the outreach and surveillance resources necessary to better understand their unique issues and needs.

Thank you, again, for the opportunity to present here today. ASAM looks forward to a continued collaboration on this and other addiction-related issues.

###

<sup>1</sup> Chalk M, Alanis-Hirsch K, Woodworth A, Kemp J, and McClellan T. FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness & Cost- Effectiveness. 2013. Available at: [http://www.asam.org/docs/default-source/advocacy/aaam\\_implications-for-opioid-addiction-treatment\\_final](http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final)

<sup>2</sup> Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1–10.

<sup>3</sup> Abraham AJ, Knudsen HK, Rieckmann T, Roman PM. Disparities in access to physicians and medications for the treatment of substance use disorders between publicly and privately funded treatment programs in the United States. *J Stud Alcohol Drugs*. 2013 Mar;74(2):258-65

<sup>4</sup> Saloner B and Karthikeyan S. Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013. *JAMA*. 2015;314(14):1515-1517.

<sup>5</sup> Lofwall, M.R. and Havens, J.R. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug Alcohol Depend*. 2012 Dec 1;126(3):379-83.

**Appendix: ASAM Position on Bills under Consideration**

<b>Bill</b>	<b>ASAM Position</b>
<p>HR 2536, the Recovery Enhancement for Addiction Treatment Act</p>	<p>ASAM strongly supports this bill as a means of improving patient access to life-saving medications that treat opioid addiction through a strategy that supports improved prescriber education, diversion control and expansion of qualified buprenorphine treatment providers. The current opioid epidemic is compounded by a documented gap in access to evidence-based treatment, including buprenorphine treatment. Expanding the prescribing limit for qualified addiction treatment providers will have an immediate, positive impact on expanding opioid addiction patient access to a clinically and cost-effective addiction pharmacotherapy.</p> <p>ASAM has also recommended an approach to expand the DATA 2000 patient limits that would gradually increase the limits for board-certified specialists and other physicians who have completed additional training requirements (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter). These recommendations propose expanding the patient limit to 250 in the first year of prescribing and 500 thereafter. Physicians prescribing to more than 100 patients under this approach would be subject to random audits by SAMHSA to ensure they are adhering national standards of care and national medical</p>

	<p>practice guidelines for the treatment of opioid addiction with agonist, partial-agonist and antagonist medications (for example, the establishment of individual treatment plans; use of individual, family and group psychosocial services; and use of diversion control strategies). This recommended approach would also expand prescribing authority to nurse practitioners and physician assistants who complete additional training (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter) and practice under the supervision of a physician qualified under these recommendations to treat more than 100 patients.</p>
<p>HR 2805, the Heroin and Prescription Opioid Abuse Prevention, Education and Enforcement Act</p>	<p>ASAM supports this bill but notes that the section directing the establishment of a Pain Management Best Practices Inter-Agency Task Force to develop best prescribing practices may be redundant to efforts currently underway by the CDC. Still, ASAM supports the reauthorization of the Byrne Justice Assistance Grant program, the advancement of public education and awareness campaigns, and the development of naloxone demonstration grants to improve naloxone access.</p>
<p>HR 2872, the Opioid Treatment Modernization Act</p>	<p>ASAM has several concerns with this bill and believes it will have significant unintended consequences on access to addiction treatment involving buprenorphine. Dramatically reducing access to evidence-based addiction treatment at a time when our nation is experiencing an epidemic of prescription opioid and heroin overdose deaths is misguided</p>

	<p>policy. This bill would create several new barriers to treatment by placing unnecessary and excessive administrative burdens on physicians to prescribe buprenorphine, as well as by creating new, additional barriers to becoming certified to prescribe this medication in the first place. In effect, it would reduce the addiction treatment workforce and further restrict already limited access to care for patients in need, particularly in rural and underserved areas where there are already access issues.</p> <p>Moreover, since the bill only amends the section of the Controlled Substances Act governing the use of Schedule III-V narcotics to treat addiction in physicians' offices, it by default only applies to the use of one of the three FDA-approved medications for opioid addiction treatment. It therefore will not be able to have its intended effect of ensuring "the full range of science- and evidence-based treatment options for opioid addiction are fully integrated into treatment," because it narrowly targets only one treatment option.</p>
<p>HR 3014, the Medical Controlled Substances Transportation Act</p>	<p>ASAM is concerned this bill would create significant loopholes that could be exploited by those wishing to transport controlled substances for illicit purposes and undermine local law enforcement agencies' ability to interrupt drug trafficking.</p>
<p>HR 3537, the Synthetic Drug Control Act</p>	<p>ASAM supports the careful regulation of dependence-producing substances. Additionally, ASAM recommends that</p>

	<p>law enforcement measures aimed at interrupting the distribution of illicit drugs should be aimed with the greatest intensity at those causing the most serious acute problems to society. The balance of resources devoted to combating these problems should be shifted from a predominance of law enforcement to a greater emphasis on treatment and prevention programs, as well as programs to ameliorate those social factors that exacerbate drug dependence and its related problems.</p> <p>ASAM would also recommend either a delayed effective date or additional funding for DEA to process research approvals for those scientists currently conducting research on these specific substances.</p>
<p>HR 3680, the Co-Prescribing to Reduce Overdoses Act</p>	<p>ASAM supports efforts to increase co-prescribing of naloxone to patients receiving high-potency, long-acting opioids, so that naloxone is available for home use in the event of an overdose situation experienced by the patient or by any others in the household.</p>
<p>Draft Bill, the Improving Treatment for Pregnant and Postpartum Women Act</p>	<p>ASAM supports efforts to increase access to opioid addiction treatment services for pregnant and postpartum women.</p>

**Attachment 1: ASAM Letter to Secretary Burwell, July 31, 2014**

July 31, 2014

The Honorable Sylvia Burwell  
Secretary, US Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell,

On behalf of the members of the American Society of Addiction Medicine (ASAM), the nation's largest medical professional society representing addiction physician specialists and affiliated addiction health professionals, we respectfully submit to you our recommendations for urgently addressing the opioid epidemic. These recommendations are informed by our members' collective expertise and reflect their myriad specialty backgrounds, the diverse patient populations they serve, and the wide range of clinical settings in which they practice.

Opioid addiction does not discriminate: regardless of income, education level or social standing, opioid addiction looks the same to the practicing addiction doctor. It leads to severe impairment and, far too often, to death. Fortunately, like other chronic diseases, opioid addiction can be prevented and the millions of Americans now suffering from this disease can be treated. As with other chronic illnesses, treatment does not consist of only one simple treatment for all sufferers. Treatment often requires multiple, overlapping therapies that may include medication, behavioral therapy, family therapy, and ongoing recovery support.

With that framework in mind, we urge the Administration to consider proposals that focus holistically on provider and community education, overdose death prevention and increased access to treatment, in order to effectively manage the epidemic. We hope the following recommendations inform and support the critical work you are doing to address this issue.

Sincerely,



Stuart Gitlow, MD, MPH, MBA, FAPA  
President, American Society of Addiction Medicine

Attachment: ASAM Recommendations to Address the Opioid Epidemic

CC:

Pamela Hyde, JD, Administrator, Substance Abuse and Mental Health Services Administrator (SAMHSA)

Elinore McCance-Katz, MD, PhD, Chief Medical Officer, SAMHSA

H. Westley Clark, MD, JD, MPH, Director, SAMHSA Center for Substance Abuse Treatment

Michael M. Botticelli, Acting Director, Office of National Drug Control Policy

## **Overdose Prevention and Opioid Addiction Treatment Recommendations**

### **Section I: Education**

Physicians receive little training about pain management or addiction treatment in medical school or in residency programs. As a result, there is a general lack of understanding and experience among most physicians related to these diseases. This lack of education reinforces the prevailing modes of practice: prescription opioids for pain management and an antiquated view of addiction as an acute behavioral problem for which treatment is only self help or weeks of inpatient rehabilitation.

It is the opinion of ASAM that a lack of education among most physicians about the proper treatment of chronic pain and chronic opioid addiction disease is a considerable contributing factor to the current opioid addiction epidemic. ASAM offers the following recommendations, in an effort to address these problems:

1. Mandatory prescriber education on addiction prevention/treatment tied to DEA certificate to prescribe controlled substances.

- a. Applies to all prescribers of controlled substances including, but not limited to, physicians, nurse practitioners, and physician assistants, as well as to pharmacists.
- b. Education would also be required for recertification.
2. Mandatory medical school education on addiction (minimum 12 hours)
  - a. Schools not in compliance with requirement would be unable to accept students using federal financial aid
3. Community Education Grants on proper use of naloxone, and the continuum of care for treatment of addictive disease

**Section II: Prevention**

Building on the infrastructure of the Drug Free Communities (DFC) program is a cost effective way to invest minimal federal dollars to prevent prescription drug abuse at the community level and get positive results. ASAM recommends:

1. New funding to allow current and past DFC grantees to apply for supplemental grants of up to \$75,000, on a dollar for dollar matching basis, to deal with their community's prescription drug epidemic in a comprehensive, community wide fashion. (\$5 million)

**Section III: Overdose Prevention**

ASAM supports the increased use of naloxone in cases of opioid overdose. Naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal harmful side effects, when used to prevent the often fatal respiratory arrest which characterizes the advanced stages of prescription or illegal "opioid" overdose. Naloxone can be

administered quickly and effectively by trained professionals and by lay individuals who observe the initial signs of an opioid overdose.

Persons provided with naloxone supplies for use in the event of drug overdose, including known illicit opioid users who are provided with these supplies under a public health program of harm reduction, should be educate about the prevention, detection, and appropriate response to drug overdose, for example, how to recognize opioid overdose symptoms and how to refer to emergency medical services. Lay persons offered prescriptions for naloxone at medical visits, or provided with nasal naloxone delivery devices through public health agencies, should also be provided education on proper use of these devices and information on accessing addiction treatment.

Therefore, ASAM recommends:

1. Increase naloxone access with recommended training including: pharmacist training; package inserts appropriate to the patient's level ; and/or community-based training and education about both opioid overdose treatment and about opioid addiction treatment options.

#### **Section IV: Treatment**

A key mission statement of the American Society of Addiction Medicine is, "to increase access to and improve the quality of addiction treatment." A 2013 survey of ASAM's membership revealed that the 100-patient prescribing limit on buprenorphine was considered a major barrier to patient access to care. Furthermore, ASAM public policy specifically recommends against laws, regulations or health insurance practices that impose arbitrary limits on the number of

patients who can be treated by a physician or the number and variety of pharmacologic and/or psychosocial therapies that may be used for treatment. No other disease, no other specialty, and no other medication are limited in this manner.

Fundamentally, the following recommendations are intended to address an escalating opioid epidemic by addressing a policy that significantly limits patient access to a clinically and cost-effective treatment by proposing alternatives that would increase access to pharmacotherapies to treat opioid addiction in a thoughtful, judicious way.

ASAM's recommendations are also supported by the development of an ASAM clinical guideline on pharmacological therapies for opioid use disorders that will establish very clear boundaries around the proper use of buprenorphine in managing opioid addiction, including strategies for mitigating diversion like the establishment of treatment plans and routine random drug screens, pill counts, and prescription drug monitoring program reviews. Recognizing that best practice of chronic diseases requires attention to all elements of a biopsychosocial approach, the guideline also specifically addresses the utility of psychosocial supports in the treatment plan by doing a literature review of all the existing clinical evidence regarding these modalities in the context of medication management of opioid addiction.

Given these considerations, ASAM recommends:

1. Increase of buprenorphine prescribing limit, phased in over 2 years (250 patient limit per physician for year 1, then a 500 patient limit per physician for year 2)
  - a. Prescribing physicians who are expert in treating addiction as evidenced by addiction medicine certification by the American Society of Addiction Medicine (ASAM), board certification in addiction medicine by the American Board of Addiction Medicine (ABAM) , subspecialty board certification in addiction

psychiatry from the American Board of Psychiatry and Neurology (ABPN), or a subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) shall qualify for an increased limit, to 250 in year 1 and 500 in year 2.

- b. Non-addiction specialist physicians seeking an increase in patient limit must satisfy additional addiction treatment training requirements as follows:
  - i. Additional training requirements for non-addiction physician specialists will be developed by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Osteopathic Academy of Addiction Medicine, or any other organization that the Secretary determines is appropriate for purposes of this subclause, in consultation with the Substance Abuse and Mental Health Services Administration (SAMHSA).
  - ii. Such training will consist of a minimum of 40 hours including both didactic and skills-based training based in the standards of high quality care using buprenorphine, as delineated in national medical practice guidelines related to the treatment of opioid addiction with pharmacotherapy (ASAM practice guidelines, to be released in Spring 2015).
  - iii. Training must include at least 2 hours each, in the following areas:
    - 1. The chronic disease of addiction
    - 2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
    - 3. 12 step models of recovery
    - 4. Individual, group and family education and counseling
    - 5. Motivational enhancement theory and skill development
    - 6. Contingency management techniques

7. Development and use of treatment plans
  8. Use of and interpretation of drug screens and tests
  9. Diversion control: random call backs, drug screens, and medication counts
  10. Medical and Psychiatric comorbidities and the coordination of care
  11. Use of prescribed or illicit drugs of abuse while in buprenorphine treatment: integrating the roles of PDMPs, care coordination, contingency management, treatment plans, family sessions, and the continuum of care
  12. Medico-legal and ethical issues in addiction treatment with buprenorphine
- c. Advance-practice providers (APPs, e.g., nurse practitioners, physician assistants) who meet the requirements to obtain a waiver to prescribe buprenorphine can only do so under the supervision of a physician who is certified to treat over 100 patients (see #1a, 1b above)
- i. APPs may not exceed the 100-patient limit.
  - ii. APPs must complete the training course as described in 1b above in order to prescribe buprenorphine to treat addiction.
  - iii. The 100 patients treated by an APP will not be counted as part of their supervising physician's limit.
- d. All prescribers are required to complete 36 hours of continuing medical education related to addiction medicine every 3 years.
- i. Physician specialists, as defined in 1a, could be waived from the ongoing education requirement if they can prove ongoing participation in their board's Maintenance of Certification requirements.

- ii. Physicians practicing under the 100-patient limit would be required to satisfy 9 hours of continuing medical education related to addiction medicine, every 3 years.
  
- 2. All practitioners who are certified to treat 250 or 500 opioid-dependent patients with buprenorphine may be subject to random site audits by the Substance Abuse and Mental Health Services Administration (SAMHSA), in order to assure that high-level prescribers are adhering to national addiction medicine standards of care and to national medical practice guidelines related to the treatment of opioid addiction with opioid agonist, partial-agonist and antagonist pharmacotherapies.
  - a. Audits by SAMHSA shall be in lieu of audits by the Drug Enforcement Administration (DEA).
  - b. Practitioners prescribing to over 100 patients who do not comply with a SAMHSA audit will be subject to an audit by the DEA.
  - c. Physicians prescribing within the parameters of the 30-patient and/or 100-patient waiver will not be subject to SAMHSA or DEA audits.
  - d. Non-physician prescribers shall be subject to audit as part of the audit of their physician supervisors.
  - e. In order to meet audit requirements, prescribers should include the following, as part of their office-based opioid treatment program protocols:
    - i. bio-psycho- social admission assessments, including appropriate physical examination and laboratory testing
    - ii. Formal treatment planning and regular treatment plan updates
    - iii. Screening for medical and psychiatric co-morbidities and referral for treatment

- iv. Utilization of individual, family, and group psycho-education and counseling modalities consistent with guidelines and treatment of other chronic behavioral health disorders
  - v. Utilization of both scheduled and random drug screens, scheduled and random drug tests when appropriate, and Prescription Drug Monitoring Program checks
  - vi. Use of contingency management protocols, with repercussions for failed drug screens/ failed PDMPs consistent with harm-reduction treatment of opioid dependence approach
3. Follow-up study on impact of increase on diversion rates (DEA) and impact on treatment access (HHS/ASPE).
- a. There is evidence indicating that geographic areas of low access to buprenorphine treatment have higher levels of buprenorphine diversion. After year 2 of the increased prescribing limits, HHS, in consultation with the DEA, will determine what impact, if any, the increase in access to opioid addiction medications has had on diversion rates and whether there has been improved patient access to the FDA-approved opioid addiction pharmacotherapies.
4. Remove restriction on initiation of buprenorphine for the treatment of opioid addiction in hospitals.
- a. Under current regulations, physicians who initiate patients for the first time on buprenorphine for the treatment of opioid addiction in hospitals are unable to have the prescription filled by a hospital inpatient pharmacy. Hospitals are currently being told, in writing, that they cannot let their inpatient DEA registration

and their inpatient medication administration procedures apply to the initiation of buprenorphine for opioid addiction.

5. \$50 million in increased Substance Abuse Prevention and Treatment block grant funding for dissemination of evidence-based models for preventing and treating opioid dependence

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Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Katz, 5 minutes for your summary.

**STATEMENT OF KENNETH D. KATZ**

Dr. KATZ. The drug epidemic confronting this Nation has exploded in recent years due to the accessibility of cheaply made, mass-produced deadly synthetic drugs. As a physician on the front line, I have witnessed how these dangerous compounds have directly led to violence, hospitalizations, and deaths. For example, in both the adult and pediatric intensive care units in Allentown, Pennsylvania, this spring, I spent countless hours at the bedside caring for many patients suffering from the toxic effects of synthetic marijuana which ripped through eastern Pennsylvania, leaving in its wake multiple patients in emergency departments, hospitals, and, unfortunately, morgues.

Mr. Chairman and members of the subcommittee, my name is Dr. Kenneth Katz, and I am board-certified in emergency medicine, medical toxicology, and internal medicine. Thank you for allowing me to testify today on behalf of the American College of Emergency Physicians to discuss the dangers posed by synthetic drugs and to advocate for enactment of H.R. 3537, the Synthetic Drug Control Act of 2015.

In every community across the Nation, my colleagues and I are treating more and more patients who have experienced synthetic drug toxicity or poisoning. It is important to understand that the term “synthetic drugs” we are using here today describes substances that are primarily manufactured in clandestine Chinese laboratories and actually represents a nimitety of chemical combinations that are designed to mimic the effects of illegal chemicals with stimulant, depressant, or hallucinogenic properties. They are nonorganic, chemically synthesized, unsafe recreational drugs that produce psychoactive or mind-altering effects.

Many of these substances are marketed as innocuous products, such as incense, plant fertilizer, or air freshener and then sold in convenience stores, gas stations, or online. Because of their commercial availability, many users presume they must be safe. However, the public should not be fooled. Even though these products may be hiding in plain sight, they are colorfully packaged poison.

Unlike most illicit drugs, synthetics can contain a vast array of different chemicals with varying potencies. For example, synthetic marijuana may contain compounds 2 to 500 times more powerful than THC. In many cases, the manufacturer’s only goal is to alter the chemical compound in such a way as to technically create a new compound, allowing them to circumvent legislative and regulatory bans.

This modification process poses increasing risk to users, who are unaware of the reactions the new chemicals or formulation may cause. It is not until these substances are ingested or inhaled that some or all of the following symptoms can occur: hyperthermia; elevated blood pressure and pulse; severe, uncontrollable agitation; seizures; coma; muscle breakdown; kidney injury; and, ultimately, death. Unfortunately, at that point, it may be too late for either my emergency medicine colleagues or even me, as a medical toxicologist, to save them.

While there is an increasingly expanding array of synthetic drugs being manufactured, of particular concern to ACEP is the availability and high use of synthetic marijuana. Whether it is the data from SAMHSA's Drug Abuse Warning Network, DEA's National Forensic Laboratory Information System, or Poison Control Centers, it is clear: Synthetic marijuana use has increased exponentially since it first appeared in the United States a few years ago.

For example, according to NFLIS, there were 21 reported by 2009. By 2012, that number grew to more than 29,000, an increase of more than 1,400 percent. Through the first 6 months of 2014, there were already close to 20,000 synthetic marijuana drug reports. My home State of Pennsylvania has been especially hit hard by the increasing use of synthetic marijuana, trailing only New York, Mississippi, and Texas in the number of reported exposures this year.

Currently, all 50 States have banned some cannabinoids and cathinones, with the majority doing so through legislation. Since synthetic compounds are easily manipulated to make new drugs, many States have passed laws targeting entire classes, substances, or used broad language to describe the prohibited drugs.

Federal statutes must also be updated to meet this constantly evolving challenge and restrain these dangerous products. The Synthetic Drug Control Act of 2015, sponsored by Representatives Charlie Dent and Jim Himes, would amend the Analogue Act so that a substance can be treated as an analogue if it is chemically similar or produces a similar clinical effect. In addition, the bill would add more than 200 known synthetic drugs to Schedule I of the CSA.

This legislation is targeted to the manufacturers and distributors of synthetic drugs, not the end users. H.R. 3537 would amend the Analogue Act so that it would only apply to the sale, manufacture, import, and distribution of drugs, not simple possession.

The easy access to and thoughtless use of synthetic drugs by those who are unaware of their dangerous toxicities not only places their health and lives at risk but can have a profound impact upon my ability to care for all my patients. When users of synthetic drugs need emergency medical attention, they are utilizing precious resources such as ambulances, emergency department beds, hospital personnel, and limited healthcare dollars.

It is both my opinion and that of the American College of Emergency Physicians that this critical issue must be addressed through the enactment of H.R. 3537 and supplemented by a national campaign to educate Americans about the dangers of using synthetic drugs.

Thank you.

[The prepared statement of Dr. Katz follows:]

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Statement of

Kenneth D. Katz, M.D., F.A.C.M.T., F.A.A.E.M.

Section of Medical Toxicology  
Department of Emergency Medicine  
Lehigh Valley Health Network

Allentown, Pennsylvania

On behalf of the  
American College of Emergency Physicians (ACEP)

Before the  
House Committee on Energy and Commerce  
Subcommittee on Health  
U.S. House of Representatives

Hearing on  
Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis

Presented  
October 20, 2015

### I. Introduction

The drug epidemic confronting this nation has been significantly transformed in recent years due to the accessibility of cheaply made, mass-produced, deadly synthetic drugs. The use of these dangerous compounds has directly led to violence, hospitalizations, and deaths. For example, in both the adult and pediatric intensive care units in Allentown, Pennsylvania this spring, I spent countless hours at the bedside caring for many patients suffering from the toxic effects of synthetic cannabinoids. Most notably, there were 11 individuals who tested positive for a novel, potent synthetic cannabinoid, named MAB CHMINACA. This exposure was further corroborated when the identical compound was found in drug material packages found on their persons.

Sadly, the majority of these patients were adolescents who required ventilators to breath and administration of potent sedatives to calm them. Several of these patients experienced seizures, and one teen even suffered irreparable brain damage and died. Needless to say, the impact on the lives of these patients and their families has been incalculable.

During this time, I worked with the Lehigh County district attorney, the Pennsylvania Department of Health, National Medical Services Laboratories and the Philadelphia Poison Control Center to try and rapidly identify the poison which ripped through eastern Pennsylvania, leaving in its wake multiple patients in emergency departments, hospitals and, unfortunately, morgues.

Mr. Chairman and members of the subcommittee, my name is Dr. Kenneth D. Katz, M.D., F.A.C.M.T., F.A.A.E.M., and I would like to thank you for allowing me to testify today on behalf of the American College of Emergency Physicians (ACEP) to discuss the dangers posed by synthetic drugs and to advocate for enactment of H.R. 3537, the "Synthetic Drug Control Act of 2015."

ACEP is the largest specialty organization in emergency medicine, with more than 34,000 members committed to improving the quality of emergency care through continuing education, research, and public education. ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia and a Government Services Chapter representing emergency physicians employed by military branches and other government agencies.

In addition to my work in the Department of Emergency Medicine and Section of Medical Toxicology at Lehigh Valley Health Network in Allentown, Pennsylvania; I am also an Assistant Professor of Emergency Medicine with the Philadelphia College of Osteopathic Medicine. I am board certified in emergency medicine, medical toxicology and internal medicine.

II. What are synthetic drugs?

In every community across the nation, my colleagues and I are treating more and more patients who have experienced synthetic drug toxicity or poisoning. It's important to understand that the term "synthetic drugs" we are using here today describes substances that are primarily manufactured in clandestine Chinese laboratories and actually represents a myriad of chemical combinations that are designed to mimic the effects of illegal chemicals with stimulant,

depressant or hallucinogenic properties. They are non-organic, chemically synthesized, unsafe recreational drugs that produce psychoactive, or mind-altering, effects, and they fall into two main categories: cathinones and cannabinoids.

Cathinones are stimulants with effects similar to cocaine and amphetamine, while cannabinoids are forms of synthetic marijuana that consists of lab-manufactured THC (tetrahydrocannabinol). Many of these substances are marketed as innocuous products such as incense, plant fertilizer or air freshener and then sold in convenience stores, gas stations, or online. Because of their commercial availability, many users presume they must be safe. They are labeled "not for human consumption" to mask their intended purpose and avoid Food and Drug Administration (FDA) regulatory oversight, and they have been given street names such as "Scooby Snacks," "Smiley," "Cloud Nine," and "Vanilla Sky" to make them more attractive and less threatening.

However, the public should not be fooled. Even though these products may be hiding in plain sight, they are colorfully packaged poisons.

### III. Why are synthetic drugs so dangerous?

Most illicit drug manufacturers aim to refine the purity of their products in order to increase the street value and profit margin. However, regarding synthetic drugs, individual products can contain a vast array of different chemicals with varying potencies. For example, synthetic cannabinoids may contain compounds two to 500 times more powerful than THC. In many cases, the manufacturers' only goal is to alter the chemical compound in such a way to technically create a "new" compound, allowing them to circumvent legislative and regulatory

bans. Furthermore, detection of substances such as synthetic cannabinoids is literally impossible using either standard or even advanced drug testing in a hospital laboratory. It can only be performed by sending samples to specialty labs outside of the hospital and, even in these cases, confirmation of a novel compound can take weeks due to the subtle changes made by the chemists producing them.

This modification process poses increasing risks to users who are unaware of the reactions the new chemicals or formulations may cause. It is not until these substances are ingested or inhaled that some, or all, of the following symptoms can occur: hyperthermia; elevated blood pressure and pulse; severe, uncontrollable agitation; seizures; coma; muscle breakdown; kidney injury; and, ultimately, death. Because there is no standard for manufacturing these drugs, the potency of each batch is different, which greatly increases the risk of toxicity. Unfortunately, at that point, it may be too late for either my emergency medicine colleagues, or even me, as a medical toxicologist, to save them.

#### IV. Synthetic drug use increasing

While there is an increasingly expanding array of synthetic drugs being manufactured, of particular concern to ACEP is the availability and high use of synthetic cannabinoids. According to the latest data available from SAMHSA's Drug Abuse Warning Network, the number of emergency department visits involving synthetic cannabinoids increased by nearly 70% between 2010 to 2011 (11,406 to 28,531). Furthermore, the number of emergency department visits for patients aged 12 to 17 doubled from 3,780 to 7,584 during that same timeframe while visits for patients aged 18 to 20 increased fourfold (from 1,881 in 2010 to 8,212 in 2011). There is a

highly disproportionate use of these drugs by males as well who accounted for nearly 80 percent of the 2011 visits.<sup>i</sup>

The 2013 National Drug Threat Assessment Summary notes that the number and type of synthetic cannabinoids have increased exponentially as evidenced by the number of reports submitted to the National Forensic Laboratory Information System (NFLIS). There were 29,467 synthetic cannabinoid drug reports in 2012, which was an increase of 1,402 percent from 2009 when there were only 21.<sup>ii</sup> According to the 2014 NFLIS midyear report, there were already 19,838 synthetic cannabinoid drug reports in the first six months of 2014.<sup>iii</sup>

In addition, the American Association of Poison Control Centers reported 5,230 total synthetic marijuana exposures in 2012. Through September 30 of this year, there have been 6,310 exposure reports, and these numbers do not account for ED presentations and hospital admissions of which the poison control centers are unaware.<sup>iv</sup>

My home state of Pennsylvania has been especially hard hit by the increasing use of synthetic marijuana, trailing only New York, Mississippi, and Texas in the number of reported exposures this year.

#### V. What has been done at the federal and state levels?

Synthetic drugs first appeared in the United States around 2009, and prior to 2010, they were not controlled by any federal or state statute. As these drugs quickly grew in availability, popularity,

and use, the medical community witnessed the terrible effects these drugs had on the lives of their victims, their families, and the communities in which they lived.

In an effort to curb access to these toxic substances, ACEP was proud to work with Representative Dent and Senators Grassley, Feinstein, Klobuchar and Portman to enact the "Synthetic Drug Abuse Prevention Act" as part of the "Food and Drug Administration Safety and Innovation Act" (P.L. 112-144) in 2012. The provisions of that law permanently placed 26 types of synthetic cannabinoids and cathinones into Schedule I of the Controlled Substances Act (CSA) and extended the period of time that the U.S. Drug Enforcement Administration (DEA) may administratively schedule substances under its emergency scheduling authority from 18 to 36 months.<sup>v</sup>

Currently, all 50 states have banned some cannabinoids and cathinones, with the majority doing so through legislation. Since synthetic compounds are easily manipulated to make new drugs, many states have passed laws targeting entire classes of substances or use broad language to describe the prohibited drugs. The intent of these general bans is to prevent new forms of synthetic drugs from remaining unregulated, while still allowing use for approved medical and research purposes.<sup>vi</sup>

#### VI. What more can Congress do?

While our combined effort to modify the CSA in 2012 was a good first step, federal statutes must be updated to meet this constantly evolving challenge and restrain these dangerous products.

The Federal Analogue Act<sup>vii</sup> provides that any chemical that is "substantially similar" to a

controlled substance listed in Schedule I or II of the CSA is to be legally treated as though it were also listed in that schedule.

However, in order to obtain a successful conviction under the Federal Analogue Act, the prosecutor must demonstrate to the jury that the chemical in question: (1) is substantially similar to the chemical structure of a controlled substance; AND (2) causes a stimulant, depressant, or hallucinogenic effect that is substantially similar to that of a controlled substance. The courts have maintained a very high bar for the interpretation of "substantially similar" and cases involving the Analogue Act often turn into courtroom battles of chemists debating the minutiae of molecular structure and endocrinology.

The "Synthetic Drug Control Act of 2015" (H.R. 3537), sponsored by Representatives Charlie Dent (R-PA) and Jim Himes (D-CT), would amend the Analogue Act to strike "substantially" from the analogue definition and allow for a substance to be treated as an analogue if it is chemically similar OR produces a similar clinical effect. This legislation is targeted at the manufacturers and distributors of synthetic drugs, not the end-users. It would amend the Analogue Act so that it would only apply to the sale, manufacture, import, and distribution of drugs -- not simple possession. Furthermore, H.R. 3537 would add more than 200 known synthetic drugs to Schedule I of the CSA.

Enactment of H.R. 3537 is critical, but improved public awareness regarding the risks associated with using synthetic drugs is equally so. ACEP has a long history of conducting public awareness campaigns related to injury prevention and public safety issues, such as: wearing

bicycle and motorcycle helmets, texting while driving, child passenger safety, drunk driving and firearm safety, just to name a few. It has been our experience that these efforts help avert emergency department visits and save lives.

#### VII. Conclusion

The easy access to, and thoughtless use of, synthetic drugs by those who are unaware of their dangerous toxicities not only places their health and lives at risk, but can have a profound impact on my ability to care for all of my patients. When users of synthetic drugs need emergency medical attention, they are utilizing precious resources, such as ambulances, emergency department beds, hospital personnel, and limited health care dollars.

It is both my opinion, and that of the American College of Emergency Physicians, that this critical issue must be addressed through the enactment of H.R. 3537 and supplemented by a national campaign to educate Americans about the dangers of using synthetic drugs.

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<sup>i</sup> Substance Abuse and Mental Health Services Administration (SAMHSA); Drug Abuse Warning Network; The CBHSQ Report; "Update: Drug-Related Emergency Department Visits Involving Synthetic Cannabinoids;" 10/16/2014

<sup>ii</sup> American College of Emergency Physicians Public Health & Injury Prevention Committee; "Synthetic Drug Overdose: An Information Paper"

<sup>iii</sup> Drug Enforcement Administration; Office of Diversion Control; National Forensic Laboratory Information System; 2014 Midyear Report

<sup>iv</sup> American Association of Poison Control Centers; Alerts; Synthetic Cannabinoids

<sup>v</sup> Office of National Drug Control Policy; Synthetic Drugs (a.k.a. K2, Spice, Bath Salts, etc.); Government Efforts to Ban Synthetic Drug Products

<sup>vi</sup> National Conference of State Legislatures; "Synthetic Drug Threats;" 1/13/2015

<sup>vii</sup> Federal Analogue Act (21 U.S.C. §813)

Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Anderson, 5 minutes for your summary.

**STATEMENT OF ALLEN F. ANDERSON**

Dr. ANDERSON. Good afternoon. I am Dr. Allen Anderson, an orthopedic surgeon specializing in sports medicine, and I am also the president of the American Orthopedic Society for Sports Medicine, or AOSSM. It is a nonprofit organization made up of 3,400 orthopedic surgeons specializing in the care of athletic injuries at every level of competition.

Eighty percent of AOSSM members are team physicians, and 60 percent of our members take care of high-contact collision sports, where serious injury can occur. A team physician has unique responsibilities and qualifications. He or she must have fundamental knowledge of on-field emergency care and treatment of musculo-skeletal injuries and medical conditions.

Today, I will discuss the need for a team physician to be able to carry controlled substances when traveling with the team and the problems with current law; the fact that workarounds are not practical; and why H.R. 3014, the Medical Controlled Substances Transportation Act, will enable team physicians to provide the best quality medical care to our injured athletes.

In emergencies or disasters where there is significant trauma, it is critical that a physician have immediate access to controlled substances. There are times, such as during air travel or on a bus, when the team physician is the only medical person available. There are documented cases of players having seizures after concussions on a flight home, and, in such situations, controlled substances are needed to stop the seizure and perhaps save the athlete's life. Additionally, it is humane care to allow a player to take a pain pill if he or she has a broken bone, dislocated shoulder, or torn ACL.

As you watch your favorite team on Saturdays, one or more athletes is significantly injured in almost every game. These players are your constituents from every State. The team physician, who is probably a member of AOSSM, is there on the sideline to render aid and take responsibility for the athlete's wellbeing. This aid is being severely restricted by current law.

The current law prohibits the transportation and storage of controlled substances away from the site of storage that is registered with the DEA. This makes it illegal for team doctors to transport a limited quantity of critical medications that are needed for pain control or emergency management. This is highly problematic for athletic team physicians, who need the ability to maintain a limited supply of controlled substances if a player is injured at an away game. The current law also precludes controlled substances from being transported within the same State or across State lines.

The current workarounds are problematic. Current options include predispensing medications to every member of the team prior to travel. That would be 80 members on a football team. This would create a logistical nightmare.

Delegating the dispensing of controlled substances to the home medical staff in the State of entry. This is also a problem. The opposing team physicians can provide medications, but they have to

independently examine the patient, and they have limited time due to demands to treat their own team. This would be create mal-practice concerns for that physician of prescribing medications and not following that patient.

There are also privacy concerns. The local physician is generally caring for the competing team. This would be unacceptable for the coaching staff to enter the training room.

H.R. 3014 would address these concerns. It allows the physician who is traveling with a team the ability to appropriately manage the injury in a similar fashion to when they are in their home facilities. It does not diminish the need or requirement for controlled substances to be monitored at the current level.

Records of controlled substances dispensed are maintained and subject to inspection by the DEA at any time. The team physician will be responsible for the security of the controlled substances throughout the entire time the team will be traveling, and the duration of transport is limited to 72 hours.

Military flight surgeons and rural large-animal veterinarians have an exemption to carry these medications. Contact sports can be much more perilous than noncombat military maneuvers. It is also hard for me to believe that horses and, potentially, cows could get better medical treatment than our athletes.

This legislation would also benefit patients and physicians who donate their time in declared disaster areas in their States or other States.

Therefore, we urge you to support H.R. 3014, the Medical Controlled Substances Transportation Act, so that we can provide the highest level of care for our injured athletes.

Thank you for giving me this opportunity to testify, and I am happy to take questions.

[The prepared statement of Dr. Anderson follows:]



The American Orthopaedic  
Society for Sports Medicine

*A world leader in sports medicine education,  
research, communication, and fellowship.*

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OCTOBER 20, 2015

Testimony of

**ALLEN F. ANDERSON, M.D.**  
**PRESIDENT**  
**AMERICAN ORTHOPAEDIC SOCIETY FOR SPORTS MEDICINE**

Before the

**US HOUSE OF REPRESENTATIVES**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**SUBCOMMITTEE ON HEALTH**

AOSSM 2016 ANNUAL MEETING JULY 7 - 10, 2016 COLORADO SPRINGS, CO



I'd like to thank you Mr. Chairman, and all of the honorable members of this subcommittee, for the opportunity to testify here today. My name is Allen Anderson, and I am an orthopaedic surgeon specializing in sports medicine. I am also president of the American Orthopaedic Society for Sports Medicine or AOSSM. AOSSM is a 501(C)(3) nonprofit educational organization for orthopaedic surgeons specializing in the care of athletic injuries at every level of competition – youth, collegiate, elite and professional. 60 percent of our members take care of high-contact/collision sports like football or ice hockey, where a serious injury can occur. A team physician must have an unrestricted medical license and be a medical doctor or doctor of osteopathy in good standing. He or she must have a fundamental knowledge of on-field medical emergency care and a working knowledge of musculoskeletal injuries, medical conditions and psychological issues affecting the athlete. The most important responsibility of the team physician is the medical care of athletes of all ages and all levels of competition, whether it be amateur or professional, grade school children or the master athlete.

Today I want to discuss the need for a team physician to be able to carry controlled substances when travelling with the team. I will explain the problems with current law, describe the fact that work-arounds are not practical, and why HR 3014, the Medical Controlled Substances Transportation Act will enable the team physician to provide the best quality medical care to an injured athlete.

In emergencies or disasters when there is significant trauma it is critical that a physician have immediate access to controlled substances in order to adequately treat the patient. Athletes who play contact sports and then fly home on the same day are at much greater risk of having an urgent medical problem than is the usual flying public secondary to recent strenuous activity. There are times, such as during air travel or on a bus, when the team physician is the only medical person available to render care. There are documented cases of players having seizures on a flight, and in such a situation, controlled substances are needed to stop the seizure and save the players life. Additionally, it is humane care to allow a player to take a pain pill in the event that he/she has a broken bone and is flying back home.

One or more athletes are injured in almost every collegiate game you watch on Saturday. These players who are your constituents come from almost every state in the Union. The team physician, who is probably a member of AOSSM, is there on the sideline to render aid and take responsibility for the athletes' wellbeing. This aid is severely restricted by current law.

Currently, the Controlled Substances Act of 1970 prohibits the transportation and storage of controlled substances away from the site of storage that is registered with the Drug Enforcement Agency (DEA) making it illegal for team doctors to transport a limited quantity of critical medications that might be needed for pain control or emergency management while travelling with their teams. This is highly problematic for athletic team physicians who need the ability to maintain a limited supply of controlled substances for those instances where a player is injured during games that are away from home. The DEA and federal law is quite strict concerning the transportation and

dispensing of prescription drugs, and especially controlled substances, in states where the physician is not licensed. A physician may only store, dispense or administer controlled substances at a physical location and address registered with the DEA. Therefore a doctor dispensing or administering controlled substances at multiple practice locations must do so at each location under that location's specific DEA registration number. This applies whether the controlled substances are transported within the same state or across state lines. Most states similarly require physicians to dispense under a state controlled substances registration. Additionally, federal law requires that registrants complete specific DEA forms and invoices for the purposes of each registered location's required records.

The current work-arounds for this are problematic for several reasons. Current options for a team's medical staff include pre-dispensing medication to specific athletes prior to travel, or delegating the dispensing of controlled substances to the home medical state in the state of entry. Travel schedules and limited availability of local physicians to prescribe/dispense controlled substances is an issue. The local physician needs to independently examine the patient, and the local physician has limited ability to follow the patient after they leave the area. There are privacy concerns – the local physician is generally caring for a competing team. The local physician also has competing demands to treat players with his/her primary team.

HR 3014, the Medical Controlled Substances Transportation Act, would address these concerns. It provides the physician who is traveling with a team with a construct in which he/she can appropriately manage the injury – short of surgery or hospitalization – in a similar fashion to when they are at their home sports facilities, including prescribing and dispensing of controlled substances when medically appropriate. It does not diminish the need or requirement for controlled substances to be monitored to a lesser extent than at the primary area of practice; nor does it limit the accountability of the physician. The team physician will be responsible for the security of the controlled substances throughout the entire time the team will be traveling.

Specifically HR 3014 requires the physician to enter into a specific agreement with the DEA in order to transport a controlled substance. The agreement includes the controlled substance to be transported, the practice setting from which the controlled substances will be transported, the practice setting or disaster area to which controlled substances are transported, the dates of transport, the anticipated travel time and the intended mode of transport. The duration of transport is limited to 72 hours and records of the controlled substances dispensed are maintained. It should be noted that these medications are registered and subject to inspection by the DEA at any time.

Thank you for your consideration of this important measure that would allow the highest level of care for an injured athlete.

Military flight surgeons and rural large animal veterinarians have exemption and are able to carry the medications they need. Team contact sports can be much more perilous than non-combat military maneuvers or treating large animals.

This legislation would also benefit rural physicians who travel long distances to see patients, physicians whose practices lie on a state line, and physicians who donate their time to assist patients in declared disaster areas.

The AOSSM appreciates the opportunity to discuss this matter with you today, and I'm happy to answer questions.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the opening statements of our second panel.

I have a UC request. I would like to submit the following documents for the record: statements from the College on Problems of Drug Dependence; the National Association of Convenience Stores; Dr. Cooper, head team physician of the Dallas Cowboys; the Fraternal Order of Police; the Society of Former Special Agents of the FBI; the American Medical Association; the American College of Emergency Physicians; the American Association of Orthopaedic Surgeons; the Center for Lawful Access and Abuse Deterrence; the American Academy of Physician Assistants; and the National Association of Chain Drug Stores.

Without objection, so ordered.

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

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

Mr. PITTS. I will begin the questioning and recognize myself 5 minutes for that purpose.

Dr. Halverson—and, Drs. Sledge and Waller, you can respond here, too—do you all agree that patients addicted to opioids should receive treatment based on their individual clinical needs?

Dr. Halverson?

Dr. HALVERSON. Yes, sir.

Mr. PITTS. Dr. Sledge?

Dr. SLEDGE. Absolutely.

Mr. PITTS. Dr. Waller?

Dr. WALLER. Yes.

Mr. PITTS. How would you each advise HHS to take this principle into account when considering how to responsibly implement Secretary Burwell's recent announcement to expand the use of medication-assisted therapy?

Dr. Halverson?

Dr. HALVERSON. Since I am not a physician, I would like to defer to my colleagues here.

Mr. PITTS. OK. All right.

Dr. Sledge?

Dr. SLEDGE. And I think that prescribing physicians should be trained in all modalities of medication-assisted therapy as well as other options, particularly psychosocial treatment, with abstinence as an option.

Mr. PITTS. Dr. Waller?

Dr. WALLER. So we have looked at this very closely in the area that I treat. I am in charge of a seven-county area with patients and figuring out how to treat that seven-county area. We have been able to delineate two separate groups of patients which we have good data for: those that started very early in life and started earlier, in their adolescence, which have a different brain disease than started later in life. Those groups of patients actually separate us out a little bit, as far as how treatment works.

So I have many patients in my clinic that are physicians, pilots, and lawyers who I don't give any medication to because generally it is not indicated. And we have wonderful outcomes without any medication-assisted treatment for those groups because of many other factors.

My groups, which are 92 percent of my patients, which are Medicaid patients or those without insurance, I find that it is a perilous journey to try to treat them without buprenorphine. And the data backs that up, with a high mortality rate associated with this group of patients specifically.

And so Dr. Sledge and I are saying the same thing. It is absolutely the right treatment for the right patient at the right time, and making sure that we allow for an expansion of use of these medications that save lives in the hands of those people who are trained best to use them.

Mr. PITTS. All right.

You have touched on this, but expand a little bit more on how should differences in certain types of patients and treatment settings and therapeutic options be addressed.

Dr. WALLER. Well, currently, we have guidelines that directly do address the utilization of the medications. These are the first guidelines that look at all three of the FDA-approved medications, and it does speak to the behavioral and psychosocial therapies without medications within there.

Generally, the medication treatment has been done in a cohort of patients that do not represent a physician or pilot or a lawyer, which, in general, we have programs within States that surround them that are different than the general programmatic treatment pathways.

And so utilizing the guidelines that we have delineated with the appropriate education to back that up would be the way that I would say.

Mr. PITTS. Dr. Sledge?

Dr. SLEDGE. An overarching principle identified by the Institute of Medicine for successful treatment included patient self-determination. And I think that H.R. 2872, the Opioid Addiction Treatment Modernization Act, brings patient self-determination back to the equation.

Mr. PITTS. And, in your opinion, what are the most significant obstacles at the present time preventing more individuals with opioid use disorders from receiving the most effective treatments?

Dr. SLEDGE. I think that one-size-fits-all treatment is very detrimental to addressing the opioid epidemic. I think that an assessment of each individual patient, with recommendation and referral based on their individual needs, is essential for successful treatment.

Mr. PITTS. Any other significant obstacles, Dr. Waller?

Dr. WALLER. I think the legal obstacles to be able to obtain the appropriate medications for patients if we deem it is the right medication for them, such as specifically buprenorphine for my patients.

I treat all of the pregnant patients in that seven-county area, and I am out of space. And so I have to turn people away to areas that are either less than optimal for them or, you know, try our best with what we can do, but, unfortunately, that doesn't turn out very well.

Mr. PITTS. Can each of you comment on the role nurse practitioners and physician assistants play in providing office-based opioid treatment?

Dr. SLEDGE. I am not a provider of office-based opioid treatment, so I will defer to Dr. Waller.

Mr. PITTS. Dr. Waller?

Dr. WALLER. Without the utilization of my physician assistants, my office doesn't run. We have the capability to see patients in volume because we have well-trained physician assistants and nurse practitioners that work directly with board-certified people in their other specialties, whether this is a neurosurgeon or an orthopedic surgeon or an addiction specialist. And, in this case, an addiction specialty—you know, coupling my physician assistants along with behavioral therapists with my patients works out really well, and we have great outcomes from this.

And this is a model that has been adopted in the medical home model of care and is relatively standardized throughout medicine. And so to eliminate this as a possibility for this specific disease doesn't make sense from a monetary standpoint nor a patient delivery standpoint.

Mr. PITTS. Thank you.

I am out of time, but, Dr. Katz, you talked about synthetic drugs. And with the movement towards legalization of medical marijuana, is synthetic marijuana considered medical marijuana, or are the advocates trying to include that in medical marijuana?

Dr. KATZ. Not that I am aware of. No, I think we are talking about two different things.

Mr. PITTS. Yes. It is completely synthetic.

Dr. KATZ. Yes.

Mr. PITTS. Yes. That is what I thought.

Thank you.

And, at this time, the Chair recognizes the gentleman from Maryland, Mr. Sarbanes, filling in for Ranking Member Green.

Mr. SARBANES. Thank you, Mr. Chairman.

Before I ask my question, I would ask unanimous consent to enter a letter from the Purdue University College of Pharmacy, Dr. Nichols, which provides some additional perspective on this issue of adding certain synthetic drugs to the Schedule I CSA and the implications of that for scientific research.

Mr. PITTS. Without objection, so ordered.

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

Mr. SARBANES. Thank you.

I appreciate the testimony, everybody.

The first question I wanted to ask was—and maybe, Dr. Halverson, from your, sort of, public health perspective, and Dr. Waller, but others, as well—the word “epidemic” is getting used a lot to describe this. And I, frankly, myself, didn't appreciate that by the CDC definition of “epidemic” we have actually gotten to that point.

Can you comment on—because, you know, “epidemic,” that is kind of used in the vernacular to just describe something that is sort of out of hand and serious. But, you know, if you are talking about “epidemic” where it could be, you know, analogous to a SARS epidemic or a MERS epidemic or an Ebola epidemic, whatever, that is of a difficult scale and degree. And if you could speak to that, any of you.

Yes?

Dr. HALVERSON. “Epidemic” is used in large part because of the fact that we don’t see an easily controllable end, that we experience the phenomenon, whatever it might be, an epidemic of flu or an epidemic related to any disease where the disease is raging beyond our ability to control it, and the disease has the potential to have profound impact.

And so, under those definitions, we certainly have seen an epidemic of opioid abuse, of deaths. And the reality is that we do have an idea of how to address the epidemic, but, at our current point in time, we haven’t reached the point where we can actually say it is controlled.

Mr. SARBANES. Any other perspectives on that?

Dr. WALLER. So the two components of an epidemic is susceptibility to something and then to be able to come into contact with that something and have it spread.

We have seen exactly that pattern with heroin. If it shows up in a community, those people who have susceptibility from a genetic predisposition and then have already been started on opioids or, in the case, unfortunately, of many areas, young people who this is the first drug they touch, in some cases in early high school, and then they have access and a genetic risk, it grows just like the disease that we look at on outbreak, where it just covers the map.

And that is what we are seeing. It kills more people in my State than anything else. And it is all people that are young and healthy as compared to other diseases that affect a whole different population of people.

Mr. SARBANES. So let’s say tomorrow you were appointed the opioid addiction czar, in the same way that we had an Ebola czar—

Dr. WALLER. I accept.

Mr. SARBANES. OK—and you could take whatever steps you thought were necessary, describe what the first two or three things would be, both ones that would require additional resources, would be resource-dependent, as well as, it seems, ones that maybe are not resource-dependent, like lifting some of the caps on the number of patients that can be treated and so forth. What would your steps be?

Dr. WALLER. Well, I think the first step would be a re-education of the population about what the disease of addiction is, that this is a chronic neurobiological disorder that has more data about the brain-disease aspect than any other mental health disease in the history that we have ever looked at—

Mr. SARBANES. So is that PSAs? I mean, what is that? How do you get that word out?

Dr. WALLER. This is a Surgeon General’s report, this is public messaging, this is rebranding of a disease that has been maligned in the face—and we have been treating this with an emotional context, rather than a science context, for years. So that has to be the first place.

Mr. SARBANES. OK.

Dr. WALLER. The second piece is access to all treatments. And the third place is to build a structure around those treatments so that they are delivered with high fidelity and low risk.

Mr. SARBANES. OK. Thank you.

I am interested because I have a piece of legislation on this topic of this idea of encouraging coprescribing of Naloxone at the time that a physician is prescribing a certain kind of opioid.

And, you know, there would be some demonstration projects around this to test the potential of this and to look at the particular circumstances under which that would be appropriate—the kind of patient, you know, their particular vulnerabilities, and the likelihood of a potential overdose, et cetera.

Can you just speak to your perspective on whether that would be a useful step?

Dr. WALLER. Well, first, Congressman Sarbanes, I appreciate that piece of legislation. It is very impactful.

I carry Naloxone in my backpack. It is sitting behind me in a ready, injectable pen, because it is something that we can do—it is an anti-death serum. And so, to have this available in a coprescribing way to family members and to patients alike and to make sure that they are trained in the utilization of this is no different than having an automatic defibrillator on a wall in a gym. I mean, this is something that should be publicly available, and this is a great step toward that. We definitely support that. I personally support this, as well as with ASAM as well.

I think the biggest issue with this—we need to make sure and dispel the myth that somehow adding an antidote changes patients' behavior to use more and more often. That has been found through research to not be true. In the areas with which we have allowed this to be legalized and given to police officers and community members and made it available to patients, we have seen nothing but a decrease in mortality. We have not seen an increase in utilization. We have not seen an increase in amount of utilization per person per time they use. That is just not true.

And when you reverse somebody, that is one more time that they are not dead, and, two, we have an opportunity to get them into treatment.

Mr. SARBANES. So you have to bring all the other measures to bear and view that as kind of a first step back to that opportunity.

Dr. WALLER. Absolutely.

Mr. SARBANES. Yes.

Thank you very much. I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the vice chair of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you very much.

And, first, as a comment to Dr. Anderson, I know you got up here early. I saw you on the airplane, I believe, coming out of Nashville this morning.

And I appreciate—and I am also working with your—not your organization, but people that practice in your area, not just for opioids that they are talking about being able to carry, but, also, a friend of mine is an emergency room physician in Auburn, Alabama, and so he traveled to Kentucky last Thursday night with the Auburn Tigers to watch over the team while they were playing our beloved Wildcats. And there is a licensing issue, too, back and forth about a physician licensed in Alabama to come travel with the

team into Kentucky. We need to fix that, as well, and that is something that we are looking forward to doing.

Second thing, a lot of my good friends back in the legislature in Kentucky, former colleagues of mine, were very aggressive on OxyContin and prescription drugs and put forth ways to manage prescription drug abuse and seemed to be very successful with it. And I know some of the physicians were really having to manage it very closely. And we thought, wow, we really are getting a big handle on the supply of the problem—which, supply is still a problem. You have to attack supply all the way. And, all of a sudden, heroin became a big component in Kentucky.

And somebody told me—I had lunch yesterday with one of our drug task force leaders, and he said it is easier to get heroin now than prescription drugs in Kentucky—I mean, illegal prescription drugs, use of prescription drugs. And so we have to attack the demand for it, as well, in what you guys do.

And so one of the questions I have for those of you who practice in this area—I know, Dr. Halverson, I have a question for you, too, but I don't think you are—you said you are not an M.D. But anyone who would like to answer.

I know there are caps on what practices can use for buprenorphine. And the question is, do you think the current caps should be lifted? And if not, why? And if so, how?

So, any of you who practice in this area, I would love for you to answer that question.

Dr. WALLER. So I can address it initially.

The short answer is: Yes, but safely.

We have identified that this medication is diverted and, in some cases, abused. I have patients that I treat for buprenorphine abuse. They show up, and I treat them for that.

And now that we have the abuse-deterrent versions, the inadvertent utilization of it through snorting or injection has significantly declined, to the point where we generally don't use the mono drug, the buprenorphine by itself, at all in my clinic.

Mr. GUTHRIE. Do the caps put limits on you that you look at it and say, wow, I could treat more people if I didn't have this cap?

Dr. WALLER. I have a 7-month waiting list, and it is purely waiting on slots.

Mr. GUTHRIE. Because of the cap.

Dr. WALLER. Because of the cap. And I have no one else in my community of 1.3 million people that has any space on their cap that is a specialist in this area.

Mr. GUTHRIE. Do the other—both of you practice in this area, I believe, as well.

Dr. Sledge, do you have the same issues with the caps?

Dr. SLEDGE. Well, again, I don't practice office-based—

Mr. GUTHRIE. OK.

Dr. SLEDGE [continuing]. Opioid treatment. And there certainly is not a cap involved with extended-release naltrexone and its incorporation as a medication-assisted therapy.

And, again, with the issue of diversion and abuse, I do think that there needs to be diversion protection in whatever measures are taken to increase—

Mr. GUTHRIE. Let me ask you a question, Dr. Sledge. So, in your comments earlier, you talked about psychosocial should be added to the—that you can't just treat through, like, buprenorphine and those kinds of things. Why is that important?

Dr. SLEDGE. Why is that important?

Mr. GUTHRIE. Uh-huh.

Dr. SLEDGE. You know—

Mr. GUTHRIE. I want you to state the obvious. I want you to say it for the record, why that is important.

Dr. SLEDGE. OK. Absolutely.

And I think just prescribing the medication is not going to effect much of a change in the course of this chronic disease. It is a chronic brain disease that affects not only with biological manifestations but psychiatric, physiological, spiritual, and social manifestations. And all of those areas have to be addressed for ongoing recovery.

I think that medication is uni-dimensional. When it is used alone, it addresses the biological manifestations of the disease. But the disease is multifaceted, and all of those areas must be addressed for recovery.

Mr. GUTHRIE. I have one more question. If anybody wants to add to that?

If not, thanks for doing that.

And, also, I guess this is really for the record, too, Dr. Halverson, because I think a lot of us understand this. But aside from the chronic health impacts of addiction and death from overdose, what other public health or social impacts are associated, in Indiana and nationally—in your role, I know you see this nationally—with opioid use disorders?

Dr. HALVERSON. Right.

So one of the things that we experienced in Indiana with the overdose patients were related to infections that occurred as a result of intravenous drug use.

So, again, part of the issue is people overdose on drugs for a number of different reasons. They frequently will also be affected by infections as well as actual other diseases that weren't intended as part of the effect that they were trying to get from the medication.

But, additionally, there are a number of other issues that are related to the community's overall health. And the ability for the community to be resilient around this kind of disease is important to take into consideration.

In part, there is, I think, a general lack of understanding around drug abuse in particular. I think one of the questions that was asked earlier was related to what would you do to address the community awareness, and part of that is helping people to understand the scientific basis of this disease. It is, indeed, a chronic disease, and we need to begin to treat it in that manner and approach it from a scientific perspective. There still are number of people, unfortunately, that believe that people ought to just quit that, they just ought to stop this. And they don't recognize the fact that this is a disease that needs to be treated.

We have to also make sure that people have access to treatment, which is—in our State as well as others, there are some problems getting access—

Mr. GUTHRIE. Thank you. I am kind of over my time, but I appreciate you answering. I know I am over my time, and the chairman needs to move on, but I appreciate your answer.

Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the ranking member of full committee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

My questions are of Dr. Waller.

As you know, or you mentioned, there are three FDA-approved medications for the treatment of opioid dependence. There is methadone, buprenorphine I guess you have been talking about, and naltrexone. And I am interested in hearing more about methadone.

Could you briefly describe how methadone is used to treat individuals with opiate dependence? And are there special requirements to treat individuals with methadone in a substance abuse context?

Dr. WALLER. Yes, sir. So methadone is a full agonist medication, which means it resembles medications like oxycodone and hydrocodone, morphine, in that way.

So for patients who have traditionally a heroin addiction and specifically injecting heroin, we have great data that states that utilizing this medication in a fully inclusive biopsychosocial environment, not just the medication itself but then specifically adding all of these, the biopsychosocial aspects with that, significantly decreases craving for a drug and, by doing that, allows them to continue to show up and have a very high retention and treatment rate.

So about 75 percent of patients will be retained in treatment on methadone as compared to buprenorphine, where you will retain at about 65 percent. And then for new onset with naltrexone, it is lower than that. That number hasn't been fully vetted. But when we look at the—

Mr. PALLONE. I guess what I am trying to be find out is why buprenorphine should not be regulated like methadone. That is what I am trying to get you to respond to.

Dr. WALLER. So the basics are that the regulations around methadone are significant. And for a primary care physician to onboard the regulations, it would be a minimum of about \$150,000 immediately, with the paperwork, the accreditation through the joint commission, the accreditation through CARF.

And then, at that point, you have to actually—there are specific issues with almost all States where you would have to then par with a community mental health, which requires a request for proposals, which requires a hearing. It almost completely negates the capability for a primary care doctor to deliver this medication at all.

Mr. PALLONE. But, again—I think you were getting at it, but I still don't understand. What are the medical reasons to justify why methadone comes with different requirements than the other two drugs?

Dr. WALLER. Well, one, those are historic, because that is how it was started, and it has been very regulated since it was initially utilized in this manner since the 1960s. Two, it does have a higher potential for abuse than buprenorphine. Three, it has a higher overdose risk than buprenorphine.

And so all of those are much lower in buprenorphine, which is why it is Schedule III and able to be utilized in an OTP, opioid treatment program.

Mr. PALLONE. OK.

One of the bills that we are discussing today, H.R. 2872, proposes bringing the regulations for physicians who prescribe buprenorphine in their offices more in line with the regulations governing methadone.

How would this proposal affect patients' access to buprenorphine, or how would this proposal affect our ability to treat special populations like pregnant women who are opiate-dependent?

Dr. WALLER. It would completely negate my ability to see my patients, and I would have 200 people without treatment immediately in my clinic.

If you look at this from a national perspective, we would shut down any extension or expansion of this pathway, given the amount of money that it takes to get into the pathway and in the amount of regulations surrounding it.

So I think that it would be a—not just me. This is pretty well understood that if that happened it would be catastrophic, and the mortality rate would sky rocket.

Mr. PALLONE. So, basically, it would profoundly affect our ability to respond to the current opioid crisis, in your opinion.

Dr. WALLER. Unfortunately, yes.

Mr. PALLONE. All right.

Now, another major access to—well, patients already face a number of barriers in accessing medication-assisted treatment, or MAT. And one major barrier to access MAT appears to be cultural, social stigma surrounding the use of these medications. Although there is strong evidence supporting the use of MATs, many people, even within the treatment field, continue to believe that using MATs is merely replacing one addiction with another.

Can you comment on this perception? Are patients on MATs merely replacing one opioid addiction with another?

Dr. WALLER. The short answer is no.

But, very specifically, if we look at what we are trying to do, the part of the brain that has been injured is the area that releases a specific chemical called dopamine. These medications re-regulate that so that we can add the beneficial psychotherapies that then stabilize that for long-term.

Unfortunately, we have found that some patients who have used this for an extended period of time, opioids and alcohol, and at very high doses, they injure that part of the brain permanently and that they may require stabilization of those chemicals for a very long time and then sometimes lifetime.

We find that we don't keep all of our patients in my clinic on this. We are able to wean a good number of them, but it takes time. And the data is very clear that, at minimum, it is 18 months to 2 years before the brain begins to heal in that setting.

Mr. PALLONE. All right. Thanks a lot.  
Thanks, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for questioning.

Mr. BUCSHON. Thank you, Mr. Chairman. I appreciate it.

Thank you to all the witnesses for being here. Very much appreciate it. This a big problem, obviously, that all of us want to help solve.

I was a practicing cardiovascular and thoracic surgeon prior to coming to Congress. And we are talking today primarily about treatment, but we all know we also have to probably address this on the front end with training of physicians, beginning in medical school and residency. I can tell you, the amount of training that I had, even as a surgeon, specifically on pain management and the use of narcotics to manage pain was really minimal other than, essentially, on-the-job training during residency. And I think we need to address that moving forward.

I had a nice conversation with Michael Botticelli about an hour ago, as you probably know, the Director of the Office of National Drug Control Policy. And I guess President Obama will be commenting on this specific subject in West Virginia tomorrow, and I will be looking forward to his comments and what they are planning to do to help all of us address this situation.

I also want to comment on what Mr. Sarbanes said about Naloxone. I think that it is important that especially first responders and law enforcement and probably family members of people who have these issues, as well as maybe the people themselves, have access, with the appropriate training. I have used Naloxone myself many times, primarily in intensive-care units when we felt patients were overnarcotized. But there are ramifications of using it, and we just need to make sure everyone has the training. But I really agree with what Mr. Sarbanes said.

The other thing is I think we need to recognize this goes across age groups. For example, in 2013, the most commonly prescribed drug under Medicare Part D was the generic version of Vicodin—not an antibiotic, but a narcotic.

So, with that said, you know, I really appreciate all of your comments today. And I agree with the team doctor, Dr. Anderson, also. We need to address that situation going forward.

Dr. Sledge, can you expand on your experience treating this problem with the available current medications that are out there? I mean, you obviously use other methods other than medication treatment, but your experience at Cumberland also, using those options also?

Dr. SLEDGE. Sure. And I appreciate the question. During the assessment process, you know, we offer options as patients come in, very clear with the course of treatment that we would recommend at the time of the assessment. There are a myriad of referents in the Nashville area if they choose to utilize a different approach.

But we use buprenorphine, typically, to detox, to get the patient opioid-free. And with a sufficient period of time, which is very difficult to achieve in an outpatient setting, but in a residential setting, with a sufficient period of time of abstinence, we can begin

to use a pure opioid antagonist or an opioid blocker, if you will, naltrexone, and administer that in an extended-release formulation that lasts for 30 days in conjunction with their biopsychosocial—

Mr. BUCSHON. OK. And Dr. Waller, I was interested in your comments about 2872, since I am one of the ones that is working on it. And thank you. With that we are still working through this, trying to make sure, actually, we expand access to treatment for patients, and we have a process we are going through that we need to continually work on.

The one thing, though, I do, maybe slightly disagree on is, that we should consider history, and we should consider money, as part of a reason why to do or not to do things as it relates to drug treatment. I understand the practical aspects of that.

So, I mean, what might you suggest? What would your suggestions be to expand, really access to outpatient treatment for these problems? Because, clearly, as you know, what we have now, we have methadone, buprenorphine, and Naloxone—well, naltrex—I keep confusing the two. You know what I am talking about.

Dr. WALLER. I do. Yes.

Mr. BUCSHON. Vivitrol. I mean, we are trying to expand access. If you don't think that we should make sure that everyone is able to offer all of the options for treatment medically, what should we do?

Dr. WALLER. Well, no. I think that I may have misspoke or been misunderstood. I think all three should be available for sure. I use all three—

Mr. BUCSHON. Yes.

Dr. WALLER [continuing]. On a regular basis. I have a number of patients on long-acting naltrexone, and we use it at the time in which it is right for the patient. For some people, it is right at the beginning. For my population in general, though, it is toward the end of treatment as we stabilize them on these other medications and let the psychosocial aspects really start to work.

So the biggest thing that I think we have to do is make sure that those of us who have access, and knowledge, and extra training, and board certification in this area, much like you did in your training, you wouldn't want a general surgeon doing cardiothoracic surgery. You know, just like we want to be able to help our colleagues in primary care by stabilizing these complex patients and helping them to maintain them over a period of time, and then in that fashion.

So I think bolstering the capability for the people who are board certified and trained and focused on this illness to be able to deliver services to a higher number of people, with all of the medications, is of the utmost importance.

Mr. BUCSHON. OK. Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman, now recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions.

Mrs. BROOKS. Thank you, Mr. Chairman, for holding this hearing. And thank you all of the witnesses for coming today.

I specifically would like to thank Dr. Halverson for being here. Welcome to Washington. It is an honor to have you before the panel and always nice to have a fellow Hoosier in the Nation's Capitol. And I have to admit, your experience—State health director,

CDC, now at IU Fairbanks School of Public Health—we are very fortunate to have in you Indiana.

And in fact, I want to thank you, because Dr. Halverson convened a roundtable, at IUPUI with prescribers, pharmacists, members of HHS and VA, and we discussed the challenges Indiana was facing then. As, unfortunately, one of the States leading the country in prescription opioid and heroin drug abuse. And we had quite a discussion that day, and we actually also had someone from the med school who attended, and we appreciated his participation.

But one thing that ONDCP, they released a report in 2011 that cited their intent to encourage medical and health professional schools, such as Fairbanks, to continue expanding the continuing education programs for prescribers. More instruction on measuring pain and prescribing to treat it. Now, that was 4 years ago. I think we are still really struggling in the country with getting our medical schools and our continuing medical education programs, embracing this concept. And could you please discuss not only your efforts, but I would be curious from the panel, what are we doing wrong? Why can we not get our med schools and our continuing medical education and other health educators to focus on the prescribing practices?

Dr. Halverson, would you please start. Because this is not a new issue. ONDCP said it in 2011, so what challenges, obstacles, what do we need to do to get our prescribers onboard with this?

Dr. HALVERSON. Well, thank you, Representative Brooks. We appreciate your interest specifically in this matter. I would also say that the need is clear. It is my understanding we are constantly looking at curriculum, and this is an important issue. I have had conversations with our medical school dean about this issue, but I also know that there are a whole lot of other issues that are also in competition for that time. But I also don't think there is any question about the importance of this education.

Certainly, as we look in Indiana around issues of continuing education and the need to inform all of the prescribers around this issue, continuing education is not in dispute. I think, really, it has been in the implementation, particularly as it relates to reimbursement, and just the logistics around getting it in place. But I don't think there is any disagreement around the importance of the education.

Mrs. BROOKS. Well, I have been involved in higher education before coming to Congress, and I understand the curriculum committees. There is a lot of discussion and a lot of work that goes into providing curriculum. However, when our med schools are saying they get 3 to 5 hours, possibly, in med school on pain, it is just simply not enough. And at this point, to come up with one set curriculum, I think, is a problem. Let's do more.

And I am curious, do we need to be requiring it? Does it need to be mandatory? Should there be certain hours that all prescribers are required to take a year?

I am a lawyer. We have continuing legal education credits that we are required to have every year. There are some requirements—what do the other panelists think? This is very troublesome for me. Not just for physicians, but nurses, dentists, others who are prescribers. What should we be doing?

Any ideas of what can we do to fix this problem? Because we have been talking about it far too long and our educators haven't resolved the issue.

Dr. WALLER. So, two very practical possible solutions, and one is to consolidate the efforts of adding to the curriculum for pain and addiction based on the governing body for the national medical schools rather than having a heterogeneous group of medical schools come up with their own curriculum.

This curriculum has already been developed by SAMHSA as well as CMS, and has put out there as a recommended curriculum. It is there, access to it online for free is available in many locations, so you don't even have to have your own specialist. But you need to have the mandate within the medical schools that this is a part of the curriculum. It is currently not.

Mrs. BROOKS. And unlike my colleague, Dr. Bucshon, who went to med school, I did not, so I don't know what is mandated. Are there other parts in the medical education that are mandated, or is it all left up to each individual med school? I am certain there must be a lot of mandatory curriculum items. Can you give us a couple of examples of a couple of them, and why wouldn't this be one of them?

Dr. WALLER. Well, a specific example is, every medical student has to rotate through the core curriculum, and the core curricula hasn't changed, in 100 years almost. I mean, when you look at it, it is internal medicine; it is general surgery, and then it is the connections between all of those. Pediatrics, and then you rotate through the critical care, the inpatient care, and the outpatient care of each of those. Adding on the specialties has always been an option. And they have seen addiction medicine and pain medicine as a high-end specialty for which many don't have access to rotate.

So until you mandate it as a part of the clinical curriculum so they actually stand next to somebody doing this, there is no way for them to glean from a book how hard it is to talk to some of these patients who have had a horrible early life, and they have to see it. And if you mandate that, they will find it, because there are people everywhere, there is a medical school. There is someone who is board certified in pain or addiction to do this.

And then, I am sorry, my friends are not going to like me for this, but I think that physicians who prescribe controlled substances should be mandated to have ongoing, you know, CME, period. And ASAM agrees with that.

Mrs. BROOKS. I would be curious—and I see that my time is up, but, Mr. Chairman, if I could just ask the panel, I would be curious if anyone on the panel disagrees with that notion?

Dr. SLEDGE. No.

Dr. KATZ. No, absolutely not.

Mrs. BROOKS. Sir?

Dr. ANDERSON. I don't disagree.

Mrs. BROOKS. Thank you. With that, I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentlelady.

Now, without objection, the gentleman, Mr. Tonko, a member of the full committee, is recognized for 5 minutes for questions.

Mr. TONKO. Thank you, Mr. Chairman.

Thank you for the thoughtful discussion by the panelists and to the many in the room who make it their passion to end this epidemic.

I understand that the Drug Addiction Treatment Act of 2000, or DATA 2000, was passed to expand access to addiction treatment, across geographic boundaries, and populations by integrating it into the general medical setting.

So for Dr. Waller, can you describe how DATA 2000 expanded access to addiction treatment services in the United States?

Dr. WALLER. Yes, sir. And, again, Congressman Tonko, thank you for all your hard work in this area. It is greatly appreciated.

Mr. TONKO. Well, we have good partners, so—

Dr. WALLER. So one of the things that it has done, is it has allowed for clinics such as mine, which I work for a medical system. I am an employee of a hospital system, to be able to open our doors and see patients based on a referral, in an outpatient setting, and then deliver the highest quality of care. So it allows for a specialist like me to work in a standard medical setting and deliver care to patients, both for pain and addiction, and all of the psychosocial aspects.

From a primary care aspect, it does allow them to treat in place. And especially in our rural areas of America, which is the largest part of America, there are no methadone clinics. There are no inpatient treatment facilities for hundreds of miles in many places. And in my home State, Michigan, we have an Upper Peninsula that is devoid of treatment. They don't have a buprenorphine prescriber in the entire Upper Peninsula now. This is a large portion of the population that is left without.

So, being able to not make this feel like a criminal act to write this medication for patients, not be fearful of the DEA walking into your office while you are seeing a patient for hypertension to write buprenorphine, and then the availability of the medication to prescribe in a thoughtful, safe way is key. It is expanded in many areas, but we still have a lot to go, and it is for all of those reasons I just stated.

Mr. TONKO. Well I say this in terms of expanding it, the law expanded access to buprenorphine in some ways, but the law did set certain limits. And it is clear from the current opioid crisis that we have outgrown those rules. And as you know, in 2012, 96 percent of our States and the District of Columbia had opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.

So I am concerned that the opioid crisis has outgrown those rules. Could you explain how the current cap of 100 patients, Dr. Waller, has limited our ability to respond to the current opioid epidemic?

Dr. WALLER. Yes. We have two areas that we have dug in pretty deeply above the national level, and me at the local level. One is the first year, you can only see 30. You take your 8 hours of education and make sure that you finish the test and then you get your certification to see 30 patients. The next year you can apply for 100. For that, those of us who were specialty trained capped out at 100 pretty quickly, because the vast majority of the patients funnel to us. And so we capped very early within our areas.

In primary care, we have a large percentage of doctors who have chosen not to write for this medication, despite having an X license. And so what it looks like is we have a large amount of capacity. Well, we have 423 primary care doctors in my medical group, and I have talked to over 300 of them to find out why they won't write this medication in their practice.

And it is consistent. They don't feel like they have the training. They don't feel like they have the support to evaluate and initiate treatment in patients and then stabilize them. They feel comfortable with the maintenance as long as they know they have backup. But the reason that we don't see a lot of primary care doctors raising that, you know, seeing up to 100 patients, or seeing the 30, is because they don't feel like they have the appropriate knowledge and backup. When we have offered that, we have seen, they do a really good job with this. I mean, once they learn about the disease, their ability to treat it is really good.

But it needs to be stabilized in a specialty setting and then handed off. Therefore, raising the cap for people who do this as a specialty, and have board certifications then it would allow us to then hand some of our patients off to primary care over time but then allow us to not have a barrier, in my case, a 7-month waiting list to see patients.

Mr. TONKO. And do you have an opinion on the current prohibition of certain—other professionals that might assist here, prohibition on nonphysician providers prescribing buprenorphine, including nurse practitioners, physician assistants? Does that limit patient access?

Dr. WALLER. It absolutely does. I have two PA, physicals assistants, in my office who are the backbone of my patient evaluation. They are seeing patients as I am sitting here. But we are limited in what they can do. So if I had an urgent intake, they are frozen. They can't see a new patient and start them on buprenorphine, even if they are under my supervision. I can't pick up a phone, they don't have the legal right to write that prescription.

So, starting this in a way in which is appropriately supervised and so that they have somebody to go to for the difficult patients and can onboard this knowledge and training is very important. But the access for them to be able to write these from a practical standpoint, it really just has to happen. They are really moving forward the biggest part of our healthcare system.

Mr. TONKO. Thank you. With that, I yield back. Mr. Chair, thank you very much.

Mr. PITTS. The Chair thanks the gentleman. That concludes the questions of the members who are present. There will be other members who have questions and follow-ups that we will send you in writing. We ask that you would please respond promptly. Members should submit their questions by the close of business on Tuesday, November the 3rd. So members have 10 business days to submit the questions for the record.

Very informative and important issues we are dealing with. Thank you for your expert testimony. It will help us as we proceed to move the legislation, the subject of the hearing. And I want to thank each of you for coming and presenting the expert testimony today.

Without objection, the subcommittee is adjourned.  
[Whereupon, at 5:12 p.m., the subcommittee was adjourned.]  
[Material submitted for inclusion in the record follows:]

**Testimony Submitted on Behalf of Sandra D. Comer, Ph.D.  
The College on Problems of Drug Dependence**

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony to the Subcommittee. My name is Dr. Sandra Comer and I am the President of the College on Problems of Drug Dependence (CPDD), a membership organization with over 1000 members that has been in existence since 1929. It is the longest standing organization in the United States addressing problems of drug dependence and abuse. The organization serves as an interface among governmental, industrial and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

I am also a Professor of Neurobiology in the Department of Psychiatry at the College of Physicians and Surgeons of Columbia University, and a Research Scientist at the New York State Psychiatric Institute. My research focus for over 2 decades has been on the development and testing of novel approaches to the treatment of opioid dependence.

**Scope of the Problem**

Drug overdose is a major cause of injury and death worldwide. For example, in a recent meta-analysis of mortality among regular users of opioids, Degenhardt and colleagues (2011) evaluated 58 prospective studies from numerous countries around the world and determined that the most common cause of death was drug overdose. In the United States, the single leading cause of injury-related mortality in 2008 was poisoning, nearly 90% of which was attributed to both legal and illegal drugs (Warner et al., 2011). For the first time in almost three decades, the number of fatalities attributed to poisoning (41,000) exceeded the number of fatalities attributed to motor vehicle traffic accidents (38,000). In New York City, the age-adjusted rate of emergency department visits related to heroin was 152/100,000 New Yorkers, which was similar to the rate reported in 2004. By comparison, the rate of emergency department visits related to prescription opioids was 110/100,000 New Yorkers in 2009, which was double the rate reported in 2004 (Epi Data Brief, New York City Department of Health and Mental Hygiene, 2011). The risk factors for opioid overdose are a previous history of overdose (Darke et al., 2007; Wines et al., 2007), recent discharge from detoxification programs (Strang et al., 2003; Wines et al., 2007), initiation or discontinuation of opioid maintenance therapy (Degenhardt et al., 2009), recreational use of prescription opioids (Centers for Disease Control and Prevention, CDC Vital Signs, November 2011; Warner et al., 2011), and recent release from prison (Seaman et al 1998; Wakeman et al., 2009).

In response to this serious public health concern, the United Nations' central drug policy-making body, the Commission on Narcotic Drugs, unanimously approved a resolution in March 2012 to promote measures to prevent drug overdose. In support of this resolution, White House Office of National Drug Control Policy (ONDCP) Director Gil Kerlikowske endorsed the need to train public health and safety personnel to recognize drug overdose and administer life-saving techniques and/or medications, including naloxone. Methadone, buprenorphine, the buprenorphine/naloxone combination and naltrexone are also effective treatment medications that would help reduce overdose fatalities. Each of these options will be discussed below, with a particular focus on more widespread distribution of naloxone to persons who are not medically trained. This description will include a summary of what we do and do not know about use of naloxone in this context.

### **One Potential Solution**

Naloxone is a potent, short-acting medication that acts as an antagonist at opioid receptors. It produces no agonist effects of its own, so the risk of abusing the medication is non-existent. Naloxone is effective in both preventing and reversing opioid agonist effects, including respiratory depression, which is the primary cause of death due to opioid overdose (White and Irvine, 1999). The antagonist effects of naloxone are evident within 5 min following administration, and the duration of antagonism at commonly prescribed doses (0.4-0.8 mg) is 45 to 90 min. It is relatively ineffective orally, so it is typically administered intravenously or intramuscularly and more recently, intranasally (Kelly et al., 2005; Kerr et al., 2009; Merlin et al., 2010). Originally approved by the Food and Drug Administration in 1971 for treating opioid overdose, naloxone is traditionally used in both emergency room and non-hospital settings, where it is administered by medically trained personnel.

Although medical professionals have used naloxone successfully for over four decades, non-fatal and fatal opioid overdoses continue to increase steadily and are now at alarming levels. In an effort to understand the circumstances surrounding opioid overdoses, several survey studies have been conducted among drug users (Baca and Grant, 2007; Lagu et al., 2006; Seal et al., 2003; Strang et al., 2000; Tracy et al., 2005). These studies reveal that a large number of users (64-97%) report that they had witnessed at least one overdose (Lagu et al., 2006; Seal et al., 2003; Strang et al., 2000; Tracy et al., 2005). The majority of witnessed overdoses occurred in the presence of a friend (70%), acquaintance (14%), or partner (10%; Strang et al., 2000). Thus, because many overdoses occur in the presence of a witness and because deaths associated with opioid overdoses typically do not occur instantaneously, programs to educate drug users and other non-medically trained persons, such as first-responders (police officers, firemen, etc.) and family members on how to identify and respond to opioid overdoses have been implemented in various countries around the world, including the United States. A particular interest is in training drug users because they are the ones most likely to witness an overdose event and therefore are able to respond immediately. While educating drug users about risk factors associated with opioid overdose is not controversial, training them on how to intervene has been a subject of much debate. In particular, teaching drug abusers how to use naloxone to reverse an opioid overdose has met with substantial resistance in some circles (Bazazi et al., 2010; Coffin et al., 2003; Tobin et al., 2005).

### **Potential Barriers**

#### *Legal Barriers*

One immediate concern with prescribing naloxone to drug users, first responders, and family members is its legal ramifications (Burriss et al., 2009). Naloxone is not considered a controlled substance by the Drug Enforcement Agency, meaning that it is not considered to have abuse potential, but it is classified by the Food and Drug Administration as a prescription medication. Therefore, properly licensed individuals (physicians, nurse practitioners, physicians' assistants, etc.) must prescribe the medication to patients. However, in a few programs in the U.S. and abroad, naloxone is being prescribed to a person who would most likely use it to reverse another person's drug overdose, which raises questions about legal liability for both the prescriber and the person who used the medication on another person. In most states in the U.S.,

dispensing naloxone in this way is illegal (Burriss et al., 2009). In response to this legal quagmire, several states have now passed legislation authorizing naloxone programs and participation by non-professional individuals. New Mexico, in 2001, was the first state to allow naloxone distribution to "lay savers" and "immunity to doctors who administer naloxone to others" (Burriss et al., 2009). In 2005, New York passed laws that were similar to those passed in New Mexico. In other states, specific counties (in California) or cities (Boston, Baltimore) received legal authority to dispense naloxone to drug users and drug non-users for the purpose of reversing opioid overdose in another person. As of December 2014, about half of the states in the U.S. have passed laws allowing for the "prescribing and administration of naloxone and/or criminal protections for bystanders who seek emergency assistance" (Hardesty, 2014 - <https://www.whitehouse.gov/blog/2014/12/17/updated-infographic-overdose-prevention-state-state>).

Although this is a good start, much work remains to be done. Efforts are being made to expand access to naloxone in other states and possible re-labeling of naloxone by the FDA as an over-the-counter medication is being pursued (Kim et al., 2009; Burriss et al., 2009). On April 12, 2012, the FDA convened a "scientific workshop to initiate a public discussion about the potential value of making naloxone more widely available outside of conventional medical settings to reduce the incidence of opioid overdose fatalities" (Federal Register Notice, 2011). In the meantime, empirical data on the effectiveness of naloxone programs in reducing fatal overdoses, as well as the complications associated with non-fatal overdoses, is critically needed.

#### *Resistance by Medical Personnel*

In addition to worries about the legal implications of dispensing naloxone to drug users, other concerns have been raised by medical personnel regarding this practice. For example, Tobin and colleagues (2005) conducted a survey among 327 emergency medical service providers and found that most (56%) of the providers felt that training drug users and other non-medically trained persons to administer naloxone would not be effective in reducing overdose deaths. The most common concerns were that non-medical persons would not be trained to administer naloxone properly, and that they would not know how to accurately identify opioid overdoses. In addition, concerns were raised that drug users specifically would feel that the medical providers were condoning their drug use. In another survey of 363 health care providers (physicians, nurse practitioners, physicians' assistants), 37% reported that they would not consider prescribing naloxone to patients at risk of heroin overdose, 33% reported that they would consider it, and 29% were unsure (Coffin et al., 2003). The reasons that they objected to prescribing naloxone to drug users were not queried, but it is likely that concerns about safety are part of the reasons for the reluctance to prescribe naloxone to drug abusers. One potential problem is that because the half-life of naloxone is shorter than heroin, a recurrence of severe respiratory depression could emerge if emergency personnel were not called and the victim was left unattended after the initial dose of naloxone was administered. Several studies, however, have demonstrated that under most circumstances, a single administration of naloxone is sufficient to provide a sustained reversal of life-threatening respiratory depression (Etherington et al., 2000; Rudolph et al., 2011; Vilke et al., 2003; Wampler et al., 2011).

In another study, cardiac complications and pulmonary edema, as well as violent behavior were reported within 10 minutes after naloxone was administered to patients (Osterwalder, 1996). However, others have reported that cardiac rate and rhythm

improve after naloxone is administered to patients in cardiac arrest (Saybolt et al., 2010). And yet others have concluded that although adverse events associated with naloxone administration during suspected opioid overdose are common (e.g., confusion (32%), headache (22%), nausea/vomiting (9%), aggressiveness (8%)), serious complications (e.g., seizures (4%)) are rare (Buajordet et al., 2004). The study by Buajordet and colleagues (2004) was conducted in out-of-hospital settings where paramedics administered naloxone. Prospective and detailed information about the potential adverse events surrounding naloxone use by drug abusers is needed, given that the incidence of adverse events surrounding naloxone use by medically untrained persons is likely to be higher than when it is used by medical personnel.

#### *Resistance by Drug Users*

While medically trained personnel have multiple concerns about dispensing naloxone to drug users, the drug users themselves have expressed concerns about intervening during overdose episodes among peers. One of the most common reasons cited by drug users for failing to call, or delaying a call, for medical assistance during an overdose was the fear of police involvement, while others reported that they believed that they could handle the event themselves (Tracy et al., 2005; Worthington et al., 2006). Unfortunately, in untrained drug users, common methods used to reverse overdose, such as immersing the victim in cold water, injecting cocaine, milk, or salt water, or pouring milk into the victim's mouth, are relatively ineffective or potentially harmful (Seal et al., 2003). Among those who had received naloxone in the past, 82% reported that the experience was extremely unpleasant (Seal et al., 2003), suggesting that previous exposure to naloxone may be a deterrent to its use among some drug abusers. Nevertheless, the majority (79%) said that they would want to receive naloxone if they overdosed and an even larger majority (87%) reported that they would be willing to participate in a program that provided naloxone and training on how to use it (Seal et al., 2003). Other studies have reported similar outcomes in terms of drug users' willingness to use naloxone to reverse overdose in a peer (Lagu et al., 2006; Strang et al., 1999). Thus, despite concerns about police involvement, most drug users appear to be open to the idea of peer-administered naloxone to treat overdose.

#### *Unintentional Negative Consequences*

Although drug users reported a willingness to administer naloxone if trained in its use and would want others to administer it to them if they overdosed, a subset of users (35%) admitted that they would feel more comfortable using greater amounts of heroin if naloxone was readily available (Seal et al., 2003). Furthermore, 62% of respondents said that they would be less likely to call 911 if naloxone was available during an overdose episode. Other objections to naloxone programs that have been cited are that drug users would be more likely to initiate heroin use if naloxone was readily available (Sporer, 2003) and that they would be less likely to seek treatment for their drug use if the perceived negative consequences of using drugs were reduced (Bazazi et al., 2010). To date, however, these latter two concerns have not been studied sufficiently.

#### **Current Data on Naloxone Distribution Programs**

In February 2012, the Centers for Disease Control and Prevention published the results of a brief online survey of 50 naloxone distribution programs in the U.S. (Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, February 17, 2012). A total of 48 programs responded to the survey from 15 states and the District of Columbia. An estimated total of 53,032 individuals have received naloxone as a take-

home medication and 10,171 overdose reversals have been reported. Many of these programs have successfully implemented naloxone as a routine part of opioid overdose prevention efforts. For example, between 2005 and 2008, 426 individuals in Pittsburgh and Allegheny County, Pennsylvania received naloxone, and 89 reported administering it during 249 individual overdose episodes (Bennett et al., 2011). Of these 249 episodes, 96% were successfully reversed, 3.2% had unknown outcomes, and 0.8% (2 cases) were unsuccessful. Between March and December 2005, 122 individuals in New York City received naloxone, and 50 reported administering it during 82 individual overdose episodes (Piper et al., 2008). Of these 82 episodes, 83% were successfully reversed by naloxone and 17% of the outcomes were unknown. Other programs have reported similar rates of naloxone use and positive outcomes in the U.S. (Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Maxwell et al., 2006; Seal et al., 2005; Tobin et al., 2009; Wagner et al., 2010; Yokell et al., 2011) and abroad (e.g., Dettmer et al., 2001; Hurley, 2011; Strang et al., 2008).

These findings are encouraging and many studies suggest that the impact of naloxone on overdose death rates is positive. For example, after naloxone prescribing was instituted in 2001 in Chicago, 10-20% decreases in heroin overdose deaths were reported between 2001 and 2003 (Maxwell et al., 2006). This trend was noteworthy because a four-fold increase in heroin overdose deaths had occurred in Chicago between 1996 and 2000. Reductions in death rates have also been reported in Massachusetts (Walley et al., 2013). And in Wilkes County, North Carolina, where community efforts to reduce opioid overdoses were instituted, the overdose death rate dropped sharply from 46.6 per 100,000 in 2009 to 29.0 per 100,000 in 2010, whereas overdose deaths increased during the same time period in virtually every other county in North Carolina (Albert et al., 2011). However, naloxone prescribing to drug and non-drug users were implemented relatively late in the program in Wilkes County, so the impact of naloxone per se on overdose death rates is not entirely unclear.

In Western Australia, Hargreaves and colleagues (2002) conducted a time-series analysis that covered the period of time before and after implementation of overdose prevention programs that included dissemination of overdose prevention information to drug users and increased use of naloxone by ambulance staff. These investigators found that after an initial reduction in heroin-related fatalities, their effectiveness declined over time. Because naloxone was not prescribed to drug users in Western Australia (it was only used by emergency medical personnel), it is likely that the reduction in fatalities was due to education alone, which is encouraging. However, the decline in effectiveness over time is a concern. Although the studies in Chicago and Massachusetts suggest that distribution of naloxone may have a measurable effect on overall opioid overdose death rates, no other studies have confirmed this finding. Clearly, more information is needed on this important topic (Compton et al., 2013).

In addition to the need for more empirical evidence of the effectiveness of overdose training and naloxone distribution programs in reducing rates of opioid overdose, some studies suggest that greater efforts could be directed toward improving the training programs themselves. For example, 46 opioid-dependent patients in London and Birmingham who were trained in recognizing and managing opioid overdose showed only partial retention of information 6 months later (Gaston et al., 2009). The number of correct responses increased significantly immediately after training, but steadily declined over time (Gaston et al., 2009). Furthermore, while 80% of the sample (37/46) still had the naloxone that had been prescribed to them 6 months previously, most of them (81%)

kept it at home, where it would only be useful if the overdose happened to occur in their home environment (Gaston et al., 2009). Reasons cited for not carrying the naloxone with them were fear of police involvement, concerns about stigma associated with carrying injection material (a "mini-jet" naloxone formulation was used that included a needle), and the inconvenience of carrying bulky items. Overall, the authors concluded that "training individuals does not seem to be sufficient for these programmes to succeed and a more systematic approach is necessary" (Gaston et al., 2009).

The recent availability of intranasal formulations of naloxone may partly mitigate drug users' concerns about carrying naloxone with them, but more concerted efforts are needed to emphasize the importance of keeping naloxone with them at all times. In addition, longer-term assessments of retention of knowledge should be conducted to determine whether "refresher" trainings are needed and when they should be provided. And finally, other approaches to improving the effectiveness of the training programs should be considered, such as training a drug-using partner or significant other in recognizing and managing opioid overdose.

#### **Other Options for Reducing Overdose Death Rates and Need for Further Research**

Several effective medications are currently available for treating opioid dependence, including methadone, buprenorphine, buprenorphine in combination with naloxone, and naltrexone, and they all have advantages and disadvantages. For example, methadone has been used for decades to treat opioid dependence and its clinical utility is clear (Strain and Stitzer, 2006). However, the stigma associated with methadone maintenance and the inconvenience of daily visits to methadone clinics make this an unattractive option for many abusers, particularly those who may have recently started abusing prescription opioids. Buprenorphine, a partial mu opioid agonist and kappa opioid antagonist, also effectively reduces opioid abuse and dependence (e.g., Carrieri et al., 2006). It is a safer medication than methadone in that it is much less likely to cause clinically significant respiratory depression (Walsh et al., 1994). The ability to obtain buprenorphine from physicians' offices also makes it an attractive treatment option. However, induction onto buprenorphine is sometimes difficult because it can precipitate withdrawal symptoms in individuals who are heavily dependent on opioids, especially longer-acting ones such as methadone (Levin et al., 1997; Walsh et al., 1995). Buprenorphine itself also has abuse potential and, in some countries, has largely replaced heroin as the opioid of choice among intravenous drug abusers (Alho et al., 2007; Comer et al., 2005; Lee, 2006; Obadia et al., 2001). While the buprenorphine/naloxone combination appears to have lower abuse potential than buprenorphine alone, it also has some abuse liability (e.g., Comer and Collins, 2002). Naltrexone, an opioid antagonist, is effective in virtually eliminating the agonist effects of heroin and other opioids (Comer et al., 2002; Navaratnam et al., 1994; Schuh et al., 1999; Verebey et al., 1976). However, compliance with medication ingestion is a problem clinically, leading to low treatment success. Sustained-release formulations of naltrexone are potential solutions to this problem and several studies are currently underway to determine whether this treatment option will be effective in the long-term management of opioid dependence (e.g., Comer et al., 2007). While the available agonist and antagonist medications are effective in reducing opioid abuse and dependence, the associated difficulties with their use highlight the need for novel medication approaches for the treatment of opioid dependence.

**Summary**

In summary, several treatment medications are currently approved by the FDA including methadone, buprenorphine, buprenorphine/naloxone, and naltrexone for treating opioid use disorders as maintenance medications, and naloxone for treating opioid overdose. All of these medications have proven to be effective, but much remains to be done both legislatively and clinically to improve their impact. Legislatively, increasing the availability of methadone, buprenorphine, buprenorphine/naloxone, naltrexone and naloxone to those with OUD will help combat this problem. Clinically, conducting research to determine the most effective ways of using the medications and targeting the interventions to suit the needs of individual patients is still needed.



October 20, 2015

Representative Charlie Dent  
2211 Rayburn House Office Building  
Washington, D.C. 20515

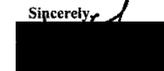
Dear Mr. Dent:

The National Association of Convenience Stores (NACS) is an international non-profit trade association representing the 151,000 convenience and fuel retail outlets in the United States – more than 60% of which are single store operations. Total industry sales in 2014 were roughly \$700 billion, including more than 80% of U.S. motor fuel sales. The industry also employs roughly 2 million people.

NACS wishes to commend you and your colleagues, Representatives Jolly, Himes, and Holmes-Norton, on the introduction of H.R. 3537, The Synthetic Drug Control Act of 2015. Our industry wholeheartedly endorses that bill and the goal of eliminating these dangerous drugs from our society. Earlier this year we joined with the Society of Independent Gasoline Marketers of America (SIGMA) in sending a letter to the National Association of Attorneys General (NAAG) indicating our willingness to work with them in any way possible to ensure these drugs stay off our streets. Today we make that same offer to you.

Please do not hesitate to let us know if NACS can be of any assistance in the future.

Sincerely,



Jon Taets  
Director  
Government Affairs

**The Association for Convenience & Fuel Retailing**

1600 Duke Street • Alexandria, VA 22314-3436 • (703) 684-3600 • FAX (703) 836-4564 • [www.nacsonline.com](http://www.nacsonline.com)

**Daniel E. Cooper, M.D.**  
SPORTS MEDICINE  
RECONSTRUCTIVE AND ARTHROSCOPIC  
KNEE AND SHOULDER SURGERY

September 24, 2015

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AMERICAN  
ORTHOPAEDIC  
SOCIETY FOR  
SPORTS MEDICINE

ACTIVE MEMBER  
ARTHROSCOPY  
ASSOCIATION OF  
NORTH AMERICA

The Honorable Joe Pitts  
United States House of Representatives  
420 Cannon House Office Building  
Washington D.C. 20515-3006

The Honorable Gene Green  
United States House of Representatives  
2470 Rayburn House Office Building  
Washington, D.C. 20515-4327

**Re: HR 3014**

Dear Chairman Pitts and Ranking Member Green:

Please accept this letter of strong support for HR 3014. This is an important issue to athletes, athletic trainers, and team physicians. The following brief discussion highlights the reasons for my strong support of this bill:

Issues-

The Controlled Substances Act of 1970 prohibits the transportation and storage of controlled substances away from the site of storage that is registered with the DEA. This makes it illegal for team doctors to "black bag" a limited quantity of critical medications that might be needed for pain control or emergency management of life threatening medical problems while travelling with their teams.

For decades, there was no awareness that this practice was in violation of Federal Law, and team physicians did travel with such limited quantities of medications that were appropriate for rendering a high level of medical care to their players while travelling. The DEA either overlooked this or was unaware of this practice until several years ago, and now is strictly and aggressively

continued...

**THE CARRELL CLINIC**  
ORTHOPAEDIC SURGERY  
9301 N. CENTRAL EXPWY, SUITE 400 DALLAS, TEXAS 75231  
TELEPHONE 214-220-2468 ANSWERED 24 HOURS DAILY - FAX 214-720-1962

Re: HR 3014  
Page Two

enforcing the law. This has made it impossible to travel with controlled substances, yet there are times such as during air travel or on a bus, when the team physician is the only medical person available to render care. Some domestic flights are 5 hours, and this is a real issue. There are documented cases of a player seizing on a flight, and in such a situation, controlled substances are needed to break a life threatening seizure. Additionally, it is humane care to allow a player to take a pain pill in the event that he has a broken bone and is flying back home to where his support group is. You should understand that athletes who play contact sports and then fly home on the same day are at much greater risk of having an urgent medical problem than is the usual flying public. These scenarios are part of the weekly occurring amateur and professional sports commerce that occurs across our country.

Simple Solution-

HR 3014 offers legislative relief to allow excellent medical care of athletes of many levels. It is reasonable and even common sense to allow a small quantity of controlled substance (less than 10 pain pills and one vial of anticonvulsive medication) to be in a locked "black bag" in the possession of the team physician for a short time during travel to cover away games. It should be noted that these medications are registered and subject to inspection by the DEA at any time. They could be signed out from the stored supply at the site of DEA registration. They would never be exempted from proper record keeping or inspection by the DEA.

Military flight surgeons and rural large animal veterinarians have exemption and are able to carry the medications they need. Please recognize that collegiate and professional contact sports are much more dangerous than non-combat military maneuvers, and that this issue applies to the constituents of all congressmen in all states. Simply said, the athletes who are your constituents and often the children of your supporters, deserve at least the same level of care that Congress affords our nation's military personnel and large animals!

continued...

**Re: HR 3014**  
**Page Three**

Please join us with your full support of a simple piece of legislation that will allow team physicians to provide the highest level of appropriate medical care to the injured athlete.

Best regards,

A black rectangular redaction box covering the signature of Daniel E. Cooper.

Daniel E. Cooper, MD  
Head Team Physician - Dallas Cowboys Football

DEC:mi



**NATIONAL  
FRATERNAL ORDER OF POLICE®**

329 MASSACHUSETTS AVE., N.E.  
WASHINGTON, DC 20002  
PHONE 202-547-8189 • FAX 202-547-8190

CHUCK CANTERBURY  
NATIONAL PRESIDENT

14 October 2015

JAMES O. PASCO, JR.  
EXECUTIVE DIRECTOR

The Honorable Charles Dent  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Representative Dent,

I am writing on behalf of the members of the Fraternal Order of Police to advise you of our support for your bill, H.R. 3537, the "Synthetic Drug Control Act of 2015."

The abuse of synthetic drugs has become a major problem, with increased reports from every region of the country indicating that individuals are committing violent acts while under the influence of these drugs. Many of these drugs induce elevated heart rates, increased blood pressure, and higher body temperature. They can also trigger seizures, hallucinations, and highly agitated states, which make them very dangerous not just to the user but also for those around them.

According to the Drug Enforcement Administration (DEA), Poison Control has seen a 229% spike in calls in relation to synthetic drugs. Hundreds of these synthetic drugs are manufactured overseas in China with no regulation or medical purpose. There have also been reports of 49,000 new chemicals used in these synthetic drugs. This is costing children and teenagers their lives. Also, these synthetics are designed to keep law enforcement from finding the origin of the chemicals. The DEA says they are three steps behind the criminals when it comes to synthetics and analogues.

In the previous Congress, the FOP supported legislation to schedule synthetic marijuana, bath salts, and other synthetic drugs as controlled substances but chemical manufacturers have found loopholes in the current law. Under the current statute, the DEA can prosecute the sale and distribution of these drugs or "analogue" drugs- which are similar, but not chemically identical to the scheduled substances. The loophole these manufacturers are exploiting is that the law on analogue drug sales and distribution does not include any substance "not intended for human consumption." By identifying their products in this way, prosecutions have been made incredibly difficult despite the fact that manufacturers, distributors, and sellers and abusers of these substances all know exactly what to do with them—ingest them or snort them to get a dangerous and unpredictable high.

The legislation you have introduced will declare the certain chemicals used in synthetic drugs as a Schedule I narcotic. This will make it illegal to manufacture, distribute, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

— BUILDING ON A PROUD TRADITION —



On behalf of more than 330,000 members of the Fraternal Order of Police, I thank you for your continued leadership and support of law enforcement. I look forward to working with you and your staff to get this bill through Congress and give the DEA the tools they need to combat the abuse of synthetic drugs. If I can be of any additional assistance, please do not hesitate to contact me or my Executive Director Jim Pasco at my Washington office.

Sincerely,

  
Chuck Canterbury  
National President



**SOCIETY OF FORMER SPECIAL AGENTS OF THE FBI, INC.**

3717 FETTLER PARK DRIVE • DUMFRIES, VIRGINIA 22025-2048  
(703) 445-0026 • FAX (703) 445-0039  
WWW.SOCXFBI.ORG

The Honorable Charlie Dent  
U.S. House of Representatives  
2211 RHOB  
Washington, D.C. 20515

October 20, 2015

Dear Congressman Dent:

On behalf of the Society of Former Special Agents of the FBI (SFSAFBI) and our more than 8,500 members, I am writing to express our support for your proposed legislation, H.R. 3537 Synthetic Drug Control Act of 2015. We have reviewed your proposed legislation and as you are well aware, the original legislation, the Federal Analogue Act of 1986, has become a source of conflict within the different federal judicial districts. Your proposed legislation provides much needed clarification for the courts and the Federal agencies charged with enforcing these laws. There are many very disturbing stories of young people seeking treatment in emergency rooms, who have been seriously injured due to the effects of these synthetic drugs. The SFSAFBI is pleased to support HR 3537 and your effort to enhance the Federal Analogue Act of 1986. Thank you very much for your efforts with regard to this matter.

Sincerely



Larry Langberg  
President  
Society of Former Special Agents of the FBI

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**TESTIMONY**

**of the**

**American Medical Association**

**before the**

**U.S. House of Representatives Committee on Energy and Commerce  
Subcommittee on Health**

**Re: Examining Legislative Proposals to Combat our Nation's Drug  
Abuse Crisis**

**October 8, 2015**

**Division of Legislative Counsel**

**202-789-7426**

STATEMENT  
of the  
**American Medical Association**  
for the Record  
**U.S. House of Representatives**  
**Committee on Energy and**  
**Commerce Subcommittee on Health**

**Re: Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis**

October 8, 2015

The American Medical Association (AMA) commends the U.S. House of Representatives Committee on Energy and Commerce's efforts, through its Subcommittee on Health and Subcommittee on Oversight and Investigations, to address our nation's drug abuse crisis. As the largest professional association for physicians and the umbrella organization for state and specialty medical societies, the AMA is dedicated to promoting the art and science of medicine and the betterment of public health. As part of this mission, the AMA believes that it is up to physicians to be leaders in preventing and reducing abuse, misuse, overdose, and death from prescription drugs and that we need a comprehensive, multi-pronged public health approach to combatting the nation's prescription opioid abuse and growing heroin epidemic. This approach must balance the treatment needs of pain patients with efforts to promote appropriate prescribing, reduce diversion and misuse, promote an understanding that substance use disorders are chronic conditions that respond to treatment, and expand access to treatment for individuals with substance use disorders. These are complex problems with no single solution, and the AMA is working on multiple fronts through the AMA Task Force to Reduce Opioid Abuse as well as our ongoing efforts with Congress and the Administration, our work with the nation's state and specialty medical societies, and through additional efforts with stakeholders in both the private and public sectors to effectuate change in how to address these issues. We welcome the opportunity to submit this statement for the record in the Subcommittee on Health's hearing today.

Physicians are on the frontlines and fully understand the human cost and the toll this growing epidemic is having on patients and their families, as well as on whole communities, across the country. Physicians must take ownership and responsibility for prevention. The AMA is providing leadership and working to offer and implement specific strategies to deal with this epidemic. We are working with a diverse array of stakeholders at the federal and state levels to effect change.

The AMA strongly supports the following legislative reforms, which we believe would help to reduce prescription opioid misuse, abuse, overdose, and overdose deaths: 1) increasing coverage for and access to treatment programs, including medication assisted treatment (MAT); 2) increasing access to overdose prevention measures, such as naloxone, and expanding Good Samaritan protections; and 3) reauthorizing and fully funding the National All Schedules Prescription Electronic Reporting Act (NASPER) to enable modernizing prescription drug monitoring programs (PDMPs). In addition, we support funding to enable expanded public education campaigns to prevent diversion and misuse of prescription drugs. Each of these reforms is discussed in further detail below.

Increasing Coverage for and Access to Treatment Programs

Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management. **However, more resources need to be devoted to ensure availability of, and access to, evidence-based treatment.** A public health-based approach to harmful drug use requires having both broad-based treatment services available for those with opioid use disorders, as well as MAT, and insurance coverage for such treatment. MAT is the use of medications, commonly in combination with counseling, behavioral therapies, and other recovery support services to provide a comprehensive approach to the treatment of opioid use disorders. Food and Drug Administration (FDA) approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone), and naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavioral therapy, motivational incentives, and other modalities. MAT has been shown to be highly effective in the treatment of opioid addiction.

However, we are deeply concerned by the barriers faced by patients who need treatment and by physicians in finding and placing patients in addiction treatment and recovery programs. Many physicians regularly face this dilemma because there is inadequate capacity to refer patients for treatment and recovery programs. There are too few physicians and programs offering treatment and recovery services. Physicians who are on the frontlines of this crisis, particularly those in primary care and emergency departments, continue to report challenges in making referrals to meet patients' needs. As noted by the *Washington Post* in a front-page article focused specifically on the heroin epidemic, which was published on Sunday, October 4, 2015:

Treatment centers are often prohibitively expensive, overcrowded, underfunded and subject to byzantine government rules. Health insurance coverage is stingy to nonexistent. And the social stigma of heroin addiction is still so potent that many users and their families are reluctant to seek help in the first place.

Many states do not offer a full range of MAT for patients in Medicaid programs, or subject Medicaid patients to various prior authorization requirements. Even if a state does cover MAT, some states impose limits on the length of time a patient may receive such treatment. And, despite parity rules for mental health and substance use disorders, some private insurance coverage also imposes limits on treatment, especially long-term coverage. Community-based programs are lacking, and mental health networks and pain or addiction specialists are nonexistent in many areas. **In addition, legislative efforts designed to reduce supply or impose restrictions on treatment can make treating patients with a substance use disorder demonstrably more difficult for physicians.**

Making certain prescription drugs, including those used in MAT, less accessible, however, without policies and strategies to provide treatment and recovery, merely pushes patients out of treatment and toward illegal drugs, such as heroin, that have no legitimate medical use. If the ultimate goal is to provide comprehensive care to our patients and ensure we are doing everything we can as a profession and a society to stop addiction, overdose, and death, a far greater effort is needed to focus on the treatment and recovery side of this crisis.

**For example, the AMA strongly supports increased access to and coverage for treatment for drug addiction and physician office-based treatment of opioid addiction.** The Drug Addiction Treatment Act of 2000 provided for an office-based option for opiate treatment utilizing buprenorphine (a potent synthetic compound that acts on the same opiate receptors as morphine and methadone). However, limits remain on the number of patients a physician may treat utilizing buprenorphine, a drug that can be used to facilitate recovery from opiate addiction. There is broad consensus in the medical community that

buprenorphine is a successful tool to help fight addiction. Lifting the cap would enable physicians to treat more patients with this highly-effective drug.

In addition, suboxone, a combination of buprenorphine and naloxone (an inhibitor of the opiate receptor), is very safe to be administered on an outpatient basis and is available to be prescribed by any licensed practitioner after completing a training curriculum that focuses on the pathophysiology of opiate addiction, screening of patients, symptom identification and management, and prescribing of the medication. Becoming certified as a prescriber for suboxone requires a fee for completion of the training, registration with governmental entities, and after a waiting period, the ability to prescribe suboxone to 30 patients for the first year. The prescriber may submit a waiver request to treat up to 100 patients after the first year.

The regulatory process for becoming a prescriber combined with the patient limits serve as barriers to increase capacity to treat opiate addiction. The advantages of reducing the regulatory burdens to prescribing suboxone would not only increase the availability of suboxone treatment for patients with opiate addiction, but would also increase clinical identification, awareness, and acceptance of opiate addiction as a disease and reduce the stigma associated with it. Several options exist to expand the current capacity to treat opiate addiction: **1) suboxone training could be offered free-of-charge to prescribers with either renewal or initial application of a prescriber's Drug Enforcement Agency (DEA) number; 2) the initial patient cap could be increased with a waiver option after six months instead of one year; and 3) Medicare reimbursement rates for suboxone treatment and counseling could be increased as an incentive for prescribers to treat opiate-addicted patients.**

#### Increasing Access to Naloxone and Expanding Good Samaritan Laws

The AMA strongly supports the national trend of states enacting new laws to increase access to naloxone, which is a safe and effective FDA-approved medication that reverses prescription opioid and heroin overdose and saves lives. Naloxone has no psychoactive effects and does not present any potential for abuse. AMA advocacy has supported new state laws to put naloxone into the hands of appropriately trained first responders and friends and family members who may be in a position to help save lives. **The AMA encourages physicians to co-prescribe naloxone to their patients at-risk who are taking opioid analgesics.**

Since the mid-1990's, community-based programs have been offering naloxone and other opioid overdose prevention services to persons at risk for overdose, their families and friends, and service providers (e.g., health care providers, homeless shelters, and substance abuse treatment programs). These services include education regarding overdose risk factors, recognition of signs of opioid overdose, appropriate responses to an overdose, and administration of naloxone. It is well documented that naloxone has saved thousands of lives across the nation. Despite this progress, however, barriers still exist to optimal use of naloxone in preventing overdose deaths. One way to reduce barriers to the use of naloxone is passage of Good Samaritan laws to protect from liability first responders, friends and family members, or bystanders who may witness an overdose and have access to naloxone. **We urge Congress to provide increased funding for increased access to naloxone overdose prevention programs and to encourage the adoption of broad Good Samaritan protections.**

#### Fully funding and modernizing PDMPs

The AMA strongly encourages physicians and other prescribers to register for and use PDMPs. PDMPs have the potential to serve as a helpful clinical tool in the fight against prescription drug misuse.

The AMA applauds the committee for taking up H.R. 1725, the “National All Schedules Prescription Electronic Reporting Reauthorization Act (NASPER),” and seeing it passed by the House of Representatives earlier this year. **The reauthorization of NASPER and full appropriations are urgently needed to ensure that physicians across the country have patient-specific information through PDMPs at the point-of-care and to incentivize further implementation of best practices and information sharing between states.** Fully funded and modernized PDMPs that contain relevant clinical information and are available at the point of care have been shown to be an effective tool to help physicians and other providers make appropriate prescribing decisions and ensure that patients with legitimate pain management needs continue to have access to medically necessary care.

#### Increased Education for Physicians/Prescribers and Patients

We support enhancing education and training of physicians, prescribers, and patients to ensure informed prescribing decisions to prevent and reduce the risks of opioid abuse. The AMA strongly supports physicians and other prescribers relying on the most up-to-date education and training to ensure that if opioid analgesics are clinically indicated, physicians and other prescribers have the education and training to do so safely and appropriately. Enhanced education—beginning in medical, physician assistant, nursing, dental, and pharmacy schools and continuing throughout one’s professional career—can help all prescribers, pharmacists, and patients identify and address the risks of prescription drug misuse and prevent diversion and overdoses. **Physicians must take the lead in training and educating themselves and their colleagues to ensure they are making informed prescribing decisions, considering all available treatment options and data for their patients, reducing inappropriate prescribing of opioids, making appropriate referrals for patients with opioid use disorders, and taking other steps to ensure appropriate treatment of patients with acute or chronic pain.** The AMA is working with the NABP, National Association of Chain Drug Stores, Federation of State Medical Boards, and other associations on this effort.

In addition, the AMA, along with several other medical organizations, is a partner in the Prescriber Clinical Support System for Opioid Therapies (PCSS-O) funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the American Academy of Addiction Psychiatry. PCSS-O is a national training and mentoring project developed in response to the prescription opioid overdose epidemic. As part of this collaborative, the AMA is developing new training materials on responsible opioid prescribing and a focused educational module on opioid risk management for resident physicians, and is seeking to engage selected states and state medical associations on collaborative approaches to address opioid-related harms.

**We also must confront stigma.** Patients in pain deserve compassionate care just like any other patient physicians treat, and the AMA strongly opposes stigmatizing patients who require opioid therapy. In medicine, we do not use terms such as “malingering” or “drug seeker” because these terms carry with them damaging psychological stigma. Patients who need care are simply “patients,” and we should seek to change the tone of the debate toward more attention on multidisciplinary, patient-centered approaches to pain management and ensuring that evidence-based alternative pain management treatments and strategies are covered by insurance, while supporting opioid-based therapies when clinically appropriate and effective. In a similar vein, we should not use terms such as “addict” or “junkie” or “user” because these terms carry with them damaging psychological stigma. Patients who need care are “patients,” and deserve our care and compassion. Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management. This educational aspect includes, but goes much further than, simply health care professional education.

Another key part of education should be focused on prevention, including public campaigns about safe practices for unused medications. Adequate funding is needed to implement public education campaigns

about how to properly store and dispose of unused opioid medication. The AMA supports the DEA's efforts to promote National Take Back Day and similar efforts to provide a safe and legal way for people to dispose of prescription drugs they do not need.

#### Improving Treatment for Pregnant and Postpartum Women

We are also concerned by the data showing an increase in the incidence of NAS in newborns. Preventing inappropriate opioid use among pregnant women and women of child-bearing age is crucial. For pregnant women who misuse and abuse drugs and alcohol, including prescription opioids, our shared goal must be a healthy outcome for both mother and baby. But we also must caution against policies that could lead to ineffectual treatment of pain for women, particularly those who are pregnant. Like diabetes or hypertension, a substance use disorder is a disease requiring a public health, rather than a punitive response. The same holds true for pregnant women with opioid dependence, who should not be criminalized or face immediate revocation of child custody. **Therefore, the AMA recommends that policymakers support the extensive work done on this issue by the nation's leading national medical specialty societies, including the American Academy of Pediatrics (AAP), the American Congress of Obstetricians and Gynecologists (ACOG), and the American Society of Addiction Medicine (ASAM).** The information from these and other medical societies can help legislators and public health officials design policies that put the interests of the pregnant woman and her baby first and foremost. There are excellent evidence-based practice guidelines (ACOG, AAP, ASAM) that are used today to effectively treat mother and baby.

The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone or buprenorphine. Safe prescribing during pregnancy includes opioid-assisted therapy. Medically-supervised tapered doses of opioids during pregnancy often result in relapse to former use. Moreover, abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. **We urge Congress to provide more resources for treatment programs specifically focused on pregnant/post-partum women and infants born with NAS.**

#### Conclusion

As physicians, we need to be equipped to balance our ethical obligation to treat patients with pain alongside the need to identify signs of diversion. However, we also need coordinated, constructive programs that support education, treatment, and prevention. The AMA is committed to working with Congress and the Administration to address the many facets of this complicated epidemic.



September 16, 2015

The Honorable Charlie Dent  
U.S. House of Representatives  
2211 RHOB  
Washington, DC 20515

Dear Congressman Dent:

On behalf of the American College of Emergency Physicians (ACEP), our 34,000 members and the more than 136 million patients we treat each year, I am writing to express ACEP's support for the "Synthetic Drug Control Act" and to thank you for your leadership on this important patient safety issue.

As emergency physicians, we see first-hand how these dangerous synthetic drugs harm users, increasingly sending them to the Emergency Department (ED) for treatment. The patients we care for often show up with symptoms such as nausea, vomiting, agitation and paranoia. Use of these drugs has even led to numerous overdoses and suicides.

Of particular concern to ACEP is the increasing availability and use of synthetic cannabinoids. According to the American Association of Poison Control Centers, there were 5,230 synthetic marijuana exposure calls in 2012. Through September 13 of this year, there have already been 5,932 exposure calls and neither of these numbers account for ED presentations and hospital admissions of which the poison control centers are unaware. Your home state of Pennsylvania has been especially hard hit by the increasing use of synthetic marijuana, trailing only Mississippi, New York and Texas in the number of reported exposures this year.

Prohibiting the sale of synthetic drugs that imitate the hallucinogenic or stimulant properties of cocaine, ecstasy, methamphetamines or other illegal drugs is critical to limiting access to these unsafe and hazardous products. ACEP believes the provisions of your legislation to: (1) add more than 200 known synthetic drugs that have been identified by the U.S. Drug Enforcement Administration to Schedule I of the Controlled Substances Act and (2) facilitate federal prosecution of the manufacturers, distributors and sellers of synthetic drugs will help curb access to these dangerous substances.

ACEP was honored to support your earlier efforts to enact the "Synthetic Drug Control Act of 2011" and we are proud to stand with you again to enact this legislation as well.

Sincerely,

Michael J. Gerardi, MD, FAAP, FACEP  
President, ACEP

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AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

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ORTHOPAEDIC SURGEONS

October 16, 2015

The Honorable Fred Upton  
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Committee on Energy and Commerce  
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The Honorable Frank Pallone  
Ranking Member  
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The Honorable Joe Pitts  
Chairman, Subcommittee on Health  
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The Honorable Gene Green  
Ranking Member, Subcommittee on Health  
Committee on Energy and Commerce  
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Dear Members of Congress,

We would like to express our support for H.R. 3014, the Medical Controlled Substances Transportation Act of 2015. The bill would authorize physicians, in agreement with the Attorney General, to transport controlled substances from a practice setting to another practice setting or disaster area.

Currently, the Controlled Substances Act of 1970 prohibits the transportation and storage of controlled substances away from the site of storage that is registered with the Drug Enforcement Agency (DEA) making it illegal for team doctors to transport a limited quantity of critical medications that might be needed for pain control or emergency management of significant medical injuries while traveling with their teams. This is highly problematic for athletic team physicians who need the ability to maintain a limited supply of controlled substances for those instances where a player is injured during games that are away from home.

In emergencies or disasters when there is significant trauma it is critical that a physician have immediate access to controlled substances in order to adequately treat the patient. It should also be noted that these medications are registered and subject to inspection by the DEA at any time. We lend our full support to this important bill that will allow our physicians to provide the highest level of appropriate medical care.

Thank you for your consideration of this important measure that will allow the highest level of care for an individual injured in a practice setting other than the physician's own or in a disaster area.

Sincerely,

**American Association of Orthopaedic Surgeons**

**American Orthopaedic Society for Sports Medicine**

**American Association of Neurological Surgeons**

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**American Academy of Ophthalmology**  
**American College of Surgeons**  
**American Orthopaedic Foot and Ankle Society**  
**American Society for Surgery of the Hand**  
**Arthroscopy Association of North America**  
**Congress of Neurological Surgeons**  
**Limb Lengthening and Reconstruction Society**  
**National Association of Athletic Trainers**  
**Orthopaedic Trauma Association**  
**Pediatric Orthopaedic Society of North America**  
**Ruth Jackson Orthopaedic Society**  
**Scoliosis Research Society**



**CLAAD** Center for Lawful Access  
and Abuse Deterrence

October 19, 2015

The Honorable Joseph R. Pitts  
Chairman  
Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Gene Green  
Ranking Member  
Subcommittee on Health  
2322A Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Green:

Thank you for your commitment to addressing our nation's prescription drug abuse and heroin epidemic and the devastating consequences on American families and communities. The not-for-profit Center for Lawful Access and Abuse Deterrence (CLAAD) would like to be of assistance to the committee as you consider federal legislation that would affect patient access to medication-assisted treatment for opioid dependence (MAT). CLAAD's policy positions are established through a consensus process, and our *National Prescription Drug Abuse Prevention Strategy* has been vetted and endorsed by 30 not-for-profit public health and safety organizations.

We urge you to ensure that any MAT-related legislation you support advances three crucial goals:

- Expanding access to MAT;
- Improving the quality of MAT; and
- Reducing the likelihood of medication diversion, misuse, abuse, and accidental exposure.

The Recovery Enhancement for Addiction Treatment Act (H.R. 2536, TREAT Act) represents a step in the right direction toward these goals. The TREAT Act would amend the Drug Addiction Treatment Act of 2000 (DATA 2000) to achieve the following desirable outcomes:

- Increasing the initial buprenorphine patient limit from 30 to 100;
- Extending buprenorphine prescribing authority to advanced practitioners, *i.e.*, nurse practitioners and physician assistants;
- Imposing either certification requirements or restrictions in treatment setting on buprenorphine prescribers who wish to exceed the 100 patient limit; and
- Requiring use of the state's prescription drug monitoring program (PDMP).

The TREAT Act could be improved by:

- Imposing an upper limit on the number of patients whom practitioners with certifications or in qualified settings may treat with buprenorphine; and
- Excluding from the limit lower-risk patients, namely:

- Patients whose buprenorphine is not dispensed to them for self-administration (e.g., administered by implant or injection by a practitioner);
- Women who are pregnant; and
- Persons in stable, long-term recovery, as evidenced by periodic definitive urine drug testing.

On the other hand, the Opioid Addiction Treatment Modernization Act (H.R.2872) does not adequately enhance access to treatment, improve the quality of care, or decrease the risk of diversion, misuse, abuse, or accidental exposure. To the contrary, the bill creates the following barriers to MAT, among others:

- It imposes repetitive training requirements on MAT providers, which would limit practitioners' ability to take courses on other important topics (e.g., ethics, prenatal care, and HIV/hepatitis C prevention and treatment);
- The bill requires practitioners to certify that they can provide, directly or by referral, all FDA-approved MAT medication; yet, not all practitioners have the ability to refer patients to methadone clinics because such clinics are not available in many areas; and
- The bill creates unnecessary waste of provider and government resources with no corresponding benefit to patients or public health and safety by requiring annual provider certifications and duplicative government reporting and oversight.

Please contact us if we may provide additional feedback on the bills before the committee or any other policy proposals. Once again, thank you for your attention to this pressing public health and safety crisis.

Sincerely,



Michael C. Barnes  
Executive Director



Karen L. Thurman  
Senior Government Relations Advisor

**Statement for the Record  
Submitted to  
U.S. House of Representatives Committee on Energy and Commerce  
Subcommittee on Health  
Hearing on "Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis" (Part II)  
October 20, 2015  
On Behalf of the American Academy of Physician Assistants**

On behalf of the more than 104,000 nationally-certified physician assistants (PAs), the American Academy of Physician Assistants (AAPA) appreciates the opportunity to submit a statement for the record regarding legislative proposals to combat opioid drug diversion and abuse. We are pleased that the Subcommittee on Health is addressing this important issue, and we believe that PAs can be a part of the solution to the opioid drug abuse crisis. **As such, we respectfully request that the Subcommittee modify H.R. 2536, the Recovery Enhancement for Addiction Treatment (TREAT) Act, by allowing all PAs to prescribe buprenorphine for the treatment of opioid addiction, subject to state laws and regulations.**

According to the U.S. Department of Health and Human Services, approximately 37% of drug overdose deaths in 2013 were associated with the misuse of prescription opioid medications. While changes have been made to curb prescription drug abuse at both the healthcare provider and drug manufacturing levels, it appears that limiting the availability of prescription opioids has led to a dangerous, unintended consequence: it has become cheaper and easier for many individuals who are dependent on opioids to turn to heroin to achieve similar effects. As a result, the U.S. saw a 39% increase in the number of deaths due to heroin use between 2012 and 2013, and a recent research report from the National Institute on Drug Abuse cited a 2012 study which found that 86% of "young, urban injection drug users" had first abused prescription opioid medications. AAPA supports Congress's desire to stop opioid addiction before it occurs; however, these statistics will not improve without enlisting the help of additional providers to treat those who are already addicted.

**PA Education and Practice**

PAs receive a broad medical education over approximately three academic years which includes coursework in anatomy, physiology, biochemistry, pharmacology, physical diagnosis, behavioral sciences, and medical ethics as well as more than 2,000 hours of clinical rotations. PA rotations include primary care, emergency medicine, family medicine and psychiatry among other areas of specialty, and they often vary in practice setting and location. The majority of PA programs award a master's degree to graduates, and PAs must pass the Physician Assistant National Certifying Examination and be licensed by their state to become certified to practice. Once practicing, PAs must complete 100 hours of continuing medical education every two years and pass a national recertification exam every ten years to maintain their certification.

PAs practice and prescribe medication in all 50 states, the District of Columbia, and all U.S. territories with the exception of Puerto Rico. PAs manage the full scope of patient care, often handling patients with multiple comorbidities. In their normal course of work, PAs conduct physical exams, assist in surgery, diagnose and treat illnesses, order and interpret tests, and counsel on preventative healthcare. The

rigorous education and clinical training of PAs enable them to be fully qualified and equipped to manage the treatment of patients with opioid addiction.

**PA Prescribing Authority and AAPA Actions**

PAs are currently permitted to prescribe in all 50 states and the District of Columbia; 41 states and D.C. also allow PAs to prescribe Schedule II drugs. PAs are currently able to prescribe Schedule III buprenorphine to their patients for pain management, but the Drug Addiction Treatment Act of 2000 does not allow PAs to prescribe this medication for the treatment of opioid addiction. In light of the shortage of physicians specializing in mental health and addiction medicine, AAPA strongly believes that PAs must be able to treat their patients to the extent allowed under state laws. As such, they should be authorized to prescribe buprenorphine to treat opioid addiction in states where they are already permitted to prescribe similarly-scheduled medications.

AAPA has been proactive in ensuring that PAs have access to continuing education and other coursework related to safely prescribing opioid medications as well as recognizing and treating patients who are experiencing addiction to such substances. Thousands of PAs have participated in the CO\*RE Risk Evaluation and Mitigation Strategy (REMS) educational activity on safely prescribing extended release and long-acting (ER/LA) opioid painkillers, and AAPA is pleased to be a partner among several other provider groups in continuing to provide opportunities for inter-professional education in this area. Additionally, AAPA has hosted multiple online and in-person CME courses addressing opioid abuse, pain management, and safe prescribing, and plans to remain active in encouraging PAs to remain up to date on current best practices surrounding the responsible prescribing of opioid medications and comprehensive assistance for those who become dependent.

**H.R. 2536, the TREAT Act**

AAPA is pleased that the TREAT Act appears to have the intention of allowing PAs to prescribe buprenorphine to patients who are experiencing addiction to opioid drugs as part of a comprehensive treatment plan, as appropriate. However, the legislative language found in Section 4 of the bill, which defines “qualifying practitioner,” gives this authority to both PAs and nurse practitioners (NPs) who are “supervised” by physicians under state law, but only does so for NPs who “collaborate” with physicians – not PAs. This is problematic because the state of Alaska, the District of Columbia, and the U.S. Department of Veterans Affairs use “collaborate” to define the relationship between PAs and physicians. As a result, the legislation as currently drafted would arbitrarily leave out a number of PAs and potentially leave out many more as other states update PA practice laws to use the term collaboration.

Due to the nature of the PAs’ national certification process, there is no practical difference in education or experience between a PA practicing in a “supervision” state versus a PA practicing in a “collaboration” state. While the term used to describe how PAs interact with physicians is chosen at the discretion of each state, states have largely given PAs a wide scope of practice, with some states even allowing PAs to own their own practices. In many rural and medically-underserved areas, it is not uncommon for a PA to be the only healthcare practitioner for miles, meaning PAs are their patients’ primary medical provider. This is particularly true in Alaska – a state known for its remoteness and limited access to healthcare – but due to the state’s use of “collaboration” in its statute, under the TREAT Act, patients in the most rural parts of the state may not have access to all of the tools necessary to combat opioid addiction.

Many states are beginning to recognize that the term “collaboration” is a more accurate description of the relationship between PAs and the physicians with whom they work than “supervision,” and several are entertaining legislation to make a change to their statutes to reflect this shift in language and thinking. In 2014, 49 states and D.C. made changes to their laws and regulations with the goal of increasing PA scope of practice. Unfortunately, the TREAT Act as written would represent a step backwards for the PA profession, and more importantly, for patients.

**Recommendations**

AAPA strongly supports the underlying intentions of the TREAT Act. However, we cannot support the legislation as drafted. Instead, AAPA requests that the language defer to state prescribing and scope of practice laws, regardless of the term used to describe PA practice. This change would ensure that the bill remains up-to-date even as state laws evolve, and it is our belief that it would ultimately represent the sponsors’ intentions of increasing access to comprehensive opioid addiction treatment to patients in every state. At the same time, AAPA would support the inclusion of additional training, continuing medical education or transparency measures for PAs who opt to prescribe buprenorphine to their patients.

AAPA stands ready to work with the Subcommittee in advancing the role of PAs in the treatment of opioid addiction. Please do not hesitate to contact Sandy Harding, Senior Director of Federal Affairs, at [sharding@aapa.org](mailto:sharding@aapa.org) or 571-319-4338, should you need further information.



Statement  
Of  
The National Association of Chain Drug Stores  
For  
United States House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Health

Hearing  
on:

“Examining Legislative Proposals to Combat our Nation's Drug  
Abuse Crisis”

October 20, 2015  
4:00 p.m.  
2322 Rayburn House Office Building

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NACDS Statement on Examining Legislative Proposals  
to Combat our Nation's Drug Abuse Crisis  
October 20, 2015  
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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Green, and members of the Energy and Commerce Subcommittee on Health for the opportunity to submit a statement for the hearing on Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis. NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement personnel, policymakers and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities aimed at preventing drug diversion and abuse. Since our members operate pharmacies in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem nationwide. We believe that holistic approaches must be implemented at the federal level.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit [www.NACDS.org](http://www.NACDS.org).

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### **Background**

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion and abuse and are collectively known as “controlled substances.” The CSA creates a closed system of distribution for controlled substances; the Drug Enforcement Administration (DEA) often refers to this as “cradle-to-grave” control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA. States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription drug abuse. Pharmacists and other pharmacy personnel are all trained to understand and comply with this complex regulatory matrix.

### **Chain Pharmacy Initiatives**

To comply with DEA's “cradle to grave” regulatory regime, chain pharmacies have created a variety of loss prevention and internal security systems that are in place from member prescription drug distribution centers right down to the point of dispensing to the patient. Our members undertake initiatives to ensure that prescription drugs are accounted for throughout every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, training employees on controlled substance laws and regulations within 30 days of hire, maintaining electronic inventories of controlled substances and

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conducting random audits. Our members work closely with law enforcement to see that perpetrators of crimes relating to controlled substances are brought to justice.

Specifically at the pharmacy level, examples of NACDS-member initiatives include training pharmacy personnel on how to handle suspect prescription drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, pharmacy and chain distribution centers are required to be highly secured with physical barriers and utilize heavy duty safes, secure cages, and complex alarm systems. Some pharmacy chains also utilize cameras and closed-circuit television surveillance to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign "codes of conduct," which commits them to compliance and some will conduct drug testing, including random, for cause, and pre-employment testing.

Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients, and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

#### **Legislative Initiatives**

NACDS shares the goals of policymakers to curb the incidence of fraud and abuse and appreciates the work that has been done over the last year, such as with the 21<sup>st</sup> Century

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Cures Initiative. NACDS believes that any potential programs aimed at “locking-in” a beneficiary to a certain pharmacy or pharmacies - such as the one included in the 21<sup>st</sup> Century Cures Initiative - must ensure that legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the beneficiaries who need them most.

While the use of a single pharmacy could decrease incidents of fraud, waste and abuse as well as provide the potential for better care coordination, a lock-in provision may actually be a barrier to care as supply chain issues exist around these medications which are beyond the pharmacy's control. Also, patients often legitimately see multiple doctors representing different specialties in different locations. In addition, there are instances due to location and /or services offered (e.g. compounded or specialty drugs) that a single pharmacy may not meet all the needs of a specific patient.

In order to protect legitimate patient access while combating prescription drug abuse and diversion, mechanisms must be included in any legislation that would allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment for beneficiaries. This includes ensuring that back-up systems are in place which would allow a beneficiary to obtain needed medication in the event their “locked-in” pharmacy is unable to supply the medication. Without this, the potential for harm from unnecessary delay in obtaining medication is possible.

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Additionally, NACDS believes a beneficiary should be able to select a pharmacy location, or number of locations that are under common ownership and that electronically share a real time, online database. The ability to share real-time data will ensure that beneficiaries are only obtaining the necessary prescriptions while protecting beneficiary access and health.

#### **The Role of DEA**

According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription. An order purporting to be a prescription that is not issued in the usual course of professional treatment is not a prescription within the meaning and intent of section 309 of the CSA (21 U.S.C. 829), and any person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the CSA.

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. As such, the CSA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the legitimate medical use of controlled substances.<sup>1</sup> As briefly mentioned above, the CSA

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<sup>1</sup> In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the

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requires that a pharmacist, prior to dispensing any controlled substance, make the following determinations—whether the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a “legitimate medical purpose” “by a prescriber acting in the usual course of his or her practice.”<sup>2</sup> The former obligation is called “corresponding responsibility,” and if the two elements are not met, the prescription is not valid. DEA interprets a pharmacist’s corresponding responsibility “as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ‘knows or has reason to know that the prescription was not written for a legitimate medical purpose.’”<sup>3</sup>

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to treat medical conditions and ease patients’ pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

### **The Role of FDA**

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided FDA the authority to impose risk management plans on

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usual course of his or her practice. The rule places a *corresponding responsibility* upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

<sup>2</sup> 21 C.F.R. 1306.04(a).

<sup>3</sup> *East Main Street Pharmacy*, 75 FR 66149, 66163 (Oct. 27, 2010).

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prescription drugs; this program is known as Risk Evaluation and Mitigation Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented is a REMS for extended release and long-acting opioid products (“ER/LA opioid drugs”). These are pain relieving medications that have an elevated potential for abuse. The central component of this “Opioid REMS” is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) so that ER/LA opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like ER/LA opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA’s Opioid REMS.

In 2011, FDA announced a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. NACDS and other industry stakeholders worked closely with FDA to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA, and believe such a collaborative effort should serve as a model for similar programs to address prescription drug abuse.

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### **The GAO Report**

Numerous groups and state and federal entities are working to reduce the problem of prescription diversion and abuse. Unfortunately, in their efforts to combat prescription drug abuse, federal agencies have not been effectively coordinating their efforts to assure access to prescription controlled substances for patients who legitimately need these medications. In GAO's recent report that examines shortages of prescription drugs that contain controlled substances, GAO found that DEA and FDA have not established a sufficiently collaborative relationship to ensure an adequate supply of controlled substance medications.<sup>4</sup> GAO found that the barriers to coordination prevent DEA and FDA from preventing or alleviating shortages<sup>5</sup>. Although critical to their efforts, a memorandum of understanding (MOU) between the two agencies has not been updated in 40 years.<sup>6</sup>

Specific to DEA, GAO found that:

- DEA does not meet its requirements due to lack of internal controls for data reliability, performance measures, and performance monitoring,<sup>7</sup>
- Insufficient internal DEA controls lead to errors in its data system,<sup>8</sup>
- DEA has not met required time frames for more than a decade,<sup>9</sup> and
- DEA is not prepared to respond to future prescription drug shortages.<sup>10</sup>

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<sup>4</sup> "Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved;" Government Accountability Office; February 2015; pp. 43-51.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid., at 46.

<sup>7</sup> Ibid., at 29.

<sup>8</sup> Ibid., at 47.

<sup>9</sup> Ibid.

Considering the patient harm that occurs due to prescription drug shortages, the concerns identified by GAO about lack of federal agency coordination, and serious DEA deficiencies, we believe that Congress should act. Federal agencies must come together behind a comprehensive approach and pursue drug abuse prevention policies that are strategically designed to target enforcement efforts while still maintaining access to prescription controlled substances for patients who legitimately need these medications.

Since NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications, we supported H.R. 471, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015," which passed in the House in April. This legislation would promote cooperation among key government agencies, such as DEA and FDA, to jointly identify obstacles to legitimate patient access to controlled substances, issues with diversion of controlled substances, and how collaboration between law enforcement agencies and healthcare stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

H.R. 471 also facilitates open dialogue on issues related to prescription drug diversion and abuse by directing key federal agencies to consult with patient groups; pharmacies; drug manufacturers; common or contract carriers and warehousemen; hospitals,

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<sup>10</sup> Ibid.

physicians, and other healthcare providers; state attorneys general; federal, state, local, and tribal law enforcement agencies; health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; and wholesale drug distributors.

We believe that bringing together stakeholders to address the problems associated with prescription drug abuse in this manner would provide better solutions than have been developed to date. Improved collaboration and coordination among federal agencies and other stakeholders would benefit all, including the patient, whose legitimate access to medication must be preserved in order for any potential solution to be successful.

#### **Additional DEA Recommendations**

Although the GAO report focuses on the quota process for prescription drugs, we have a number of additional concerns about DEA processes and functions that should be brought to light. DEA's enforcement activities include conducting inspections of the entities that are subject to its regulatory oversight. Although such enforcement activities are essential to its mission, DEA has been criticized for an alleged lack of transparency in its inspection and other enforcement actions, and even inconsistency among the actions of its numerous field offices. Such opaqueness and inconsistency impose challenges on the compliance efforts of DEA registrants.

To help address the problems of DEA opaqueness and inconsistency, we support efforts to promote accountability and transparency with respect to DEA's inspection and

enforcement programs. The following recommendations, drawn from FDA transparency and oversight and enforcement initiatives, could serve as a model for DEA:

1. Development of a Comprehensive DEA Investigation Program, Corresponding Inspector Manual & Compliance Policy Guides: Specifically, DEA would set forth guidance for its oversight of regulated facilities inspections that provide clear and firm direction.
2. Accountability & Consistency Among Field Offices: DEA would ensure the uniformity and effectiveness of its inspection program and oversight over field offices. DEA would provide public training for inspectors and develop an audit process to ensure that inspections are carried out consistently across field offices.
3. Transparency & Communication - DEA Inspection Observations: DEA would provide substantive and timely feedback to inspected regulated facilities regarding agency observations and facility compliance. Specifically, DEA would provide regulated facilities with substantive written feedback upon completion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the CSA and implementing regulations. Without receiving such information, it is difficult for regulated facilities to implement requisite facility and process improvements and take corrective actions where necessary.

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4. Public Disclosure - Oversight of Inspections: An important mechanism of accountability is public disclosure of information. Disclosure of final inspection reports of regulated facilities would provide the public with a rationale for DEA enforcement actions and the industry with transparency into agency decision-making, allowing them to make more informed actions to enhance facility compliance.
  
5. Ombudsman Office: An ombudsman office would address complaints and assist in resolving disputes between companies and DEA regarding interactions with the agency on inspections and compliance issues.

We believe these recommendations would greatly increase predictability and transparency in DEA regulation. The adoption of such recommendations would greatly enhance the compliance efforts of DEA registrants, thus leading to more effective DEA regulation and oversight. Enhanced compliance efforts by DEA registrants and more effective DEA regulation and oversight would have highly beneficial impacts on efforts to combat prescription drug diversion and abuse.

**Conclusion**

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.



COLLEGE OF PHARMACY

October 20, 2015

The Honorable Fred Upton, Chairman  
 House Committee on Energy and Commerce  
 United States House of Representatives  
 Washington, D.C. 20515

The Honorable Frank Pallone  
 Ranking Member  
 House Committee on Energy and Commerce  
 United States House of Representatives  
 Washington, D.C. 20515

Dear Chairman Upton and Ranking Member Pallone:

I believe that H.R. 3537 will have serious unintended damaging consequences for scientific research. As a research scientist who held a DEA schedule 1 license for most of my career at Purdue University, I can attest to the hurdles that obtaining a schedule 1 license entails. Further, significant research often can be conducted (e.g. in mice, rats, or biochemical experiments) with less than one human dose of many psychoactive drugs, yet a license is required to work with even miniscule amounts of schedule 1 substances. Many colleagues over the years have told me that they didn't work with these substances because of the need to obtain a schedule 1 license.

Further, I do not believe sufficient research was done before deciding which substances should be included in this bill. For example, compounds listed as BBBBB (N-benzylphenethylamine) and CCCCC (N,N-dimethylphenethylamine) are not, to my knowledge, biologically active. Phenethylamine is a natural chemical that is produced in the body, and neither it, nor its N-methylated derivatives are active. Has 6-chloro-aminotetralin (DDDDD) ever been seen as an abused chemical? Is it a 1-amino, 2-amino, 3-amino, or a 4-aminotetralin? The name is ambiguous. EEEE is a compound we discovered in my laboratory named MMAI. Although it briefly appeared as a "research chemical," it does not have reinforcing properties and thus has no abuse potential. In the tryptamines, S is an inactive compound known as bufotenin, and W is simply bufotenin acetate. There are other examples. My point is that no apparent logic has been used in selecting many of the compounds proposed for scheduling, and in fact from a scientific perspective it appears that the list was carelessly created. I believe there should be a clear and compelling rationale for listing each new compound for scheduling.

Will scheduling all these compounds hinder scientific research? I can point to one compound in particular and state unequivocally that if it is included it will greatly hinder scientific research. That compound is phenethylamine SSSS commonly known as DOI. DOI is the only unscheduled compound of this type that has been available to scientists for research and indeed its commercial availability allowed the recent remarkable discovery that it has unprecedented anti-inflammatory and anti-asthma properties, now leading to its development as a medicine. There are literally many hundreds of scientific reports that utilized DOI, and if DOI is placed into schedule 1, research with this compound will virtually cease. The so-called hallucinogens, including DOI, activate a brain receptor known as the 5-HT<sub>2A</sub> receptor. This receptor is extremely important in brain function, and is known to be implicated in depression, schizophrenia, and anxiety, among others. Further, several recent clinical studies with psilocybin, currently a schedule 1 compound, have now shown efficacy in treating anxiety, depression, and alcohol and nicotine addiction. How will scientists study the role of this receptor in health and disease if all of the molecular tools that activate it are controlled substances?

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DEPARTMENT OF MEDICINAL CHEMISTRY AND MOLECULAR PHARMACOLOGY  
 575 STADIUM MALL DRIVE • WEST LAFAYETTE, IN 47907-2091  
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I believe the current Federal analogues act has sufficient breadth to allow prosecution of new research chemicals, and there is no reason to create a new list of controlled substances that will prevent any possibility of scientific study of their potential. In my opinion, there is no need for this legislation, and it will cause problems for scientists who wish to study them.

*Dave*



David E. Nichols, Ph.D.  
Distinguished Professor Emeritus  
Former Robert C. and Charlotte P. Anderson Chair  
in Pharmacology  
Adjunct Professor, UNC Chapel Hill

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-3927  
Minority (202) 225-3641

November 24, 2015

Dr. Chapman Sledge  
Chief Medical Officer  
Cumberland Heights  
P.O. Box 90727  
Nashville, TN 37209

Dear Dr. Sledge:

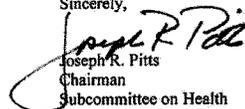
Thank you for appearing before the Subcommittee on Health on October 20, 2015, to testify at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis."

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.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 8, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [graham.pittman@mail.house.gov](mailto:graham.pittman@mail.house.gov).

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

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3641

November 24, 2015

Dr. Robert Corey Waller  
Chair, Legislative Advocacy Committee  
American Society of Addiction Medicine  
4601 North Park Avenue  
Upper Arcade, Suite 101  
Chevy Chase, MD 20815

Dear Dr. Waller:

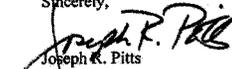
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

**"Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis"**

Questions for the Record

R. Corey Waller, MD, MS

American Society of Addiction Medicine

**The Honorable Representative Tim Murphy**

1. **In your testimony you cite research from the University of Kentucky about the motivation to use diverted buprenorphine was the inability to find treatment. Are you aware that the research abstract clearly states: "Results: Lifetime buprenorphine use "to get high" was 70.1%. Nearly half (46.5%) [of the patients in the study] used diverted buprenorphine over the 6-month follow-up period." Doesn't the use of buprenorphine to "get high" suggest that this medication is being used recreationally, and doesn't recreational use suggest to you that diverted buprenorphine is helping to spread and maintain addiction?**

Thank you for this question. As with all opioids, buprenorphine is sometimes used recreationally. While 70.1% of participants in this study reported using buprenorphine "to get high" at least once in their lifetime, which could be as little as once over the last decade, less than half (46.5%) had used diverted buprenorphine at all during the 6-month study period, yet all (100%) participants reported non-medical prescription opioid use "to get high" in the past 30 days, indicating that opioids other than buprenorphine are far more likely to be used "to get high."

However, the authors' main finding, which is insightful as Congress considers how to increase access to addiction treatment while mitigating diversion risk, is that the "strongest predictor [of diverted buprenorphine use] was attempting but failing to access buprenorphine treatment." Based on this finding, the authors conclude that "increasing, not limiting, buprenorphine treatment access may be an effective response to buprenorphine diversion among persons not in treatment."

Moreover, no research has shown buprenorphine as a "first drug" or even a first opioid, so the assertion that it is spreading addiction is baseless. Given that addiction is a chronic neurobiological disorder, it is "maintained" on its own without any need for help from buprenorphine. In fact, the contrary could be said, given that when a patient uses buprenorphine they are much less likely to use heroin or other opioids. This decreases the risk of overdose, HIV, hepatitis C and overall criminogenic behavior.

No one is more worried about the specter of the possible diversion and misuse of buprenorphine products than the addiction treatment field. We are also the most trained to identify it and prevent it. With evidence based dosing, regular follow-up appointments and prudent toxicological evaluations, we can mitigate the risk of diversion and misuse of buprenorphine so that the benefit continues to far outweigh any harm.

**The Honorable Representative Gus Bilirakis**

**Dr. Waller, ASAM has concerns that HR 2872, the Opioid Treatment Modernization Act, will unintentionally lead to reduced access to treatment. However, I have heard several concerns aligned with Dr. Sledge's testimony, which is that there is no one size fits all approach and that simply raising the caps could lead to the unintended consequence of increased diversion and prescription drug abuse if other services, such as counseling and patient monitoring, are not mandated.**

**1. Can you provide some detail about ASAM's recommendations for preventing diversion if requirements, such as those included in HR 2872, are not enacted?**

Thank you for this question. ASAM shares concerns about buprenorphine diversion and the quality of addiction treatment that patients receive. ASAM also believes that patients should have treatment options and supports access to the right medication at the right time for each patient. That is why ASAM has developed Standards of Care for Addiction Physician Specialists, accompanying performance measures, and, most recently, a National Practice Guideline on the Use of Medications for the Treatment of Addiction Involving Opioid Use (available here: <http://www.asam.org/practice-support/guidelines-and-consensus-documents/npg>) which provides clinical guidance for the use of all three FDA-approved medications for the treatment of opioid use disorder as well as the use of naloxone to treat opioid overdose, including what strategies are recommended to mitigate buprenorphine diversion risk. Specifically, ASAM's practice guideline recommends that physicians see patients weekly at the beginning of their treatment until they are determined to be stable, access PDMP data to check for other medications the patient may be receiving, and conduct urine drug testing to assess medication adherence and the use of other controlled or illicit substances. It recommends physicians take steps to reduce the chance of diversion, including strategies such as frequent office visits, urine drug testing, observed dosing, and recall visits for pill counts. It further recommends patients be counseled on safe storage and disposal. As with most other clinical practice guidelines issued by national medical specialty societies, state medical boards, rather than the federal government, are best poised to issue regulations to encourage the adoption of its recommendations, and state Medicaid programs as well as commercial insurers have the authority to choose which services and what level of quality they will pay for. It is worth noting that full enforcement of the Mental Health Parity and Addiction Equity Act could help mitigate diversion and other poor treatment practices by ensuring that patients' receive coverage for evidence-based, comprehensive care.

Moreover, ASAM shares concerns about lifting the DATA 2000 prescribing limits without simultaneously implementing measures to ensure patients receive high-quality care. That is ASAM recommends specific and extensive training requirements for practitioners who would be permitted to treat more than 100 patients, as well as ongoing continuing medical education (CME) and random site audits by the Substance Abuse and Mental Health Services Administration (SAMHSA) for practitioners who treat more than 100 patients. These recommendations are detailed in ASAM's July 2014 letter to Secretary Burwell (available here: [http://www.asam.org/docs/default-source/advocacy/letters-and-comments/opioid-epidemic-recommendations\\_secy-burwell\\_2014-07-31.pdf?sfvrsn=4](http://www.asam.org/docs/default-source/advocacy/letters-and-comments/opioid-epidemic-recommendations_secy-burwell_2014-07-31.pdf?sfvrsn=4)). ASAM feels that these training requirements and oversight structure are sufficient to ensure patients receive high-quality care without dis-incentivizing those physicians who currently treat fewer than 100 patients from continuing to offer this valuable treatment service, as we feel the mandates included in HR 2872 would do. In particular, as your question suggests, mandating counseling services is especially concerning, as many patients' insurance plans do not cover counseling services and counseling services are simply unavailable in many parts of our country. While psychosocial interventions are recommended for patients receiving buprenorphine, they should not be required, especially for stable patients who have been in recovery for many years, for patients whose insurance plans do not cover counseling, and for patients living in areas where such services are unavailable. Tying such a mandate to the ability to offer treatment with buprenorphine would most certainly restrict access to what has been proven to be an effective treatment even without concurrent counseling.

**2. How will ASAM's proposals not only prevent diversion, but also ensure patients receive comprehensive, effective treatment?**

ASAM believes that ensuring physicians and other health care providers who treat patients with opioid addiction are sufficiently educated about the disease of addiction is the most effective way to ensure patients receive comprehensive, effective treatment. That is why ASAM's recommendations for increasing the prescribing limit include detailed training requirements, so that prescribers have a solid understanding of:

1. The chronic disease of addiction
2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
3. The use of the full range of FDA-approved medication options for all addictive disorders with special attention to controlled substances
4. The behavioral interventions required to stabilize and maintain a patient in long term recovery including but not limited to: Mutual help models of recovery, Cognitive Behavioral Therapy, Motivational Enhancement Therapy, Trauma Informed Care, Contingency Management and the team based approach to care with integrated and/or off-site behavioral therapist
5. Development and use of treatment plans
6. Use of and interpretation of drug screens and tests
7. Diversion control: random call backs, drug screens, and medication counts
8. Medical and Psychiatric comorbidities and the coordination of care
9. Use of prescribed or illicit drugs of abuse while in buprenorphine treatment: Integrating the roles of PDMPs, care coordination, contingency management, treatment plans, family sessions, and the continuum of care
10. Medico-legal and ethical issues in addiction treatment with buprenorphine

ASAM has also advocated for mandatory education related to pain management and addiction for all prescribers of controlled substances, which we feel will lead to more judicious prescribing of medications with addictive potential (including opioids and other prescription drugs such as benzodiazepines, which contribute to overdose deaths), reduced stigma of both pain and addiction, and increased screening for the risk factors for addiction and referrals to treatment when indicated. Such legislation has been introduced by Rep. Yvette Clark (HR 3889) and ASAM encourages the Energy and Commerce Committee to consider it and report it out.

**The Honorable Representative Frank Pallone, Jr.**

**The Controlled Substances Act currently prohibits the transportation of controlled substances outside of registered locations, making it illegal for physicians to transport controlled substances from one practice setting to another. At the hearing, we heard from a witness about the problems this creates for team physicians who need to transport controlled substances from one state to another for an athletic game or tournament. However, at the same time, we heard from you and other witnesses**

that the substance abuse epidemic this country is facing is fueled in part by diversion of prescribed opioid medicines.

1. Please discuss any issues or potential unintended consequences the Committee should think about when considering legislation to facilitate the ability of doctors to transport controlled substance pain medications with them when they travel with sports teams, or otherwise need access to such controlled substance medicines. What additional safeguards, if any, should be put in place to allow for the safe transport of these substances in the instance of sports travel or for disaster assistance?

My concern is that there is no shortage of opioids in any State or in any city where an NFL or other professional sports team plays. There only needs to be a better contractual relationship between team doctors so that the prescriptive liability is waived to the away team's physician. Also, it is well documented that there is a significant opioid overuse issue in the NFL. As a Pain and Addiction Physician I would be concerned about the routine use of opioids for standard game related trauma. As an aside, opioids also significantly mask concussion symptoms and would make it difficult to do an accurate post-game assessment.

We already have many ways to transport opioids and other pain relievers. This is accomplished via the Red Cross, the National Guard, local hospitals, FEMA and local ambulance companies. Each of these has to account for every dose given and is responsible for the appropriate and safe storage of the controlled substances.

I see nothing but risk with this bill, especially given the very plausible alternatives and current pathways.

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3841

November 24, 2015

Dr. Kenneth Katz  
Lehigh Valley Health Network  
Department of Emergency Medicine  
Cedar Crest and I-78  
Allentown, PA 18105

Dear Dr. Katz:

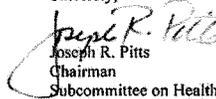
Thank you for appearing before the Subcommittee on Health on October 20, 2015, to testify at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis."

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.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 8, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [graham.pittman@mail.house.gov](mailto:graham.pittman@mail.house.gov).

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

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

December 8, 2015

The Honorable Joe Pitts  
Chairman  
House Energy and Commerce Committee  
Subcommittee on Health  
2125 RHOB  
Washington, D.C. 20515

Dear Chairman Pitts:

Thank you again for giving me the opportunity to testify on behalf of the American College of Emergency Physicians (ACEP) before your subcommittee on October 20, 2015 at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis." As I stated at the conclusion of the hearing, I am happy to respond to any follow-up questions posed by members of the subcommittee.

**The Honorable Representative Gus Bilirakis**

Dr. Katz, synthetic drug use has been a growing problem in Florida and has recently garnered the state significant media attention. Changing the statutory language to ban "chemically similar" substances or substances that "produce a similar clinical effect" will hopefully reduce the incentive to tweak formulas in an attempt to create drugs that are not technically illegal, which has been a root cause of this epidemic.

1. However, the drug known as flakka is already illegal in the United States, yet this has not prevented the widespread use of it in southern Florida. What steps can Congress and the public take to improve awareness of the dangers of these synthetic drugs and reduce access within our communities?

This is the million dollar question, and one that is not easily answered. Unfortunately, despite the efforts to date to inform and educate individuals about the inherent dangers of illicit synthetic drugs, such as flakka, inappropriate use of synthetic drugs continues. As health care professionals and policy makers, we are obligated to use every tool at our disposal to warn the public about these poisons so that they are not misled by claims that these are "safe," or "legal," alternatives to other illicit drugs.

As both a board certified emergency physician and medical toxicologist, I use every opportunity available to help patients and families understand these perils by educating at the bedside and also by lecturing to a myriad of colleagues and other health care professionals. Continued education at all levels is likely the only pragmatic answer, and this effort must remain steadfast and diligent.

The American College of Emergency Physicians (ACEP) has a long history of conducting public awareness campaigns related to injury prevention and public safety issues, such as: wearing bicycle and motorcycle helmets, texting while driving, child passenger safety, drunk driving and firearm safety, just to name a few. It has been our experience that these efforts, done correctly, distributed widely and appropriately funded, help avert emergency department visits that might otherwise have been avoided.

Moreover, I firmly believe parents must take responsibility for their children and teach them about these issues because this is the first line of defense against drug abuse.

**The Honorable Representative Frank Pallone**

The synthetic drug crisis has had tragic consequences for individuals who take these substances and for our health care system. H.R. 3537, the "Synthetic Drug Control Act of 2015," would add over 300 chemicals to Schedule I and would lower the standard for whether a chemical is similar enough to an already-scheduled drug to become subject to the same schedule. While lowering this standard would make it easier for law enforcement to prosecute individuals who were trying to get around the law, concerns have been raised that it could lead to prosecution of people who were unaware they were using an illegal drug, such as young adults.

1. The intent of H.R. 3537, the "Synthetic Drug Control Act of 2015," is for the penalties to fall onto the manufacturer, distributor, importer and seller, and not the end user. As drafted, does H.R. 3537 achieve this goal?

Yes, I believe that H.R. 3537, as written, will achieve its goal of focusing prosecution on all parties involved in the development and sale of these dangerous drugs except the end user. The bill sponsor, Representative Charlie Dent (R-PA), indicated this was his intent, and the legislation is clearly crafted to this end.

2. Further, will you please explain what more you believe can be done to prevent young adults from using synthetic drugs and other drugs that are susceptible to abuse?

A successful solution will include equal parts enforcement and education to address both the supply and demand of these deadly drugs. Federal, state and local law enforcement officials should work cooperatively to help prevent these poisons from first reaching the United States and, barring that, to shut down the distribution supply lines. Pressure should also be applied through diplomatic channels to encourage China and other countries where these poisons are manufactured to intercede and close these manufacturers at the source.

Educating Americans about how truly dangerous these substances are must be a collective, diligent and steadfast effort that cannot waiver. Efforts to educate the public, from government sponsored campaigns to school programs and the health care professionals at the bedside, are critical elements to a successful outcome. Furthermore, I truly believe this education must start in the home. Parents must be accountable and responsible as much as possible for the actions of their children.

One aspect that ACEP strongly encourages federal lawmakers to pursue is the reauthorization and funding of the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015" (H.R. 1725/S. 480). ACEP applauds you and your colleagues on the House Energy and Commerce Committee for expediting approval of this legislation in order to get its approval under the House suspension calendar in September. Please work with the U.S. Senate to enact this legislation as soon as possible. An effective, interstate prescription drug tracking system would be of tremendous value to all physicians (especially emergency physicians) and other health care prescribers who are working to prevent drug abuse and misuse.

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Thank you for your leadership on this important issue. ACEP and I look forward to working with you to enact H.R. 3537, the "Synthetic Drug Control Act of 2015." If I may be of any further assistance to you or your colleagues on this matter, please let me know.

Sincerely,

Kenneth D. Katz, M.D., F.A.C.M.T., F.A.A.E.M.

FRED UPTON, MICHIGAN  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
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WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3841

November 24, 2015

Dr. Allen Anderson  
President  
American Orthopaedic Society for Sports Medicine  
6300 North River Road  
Rosemont, IL 60018

Dear Dr. Anderson:

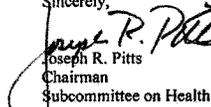
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment



The American Orthopaedic  
Society for Sports Medicine

*A world leader in sports medicine education,  
research, communication, and fellowship.*

9400 W. Higgins Road  
Suite 300  
Rosemont, IL 60018  
P: 847/292-4900  
F: 847/292-4905  
aossm@aossm.org  
www.sportsmed.org

December 3, 2015

Honorable Joseph R. Pitts, Chairman  
Energy & Commerce Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, DC 20515-6115

Dear Chairman Pitts:

The American Orthopaedic Society for Sports Medicine (AOSSM) is pleased to submit its response for the record to the question posed by Honorable Representative Frank Pallone, Jr. Thank you for your continued interest in this important issue.

Sincerely,



Allen Anderson, MD  
AOSSM President

CC: The Honorable Gene Green, Ranking Member, Subcommittee on Health

AOSSM 2016 ANNUAL MEETING JULY 7 - 10, 2016 COLORADO SPRINGS, CO



Honorable Representative Frank Pallone, Jr.

The Controlled Substances Act currently prohibits the transportation of controlled substances outside of registered locations, making it illegal for physicians to transport controlled substances from one practice setting to another. At the hearing, you testified about the programs this creates for team physicians who need to transport controlled substances from one state to another for an athletic game or tournament. However, at the same time, we heard that the substance abuse epidemic this country is facing is fueled in part by diversion of prescribed opioid medicines.

1. Please discuss the anti-diversion safeguards in place in HR 3014 and why you believe they will be effective in preventing further diversion of controlled substances.

The changes proposed in HR 3014 tighten the regulation over disbursement of controlled substances and would limit the opportunity for further diversion. Following are several important features of the law that demonstrate why this would be the case:

- The bill does not bypass or limit the current record keeping requirements already in place for dispensing controlled substances;
- In addition, the bill would require the provider to notify the Attorney General of the following in advance and on each occasion in which controlled substances are transported:
  - The controlled substance(s) being transported
  - The practice setting from which controlled substances are transported
  - The practice setting to which the substances are transported
  - The dates of transport
  - The travel time expected during transport
  - The mode of transport
- Each episode of transport is time limited to 72 hours – 3 days.

These are reasonable requirements for clinicians who are legitimately dispensing controlled substances away from the “home” practice setting. At the same time, these requirements would dissuade individuals from diverting controlled substances for nefarious purposes because they are reporting to the Attorney General in advance each time they are transporting controlled substances. They are also reporting other critical details, including what substances are being transported, the source of those substances, the purpose for transport, the time of transport, and ultimately the recipient of any controlled substances. This information facilitates the auditing of records and monitoring of drug disbursement, as well as highlighting instances where there are deviations from normal clinical care. A person wanting to abuse the system would not want to provide this additional documentation to the Attorney General, especially when that documentation can readily be verified. It would compound their exposure rather than diminish it.