HEROIN AND PRESCRIPTION DRUG ABUSE

WEDNESDAY, MAY 14, 2014

U.S. Senate,

Caucus on International Narcotics Control,

Washington, DC.

The hearing was convened, pursuant to notice, at 2:28 p.m., in room 192, Dirksen Senate Office Building, Hon. Dianne Feinstein (co-chairman of the caucus) presiding.

Also present: Senators Whitehouse, Udall, Grassley, and Risch.

OPENING STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR FROM CALIFORNIA, CO-CHAIRMAN, CAUCUS ON INTERNATIONAL NARCOTICS CONTROL

Co-Chairman Feinstein. Our hearing will come to order.

I'd like to welcome our distinguished witnesses and they will be introduced shortly.

Recently, the media has chronicled a resurgence of heroin abuse in the United States, and actually more heroin being moved into the country. According to a 2012 national survey, 666,000 Americans reported using heroin during the previous year. That number has steadily grown over the past several years.

So this begs the question: why are more people using heroin? This is the Senate Caucus on International Drug Control, but the reason to control it is to keep it out of our country and to do those things which prevent opiate use, not to enable it.

But one answer, according to the experts, may be the country's addiction and use of prescription pain medications, and here is why: a report released by the Substance Abuse and Mental Health Services Administration indicates that individuals who use prescription pain relievers for non-medical purposes were 19 times more

likely to use heroin in the past year than those who had not. That is an amazing thing to me.

Furthermore, 4 out of every 5 heroin abusers had abused prescription pain relievers in the past. So pain relievers like Oxycodone and Hydrocodone affect the central nervous system in much the same way as heroin, so the lesson here is that rather than thinking of two separate addictions, prescription pain medications and heroin, we should realize that we are facing a much larger opiate addition epidemic that includes both.

So the strategy to battle these drugs should have three parts: preventing drug abuse, treating addicts, and reducing the number of overdoses. But the first and most important strategy is to prevent drug abuse before it starts, and this means educating communities and youth about the dangers.

Now, some communities already do this through the Federal Drug-Free Communities program. In California, there is a program call Placer Youth. That program has contributed to a 50 percent reduction in prescription drug use among 11th graders between 2011 and 2013. So, these programs, I believe, can work.

It also means, though, recognizing that all stakeholders share a responsibility that prescription opioids are prescribed and dispensed only--only--for

legitimate medical purposes. State-based prescription drug monitoring programs, along with mandatory checks of electronic databases, can help doctors and pharmacists identify drug abusers.

Since requiring mandatory checks, New York has seen a 75 percent decrease in doctor shopping and significant reductions in pain reliever prescriptions. So drug take-back programs can also help reduce opioid abuse because they get unused prescription pain medicines out of families' medicine cabinets where too many young adults first obtain these drugs.

So heroin entering the United States from other countries also must be addressed. The DEA's Heroin Signature Program, in 2012, determined that 90 percent of wholesale heroin seizures were able to be traced from Mexico or South America.

DEA also reports that the Mexican based Sinaloa drug cartel is expanding its market eastward and producing and selling heroin that is more pure, in other words, going from the brown to the white heroin. Between 2008 and 2013, heroin seizures along the southwest border increased nearly four-fold, from 559 kilograms to 2,196.

The second key strategy in this fight is successful treatment, which often includes medication-assisted therapies using drugs like methadone and--I am going to

have trouble with this one--buprenorphine.

Unfortunately, in 2012, 2.5 million people in our country were addicted to these opioids, while only 351,000 received these methadone or buprenorphine to treat their addiction, so that means that the rest are not receiving treatment.

Finally, the third strategy is to address overdose deaths. In 2010, the latest year for which data is available, the Centers for Disease Control and Prevention reported more than 19,500 unintentional opioid overdose deaths. Now, there are steps that can be taken. There are drugs that immediately reverse these overdoses, and 18 States, including California, have taken actions to improve access to these drugs.

So I think we need to find a way to make these drugs more readily available to properly trained individuals, including first responders. So I think we have an interesting hearing. I do want to point out, if you look over at those charts, you see the rate of opioid sales, overdose deaths, and treatment between 1999 and 2010.

In this--here is the chart--the green is treatment admissions, the red are deaths, and the blue are sales. As you can see, they are all going up in this country. So I think that is a good chart that really discusses what we are about.

The other quick point is that heroin abuse increases as access to prescription painkillers decrease. Now, that is a brand-new thing for me and that is what this other chart shows. So I would hope that some of you, in your testimony, would remark on this.

Now, I would like to recognize the distinguished Vice Chairman.

Senator Grassley. Can I defer to the Leader?

Co-Chairman Feinstein. You certainly can.

Senator Grassley. I would like to defer to Senator McConnell and thank him for his interest in this issue, and then --

Co-Chairman Feinstein. And I thank you as well, sir. Thank you.

STATEMENT OF HON. MITCH McCONNELL, A U.S. SENATOR FROM KENTUCKY

Senator McConnell. Well, thank you, Senator Feinstein and Senator Grassley, for the opportunity to be here today to testify on the scourge of heroin abuse that is devastating, as Senator Feinstein indicated, too many families in communities across America, and in particular--in particular--in my home State of Kentucky. Thank you for your willingness to focus on this growing threat.

I'd like to share with you the story of a wonderful, vibrant community that I have the pleasure of representing here in the U.S. Senate. It could be many places in America, but it happens to be in northern Kentucky. The northern Kentucky area of suburban Cincinnati is the center of cultural arts and American history. It is home to the Cincinnati Northern Kentucky International Airport and the gateway to the Bluegrass State from the north.

Residents of the three counties up there--Kenton, Boone, and Campbell--the area we refer to as northern Kentucky, live in a time of great opportunity. They have the benefit of living in a major metropolitan area of

more than 2 million people, with all the livability and charm of a small town.

They can take advantage of the cultural amenities like the Cincinnati Zoo and Botanical Gardens, Newport on the Levee, Newport Aquarium, and Kentucky Speedway, to name a few, or they can take in a Cincinnati Reds game or a Cincinnati Bengals NFL game, or the Cincinnati Art Museum, and over 25,000 acres of parkland give free reign to relaxation and recreation on a temperate day.

Northern Kentucky offers all of that, and yet this proud community is also saddled with the terrible distinction of being the very epicenter--the very epicenter--of heroin addiction in Kentucky and in the Nation. Many believe that the problem started because of prescription pain pill abuse, as Senator Feinstein was pointing out. Kentucky has the third highest drug overdose mortality rate in our country.

On the street, these pain pills are expensive--they can cost between $60 and $100--compared to a bag of heroin at just $10 a bag. So given the progress we have made in Kentucky in fighting the illegal sale and use of prescription narcotics, it is no surprise that we have seen an uptick, as Senator Feinstein was just pointing out, in heroin usage once we understand the economics of it.

A few months ago I discussed the relationship between the prescription painkiller abuse and growing heroin threat with layers of Federal agencies responsible for curbing these threats, and I am going to continue to work with them as we all work together to fight this epidemic.

I want to highlight for the Drug Caucus some hard but true facts about the extent of heroin abuse in northern Kentucky, and I would like to credit the northern Kentucky Chamber of Commerce for the data. The fact that these numbers come from a Chamber of Commerce and not a law enforcement or public health agency demonstrates how pervasive--how pervasive--the threat to the community is.

These are the facts: in 2012, there were 61 heroin overdose deaths in the three counties referred to as northern Kentucky. In fact, the number of overdose cases at the region's largest hospital increased by more than 75 percent--75 percent--in 2012, while the number of heroin overdose cases by just August of 2013 had already doubled the number in all of 2012.

Rates of acute hepatitis C infections in northern Kentucky are double--double--the State-wide rate and 24 times the national rate. Twenty-four times the national rate! Public health officials attribute the region's

high infection rate to the region's high level of heroin use. What is more, the northern Kentucky Health Department has reported that for every one death there is one new case of hepatitis C that incurs a lifetime cost of $64,500.

The smallest among us are not spared from the scourge. Sadly, newborn babies are born with drug withdrawal syndrome. Each case is heartbreaking and is not only costly in human terms, but fiscally as well, incurring an average hospital cost of $14,257.

Law enforcement is on the front lines of this battle to protect Kentucky families. According to the Northern Kentucky Drug Strike Force, the number of court cases for heroin possession and trafficking has increased by 500 percent from 2008 to 2012 in the three counties that I mentioned, and is expected to double again in 2013.

To put this in perspective, the three counties of northern Kentucky contain 60 percent of my State's heroin prosecutions in 2011, even though they are home to less than 10 percent of the State's population.

Let me add here that it is fitting you are holding this hearing during National Police Week, when thousands of police officers from across the country visit the Nation's capitol. We owe these officers our profound thanks and gratitude for risking their lives to combat

the drug problem and the many ancillary violent and property crimes driven by the growing trend.

Clearly, the troubling facts I have just related show northern Kentucky has a serious, serious heroin abuse problem. It is a major problem not for a few, but for the entire region. While northern Kentucky may be ground zero in my State, the problem of heroin abuse is spreading like a cancer across the Bluegrass State where we are losing close to 100 fellow Kentuckians a month--a month--to drug-related deaths. We only have 4 million people in our whole State. This is more lives lost than to fatal car crashes.

This March, I held a 90-minute listening session in that area of our State to hear from those closest to the problem how Federal resources could best be devoted to fixing it. As I said, in Boone County, one of the three counties I referred to, there are great heroes in this tragic story, such as the medical professionals who save lives, the business leaders who raise money for prevention and awareness efforts, the prosecutors, and dedicated investigators who take drugs off the streets, and the recovered addicts themselves who find the courage to live despite their addiction.

I heard from informed Kentuckians in the medical, public health, and law enforcement fields and the

business community, and in particular I want to point out one brave young man, Patrick Kenyon, who had been ensnared by heroin and saw his friends use it and overdose.

It took repeated attempts for him to break his addiction, but he said proudly in the listening session he was 4 years and 10 months clean. I can't stress enough how helpful it was to hear about this issue from so many thoughtful perspectives, and that is why I am pleased you are holding this hearing today.

Let me just report briefly three take-aways from the listening session I held several months ago. First, as noted, it is clear that the increase in heroin addiction is tied to our fight against prescription drug abuse, which is largely driven by the abuse of prescription painkillers.

Second, while Kentucky is making progress with greater education and more aggressive prosecutions and enhanced regulatory authority at the State level, we need a combination of both treatment and incarceration to be part of the solution.

Lastly, the heroin trade is no respecter of borders, which is why multi-jurisdictional and multi-agency law enforcement efforts, such as in my State the Appalachian High-Intensity Drug Trafficking Area, or HIDTA, are so

crucial. In this area of finite Federal resources we must use these inter-agency partnerships to the best extent to maximize our return from Federal dollars we spent to combat the epidemic.

My friend Frank Rapier, the executive director of Appalachian HIDTA, never fails to remind his law enforcement partners that there is no limit to what we can accomplish when no one cares who gets the credit. The very same credo must also guide our efforts at the Federal level.

So, Senator Feinstein and Senator Grassley, let me return to the picture I painted of a northern Kentucky ripe with promise, and yet beset--beset--by heroin abuse. Thankfully, the ending to the story has yet to be written. That is why I am here today, to share with you the gravity of the heroin threat to my constituents and to pledge to work with all the stakeholders to save lives in Kentucky from this terrible, growing threat.

With the efficient leveraging of Federal resources and authorities using best practices learned from both the law enforcement and correction agencies, as well as the medical and public health communities, we can and will eliminate the shadow of this terrible heroin epidemic from healthy and robust communities all across America like northern Kentucky.

Thank you very much, Senator Feinstein.

Co-Chairman Feinstein. Thank you very much, Senator McConnell.

Senator Grassley, you haven't made your statement, and then Senator Klobuchar would also like to make an opening statement.

OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM IOWA

Senator Grassley. I think since you described the situation very well I am going to start out at the middle of my statement and refer to something that you and I learned about, the existence of a database by doctors maintained by Purdue Pharmaceuticals.

Purdue markets Oxycontin, one of the most abused prescription opiates. The database allegedly contained information about doctors who engaged in reckless prescribing practices. Your and my investigation revealed that many State Medical Boards, as well as the Centers for Medicare and Medicaid Services, did not know

about this database. We encourage these organizations, as well as DEA, to contact Purdue about it.

As a result, the information is now in the hands of authorities who can take action against irresponsible doctors. The purpose of this hearing is to learn more about what else is being done to combat this epidemic and what role Congress can make. A multi-faceted approach makes common sense. Prevention efforts, through which doctors and the public are educated about the dangers of opioids and other addictive drugs should be a part of that solution.

This is why the mixed signals the Obama administration sends to young people about marijuana use are all so damaging. Young people, and all those looking to climb up the ladder of opportunity in America, do not need another pathway to addiction. But that is what -- I think what the President said provides -- by failing to enforce Federal laws and dismiss marijuana use as just another bad habit.

Treatment for those who have become addicted is also a part of the solution as well. A drug called Naloxone has shown effectiveness in countering the effects of heroin overdoses, and finally law enforcement will have a critical role to play. Of course we cannot arrest our way out of this crisis, but we can, and must, maintain

the current law enforcement tools to go after those who are trafficking heroin into our Nation and our communities.

Unfortunately, sentencing reform bills that are now before Congress do just the opposite. The proposed Smarter Sentencing Act that recently passed out of Judiciary cuts the mandatory minimum sentences for those who manufacture, import, and distribute heroin and do that by cutting them in half. These are penalties for dealers, not for users. In the midst of an epidemic, in my opinion, this makes no sense.

Federal prosecutors themselves wrote that the current system of penalties is the cornerstone of their ability to "infiltrate and dismantle large-scale drug trafficking organizations and to make violent, armed career criminals -- to get them off the street". I don't want to remove this cornerstone, least of all at this particular time.

Thanks to the witnesses for being here. I am going to put my entire statement in the record in place of what I just said.

Co-Chairman Feinstein. Please do. Thank you very much, Senator Grassley.

[The prepared statement of Senator Grassley appears in the appendix.]

Co-Chairman Feinstein. Senator Klobuchar?

STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM MINNESOTA

Senator Klobuchar. Well, thank you very much. First, I'd like to thank you, Senator Feinstein and also Senator Grassley, for holding this important hearing and for inviting me to participate. Just yesterday afternoon I was with President Clinton at Johns Hopkins, where the Clinton Health Matters Initiative held a very important forum on this very topic with the focus on prescription

drug addiction and some discussion about heroin.

I was on a panel with Commissioner Hamburg and Representative Patrick Kennedy that followed President Clinton's speech and he is really taking this issue on, which I thought was a positive. He has a lot of energy, as you know.

I would say I'd start with prescription drugs because when I look at the facts on heroin, the fact that while the vast majority of prescription drug users do not start to use heroin, something like 97 percent of them, in fact 4 out of 5 heroin users today started with prescription drugs.

So I start with the demand issue with the prescription drugs and how we get to that. I would say first of all we have to do everything we can to reduce the supply. This means, to me, the drug take-back programs and getting them out of the hands of kids when it's the number-two thing that they're addicted to.

Senator Cornyn and I passed a bill back in 2010--it seems like quite a while ago but we are still waiting on the rules--that makes it easier and sets out some clear standards for how these drugs can be transported when they are put into take-back programs.

We did that because there are certain police departments and long-term care facilities that still are

not doing these programs and they're concerned about liability. What the bill does, it makes it easier for pharmacies, which would be excellent if they voluntarily did this.

I have done some events with pharmacies. If you can imagine people bringing back their prescription drugs, getting them out of their medicine cabinets, bringing them back voluntarily and doing it long-term care, you name it. So that is one thing.

If you think it is a small thing, how many tons do you think were collected just last April in one day in the United States of America of prescription drugs? Maybe you are thinking 10 tons, 20? Three hundred ninety tons of prescription drugs were collected on a day in April just this last month, so that is what we are dealing with when we talk about the problem.

Second, is drug courts. The more we can cut down the demand by getting people involved in drug courts, and we are working on more funding for that because 3 out of 4 of the graduates never get in trouble again with the law.

Then the last thing I'd say on the supply side would be prescription drug monitoring. It's a patchwork system where the head of Hazelden in Minnesota isn't able to tell doctors when someone comes in who he knows is doctor

hopping to get to different prescriptions of Oxycontin.

It's patchwork, it's not mandatory, it's not interoperable, it won't go across State lines, there are funding issues as well. So, I think that would be a big thing.

So then we get to the heroin. We have had a huge increase in heroin overdoses in Minnesota in the first half of 2013. Ninety-one people died in just Hennapin and Ramsey Counties in the Twin Cities area. Why? Well, as we have probably heard, the heroin is more pure, it's coming up on the 35W corridor, mostly out of Mexico.

Fifty percent of the heroin in the U.S. is grown in Mexico, now 60 percent is transported through Mexico. Because of that and other reasons, including sex trafficking, I led a trip down to Mexico last month with Senator Heitkamp and Cindy McCain, the wife of Senator John McCain, and we focused on two issues: sex trafficking and heroin.

We met with the head of the Federal police in Mexico, we met with the attorney general. Coming out of those meetings I came back with this. I think the Mexican authorities are more devoted than ever to do something about the violence and drugs in their country. They want to be part of this new economy in North America. They see getting rid of the drug problem and

the violence as they key to that.

They have gone after El Chapo, the head of their long-time powerful Sinaloa drug cartel, but there is much more work to be done. This includes eradication of the new poppy fields that are pure-white heroin, different than the black tar they used to be using in Mexico.

It includes strengthening their southern border where the heroin is coming up from countries south, not just our border but also the southern border. The third thing would just be continuing coordination with U.S. law enforcement and the work that we have to do on the demand side back here.

So I am very excited you are doing this hearing. I have heard the other Senators talk about a major problem, but I think we have to be really smart in looking at what the answers are and I'm looking forward to hearing from our witnesses. Thank you.

Co-Chairman Feinstein. Thank you very much, Senator Klobuchar.

Let me introduce our witnesses today. We would ask each one of you to confine your remarks to five minutes. If they're in writing, we'd like to have them for the record so that we can have a robust discussion.

Let me begin with the Acting Director of the Office of National Drug Control Policy, Michael Botticelli. He

has been here before and we welcome him back. Director Botticelli has more than two decades of experience supporting Americans who have been affected by substance use disorders. Prior to joining ONDCP, he served as director of the Bureau of Substance Services at the Massachusetts Department of Public Health.

Next, we welcome Dr. Nora Volkow back to the caucus. She is the Director of the National Institute on Drug Abuse which, coincidentally, was founded 40 years ago today, so let me be the first to wish the Institute a happy birthday!

Dr. Volkow's work has been instrumental in demonstrating that drug addiction is a disease of the human brain. Among her many accomplishments she pioneered the use of brain imaging to investigate the toxic effects and addictive properties for drugs that are abused.

Next, we are pleased to have Dr. Westley Clark. He is the Director for Substance Abuse Treatment within the Substance Abuse Mental Health Services Administration. As Director, Dr. Clark leads the agency's nationwide effort to provide effective and accessible treatment for addiction disorders. He is a noted author and educator in the field of substance abuse treatment and has received many awards for his service.

Next, we have Joseph Rannazzisi. We are pleased to welcome you, sir, back to the caucus. You are the Deputy Assistant Administrator of the Office of Diversion Control at the DEA. As Deputy Assistant Administrator, Mr. Rannazzisi is responsible for assuring that the more than 1.5 million DEA registrants comply with the Controlled Substances Act and its implementing regulations. He was named as Deputy Assistant Administrator in January of 2006 and has served with the DEA for some 25 years now.

Last but certainly not least, we are pleased to have Dr. Andrew Kolodny. Dr. Kolodny is the chief medical officer of Phoenix House, one of our Nation's leading nonprofit drug rehab organizations. He's an expert on our Nation's opioid addiction epidemic and he is a practicing psychiatrist in the field. He has helped develop and implement multiple effective substance abuse treatment programs in New York and is a past recipient of the Daniel X. Freedman Congressional Health Policy Award.

So we welcome you all. Perhaps we would begin with Mr. Botticelli and we will just go right down the line, hopefully with five-minute statements so that we can then have some time for questions.

Please proceed.

STATEMENT OF MICHAEL BOTTICELLI, ACTING DIRECTOR OF THE OFFICE OF NATIONAL DRUG CONTROL POLICY

Mr. Botticelli. Chairman Feinstein, co-Chairman Grassley, Senator Klobuchar, thank you for the opportunity to appear today to discuss what is perhaps the most important public health issue facing the United States, namely the abuse of opioid drugs, including prescription painkillers and heroin.

I know that given recent media attention to overdose deaths, there is a heightened public interest in the threat of opioid drug use. While this might be a new phenomenon for many of our communities, some have been dealing with this issue for a very long time and it is a matter of great concern for this administration.

As we discussed, according to the Centers for Disease Control and Prevention, drug overdose deaths, primarily driven by prescription opioids, now surpass homicides and traffic crashes in the number of injury deaths in America.

In 2010, the latest year for which we have nationwide data, approximately 100 Americans died on average from overdose every single day. Prescription analgesics were involved in almost 17,000 deaths that year, and heroin was involved in another 3,000. More

recent data posted by several States indicated that deaths from heroin continue to increase.

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

It is clear that we cannot arrest our way out of the drug problem. Science has shown us that drug addiction is a disease of the brain, a disease that can be prevented, treated, and from which one can recover. We know that substance use disorders, including those driven by opioids, are a progressive disease. It is important to consider and understand that many people who develop a substance abuse disorder begin using at a very young age and often start with alcohol and tobacco.

We know that as an individual's abuse of prescription opioids becomes more frequent or chronic, that person is more inclined to purchase these drugs from dealers or obtain prescriptions from multiple doctors rather than simply getting them from friends and family for free or without asking.

Left untreated, this progression of an opioid use disorder may lead an individual to pursue lower cost and more potent alternatives, particularly heroin. With

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

Three years ago, the administration released the first comprehensive action plan to combat the prescription drug use epidemic. The prescription drug abuse prevention plan strikes a balance between the need to prevent diversion and abuse and the need to ensure legitimate access to prescription pain medication.

The plan expands on the national drug control strategy and brings together a variety of Federal, State, local, and tribal partners to support: 1) the expansion of State-based prescription drug monitoring programs; 2) more convenient and environmentally responsible disposal methods to remove expired or unneeded medication from the home; 3) educating patients about opioid drugs and instructing health care providers in proper prescribing practices and treatment of substance use disorders; and 4) reducing the prevalence of pill mills and doctor shopping through enforcement efforts. This work has been

paralleled by efforts to address heroin trafficking and heroin use.

The administration is also focusing on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions and increasing access to Naloxone, an emergency overdose reversal medication.

Because police are often the first on the scene of an overdose, the administration has strongly encouraged local law enforcement agencies to train and equip their personnel with this lifesaving drug. Twenty-two States plus the District of Columbia have implemented a law or developed a pilot program to allow the administration of this medication by a professional or lay person to reverse the effects of an opiate-related overdose.

We are also working with States to promote good Samaritan laws so that bystanders to an overdose will take appropriate action and help save lives. We are heartened that 17 States, plus the District of Columbia, have now adopted Good Samaritan laws.

While it is critical for us to save lives, we also need a comprehensive response to prevent overdose deaths. A smart public health approach requires us to catch the signs and symptoms of substance use earlier before it develops into a chronic disorder. We have been

encouraging the use of screening and brief intervention to catch risky substance use before it becomes an addiction.

And since only 11 percent of those who needed substance use disorder treatment in 2010 actually received it, the administration is dramatically expanding access to treatment. The Affordable Care Act and Federal parity law are extending access to substance use disorders and mental health benefits for an estimated 62 million Americans, helping to close the treatment cap and integrate substance use treatment into mainstream health care. This represents the largest expansion of treatment access in a generation and will help guide millions of Americans into successful recovery.

The standard of care for treating substance use disorders driven by heroin or prescription opioids involves the use of medication-assisted treatment, an approach to treating opioid addiction that utilizes behavioral therapy along with FDA-approved medications, either methadone, buprenorphine, or Naltrexone.

Medication-assisted treatment already has helped thousands of people in long-term recovery. A prime goal of our office is to increase access to medication-assisted treatment within existing treatment programs and through integration with primary care.

There are some signs that these national efforts are working. The number of Americans 12 and older initiating the non-medical use of prescription opioids in the past year has decreased significantly since 2009. Additionally, according to the latest Monitoring the Future survey, in 2013 the rate of past-year use of Oxycontin and Vicodin among high school seniors was at its lowest since 2002.

Recent studies have shown that the implementation of robust Naloxone distribution programs and the expansion of medication-assisted treatment programs can reduce overdose deaths and also be cost-effective.

Nonetheless, continuing challenges with prescription opioids and the reemergence of heroin use underscore the need for leadership at all levels of government. We will, therefore, continue to work with our Federal, State, tribal, and community partners to continue to reduce and prevent the health and safety consequences of prescription opioids and heroin.

Thank you.

Co-Chairman Feinstein. Thank you.

[The prepared statement of Mr. Botticelli appears in the appendix.]

Co-Chairman Feinstein. Could you just tell me, you said that heroin use has doubled. That is in the last

five years?

Mr. Botticelli. I believe that was 2007, so this is --

Co-Chairman Feinstein. Five years, or a little more.

Mr. Botticelli. This is information from the most recent National Survey on Drug Use and Health and it looked at people who used heroin in the past year. That went from 373,000 past-year users in 2007 to 669,000 in 2012.

Co-Chairman Feinstein. That's very striking. Five years?

Mr. Botticelli. Five years.

Co-Chairman Feinstein. A very striking figure. Thank you.

Dr. Volkow, please.

STATEMENT OF NORA VOLKOW, DIRECTOR OF THE NATIONAL INSTITUTE ON DRUG ABUSE

Dr. Volkow. Good afternoon. Senator Feinstein and Senator Grassley, I want to thank you for the opportunity and inviting me to speak about what NIDA is doing in order to address the problem of prescription opioid abuse in our country.

Opiate medications are the most effective interventions we currently have for managing acute severe pain. Unfortunately, these drugs not only inhibit pain centers, but they also activate brain reward regions which is why they are abused and why they are so addictive.

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

is estimated that 2.1 million Americans are addicted to opioid painkillers, which reflects in part the widespread availability of these drugs.

Indeed, the number of yearly prescriptions for opioids more than doubled over the past 20 years from 76 million to 207 million prescriptions a year, while at the same time in parallel there was a four-fold increase in overdose deaths from these medications during that time period.

Painkillers like Oxycontin and Vicodin affect the brain similarly to heroin. They can cause euphoria, which some abusers intensify by taking higher doses, snorting or injecting them, or combining them with alcohol or benzodiazepines, which makes them much more addictive and also much more dangerous because it increases the risk of respiratory depression, which is the main cause of death from opioid overdoses.

Recent trends also indicate a significant rise in heroin abuse in our country which currently affects more than half a million Americans and is driven in part, although basically predominantly the new cases, by individuals switching from prescription opioids to heroin because it is cheaper and easier to access.

So what is NIDA doing about the problem? It relates to three things: safe management and better management of

pain; prevention of overdose deaths; and the treatment of opioid addiction. How do we treat pain better and how do we protect those that are suffering from becoming addicted and dying of overdoses?

We do not know enough about the risk of addiction among people that have chronic pain, so there is basic research in that area. But in parallel, we are developing medications to treat pain effectively that are not addictive, at the same time while funding research to develop ways of administering opioids that minimize their diversion and abuse. Finally, we are funding research for non-medication strategies to help manage pain, such as transcranial magnetic or electrical brain stimulation.

What about preventing overdoses? We have a very effective medication that is actually quite safe, Naloxone, that prevents deaths from overdoses. Recently, the FDA approved a self-injecting Naloxone that will facilitate its administration by non-medical personnel. NIDA is funding other user-friendly ways of administering Naloxone so that the patients themselves can use it.

Also, since many of the overdoses occur when no one is around or the patient is asleep, NIDA is supporting the development of self-activated systems that initiate an emergency response when wireless sensors seek out that an overdose is occurring.

Finally, research related to the treatment of opioid addiction. Medication assisted therapies--methadone, buprenorphine, Naltrexone--are all effective and they are effective in decreasing overdoses, but these medications are used in less than one-third of patients who need them. NIDA is working to overcome the barriers that interfere with the adoption, and in parallel while doing research for alternative treatments such as vaccines against heroin addiction.

Additionally, NIDA works closely with its partners, CDC, SAMHSA, ONDCP, DEA, and ONC, in implementing and evaluating evidence-based interventions towards prevention and treatment of this problem.

I want to thank you again for organizing this meeting and for inviting us to participate.

Co-Chairman Feinstein. Thank you very much, Doctor.

[The prepared statement of Dr. Volkow appears in the appendix.]

Co-Chairman Feinstein. Dr. Clark?

STATEMENT OF H. WESTLEY CLARK, DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Dr. Clark. Good afternoon, Chairman Feinstein, Senator Klobuchar. I am sorry Senator Grassley had to leave, but I wanted to thank you for inviting the Substance Abuse Mental Health Services Administration to participate in this panel.

I echo the testimony of my colleagues regarding the importance of the topic of this hearing. I will focus on SAMHSA's programs and activities, though we work with our Federal partners, States, tribes, and local communities.

According to the National Survey on Drug Use and

Health which SAMSHA conducts, 4.9 million people reported non-medical use of pain relievers during the past month in 2012; 335,000 reported past month use of heroin, a figure that has more than doubled in six years. In 2012, more than 1.89 million people reported initiating non-medical use of pain relievers and 156,000 reported initial use of heroin.

One challenge in combating the misuse of pain relievers is educating the public on the dangers of sharing medications. According to our national survey, 54 percent of those who obtained pain relievers for non-medical use in the past year received them from a friend or relative for free, another 14.9 percent either bought them or took them from a friend or relative, thus we have both a public health problem intertwined with a cultural problem.

SAMSHA has several programs focused on educating the public, including the not-worth-the-risk-even-if-it's-legal campaign, which encourages parents to talk to their teens about preventing prescription drug abuse. Our prevention of prescription abuse in the workplace effort supports programs for employers, employees, and their families. Our Partnership for Success grant includes prescription drug abuse prevention as well as the capacity-building activities in communities of high need.

Our Screening, Brief Intervention, and Referral to Treatment program includes screening for illicit drugs, including heroin and other opioids. We have also developed programs to help physicians maintain a balance between providing appropriate pain management and minimizing the risk of pain medication misuse.

Our Screening, Brief Intervention, and Referral to Treatment Medical Residency Program includes modules for prescription opioids, for pain management, and opioid misuse. Over 6,000 medical residents and over 13,700 non-residents have been trained nationally.

Physician clinical support systems for medication-assisted treatment training is available via live in-person, live on-line, and recorded modules, accessible at any time. SAMSHA funds the Prescribers' Clinical Support System for Opioid Therapies, a collaborative project led by the American Academy of Addiction Psychiatry, with six other leading medical societies. We will be funding a provider's clinical support system on the appropriate use of opioids in the treatment of pain and opioid-related addiction this fiscal year.

At the end of April, in an article in the *New England Journal of Medicine* authored by HHS leadership, including Dr. Volkow and SAMSHA's administrator Pam Hyde, describes the under-utilization of vital medications in

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

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

SAMSHA is responsible for overseeing the regulatory compliance of certified opioid treatment programs which use methadone and/or buprenorphine for the treatment of opioid addiction and are being encouraged to use Naltrexone.

We estimate that there are approximately 300,000 people receiving methadone maintenance. There are currently 26,000 physicians with a waiver to prescribe buprenorphine.

Co-Chairman Feinstein. Can I stop you? Three hundred thousand people receiving what, did you say?

Dr. Clark. Methadone.

Co-Chairman Feinstein. Methadone.

Dr. Clark. Yes.

Co-Chairman Feinstein. And that is throughout the United States?

Dr. Clark. That's throughout the United States.

Co-Chairman Feinstein. Okay.

Dr. Clark. There are currently 26,000 physicians with a waiver to prescribe buprenorphine. Of these, 7,700 are authorized to prescribe 100 patients. We estimate that $1.2 million people receive buprenorphine. SAMSHA also issued an advisory encouraging drug courts to utilize Vivitrol in their treatment programs. We estimate between 7,000 and 10,000 people are on Vivitrol, an unfortunately low number because Naltrexone is useful for both alcohol dependence and opioid dependence.

In August of 2013, we published the *Opioid Overdose Tool Kit* to educate individuals, families, and first responders, prescribing providers, and community members about steps to take to prevent and treat opioid overdose, including the use of Naloxone. When administered quickly and effectively, Naloxone restores breathing to a victim in the throes of opioid overdose.

This can be a teachable moment to assess treatment need and refer a person to the appropriate resources. We inform States and jurisdictions that the Substance Abuse Prevention and Treatment Block Grant, primary prevention set-aside funds, may be utilized to support overdose prevention, education, and training.

In addition, we notified jurisdictions that block grants other than their primary prevention set-aside

funds may be used to purchase Naloxone and the necessary materials to assemble overdose kits and to cover the cost associated with the assembling of such kits. SAMSHA continues to focus on our mission of reducing the impact of substance abuse and mental illness in America's communities. We thank you and the members of this caucus for convening this important hearing and providing SAMSHA with the Obamacare to address this very critical issue.

Co-Chairman Feinstein. Thank you very much.

[The prepared statement of Dr. Clark appears in the appendix.]

Co-Chairman Feinstein. Before Mr. Rannazzisi speaks, I was just astonished at a statistic I just found, and this is for the most recent take-back day. Nationally, there were 6,000 collection sites. Three hundred and ninety tons of medication was picked up. That is 780,000-plus pounds. It is amazing.

Mr. Rannazzisi?

Mr. Rannazzisi. It is amazing in the fact that we brought all these Federal, State, and local law enforcement agencies together with community groups on one Saturday for four hours to pick up that much.

Co-Chairman Feinstein. Is that right?

Mr. Rannazzisi. And it was a collaborative effort.

Mr. Rannazzisi. Yes. Six thousand sites, all that

are stocked with police officers, local, State, county, Federal police officers, as well as community groups, pharmacists, whoever would like to come out and work with law enforcement. So it was truly a collaborative effort and a wonderful, wonderful day.

Co-Chairman Feinstein. Wow! Thank you.

Please proceed.

STATEMENT OF JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION

Mr. Rannazzisi. Thank you. Chairman Feinstein and distinguished members, on behalf of DEA Administrator Michele Lionhart and the men and women of the Drug Enforcement Administration, thank you for the opportunity to discuss today the relationship between prescription opioids and heroin and how DEA is addressing this public health problem.

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

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

To give you an example, we know that many teens and young adults can get prescription opioids for free from the medicine cabinet or their friends. Let us assume a teenager gets Hydrocodone, a Schedule III prescription opioid and also the most prescribed drug in the United States today, from a family medicine cabinet or a friend.

Once that free source runs out, it can cost as

little as $5 to $7 per tablet on the street, but then the teen will eventually need more opioid to get the same effect so he will increase his dose or move to a stronger opioid, thus the cycle begins. Black market sales of prescription drugs are typically 5 to 10 times their retail value.

On the street, a Schedule II prescription opioid can cost $40 to $80 a tablet, depending on the relative strength of the drug. These increasing costs make it difficult to continue purchasing, especially for teens and young adults who do not have a steady source of income.

Given the high cost to maintain the prescription drug abuse habit, the teenager turns to heroin at a street cost of generally $10 a bag. The teenager gets a high similar to the one he got when he abused prescription drugs. It is just that easy.

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

DEA currently has 66 operational tactical diversion

squads in 41 States, the District of Columbia, and Puerto Rico. These groups capitalize on criminal law enforcement authorities, task force officers, and DEA agents to conduct criminal investigations of diversion of pharmaceutical drugs. DE

A regulates more than 1.5 million registrants. DEA diversion groups concentrate on the regulatory aspects of enforcing the Controlled Substances Act utilizing increased compliance inspections. This oversight enables DEA to proactively educate registrants and ensure that DEA registrants understand and comply with the law.

The tactical diversion squads and diversion groups have brought their skills to bear on what was previously known as ground zero for prescription drug use, Florida-based internet pharmacies, and then pain clinics.

As the current pill mill threat is driven out of Florida and moves towards the north and northwest, DEA will continue to target the threat with TES groups' proven law enforcement skills, diversion groups, regulatory expertise, and by educating registrants.

DEA and our law enforcement partners have aggressively targeted both prescription drug diversion and heroin trafficking. From 2001 to 2012, there was a staggering increase in drug analysis of opioid pain medications, a 275 percent increase for Oxycodone, 197

percent increase for Hydrocodone, and a 334 percent increase for morphine.

There has also been a significant increase in heroin cases.

Co-Chairman Feinstein. Could you repeat that once again?

Mr. Rannazzisi. Yes, ma'am. These are coming from our NFL data, our National Forensic Lab data. From 2001 to 2012, we saw an increase in analysis of Hydrocodone to the extent of 197 percent, a 275 percent increase in an analysis of Oxycodone.

Co-Chairman Feinstein. What does analysis mean?

Mr. Rannazzisi. When a drug is submitted for analysis it is usually either seized pursuant to arrest, purchased undercover. So what it shows is our cases were moving from the standard drug cases over to an increase in cases related to prescription drugs. These analyses occur across the country. So if an undercover agent or an undercover officer at a local county sheriff's department makes a purchase undercover of Oxycodone, he submits that for analysis. We get those reports.

Co-Chairman Feinstein. So it is -- what is it, tripled? Is that the figure?

Mr. Rannazzisi. Two hundred and seventy-five percent in an 11-year period.

Co-Chairman Feinstein. So what do you deduce from that?

Mr. Rannazzisi. I deduce that we have a major prescription drug problem and it is just getting worse. Heroin is just a symptom of a prescription drug problem.

Co-Chairman Feinstein. Well, and what you are also deducing is that the prescription drug is a gateway drug to heroin because if it gets too expensive, then the young person turns to heroin, which is much cheaper.

Mr. Rannazzisi. I would absolutely agree with that.

Co-Chairman Feinstein. Yes.

Mr. Rannazzisi. Yes. There was an increase in our heroin cases from 2008 to 2012 of about 35 percent. If the data for 2013 remains constant, the increase will be about 51 percent for 2013. We are still getting reports in.

The increase in heroin abuse and trafficking is a symptom of our country's insatiable appetite for prescription opioids that could ultimately lead to abuse and addiction. It is a natural progression from the abuse of prescription opioids. There is a dangerous misperception that abusing prescription drugs is safer than abusing heroin, but abuse of both prescription opioids and heroin could lead to addiction and death.

Preventing the availability of pharmaceutical controlled substances to non-medical users and educating practitioners, pharmacists, and the public about pharmaceutical diversion, trafficking and abuse are priorities at DEA.

As such, we will continue to work in a cooperative manner with our Federal, State and local officials, our law enforcement partners, professional organizations, and community groups to address this epidemic. Thank you for the invitation to appear today, and I look forward to answering any questions you may have.

Co-Chairman Feinstein. Thank you very much.

[The prepared statement of Mr. Rannazzisi appears in the appendix.]

Co-Chairman Feinstein. Dr. Kolodny?

STATEMENT OF ANDREW KOLODNY, CHIEF MEDICAL OFFICE OF PHOENIX HOUSE, A NONPROFIT DRUG REHABILITATION ORGANIZATION

Dr. Kolodny. Chairman Feinstein, Senator Whitehouse, and Senator Klobuchar, thank you for the opportunity to discuss our Nation's opioid addiction epidemic.

The increasing use of heroin in suburban and rural counties across the country is easily explained. If you speak with a new heroin user, they will tell you that they began using heroin after becoming addicted to opioid painkillers. This phenomenon is not new. People have been switching from painkillers to heroin since the epidemic began 18 years ago.

Like heroin, opioid painkillers are made from opium and the effects they produce in the brain are indistinguishable from heroin. What this means is that when we talk about opioid painkillers we are essentially talking about heroin pills.

That said, these are also important medications for end-of-life care and when used to treat pain on a short-term basis. But these non-controversial uses--cancer care or short-term use for acute pain--account for a small portion of our overall consumption.

The CDC has been perfectly clear about the cause of this crisis. The chart with the three lines rising up behind you is a CDC chart. The rising green line

representing opioid consumption, according to the CDC, is pulling up the red line which represents deaths and the blue line which represents addiction. Please keep in mind that the red line represents the loss of 125,000 lives.

What this graph represents is a public health disaster of catastrophic proportion. According to the CDC, increased prescribing of opioids has led to parallel increases in addiction and overdose deaths. In other words, this epidemic was caused by the medical community. We did not do this out of malicious intent; for most of us it was a desire to treat pain more compassionately that led to over-prescribing. We were responding to a campaign that encouraged long-term use. The risks were minimized, especially the risk of addiction, and benefits were exaggerated.

In fact, most patients with chronic pain on long-term opioids are not doing well. We are probably harming far more chronic pain patients than we are helping when we put them on long-term opioids.

To help bring this crisis under control the CDC is calling for reduced prescribing, especially for chronic pain. Unfortunately, the FDA has not been listening to the CDC. FDA continues to approve dangerous new opioids, even over the objection of its own scientific advisors,

and FDA continues to allow marketing of opioids for common problems like low back pain, where risks are likely to outweigh the benefits of use.

With only 5 percent of the world's population, we now consume 84 percent of the world's Oxycodone and 99 percent of the Hydrocodone supply. On what basis is FDA concluding that we need more opioids? To end this epidemic, the two things we must accomplish are the same two things we would need to do for any disease epidemic: 1) we must prevent people from developing the disease in the first place; and 2) we must see that people who have the disease are able to access effective treatment.

To prevent people from getting this disease in the first place, the medical community, including dentists, must prescribe more cautiously so that we do not directly addict our patients and so that we don't indirectly cause addiction by stocking medicine chests with a hazard.

For the millions of Americans now struggling with addiction, we have effective treatments that will allow them to lead fully productive lives. Unfortunately, in communities hit hardest by the epidemic, treatment capacity does not come close to meeting demand, especially for buprenorphine treatment where strict limits on who can prescribe and patient caps prevent many from accessing the treatment that can save their lives.

Co-Chairman Feinstein. Explain what you mean by patient caps.

Dr. Kolodny. Well, the law Data 2000, which is the law that makes buprenorphine prescribing possible out of offices, limits doctors to treating 30 patients in their first year. After they have a year of experience, they are limited to treating only 100 patients, whereas a doctor who wants to treat low back pain with oxycontin can prescribe to hundreds or as many patients as they would like, no limits. Buprenorphene, I should add, is a much safer medication than Oxycontin, much lower risk of an overdose.

If we don't rapidly expand access to treatment, the outlook is grim. Overdose deaths will remain at historically high levels. Heroin will continue flooding into our neighborhoods and our families and communities will continue to suffer the tragic consequences.

Thank you.

Co-Chairman Feinstein. Well, thank you very much.

[The prepared statement of Dr. Kolodny appears in the appendix.]

Co-Chairman Feinstein. We have just been joined by Senator Udall of New Mexico. Candidly, as I listened, I am really struck. You know, 30 years ago I was mayor of a big city and we had our share, nothing like today.

Nothing like today. I think this testimony is amazing in terms of the tripling of heroin users, the enormous abuse of Oxycontin and Oxycodone and Hydrocodone.

The question is, you mentioned the FDA just keeps on licensing regardless. I think that is something that I am going to look into. I have this question. I was the Senate sponsor of the Ryan Haight Act which went into effect in 2008. That provided that no controlled substance that is a prescription drug, as determined under the Federal Food, Drug and Cosmetic Act, may be delivered, distributed, or dispensed by means of the internet without a valid prescription. Then it describes what it takes to do a valid prescription.

I thought that would cut down on some of the use, which Ryan Haight--and his mother called me from San Diego--was an 18-year-old who essentially overdosed on it and died, bought it over the internet. Has that been controlled, do you think, by this restriction? Do you have to have a prescription?

Dr. Kolodny. Maybe that was effective because internet purchase of Schedule II opioids doesn't seem to be a big problem right now.

Co-Chairman Feinstein. Really?

Dr. Kolodny. So these opioids are coming from doctors who are prescribing them.

Co-Chairman Feinstein. Wow.

Dr. Kolodny. Vicodin can be phoned in very easily, prescribed with multiple refills because it's in the wrong schedule right now, but for other opioids it does require a doctor's visit.

Co-Chairman Feinstein. Well, let me -- so we solved that problem. So now we have the problem of doctors over-prescribing. What would you recommend?

Dr. Kolodny. Well, for doctors to prescribe more cautiously they need accurate information about the risks and benefits of these medications. What caused this epidemic in the first place, what caused the prescribing to just take off, was a very well-funded campaign with quite a bit of misinformation.

Doctors were taught--I was taught--that you shouldn't worry about getting patients addicted, that the compassionate way to prescribe is aggressively. There really isn't that much being done to correct the record.

Co-Chairman Feinstein. Anybody else on this point? Yes, Mr. Botticelli? Then we'll go right down the line.

Mr. Botticelli. I would absolutely agree that part of what we have to look at, and all of our colleagues talked about the vast over-prescribing of prescription medication by physicians, that part of the efforts that the Federal Government has been doing in conjunction with

both NIDA and with SAMSHA is providing online training courses for physicians to really look at appropriate and safe opioid prescribing.

We think there is more to be done in this area and we think that promoting mandatory prescriber education, as many States have done, is really part of providing and ensuring that physicians are getting accurate information other than information that has been provided in terms of pain prescribing patterns.

We keep pointing to the data and it's very, very clear that this is driven by well-meaning physicians in many cases who don't understand the lethality of these drugs, the addictive properties, and are really not trained in terms of looking at alternatives and how do we monitor people who might be developing an addiction.

Co-Chairman Feinstein. Anybody else on this? Dr. Volkow, go ahead. Then we'll go to Dr. Clark.

Dr. Volkow. Yes. In addition to the issue of education, which is crucial, and that overall there is missing education on screening, proper prescribing, and management of pain in medical schools and in pharmacy schools, there is also what you mentioned, improving access and friendliness of the prescription monitoring programs so that physicians, when faced with a patient, can access that information not just in their States but

in other States. I think that the third issue that we really need to address is the fact that we have also a serious problem of severe pain, numbers of people with severe pain, and we do not have adequate treatments to address pain in patients. It is another reality that we need to face.

Co-Chairman Feinstein. Thank you.

Dr. Clark?

Dr. Clark. We also have, with the advent of the Affordable Care Act, an opportunity to offer alternatives to pain medication for the treatment of pain. I think that's something that we should also keep in mind. Historically one of the problems was that there were few alternatives to pain medication for pain management because physical therapy was not available to a lot of people who suffered from pain depending on the community in which you live, and other strategies could not be supported if the insurance companies chose not to support them. So pain medications themselves are actually relatively inexpensive, despite some of the new formulations. So with the ACA, having an opportunity to get non-prescription strategies to address pain becomes more available.

Co-Chairman Feinstein. Thank you.

Dr. Rannazzisi?

Mr. Rannazzisi. Just, pre-Ryan Haight we had a massive problem with Schedule IIIs and IVs coming off the internet. We had one case where 30 -- well, the average pharmacy in 2006 was dispensing about 66,000 Hydrocodone tablets a year. That's not that much. In one case we had 34 internet facilitation sites, 34 brick-and-mortar pharmacies that dispensed over 98 million Hydrocodone tablets.

Co-Chairman Feinstein. Wow.

Mr. Rannazzisi. What Ryan Haight did was shut that down, but what did we see overnight? These were not physicians, these were traffickers. They gave up their white coat for trafficking and money. What we saw is, overnight, they moved from internet trafficking to pain clinic trafficking. We went from 4 to 7 clinics in Broward County in 2006 to over 142 in 2010. That doesn't make any sense.

Co-Chairman Feinstein. So what you're saying is that the pain clinic is part of the problem.

Mr. Rannazzisi. The rogue pain clinic -- true. The rogue pain clinic is definitely part of the problem. These are doctors that are not practicing medicine, these rogue clinics -- these are doctors that are just dispensing to patients, directly prescribing.

Co-Chairman Feinstein. I thought that had been

abated. I think in Florida a big one was shut down. Is that right?

Mr. Rannazzisi. We decreased the number in Florida through a collaborative effort between law enforcement, Federal, State and local law enforcement. They just moved into Georgia. Now they're up in Tennessee. There is over 300 clinics operating in Tennessee right now. Georgia has got over 100, or almost 200, clinics operating right now. They're moving north and west. These are just prescription pain mills. These are not --

Co-Chairman Feinstein. So what can we do?

Mr. Rannazzisi. We need to get aggressive. It's a two-prong approach. We need to aggressively attack these clinics and get them out of business as soon as possible, but the regulatory boards in the States need to take control. A lot of these clinics could have been shut down if the regulatory boards would have exercised their authority.

Co-Chairman Feinstein. All right.

Mr. Rannazzisi. Some States don't give them enough authority.

Co-Chairman Feinstein. I'm way over my time.

Senator Grassley, thank you.

Senator Grassley. My first question would be to Mr. Rannazzisi. It comes from news reports that we've

had about the countless deaths linked to a mixture of heroin and the painkiller fentanyl. In Philadelphia just this week, it said at least 28 people have died from the mixture, so it gives you a chance to educate us and the public.

Take the opportunity to tell the public what DEA knows about the dangers associated with the mixture and explain why drug dealers might mix, and tell us what steps DEA can take to locate its sources and arrest traffickers.

Mr. Rannazzisi. First of all, a little bit about fentanyl. Fentanyl is a synthetic opioid. It's totally synthetic. It's not manufactured from the plant, it's manufactured in a lab. We've seen this over the years. Over the past 35 years, we have seen clusters of deaths related to clandestinely produced fentanyl.

What we see is most of the fentanyl is clandestinely produced. Most recently in 2005 or 2006, we had a rash of fentanyl deaths that were related to a lab that we tracked back into Mexico, to Toluca, Mexico. Working with the Mexican authorities, we closed that lab down. Fentanyl rears its head pretty much every few years.

Now, this particular drug, it could be fentanyl or it could be an analog of fentanyl called acetyl fentanyl. It could be another analog that we're just not familiar

with. But the reason they use it is because it's approximately -- fentanyl, I think, is approximately 100 times more potent than morphine on a standard dose. So if they have bad heroin or the heroin is not potent enough, or if they do not have heroin they'll use the fentanyl and sell it as heroin.

People don't realize how potent fentanyl is. People don't realize how difficult it is to cut fentanyl. It's measured in micrograms, so the fact is if you don't know how to cut it people are going to be getting hot shots and die of overdoses. So it's very, very important that we find the labs. We have specific clandestine lab groups, as well as heroin groups out there looking for the source just like we did in Toluca, and once we find the source, domestically or abroad, we'll take care of it.

Senator Grassley. Okay. Dr. Volkow, common sense tells us that efforts to prevent all kinds of addictive behavior should begin as early as possible in life. I'm concerned about the increasing use of marijuana among young people leading to other addictions.

You are obviously an authority on drug abuse and addiction and you have been outspoken in our views about marijuana itself being addictive. Are you concerned that marijuana use by young people elevates their risk for

other addictions later in life, such as abusing prescription painkillers or heroin, and what does science tell us about this?

Dr. Volkow. Well, epidemiological studies tell us that most people that are addicted to drugs started by consuming marijuana and many of them started also by consuming tobacco and alcohol, so this relates to the concept of gateway theory of addiction. What we know from animal studies is exposure to marijuana-like substances in animals early on during the period of adolescence, or even younger, increases the sensitivity to the addictiveness of other drugs.

In studies of twins, they have also shown that when the twin that starts early before age 17, they have a much greater risk -- starts the use of marijuana before age 17, has a much greater risk of becoming addicted to a wide variety of drugs than the co-twin that started after that period of time. Those studies are important because they control for common genetic and environmental factors that are also very important drivers of using and experimenting with drugs.

So the data do not seem to suggest that use of marijuana during adolescence would have deleterious effects vis-a-vis making that person more vulnerable to the addictiveness of other drugs, including prescription

opioids.

Senator Grassley. Mr. Botticelli, you referenced in your testimony about the administration's prescription drug prevention plan that goes back to April of 2011. The plan focused on prescription opioids. One of its goals was to reduce deaths associated with the drugs.

Do you think the plan needs to be revised in light of alarming developments over the last three years, and if so, how? Or are the solutions to this epidemic a question of doing a better job of implementing it?

Mr. Botticelli. I think it's two-fold, sir. Clearly we have to look at the emerging evidence. I think any strategy work its salt has to acknowledge the changing times and really look at how our strategy continues to evolve to address those issues.

As we've talked about today, the prescription drug abuse prevention plan clearly falls in the area in terms of how we attack, in a multi-faceted way, these issues. We will continue to update our strategy to talk about the evolving heroin issue. We have been continually promoting the use of medication-assisted treatment, expansion of access to treatment particularly in primary care settings, and the more widespread use of overdose prevention tools. So we will clearly evolve our strategies to reflect the changing demographic and

changing use patterns, and also changing strategies that we need to address it.

Senator Grassley. I will submit my last question in writing to Dr. Volkow and Dr. Clark. I would appreciate your answer, and I will yield the floor.

Co-Chairman Feinstein. Thank you, Senator.

We do early bird. Senator Klobuchar?

Senator Klobuchar. Thank you very much, Senator Feinstein.

I wanted to follow up. Senator Feinstein asked some very good questions about the drug take-back program. You know, Mr. Rannazzisi, that I have a bill that Senator Cornyn and I passed four years ago to make it easier to do drug take-backs. She talked about the 390 tons, but our problem is, we do not have the rules. I talked to Director Leonard, I think, three or four times. She's from Minnesota. I like her a lot.

I know you guys are working on this and I know we just got them back from OMB, which was a great thing. But when do you think those rules will be done, because we can't support these drug take-back programs to the extent that we want if we do not have the rules from the DEA when it is taking four years?

Mr. Rannazzisi. Thank you, ma'am, for that question. Thank you for your support and your leadership

on that bill. That was a very important bill for us. Right now, there is one issue that we're trying to address.

Senator Klobuchar. Right. With long-term care facilities, yes, or something like that. You don't have to tell me. I don't know what it is.

Mr. Rannazzisi. There's one issue we're trying to address and we're trying to do it as expeditiously as possible.

Senator Klobuchar. Okay.

Mr. Rannazzisi. The fact is that OMB has done their job, they've vetted it through, it came back to us. We're trying to work on this one problem.

Senator Klobuchar. Yes. Well, I just know, given what the Senator said about the importance of that 390 tons, we could multiply that over if we could make it easier to have these drug take-backs on a weekly basis or have them on a daily basis in pharmacies so people can just bring them back.

Mr. Rannazzisi. If I may, ma'am, the problem with this bill in particular was this bill and these regulations touch on several different --

Senator Klobuchar. I know. Transportation and --

Mr. Rannazzisi. Transportation, EPA, even the military. So we have to be very cautious because we

don't want to have them to go back and make serious corrections in their statutes.

Senator Klobuchar. Right. I understand. Then you also brought up when Senator Grassley was asking you about synthetic drugs, and thank you for bringing up that issue as well which is contributing to these addictions, the fact that people can manufacture them from compounds.

We of course--Senator Grassley and Senator Schumer and I, and Senator Feinstein, were very helpful in this--supported moving on these synthetic drugs. She and I have two different bills that are both supporting each other's bills about synthetic drugs with analogs and things like that. You think that would be helpful to make it easier to prove up these cases?

Mr. Rannazzisi. I believe any help we could get at this moment in time is going to be beneficial.

Senator Klobuchar. Okay.

Mr. Rannazzisi. We have about 200 compounds we have identified that are outside the act, outside the Controlled Substances Act, non-controlled drugs representing every class of drug of abuse out there today, including PCP.

Senator Klobuchar. Okay. Thank you so much for what you're doing.

Dr. Clark, I appreciated what you said about

Naloxone. As you know, the FDA just approved it, quicker than usual, to be used in emergency situations. I know my State, this month, passed a bill allowing first responders to use it. I am going to move on because I'm somewhat obsessed with this prescription drug monitoring issue, but I wanted to thank you for raising it. It's very important. And just so you know, it was the number-one thing that President Clinton talked about yesterday in Baltimore, so it's a very big deal. So, thank you.

Prescription drug monitoring. This is this idea that, as we are seeing all of these clinics that shouldn't be prescribing -- and Dr. Volkow, I had never heard those numbers. What did you say about the increase in the number of prescriptions, the number you used?

Dr. Volkow. More than double over 20 years.

Senator Klobuchar. More than double.

Dr. Volkow. -- 207 million prescriptions per year are between Hydrocodone and Oxycodone products.

Senator Klobuchar. Right. Without that much change in our population.

Dr. Volkow. No.

Senator Klobuchar. Okay. So there's just no way that all these -- yes. So Senator Whitehouse is just saying I guess this many more people are in pain, and I think we know that's not the case. I think what we know

is going on is people are being prescribed these drugs that should not be. So tell me some ideas you have and how you think this -- if this prescription drug monitoring, where at least we can put a check on these, and Mr. Botticelli could help. Both of you.

Dr. Volkow. What you said, the 290 tons --

Senator Klobuchar. That's the drug take-back.

Dr. Volkow. Yes. What it tells us is, why are we ending up with so many medications --

Senator Klobuchar. That is a very good question.

Dr. Volkow. That speaks for itself.

Senator Klobuchar. Right. And this gets to the root of it. The take-back is good. I want to get it done but I am not naive to think that's going to fix our problem. So it's going to help and it's going to get it out and help with kids especially that are grabbing it from their parents' medicine cabinet. So what do you think we can do?

Dr. Volkow. We need to prescribe much, much better and we need to treat pain much, much better and monitor things, because we have the technology. The prescription monitoring program should work. If I can order from Google and get things immediately--immediately--why can we not have a system like that that is inter-operational that I can have information from one State to the other?

Senator Klobuchar. Okay.

Mr. Botticelli, very quickly, and then Dr. Kolodny, because then I'm out of time.

Mr. Botticelli. So these are two very complementary strategies. Clearly when people start misusing prescription drugs they're getting them from the medicine cabinet, so getting them out of the medicine cabinet is the first strategy.

Clearly as people progress to more chronic use they often turn to doctor shopping to be able to do this, so a large part of our prescription drug abuse strategy is getting every State to have an operational and effective prescription drug monitoring program.

We have 48 now that are operational, 1 that is in the process, and we have 1 State, unfortunately, that refuses to invest in a prescription drug monitoring program. A big part of our work with SAMSHA and the Office of National Coordinator has been easier-to-use programs as well as interoperable programs, so a number of Senators said that these programs need to communicate across State lines. So we now have 20 States that have interoperable prescription drug monitoring programs.

Senator Klobuchar. Okay. I know you want to answer, but I know Senator Udall has a bill on this so he'll have some follow-up questions and maybe he can

direct one to you because they're teasing me for going way beyond my time.

Co-Chairman Feinstein. Oh, that's all right. We've all been known to go beyond our time. You have a relaxed Chair.

Senator Whitehouse?

Senator Whitehouse. Welcome. This is a terrific panel and I thank Chairman Feinstein and our Ranking Member Senator Grassley for pulling this together. This is a very, very important topic. Thirty-eight Rhode Islanders died of opioid overdoses in the first six weeks of this year. If you expand that to the population of the country and to a full year, that's 100,000 Americans dead per year. It's really very serious.

Some good steps have been taken. The State Police, for instance, have just issued Naloxone to all of their folks and recommended that local police departments, as well as EMT first responders, have that available. So I think we're responding in some good ways.

One that worries me a little bit is something that's been raised a bunch here, and that's these prescription drug monitoring programs. I fought for years with, Mr. Rannazzisi, your agency, DEA, to try to get scheduled narcotics onto electronic prescribing.

After--Senator Klobuchar, you'll be glad to know it

wasn't just you--years of bureaucratic battle, finally the regulations came out. I think that facilitates, via electronic prescribing, prescription drug monitoring. When you no longer have to go and ask for the paper scripts from individual doctors or from individual pharmacies, you can look at a database and you can see, wait a minute, this fellow is a podiatrist, why are they prescribing Oxycodone; wait a minute, this person prescribed 500 capsules last month and now they're prescribing 5,000; wait a minute, this person has gone to five different doctors and five different pharmacies for the same prescription, what's going on? It opens investigatory doors.

Yet, years later it is now electronic prescribing for all this stuff. The prescription drug monitoring programs don't seem to have yet really come online as a proper investigative tool to give us the common-sense information that we need to make these determinations.

What are the best next steps that we should be pursuing to try to get this prescription drug monitoring program to a place where we're getting these warnings before we have to go and run up a fake pain clinic that has sold 100,000 prescriptions? You know, you should be able to catch that a lot sooner if you're actually watching the data as it comes up. What are our best next

steps? Dr. Volkow, let me ask you first because you talked about this very well.

Dr. Volkow. Well, I would say that we should put the resources that are necessary to make these systems the way they should be, immediate information right away and access to data that is relevant. There is no reason technologically that we cannot do it.

Senator Whitehouse. And privacy concerns?

Dr. Volkow. The privacy concerns are equivalent to those that you have in electronic medical records.

Senator Whitehouse. So the data is there anyway, we're just not accessing it in an intelligent fashion.

Dr. Volkow. Correct.

Senator Whitehouse. Correct. Okay.

Dr. Clark?

Dr. Clark. SAMSHA, working with ONC and with Rhode Island, promulgated PDMP electronic health record integration and interoperability programs. It has got a small portfolio. We also work with Department of Justice, which has the lion's share of the primary focus of PDMPs.

But we have been working with Rhode Island to improve access to PDMP data for healthcare providers by integrating Rhode Island's PDMP functions into electronic software used by hospitals and physicians' offices and by

integrating the PDMP functions in the pharmacy dispensing software of our pharmacy and sharing PDMP data with other States, including two geographically bordering States.

This work has to be done in order to make this effective. With new technologies you do not necessarily get greater efficiencies unless you iron out the bugs, so we're working with the Rhode Island Health Department to address this so we can establish these models that we can share with --

Senator Whitehouse. Yes. I think Mike Fine, who is our Director of Health, is probably the best person in the country on this. And yes, thank you, Michael Botticelli, for nodding your head, and Andrew Kolodny is nodding. I'm glad to hear Rhode Island gets some cheers here.

Let me wrap up by thanking Dr. Kolodny for being here--Phoenix House has got a very important role in Rhode Island, and Dr. Kolodny has been very, very helpful--and to urge that as we -- particularly as DEA does the enforcement in this area, let's not throw the baby out with the bath water.

Let's do remember that these drugs have a purpose to alleviate human suffering. My particular concern is that when you have got people who are weak and not particularly good advocates for themselves, particularly

elderly people, particularly in nursing homes, if they run into an episode of very, very severe pain then you've ratcheted it down so tight that you need to wake up a doctor at 2:00 in the morning and come in and prescribe them their medication. In the real world they're going to suffer for hours until somebody can be found to come in. So I hope that you'll be balanced and thoughtful and precise in the way we go about pursuing this and not risk the beneficial effects of these drugs in the pursuit of eradicating their abuse.

Mr. Rannazzisi. May I respond just briefly? I believe the clinics and the practitioners that we investigate and prosecute are not doing any type of medical care, and you would not want an elderly person, let alone a healthy person, to go to them. What we're seeing is drug seekers go to them and they're just facilitating addiction.

Senator Whitehouse. No, I don't defend the pain clinics for one second. I think that's a racket out there. But if you've got a situation where you need a doctor to prescribe for somebody at 2:00 in the morning in a nursing home and you've got to wake somebody out of bed, that's a problem, I think. I think a legitimate nursing home that's been there for years you need to think of as differently than a pain mill that just got

stood up six months, six weeks ago.

Co-Chairman Feinstein. Thank you, Senator.

Senator Udall?

Senator Udall. Thank you, Senator Feinstein. Good to be here with you.

Co-Chairman Feinstein. Good to have you here.

Senator Udall. Let me just thank you and Senator Grassley for focusing on a tremendously important issue. I mean, this testimony we've seen, this chart that I think was in your package, this astronomical growth is just astounding. In light of Senator Klobuchar's discussion with me, I first want to turn to you, Doctor, and ask you on the prescription drug monitoring issue, I think you wanted to say something there and so I hope that you have an opportunity to do that.

Dr. Kolodny. I did. Thank you for asking me. So most States, as we've heard, have prescription drug monitoring programs and we can invest in interstate data sharing, but unfortunately they're not being used. PDMPs may be one of the best tools we have in the country for bringing this crisis under control and except for New York, Kentucky, and Tennessee, the three States that made it mandatory for doctors to use them, they're just not being used. So if there is some way that you can incentivize States to make it mandatory for their

physicians to use them, I think that would be very helpful.

Co-Chairman Feinstein. Use what?

Senator Klobuchar. Prescription drug monitoring.

Co-Chairman Feinstein. Oh. Well, we ought to do that. I mean, that's something we can do.

Senator Udall. Yes. That's what you're saying we should do, we should make that mandatory.

Dr. Kolodny. Absolutely.

Senator Udall. Yes. Yes. Right.

Co-Chairman Feinstein. Unfunded mandate.

[Laughter].

Senator Udall. A worthwhile one, though. Worthwhile one.

Let me -- I had an opening statement too, but Madam Chair, I'm just going to ask to --

Co-Chairman Feinstein. You are free to give it.

Senator Udall. -- put that in the record and go on to questioning because I think such good issues have been raised here.

[The prepared statement of Senator Udall appears in the appendix.]

Senator Udall. Last month--and this goes to Dr. Rannazzisi -- I don't think you are a doctor, but anyway. Last month, Senator Portman and I sent a letter, signed

by 14 of our colleagues, to Attorney General Holder urging the Department of Justice to draw on the many evidence-based strategies that are being successfully employed in States to address heroin and opiate addiction epidemic.

Can you explain what efforts are under way to find solutions that are working in the States and then expand them nationwide?

Mr. Rannazzisi. I think for starters, the States have taken a lead in having prescription drug summits, not only for the prescribers, pharmacists, nurses, but also for community leaders. The States have basically leveraged their community coalitions and had the community coalitions out there doing education.

Using that as a force multiplier we can get the word out to our schools. I think the States are doing a remarkable job. We're working together in investigations related to rogue pain clinics and rogue practitioners.

I think that this problem, if we don't work as a team, both State, Federal, local investigators and regulatory boards, it's just going to get worse. We have more collaboration with regulatory boards and State and local task forces now than ever before just to address this problem. Florida is a perfect example. So I think the States and the Federal Government together are doing

a fine job addressing the problem.

Senator Udall. Well, the great thing about our system is having the States as laboratories. As you said, they've come up with some very good examples that I think we can spread nationwide.

Mr. Botticelli, drug abuse -- I have a very large Native American population, 23 tribes in New Mexico. Drug abuse in Indian country is a significant problem. According to a SAMSHA survey, the rate of non-medical use of prescription drugs among American Indian or Alaska Native adolescents was almost twice the national rate.

During fiscal years 2006 and 2009, the High-Intensity Drug Trafficking Areas Program provided a small amount of discretionary funding for a Native American program to combat drug trafficking on tribal lands. Is this something you'd be willing to consider as Director?

Mr. Botticelli. Sure. We've been significantly concerned in terms of substance use, and particularly this issue, on tribal lands. We've actually been working with the Indian Health Service to look at how they might increase capacity around medication-assisted treatment. We have also actually gotten great cooperation from the Indian Health Services in making sure that all of their prescribers are appropriately trained on safe prescribing. So we've got great coordination with that,

but we are also working, and we will continue to work, with our HIDTAs about how we might look at discretionary dollars to focus on that population.

Senator Udall. Great. Thank you very much. That is a perfect, I think, collaboration between the Indian Health Service and you to move this whole issue forward.

Thank you very much, Madam Chair.

Co-Chairman Feinstein. Thank you very much, Senator. Appreciate it.

Senator Markey, welcome.

Senator Markey. Thank you, Madam Chair. Thank you for inviting me. I very much appreciate it.

Dr. Botticelli, thank you for your good work in Massachusetts. Thank you for your good work for the country. As you know, we've been a pioneer in Massachusetts in programs that distribute Naloxone widely in the community to those who are likely to observe an overdose, such as the family and friends of an opioid user.

These programs save thousands of lives. My understanding, however, is that some physicians, first responders, community volunteers, members of the general public, have expressed concern about being held liable for lawsuits if they administer Naloxone in emergency overdose situations. Have you also heard these concerns?

Mr. Botticelli. I have.

Senator Markey. If we were to eliminate those liability concerns, do you think we could increase dramatically the number of people who are ready, willing, and able to save the lives of people who overdose?

Mr. Botticelli. I do. I think guaranteeing some level of immunity for people who respond to an overdose with the use of Naloxone is a strategy that we should continue to investigate.

Senator Markey. And I agree with you. I don't think anyone should be afraid to save the life of a family member or a loved one because of legal liability. I recently introduced a bill called the Opioid Overdose Reduction Act. It's a really simple solution to a problem. It extends protections to people who step in to save the lives of a person who is overdosing by administering a drug like Naloxone, and we need a national Good Samaritan law so that people will step in. How many lives do you think would be saved if we had such a law?

Mr. Botticelli. We know one of the prime issues why people overdose and die is failure to call 911 in an emergency. Clearly signaling to people that they shouldn't be afraid to call 911 is a significant advancement in how we're going to reduce overdose deaths.

Senator Markey. So a Good Samaritan law would really help here?

Mr. Botticelli. Absolutely, yes.

Senator Markey. Do you all agree with that?

Dr. Volkow. Yes.

Senator Markey. Yes. I think that's really something we can do, to pass a law which does provide Good Samaritan protection.

Dr. Volkow, isn't it true that for opioid addicts in prison the treatment approach that works best is combining medication-assisted therapies with community-based treatment for reentry?

Dr. Volkow. Yes, indeed. We have the best outcomes on prisoners that, when they leave the prison system to go into the community, were initiated either on methadone or buprenorphine and are sustained with it not just in their ability to stay off drugs, but also in decreasing the number of overdoses. That transition from prison into the community increases the risk of dying from overdose something like 13- or 17-fold.

Senator Markey. So there are currently very few medication-assisted therapy programs in our prisons?

Dr. Volkow. Unfortunately, that is correct.

Senator Markey. What do you think are the barriers to expansion of medication-assisted therapies in Federal

and State prisons?

Dr. Volkow. I think that it does relate to a culture that we observe in many of the treatment programs that rejects the use of opioid-assisted therapies as medications because of the belief that you are changing one drug for another, when in fact we know that they are very, very different and they are therapeutically beneficial and cost-saving.

Senator Markey. So Mr. Botticelli, after a life is saved from an overdose by Naloxone, people with chronic addiction need to be linked into effective, ongoing treatment for their conditions. I understand that you were instrumental in Massachusetts in helping to increase access to medication-assisted treatment programs within community health centers. Do you believe this model, the Massachusetts model, can be used to expand access to these therapies across the country?

Mr. Botticelli. I do. You know, one of our challenges is, how do we continue to expand access without building bricks and mortar? Our Federally qualified health centers are uniquely situated, both in rural areas, to really look at doing that and we found by giving minimal assistance to Federally qualified health centers we could increase by about 10,000 the number of Massachusetts residents who were able to get very

effective, comprehensive medication-assisted treatment with the rest of the services that they needed.

Senator Markey. Dr. Clark, do you agree that expansion of medication-assisted therapies into primary care settings such as community health centers would be helpful?

Dr. Clark. One of the things that we supported at SAMSHA is integrated treatment, which would include Federally qualified health centers. The other thing that we would support is the transition from the Criminal Justice System back to the community using medications like Naltrexone, which buys both the addict and the community enough time so that the person can reengage in follow-up treatment.

What often happens is the person uses shortly after being discharged from the penal facility and then they overdose, so if we could have Naltrexone administered, the injectable Naltrexone administered prior to discharge from those facilities, we would have at least a month's time to engage in a Federally qualified community health center or substance abuse treatment program or an opioid treatment program that would be using Naltrexone to help facilitate reentry into the community.

Senator Markey. Thank you.

May I continue?

Co-Chairman Feinstein. You go ahead.

Senator Markey. Please. Thank you, Madam Chair.

Dr. Volkow, I'm kind of surprised at how remarkable it is that we have so few medications available to treat addiction. I'm concerned that our desire to find treatments that completely eliminate drug use may keep us from finding treatments that will reduce drug use or reduce the harms associated with drug use, harms like incarceration, family instability, difficulties holding a job. What do you think is needed to further the development of treatments that reduce drug use or related harms?

Dr. Volkow. Well, it's unfortunately a paradoxical situation because we have a disease that has a tremendous impact in terms of morbidity and mortality. The science has identified several potential targets that, if developed, could be beneficial for the treatment. And yes, we do not have the interest from the pharmaceutical industry in developing medications for a series of reasons that have been delineated in a study done by the Institute of Medicine.

One of the recommendations is help to incentivize the pharmaceutical industry in order for them to invest in the development of medications. The targets are there and you have a condition that actually is chronic, so one

of the arguments that they would not be able to recover their investment is not even correct. The Institute of Medicine went further because they actually identified ways that the government could incentivize pharmaceuticals without it costing a single dollar to the government, but they have not been implemented.

Senator Markey. If I may just ask one final question. Of all of the prescription opioid painkillers prescribed in the world of 6 billion people, 90 percent of them are prescribed in the United States. Four percent of the population of the world has 90 percent of the prescription opioid painkillers.

So what does that tell us about the United States? What does it tell us about our society?

Dr. Volkow. I think that the numbers speak for themselves. I don't think that we can argue that we have much more severe chronic pain than other countries. I think that the numbers are telling of something very clear: we are over-prescribing, while at the same time it does not negate that we are not necessarily properly treating patients that suffer with chronic pain.

Senator Markey. Yes. So I thank each of them for their tremendous service. But at the end of the day there is one thing we can do, and that is pass a Good Samaritan law. I think thousands of people's lives would

be saved immediately across the country because people would not be afraid then to just inject someone or to give them the help that they need for fear that they'd be sued if something went awry. But we know that most people would just thank God that the fear is gone.

I think firefighters across the country, policemen across the country, they would all be more willing just to rush in and just apply, because if you do it in a timely fashion you've saved a life. Then you need to deal afterwards with what happens to the person. Do you have a bed for them? Do you have the treatment for them? But at least you've kept them alive. Then we have a responsibility subsequently. We don't have either right now, and until we put both in place I think this problem is just going to continue to escalate.

Thank you, Madam Chair.

Co-Chairman Feinstein. Thanks, Senator Markey.

Just in conclusion, three things jumped to me, and of course that's the pill mill that exists. What proportion of the problem is the pill mill?

Mr. Rannazzisi. We always say that 99 percent, 99-plus percent of the practitioners that are prescribing, the doctors, are doing a great job doing what they do. But that very small percentage of doctors that have crossed the line are truly hurting a lot of people.

I can't give you a percentage because I just don't know what that number is, but what I do know is if you have a rogue pain clinic in your community you're going to see an overdose increase, you're going to see the general problems that you get with any other type of open-air drug activity. And it is open-air drug activity.

Co-Chairman Feinstein. Now, we talked about medical education programs proceeding. Should this be done through the AMA, should it be done through the State Medical Associations? Any opinion on that, Doctor?

Dr. Kolodny. Yes. Sure. If I could also just quickly answer about pill mills.

Co-Chairman Feinstein. Sure.

Dr. Kolodny. It is important to recognize -- I think of course we have to close down pill mills. They account for a very large number of the overdose deaths. But in terms of the overall strategy for controlling this problem, the people who go to pill mills are usually -- either they're addicted, already addicted, or they're drug dealers, or could be a little bit of both.

So you could shut down all of the pill mills and it won't get at the problem of creating new people with cases of addiction. That's where doctors who mean well are more of a problem, or dentists who give a teenager 30 pills when they needed one or two. It kind of takes us

to the question that you were asking about medical education.

If we want dentists to give one or two pills instead of 30, if we want doctors to recognize that these are not good treatments for headache, fibromyalgia, and low back pain, they would need very good information on this. Unfortunately, the bulk of the education on this topic right now is not teaching doctors that using these medicines long term is a bad idea.

The CDC has put out educational programs like that, but it's a minority of what's out there. The bulk of the education is really telling doctors that if you follow certain rules when you prescribe, it'll all turn out rosy in the end. If you use a PDMP, if you check a urine, that somehow that patient won't wind up addicted.

Close monitoring is a prudent thing to do for the people who are on this treatment, but it doesn't turn it into something that's safe. These strategies don't prevent addiction, so really the education needs to be that these are not good treatments for most people with chronic pain.

Co-Chairman Feinstein. Okay. Do you think we should mandate the States to mandate that medical programs, essentially to mandate physicians licensed to use drug monitoring programs?

Dr. Kolodny. Yes, I absolutely do. I think that New York, Tennessee, and Kentucky did that and use went way up. In States that don't require a prescriber to consult the database before writing a prescription, very few doctors look at the database. A doctor thinks they know what an addict looks like. They think they know what somebody with this disease looks like, and they don't.

Co-Chairman Feinstein. Well, thank you very much, everybody. I think it was a very good hearing. We've got some very good notes and food for thought. So, thank you very much. It is appreciated.

The hearing is adjourned.

[Whereupon, at 4:13 p.m. the hearing was adjourned.]

I N D E X