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FEDERAL EFFORTS TO COMBAT OPIOID CRISIS: A STATUS UPDATE ON CARA AND OTHER INITIATIVES

WEDNESDAY, OCTOBER 25, 2017

House of Representatives

Committee on Energy and Commerce

Washington, D.C.

The committee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Greg Walden [chairman of the committee] presiding.

Members present: Representatives Walden, Barton, Upton, Shimkus, Burgess, Blackburn, Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley, Kinzinger, Griffith, Bilirakis, Johnson, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, Cramer, Walberg, Walters, Costello, Carter, Duncan, Pallone, Eshoo, Engel, Green, DeGette, Doyle, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko, Loebsack, Schrader, Kennedy, Cardenas, Ruiz, Peters, and Dingell.

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Ray Baum, Staff Director; Mike Bloomquist, Deputy Staff Director; Adam Buckalew, Professional Staff Member, Health; Karen Christian, General Counsel; Kelly Collins, Staff Assistant; Zachary Dareshori, Staff Assistant; Jordan Davis, Director of Policy and External Affairs; Paul Edattel, Chief Counsel, Health; Adam Fromm, Director of Outreach and Coalitions; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Clerk, Health; Brittany Havens, Professional Staff, Oversight and Investigations; Zach Hunter, Director of Communications; Peter Kielty, Deputy General Counsel; Alex Miller, Video Production Aide and Press Assistant; Christopher Santini, Counsel, Oversight and Investigations; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Danielle Steele, Counsel; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Chris Knauer, Minority Oversight Staff Director; Jourdan Lewis, Minority Staff Assistant; Miles Lichtman, Minority Policy Analyst; Jessica Martinez, Minority Outreach and Member Services Coordinator; Kevin McAloon, Minority Professional Staff Member; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of

Communications, Outreach and Member Services; and Kimberlee Trzeciak, Minority Senior Health Policy Advisor.

The Chairman. If our members and guests would take their seats, it is 10 o'clock. We want to get started on time. I want to thank our witnesses for being here. Before I start, I especially want to thank the head of the FDA, Dr. Gottlieb. I think we are going to have to give you an office you have been here so much this week, the third or fourth time, and we really appreciate your cooperation with our committee and your assistance in this and many other matters.

Okay, I will call to order the Energy and Commerce Committee. This is, I think, our first full committee on a matter and I think it points to the concerns we have about this issue as a committee and as a country.

Each day, more than a thousand people are treated in emergency rooms for misusing prescription opioids. Each day, 91 Americans die from an opioid overdose. In last year alone, opioid overdoses have claimed the lives of more Americans than the entire Vietnam War. In my home state of Oregon, more people died last year from drug overdoses than from car accidents.

We hear these statistics over and over again at roundtables throughout my district, most recently in Grants Pass in Southern Oregon and Bend in Central Oregon. I have heard the stories of Oregonians, put names and faces to these data points. Addiction and overdoses are happening at alarming rates in every community in our nation. Just scan the headlines on any given day and you will hear about a life destroyed by addiction or about a raid

that seized obscene quantities of prescription painkillers or illicit drugs.

The United States is in the midst of a crisis that has become a national emergency. The number of individuals dying from opioid overdoses has reached epidemic proportions and even more individuals with substance use disorders have become estranged from their families, they are unable to work, or living as shells of their former selves because of their addiction. It is truly heartbreaking.

To respond to this growing epidemic, the Energy and Commerce Committee has held countless conversations and numerous hearings with experts and stakeholders, law enforcement, individuals in recovery, and family members of opioid abuse victims in order to improve the prevention and treatment of this terrible addiction.

From the earliest hearings before our Oversight and Investigation Subcommittee to legislative solutions tested in our Health Subcommittee, our multiyear, multi-Congress findings have led to bills that are now law, namely the Comprehensive Addiction and Recovery Act known as CARA, and the 21st Century Cures Act.

This year, this committee has initiated multiple bipartisan investigations into allegations of pill dumping in West Virginia and patient brokering schemes elsewhere in the country. We have held hearings on the growing threat of fentanyl, innovative ideas

in the States, we have heard directly from more than 50 members of Congress both on and off this committee just 2 weeks ago, but more work needs to be done and we must redouble our efforts to combat the growing crisis.

The primary purpose of this hearing is to hear from the federal agencies charged with implementing the provisions of CARA and the 21st Century Cures Act and we appreciate you all being here, but it also allows this committee to have an important conversation with the DEA, first, to discuss recent news reports that suggested a bipartisan bill that passed through this committee and signed into law by President Obama has negatively impacted the DEA's ability to combat the opioid crisis. Second, we are looking for some long overdue answers to basic questions and requests for data that this committee has made to the DEA related to our ongoing investigation into alleged pill dumping in the state of West Virginia.

I am going to be very blunt. My patience is wearing thin. Our requests for data from DEA are met with delay, excuses and, frankly, inadequate response. People are dying, lives and families are ruined. It is time for DEA to get to this committee the information we need and to do it quickly. No more dodges, no more delays. We look forward to finally hearing directly from DEA on these matters. In addition to the DEA, we will be hearing testimony from officials at the Food and Drug Administration, the Substance Abuse and Mental Health Services Administration,

the Centers for Disease Control and Prevention, and the National Institute on Drug Abuse at the National Institutes of Health.

It is our hope that today's testimony will allow us all to learn more about the government's shared efforts to address this crisis, allowing us the opportunity to drill deeper to learn about what is working and what is not working. It is our job to always do that oversight and fix problems. We will also have an opportunity to discuss how we can better prevent lawful prescription use from spiraling into abuse and, more importantly, we will discuss what more we can do to reduce overdoses and save lives.

To the witnesses before us today, consider this another call to action. We need your help as we pursue both our investigative and our legislative work. It is imperative we confront this problem from every side and it is crucial that everyone remembers we are on the same team. This crisis requires an all-hands-on-deck response.

We all want to end this scourge but we must be willing to work together. From the most basic requests for data to crafting and implementing laws, the lines of communication must be open. If there are changes we need to make in the law, please tell us. We have a duty to our constituents and the American people to combat the epidemic from all angles. Everyone has a stake in this fight.

And with that I yield back the balance of my time and I

recognize my friend from New Jersey, the ranking member of the committee, Mr. Pallone, for an opening statement. Mr. Pallone. Thank you, Mr. Chairman, for calling today's hearing. It provides the opportunity to hear from several agencies within the Department of Health and Human Services as well as the Drug Enforcement Administration about the opioid abuse epidemic and the status of federal efforts to combat the crisis, including the implementation of CARA and 21st Century Cures.

While I am pleased to hear from the witnesses before us today, I am disappointed that you did not invite the Centers for Medicare and Medicaid Services or CMS. Most people access substance abuse treatment through their health insurance coverage and it is a fundamental link and one without the other leaves the millions of people of all ages that struggle with this addiction out in the cold.

Between Medicare, Medicaid, CHIP, and the ACA marketplace, it is well over a third of the population receives health insurance through the programs that CMS oversees. Medicaid alone is the single largest payor for behavioral health services in the U.S. Put simply, a full and appropriate review of this issue requires the presence of CMS.

Unfortunately, we all are too familiar with the tragic consequences of the opioid crisis. Ninety one Americans lose their lives to opioid overdose every day and millions more are battling this chronic and potentially deadly health condition.

No community is immune. I know that like me each member here today has heard far too many tragic stories about lives cut short, families torn apart, and people left with few places to turn as they struggle to find treatment.

In New Jersey, more than 1,900 people died from opioids last year. The crisis has taken such a toll in my community that we are hearing cries for help from some unlikely places. Earlier this year, Peter Kulbacki, the owner of the Brunswick Memorial Funeral Home in East Brunswick, New Jersey, published a blog on the funeral home's website expressing his frustration with the monthly calls he receives telling him that someone has passed away from an opioid overdose.

I would like to share a brief excerpt from his blog because I think it helps capture the true toll of this epidemic on families, and I quote, I am witness to the parents left with inexplicable grief. I am witness to the spouses left to carry the emotional and economic burden of raising a family alone. I am witness to the children who are left wondering why, and experiences like this reinforce the need for federal action to address this crisis.

I am happy that last year we were able to work together on a bipartisan basis to pass CARA and 21st Century Cures. These laws are expanding access to treatment and recovery support services as well as advancing efforts to prevent the misuse and abuse of opioids. For example, New Jersey is using the $13

million it received as part of the larger CURES law to expand treatment and support services, invest in primary and secondary prevention and training. Through CARA we also took steps to reduce the amount of opioids in circulation by permitting for the partial fill of controlled substance subscriptions and supporting the expansion of drug disposal sites for unwanted prescriptions.

These were positive steps in the right direction, but committee Democrats have repeatedly stated that they were never enough and, sadly, the growing epidemic proves that today. These laws were a down payment on the types of efforts and increased funding that Congress must support to respond and eventually end this epidemic.

In addition to supporting positive bipartisan laws and increase funding for substance abuse initiatives, Republicans must end their pursuit of taking away health coverage for millions of Americans. This is the very thing that ensures people can actually access treatment. Republicans have spent all year sabotaging the Affordable Care Act and attempting to gut the Medicaid program by more than $800 billion.

This week, House Republicans including most on this committee will support a budget that includes these cuts and more. If successful, these actions by Republicans would have an immediate and harsh impact on those struggling with addictions and I will continue to fight these efforts. Advancing

efforts to respond to this crisis also means Congress has a responsibility to figure out what went wrong, how it went wrong, and how to make sure something like this never happens again. That is why this committee is conducting a bipartisan investigation into the role drug distributors may have played in the ongoing opioid crisis and what systems failed to protect communities.

The committee has sent a number of letters to several distributors and DEA requesting information about drug distribution practices including the amount of opioids shipped into certain communities. Unfortunately, however, up to this point we have had difficulty getting answers from DEA. In fact, I asked a number of follow-up questions to DEA following a committee hearing in March about opioid distribution in rural West Virginia.

After 6 months, DEA just last night sent us the responses to these questions. Of course there are also still many questions in our letters to DEA that remain unanswered and DEA has pledged its cooperation to work with the committee. So I hope, moving forward, they can help us determine what systems failed in West Virginia and what needs to be done to make sure other communities are protected from such abusive practices.

So it is clear, Mr. Chairman, the nation is in crisis and Congress must do more to address the opioid epidemic. And I thank you and yield back. The Chairman. The gentleman yields back.

We now go to our witnesses. Full committee hearing, only The Chairman and the ranking member give opening statements just for our committee's benefit, so now we go to our witnesses. We want to thank you all for being here today and taking time to testify before the committee. Each witness will have the opportunity to give an opening statement followed by a round of questions from members.

So today we will hear from Dr. Elinore McCance-Katz, assistant secretary for Mental Health and Substance Abuse and Mental Health Services Administration, easily known as SAMHSA; Dr. Anne Schuchat, principal deputy director, Centers for Disease Control and Prevention at CDC; Dr. Nora Volkow, I believe -- is it Volkow? -- who is the director of National Institute on Drug Abuse, NIDA, at National Institutes of Health, NIH; and Dr. Scott Gottlieb, commissioner of Food and Drug Administration, FDA; and Mr. Neil Doherty, deputy assistant administrator, Office of Diversion Control, Drug Enforcement Administration.

We appreciate you being here today and we look forward to your testimony. We will start at this end of the table with the gentleman who has been here at least one other time this week and maybe more.

Dr. Gottlieb, thank you for your work with our committee. We greatly value your work there and at FDA and we look forward to hearing your testimony this morning on this matter, sir.

STATEMENTS OF SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ELINORE MCCANCE-KATZ, M.D., ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION; ANNE SCHUCHAT, M.D., PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; NORA VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONALS INSTITUTES OF HEALTH; AND, NEIL DOHERTY, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION.

STATEMENT OF SCOTT GOTTLIEB

Dr. Gottlieb. Thank you, Chairman Walden, Ranking Member Pallone. Thank you for the opportunity to testify today before the committee. The epidemic of opioid addiction that is devastating our nation is the biggest crisis facing public health officials, FDA included. As this crisis grew many of us didn't recognize the consequence of this threat. In the past we missed opportunities to stem its spread so we find ourselves at a tragic crossroad.

We have a crisis of such massive proportion that the actions we need to take are going to be hard. We will need to touch clinical practice in ways that may make certain parties uncomfortable. This may include steps such as restrictions on prescribing or mandatory education on providers. Long ago we ran out of straightforward options.

At FDA we are working across the full scope of our regulatory obligations to impact this crisis. That means updating and extending the risk management plans and educational requirements that we impose on sponsors as a condition of a product's approval. It means doubling our efforts to promote the development of new, less addictive pain remedies as well as opioids that are harder to manipulate and abuse. It means updating our risk benefit framework to take measure of the risks associated with misuse and abuse of opioids and using this information to inform our decisions, including recommending that products be withdrawn from the market.

These steps and others are needed to prevent new addiction, but given the scale of this epidemic with millions of Americans already affected, prevention is not enough. We must also help those who are suffering from addiction by expanding access to lifesaving treatment. I would like to announce three new steps today towards this goal.

First, FDA will issue guidance for product developers as a way to promote the development of new addiction treatments. As part of this guidance we will clearly lay out our interest in the development and use of novel, non-abstinence-based endpoints as part of product development. We also want to make it easier to develop new products that address the full range of symptoms of addiction such as craving.

Second, FDA will take steps to promote more widespread use

of existing, safe and effective, FDA-approved therapies to help combat addiction. There are several FDA-approved treatments. All of these treatments work in combination with counseling and psychological support. Everyone who seeks treatment deserves the opportunity to be offered all three options as a way to allow patients and providers to select the treatment best suited to the needs of each individual patient.

Unfortunately, far too few people who are addicted to opioids are offered an adequate chance for treatment that uses medications. In part, this is because insurance coverage for treatment with medications is often inadequate. To tackle the treatment gap, FDA plans to convene experts to discuss the evidence of treatment benefits at the population level such as studies that show community-wide reductions in overdose following expansion of access to therapy.

There is a wealth of information supporting the use of these medications. We are focusing on the data and the drug labeling that can help drive broader appropriate prescribing, so one concept that FDA is actively pursuing is the research necessary to support a label indication for medication-assisted treatment for everyone who presents with an overdose based on data showing a reduction in death at a broader population level. Such an effort would be a first for FDA. We believe that granting such an indication can help promote more widespread use of and coverage for these treatments.

A common question that arises with treatment is the proper duration of medical therapy. Clinical evidence shows that people may need treatment with medications for long periods of time to achieve a sustained recovery. Some may even need a lifetime of treatment. Recognizing this, FDA is revising the labels of these medical products to reflect this fact.

Now I know all this may make some people uncomfortable. That is why the third step I am announcing today is that FDA will join efforts to break the stigma associated with medications used for addiction treatment. This means taking a more active role in speaking about the proper use of these drugs. It is part of our existing public health mandate to promote the appropriate use of medicine.

Misunderstanding around the profile of these products enables stigma to attach to their use. This stigma serves to keep many Americans who are seeking a life of sobriety from reaching their goal. In this case, in the setting of a public health crisis, we need to take a more active role in challenging these conventions around medical therapy. This stigma reflects a view some have that a patient is still suffering from addiction even when they are in full recovery just because they require medication to treat their illness. This attitude reveals a flawed interpretation of science. It stems from a key misunderstanding that many of us have about the difference between a physical dependence and an addiction. Because of the biology

of the human body, everyone who uses opioids for any length of time develops a physical dependence, meaning there are withdrawal symptoms after the use stops. Even a cancer patient requiring long-term treatment for the adequate treatment of metastatic pain develops a physical dependence to the opioid medication. That is very different than being addicted.

Addiction requires the continued use of opioid despite the harmful consequences. Addiction involves a psychological craving above and beyond a physical dependence. Someone who neglects his family, has trouble holding a job, or commits crimes to obtain the opioids has an addiction. But someone who is physically dependent on opioid as a result of the treatment of pain but is not craving more or harming themselves or others is not addicted.

The same principle applies to medications used to treat opioid addiction. Someone who requires long-term treatment for opioid addiction with medication including those that cause a physical dependence is not addicted to those medications. Here is the bottom line. We should not consider people who hold jobs, re-engage with their families, and regain control over their lives through treatment that uses medications to be addicted.

Committee members, we need to embrace long-term treatment with proven therapies to address this crisis. At FDA we will step up our efforts to do our part to promote these goals. I look forward to discussing these issues with the committee and

appreciate the opportunity to be hear today.

The Chairman. Dr. Gottlieb, thank you for your testimony and your good work at FDA.

We will now go to Dr. Elinore McCance-Katz, assistant secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration, SAMHSA.

Dr. McCance-Katz, thank you for being here today, please go ahead with your opening statement.

STATEMENT OF ELINORE MCCANCE-KATZ

Dr. McCance-Katz. Thank you. Chairman Walden, Ranking Member Pallone, and members of the House Energy and Commerce Committee, thank you for inviting me to testify at this important hearing. I am honored to testify today along with my colleagues from the Department of Health and Human Services and the Drug Enforcement Administration on federal efforts to combat the opioid crisis, a status update on CARA, and other initiatives.

Over the past 15 years, communities across our nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. In 2016, over 11 million Americans misused prescription opioids, nearly one million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. Most alarming are the continued increases in overdose deaths, especially the rapid increase in deaths involving illicitly made fentanyl and other highly potent synthetic opioids since 2013.

The Trump administration is committed to bringing everything the federal government has to bear on this health crisis. HHS is implementing five specific strategies that are guiding our response.

The comprehensive, evidence-based strategy aims to improve access to treatment and recovery services to prevent the health, social, and economic consequences associated with opioid

addiction and to enable individuals to achieve long-term recovery; to target the availability and distribution of these drugs and ensure the broad provision of overdose-reversing drugs to save lives; to strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves; to support cutting edge research that advances our understanding of pain and addiction and leads to the development of new treatments and identifies effective public health interventions to reduce opioid related health harms; and to advance the practice of pain management to enable access to high quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

HHS appreciates Congress' dedication to this issue as evidenced by passage of the 21st Century Cures Act and the Comprehensive Addiction and Recovery Act. In my role as Assistant Secretary for Mental Health and Substance Use at HHS, I lead the Substance Abuse and Mental Health Services Administration. I appreciate the opportunity to share with you a portion of SAMHSA's portfolio of activities in alignment with HHS's five strategies and how SAMHSA is implementing CARA and the 21st Century Cures Act.

SAMHSA is administering the Opioid State Targeted Response grants program created by the 21st Century Cures Act. By

providing $485 million to states in fiscal year 2017, this program is increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose-related deaths through the provision of prevention, treatment, and recovery services. HHS is working to ensure the future funding allocations and policies are as clinically sound and evidence-based, effective, and efficient as they can be.

SAMHSA has several initiatives aimed at advancing the utilization of medication-assisted treatment for opioid use disorder. For example, in the past 4 years, more than 62,000 medical professionals have participated in online or in-person SAMHSA-funded trainings on medication-assisted treatment for opioid use disorders. SAMHSA regulates opioid treatment programs and provides waivers to providers that prescribe buprenorphine. Last year, SAMHSA published a final rule allowing qualified physicians to obtain a waiver to treat up to 275 patients. SAMHSA has also implemented the CARA provision that allows nurse practitioners and physician assistants to prescribe buprenorphine.

SAMHSA has been actively implementing new initiatives to address the opioid crisis made possible by CARA. In September, SAMHSA awarded $4.6 million over 3 years in the Building Communities of Recovery grant program created by CARA. Last month, SAMHSA also awarded $9.8 million over 3 years for new State Pilot Pregnant and Postpartum Women grants authorized by the CARA

act and $49 million over 5 years in new service grants to help pregnant and postpartum women and their children.

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing the availability and use of naloxone to reverse overdose. SAMHSA is currently providing grants to prevent opioid overdose related deaths which are being used to train first responders as well as to purchase and distribute naloxone. In September, SAMHSA awarded additional grants authorized by CARA including almost $46 million over 5 years to grantees in 22 states to provide naloxone and related resources to first responders and treatment providers. SAMHSA's National Survey on Drug Use and Health provides key national and state level data and is a vital part of the surveillance effort related to opioids.

Thank you again for the opportunity to share with you our work to combat the opioid epidemic and I look forward to answering any questions you may have.

The Chairman. Thank you very much. We appreciate your testimony. We are going to stay on the healthcare side of this and go to Dr. Anne Schuchat now, the principal deputy director, Centers for Disease Control and Prevention, CDC.

Dr. Schuchat, thank you very much for being here and the good work you do. Please go ahead with your statement. You might pull the microphones a little closer. Thank you.

STATEMENT OF ANNE SCHUCHAT

Dr. Schuchat. Good morning Chairman Walden, Ranking Member Pallone, and members of the committee. CDC has vast experience in defending Americans against epidemics and I appreciate the opportunity to be here today to speak about the issues surrounding the opioid crisis facing our nation. CDC's expertise as the nation's public health and prevention agency is essential in reversing the opioid overdose epidemic. CDC is focused on preventing people from becoming addicted in the first place. CDC has the unique role of leading prevention by addressing opioid prescribing, tracking trends, and driving community-based prevention activities.

America's opioid overdose epidemic affects people from every community and it is one of the few public health problems that is getting worse instead of better. Drug overdoses have dramatically increased, nearly tripling over the last 2 decades. The opioid overdose crisis has led to a number of other problems including increases in babies born withdrawing from narcotics and a drop in life expectancy for the first time since the AIDS epidemic in 1993. But today's overdose fatalities are just the tip of the iceberg.

[Chart.]

Dr. Schuchat. For every one person who dies of an opioid overdose, over 60 more are already addicted to prescription

opioids. Almost 400 misuse them, and nearly 3,000 have taken one. Using a comprehensive approach as outlined in the HHS priorities, we will work together to stop this epidemic.

CDC has been on the front lines since the beginning. Over a decade ago, after hearing alarming news from medical examiners about increases in overdose deaths and after an outbreak investigation in North Carolina, CDC scientists made the connection to prescription opioids. Today, we are working closely with state health departments and providing guidance on best practices so states can rapidly adapt as we learn what works best in this evolving epidemic.

CDC now funds 45 states and Washington, D.C., to advance prevention in key areas at the community level including improving prescription drug monitoring programs, improving prescribing practices, and evaluating policies. In Kentucky, prompts were added to the prescription drug monitoring program to alert to high doses, which resulted in a 25 percent reduction in opioid prescribing to youth. Illinois has expanded efforts to integrate patient health information into their prescription drug monitoring programs improving the completeness of data available to prescribers and leading to much greater PDMP use.

These are just a few examples of the great work being done. These are the kind of improvements that can literally save lives. CDC is also leading improvements to the public health data we rely on to understand the crisis. We are now releasing

preliminary overdose death data and have improved reporting significantly from a lag of 2 years down to a lag of 7 months.

As part of our funding to states, we are ramping up efforts to get more reliable and timely data from emergency rooms, medical examiners, and coroners through our enhanced surveillance program. For the first time, we are tracking non-fatal opioid overdoses so that we have a better understanding of the changing epidemic so that states can respond accordingly.

This is the value of nimble public health. States call on CDC to provide on-the-ground assistance when they experience an opioid-related crisis. We helped Massachusetts identify that a surge in opioid deaths was caused by fentanyl and we assisted Indiana to identify and contain an HIV and hepatitis C outbreak related to injections of prescription opioids.

We truly appreciate the support we received from this committee for our guideline for prescribing opioids for chronic pain which we released last March 2016. Now we are focused on making the guideline easy for clinicians to implement through interactive trainings, mobile apps, and other ways. We are also focusing on patients and their families. Just last month, CDC released Rx Awareness, a communication campaign aimed to raise awareness about the risk of prescription opioids. The campaign features real-life stories like the one you described, accounts of individuals living in recovery, and those who have lost someone to an overdose.

CDC's unique approach to surveillance and prevention will be key in reducing the opioid epidemic. We continue to be committed to the comprehensive priorities outlined in the HHS strategy and to saving the lives of those touched by this epidemic. Thank you.

The Chairman. Thank you, Doctor. We appreciate your testimony. Now we go to Dr. Nora Volkow, director, National Institutes on Drug Abuse in the National Institutes of Health.

Doctor, thank you for being with us as well, please go ahead with your opening statement. Well, you need to push the little button there. There you go.

STATEMENT OF NORA VOLKOW

Dr. Volkow. So good morning, everybody. Chairman Walden, Ranking Member Pallone, and distinguished members of the committee, I am extremely grateful for your support and commitment to addressing the opioid crisis and for having me here along with my colleagues to actually try to integrate our efforts. You have already heard about the devastating scope of the opioid epidemic. Today, I would like to discuss how science is helping us address this crisis.

The story of a patient named Jeff illustrates the impact research can make in the lives of those suffering from addiction. Jeff developed a heroin use disorder after returning from serving in the war in Afghanistan. He ended up homeless in the streets of Seattle and eventually sought treatment. NIDA-funded researchers at the VA in Seattle enrolled him a pilot buprenorphine treatment program. Unlike traditional treatment programs with long waiting lists, Jeff was started right away on oral buprenorphine which immediately helped him stop using heroin. The treatment helped Jeff recover. He has not used heroin since for several months, he is no longer homeless, and now has a regular job.

Unfortunately, Jeff's story is not typical. Most people who suffer from an opioid addiction do not receive treatment and when they do it is frequently not evidence-based. Jeff's story

illustrates how implementing research findings can significantly improve treatment outcomes.

Addiction is a brain disease that is associated with disruption of brain sequence that make it progressively more difficult to stop using drugs even at the risk of losing one's own life. When people suffering from addictions seek help, we owe it to them and their families to provide the treatments that research has proven most effective.

Thanks in part to NIDA support there are now three FDA-approved medications for opioid use disorders: buprenorphine, methadone, naltrexone. While significantly improving outcomes, these medications are vastly underutilized and relapse rates are still too high. Thus, more research is needed to develop new treatments so we can reduce relapse rates in all patients.

NIDA has a successful record of partnering with industry to develop new treatments. For example, NIDA and the FDA partner with Lightlake and other pharma to develop a user-friendly naloxone. Anyone can use this and it will deliver very rapidly, very high concentrations of naloxone into the bloodstream which is what you need in order to reverse an overdose. This product which was done in partnership with pharmaceutical, as I mentioned, was taken from concept into a product in basically 3 years. So we can do it.

In the face of this opioid crisis, NIH wants to expand on

these alliances and is working on establishing a public-private partnership in collaboration with the FDA, academic research centers, and the pharmaceutical industry that will focus on two major goals: Goal number one, to develop effective non-addictive pain medications to prevent Americans from developing opioid use disorders while providing them relief from the pain condition that they suffer.

The second goal is to expand medication options to treat opioid addictions and to prevent and reverse overdoses. A short-term focus will be the development of new formulations of existing medications to facilitate compliance and the treatment of hard-to-reach populations. Weekly and monthly depot formulations of buprenorphine have already been submitted to FDA approval. It would be a real gamechanger especially for people who live in rural communities and face significant logistical challenges accessing treatment. Other research is building on our growing understanding of the neurobiology of addiction to identify potential targets for treating it. This includes not only medications, but also known pharmacological therapies including vaccines.

In parallel and in collaboration with SAMHSA, we are expanding services and implementation research to develop new strategies for delivery of addiction treatment across healthcare and criminal justice settings. An example is a story that recently showed that initiating buprenorphine in the emergency

room to help ensure people will prevent them from overdoses and effectively engage them in ongoing treatment.

We have an urgent crisis and as stated by the Chairman, an all-hands-on-deck approach is needed to solve it. NIH and NIDA are fully committed to integrate our efforts with those from other federal agencies, industry, community organizations, patients and their families, and Congress to solve it. Thanks very much.

[The prepared statement of Dr. Gottlieb, Dr. McCance-Katz, Dr. Schuchat, Dr. Volkow and Mr. Doherty follows:]

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The Chairman. Thank you, Doctor.

And now our final witness, Mr. Neil Doherty, deputy assistant administrator, Office of Diversion Control, Drug Enforcement Administration. We appreciate your being here as well.

Mr. Doherty, please go ahead with your opening statement.

STATEMENT OF NEIL DOHERTY

Mr. Doherty. Chairman Walden, Ranking Member Pallone, and distinguished members of the committee, thank you for holding this hearing today to discuss the opioid epidemic and DEA's response to this ongoing threat. For DEA, the opioid is the top drug threat facing our nation. This unprecedented epidemic includes not only prescription opioids otherwise known as controlled prescription drugs, or CPDs, but also the proliferation of heroin and fentanyl trafficking, ultimately leading to record levels of overdose deaths.

I believe that all of us at this table are collectively making progress on CPDs, but I fear we are witnessing a fundamental shift towards cheaper, easier to obtain heroin and fentanyl. With illicitly produced fentanyl you have substances up to 50 times more potent than heroin, sold as heroin, mixed with heroin, and increasingly and often with a fatal result, pressed into pill form by criminal networks as counterfeit prescription painkillers. Of the estimated 64,000 Americans who overdosed in 2016, 54 percent died of an opioid overdose. That is one life taken every 15 minutes. Mexican cartels are continuing to exploit the opioid use epidemic and are continuing to produce and transport heroin across the Southwest border. These cartels are aggressively purchasing illicitly produced fentanyl from China, shipping it into Mexico, mixing it with heroin and other

substances, pressing it into pill form, and shipping it into the U.S. through established distribution networks.

What is the motivation behind the often deadly tactics employed by the cartels regarding fentanyl? In a word, profit. Fentanyl and associated analogues provide criminal organizations with highly elevated margins for illicit revenue. For example, one kilogram of fentanyl in China costs between 3- and $5,000, yet yields approximately 1.5 million on the streets of the United States.

DEA stands with our interagency partners including those represented here today to combat this epidemic across all fronts. For DEA and our federal, state, and local partners to be successful in dealing with this threat we need a balanced, whole of government approach, one that attacks supply and also works to reduce demand. We need to continue to lean forward and use all available tools to identify, infiltrate, indict, capture, and convict all members of these organizations, foreign and domestic. With 221 domestic offices, 21 field divisions, and 92 foreign offices in 70 countries, DEA is well positioned to engage in this fight. Foreign-based fentanyl manufacturers and domestic distributors often operate with impunity as they exploit loopholes in the analogue provisions of the Controlled Substance Act and capitalize on the lengthy, resource-intensive process to temporarily or permanently control these dangerous substances. Every day, criminal chemists in foreign countries

are altering the molecular structure of different fentanyl analogues keeping the same dangerous pharmacological properties as the substances that are already controlled.

Despite these challenges there is good news. Our partnership with our counterparts in China has resulted in the scheduling of 128 new pyschoactive substances since October 2015 including numerous fentanyl and fentanyl analogues. In addition, you probably heard last week that two Chinese nationals were indicted as part of an investigation conducted by DEA and other agencies and these individuals were designated as CPOTs, Consolidated Priority Organization Targets, the designation reserved for the most prolific drug traffickers in the world.

Our investigators remain relentless in their pursuit to dismantle these organizations and bring those responsible to justice. DEA along with our global network of enforcement partners will go after these types of criminals wherever they operate. The DEA will continue to address these threats by investigating and bringing to justice not those suffering from opioid use disorders, but those who are exploiting human frailty for profit.

DEA will use all criminal and regulatory tools available to identify, target, disrupt, and dismantle organizations and individuals responsible for the diversion and illicit distribution of pharmaceutical controlled substances in violation of the CSA. We will also work to reduce demand with

our community outreach and prevention efforts throughout the country.

One example of such efforts is the DEA 360 Strategy which brings together three distinct pillars of law enforcement aimed at addressing the opioid, heroin, and violent crime crisis: traditional enforcement, diversion control, and community outreach. Now in its 2nd year, this strategy has been deployed to some of the hardest hit communities in the nation.

The brave men and women of the DEA remain committed to doing everything they can to address this threat. One pill is enough; one life is worth it. Every pill that we stop from hitting the street through diversion or counterfeiting potentially stops it from getting into the hands of a young American and saves them from opioid dependency, heroin use, and possibly a fatal overdose.

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

[The prepared statement of Mr. Doherty follows:]

**********INSERT 2**********

The Chairman. Mr. Doherty, thank you. We certainly appreciate the work that your agents and you all do in this cause and they have dangerous work and it is important work and we do appreciate what they do.

I do want to start with you, however, with a simple question that this committee has been asking the DEA for months. Which companies supplied the pharmacy in Kermit, West Virginia that received nine million opioid pills in 2 years, and the pharmacy in Oceana, West Virginia that received 600 times as many oxycodone pills as another pharmacy just eight blocks away between 2005 and 2016? Can you give us the names of those companies?

Mr. Doherty. Thank you for that question, Chairman. Currently, we are reviewing the request from the committee and I do not have that data with me today. I apologize.

The Chairman. So we have asked for this information in a meeting. We have asked for this information in an email. We have asked this information in a letter and we have asked this information now in a hearing. If you needed to get this information for enforcement action, I suspect and hope you would get it very quickly, right, within hours or days?

The bipartisan letter this committee sent to your agency earlier this month asked the DEA to produce data and documents answering this question and others that we asked by this Friday. Is the DEA going to give us this information and documents that we have requested by Friday?

Mr. Doherty. Sir, thank you for the follow-up. To your point, sir, the DEA, we realize the importance of all the requests from the committee and we treat them as such in light of the opioid epidemic. With respect to the questions, for the record, we did turn those over last night, sir.

The Chairman. Questions from April, I think, right?

Mr. Doherty. Yes, sir. And in terms of a May 8th letter, we have been providing the answers on a rolling basis as to not delay an overall lengthy response. Those have been provided to the committee on a rolling basis and we continue to work on the few outstanding questions. And to your point, sir, the most recent letter, we are in receipt of that and we are preparing a response.

The Chairman. So I hope you can appreciate our frustration on this side. We have been trying to get to the bottom of this pill dumping issue.

Can we please silence our phones?

We have been trying to get to the pill dumping issue in West Virginia for a very long time. To me, this is a pretty basic question, who are the suppliers? Just yesterday, we finally received answers to the questions as you mentioned that we asked for back in April. We still don't have all the answers to the bipartisan letter we sent in May.

Some of the responses the DEA provided, frankly, are not adequate. For example, in the May letter we asked the DEA to

produce documents about delayed or blocked enforcement actions. Do you know how many documents your agency has produced? The answer is zero. The agency responded and this is a direct quote, DEA is unaware of documents related to the delayed or blocked enforcement actions and suspension orders, close quote.

We obtained from another source a whole bunch of documents that look pretty responsive to our request, and yet from the agency we are told you are unaware of documents related to delayed or blocked enforcement actions and suspension orders. This is a problem. Enough is enough. Will you on behalf of the DEA commit today to producing the documents and information we have requested and soon, or do I simply need to issue a subpoena because we are done waiting?

Mr. Doherty. Sir, we appreciate your concern and absolutely we are treating it with the utmost importance as it should be treated. There is no reason for the extended delay of the questions for the record which is now in the possession of the committee. We will make every effort to expedite every request that is outstanding to the committee.

The Chairman. I mean just for members' awareness on both sides of the aisle, the committee received yesterday a set of documents from an anonymous source. Bipartisan committee staff are now reviewing these documents.

Mr. Doherty, I have one more question before I move on. Have you or anyone at the DEA that you are aware of received any

instructions or directives to erase emails or otherwise destroy documents on this matter or any others?

Mr. Doherty. No, sir. I am not aware of that nor have I been involved in any conversation relative to that matter.

The Chairman. Dr. McCance-Katz, let me move to you. Given SAMHSA's central role in much of the federal government's efforts to combat the opioid epidemic, it is imperative that you and your staff have all of the tools necessary to perform these duties. Are there currently any obstacles or barriers hindering you and your staff's ability to respond effectively to this crisis and, if so, what can Congress do to help?

Dr. McCance-Katz. Thank you, Chairman Walden. We have -- we are very grateful, actually, for the legislation that has recently been passed by Congress in the 21st Century Cures Act and in CARA that adds to the armamentarium that SAMHSA had available to it to work with states and communities on issues related to mental disorders and substance use disorders, and so at this point we are in the process of implementing the laws and are looking to have feedback to then determine whether we need more than what we have.

We have, as you know, through the Cures Act made $500 million, each of 2 years, available to the states. We are working with the states to develop their plans for evidence-based interventions and treatments in their communities and we are following up with them to determine outcomes. We collect data

as required by law and as we get that data we will be looking at it to determine if more is needed.

The Chairman. Thank you very much.

Ms. DeGette. Mr. Chairman?

The Chairman. For what purpose does the gentlelady from Colorado --

Ms. DeGette. I have a unanimous consent request.

The Chairman. -- seek recognition? Proceed with your request.

Ms. DeGette. Mr. Chairman, I would ask unanimous consent to place two letters into the record. One is the May 8th, 2017 letter that you referred to which the DEA gave incomplete responses in particular documents to that was signed by you, Mr. Pallone, Mr. Murphy, me, and Mr. McKinley. And then I would also ask unanimous consent to put the October 13, 2017 letter in the record. That is the one that was signed by you and Mr. Pallone and Mr. McKinley and me which you referred to under which we have received none of the documents that are referenced in that letter.

And I just think it would be really useful to this hearing if the witnesses and the public would know that we have been trying to get these documents out of the DEA for quite some number of months now.

The Chairman. Without objection, those letters will be entered into the record.

[The information follows:]

**********COMMITTEE INSERT 3**********

The Chairman. And I would encourage our colleagues and others to avail themselves of those letters. I think they ask pretty specific questions that shouldn't be this difficult to get answers to.

Now I would turn to Mr. Pallone from New Jersey for 5 minutes for questions.

Mr. Pallone. Thank you, Mr. Chairman. And let me just reiterate again representing the Democrats in support of what Chairman Walden has been saying that we have sent these bipartisan letters to DEA requesting specific information, but we have had a very difficult problem in getting any answers. So I guess I just wanted to start out, Mr. Doherty, by getting a commitment that you will provide the committee with timely information and answers to our questions as we move forward because I totally agree with everything that The Chairman has said. I just -- yes or no, please.

Mr. Doherty. Ranking Member Pallone, you have our commitment that we will take every request from this committee seriously. We will review it carefully and we will try to make every effort whatsoever to respond in a timely, timely fashion. Yes, sir.

Mr. Pallone. Thank you. Now I wanted to move to another issue here. Coverage of the response to the epidemic often focuses on expanding access to treatment and increasing the availability of naloxone and, however, there are two elements

that must fit into a larger more comprehensive response.

Let me go to Dr. McCance-Katz. Could you briefly discuss the importance of deploying a comprehensive response to this epidemic spanning the entire spectrum from prevention to recovery?

Dr. McCance-Katz. Yes, Ranking Member Pallone. What I can say is that there are issues that we need to address in terms of prevention, prevention in terms of working with children and families around education, prevention that is targeted to individuals at risk for opioid overdose that includes making available the antidote naloxone widely available. It also includes providing training to first responders and to family members and to getting to physicians and other prescribers to help them understand who is at risk given medications they may be receiving in the course of treatment, and co-prescribing naloxone when needed.

In addition, when people develop opioid use disorders they also may be at high risk for overdose. They are at risk for overdose death and they also need access to the naloxone antidote. We address this in a number of ways. We do that through our treatment programs that provide medication-assisted treatment for opioid use disorder. And by the way that is a great way for demand reduction. We need to increase access to treatment so that people have less demand for illicit opioid use.

Mr. Pallone. Let me just -- I am just running out of time.

Dr. McCance-Katz. Oh, sorry.

Mr. Pallone. Look, let me just say this. I know you mentioned CARA, you mentioned the grants that had been available with the 21st Century Cures bill, and obviously as I have said, you know, I consider these down payments. I still think we need a lot more funding for some of these things that you are mentioning and that you know, we shouldn't just see those as down payments.

I know, tomorrow, the President is having an event at the White House and he is going to talk about establishing a national emergency, but I really think that we have to talk about more funding for some of these things. Not just the grants that are already out there, which are great, don't get me wrong, but there just needs to be a lot more.

Let me just get to the second question, and this is my only other question but I will ask it to you as well as to Dr. Volkow. As previously mentioned, treatment must be part of our comprehensive respond efforts. Could you discuss how limiting access or creating barriers to treatment could hinder our ability to respond to the crisis? I will ask you and then I will ask Dr. Volkow the same question.

Dr. McCance-Katz. Individuals who have opiate addiction, which means they are physically dependent on opioid as well as have the behavioral dysfunction associated with addiction, are at risk for overdose and death and cannot live productive lives. If they cannot get access to evidence-based treatment, which

includes medication-assisted treatment and psychosocial interventions, then that places them at greater risk and it is, I will just say it is very near impossible to recover without getting assistance in the form of these evidence-based interventions.

And by evidence-based interventions I do mean medication and psychosocial services and one of the problems that we see is that too often people do not get all of the components of treatment that they need to recover.

Mr. Pallone. Dr. Volkow, did you want to add to that?

Dr. Volkow. Yes. No, I agree with Dr. McCance. And there are three, I would add three things. One of them has to do with the notion of how do you get access to medication-assisted treatment? One of them is stigma, the other one is lack of sufficient treatment programs to be able to deliver it, and the third one is actually the lack of reimbursement for these treatments.

And I think that there are unique opportunities to change these and in particular, for example, one of the aspects that we are very much invested in partnership with SAMHSA is engaging the healthcare system in the expansion of the treatment of individuals with substance use disorders. And also I think an opportunity is to actually create policy to ensure that individuals are offered, as was mentioned earlier by Dr. Gottlieb, the opportunity of having access of to any one of the three

medications and that they will be reimbursed for them and there will be no place of limitations on that time that these medications are actually prescribed.

Mr. Pallone. I thank you.

And Mr. Chairman, just let me say again that my concern continues to be that if the effort continues on the Republican side to repeal or sabotage the ACA or cut back on Medicaid that this type of treatment will be even more difficult for people to access. But thank you, Mr. Chairman.

The Chairman. The chair now recognizes the vice chair of the full committee, Mr. Barton, for 5 minutes.

Mr. Barton. Thank you, Mr. Chairman.

I wasn't aware until I listened to your questions the difficulty the committee has had in receiving answers to questions on a bipartisan basis, so I am going to direct what would normally be my question period and opening statement to Mr. Doherty.

We represent the people of the United States. When you get a letter or your agency gets a letter from this committee that is signed by the chairman and the ranking member and maybe the subcommittee chairman you are supposed to answer it. You are not supposed to dodge it. Now I am a former subcommittee chairman of this committee and I am a former full committee chairman of this committee. I have issued subpoenas with the support of the minority to members of an administration of my own political party. I have had confrontations with cabinet secretaries, with

directors of agencies that were appointed by Presidents of my own political party.

It is absolutely unacceptable to listen with a straight face to your answers to our chairman. Now if I were you I would go back, get the answers in plain English as quickly as possible. If you don't -- and I know you are just the spear carrier you are not the decision maker, it is your agency -- I am going to recommend to the chairman that we bring the wrath of this committee down on DEA. It is inexcusable when people are dying every day from opioid overdoses that we have got apparently a 3-month, 4-month running dodge from the Trump administration.

Now our Chairman is much more polite than I am, you know, but you look up the definition of subpoena, the Constitution of the United States and the American people, and get the answers. Can you say yes sir to that? I don't want a dodge answer, I want a yes or no answer. Are you going to go back and tell whoever is running the show to get the answers our committee chairman on a bipartisan basis wants, yes or no?

Mr. Doherty. Yes, sir.

Mr. Barton. Thank you. We will follow up on that.

Now I want to go to Dr. Gottlieb. What percentage of the opioid crisis is prescription drugs versus illegal drugs? Which --

Dr. Gottlieb. I will defer to my colleague from SAMHSA for the current data. It has shifted a lot.

Dr. McCance-Katz. So if we look at the most recent NSDUH data from 2016 there are about 11.5 million opioid misusers in the country, about 948,000 are heroin users. So that --

Mr. Barton. So it is kind of 10 to 1?

Dr. McCance-Katz. Yes, sir.

Mr. Barton. Okay. On the legal prescriptions should we on this committee consider criminalizing the prescription, the prescribing of legal opioid prescriptions if it is considered excessive? Should that become a federal criminal act?

Dr. Gottlieb. I don't know who the question is directed, I mean that would fall within the context of the Controlled Substances Act. We don't have jurisdiction over the criminalization of prescribing in that context.

Mr. Barton. Well, we know we have a problem on the illegal side and we have been dealing or not dealing with it successfully for a number of years. But this excessive use of legal prescription drugs, at some point in time the finger points to the doctor that is prescribing the drug and that is currently not an illegal act. Should we make that an illegal act? When Chairman Walden says some pharmacy in West Virginia gets 11 million pills or 9 million pills, somebody is prescribing those excessively. Should that be a criminal act, federal criminal act?

Dr. McCance-Katz. So if I could, if there is excessive prescribing and there is harm to a patient or death of a patient

that does become a criminal act. If it is found to be excessive and negligent it can be charged as a criminal act. There have been many prescribers who have been prosecuted under current law. The difficulty becomes people who are not dying or having those kinds of adverse events that really get to public attention and so that excessive prescribing that puts you at risk for addiction.

Mr. Barton. My time is expired. I know on an individual basis it is difficult to determine what is excessive prescription --

Dr. McCance-Katz. Yes.

Mr. Barton. -- you know, in terms of the patient. But the prescriber, if you have a prescriber who is routinely prescribing a hundred times opioid prescriptions to the average doctor in the area that is somebody I believe we ought to look at. With that Mr. Chairman, I yield back.

The Chairman. I think Dr. Schuchat wanted to --

Dr. Schuchat. I just wanted to say that quite a lot of the overprescribing is not at that very extreme level, but we are really just at the beginning of getting clinicians to do better prescribing. It is only a year and a half since the CDC guidelines on prescribing for chronic pain and in places that are implementing them we are seeing pretty rapid changes in prescribing. So I think we need to do a lot with prescribing that was sort of within the range of practice.

The Chairman. All right, thank you. We will now go to my

friend from California, the gentlelady Ms. Eshoo, for 5 minutes for questions.

Ms. Eshoo. Thank you, Mr. Chairman. Thank you to all of the witnesses. I read your testimony very carefully last night and I am left with the following observations. We have passed laws to address the opioid crisis in our country and those two laws have been mentioned. We have all of the respective agencies before us working on it. We have a raft of statistics that are the horrible of horribles in terms of what this is doing to the country, how many people are addicted, how it is ravaging families, communities, et cetera, et cetera.

How much of the crisis is due to opioids being prescribed legally? I know that CDC handed this out and I think it tells part of the story. For every one prescription or illicit opioid overdose death in 2015, there were -- and then it goes through all of these numbers. But what I am trying to figure out is, are we a nation that is just almost hopelessly addicted to heroin -- and just say that out loud. How much is due what is legally prescribed for pain management, whatever, and versus how much is due to illegal use?

And I ask that question because I think we need to direct what we are doing. If we are going to put in place new laws or see how the laws are already working we need to know this. So who can answer that question just very briefly?

Dr. Schuchat. Yes. This is not an either/or situation.

Ms. Eshoo. I am not presenting it that way.

Dr. Schuchat. But to say that --

Ms. Eshoo. But I want to understand it better.

Dr. Schuchat. Sure.

Ms. Eshoo. I mean is it tilted towards just prescriptions that are written?

Dr. Schuchat. We got into this issue with the prescribing.

Ms. Eshoo. Pardon me?

Dr. Schuchat. We got into this issue with prescribing of opiates. We prescribe three times higher levels.

Ms. Eshoo. No, I understand that. I want to know what the --

Dr. Schuchat. And most people --

Ms. Eshoo. -- where the dividing line is. Is it 10 percent prescription drugs and 90 percent people that love heroin?

Dr. Schuchat. Over the last 2 years we had a spike in illicit drug related overdose deaths.

Ms. Eshoo. But can you tell me what the numbers are?

Dr. Schuchat. And that was --

Ms. Eshoo. Does anyone know?

Dr. Schuchat. Yes. Well, we had 65,000 deaths in 2016.

Ms. Eshoo. I know about the deaths.

Dr. Schuchat. About 49,000 of them were --

Ms. Eshoo. I want to know what is bringing it about though --

Dr. Schuchat. -- related to --

Ms. Eshoo. -- in terms of usage.

Dr. Schuchat. Yes. The increase in 2016 was fentanyl illicit laced with heroin. So the increase is the illicit drugs, but most of the people who are using illicit drugs became addicted through prescribing, through prescription opioids. That was their initial addictive product.

Ms. Eshoo. Have the agencies come together to examine, set down the, you know, CARA and the 21st Century Act and what was contained in them kind of as an overlay on this whole issue on opioids and made any kind of determination as to the early effectiveness of these laws; do we know? We don't know.

Dr. Volkow. No. We don't know, but we know that --

Ms. Eshoo. We don't know because it is too early?

Dr. Volkow. It is too early.

Ms. Eshoo. It is too early to know. In the area of treatment how much in terms of federal health insurance programs contain the money for this for treatment overall, does anyone know? Well, maybe someone can respond later in writing. It would be good to know, because if we are busy cutting and undermining that then it upends the underlying purpose of this hearing. I mean we can talk and talk and talk. We know we have a tremendous problem. People are dying daily. But if we are undermining the treatment at the same time, I think we need to have that documented.

Mr. Doherty, how many -- you testified that your agency is doing everything you can possibly do, overwhelming commitment, et cetera, et cetera. I believe you or I would like to believe you. How many opioid-related cases have actually been successfully adjudicated and how many open, active cases are there coming out of your agency and its work doubling down on the opioid crisis in our country?

Mr. Doherty. Ma'am, historically, in the --

Ms. Eshoo. No, I don't want to know historically. I want to know up to date.

Mr. Doherty. Well, ma'am, during the last year there have been approximately 2,000 arrests made with respect to diversion control cases and that would represent approximately 1,600 cases that were initiated. Those represent sweeping enforcement actions such as a week-long action that took place this past July in partnerships with HHS and the FBI, the National Health Care Fraud Takedown initiative.

This was the first year the DEA was a full partner, 120 of the 412 --

Ms. Eshoo. Does it include the companies that you haven't identified yet?

Mr. Doherty. I am sorry, ma'am?

Ms. Eshoo. Does it include the companies that you have not identified yet?

Mr. Doherty. That did not include companies. These were

120 individuals prescribing opioids of which 115 of the 412 were medical professionals.

Ms. Eshoo. I am way over my time. Thank you, Mr. Chairman.

The Chairman. Thank you. We now go to the gentleman from Illinois, Mr. Shimkus, for 5 minutes on questions.

Mr. Shimkus. Thank you, Mr. Chairman. Thanks for the hearing. Thank you all for being here.

I am going to shift some of the tone. Just a couple days ago I tweaked my back. I was in pain. When we went through this process last Congress, I was visited by a lot of patient groups who were just concerned that the pendulum would shift. And we use the term chronic pain you know people who have it forever and I want to make sure that we don't lose them in this debate, people who wouldn't be able to get out of bed without some assistance.

So I do have a statement for the record, Mr. Chairman, I would ask unanimous consent, from the American Physical Therapy Association addressing this.

The Chairman. Without objection.

[The information follows:]

**********COMMITTEE INSERT 4**********

Mr. Shimkus. Because then it goes into my first question for Dr. McCance-Katz. In your question and answer and some of your comments you talked about all of the components of treatment, which as I am getting more educated in this process it seems to me that we are not always considering all of the components, or maybe physicians, they may get stovepiped into one delivery system. And every patient is different, every pain issue, and that is kind of where the physical therapists are saying, hey, this should be part of some treatment.

So can you for the sake of all of us kind of talk about the difference between naltrexone, Suboxone and methadone, just briefly?

Dr. McCance-Katz. I will try. Yes, so naltrexone is an opioid antagonist. What that means is that it will block the effects of an opiate. So if somebody is opiate-addicted and they are withdrawn from those opioids and then started on naltrexone and then they use an opioid again they will not get the effect that they were expecting, so it will block them from getting high. So that is the value of naltrexone. It is often seen as a medication that gives a person a chance to get back to counseling because they may relapse while they are in their regular using environments --

Mr. Shimkus. Okay, just pushing you -- Suboxone.

Dr. McCance-Katz. I am sorry? Oh, you want me to go on.

Mr. Shimkus. Just pushing you.

Dr. McCance-Katz. Okay, here you go. Suboxone is what we call an opioid partial agonist, and what that means is that it has lower abuse liability and has less potency in terms of euphoric effects --

Mr. Shimkus. Okay, methadone.

Dr. McCance-Katz. -- than does methadone which is what we call a full agonist and it is a medication that is only available for the treatment of opioid use disorder through federally regulated opioid treatment programs which my agency regulates.

Mr. Shimkus. Okay, let me go to Dr. Schuchat. How does CDC inform evidence-based best practices? So if you are using these three different things how do you collect that data?

Dr. Schuchat. CDC is working to evaluate the medication-assisted treatment and counseling efforts that SAMHSA has right now, so we actually have a study in the field with these different modalities, look at outcomes --

Mr. Shimkus. So then the information can get out and people --

Dr. Schuchat. Right, so that we can share --

Mr. Shimkus. -- can make better determinations.

Okay, let me go to Mr. Doherty. This will be a friendly question. Category II or III what is the difference?

Mr. Doherty. Schedule?

Mr. Shimkus. Schedule, yes, Schedule II or III on the drug listing.

Mr. Doherty. Yes, sir. So with respect to Schedule II, for instance, those are controlled prescription pain medications in the oxycodone, hydrocodone family and we certainly, they go in a range from III, IV, and so on.

Mr. Shimkus. So what is the difference between a II and a III?

Mr. Doherty. The difference is, sir, is that it is more strictly controlled within DEA on the schedule.

Mr. Shimkus. Why?

Mr. Doherty. Based on the scientific dependency of it too.

Mr. Shimkus. Okay, dependency, what else?

Mr. Doherty. Danger for abuse.

Mr. Shimkus. Danger for abuse.

Okay, let me go to Dr. Gottlieb, FDA black box labeling. It is my understanding there is no communication based upon Schedule and what might be labeled. Now you see where my whole thrust of these questions is more information, more different practices, and then that would also go to labeling. If DEA says Schedule III is less addictive, shouldn't that maybe be listed on the label?

Dr. Gottlieb. I could certainly take it back to the agency. There is labeling language that reflects some of the qualities of the drugs that relate to their abuse potential currently.

Mr. Shimkus. Do you agree that there may or, I mean I would hope that we would talk together and that our agencies would

communicate that. That might give the practitioners a little more information.

Mr. Chairman, my time is expired. I yield back.

The Chairman. I thank the gentleman's comments. It is interesting in Oregon, I think through the Oregon Health Plan, they actually often give the antidote naloxone with the prescription for opioids, which the people in the roundtables I have been in sends a real signal of seriousness about what people are being given to take, the opiates, because here is the antidote because it may kill you. And they tell me that gets the attention of those receiving the prescription.

With that we will turn to the gentleman from New York, Mr. Engel, for 5 minutes for questions.

Mr. Engel. Thank you, Mr. Chairman and Mr. Pallone for convening today's hearing.

This epidemic has touched so many people in each of our districts in so many ways, so I would like to talk about the specific challenges in my district facing Westchester County in New York and the Bronx in New York City. I represent a large portion of Westchester where opioid-related deaths shot up more than 200 percent between 2010 and 2015, but that changed in 2016 when the rate of opioid-related deaths in Westchester fell nearly 30 percent and evidence suggests this was thanks to the overdose reversal drug naloxone. Naloxone. That is why I didn't go to medical school, law school was easier.

Between 2015 and 2016, Westchester EMS workers and law enforcement began using this medication much more frequently following state and local efforts to make it more accessible and ensure first responders know how to use it, so I believe this shows what is possible when we afford communities the resources they need. So Congress must continue to invest the necessary funds to respond to the opioid epidemic and support proven public health approaches spanning the entire spectrum from prevention all the way to recovery.

I am so encouraged to see a devastating trend reversed in Westchester, but this battle obviously is far from over. Naloxone is certainly a lifesaver but it could also be a gamechanger, and if we can connect people with treatment after they have overdosed we might even save more lives.

So Dr. McCance-Katz, how are we doing as a country with respect to connecting Americans with treatment after they have overdosed and how can Congress help us do even better?

Dr. McCance-Katz. Yes. Thank you for that question.

And so we have, SAMHSA has a number of programs that are demonstration programs across the country that address issues around the need for naloxone as an antidote. Treatment in EDs and what we are doing in the models that we are working with include bringing peers, people with lived experience of opiate addiction into the emergency departments so that they can talk with people who have experienced an overdose and provide them some guidance

and help and support to get them to treatment. And we are in the process of having these programs under -- they are ongoing right now and we will be evaluating those programs.

I will tell you though I am from Rhode Island. I come to federal service having been a practicing physician, a psychiatrist in Rhode Island, and was involved with the opioid epidemic in Rhode Island. And one of the things that we observed in Rhode Island was that a lot of times when people are reversed they are not comfortable, that sometimes they will experience opiate withdrawal when they are given naloxone and they are not ready. They are not ready to commit to treatment at that time.

And so what we started doing was getting consent from people so that our peers could follow up with them in communities. And we think this is going to be a key piece of connecting people to treatment and we will be expanding those kinds of models at SAMHSA.

Mr. Engel. Well, thank you. And let me say the other part of my district is the Bronx. We are not seeing, unfortunately, the same signs of hope there. More New Yorkers die of overdoses in the Bronx than in any other city borough last year. Eighty five percent of those deaths involved opioids.

And despite the proximity and attached to each other, Westchester and the Bronx have many differences. On average, communities in the Bronx have fewer resources, the uninsured rate is higher, and communities are more diverse. So the disparity

that we are seeing and the trajectory of these counties' opioid epidemics is also an economic disparity and a racial disparity. So the consequences of this disparity are really heartbreaking. Your ZIP Code should not determine your health or what you get to make you better. We need to do better.

So on the basis of that statement, let me ask Dr. Schuchat and Dr. McCance-Katz again, how can Congress address these disparities and ensure that every person regardless of sex, race, location, or income has the same ability to get treatment?

Dr. McCance-Katz. I will just say SAMHSA has an Office for Behavioral Health Equity. We are very involved in monitoring those kinds of issues and we work very hard to provide guidance to states and communities on culturally appropriate, culturally sensitive interventions, and we will be continuing that work.

Mr. Engel. Dr. Schuchat?

Dr. Schuchat. Yes. And one of the things CDC was able to do with the increased funding this past year was strengthen the syndromic surveillance goal from 12 states to 32. And what that has allowed is better data on where the problems are, hotspots or inequities can be followed up and so you can get more resources. Even the naloxone distribution can be targeted to where the overdoses are highest and expanding services into those areas.

I know in the New York area, in New York City area that has been done, trying to figure out where the need is and get the clinical services closer to those hotspots.

Mr. Engel. Thank you both. Thank you, Mr. Chairman.

The Chairman. Thank you, Mr. Engel. We will now go to the chairman of the Subcommittee on Health, the doctor from Texas, Dr. Burgess.

Mr. Burgess. Thank you, Mr. Chairman, and thanks for holding this hearing. First off, I am going to ask unanimous consent to my opening statement being made part of the record.

The Chairman. Without objection.

[The information follows:]

**********COMMITTEE INSERT 5**********

Mr. Burgess. And I will point out that your attention to this issue has been important. At the subcommittee level as you know we heard from over 50 members, not just from on the committee but throughout the Congress, 50 members. We held a Members' Day on problems that people were having with opiate abuse back in their districts and we did hear that it literally touches every part of the country.

I am going to ask questions of the doctors on the panel. I have been on this committee long enough to remember when we had a hearing on the underprescribing of pain medicine in 2005, so just for those of you who are still in practice, what is a doctor to do? You have a patient that has a condition that is painful and you want to alleviate that suffering. How do you now approach that? Are you not going to use an opiate where you might have otherwise thought it was appropriate?

Dr. Gottlieb, you referenced that it is going to cause us to think in some uncomfortable ways because we have run out of reasonable options. So starting with you I would just like to go down the panel and hear from you.

Dr. Gottlieb. Thank you for the question, Congressman. There is a role for these medications in medical practice and there is patients who have acute pain conditions where these medications can be effective. There are some patients with chronic conditions like metastatic cancer pain that are going to require long-term treatment with opioids. But I do think that

there was a generation of physicians trained, and I think it was my generation of physicians trained, to make more indiscriminate use of these drugs than we should have. I remember when I was practicing in the hospital as a resident and that is not too long ago, every patient had a standing order for Percocet. Every 6 hours a patient had a standing order for two tabs of Percocet that could be prescribed at the nurse's discretion, almost every patient. That wasn't good medical practice we now know. That sensitized a lot of patients who were hospitalized for 5 or 6 days to round-the-clock immediate release formulations of opioids and some of those patients left the hospital addicted.

So I think we need to rethink how we use these drugs and I think we are in the process of doing that. But that is going to also require to reeducate a generation of physicians and that is what we are doing.

Mr. Burgess. Since you brought up your residency I will bring up mine. My generation of doctors was able to put a refill on a prescription that we sent home with the patient and somewhere along the line that ended. Now I realize those are state laws, but the inability to refill a prescription, and really this is for any of you, the inability to refill a prescription without going back and seeing the doctor and having that face-to-face encounter, I mean it seems to me that human behavior might dictate that a doctor would -- I don't want to get calls for a refill on a pain medicine so I will write it for twice the amount that

I used to write it for. Does that happen?

Dr. Gottlieb. Look, I will defer to my colleagues who have more substantive data on these issues. But when we look at the epidemiology we see too many 30-day prescriptions being written for indications for which, you know, the proper course would be a 4- or 5-day prescription. You have dental procedures, minor surgical procedures, so we do see that happening.

And to the extent that we believe that addiction correlates with exposure, and one of the keys to solving the new addiction crisis is to reduce overall exposure to opioid drugs, you would want to encourage approaches that make it easier if not try to create more direct incentives to prescribe shorter duration uses. That includes packaging. It includes proper education. These are things we are looking at doing.

Mr. Burgess. Sure. I am going to have to jump ahead so I am going to ask all of you to respond to that question in writing to me if you would, because I do need to ask Mr. Doherty a question on -- you used a term that I was not familiar with, the CPOT; is that right?

Mr. Doherty. That is correct, sir.

Mr. Burgess. And that stood for?

Mr. Doherty. CPOT stands for Consolidated Priority Organization Target, and it is a Department of Justice term designated for our most prolific trafficking organizations in the world.

Mr. Burgess. And what legal tools do you have? When you arrest a CPOT and bring a successful prosecution what are you charging them with, just the drug laws or are you able to charge them with injury to a person or murder?

Mr. Doherty. Well, with respect to your question, sir, and thank you, the CPOT designation is typically affiliated with organizations, mainly international organizations, our large target list in China, our target list in Mexico. So to point out the press release last week of the two Chinese nationals that I mentioned in my opening statement --

Mr. Burgess. Right.

Mr. Doherty. -- these individuals are prolific in nature shipping massive amounts of fentanyl to our country.

Mr. Burgess. So if you are successful in prosecuting them, what statute are they prosecuted under?

Mr. Doherty. Sir, they would be prosecuted under a variety of violations, importation.

Mr. Burgess. So how long do they go away for?

Mr. Doherty. Sir, I can't comment on that particular case.

Mr. Burgess. But in general what would the sentencing guidelines be?

Mr. Doherty. Generally speaking, if we were to go after a CPOT and either arrest him in the United States or have him extradited, potentially, hypothetically he could stand RICO charges. He could stand murder charges. He could stand money

laundering charges. He could stand wire fraud charges. So really --

Mr. Burgess. Is it theoretically possible to bring murder charges against someone in that situation?

Mr. Doherty. If we can definitely prove, and again I realize this is a hypothetical situation.

Mr. Burgess. Sure.

Mr. Doherty. If we can definitively prove that either he was directly involved, he or she was directly involved in murder or supplied fentanyl to individuals in this country that overdosed and died, we would definitely, unequivocally, bring murder charges, death resulting charges on these individuals.

Mr. Burgess. And I would make that widely known and dispersed. Thank you, Mr. Chairman. Thank you, sir.

The Chairman. Thank you, Mr. Chairman. And one of those folks, an Oregonian overdosed related to that case where the indictments came down, so it is personal to our state. We will go now to the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. Green. Thank you, Mr. Chairman and our ranking member for this really important hearing today. The 21st Century Cures Act contained a billion dollars to fight the opioid epidemic. This is substantial but certainly not enough to win the fight.

Dr. Schuchat, can you talk about how this funding is being used on the ground?

Dr. Schuchat. Well, the 21st Century Cures Act didn't

actually provide funding to the CDC, so I probably want to let my colleagues talk about that. The committee in last year's 2017 appropriation did give, separately give CDC a $50 million increase which has been incredibly helpful in our reaching out to more states to speed up the timing of the quality data that helps them know what they are doing and to increase the consumer awareness with the communication effort.

But I should probably let my colleagues talk about the funding.

Mr. Green. Whichever has the information, I was wondering what the outreach was. You know, it is relatively soon for even though the bill was passed, but what are we seeing changed now because of that?

Dr. McCance-Katz. Yes. So SAMHSA is responsible for the State Targeted Response. This is the 500 million a year for each of 2 years. The first year was allocated to the states. We have been working with the states on developing their plans based on their assessments of their communities and their needs related to prevention, treatment, and recovery services.

We review those. We make sure that evidence-based practices are being used and then the states will procure the services that they need to implement those plans and we are at that point right now, sir.

Mr. Green. Okay. I would hope you would continue because, you know, we want to see where this -- and you are learning I

guess from different states on what works and what doesn't.

Dr. McCance-Katz. Yes. And we would be happy to provide additional information as time goes on to this committee.

Mr. Green. Okay, thank you.

Dr. Volkow, I understand that NIH is partnering public and private stakeholders to accelerate the research in the non-opioid, non-addictive therapies. I also understand that Dr. Gottlieb has taken proactive steps to provide information and to reshape the provider behaviors as it relates to prescribing practices for opioid.

This panel would be the experts who are actively engaged in fighting the public health battle, so I want to ask you what I believe is a key question on the strategy going forward. How do we elevate the value and utilization of alternatives of the opioids across the healthcare system? Some alternatives do exist today and are we hearing more are in the development?

But given the rampant rate of prescribing and use of opioids how do we change that part of the problem? And that was any --

Dr. Volkow. Yes. No, and I think that the point has to do with how do you change the practice of clinicians that have been overrelying on the utilization of opiate medications for a variety of reasons to treat severe pain and become actually to treat not so severe pain.

So one of the big challenges is how do you implement the CDC guidelines, number one. And number two, among one of the

challenges is to ensure that physicians will be reimbursed for actually following the guidelines. Because what they recommend is a multi-pronged approach for the management of pain, integrated response that is much more expensive than what it would cost to give you an opioid prescription.

So as we are discussing the notion of changing and educating and training physicians on the use of prescription opioids and management of pain, we need to change the structure of reimbursement so that the doctors can do the right thing for their patients and get reimbursed for it.

Dr. Gottlieb. I will just, I can pick up just to add that we do see innovations in the pipeline that could provide alternatives to opioids and provide opioids that are harder to manipulate in ways that could help defeat abuse. We see technologies that where the opioid-like drugs but are biased at the mu-opioid receptor in ways that might not have the same addictive potential. We see second and third generation abuse deterrent formulations that are potentially much harder to abuse, things like prodrugs in development. So there are very interesting, very promising technologies available that could potentially treat chronic and acute pain in ways that don't lead to the same addiction.

And I would also offer that there is a lot of medical device alternatives. We have approved about 200 different medical devices that have components that treat pain, about ten of those

are very novel devices. And so we see a lot of opportunity looking across the continuum of medical devices as well to help address painful syndromes locally rather than systemically.

So there is a lot of opportunity and we have fast tracked some of these products. These products would be also eligible for the breakthrough therapy designation that this committee made available to the agency.

Mr. Green. Thank you, Mr. Chairman.

Mr. Burgess. [Presiding.] The gentleman's time has expired. The gentleman yields back. The chair recognizes the gentlelady from Tennessee, 5 minutes for questions, please.

Mrs. Blackburn. Thank you, Mr. Chairman. We appreciate that all of you are here. As you have heard from everybody, this is work we have been working on for years and trying to figure out how to best get a handle on this issue and end this epidemic and it is so important that we hear from you.

What I want to start with, and this is to each of you on this panel, are there any existing statutes that prevent your agency, your respective agencies, from effectively responding to the opioid crisis?

Dr. Gottlieb. Well, Congresswoman, we would be delighted to work with the committee to look across the range of our different authorities and what more we can be doing. The one that I would just point out in response to your question is where we are trying to take some new steps to think about how we step

up our oversight in the international mail facilities to target synthetic drugs coming in through the mail. And in this regard we have worked very closely with Customs and Border Patrol, the commissioner there has been a very good colleague to FDA.

But there is the potential that we might want to take a look at some point at some of the seizure authority we have --

Mrs. Blackburn. Okay.

Dr. Gottlieb. -- to perhaps make it more efficient to operate inside those IMFs.

Mrs. Blackburn. Okay, anyone else have any existing statute that is an impediment?

Mr. Doherty. Ma'am, from DEA's standpoint, and I will address what was recently reported in the media, one of our administrative tools, an immediate suspension order recently came under report in the media.

We would be happy to work with Congress and we look forward to working with Congress with Department of Justice oversight to ensure that from an enforcement, criminal enforcement perspective, a civil sanction perspective, and an administrative perspective, which are all tools that we use to prevent the diversion of illicit pharmaceuticals, we would be more than happy to work, as I said, with Congress with Department of Justice oversight to ensure that we have the most updated and applicable tools moving forward to attack the opioid crisis.

Mrs. Blackburn. Okay, anyone else?

Dr. Volkow. Well, I think that on following my DEA colleague, I think one of the issues that becomes very important on the aspect of research is our ability to work with substances that are being abused, illicit substances that are very, very dangerous. And that is important because if we don't understand it from microbiological properties we cannot actually develop treatments. And one of the aspects on it is that because they are Schedule I substances then it can become very, very difficult to actually do research on them.

So being able to generate the category that allows us to protect the public from these substances what allows us to do that research would facilitate our ability to respond to this.

Mrs. Blackburn. Okay. That is great. And if any of you would like to submit something to us in writing that would be helpful.

And Dr. McCance-Katz, you mentioned and I will just ask you to submit this in writing, you talked about implementation of 21st Century Cures. If you will give us your timeline for where you are on that because, and you can just give it to us in writing.

Dr. McCance-Katz. I will.

Mrs. Blackburn. We are all interested in that because that is getting the money out to our states and that is an imperative for us.

Mr. Doherty, I am coming back to you on the Ensuring Patient Access and Effective Drug Enforcement Act. It required, it

required the DEA and HHS to submit a report to Congress identifying current issues with diversion efforts including information on whether coordination between the industry and law enforcement has helped. And that report was due to us in April, so it is now 6 months late.

I sent a letter over this week asking about this report, so why don't you -- and Mr. Chairman, I would like to submit for the record the letter that was sent over requesting the delayed report.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 6**********

Mrs. Blackburn. And what I would like to hear from you is what is the status of that report? You have heard the frustration with this panel for not getting information we need from the DEA, so we are adding this to the list. Where is the report? What is the status of it, when should we receive it?

Mr. Doherty. Congresswoman, thank you for that question. And with respect to the report that you mentioned, DEA has engaged with Health and Human Services on that report and it is my --

Mrs. Blackburn. Engaging isn't getting a report to us that is now 6 months late. So when do we get the report?

Mr. Doherty. It is my understanding, ma'am, that HHS has the lead on this report that you reference.

Mrs. Blackburn. Have you all submitted your needed information to HHS to write this report?

Mr. Doherty. I believe we have and we have been actively working on our part of the report with them.

Mrs. Blackburn. Okay, thank you, yield back.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the gentlelady from Colorado, Ms. DeGette, for 5 minutes for questions, please.

Ms. DeGette. Thank you, Mr. Chairman.

Mr. Chairman, we have been talking today about 21st Century Cures and the billion dollars that Fred Upton and I were pleased to put into that bill for state funding to develop opioid prevention programs. Just for the record, in Colorado we have

a program called the Consortium for Prescription Drug Abuse Prevention. They are already taking this money from Cures and they are already doing work to reduce overdose deaths. It is really important that we do this on a state-by-state level because the states have different needs, and I would hope that we would work as a committee to extend that funding out past 2018 because it expires in 2018.

I want to, Mr. Doherty, I just want to follow up -- I am over here. I want to follow up on a couple of the Chairman's questions and others. We have been talking to you about that May and that October letter that we sent to the DEA asking for responses and documents. Were you aware that the Chairman and several other members also met with the acting director of the DEA in July, on July 28th of this year? Were you aware of that meeting?

Mr. Doherty. Yes, ma'am.

Ms. DeGette. And were you aware that at that meeting we also asked him to provide that documentation and those answers and he said he would?

Mr. Doherty. Ma'am, I am generally aware of the meeting. I am not sure what was discussed at the meeting.

Ms. DeGette. Okay. Well, I will tell you that is what happened. Now I also want to ask you, as the Chairman said we have been investigating reports of shipments of large amounts of opioids to Kermit, West Virginia. Can you tell us today which

distributor, or distributors, supplies those large amounts of opioids to the pharmacies in Kermit, West Virginia?

Mr. Doherty. Ma'am, as I said before I don't have that information with me.

Ms. DeGette. When can we expect to get that information from you?

Mr. Doherty. And we will expedite that information and after the hearing.

Ms. DeGette. 1 week, 1 month, 1 year; when can we expect to get it?

Mr. Doherty. Ma'am, I would not be able to put a timetable on that.

Ms. DeGette. You are not going to tell me.

Mr. Doherty. I will --

Ms. DeGette. Chairman, I think that subpoenas may be really considered in this point.

Let me ask you another question. On the October 13th letter which I put into the record a little awhile ago, the committee using DEA's collected ARCOS data looked at the amount of hydrocodone and oxycodone that went into the various regions of West Virginia and they show that from 2000 to 2010 there were dramatic increases in the distribution of opioids to the regions examined by the committee. Would you agree that some of these trends are troubling?

Mr. Doherty. Yes, ma'am. I would.

Ms. DeGette. Okay. And has the DEA conducted its on analysis of its ARCOS data regarding the trends in West Virginia and does the DEA know which distributors were responsible for this?

Mr. Doherty. Ma'am, the DEA has upgraded our office --

Ms. DeGette. I think yes or no will work. Do you know who did this?

Mr. Doherty. Ma'am, with respect to the shipments, the ARCOS data provides information and we are currently unable to determine definitively --

Ms. DeGette. So you don't know.

Mr. Doherty. It is my understanding currently that we have information relative to companies involved and we are reviewing that data to determine what we can legally --

Ms. DeGette. And I assume we will get that answer too, correct?

Mr. Doherty. Yes, ma'am.

Ms. DeGette. Okay.

Dr. Volkow, I wanted to ask you a question about the naloxone. You had a really snappy spray of the naloxone that you used, but I think you can probably tell us that most of the people who are distributing naloxone cannot afford that; isn't that accurate?

Dr. Volkow. Thanks for the question because I think it is very important.

Ms. DeGette. Okay.

Dr. Volkow. We can have very fancy scientific tools that are so expensive that nobody can afford it.

Ms. DeGette. Right.

Dr. Volkow. This thing costs $37.50.

Ms. DeGette. Well, unfortunately, I -- what is the manufacturer of that?

Dr. Volkow. This is Opiant and it is in partnership with the Adapt Pharma, so.

Ms. DeGette. Okay. So the Adapt price in 2016 according to the New England Journal of Medicine was $150. And in fact, in the August recess this year, I went over to the Harm Reduction Center in Denver. I actually got trained how to use naloxone and they gave me some naloxone that they give out to people. They told me they can't afford to use that. And what they gave me was this little vial of chemicals and they gave me a syringe and another little vial which I actually learned how to inject somebody, and the reason they use that is because that one costs only $39.50. And so my point to you and the point I want to make to the chairman, we are going to have to do some more investigation in this committee. This is where it intersects with the increase in prescription drug prices. Because the auto injector was $690 and now it is $4,500, the one that you have got there it is $150. Even the one I have here, between I think 2014 and 2016 has gone up to 39.60.

So it is great to have naloxone for people, but if you don't have something that is easy to administer because the prices are just going up, then it is not going to be usable.

Dr. Volkow. And I completely resonate with you we want to do things that are affordable. But I want to comment on the notion that this implementing the syringe does not deliver naloxone at sufficiently high concentrations because it is very diluted. So we not only have to give something that is affordable, but we need to give something that is effective.

Ms. DeGette. You are totally right. I agree, thank you. Thanks, Mr. Chairman.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for questions, please.

Mr. Latta. Well, thank you very much, Mr. Chairman. And thank you very much to our panel today. We really appreciate you being here and this is a very, very important hearing that we are having today. Ohio, in 2015, we lost 3,050 people because of opioid overdoses and last year that total went up to 4,050. And our county coroners are now predicting that unfortunately we are on a pace to exceed the 2016 numbers.

And I have my second opioid forum and that was held last week and, you know, when you are talking about these statistics of 3,050 or 4,050 people losing their lives, you know, those are the statistics but you put a face with them. And I talked with

a parent who had lost a child because of opioid overdose and it is, you know, it is heartbreaking. And so I am very happy that you are here today because this is a very important subject and we are in an epidemic across this country.

And Dr. McCance-Katz, if I can start with you, CARA provided significant funding for states to expand substance use disorder treatment through grants administered by SAMHSA. In addition, CARA required that grantees submit data that will be posted online and easily searchable. Can you provide us with a status update of those requirements?

Dr. McCance-Katz. Yes. So SAMHSA has awarded grants under the CARA initiative, the legislative requirements. Some of those we call this our MAT-PDOA program which is focused on medication-assisted treatment specifically for prescription opioids and heroin users. And so we are collecting data and that data will be available at the end of the program and it will be available to individuals to easily analyze, yes.

Mr. Latta. Let me follow up too. And what accountability measures is SAMHSA requiring to make sure of states to make sure that that grant money is being wisely spent out there?

Dr. McCance-Katz. Yes. Thank you for that question. What is required is that they submit to SAMHSA their plans for their states and what practices they intend to use. We review those. We provide guidance to them. And in the terms and conditions of grant award they are required to use evidence-based practices

going forward and so we will be working very closely with them.

Now that requires that we provide them technical assistance and so that they can make determinations of what evidence-based practices are best for their communities, every state being different of course. And we are developing a new program of enhanced technical assistance where we will help states to get experts from the various fields that provide care in substance use disorder treatment -- psychiatrists, addiction medicine specialists, advanced practice nurse practitioners, physician assistants, social workers, peers -- that will be available to states to help them as they think through their needs and put evidence-based practices in place.

Mr. Latta. Well, thank you. And when we had the forum last week in my district one of the things that came up, and this will pretty much be a yes or no answer for all of the panel that is here today, part of the issue is for a lot of the folks out there is a lack of reliable information and data that is available out there and it is difficult for many of especially smaller communities to find funding streams and access information on how effective government programs have been to combat opiate abuse. I am working on a bill right now that would create a publicly accessible electronic database to help mitigate these problems.

And I would just like to ask each of you real quickly if yes or no would you all be, as we are working on this legislation

to collaborate with me to make sure we can get this information out there to the public, because again it is a very, very difficult thing for the smaller communities, smaller agencies to do. So if I could just go right down the line, if I could ask for your cooperation on that.

Dr. Gottlieb. Yes, sir, Congressman.

Dr. McCance-Katz. Yes, happy to do that.

Mr. Doherty. Yes, sir. We would be happy to work on that.

Dr. Schuchat. Absolutely.

Dr. Volkow. We would be delighted.

Mr. Latta. Well, thank you very much. And maybe if I can just follow up with the remaining time that I have with FDA. You know, when we were talking and you mentioning, Doctor, about that you know what we have with the epidemic we have in the United States, but looking around the world, do other countries have the same situation that we have with this opioid epidemic?

Dr. Gottlieb. I would defer to my colleague from SAMHSA, but my experience with the data is no, Congressman, and prescribing in other countries isn't as rampant as it is here in the United States.

Mr. Latta. So you are saying it is on the prescribing side because of where we have gone.

Maybe I could, Mr. Chairman, I am a little bit over my time but --

Dr. Gottlieb. Certainly that started on the prescribing

side. We still have, I think it is a fair assessment we still have too many prescriptions being written particularly for the IR formulations of these drugs, 190 million prescriptions a year represents 90 percent of all the prescriptions that are written for opioids. But increasingly, it is shifting to a problem of illicit drugs and low-cost alternatives which are the heroins and the synthetic fentanyls.

Mr. Latta. Well, thank you very much, Mr. Chairman. My time is expired.

Mr. Burgess. The gentleman is correct, his time has expired. The chair recognizes the gentleman from Pennsylvania, Mr. Doyle, 5 minutes for questions, please.

Mr. Doyle. Thank you, Mr. Chairman.

Based on CDC data in 2015, over 4,200 individuals age 15 to 24 died of drug-related overdose deaths. This is an increase of almost 200 percent since 2000 when the number was less than 1,500. So we know that children, adolescents, and young adults are part of this epidemic. Not just because they are losing parents and being sent to foster care, but because they are using drugs, getting addicted, and dying. The Children's Hospital of Pittsburgh has screened more than 31,000 children in the first 3 months of their new program rollout and has already found 60 children to be at high risk for or at levels of substance abuse.

So my question for the panelists, and I would start with Dr. McCance-Katz, what resources are being directed across the

agency to the prevention and treatment of substance use disorder in children and adolescents?

Dr. McCance-Katz. We have a number of initiatives that address substance abuse and substance abuse prevention in children and adolescence and I will just start with pregnant women who are opioid-dependent and we have programs to assist them with treatment. We also make technical assistance available to providers so that they can provide the best care to women and their infants who may be born physically dependent on opioids and need treatment. We also have a program that has just recently started that will address issues and what we call transitional age youth.

And so the age group that you are speaking of and this would be 18 to 25 year olds is a difficult group to treat. Traditionally, they are more difficult to engage in treatment. We don't have a lot of information as we do in older, in adults as to what works best for them. And so we are bringing experts into SAMHSA to give us information about how to work best with this age group and to provide that guidance then to states and communities.

In addition, we are also putting together a workgroup that will look at the effects of opioids on the developing fetus, and so what kinds of issues could be expected in terms of development of children who have been opioid-exposed in utero. That is an ongoing project.

I might though ask my colleague Dr. Volkow to mention some of the initiatives and research they are doing, some excellent research at NIH on these issues as well.

Dr. Volkow. I want to highlight only one because I think that the issue of preventing the drug use among teenagers and young individuals is one of the most impactful things that we can do. So one of our main initiatives in partnership with other institutes is that a story that will be prospectively following 10,000 children as they transition into adulthood and periodically assessing them for their brain development in order to understand how exposure to drugs actually influences the development and architecture of the brain.

And that is very important, because if we understand it then that we can tailor intervention to try to reverse them, to reverse them and provide resilience for those that may have vulnerabilities. So this is one of our top priorities, to actually protect that adolescent from getting exposed to drug and if they get exposed how do we actually restructure it into one intervention that will provide them with resilience.

Mr. Doyle. Yes.

Dr. Schuchat. Maybe I could just say some of the CDC initiatives really do target that age group. In terms of improved prescribing, we know that a lot of people who become addicted's first prescriptions were for, you know, youth sports-related problems for instance. Our consumer-facing communication

campaign really targets the families of survivors, the parents who have lost a child.

And then the last thing I would mention is a technical package that CDC released about efforts that can intervene against the problem of youth suicide which has an overlap with the opioid issue.

Mr. Doyle. Thank you. I would just like to, you know, I appreciate all these answers, but I would just like to add that it seems a lot of what is being discussed also needs to be tied into children having health insurance and access to care.

And in my state in Pennsylvania, over 1.2 million kids rely on Medicaid and CHIP for their health care and as we all know, we have spent a lot of time this year talking about huge cuts to Medicaid and this body, unfortunately, has yet to come to an agreement on how to fund CHIP. So I guess it really begs the question how much do all of these programs matter if children don't have basic health insurance.

Mr. Chairman, with that I see my time is expired and I will yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from Kentucky, the vice chairman of the Health Subcommittee, 5 minutes for questions.

Mr. Guthrie. Thank you, Mr. Chairman. Thank you for yielding. I appreciate everybody being here, this is important.

Kentucky is like a lot of states has had its share of tragedies through the heroin and opioid overdoses. Our state legislators, our governor, and everybody is working very hard, our physicians, trying to move forward, and our Drug Task Force folks, I mean it is all-out effort and it is still a very, very serious problem as that is why we are here today.

Dr. McCance-Katz, I wanted to ask you a question. A behavioral health provider in my district reported that it is not uncommon -- not uncommon, I guess that means it is a little less than common, but not uncommon -- for some of the managed care organizations to request up to 70 pages of authorizing paperwork from their board-certified addiction specialists to treat one patient with medication-assisted treatment. This provider stated that it can require 2 to 3 hours of staff time to submit the requested paperwork to treat one patient.

In your testimony you mentioned the Medication Assisted Treatment for Prescription Drug and Opioid Addiction grants within SAMHSA. Would you please elaborate on this program and inform me of what SAMHSA is currently doing to evaluate and ensure patients receive timely treatment and quality providers are able to deliver care to their patients?

Dr. McCance-Katz. So SAMHSA has a number of initiatives to bring people to medical attention early on. We have a program that has been in place for a number of years. Not the program that you are speaking of, but it is called our SBIRT program which

is Screening, Brief Intervention, and Referral to Treatment. This is a paradigm that involves training primary care providers on how to screen for hazardous substance use or use that has evolved into a use disorder and get people to appropriate treatment. So we do a lot of work in that area.

In addition, we have our what I said was our MAT-PDOA, Medication Assisted Treatment program that is funded through the CARA act and this is a program that allows states to develop programs that focus on medication-assisted treatment to getting that to their community. States can do this in any number of ways.

In fact, before I had this position I had one of those MAT-PDOA grants in Rhode Island and what we did was we put together what we called a center of excellence for the treatment of opioid use disorder to stabilize people coming into treatment for serious opioid addiction and then to transfer them to community providers who were willing to take on this care. They previously were not willing to do that because, because they were concerned that they didn't have the skill set needed to deal with all of the aspects that addiction brings to care.

And so every state will do this differently, but those are the types of programs and there are different iterations. We call them sort of hub and spoke models where you have -- well, I will stop there.

Mr. Guthrie. Okay, thanks. Well, I think we agree that

patients have to receive timely treatment.

Dr. McCance-Katz. Yes.

Mr. Guthrie. And at the facility in my district they found that in 1-year follow up the majority of patients on medication-assisted treatment are still actively involved in the treatment and these individuals are less likely to be incarcerated and to relapse, and to be employed. So, you know, it is important.

One more question for you then. One of the recommendations of the interim report of the President's opioid commission was to repeal the prohibition of Medicaid paying for services for some patients in an institution for mental diseases or IMD exclusion as we all refer to it here. I have heard from many that we should dial back this limitation in certain instances, if not entirely, particularly in the midst of a national opioid epidemic where only a small percentage of individuals who need treatment are getting it.

Do you support some kind of repeal of the IMD exclusion and if so what should it look like?

Dr. McCance-Katz. What I would say is that this is an issue for the President and Congress to deal with, and at HHS we would be happy to implement whatever you decide on in that area.

Mr. Guthrie. Okay. One of the issues that when we deal with this repeal of the IMD exclusion has been the subject of a lot of debate for a couple years and the greatest barrier that is preventing is the cost to the federal government. In 2016,

CBO estimated a 40 to 60 billion year cost over 10 years. What do you think Congress and CMS and SAMHSA or the states could do to try to counter this major cost increase?

Dr. McCance-Katz. Again this is not an area that the Administration has a position on that I can provide to you today, but certainly we would be happy to work with you on those kinds of issues. But I will say one thing. Not everything with addiction needs to be in an inpatient setting and in fact most people can be treated very effectively on an outpatient basis with medication-assisted treatment, psychosocial supports, and community supports.

Mr. Guthrie. Okay, thank you very much. I appreciate those answers and I appreciate your position. And my time is expired and I yield back. Thanks.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions, please.

Ms. Matsui. Thank you, Mr. Chairman, and I want to thank the witnesses for being here today.

We all know the opioid epidemic affects us all and certainly no community is immune to this disorder. This committee has done important work to begin addressing the epidemic but I must reiterate the point that we can't talk about this crisis without

acknowledging the importance of protecting Medicaid. Addiction is a medical condition and requires treatment. And for many, that treatment is made available through the Medicaid program, which the ACA expanded to millions more adults in need. Taking away those critical services will certainly take us backwards.

The Prevention and Public Health Fund created by the ACA to make targeted investments in prevention programs in our Nation's public health infrastructure now funds 12 percent of CDC's annual budget. If the Prevention Fund were to be repealed, states would lose billions of dollars to spend on programs in communities, including programs to address the opioid crisis.

Dr. Schuchat, can you discuss the work that CDC has done on public health research and infrastructure relating to the opioid epidemic?

Dr. Schuchat. CDC is really focused on strengthening prevention by improving prescribing implementation of our treatment guidelines for chronic pain, the use of opioids and chronic pain with efforts to find out how can we best implement them, making it easy for clinicians, doctors, pharmacists, nurse practitioners to prescribe carefully.

We are also focused on evaluating the medication-assisted treatment that we hear about to understand what works best for different circumstances and evaluating the naloxone distribution program that SAMHSA has as well.

Lastly, we are focused on this consumer-facing campaign, evaluating its impact as we try to scale it up. Right now, we have been able to fund four states to launch the campaign and 22 of the states that receive funding from CDC will be using their funds to mount it but we really hope that that will be able to go nationwide and reach the public.

Ms. Matsui. Well would that be affected if CDC funding were cut by 12 percent across the board?

Dr. Schuchat. No. Every dollar that goes for prevention is lifesaving and cost-saving. And so we will work with Congress with the resources that we get to do the most good.

Ms. Matsui. Okay, in order to truly address the opioid crisis, we will need to build up our behavioral health system so that everyone has access to prevention and treatment in their communities. That is the goal of the Excellence in Mental Health Demonstration Project that my colleague, Representative Lance and I worked to create and that is now being administered by SAMHSA in eight states.

Dr. McCance-Katz, can you give us an update on the implementation of Certified Community Behavior Health Clinics?

Dr. McCance-Katz. Yes, I can. So those funds have been released to the states that were -- the eight states as you mentioned that were selected. These states are putting together what we call Certified Community Behavioral Health Centers, which

bring together the elements of treatment, evidence-based treatment for serious mental illness and for substance use disorders so that an individual can get all of the care they need because we know that co-occurring disorders are quite common in one place.

We think the model is quite nice. It is a model that is not a standard fee for service model but it is a bundle payment similar to what goes on in community health centers. We are very hopeful that that is going to be a model that will yield positive results and we hope can be sustained.

Ms. Matsui. Well, we hope so, too, absolutely.

Now, in addition to the short-term funding we provided in 21st Century Cures, we authorized additional funding for a variety of programs intended to address the mental health and substance use treatment system in a more long-term manner. For example, we authorized additional funding for treatment and recovery for homeless individuals, behavioral health integration and community health centers, mental health awareness training, and more.

Dr. McCance-Katz, can you provide an update on some of these programs authorized or reauthorized in 21st Century Cures?

Dr. McCance-Katz. So we are working with Federal partners to address issues of behavioral health and primary care. We have a strong alliance with HRSA. And as you know, HRSA just released

$200 million in new grant funding to integrate substance abuse treatment into community health centers. SAMHSA works with them on technical assistance to assure that evidence-based practices are being used.

We also continue our homeless grant initiatives at SAMHSA and we could get you the data if you would like to have it but --

Ms. Matsui. That would be lovely.

Dr. McCance-Katz. -- we see very positive results in getting people stably housed.

Ms. Matsui. Okay, thank you very much and I see my time has expired. Thank you.

The Chairman. The chair now recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes.

Mr. Lance. Thank you, Mr. Chairman and good afternoon to the panel.

Congresswoman Matsui and I are a tag team on the demonstration projects in the eight states and I am sure you are shocked to learn that New Jersey and California are two of the eight states.

Now I am increasingly of the view that fee for services is outdated and outmoded. To Dr. McCance-Katz, do we have analysis yet on the bundled payment system for the eight states?

Dr. McCance-Katz. No, sir, we don't. We don't but we will

be following that very closely and happy to share when we get it.

Mr. Lance. Do you have any indication when that might be within the next year or --

Dr. McCance-Katz. I think within a year but this has -- really it has just started. And so I would say in a year, yes.

Mr. Lance. Thank you. And the Congresswoman and I are working on expanding that program. I think we are both of the belief that this is the wave of the future and, certainly, I will continue to work with my colleagues in that area.

According to CMS, the Medicare population has among the highest and fastest growing rates of diagnosed opiate use disorder; if I understand it, currently six of every one thousand beneficiaries. But CMS policy appears to be blocking access for our Nation's senior citizens to receive treatment for their substance use disorder with two primary treatment modalities, buprenorphine and methadone.

I know this is not your agency, Dr. McCance-Katz, but in what ways, in your judgment, could CMS work with SAMHSA and other Federal partners to ensure that senior citizens utilizing Medicare who need treatment can get the help they need?

Dr. McCance-Katz. Yes, so we do work collaboratively with all of our sister agencies within HHS, CMS being one of them. And SAMHSA has the ability to provide CMS any information on

the effectiveness of these treatments in all age groups and we would advocate for that.

Mr. Lance. Thank you very much.

Mr. Doherty, my understanding is, as the legal prescription drug supply is constrained the use of street heroin increases. I suppose this is logical because addicts seek to get the drugs, they, unfortunately, are addicted, and regardless of the source or the medium.

Is there a direct statistical correlation between the availability of prescription opioids and increased usage rates of illegal heroin?

Mr. Doherty. Yes, sir. As you correctly point out and we appreciate your question, the statistics show that 80 percent of first initiate heroin users, so 80 percent of first-time heroin users are now getting to that dark place through the use of prescription opioid pain killers.

Mr. Lance. Eighty percent?

Mr. Doherty. Eighty percent of first-time heroin users. Four out of five first-time heroin users are now using heroin and turning to cheaper heroin. And with the advent of fentanyl coming into our country in pill form, many times these individuals are playing Russian roulette. They truly do not know what they are getting and they truly are taking their own lives in their hands. And DEA is committed to not only stopping counterfeit

prescription pill manufacturing but also elicit importation of fentanyl, as I mentioned in my opening statement.

Mr. Lance. Is there a way that we can use advanced data metrics to predict where users will seek illegal heroin so that we can direct interdiction resources to those places?

Mr. Doherty. Sir, we have many programs currently initiated that normally use data analytics but also use investigative resources across the spectrum to show where places will eventually have heroin imported to.

So in other words, our DEA 360 Strategy has hit some of the hardest communities in the country that have been plagued by this disease and this opioid scourge.

Mr. Lance. Where would some of those places be in the country, the hardest hit places?

Mr. Doherty. Dayton, Ohio; Albuquerque, New Mexico; Manchester, New Hampshire. These are places that our DEA 360 Strategy has been deployed to. It is a three-prong strategy. We use traditional enforcement, data analytics, diversion control, and community outreach in bringing the communities back.

Mr. Lance. So you mentioned Dayton, for example. So these are just average American cities with the same challenges that the rest of the country has.

Mr. Doherty. Well, yes, sir. And certainly the opioid epidemic is exasperated by the controlled prescription drugs now

getting people to the point where they have an opioid disorder, switching to cheaper heroin and now really playing, as I said Russian roulette with respect to content.

Mr. Lance. And my time has expired. I yield back.

Thank you, Mr. Chairman.

The Chairman. The chair thanks the gentleman. The chair recognizes the gentleman from California, Mr. McNerney, for 5 minutes.

Mr. McNerney. Well I thank the chair and I thank the witnesses.

Ms. McCance-Katz, how would limiting access to treatment impact the opioid epidemic? So how is that going to affect it, limiting treatment?

Dr. McCance-Katz. Well if treatment were limited, people would have more serious adverse events, deaths, inability to function in society, all of the fallout of opioid addiction.

Mr. McNerney. What about limiting early intervention care?

Dr. McCance-Katz. I am sorry?

Mr. McNerney. Early intervention.

Dr. McCance-Katz. Early intervention.

Mr. McNerney. Same story, right?

Dr. McCance-Katz. Yes, sir.

Mr. McNerney. Well the Affordable Care Act and Medicaid

expansion have been crucial for treatment for those with opioid use disorders and also for providing early intervention care. I know this has been the case in my district, which includes Stockton, California, a city where opioid overdoses up to six times higher than the State average.

So I am very disappointed that instead of focusing on finding solutions to address the opioid epidemic, Republicans have been engaged in an nonstop effort to repeal Affordable Care Act, which would have a devastating impact on people struggling with opioid use disorders and would be catastrophic for combating the opioid epidemic.

So, Ms. Volkow, your written testimony mentions the HHS 5-Point Opioid Strategy. The fourth pillar of the strategy is to support cost -- support cutting-edge research that advances our understanding of pain and addiction. What are some examples of recent developments in this area of non-addictive pain management that resulted from your research?

Dr. Volkow. This is quite extensive. And as Dr. Gottlieb was mentioning, in the area of pain, for example, one of our partnerships has been to develop abuse deterrent formulations of opioid medication so that the person cannot divert them and abuse them and there are several drugs already approved by the FDA.

We are also working with pharmaceuticals to develop

non-opioid based medications that are going to be effective in addressing pain.

And in the field of opioid use disorder, for example, we have partnered with pharmaceuticals to develop extended release formulation such that the patient does not need to go to the clinic on a daily basis to get their medication but can go every week, every month, every 6 months and that improves compliance. And as a result of compliance, they are also protecting them from actually overdosing.

So these are some of the examples in terms of successful partnerships that are developing treatments for those that need them.

Mr. McNerney. So what are the ultimate goals of this partnership, then?

Dr. Volkow. To accelerate and incentivize pharmaceutical industry to get into these spaces. Pharmaceutical industry has not been traditionally engaged in developing medications for addictions. Addictions are too stigmatized. It was felt that they wouldn't recover their investment. So we have to reach them, by being a Federal agency to reach those products and then present it to pharmaceuticals so that they can bring them to the market.

In the pain space, also, there is a need of energizing pharmaceuticals because they have been decreasing their investment on medications for brain-related diseases, including

pain. So how do we create a partnership engaging also FDA to ensure that they see an incentive to move forward and develop pain treatments? Because right now, of course, they are making already a lot of money from selling opioid medications. So it is a little bit they are in competition with themselves. So how do you incentivize them to go beyond that?

Mr. McNerney. So it sounds like we would have -- Congress would have a role in --

Dr. Volkow. Yes.

Mr. McNerney. -- developing those practices.

Dr. Volkow. And, indeed, there are ways in which Congress can help develop, facilitate. I mean for example, in terms of how do you make an incentive for a pharmaceutical to go into the development of medications for addiction, could you not treat them like you treat for example developmental vaccines? So can you get them expansion of their paths? Can you give them priority evaluation?

So the Institute of Medicine did an analysis on how actually changes in policy could lead to incentivizing pharmaceuticals to help us develop better treatments for opioid addiction.

Mr. McNerney. Thank you.

Ms. Schuchat, do you think that high school sports are a significant role in opioid addiction?

Dr. Schuchat. What I would say is I don't know. I think

that the principle issue is to change the culture in the doctor's office or the nurse practitioner's office to help people follow our recommendations about chronic pain. We say think twice before starting an opioid. Start low. Go slow, if you are increasing it. And follow-up regularly about whether the goals of treatment are being met.

A lot of our history as docs over the past 15 years or so has been to begin with opioids, where we really don't think that is a good idea.

Mr. McNerney. Thank you.

Mr. Chairman, I yield back.

The Chairman. I thank the gentleman.

I now recognize the gentleman from Mississippi, Mr. Harper, for 5 minutes.

Mr. Harper. Thank you, Mr. Chairman and thanks to each of you for being here on this very critical subject.

I mean the opioid epidemic is certainly destroying our country and we see this every single day and how it is impacting lives and families. You know you have seen families that have been lost and destroyed because we haven't been able to provide perhaps the resources, perhaps the right action to take. And I know we have made great resources in making -- great strides in making those resources available. But one of the biggest concerns that I have -- and I will say this. I think this may

be some of the most important work that our committee is going to do this year is to try to assist and provide some guidance and those resources here.

But one of the biggest problems that we see on the ground is how do you get those resources that we put out to the local level, particularly predominantly this country is still rural in most of our geography. So how do you get that to rural America? How do we do that?

Because you know when you have, perhaps, a county with some small cities or municipalities, law enforcement is stretched so thin that these groups can operate with impunity on selling and destroying those lives.

So that would be my question is, How do we get this down to rural America? And I would like each of you to give me your quick thoughts on that.

Dr. Gottlieb. I would defer to my colleague from SAMHSA on that, Congressman, but I would echo the need to get the treatments into those settings.

Dr. McCance-Katz. Yes, and so we have to use technologies to reach rural communities and we have a couple of programs at SAMHSA that address rural health directly. One of those is telehealth. That is an evolving way of providing care so that you can really extend the reach of a single practitioner who may be a distance away from where they are providing care but that

is a model that we are very much working on at SAMHSA with partners in various states and we are supporting efforts in developing those models.

And the other way that we do this is through some of our training programs. We have a lot of very effective training programs that SAMHSA sponsors and one of them is something called Project ECHO. What that is is a program where at a site you will have experts that get together and will be able to do conferencing, conference calls, video conferencing, and be able to talk with clinicians in distant areas about problems that they are having and how to provide care to patients.

Mr. Harper. You mentioned telehealth, which obviously is an amazing item and certainly very important in my home State of Mississippi because University of Mississippi Medical Center has been one of leading proponents of that for almost 15 years that have developed that in a great way.

But then we are talking about rural America. So yes, we have telehealth but then we also have problems with broadband access in those same rural areas that are stretched for resources. So we have got to come up with a plan here that actually will help not only in law enforcement and prosecution. And while these things are here, usually you see these people after they have entered into a problem and are looking for treatment and help.

We want to stop this before it can happen and so that is

why I think we are in a great need there.

We are very limited on time. Dr. Schuchat, why don't you give me your response?

Dr. Schuchat. Yes, just to say that CDC is funding 45 states and D.C. right now. And in many of those states, it is the rural populations that are being harder hit with the opioid epidemic. We just did a report on that in our Morbidity and Mortality Weekly Report.

But we have injury control research centers, for instance in West Virginia, that have been doing rural pilots of distribution of naloxone, the Kentucky coalitions that are really looking at what works in those rural communities that have been hardest hit. I think we heard it before that every State is different and there are different solutions but we have really been trying to get resources out there to the front line so that the solutions will make sense for the communities.

Mr. Harper. And you have had a rollout of communications program, obviously, that I know you have discussed. Is that having the right impact? Is that going to be something that will help on that preventive end?

Dr. Schuchat. It is just beginning and the four states that we have just launched it in were hard-hit states, including Kentucky, New Mexico, Ohio, and Massachusetts. Those are areas that high burden. We are hoping, though, that it will get rolled

out much more widely.

Mr. Harper. And we look forward to seeing the impact of that.

With that, I yield back.

The Chairman. I thank the gentleman.

I now turn to the gentleman from Vermont, Mr. Welch, for 5 minutes.

Mr. Welch. Thank you very much. I am delighted to have you here and I want to talk to Mr. Doherty from the DEA.

All of us on this panel were involved in hearings on the Ensuring Patient Access and Effective Drug Enforcement Act and it passed out of this committee unanimously. I was one of the co-sponsors, along with Mrs. Blackburn and Mr. Costello. And that was the subject of a commentary or a report by 60 Minutes and the Washington Post, both respected journalistic organizations.

And those of us who supported the bill, and that is all of us here, were very concerned and we want to get to the bottom of it. In fact, I have sent a letter to Mr. Walden, the chairman, asking for a full investigation allowing the whistle blower to come in, allowing the DEA to get in because bottom line, we are on the same page. We want to do everything we can to stem the tide of illegal opioids and we want to pass legislation that by no means handcuffs the ability of your organization to do its

job.

But I have got a chart here because I want to ask a couple of questions. The focus of that report had to do with the falloff in the use of immediate suspension orders. And as I understand it, that order was one where pretty much on any suspicion that the DEA had, they could close down a distributor. But if you look at the chart, the reduction went from 65 immediate suspension orders in 2011 down to five. That was a low point and that was in 2015, correct?

Mr. Doherty. Yes, sir.

Mr. Welch. And it went up to nine in 2016. So the law that we supported was signed into law in 2016. So here is my question. Unless the effect of the law occurred before the passage of the law, the law that we passed was after there had been already a decline in the use of that tool, one of many tools by the DEA. Is that correct?

Mr. Doherty. That is absolutely correct, sir.

Mr. Welch. So is it fair to say, because I think that we need some reassurance on this, that the law we passed, whatever its issues and I want to get to those, was not responsible for the preexisting decline in the use of that tool, the immediate suspension order.

Mr. Doherty. Sir, to answer your question, the law that was passed in April of last year, it is too early to tell what

the demonstrative impact of the --

Mr. Welch. No, wait. I am asking something else because I want to get to that.

Mr. Doherty. Yes, sir.

Mr. Welch. But isn't it irrefutable that the demonstrable impact on immediate suspension orders, that those started declining before the law was in effect in 2016? You went from 65 to 5 before the law had passed.

Mr. Doherty. That is correct.

Mr. Welch. So the law, obviously, was not what caused the decline in the use of that tool. You had many other tools and were using them vigorously. Thank you. Correct?

Mr. Doherty. We have many tools. You are correct, sir, yes, we are using --

Mr. Welch. Right but the immediate suspension -- because this is the heart of the question and we really have to know. We have to know. All of us have to know. That law that we passed occurred after immediate suspension orders had already declined from 65 down to 5, right?

Mr. Doherty. That is correct.

Mr. Welch. And then after the law was passed, it went up to nine.

Mr. Doherty. That is correct.

Mr. Welch. Okay. So we all want to help. And do you have

some specific legislative recommendations for our committee that we could take that would give additional authority within the Constitution to assist you in getting your job done?

Mr. Doherty. Sir, thank you for that follow-up. And let me say from the diversion control perspective, we use a variety of tools. The tool you mentioned is an administrative action and we certainly look forward to working with Congress with Department of Justice oversight to ensure we have the most up-to-date tools.

Mr. Welch. Look, you have got a very important job. We support it. Do you have recommendations, including any specific things you suggest we should do to amend the law we passed or even repeal the law we passed?

Mr. Chairman, I bet I speak for every single member of this committee. We want to know that information because we would take that up immediately.

Mr. Doherty. Yes, sir, and DEA shares your concern. And that matter is under coordination with the Department of Justice as we speak.

Mr. Welch. All right. We need a date certain. I mean time is marching on. This story shocked folks and rightly so because everybody in America is just devastated by what is happening to friends, to family, to loved ones. Okay? So, we are ready to go.

And Mr. Chairman, I will leave it up to you but we are having a hard time, at times, getting the responses back. And now that this question is out there about a law where the suggestion is we did harm, not good, I think all of us want to correct that.

The Chairman. Correct.

Mr. Welch. I will leave it to you.

The Chairman. Yes, Mr. Welch. And on behalf of the committee, my view has always been, when we pass a bill that is just the starting place. By the way, that is why we are having the hearing today is to look at is CARA working. Is 21st Century Cures Working? You need to go back and do the oversight and see what is working. And if something is not working, we need to know so that we can fix it.

My question is, What led to the decline in use of what you showed there on the graph? Was there an internal decision that led to that? Are there people that are upset about it? I mean because that clearly all happened, as you point out, the law ever was passed, unanimously, by the way, House, Senate, President Obama signed it.

So the question is, Why did the agencies stop using that tool or dramatically reduce use of that tool? That is the heart of the matter here. Who made those decisions? But when we can't even get basic information about who is supplying a pharmacy or two in West Virginia nine million pills in 2 years, it leads me

to believe we have much bigger issues at stake here we also have to deal with.

So we look forward to working in partnership with you on this, Mr. Welch.

I will now go to the gentleman from Texas, Mr. Olson for 5 minutes.

Mr. Olson. I thank the chair and welcome to our witnesses.

Mr. Chairman, this may be the most important hearing this committee has in the 115th Congress because we are dealing with life and death. Life and death. I will bet someone in this room knows someone who has been addicted to prescription opiates. Some in this room may know someone who has died from the addiction. Some in this room may know someone who is addicted to illicit opiates. I guarantee you the people watching on C-SPAN know these people and they are hurting.

My first question is for you, Mr. Doherty. You mentioned that the opioid prescription crisis is now expanding to other illicit drugs, mostly heroin. It is roaring back with a vengeance with a new synthetic sidekick cousin, fentanyl. I have been told a piece of fentanyl the size of a grain of salt can be lethal to a human being. It is that dangerous.

The cartels, as you mentioned, are mixing up down there with heroin with stuff coming from China. There is no quality assurance. It is the cartels. That poison is coming to America.

And that means it is coming across the southern border, my own State of Texas.

I talked to our Border Patrol yesterday about their enforcement actions. They say right now they capture about 50 percent of the traffic coming across our border. They can do better. They will do better with more resources and support from Congress.

But the cartels, they are good at adapting. When I was in the Navy, we were trying to get them down in Panama. And I would see submarines. They would come up here, go across, come up Northern Mexico, go across by San Diego, pop up at night. You can't see them. They dig tunnels. They can get over.

So my question is, What is DEA doing to combat the opioid crisis coming across the border working with CBP, probably some of the Drug Task Forces, and also local authorities? What are you doing right now to stop drugs from coming across, the fentanyl mixed with illicit opiates?

Mr. Doherty. Congressman, thank you for that question. I would point directly to our Special Operations Division, our Fentanyl Heroin Task Force. It is a multi-agency task force that collates, coordinates, and deconflicts information across all of the United States and all over the world, quite frankly. And we work closely with CBP and all of our Federal, State, and local partners.

However, as a command and control targeting center, our SOD, Special Operations Division, is specifically designed to look at cartel activity, and to target them at the appropriate level, and then, obviously, bring those seizures to bear, and follow up on leads within the domestic United States. We stand with all of our Federal partners in combatting this and share information on a routine basis.

I truly believe it is a whole of government approach in that DEA partnered with Federal, State, and local agencies. We need to redouble all of our efforts. We can do better and we should do better.

Mr. Olson. Another question. What is DEA doing to combat online sales of fentanyl and new psychoactive substances via the dark web, online sales, getting around the border?

Mr. Doherty. Thank you for the follow-up, Congressman. With respect to online pharmaceutical sales, fentanyl sales, NPS, new psychoactive substances, DEA has been very aggressive in this area.

Just last month, there was a joint takedown of AlphaBay, the world's largest dark net network for criminal activity, however, selling fentanyl and other dangerous drugs. It was estimated that this network earned approximately $1 billion annually. It was a sweeping investigation with DEA, and the FBI, and others. And we think that DEA, in partnership with other

Federal agencies, in concert with our state and local agencies can make a difference with respect to dark net trafficking and internet trafficking. And we will stand with all of our partners in doing so.

Mr. Olson. Thank you. I am out of time. I want to conclude by saying the fact that thousands of Americans have died with these prescription drugs, illicit drugs is a collective failure of American society. And Americans know that failure is not an option. It never has been. It never will be. Let's get this fixed ASAP.

I yield back.

The Chairman. The gentleman yields back. The chair recognizes Mr. Tonko for 5 minutes.

Mr. Tonko. Thank you, Mr. Chair. Thank you to our witnesses for your work on this critical issue.

Something that keeps me up at night when thinking about this epidemic is the so-called treatment gap, the idea that when someone is struggling with the disease of addiction has that moment of clarity and attempts to get help, that they will be met with a closed door and a waiting list.

This idea is not simply theoretical. Last year I toured and addiction clinic in my district, where I spoke to a person who had waited over a year to get off of the waiting list to access treatment. Nationwide, we know that only 20 percent of those

with opioid use disorder are engaged in any form of treatment. These delays are deadly. Our Nation wouldn't tolerate a diabetic having to wait 1 year to get insulin and we can't tolerate this delay.

Now, this committee took some good first steps to address this issue last Congress by passing legislation offered by Dr. Bucshon and myself to expand buprenorphine prescribing privileges to nurse practitioners and physician assistants, an option that almost 4,000 NPs and PAs have utilized to date, however, I believe we need to do more.

So Dr. McCance-Katz, would you agree that we currently lack the treatment capacity that we need as a nation to take care of everyone who is seeking help from this deadly disease without delay?

Dr. McCance-Katz. I would agree with that.

Mr. Tonko. Thank you. And with the passage of CARA and the new DATA 2000 regulations promulgated by SAMHSA IN 2016, NPs and PAs are now able to treat patients with buprenorphine and certain doctors are able to treat up to 275 patients at a time.

How has the healthcare work force responded to these new authorities? And has SAMHSA heard any feedback from the provider community about barriers that still exist which are preventing additional providers from seeking a DATA 2000 waiver?

Dr. McCance-Katz. So we do have some data. What I can tell

you is we checked. As of yesterday, we have 3,656 physicians who have asked for a waiver to prescribe to up to 275 patients. We have had over 3,000 nurse practitioners get the DATA waiver. And a little over 800 physician assistants get the waiver.

There are multiple reasons that people in the healthcare professions don't get the waiver. There is still a lot of stigma attached to the treatment. We don't do a lot of training in medical and pre-graduate programs for advance practice clinicians in the area of addiction medicine and so we need to increase our workforce.

Mr. Tonko. I thank you for that.

I have heard from other advanced nursing professions, such as certified nurse-midwives who are willing and able to provide additional medication-assisted treatment capacity but are prevented from doing so under current law. An expansion of DATA 2000 privileges to these professionals would, in particular, help vulnerable populations like pregnant and postpartum women. While this change would ultimately require new legislation to implement, would you commit to working with Congress in helping to examine the feasibility of including additional highly-trained medical professionals in the DATA 2000 waiver program?

Dr. McCance-Katz. Oh, yes, indeed.

Mr. Tonko. Thank you.

And shifting gears, quickly, I wanted to talk about another

population that is particularly vulnerable to opioid overdose and that is individual reentering society after a stay in jail or prison. I have read research that indicates that these individuals are up to eight times more likely to die of an overdose during their first 2 weeks post-release than at other times.

Can anyone on the panel validate that number and provide some context on why these individuals are at such high risk?

Dr. Volkow. This is correct. And one of the reasons why they are at greater risk is once you actually have been away from taking opioids, you lose your tolerance but the addiction still persists unless you have actually attempted to treat it.

So if you don't treat it, the prisoner leaves jail or prison and then they immediately relapse without the tolerance. And that is why the risk of overdose is much higher. And that is why we are proposing research that actually implementing the medication-assisted treatment at the time of release from jail or prison to protect them from overdosing.

Mr. Tonko. Thank you. Anyone else?

Dr. McCance-Katz. I would just add that SAMHSA has an offender reentry program. That is one of the focuses of that program. We are also working with the Bureau of Prisons on identification of inmates with opioid use disorder and how to address when they are about to leave.

Mr. Tonko. Okay, might I just add -- I thank you for that.

I just want to add that I believe that Medicaid could play a key role in improving outcomes during reentry and I hope to work with our witnesses and my colleagues on this committee on legislation I have introduced to explore this concept further. In other words, providing Medicaid coverage 30 days before release so that we can get these individuals under some sort of structured program before they are released and at such high risk of overdose.

With that, I yield back.

The Chairman. I thank the gentleman.

I will now turn to the gentleman from West Virginia, Mr. McKinley, for 5 minutes for questions.

Mr. McKinley. Thank you, Mr. Chairman.

I tried to come up with questions that haven't been raised so far with it and my first question primarily would be just how much Federal resources are truly being allocated to this issue. Do any of you have a grasp of how much money? I am talking from NIH, CDC, DOJ, DEA. How much money are we putting into this program nationally?

Dr. Volkow. Well, I can speak for NIH because it is actually the agency that I am representing. And from the perspective, for example, there are two components to it, one of them addressing --

Mr. McKinley. Can you just give me an amount, an approximate

amount?

Dr. Volkow. For paying, we are putting $500 million on opioid use disorders.

Mr. McKinley. Collectively. Collectively. We have a short time. So collectively, are we talking $2 billion, $5 billion?

Dr. McCance-Katz. We have a little over $2 billion in our block grants for substance abuse, prevention and treatment, plus discretionary.

Mr. McKinley. But is there some way that one of you or however can collectively come up with how much money is the Federal allocating? Because Mr. Pallone suggested in his testimony -- in his comments we need to put more money into it. I don't know how much money we are currently putting into it.

If I could move on to the second -- so if someone could get back to me, maybe from CDC.

Dr. Schuchat. We just have $125 million at CDC.

Mr. McKinley. Yes, okay but collectively. Everybody, what priority are we really setting on this issue?

Secondly, I would like to know how much money is coming to West Virginia. We have been asking for over a year. We can't get answers from any of you.

So here is a chart that shows it. We have opioid-related deaths. We are the highest in the Nation at 41 per 100,000.

That 30 percent -- 20 percent higher than the number two state and almost 40 percent higher than the number three state. It is nearly two and a half times the national average. I don't understand why more resources aren't flowing to help out a rural State like West Virginia.

Let me give you an example, though, on the neonatal births with opioid dependency. The national average is six per thousand but in West Virginia it is 140, nearly 25 times worse than the national average.

So when West Virginia applied for a grant from you all, SAMHSA, they were denied. I would sure like to know why because you all stood up, sat there and talked about how you are dedicated to this issue and here we are with a desperate situation, we are under water, and we put in a grant and we are turned down.

We also were excluded under their first round of the CARA, $180 million were supposed to be assured; $144 million was distributed. West Virginia got zero in that first round.

This has got to stop, this idea coming from the Beltway, you all sitting back here. We are on the front lines. And I want to build back on what Harper was talking about in rural America.

I just came from a county, Taylor County, 27,000 people, 125 arrests already this year. They have no resources from the Federal government for help on this. They have, for 5 years,

gotten not one dime to help out on the opioid problem they are having in Taylor County with 27,000 people.

And then I went to another county, Preston County. Three little towns, all collectively, between the three of them have less than a thousand people. They don't have the resources to have a teleconference. They don't have the resources to apply for a grant, to seek money. They are getting zero. No money is going to that rural county because they can't apply for it.

I would like to hear how we do this for rural America. Are we telling them you have got to file for an application? We did and we were denied by your group. What is the other group? Are we telling this little counties or towns that have 200 or 300 people you have to get a grant writer to submit something for you? They can't afford it. They don't know how to do it.

What is your suggestion? And get out of the Beltway and come with me back into rural America to find out how this physically works in a town of 200 people with an 84-year-old mayor. How are they supposed to address it when they know, the mayors talk, they know they are selling drugs in the Post Office parking lot and they don't have a police officer in that community to make an arrest? They physically see it every day drugs being sold there. How do we stop it?

I am sorry, did I miss something?

Dr. Schuchat. I can just say that CDC's funding the State

of West Virginia to work with all the counties. I am so sorry that the people in the towns you have been reaching haven't been getting support.

Mr. McKinley. Zero.

Dr. Schuchat. We need to do better. We are getting $2.6 million to the State of West Virginia to work statewide for --

Mr. McKinley. We have got the worst situation in the country and we are saying file applications. Make an application. They don't know how to make an application. They don't have the resources to do it. There is no grant writer. And then when we did, we were denied. Twenty-five times worse than the national average and we were denied on neonatal. Someone has got to tell me what we did wrong or why we don't deserve to have more treatment.

Dr. Volkow. And you deserve and I have actually gone to the communities in West Virginia and Kentucky. I am going to Ohio. I think that what we are trying to understand is the infrastructure and create partnerships.

And also, interestingly, West Virginia learned from what the communities have developed that actually have been effective to help other communities with similar problems.

But you are absolutely right, the needs of rural America are some that require special attention.

Mr. McKinley. Thank you. I yield back.

The Chairman. The gentleman's time has expired.

The chair recognizes the gentlelady from Michigan, Mrs. Dingle for 5 minutes.

Mrs. Dingell. Thank you, Mr. Chairman. I want to thank all -- I have no voice. I have no voice because I did ten town halls in the last district work period on opioid drug addiction. And I thank all of you for your service.

It is a really complicated issue, which we can tell by all the questions. And I put a human face on it. My father was a drug addict from prescription drugs before anybody ever talked about it or knew what it was. And my sister started young and there is nothing that I didn't do. I know what it was like to go look on the streets to see people selling the drugs, to have her in and out of drug treatment centers, and ultimately she lost the battle and died of a drug overdose.

I am married to a man, who is not going to be happy I am saying this publicly, who this room is named after, who has a legitimate pain need. And I have learned more about pain drugs than I ever wanted to do and it is becoming an even more serious problem with people with chronic disease.

And at these town hall meetings because I have said this is a complicated issue and we have to make sure that the pendulum doesn't go too far the other way, how do we make sure those who need pain pills and the oncologists are coming out -- I did a town hall with Joe Kennedy last week and I have been hearing at

every town hall -- and we have started community coalitions, and we have got the law enforcement, and the police, and the hospitals, and school teachers, and the kids all part of it. And we have all got to be part of it.

But it is complicated and we all need to understand it is complicated. But how do we work together to start to address it?

So my first question, Dr. Gottlieb, I am going to address it to you because you talked about it a little earlier. In order to mitigate the opioid crisis, we have got to change the paradigm.

The other point I will make before asking this question, because there has been very little discussion about mental illness today, and the fact of the matter is too many people are self-medicating for anxiety and depression. And I will bet that half the constituents in West Virginia don't have jobs. They are turning to that for solace and now they can't get a job. People don't understand that most of the jobs in this country that are open are going unfilled because people are failing those urine tests. We need to start to do some reality but I want to make sure that people who have legitimate pain needs are getting treated, too.

So what are we doing to change the paradigm for treating pain and addiction in America? One way to do this is to advance the understanding of the biology of pain and addiction in order

to enable the development of innovative treatments.

Dr. Gottlieb, how are you partnering with industry in order to ensure that novel and safer treatments for pain and addiction are being developed?

Dr. Gottlieb. Thank you, Congresswoman. I will just echo your comments.

In economically- and socially-challenged environments where the drugs are abundant and treatment is scarce, I think widespread addiction only seems inevitable.

We announced a series of steps today that we are going to take. Principle among them is trying to look at how we advance the guidelines that we have in place to help innovators and drug developers develop novel treatments for the treatment of addiction. We want to advance the endpoints that we use in those clinical trials to perhaps open up a full range of potential treatments that can address aspects of addiction like craving, and look at novel endpoints like perhaps reduction in overdoses, or hospitalization.

But I will just close by saying that we also know that the medical treatments, while highly effective, need to be delivered in the context of psychosocial interventions and services that help them be most effective. The evidence shows us that these treatments are most effective when they are delivered in the context of services and also deliver other forms of treatment

that address some of the psychosocial aspects of addiction.

And I would just point to my colleague from SAMHSA, who was a pioneer in developing these kinds of programs in Rhode Island and really developed a model for how this can be done successfully nationwide.

Mrs. Dingell. I would come back at though and we are talking about the addiction that has happened. We need to be developing new ways to treat pain and come up with alternatives so we are using non-addictive pain medicine.

Dr. Gottlieb. So I appreciate the question. I might have misunderstood it, Congresswoman.

Mrs. Dingell. Well, it is both but we need to be talking about that.

Dr. Gottlieb. I fully agree with you and you know there are products in development right now and products in the pipeline that address aspects of pain through pathways that we think might not have the same addictive potential as opioids. That, obviously, needs to be demonstrated scientifically. We are looking at abuse-deterrent formulations.

I would also just point out to the committee that if you look at the clinical data on NSAID use in arthritic patients, it went down sharply after we imposed some additional warnings related to NSAID use. And I think we have to look at that in the context of the current crisis because it seems intuitive that

some of those patients who might have been prescribed NSAIDs now were prescribed immediate release formulations of opioids instead.

And so I think we need to look at the risk benefit of all these drugs in concert. We sought to do that with the blueprint we advanced with respect to new educational requirements for physicians for the first time asking physicians to be educated not just on proper prescribing of opioids but proper prescribing of opioids in the context of all of the available therapy for treating pain.

Mrs. Dingell. Thank you.

The Chairman. I thank the gentlelady.

I will now go to the gentleman from Illinois, Mr. Kinzinger for 5 minutes.

Mr. Kinzinger. Thank you, Mr. Chairman. Again, all of you, thank you for being here.

And I want to make it clear you know this is a tough hearing I think but we know that you guys all want to solve this problem. And you are working hard to do it whether it is whatever agency. This is something that we wish would go away but there is some difficulty in what we are dealing with.

You know one of the conundrums we have is the idea that people, as was mentioned, have a legitimate need for pain medicine. Some people find themselves addicted with that. Some

people don't. And then we very strictly regulate how that pain medicine is put out. And in many cases they just transition to heroin, then, because they can't get access to the drugs that hooked them.

In fact in my district, law enforcement agencies say that heroin is cheaper on the street than marijuana right now, which is incredible. And that is why you see a lot of what you do.

I was just, about 3 or 4 weeks ago, I was leaving church going to the gym. And I pulled into the parking lot and there was a wrecked vehicle in the gym parking lot and somebody I knew was standing outside of it. So I went over and there was a guy, probably my age, slumped over in the car in an apparent heroin overdose. So EMS came over, we called 911, and they administered Narcan. And he came back and then proceeded to not talk about what happened at all.

So I, in fact, as I think we all did, a lot of us did, in the last district work period, we had these opioid roundtables to hear from people what is going on. And I remember a funeral director in LaSalle County saying that he buried his own son to a heroin overdose and that it used to be 20 years ago they would have one death a year related to ODing and now it is one a month. And he says every time he has to deal with a family with something like this, it like reopens all his old wounds.

And so I hear all these stories. You know but I am hopeful.

There are groups like The Perfectly Flawed Foundation in LaSalle, which is a recovery addict that started this to help folks, or Safe Passage, which is a program in Dixon, Illinois run by the police. So I know the communities are rising to the challenge.

One of the concerns we have, though, is in rural areas like my district, the access to treatment facilities. You know usually if somebody wakes up from an overdose, or is pulled out, or whatever, they have about maybe 30 minutes to an hour where they want to recover. But then once that hour is up, the addiction takes back over. And so when you have a massive delay in being able to get people treatment, obviously in many cases they choose, at the time they can finally get in they have either gone back to drugs or the addiction has just taken back over.

So I just want to kind of open it to the floor and just say you know what are your agencies doing to kind of address the unique challenges that are specific to rural communities. And I know this question may have been asked already but if you guys just want to take that over, we will start here.

Dr. Volkow. Yes, from the perspective of research, we are actually funding researchers to develop new models of care that actually can address the unique needs of rural communities. And one of them is the spokes and hub, for example, where you can have one physician with expertise actually linked with nurse practitioners that deliver the care. The telehealth is another

approach that is actually quite widely utilized.

We are also evaluating models that will expand our ability to provide with medication-assisted therapy, for example. In Rhode Island, we are funding a project where the pharmacists are actually not only dispensing the buprenorphine but actually following it up. And that gives the visibility of touching a much greater number of individuals. We are --

Mr. Kinzinger. Could you keep it brief because I want to make sure everybody gets a chance here?

Dr. Volkow. So we are taking this, providing these evidence-based treatments in communities and then we try to transfer them or translate them into other communities. So we are funding research on those in that model.

Mr. McKinley. Okay, next?

Dr. Schuchat. Yes, I would just say that the state funding that we give has a requirement that public health and public safety work closely together. And what that really means is at that local or town level you have the right people coming together, like in that parking lot that you were talking about.

Mr. Kinzinger. Yes, sir?

Mr. Doherty. Sir, from a law enforcement perspective, DEA, I would also say a 360 Strategy is effective in the rural areas. We are leveraging our state, local, and district partnerships with police departments. We have become adept, more adept, in

my opinion, at data analytics. We are putting out threat assessments to all 21 of our field divisions to look at every area of potential diversion of pharmaceutical controlled substances.

DEA, along with HHS, and FBI is part of the Attorney General Opioid Fraud and Detection Unit that is in 12 select districts, Federal districts in this country. So we are getting better at intelligence, sharing intelligence, providing additional resources.

Mr. McKinley is no longer with us in the room but I wanted to address his concerns about West Virginia. We have devoted tremendous resources to West Virginia in the last 2 years, namely, an upgrade in the office in terms of leadership, tactical diversion teams, mobile tactical diversion teams, and data analytics. So we are very concerned, as the committee is, with respect to rural areas and we are doing all we can. Thank you.

Mr. McKinley. Thank you. And let me just conclude by saying I am still a pilot in the Air Guard and we do a lot of border stuff. And the amount of drugs coming over the border is just absolutely mind-blowing.

With that, I will yield back.

The Chairman. I thank the gentleman.

I will now turn to the gentleman from New Mexico, Mr. Lujan for 5 minutes. Mr. Chairman?

Mr. Lujan. Mr. Chairman, thank you very much. I really appreciate you calling this important hearing, Mr. Chairman and I think I will begin where Mr. McKinley left off.

I also represent a rural district, 47,000 square miles across the entire Colorado border, Arizona to New Mexico. I have heard at least two of the witnesses today talk about resources that they are taking to the state. We have a problem. And people at home don't feel like they are getting help. There is a big concern.

I would highlight the handout that the CDC gave us today, which those red dots that follow that top brown dot show that there is 18 for every one; 18 heroin users for every one that we are also seeing with prescription or illicit opioid deaths in 2015 alone.

Even as we take a step back, Mr. Chairman, I think that you know sometimes we need a history lesson, understanding that we tried to curb opium use and addiction in the 1800s. There was a response by a drug manufacturer in Germany to come up with morphine. And then in response to the morphine epidemic that we saw across America, a drug manufacturer said well, in 1874, we have another answer and it is called heroin. We will manufacture that and we will ship it to the United States.

Then in 1937, another manufacturer said well, we can come up with methadone. And that hit the streets and hit the

communities.

This isn't a new problem. And I just hope that we are asking are we doing something different.

I appreciate the testimony associated with looking at non-addictive pain treatment. There is a letter, Dr. Gottlieb, that I sent to you. I appreciate your testimony today, the work that you are doing. I just put that on your radar so that way we can work with your team to get a response. And it is in the area of non-opioid drug products.

We need to have something game-changing with all that we are doing in this space. We can't repeat what was done in 1800, and 1847 to 1850, to 1874, to 1927, and then 1947, and we wonder why people are dying in our communities. They are getting the same stuff.

But that heroin that is coming in, we know that 90 percent of those poppies are grown in Afghanistan. We know that less than four percent of that is making its way to the United States. We know that Southeast Asia heroin is coming into the United States as well. We also know about the heroin from Mexico and from South America.

We also know that it is coming in through Canada. It is not just the southern border. It is the norther border and it is the ports.

We have a huge problem. And I hope that when we talk about

the expansiveness of what we are dealing with that we look at it through that lens.

And I just, in the limited time that I have, one question that I wanted to bring to your attention is, like many of our colleagues, I went to visit a few facilities this last week. One is in Espanola, New Mexico in Rio Arriba County. It is called Hoy Recovery. Some incredible leaders committed to our community but, Mr. Chairman, this is going to impact all of us in rural communities.

They told me about a few of these grants that they were going after, one in particular, by the way, that was trying to get someone to help them go after additional grants for capacity building but they were told that because they didn't have the person to write the grant that they were trying to get to expand capacity, that they didn't qualify.

Another one that said that unless they were serving a community of 100,000 people, that they wouldn't qualify. These are small rural towns.

We have got a problem and I am hoping that we can get a commitment to work with you, Dr. McCance-Katz, to work with you on this issue.

And then the last question I would ask is the budget that you all submitted to us on behalf of the administration, are you getting what you need to do what we are talking about today?

Yes, no?

Mr. Doherty. Sir, from a DEA perspective, we fully support the Department of Justice budget that we are a part of. Some of our major initiatives with respect to cartel infrastructure investigation, intelligence initiatives, and the --

Mr. Lujan. Let me just interrupt, Mr. Doherty. It is not necessarily towards you, sir. This is towards the others around the table.

The Trump administration budget cuts HHS by 60 percent. The CDC gets cut by 17 percent. The National Institutes of Health gets cut by 19 percent. The funding for addiction research treatment and prevention, even the White House Office on National Drug Control Policy takes a hit.

So we are talking about not enough out of here. And I know we need to be smart. These are tough times. I get that. But as we dig in here and, Mr. Chairman, the impacts to these rural communities and what we can be doing across the country, this hearing and pulling everyone in here is critically important.

And I just thank the chairman. I will submit my full statement and all my questions into the record, Mr. Chairman.

The Chairman. Without objection.

[The information follows:]

**********COMMITTEE INSERT 7**********

Mr. Lujan. But please, we need your help in a profound way.

The Chairman. The gentleman's time has expired. I thank the gentleman.

We will now go to the gentleman from Virginia, Mr. Griffith for 5 minutes.

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

Mr. Doherty, isn't it true an immediate suspension order is a law enforcement tool that can empower the DEA to freeze suspicious narcotics shipments from companies? Yes or no, please.

Mr. Doherty. Yes, sir.

Mr. Griffith. Thank you. And isn't it also true that a similar enforcement measure would be a show cause order?

Mr. Doherty. Yes, sir.

Mr. Griffith. Thank you. And all these questions are going to be yes or no. Thank you.

The DEA told this committee, in response to an Oversight request dated May 8, 2017, that the "DEA is unaware of documents related to delayed or blocked enforcement actions and suspension orders."

Over the last 6 years, have there been enforcement actions proposed by DEA personnel that were not approved by DEA; yes or no?

Mr. Doherty. Yes.

Mr. Griffith. And if you could detail those for me at a later time, I will follow up with that after the hearing.

Over the last 6 years, to the best of your knowledge, was there any communication within the DEA about suspension orders; yes or no?

Mr. Doherty. Yes.

Mr. Griffith. Likewise, we will want to get copies of those. Thank you.

Over the last 6 years, to the best of your knowledge, were there any communications at DEA related to additional evidence needed to support a proposed suspension order that resulted in delays; yes or no?

Mr. Doherty. I am not sure of that, sir. I would have to check.

Mr. Griffith. I would appreciate that.

Over the last 6 years, to the best of your knowledge, as a DEA enforcement official, when a DEA enforcement action is approved or not approved, was such a decision ever communicated writing; yes or no?

Mr. Doherty. I would have to check on that as well, sir.

Mr. Griffith. All right.

Over the last 6 years, to the best of your knowledge, has a DEA enforcement official, when there were discussions by DEA enforcement officials with DEA attorneys about the need for

additional evidence in an enforcement action, would such concerns only be conveyed verbally and never in writing; yes or no? Were these communications oral only?

Mr. Doherty. No.

Mr. Griffith. No. So there are some written documents is what you are telling me; yes or no?

Mr. Doherty. So are you referring to documents that would request additional evidence, sir?

Mr. Griffith. Yes, sir.

Mr. Doherty. Yes.

Mr. Griffith. They were all oral or there are writings?

Mr. Doherty. There would be documents --

Mr. Griffith. Thank you.

Mr. Doherty. -- that would have requested case-related evidence.

Mr. Griffith. Thank you.

Do you an attorney in the DEA by the name of Clifford Reeves; yes or no?

Mr. Doherty. Yes, sir.

Mr. Griffith. And did you ever have any communications with Mr. Reeves about cases brought by the DEA's Diversion Control Office; yes or no?

Mr. Doherty. Yes, sir.

Mr. Griffith. And were any of these communications with

Mr. Reeves in writing; yes or no?

Mr. Doherty. Yes, sir.

Mr. Griffith. Is it your experience with DEA lawyers that they never communicate in writing?

Mr. Doherty. No, sir.

Mr. Griffith. Thank you.

Both 60 Minutes TV program and the Washington Post, in their reporting, featured former DEA law enforcement officials such as Mr. Jim Geldhof, who detained their concerns about the handling of enforcement cases at the DEA.

Because of your denial of documents to this committee, should we assume that these officials never put anything in writing about their concerns while they were at the DEA; yes or no?

Mr. Doherty. Sir, having not been assigned to the Diversion Control Division at that time, I don't know what the correspondence would have been. I don't have the background to answer that question.

Mr. Griffith. You don't have the correspondence, don't have the background but it would be -- okay, never mind.

Are you familiar with DEA's Chief Administrative Law Judge John Mulrooney; yes or no?

Mr. Doherty. Yes, sir.

Mr. Griffith. And were you aware that the Washington Post reported that Chief DEA Judge Mulrooney wrote in a 2014 quarterly

report that there was a decline in the number of orders to show cause or enforcement actions by the DEA?

Mr. Doherty. And what was the date of that, sir?

Mr. Griffith. June 2014.

Mr. Doherty. I am unaware of that, sir.

Mr. Griffith. You are not aware of that.

Would such a quarterly report be in the form of a written document; yes or no?

Mr. Doherty. Yes, sir.

Mr. Griffith. Mr. Doherty, did you play any role in the development or clearance of the answer to the committee that "DEA is unaware of documents related to delayed or blocked enforcement actions and suspension orders?" Yes or no?

Mr. Doherty. No, sir, that was provided by my staff, by the Diversion Staff.

Mr. Griffith. By the Diversion -- somebody that works under your division?

Mr. Doherty. Someone that works in the Diversion Staff, yes, sir.

Mr. Griffith. All right. Mr. Doherty, were you asked to search your documents in your possession to respond to the committee's request; yes or no?

Mr. Doherty. I don't believe I was asked directly, sir.

Mr. Griffith. And do you personally have emails or document

going back to 2011; yes or no?

Mr. Doherty. Yes, sir, but not on this subject. So I have documents from my employment prior to my assignment to the Diversion Control Division, yes, sir.

Mr. Griffith. All right, thank you.

And do you know if there was -- because former Agent Jim Geldhof told the Washington Post that before Reeves' arrival in the DEA Diversion Control Office in December of 2012, DEA investigators had to demonstrate that they had amassed a preponderance of evidence before moving forward with criminal enforcement cases which are administrative not criminal? And prior to December 2012, was there a preponderance of evidence standard for enforcement cases on opioid distribution; yes or no?

Mr. Doherty. Yes.

Mr. Griffith. Was that standard later changed to a beyond a reasonable doubt standard; yes or no?

Mr. Doherty. I am not aware of that change, sir, no.

Mr. Griffith. All right, I appreciate you answering the question. I see that my time has expired and I yield back.

The Chairman. I thank the gentleman.

All right, so we go to Mr. Cardenas next is what I am instructed. So the gentleman from California. I will let you two fight it out but --

Mr. Cardenas. We are both from California.

The Chairman. Yes, there you go.

Mr. Cardenas. Well, thank you, Mr. Chairman. I appreciate this opportunity for us to bring this important issue before the public with so many of our dedicated Federal individuals in various departments who are somehow involved in making sure that we get in front or on top of this epidemic.

My first question is, Is there anybody on the panel that would like to defend whether or not we, in the United States of America, were in front of this issue and on top of this issue and it is already getting under control?

[No response.]

Mr. Cardenas. So the answer is no. Okay. So we have much work to do, correct?

Is part of the effort of making sure that we go from crisis -- I would like to describe it as a crisis. I don't know if anybody on the panel is saying that it is not a crisis.

Does anybody on the panel want to defend that it is not a crisis in the United States at the moment, this opioid epidemic?

[No response.]

Mr. Cardenas. Okay. So that being the case, if we, Congress, were to reduce the access, or in some way by policy, or allowing the providers of health care out there in the United States to reduce the current level of care, such as mental health

and/or substance abuse care that is now afforded individuals since the ACA has now become law, if we were to reduce that, would that make the situation better or worse in the United States for individuals and families who are faced with this crisis?

Would anybody like to say whether it would be better or worse if we were to roll back the current status within the ACA law that many insurers today are now providing more substance abuse and mental health services today that they were not providing before the ACA?

[No response.]

Mr. Cardenas. Anybody that would like to say or give me an example of whether or not you believe it would be better to reduce those benefits to millions of Americans or worse?

Please.

Dr. Volkow. Well I think that evidently we need to address the treatment needs of those that are suffering from an opioid use disorder if we are going to solve the problem and we need to prevent the overdoses. But we also need to look at the structure and understand how changes that we are making ultimately are having an impact and that is where the data is still lacking.

And I was expecting that there would be a significant increase in number of individuals given access to opioid use disorder with the expansion of the insurance to these individuals. And what is surprising is because many of these treatment

programs don't have the knowledge of how to get reimbursement, something as simple as that, they are not taking advantage of it.

So my perspective in all of this is that we need to create a structure that will increase the likelihood of people that are suffering from the disease to get treatment. That is what we need to achieve.

Mr. Cardenas. Okay. So if we were to reduce the access, that would not help, correct?

Dr. Volkow. Anything that decreases access that does not provide an alternative -- that does not provide an alternative --

Mr. Cardenas. Would it make the situation worse?

Dr. Volkow. If it does not provide an alternative. And all evidence, good quality care, if you don't provide that, anything that doesn't provide that will not help us address the crisis.

Mr. Cardenas. Will it make it worse; yes or no?

Dr. Volkow. Without, it is --

Mr. Cardenas. Okay, I am sorry. I only have 1 minute left.

I contend that it would make it worse. I contend that it would make it worse. I understand that you went into a bit of a -- tried to go into detail in a limited amount of time as to the some of the issues that we still have yet to tackle. But

I truly do believe that, for example, by repealing mental and substance -- access to substance abuse disorder coverage, provisions that are currently in the ACA, this would impact working families across America.

And one last question that I would like to ask in the limited time. Please point out to me what community in the United States of America is immune to this crisis. Has this affected every strata of the United States' individuals? Are rich people immune? Are poor people immune? Are people who work for a living immune? Are people who work on Wall Street immune?

My point is this, ladies and gentlemen. This is something that is affecting every part of America and it is, in fact, a crisis. And I would venture to say that this was a crisis in what we believed, and we were wrong, we believed that this was a crisis of poor communities. And this has always been an American crisis and it is about damn time that we are actually facing this. But Congress a lot of work to do and with it comes the resources necessary to combat this crisis.

I yield back.

The Chairman. The gentleman yields back.

The chair recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. Bilirakis. Thank you, Mr. Chairman; I appreciate it. And I really appreciate you holding this hearing. You know I

am glad for the most part it is a bipartisan hearing and this is a major issue. I can't think of a more important issue to tackle.

So but I want to start with Mr. Doherty, if that is okay. The law has been written again about the Ensuring Patient Access and Effective Drug Enforcement Act. I want to take the opportunity to ask you a couple of questions. Yes or no, please, because of time.

Was DEA part of the negotiation for the final language of this particular bill?

Mr. Doherty. Yes, sir.

Mr. Bilirakis. Okay. Did DEA recommend that President Obama veto the bill?

Mr. Doherty. No, sir.

Mr. Bilirakis. Okay. Has DEA made any communication to this committee, this particular committee, Energy and Commerce Committee, about the need to change statute?

Mr. Doherty. Not to my knowledge, sir, no.

Mr. Bilirakis. Did DEA include any requests for statutory changes in their budget submission this year, dealing with this particular law?

Mr. Doherty. Not to my knowledge, sir.

Mr. Bilirakis. Okay. Has DEA's ability to enforce our Nation's drug laws been compromised because of the passage of

this particular bill?

Mr. Doherty. This changes the way we look at the ISO, sir, but we use an array of other tools.

Mr. Bilirakis. All right. Let me ask you this briefly because I have other questions.

Give us suggestions. Talk to us. We want to do the right thing. We all, everyone on this panel, wants to do the right thing and solve this public health crisis. I commend the President for addressing it tomorrow, as well.

So, please, give us suggestions. We need to know the tools that you need to handle this. We are on the same team with regard to this. So please, I want you to respond to me, personally, but I am sure every member of the committee, particularly the chairman, would like a response as well.

Okay, Dr. McCance-Katz, currently there isn't a clear standard for medication-assisted treatment, MAT, prescribing. And we have heard reports of an increasing number of rogue actors offering MAT. In many cases, these popup clinics actively recruit vulnerable client populations to provide substandard service with minimal oversight.

While we support consumer choice and market competition, we also want to balance this with the consumer safeguards to ensure that this problem improves and not worsens -- so we need to solve this -- and that bad actors are not rewarded via Federal dollars.

Additionally, questions have been raised as to whether states are requiring evidence-based practices to be used in the STR Grant Program.

The question is, What is SAMHSA doing to ensure rogue actors are not the recipient of Federal dollars and evidence-based practices are being used so that the funds expended go to providing the best possible treatment and recovery services?

Dr. McCance-Katz. So, as I mentioned earlier, we have a program in place to review the State plans. The States make the decisions about what providers in their states they wish to fund with dollars that SAMHSA has oversight for. And we assist them with determining and making sure that evidence-based practices are being used.

In terms of the kinds of rogue providers that you mentioned, SAMHSA has purview over a couple of things. One, we regulate opioid treatment programs and, two, we also certify physicians and other practitioners named in law that can provide office-based treatment of opioid use disorder, nurse practitioners, physicians' assistants. So we regulate and manage that.

However, we don't have, we do not have any jurisdiction over these other types of providers within states. What we do is we try to inform states about what constitutes best practices so that they can decide how they want to regulate within their boundaries.

Mr. Bilirakis. Thank you.

A question for Commissioner Gottlieb. Last August, FDA authorized a blog post titled FDA Supports Greater Access to Naloxone to Help Reduce Opioid Overdose Deaths. I know you are familiar with that.

Can you provide this committee with an update on the development of any over-the-counter version of naloxone?

Dr. Gottlieb. We have had conversations with a number of sponsors about naloxone over the counter. And as you know, we are working on an actual use study, where we would, I think for the first time, actually publish in the Federal Register the specifications, the scientific specifications on how a sponsor could demonstrate that a product can be properly labeled for the purposes of bring it over the counter.

So rather than putting the obligation on the sponsors to go out and do that study, we would proactively, effectively publish the specification that they can follow to help facilitate a more rapid entry of an OTC alternative into the marketplace. And we are fully committed to that and working pretty actively on it.

Mr. Bilirakis. I appreciate it. Please, we need to work together and solve this problem. It is a real crisis in this country.

Thank you very much and I yield back.

The Chairman. The gentleman's time has expired.

The chair recognizes the gentleman from Iowa, Mr. Loebsack, for 5 minutes.

Mr. Loebsack. Thank you, Mr. Chair. This is one of those rare opportunities that we can take here in Congress, where we all have the same concerns, I think. And we may differ about how to resolve the problems but we share the very same concerns about this crisis.

You know this epidemic is more than tragic, I think, and it has hit every corner of America, rural, urban, suburban areas alike. I am in a rural area. I have got 24 counties in my district. The chair likes to remind me that his district is bigger than the whole State of Iowa but, nonetheless, I have got a lot of rural areas.

And I get around. This weekend, I am going to go with the police chief or one of his deputies, a small town in Iowa, in Pella, Iowa. And I hear these stories all the time more and more. I have been in -- this is my 11th year now and we really didn't think too much about opioids at that time but, clearly, we do now.

Just some quick numbers, according to the University of Iowa. In the past 15 years, heroin deaths have increased nine-fold in the State of Iowa and prescription opioid overdose deaths in Iowa have quadrupled since 1999.

Clearly, we have got to do more about this. And maybe some folks -- I have to go sort in it now, maybe some folks have covered kind of the rural aspect of this but given that I represent so much rural area and I do hear of the same concerns in rural America as I do in some of my bigger towns and probably the bigger cities in the country.

What are the differences, if there any, and I will open this up to the whole panel, that you are seeing in the rural opioid crisis compared to urban counterparts? And given the differences, if there are any, how do your agencies -- how do you strategize, if you will, for rural communities? How do your rural community strategies differ from our urban areas?

I am going to open that up to whoever wants to answer that question.

Dr. McCance-Katz. So we know that we have difficulty with getting providers to rural areas.

Mr. Loebsack. Definitely.

Dr. McCance-Katz. And so we, as I mentioned earlier, we try to use innovative ways of reaching individuals by extending the ability of a practitioner, say in an urban area, to reach out to rural areas and provide care.

We also try, as best we can, to leverage primary care. We do a lot more work now with integration of behavioral health care into primary care settings, which rural areas still don't have

as much as they need but are much more likely to have primary care services often than they would behavioral health services.

Mr. Loebsack. And I have a bill that attempts to address that by providing more behavioral health training for those primary care folks as well.

Dr. McCance-Katz. And so that is where I was just going to go with that and talk about that we do have programs. We do work very hard to expand those programs as best that we can and we agree that that is one of the keys to providing care to those communities.

Mr. Loebsack. Thank you. And we did have, unfortunately, have something happen a few years back. Our governor did close down a couple of mental health institutes and one of them also dealt with substance abuse. And so that dual purpose is really, really critical, clearly there.

Yes, anyone else? Yes.

Dr. Schuchat. Just to say CDC has been doing a series of tracking the health issues in rural America and there are a number of disparities. The opioid overdose problem has now started to be worse in rural areas than urban or metropolitan areas and there are a number of other chronic conditions that are worse off. The solutions are probably going to be different. And one of the things that we do is support states to get better data that is locally granular and to track interventions into the hot spots,

if they are rural, or urban, or suburban.

Mr. Loebsack. So that is great. We have got to have good data. There is no question about it.

Yes, anyone else?

Dr. Volkow. So and we are planning also pilot trials to actually address the unique needs of the rural communities in places that have been hard hit by the epidemic to try to understand why the interventions are the most effective.

Mr. Loebsack. Right. And when meth was -- and meth is still a problem but when that was a real problem, even greater than it is now, it hit rural areas big time. There was a lot of cooking of meth that was going on at that time, too. We cracked down on some of that through some state laws but you know, again, we can't leave out the rural areas. I think that is the important thing to keep in mind. We don't hear much about them but it is important for someone like me to continue to voice those concerns.

So thanks to the panel. Thank you, Mr. Chair, I really appreciate it. Thanks, everyone.

The Chairman. Thank you, Mr. Loebsack, I appreciate it.

The chair now recognizes the gentleman from Ohio, Mr. Johnson for 5 minutes.

Mr. Johnson. Thank you, Mr. Chairman and I thank the panelists for being here today. This is a critical, critical issue that we are talking about.

In my district, as in so many communities around the country, the opioid and drug abuse epidemic is a blight that is infecting and engulfing entire communities.

We here on the Energy and Commerce Committee did some important work when we passed the 21st Century Cures Act and CARA on a bipartisan basis last year but we can't rest on our laurels. There is a lot more work to do. We must ensure that our efforts empower communities, healthcare providers, patients, and families to fight back against this vicious cycle of substance abuse.

I recently visited an organization called Field of Hope. It is a facility, a faith-based, nonprofit treatment facility in my district. It is founded by a father whose daughter struggled with and eventually overcame addiction herself and now she works in the facility there.

And in hearing the stories of the dozens of men, women, and children impacted by the work done by organizations like the Field of Hope, it becomes glaringly apparent that we are in danger of losing an entire generation. I mean hundreds of Americans are dying every day as a result of this epidemic and many of those people are in some of the most impoverished, low-income, high unemployment places around our country.

Too many people began their slide into addiction as young people, as young as 12 years old, through prescription drugs for

a sports injury, or getting in with the wrong crowd, or even taking what parents think are safe medications over the counter for common cough and cold. We see that happening, too.

So many of the testimonies document years of unrealized potential, frayed or destroyed relationships, and physical, emotional, and spiritual suffering but the testimonies also speak to the hope and the joy of recovery, if only people have access to the resources and the support that they need.

And I am proud of the work that we have done on this committee and I am grateful, Mr. Chairman, for the continued focus that our committee is putting on it.

So Dr. Gottlieb and Dr. Volkow, innovative non-opioid treatments for pain are being developed that can prevent addiction before it starts. How can we better align the approval process with Federal reimbursement policies for approved medications and devices so that, once new treatments are approved, patients are not barred from accessing them because they are not covered by Medicare, for example?

Dr. Gottlieb. I can start, Congressman. I echo your sentiment. I think the Nation has weathered epidemics before but the current affliction is very different and very pervasive.

We don't speak specifically to issues of reimbursement but it is the case that a lot of the drugs that are most commonly used are now generic drugs and they are very inexpensive. So

you do see preferential treatments on formularies for some of the drugs that are more addictive, or lack the abuse-deterrent formulations.

We have taken steps recently, we will be issuing a final guidance document to delineate a more efficient pathway to bring generic versions of abuse-deterrent formulations to the market. And we have also taken steps to try to facilitate non-addictive forms of pain relievers. But it will be the case that some of those newer drugs will be more expensive than the older formulations and I think we need to think about how we provide incentives for those to be used, perhaps preferentially, if we think the public health outcome is going to be better.

Mr. Johnson. Okay, my time has actually expired but can Dr. Volkow respond as well?

The Chairman. Yes.

Dr. Volkow. Yes, and I will just echo what Dr. Gottlieb said. And that is why in this public-private partnership not only are we working very closely with the FDA but it is important that we work with CMS. Because it is not just in terms of the patients being prescribed but in order to incentivize pharmaceuticals to develop products to invest, they need to have assurance that there will be a mechanism by which they are going to be able to recover their investments.

Because if we are going to develop an opioid that has much

less vulnerability for abuse, diversion, and addiction, this is going to be more expensive but no one is going to cover for it, then they don't even start there. So it is also at the essence of being successful in getting them engaged in development of other medications.

The Chairman. The gentleman's time has expired.

Mr. Johnson. Thank you, Mr. Chairman.

The Chairman. I recognize the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. Sarbanes. Thank you, Mr. Chairman. I want to thank the panel.

Dr. Volkow, I want to thank you for your terrific work. I had the opportunity, as you know, to come out to Bayview and see some of the research that is being done there, particularly with respect to kind of the brain response to these various medications and opioids and so forth and how we can use that research to develop effective responses to it.

I also want to thank you, Ms. McCance-Katz in terms of your describing the importance of making naloxone available. I was proud that we were able to have included in one of the bills that we passed here on the Hill, a demonstration program to look at the co-prescribing of naloxone. And that is an important best practice, I think, for physicians to take up. And as more physicians are examining their practices, we can, hopefully, make

some progress in addressing this crisis.

So thank you for referring to that. And that was a very bipartisan approach I wanted to add.

I wanted to focus a little bit on the issue of workforce because I have been very focused for many years now on the kind of workforce side of our healthcare system and whether we have adequate people to provide whatever the particular care needs are but in this context, it is around the issue of treatment. And certainly we heard from Commissioner Gottlieb about some of the important medication responses that can be undertaken in response to this crisis and that is a critical component of it. But I am interested in hearing from you about what we need to do with some of these other treatment elements.

I mean who are the kinds of professionals that need to be deployed as part of robust, meaningful treatment programs that can make a difference? I think, Dr. Volkow, you talked about key elements, being addressing the stigma, the lack of treatment slots in a lot of these programs, the lack of reimbursement for certain kinds of things.

So let me ask -- why don't I start here? And then any others who want to come, I invite your perspective on the workforce side of this. Are there gaps? Are there shortages? Which of the kinds of professionals along the care continuum that we need to respond to this crisis where we have got put more resources,

recruit people into this?

Dr. McCance-Katz. Well there definitely are gaps. We have, I don't have the exact number but I will guess around 10,000 physicians who are addiction specialists in this country. We graduate only 1200 psychiatric residents a year to go into psychiatry, a very high-need area, where a lot of addiction work is done. We don't have enough advance practice clinicians.

But what we need to do, one of the ways we can address this, is to integrate better addiction curriculum into the pre-graduate training. I actually wrote about a model that my colleagues and I at Brown University developed for our medical school, where every medical student will graduate qualified for a DATA waiver. And we do that through the addiction curriculum that we have put into our medical school. This not only makes people eligible to practice, once they become residents that are fully licensed with the DEA registration, but it also legitimizes addiction treatment. It makes addiction treatment a regular part of medical care, regardless of specialty. We need to do that in all medical schools, in all advance practice clinician programs, and we also need more psychologists, more counselors, more peer professionals. We lack all of these and it is one of the reasons-

Mr. Sarbanes. I would love to get more information from you on that initiative.

Dr. Volkow, I am going to run out of time so maybe I will

just come to you. You talked about sort of the psycho-social services component of the treatment response.

Can you speak to the needs we have there in terms of the workforce?

Dr. Volkow. One of the issues that has been brought up in the opioid crisis is yes, we over-prescribe opioids in our country. But the question is, What allowed it to disseminate so rapidly? And there is this concept of addiction being a disease of distress, and the fact that we have addiction is very, very frequently comorbid with mental illnesses, and there is some diseases that relate to adverse conditions that make you vulnerable.

So as we are discussing the opioid crisis, we need to be mindful that we are going to need to have interventions that address those behavioral needs and psychological and psychiatric needs that many of these patients have.

Mr. Sarbanes. Thank you. I yield back.

The Chairman. The gentleman yields back.

Just for the committee and for our witnesses, who I am sure would appreciate a break here at some point, we are going to go to Mr. Bucshon for 5 minutes.

We have votes on the House floor that have been scheduled. So we will take a break. I think we have got three or four votes; probably 1/2 an hour, 45 minutes before we would we would

reconvene. Dr. Burgess will take over as subcommittee chair and run the remainder of the hearing.

So there are members I know who want to ask some additional questions. So Mr. Bucshon, we will go with you, then we will recess, then we will return after the votes.

Mr. Bucshon. Thank you, Chairman.

The question is for Dr. McCance-Katz. Section 303 of the CARA Act, which I co-authored, requires that all office-based providers of addiction treatment have, and I quote, "the capacity to provide directly, by referral, or in such other manner as determined by the Secretary," all drugs approved by the FDA for the treatment of opioid use disorder and appropriate counseling and appropriate ancillary services.

What has been SAMHSA's role in implementing this particular statute in CARA?

Dr. McCance-Katz. Yes, so SAMHSA has implemented the required 24 hours of continuing education for nurse practitioners and physician assistants who wish to obtain a waiver for office-based treatment of opioid use disorder and we manage these. We keep the certifications. We provide that certification to the practitioners. And we continue to provide ongoing education through our provider clinical support system for medication-assisted treatment.

Mr. Bucshon. Okay, that is not specifically what I asked

but so what is the current status of fully implementing Section 303?

Because you described expanding providers that are available but you haven't implemented what the providers actually have to do. I mean because -- is that true or not true? The capacity to provide direct, by referral, or such other manner determined by the Secretary for all treatment options. Does that make sense?

Dr. McCance-Katz. Yes, so the education, the waiver education requires that all forms of approved medication-assisted treatment be taught.

Mr. Bucshon. Okay because I am just being told that you haven't implemented a lot of Section 303.

Dr. McCance-Katz. We have implemented all of Section 303.

Mr. Bucshon. Okay, then I stand corrected.

Within 18 months of enactment, HHS is required to update the practice guidelines for office-based treatment settings so as to conform with Section 303. What is the status of the practice guidelines?

Dr. McCance-Katz. I got to SAMHSA 2 months ago. I will tell you that I have reviewed that document. That document, in my opinion, needs additional work but it is in the clearance process and we will get that done.

Mr. Bucshon. Very good to hear that. Thank you very much.

Mr. Doherty, what percentage of illicit drugs that are in

the United States come across our southern border, do you have any idea?

Mr. Doherty. Sir, I could not give you an exact percentage but we determined that the Sinaloa Cartel, who currently has the control of the U.S. market share for heroin and now, alarmingly, fentanyl, they control a predominately large portion of the southwest border in terms of importation routes and transportation routes.

Mr. Bucshon. So at least for them, it is 100 percent?

Mr. Doherty. Yes, sir.

Mr. Bucshon. And so do you think we are doing enough to stop it?

Mr. Doherty. Sir --

Mr. Bucshon. That is not a criticism, by the way. I mean overall, as a country, do you think we doing enough to stop it?

Mr. Doherty. Sir, as a DEA agent for 28 years and someone that worked in Arizona and knows the border area, I would say that a comprehensive strategy, one that involves technology and power, boots on the ground, as well as intelligence is crucial to stopping the, for lack of a better term, poly-criminal organizations, ones that traffic in drugs, humans, contraband, weapons along our southwest border.

So we would stand with all of our Federal, State, and local partners in coming up with new innovative solutions; however,

it has to be a comprehensive approach, sir.

Mr. Bucshon. Yes, I don't want to cause you too much grief but is a physical barrier part of that?

Mr. Doherty. Sir, again, it would have to be a comprehensive strategy and any measure that would lend itself to stop drug trafficking and other means of illegal activity from entering the United States, fold into an overall approach. As I said, technology, manpower, and intelligence I think would be beneficial.

Mr. Bucshon. Great. Thanks for that.

So I don't think we can overstate the importance of decreasing the demand for the product but also it is very important to prevent the supply. And I would encourage all my colleagues across Congress to work with the administration to secure the southern border using, as described, a multi-pronged approach, which may or may not include a physical barrier, and to quit actively preventing the administration from trying to secure the southern border.

With that, Mr. Chairman, I yield back.

The Chairman. The gentleman yields back.

I recognize the gentleman from New York.

Mr. Tonko. Mr. Chair, I asked that three letters be included in the record. They include the American Hospital Association, a second from Protecting Access to Pain Relief Coalition, and

finally, the American Society of Addiction Medicine.

The Chairman. Without objection, they will be entered into the record.

[The information follows:]

**********COMMITTEE INSERT 8**********

The Chairman. For our witnesses, we probably won't be back for 1/2 an hour. So if you want to grab something to eat and whatever else, probably at least a 1/2 an hour before the committee starts, probably closer to 2:30.

And Dr. Burgess will take over there because I know we still have members that want to ask questions.

So with that, we will stand in recess.

[Whereupon, at 1:43 p.m., the subcommittee recessed, to reconvene at 2:27 p.m., the same day.]

Mr. Burgess. [Presiding.] Very well, I will ask everyone to take their seats and I will call the subcommittee back to order.

When the subcommittee adjourned for votes, pending for questions was Dr. Raul Ruiz. So we will recognize Dr. Ruiz for 5 minutes for questions, please.

Mr. Ruiz. Thank you, Mr. Chairman. Welcome back, everybody. I hope you had a little nice break. I would like to thank all the witnesses for joining us.

Many of you know I am an emergency physician. I have taken care hundreds of patients who have come in respiratory arrest from opioid overdose. I have taken care of toddlers who accidently got into the cabinet. I have taken care of adolescents and young adults who took it for the high, while they were partying. And I have taken care of seniors who have gotten addicted throughout the time because of chronic pain usage of

opioids and took that extra sedative to help them sleep, you know the sleep pill, and also maybe a little cocktail, two cocktails at night. The next thing you know, they stop breathing during the night, and their spouses wake up, and they are blue, and they bring them into the emergency department.

And most of the time, we are able to resuscitate and put them on mechanical ventilation, give them the appropriate medication soon enough to reverse it but sometimes, it is unfortunate, they are pronounced dead on the field or, after an incredible amount of resuscitation, their hearts don't come back, and so we can't get a beat, and we have to pronounce them dead.

So this is something that I know firsthand in the community and in emergency departments that we are faced with. And I am extremely proud of our first responders who, in the patient's home, in the streets, at the clubs, at the bars, like are the first people on scene and provide the first live-saving resuscitation, anywhere from paramedics, EMTs, the firemen and women, men and women who wear the badge in our law enforcement. You know they are there. And they oftentimes then come to us in the emergency department with the handoff and we take over.

We know that last Congress and during the Obama administration, we took some steps to expand the workforce and efforts to ease the access due to buprenorphine so that these first responders and healthcare providers can provide a

treatment.

I want to revisit the workforce effort because we know there is folks in prevention that oftentimes we don't really think of. These are the high school counselors and teachers, the public health educators, the community health workers, the primary care docs, family medicine, internal medicines that can identify risks and education. Then we have the acute crisis, right, the emergency medicine, the first responders, the law enforcement, the nurses in the emergency departments. And then we have the detox and treatments, the addiction services for adolescents, adults, emergency physician nurses, psychiatrists, psychologists, mental health. And then we have the long-term rehabilitation services.

So in your opinion, are we working in a coordinated mechanism with a strategic vision to provide enough training to all these different workforce healthcare providers with a clear set of priorities and understandings or is it scattered from here and there?

I will ask Dr. Schuchat.

Dr. Schuchat. Yes, I can begin and then I think my colleagues will probably expand.

Our piece is the prevention piece, prevention for prescribing, and then supporting state and local public health, who have a role in the data to speed up the information so we

know where the hot spots are, and a role in evaluating the policies.

Mr. Ruiz. Is it coordinated in curriculum and outreach to these individuals?

Dr. Schuchat. Yes, so what I can say is that the guidelines for treatment of chronic pain have been adopted by dozens of states, and medical societies, and are now being taken up by the medical schools, the pharmacy schools, and the nursing schools.

Mr. Ruiz. So your answer is no because every different groups are working in silos and what we need is a coordinated response with leadership from the top.

Let me ask another question. I have a minute left.

We know what the public health motto is. We do have a plan. There is a framework. You are trained in it. I am trained in it. You know the framework to come to the answer to identify high risk, to institute programs catering to high risk, and then measuring the outcomes of those and expanding those to the population.

So what are the highest risk individuals, and what are the programs out there where we are addressing them to prevent them from being evicted, and also the highest risk for relapse, and what are we doing for them, Dr. McCance-Katz?

Dr. McCance-Katz. So we have training programs that one is our Providers' Clinical Support System for Medication Assisted

Treatment and that provides structured training and mentoring --

Mr. Ruiz. What is the population base most at risk of starting an addictive addiction and what are you doing to combat those in the public?

Dr. McCance-Katz. So we know from a lot of research studies that people who are at highest risk are people who have a history of substance use disorder, a history of previous opiate addiction, a history of mental illness. We know that. And that is curriculum that is taught within our Providers' Clinical Support System, which is a consortium of a large number of different types of professional health organizations that do outreach to their members so that we can train them.

We also have the Addiction Technology Transfer Centers that have the Nation divided into ten regions and we have one that also focuses on Native American issues. And those provide training to other types of practitioners, counselors, nurses, et cetera.

Mr. Ruiz. Thank you.

Mr. Burgess. The gentleman's time has expired. The gentleman yields back.

The chair recognizes the gentleman from Michigan, Mr. Walberg, for 5 minutes for questions please.

Mr. Walberg. Thank you, Chairman, for that opportunity and

thank you for being here today. As has been noted on numerous occasions -- I am having a hard time working with one wing here, Doctor, but we will get it working right -- we all share the concerns together. It is how we meet the needs, and how we can be an assist to all the things that you do, and have the communications that make us a resource and a partner alongside.

Dr. McCance-Katz, PDNPs normally include a patient's history of prescriptions for controlled substances using data submitted by pharmacies and dispensing practitioners. Under Jessie's Law, a bill that I have introduced with Representative Dingle, HHS would be required to develop best practices for including a patient's history of addiction treatment with patient consent, of course, in their electronic health records. This information helps to better inform, I believe, a provider and avoids risk for relapse or dangerous side effects when a patient seeks treatment for a condition or illness separate from their addiction. And that was the genesis for this piece of legislation because of a very unfortunate outcome where things were missed.

For similar reasons, should this same information be made available in PDNPs across the country as a way to better inform providers?

Dr. McCance-Katz. So those kinds of questions I think are best left to Congress and the administration. The administration, to my knowledge, does not have a position on that

but we would be happy to work with you and provide any technical assistance to move that forward.

Mr. Walberg. I appreciate that and I understand that a position has to be taken when the administration takes a position but this is something that would be of great help so that we don't run amuck of a lot of things that you have to consider in the day-to-day practice in meeting the needs. And while we want to make sure those needs are met, we provide resources, we need the support. So we will take you up on that.

Dr. McCance-Katz. Thank you.

Mr. Walberg. Mr. Doherty, drug diversion remains a serious problem and I have become aware of a particular challenge that exists in circumstances of in-home hospice care. DEA regulations issued in 2014 specifically forbid hospice staff from destroying leftover controlled substances, unless allowed for by state law. As a result, leftover pills belong to the family, which has no legal obligation to destroy them or give them up.

I believe hospice staff could play a very meaningful role in helping to prevent instances of diversion but those regulations prohibit hospice personnel from taking a more active role in disposing or removing medications from the home.

And so for the first question, I would ask is your agency willing to work with me and this committee to help establish a uniform set of practices that will allow hospice professionals

better to assist families to dispose of leftover drugs?

Mr. Doherty. Congressman, thank you for that issue. And of course we can all look to all of our resources to do better and do more. We will be happy to work with Congress and the Department of Justice on that issue.

Mr. Walberg. Well along that line, in addition to prescription takebacks, what other opportunities exist for families in this situation to properly dispose of opioids?

Mr. Doherty. Sir, DEA has been a leader in the proper disposal, safe and effective disposal of unwanted and unused prescription drugs through our Take Back Initiative. As you mentioned, sir, we have run that program since 2011. We have had 13 iterations of that program and, collectively, we have taken in 8.1 million pounds of unused and unwanted prescription pain medication. And we feel it is terribly important due to the fact that we need to keep these things out of the medicine cabinet.

Another issue I would point to, sir, is under CARA we have a provision that we worked on in conjunction with our partners that allows the option to not fill a complete prescription when you are going to get your medication. We think that is certainly important for, for example, teenagers that have their wisdom teeth out and you have a parent caring for them. It is certainly ethical and reasonable to take only take 5 out of 30 oxycodone if you are caring for a teenager with that procedure.

So we think that is another important factor. DEA has worked hard with HHS on that issue. Thank you for your concern, sir.

Mr. Walberg. We appreciate that and we will be looking forward to working with you.

I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

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

Ms. Castor. Thank you. I would like to focus on an issue that this committee has been investigating and that I raised in committee last spring after the reports in the Charleston Gazette Mail that drug distributors shipped 780 million hydrocodone and oxycodone pills to West Virginia over 6 years, which amounted to 433 pills for every man, woman, and child in the state. And another news network further reported that one pharmacy in the small town of Kermit, with just 392 residents received nine million hydrocodone pills in just 2 years.

So after our previous hearing in March, the committee asked the DEA what actions it took in response to the reported oversupply of opioids in West Virginia over the course of the 6 years. In DEA's response that we just received last night, DEA noted that it established a tactical diversion squad in Clarksburg, West Virginia in December 2016. But DEA's own data would suggest that

the distributors began sending large shipments of opioids to West Virginia well before that date.

Mr. Doherty, please refer to the committee's October 13th letter to DEA. The charts in this letter, which utilized DEA's ARCOS data, showed that these massive shipments began taking place as early as 2007 and 2008.

I am glad that DEA has now established a greater presence in West Virginia but, in hindsight, should DEA have spotted these trends earlier?

Mr. Doherty. Ma'am, thank you for that question. And DEA agrees the amount of pills going into that area was excessive in looking back. At the time that you referenced, ma'am, and to your point, we had another phenomenon going on in this country. It was the proliferation of rogue pain clinics and pill mills in Florida. Florida was the epicenter of the beginning, in some ways, of the opioid crisis that we face today.

DEA devoted a tremendous amount of resources and then we shifted our resources. We shifted our resources to areas like West Virginia when we realized this problem.

Ms. Castor. So that tells me, though, that maybe DEA did not have the information on the flood of opioids going into West Virginia because certainly if you knew 780 million hydrocodone/oxycodone pills -- I mean that is your own, the data of the pills flooding in there.

How were you monitoring the flood of opioids into a particular community at that time?

Mr. Doherty. Ma'am, I was not assigned to the Diversion Control Division at that time. I could tell you --

Ms. Castor. How as the agency?

Mr. Doherty. I could not speak to that, ma'am.

Ms. Castor. Don't they have the tools to monitor shipments, a flood of opioids into a particular community? Weren't you able to monitor that?

Mr. Doherty. Ma'am, the way these are monitored in conjunction with distributors, they are monitored through the submission of suspicious orders. And the distributors have an obligation to report that to DEA and that was a flaw and that is why --

Ms. Castor. Are you saying they did not report it and DEA had to rely on news reports? That can't be the case.

Mr. Doherty. No, ma'am, that is not what I am saying. What I am saying is in combined with the suspicious orders that are reported in oversight of our regulatory registrant community, specifically the distributors, as you mentioned, we realized that some were not reporting as required. And then we shifted resources to those areas and we became more stringent with our distributors by initiating a --

Ms. Castor. So besides some suspicious, besides the

distributors reporting and some suspicious filing, DEA didn't have any other tools at its disposal to understand the flood of opioids into a community?

Mr. Doherty. Ma'am, we do have, as you mentioned, in these charts, ARCOS data, which is not real-time data. And we use data analytics and we are getting better at data analytics to prevent this from happening again.

Ms. Castor. What is the lag time in the ARCOS data?

Mr. Doherty. I do not have that information, ma'am.

Ms. Castor. So clearly, there is a breakdown here.

What can you say to other communities across the country that maybe experiencing something similar right now, a flood of opioids, some new epidemic, some hot spot? What is DEA able to do to monitor that situation so it is not too late?

Mr. Doherty. Ma'am, as I mentioned earlier, we are providing threat assessments to our 21 Domestic Field Divisions, with respect to ARCOS data specifically, and we are conducting a long-term overhaul of our SORS system, Suspicious Order Report System, to keep distributors in line and to prevent this from ever happening again.

Ms. Castor. And then what other tools do you need from the Congress?

Mr. Doherty. Ma'am, we would be happy to work with Members of Congress through the Department of Justice and we would also

advocate for full support of the President's budget.

Ms. Castor. Well, we need to get to the bottom of this to protect communities that have been damaged by opioids and to ensure that other communities do not suffer the same fate.

And people are relying on DEA to be the safeguard. And I hope the agency can be more proactive and use all the data at its disposal.

Thank you very much.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady.

The chair recognizes the gentleman from Pennsylvania, Mr. Costello, for 5 minutes, please.

Mr. Costello. Thank you.

Mr. Doherty, what is your title with DEA?

Mr. Doherty. Deputy Assistant Administrator Office of Diversion Control Operations.

Mr. Costello. Amongst your duties is to stem the flow or ensure that the excessive illegal distribution of opiates around this country does not occur. Is that correct?

Mr. Doherty. Yes, sir.

Mr. Costello. If we could refer to the chart, if you could put that chart up, I am going to reference the bill that passed last year that is the subject of some journalistic inspection right now.

Clearly, between 2011 and 2016, prior to this bill being passed, the number of immediate suspension orders has reduced substantially, correct?

Mr. Doherty. Yes.

Mr. Costello. And an immediate suspension order is an order that, without prior notice, terminates a distributor's ability to distribute controlled substances. It is an extraordinary measure intended to supplement standard agency procedures in cases of imminent danger. Is that correct?

Mr. Doherty. Yes, sir.

Mr. Costello. And the legislation sought to define the term imminent danger because there was litigation and concern raised by many patient advocate groups, local pharmacies, et cetera, that that standard was unclear. Is that correct?

Mr. Doherty. That is my understanding, sir.

Mr. Costello. Is it true that since passage of the bill the number of ISOs has actually increased?

Mr. Doherty. That is not true, sir.

Mr. Costello. I believe that eight orders have been issued subsequent to the passage of the bill. Isn't that correct?

Mr. Doherty. I stand corrected, sir. Since the passage of the bill, yes, sir.

Mr. Costello. It has increased. Has the amount of opiates distributed decreased since passage of the bill?

Mr. Doherty. I would have to confer with my diversion staff and get back to you on that.

Mr. Costello. If I read data points that indicated that amount of opiates manufactured and distributed in 2017 is less than 2016, would that be accurate?

Mr. Doherty. That would be accurate, sir.

Mr. Costello. So is it fair to say that since passage of the bill, the number of opiates manufactured and distributed has been less than before it was passed?

Mr. Doherty. Yes, sir, and that would be directly in line with the reduction in the APQ, the aggregate production quota --

Mr. Costello. Yes.

Mr. Doherty. -- that DEA oversees.

Mr. Costello. So if someone says the law has helped fuel the opiate epidemic, would that have any basis in fact, given the fact that the number of ISOs has increased since passage of the bill and then the number of opiates manufactured and distributed has decreased since the passage of the bill?

Mr. Doherty. No, sir, I don't believe the data shows that.

Mr. Costello. Okay, thank you.

DEA and DOJ contributed significantly to the language of the bill that was passed. This has been generally represented by Senator Hatch and Senator Whitehouse, a Republican and a

Democrat, in the Senate. Do you agree that the DEA and the Department of Justice provided technical assistance to the bill that was ultimately passed and signed into law?

Mr. Doherty. Yes, sir, that is my understanding.

Mr. Costello. And if DEA had opposed the bill, they would have provided testimony, or correspondence, or done some level of advocacy with Members of Congress. Is that correct?

Mr. Doherty. Yes, sir, I believe there was a technical advisement period and then, ultimately, the bill moved forward and was signed into law last April.

Mr. Costello. And it is fair to say that there were previous iterations of the bill that the DEA took issue with and they did object to it. Is that correct?

Mr. Doherty. That is my understanding, yes, sir.

Mr. Costello. Is it further true, based upon reports that the Obama administration actually requested of the DEA whether or not they recommend that the President sign it and the DEA must have said, in some form or fashion, yes, this bill is appropriate to sign. Is that correct?

Mr. Doherty. That is correct, sir.

Mr. Costello. Let's talk about this. Do you think that the law should be repealed?

Mr. Doherty. Sir, in terms of the bill that affects, as you say, the ISOs that we use in our administrative toolbox, we

also use criminal tools.

Mr. Costello. Absolutely.

Mr. Doherty. We also use investigative tools.

Mr. Costello. There is a lot of other things you do.

Mr. Doherty. Right.

Mr. Costello. And you do it effectively in very many measures. But on this specific bill, which deals with ISOs, do you think it should be repealed or do you think that it is doing what it what it was intended to do, which was provide clarity so that you can actually go out and issue ISOs without having to deal with litigation that might actually call into question your enforcement powers in the first instance?

Mr. Doherty. Sir, let me say that the bill -- the law changed the way that we looked at ISOs. It did not stop DEA from doing its job in the diversion space and we would be happy to work with Congress and DOJ, who is looking at this issue, as I said earlier, currently, to make sure that DEA has all the appropriate and updated tools.

Mr. Costello. Do you agree that if we did repeal this law, and didn't supplement it with something else, then the same vagueness that caused litigation to occur, that raised concerns from a whole host of constituencies would come to bear once again?

Mr. Doherty. Yes, sir, I believe we do need a mechanism at that level with respect to that tool.

Mr. Costello. One final question I am going to try and sneak in.

Was there an internal policy change why the DEA so dramatically reduced ISOs between 2011 and 2016?

Mr. Doherty. Not to my knowledge, sir.

Mr. Costello. Thank you. I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman and thank you for this most important hearing.

Mr. Chairman, I would ask unanimous consent to add into the record the written testimony from the International Chiropractors Association about non-pharmacological treatment of pain. Mr. Chairman?

Mr. Chairman --

Mr. Burgess. Is that your unanimous consent request?

Mr. Carter. Yes.

Mr. Burgess. Would you restate it, please?

Mr. Carter. Yes, sir. Mr. Chairman, I would ask unanimous consent to add into the record the written testimony by the International Chiropractors Association on non-pharmaceutical treatment of pain.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 9**********

Mr. Carter. Thank you.

Dr. Schuchat, last year there was a study done that I believe was done in collaboration with the CDC and John Hopkins, and HHS, and NIH, and CMS that was called examining insurance coverage for acute and chronic back pain treatment pilots. Now are you familiar with this, dealing with insurance companies and how they can actually not approve non-pharmaceutical treatments and actually push more opioid use by what they cover and what they don't cover?

Dr. Schuchat. I am not familiar with the specific study but I am familiar with that issue of what is reimbursed and what isn't and that there has been a problem with opioids being easily reimbursed and the alternative approaches were recommended not to be paid.

Mr. Carter. Okay, well this is the study that I am speaking of. Because I want to make sure because CMS has actually cited this as being a problem.

Also, in the New York Times, there was an article last week that addressed this well that I want to bring to your attention. And essentially what it says, it gave very many examples about how pharmacy benefit managers, PBMs, if you will, and insurance companies are actually pushing more opioid use by the fact that they are not approving the use of non-pharmaceutical or non-opioids.

Whereas, I agree with Dr. Gottlieb that there is a gap there between ibuprofen and the NSAIDs and then we go to opioids and we need to fill in that gap but there are some things can be used. You can use gabapentin. You can use Neurontin, Lyrica, those type of things but, in many cases, the insurance companies don't cover them. The PBMs don't cover them. The copay is higher, or you have to get a prior approval, or it is another tier, a higher tier so that you have to go through more hoops in order to get it approved which, of course, is leaning to more opioid use.

Do you care to comment on that? Is that something you see?

Dr. Schuchat. Yes, our incentives have been going the wrong way to get better practice, better paying management, and avoiding the harms of opioids.

Mr. Carter. What can you do? What can CDC do? I mean is there anything you can do to encourage -- I have not had any success in dealing with the PBMs, I can tell you that, but perhaps you will.

Dr. Schuchat. You know CDC's guidelines for the treatment of chronic pain are now being taken up by a number of health plans, insurers, medical societies and the defaults in the electronic medical records --

Mr. Carter. Okay.

Dr. Schuchat. -- and the ordering are better in many

places.

But I wanted to say something about the pharmacy benefit managers and the --

Mr. Carter. Please hurry.

Dr. Schuchat. Sorry. Just that they have actually been helpful in spotting the problematic providers.

Mr. Carter. They have been helpful to a certain extent but also they have been part of the problem because they have been not approving some of the drugs that could have been used and, instead, have been approving the cheaper opioids; therefore, increasing the amount of opioid use. So that is the point that I am trying to make here.

Dr. Schuchat. Yes, absolutely.

Mr. Carter. Okay.

Dr. Schuchat. We need better prescribing.

Mr. Carter. Okay, Dr. Gottlieb, I want to first of all applaud you. In July you made an announcement that you were expanding, that FDA was expanding prescriber educational opportunities for instant release opioids. And this is a step in the right direction. There is no question about that. As a practicing pharmacists for many years, I can tell you we need more physician education.

And you also said at that time that you were exploring making prescription training mandatory. Has FDA addressed that in any

way at all?

Dr. Gottlieb. We also expanded that education for pharmacists as well, Congressman Carter.

Mr. Carter. And thank you for doing that. That needs to be done.

Dr. Gottlieb. Right. We are still working -- we have a task force, a working group that is looking at different ways that we would operationalize a potential mandatory requirement for education, some of which could be contemplated by working in close concert, which we have been doing, with our partners at DEA. But we are looking at alternatives for how we could make education mandatory.

Mr. Carter. One other thing I want to get in before my time is up and that is this. Dr. Gottlieb, I thought you made a great point in your opening statement when you made the point that there really are two problems we are facing here.

First of all, we are facing the prevention of this happening and trying to prevent people from being addicted. But another problem that we have is that we have got over 11 million people that are addicted now. We have got to deal with that and that is a big, big problem.

My question is -- you know last week I was in the treatment centers -- what will work? It is going to take more than just throwing money at it. This is not a situation where we can say

okay, we have hit $50 billion; therefore, we have done our job. That is not what I am looking for at all. I am looking for effective treatments that are going to work.

And I can tell you from personal experience I have seen opioid abuse firsthand. I have seen it ruin lives. I have seen it ruin families and careers. It is tough.

What do you know, Dr. Volkow -- I have served on many panels with you and you do a great job. What works? What works in the way of rehabilitation?

Dr. Volkow. First of all, I want to thank you for bringing up the issue that it is not just throwing money at something. You have to actually throw money at a solution that is going to be effective. And I think that what we are demanding. That is why one of the things that we are demanding is that the treatment that is provided for individuals with opioid use disorder with quality care treatment for which there is evidence of benefit and that we need to actually change the way that we provide that treatment so that we have a means to monitor the outcomes of the patients such that we can learn from what leads to a good response in a given patient and what in another one.

We know, in general, that medication-assisted treatment significantly improved the outcomes and it prevents overdoses but we also know that not every patient responds and there is still significant relapse.

Mr. Carter. And thank you for that.

And I am way over my time but one thing I want to warn all of us is that let's don't become too dependent on naloxone because it becomes a crutch and that is just not good.

We have had problems already in Jacksonville, Florida, south of my district, where they can't even carry it on the ambulances anymore because of the high cost and people getting it three or four times a week. It does not need to become a crutch for these people as well, although I understand fully the value of it.

Thank you, Mr. Chairman.

Mr. Burgess. The gentleman's time has expired.

The chair recognizes the gentleman from South Carolina, Mr. Duncan, the newest member of the committee, 5 minutes for questions, please.

Mr. Duncan. Thank you, Mr. Chairman. And I have waited a long time to be on this committee. It is an honor to be part of Energy and Commerce.

I would be remiss if I didn't mention the work of a good friend of mine, State Representative Eric Bedingfield in South Carolina, who lost his son a year ago after a decade-long battle with opioids. And Eric and his family are very much in my thoughts as we have this hearing today. So I want to honor his continuing work and the state legislature on this issue.

As we have seen today, this is an issue that transcends

partisanship. It affects Americans in all 50 states. The opioid epidemic is real.

Mr. Doherty, you mentioned tools that you had in your tool box for combatting the opioid epidemic. Could you tell me what some of those tools are, if not all of them? And then what would you say is the most valuable tools you have in this fight?

Mr. Doherty. Congressman, thank you for that question. And I would say that from a law enforcement perspective and a DEA perspective, first of all, the scope of the problem is enormous and we need, literally, all hands on deck across the Federal, State, and local level, the medical community, the scientific community, and the law enforcement community.

In terms of addressing the problem, we need to attack supply with the overseas suppliers with respect to heroin and fentanyl. We need to work to take the gang element out.

Mr. Duncan. How do you do that without cooperation of the foreign governments? Are they cooperating, I guess is what I am asking?

Mr. Doherty. Yes, sir, we have had great cooperation at the international level, the bilateral level, and the multilateral level. Yes, sir.

Additionally, I would add that domestically we are initiating additional 360 Program cities for fiscal year 2018 and the 360 Program has been a crucial part of having, as I said,

three distinct pillars of law enforcement attack this problem.

We are also very much into the prevention space with the 360 Prevention and also with Operation Prevention, which is a web-based curriculum that is cutting edge and designed to teach young adults the dangers of opioid use. And it is free. It is distributed to educators throughout the country and it has been viewed by hundreds of thousands of individuals so far.

And we feel that partnership across government is key to establishing a dialogue, number one, about new and innovative ways to attack the opioid crisis. And I think that no idea facing all of us is off the table with respect to this problem.

Mr. Duncan. All right. It is an immense challenge.

I came to this committee from Homeland Security Committee and also the Foreign Affairs Committee, where I chaired the Western Hemisphere Subcommittee. Opioids is the focus of this today but let me just let the committee know that due to circumstances in Colombia and Peru, the cocoa production has been up over the last year, 18 months. Coca production has been up. As a result, there is a lot of cocaine out there ready to come north. They are not flooding the market with it. That is going to be our next issue to deal with with regard to drugs.

I appreciate the work you guys do, your men and women around the globe. And I have dealt with them in South America, so I know the challenges they face.

Mr. Chairman, thank you so much and I yield back.

Mr. Burgess. The chair thanks the gentleman.

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions.

Mrs. Brooks. Thank you, Mr. Chairman and I appreciate the fact that you all got a break. I want to thank you all so very much for your work because each of your agencies is so critically important.

And I want to start out because in the CARA effort the first section of that bill was a section that my colleague from Massachusetts, Representative Kennedy and I worked on, and it was to establish an interagency and medical professional task force to review and, when necessary, update and modify the CDC best practices guidelines for pain management.

And so, Dr. Schuchat, can you tell me did you know about this formation and that it needs to be formed by the end of December of 2018 and report? And you are looking at Dr. McCance-Katz. So I am curious. I just want to know. Is it happening? Is it in formation and will we get a report without great detail? I just want to know. You know we have had a change in administration. So I want to know that it is on people's radars.

Dr. McCance-Katz. Yes, it is. And so we have members of the public that the application process closed. They are in the process of being selected now. And that committee is definitely

going to be in place and you will get the report.

Mrs. Brooks. Okay, outstanding. Thank you.

Dr. Gottlieb, building on what Representative Carter talked about with respect to prescriber education, you talked about we are at a point, in your opening remarks you said, where we might be doing some hard things, things we are not really comfortable with. And you talked about prescriber education and that we have a generation of prescribers that need more education.

Can you -- and I am interested in the entire panel's very quick answer because I have like so many things I would like to ask all of you. Do you believe that mandatory prescriber education for either renewal, or for the first DEA licensure of someone who gets a DEA license or for renewal, that should come up with some mandatory prescriber education?

Dr. Gottlieb. I would certainly support that goal and I have said as much.

One caveat I would add is I don't think it needs to be a 3-day course. I think it is more efficient if it a short course and we hit doctors with some key principles. I think there is ways to do that.

Mrs. Brooks. Okay, where does a 3-day course come in?

Dr. Gottlieb. I just threw it out there because there some states that have these long courses.

Mrs. Brooks. Okay.

Dr. Gottlieb. But I think something short, and targeted, and focused would be the most effective way to try to operationalize this.

Mrs. Brooks. Do you agree with that, Dr. McCance-Katz?

Dr. McCance-Katz. I agree with it in general. I think that any prescriber who wants to prescribe controlled substances needs to have that education.

Mrs. Brooks. Needs to have that education.

Dr. McCance-Katz. Absolutely.

Mrs. Brooks. Does anyone disagree with that?

[No response.]

Mrs. Brooks. Okay, thank you.

Mr. Doherty, you may not know but I am a former U.S. Attorney and I did an OxyContin case against a physician that distributed to a community in southern Indiana and where people died, an OxyContin mill that was happening.

So this type of challenge has been with us for a long time but when I met with IMPD last week, our Indianapolis Metropolitan Police Department, they said they took off a 55-gallon drum of pills in our community, full of pills laced with fentanyl. And can you tell me do you need any additional authorities that would help DEA improve its enforcement actions that have to do with pill presses?

Mr. Doherty. Ma'am, DEA has been very active in leaning

forward on issues with respect to pill presses. We have formalized a rule that requires the import/export of pill presses to be electronically sent to DEA. We work very closely with CBP.

That said, we would certainly welcome a dialogue with Congress and with the Department of Justice to look at --

Mrs. Brooks. Do you need more teeth? Do you need anything? And if you would please give some thought to that, whether or not legislation needs to happen. Because as I understand, some of these pills that are coming in our police department believes that the traffickers don't even know what is in them. They don't even know that they are dealing fentanyl, necessarily.

Is that something that you have seen?

Mr. Doherty. Yes, ma'am, we have seen the fact that certainly the end user doesn't know what they are getting and some individuals in the supply chain are also unwitting, to a certain extent in terms of what they are trafficking.

So I would be happy to take that back, ma'am, and have a dialogue on that and reengage with Congress and the Department.

Mrs. Brooks. And then finally, Dr. McCance-Katz, in the context of the opioid crisis, do you believe it is important that a patient's provider, their primary care or their main doctor, has access to his or her substance use disorder records? Because I understand there is not a connection between the behavioral specialists -- and I am seeing nodding here from Dr. Volkow and

Dr. Schuchat.

And so why is that a problem and how do we fix that, that a primary care provider or another physician cannot have access to the mental health provider record?

Dr. McCance-Katz. So there are several laws in place that prevent certain types of communications and the 42 CFR prevents organizations or treatment providers, if you will, that hold themselves out as substance abuse treatment providers from sharing records without specific permission from the patient.

I will tell you that this is something that the Trump administration has been looking at since before I got here. We will be coming out in a couple of months with some revisions to communication that could be allowed under 42 CFR to better serve communication with physicians who are not substance abuse treatment providers but may be treating a patient with a substance use disorder.

Why is this important? Because very often, somebody has got a co-occurring illness which will require them to be on a medication and could have a significant drug-drug interaction that could place a person's life at risk, even on standard doses of medication. So it becomes a very important issue clinically.

Mrs. Brooks. Thank you.

And if I could just close with, and I know I am over time, but I think what hopefully you have seen is that if there is

legislation that anyone on either side of the aisle of this hearing we want to either resolve issues that occur either in statute or in regulation and please make sure we know what those are.

Thank you. I yield back.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back.

I recognize the gentlelady from California, Mrs. Walters, 5 minutes for questions.

Mrs. Walters. Thank you, Mr. Chairman. And I have a letter from the Peace Officers Research Association of California that I would like to submit for the record.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 10**********

Mrs. Walters. Thank you, Mr. Chairman.

An increasing number of reports have revealed problems resulting from the dramatic surge of addiction facilities in sober homes. My home of Orange County, California has a significant number of these facilities.

These reports detail how individuals, as patient brokers, are recruiting patients and, in many cases, are flying them to a treatment facility across state lines, California being a very common destination. These patient brokers receive a generous financial kickback, amounts reportedly ranging from $500 to $5,000 for each patient who has successfully entered into a treatment facility or sober home.

It is appalling that there are individuals treating those fighting addiction as a commodity and prioritizing profit over the well-being and sobriety of these vulnerable individuals.

In light of these disturbing reports, the committee has sent HHS a letter on this very issue on July 13th. HHS provided a response last month and I have some questions for Dr. McCance-Katz following up on that response.

Dr. McCance-Katz, in response, HHS noted that 80 percent of treatment facilities are licensed or certified by state bodies. First question: Who licenses and certifies these facilities?

Dr. McCance-Katz. The states do and some of these facilities are not licensed or regulated within states.

So the Federal Government -- SAMHSA regulates opioid treatment programs and certain types of credentialing of providers but we do not have purview over what goes on in the states regarding other types of substance abuse treatment programs or recovery housing.

Mrs. Walters. Okay so if you flip that 80 percent figure, that means that 20 percent of the facilities are not licensed or certified.

Okay, so why aren't all facilities licensed or certified?

Dr. McCance-Katz. Different states take different approaches to this. I would recommend that one of the things that states consider is requiring that these types of facilities get credentialed. There are national accreditation bodies that could do this. States would need to require it and then states would charge a licensing fee.

The other thing that happens at these facilities is that they often use practitioners, or what they call practitioners, who have no certification or qualifications in the field. That can also be addressed by state regulatory bodies.

Mrs. Walters. So do you know which states do require certifications and licenses and which don't?

Dr. McCance-Katz. I don't have that information at my fingertips.

Mrs. Walters. Okay. HHS also noted in its response that

SAMHSA is working with states to share best practices on how to address patient brokering with provider associations. And what are those best practices and who developed them?

Dr. McCance-Katz. So SAMHSA does have a work group on this and that work group met over the summer. There is a report that is being put together right now.

But I can tell you that some of the best practices that will come out will be, as I mentioned, requiring the licensure of practitioners in these programs, requiring accreditation of the programs themselves.

We are going to make a bigger effort than we already do to put families in touch with our treatment locator system. We actually have a treatment locator system on our SAMHSA website that is linked to by other HHS agencies as well that has investigation that goes on. All of the programs on our system are approved by the SSAs in the different states. So they have a certain quality indicator if they are on that treatment locator.

We also think it is important for families to be able to ask specific questions. So if I am a family member looking for a provider, I need to ask, What are your credentials? Are you accredited by a national organization? Have you been inspected? And if you have been inspected, were there any citations of your facility and what did you do about them? Those questions right there can tell families whether that is a facility that they would

want their loved one at.

Mrs. Walters. Okay, just shifting gears a bit to focus on sober homes, which, based on the aforementioned reports, are equal offenders in the patient broker scheme.

It is the committee's understanding that sober homes are regulated much differently than treatment facilities. Is that correct?

Dr. McCance-Katz. That is my understanding.

Mrs. Walters. Okay and what is SAMHSA's role in overseeing or regulating sober homes?

Dr. McCance-Katz. We have no authority over sober homes.

Mrs. Walters. Okay. Well, I will yield the balance of my time.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back.

And I believe that concludes members' questions. I was going to yield 5 minutes for questions to Mr. Green because he has been sitting her so patiently, if you have a follow-up or redirect.

Mr. Green. Thank you, Mr. Chairman.

Mr. Doherty, among the things the Controlled Substances Act establishes is a quota system that controls the qualities of basic ingredients needed to manufacture controlled substances. These quotas serve to try and reduce diversion, while also providing

the adequate supply of controlled substance for legitimate medical need.

DEA sets these quotas using data regarding manufacturing history, forecasts, prescriptions dispensed, past quota histories, and internal DEA data on controlled substance transactions.

Deputy Assistant Administrative Doherty, I would like to ask about DEA's process on establishing these quotas. In reviewing the aggregate production quota history of oxycodone, hydrocodone, and morphine, and fentanyl, the quotas from 2007 to 2015 show dramatic increase.

For example, the quota for oxycodone doubled from 70,000 kilograms in 2007 to 149,000 in 2014. This is true for hydrocodone, which increased from 46,000 kilograms in 2007 to 99,000 kilograms in 2014.

Can you explain to the committee the process DEA undertakes in setting these quotas?

Mr. Doherty. Sir, thank you for that question. Sir, my oversight responsibilities with respect to the Diversion Control Division are over the criminal investigative side of the house, the law enforcement side of the house.

Last year, the DEA Diversion Control Division was reorganized in such that we are now a complete division. We were formally an office, an Office of Diversion Control under the

Operations Division of DEA. We are now a standalone division and we have two offices, the Office of Diversion Control Operations, which I oversee, as the law enforcement arm, running the criminal investigations and technology aspect. And then we have a regulatory compliance oversight arm, which is the Office of Diversion Control Regulatory.

So, sir, I am generally aware of the quota system, in terms of the points you mentioned. And I can state that last year the APQ, the aggregate production quota, was reduced 25 percent across the board and additional reductions are proposed for, as you mentioned, certain drugs, hydrocodone, oxycodone, and fentanyl for an additional 20 percent.

I would be happy to take that back and get you a complete answer, sir.

Mr. Green. Yes, if you could, just to share with the committee, to the chair of how that decision is made. Because again, from 2007 to 2015, the quotas were double and I wanted to see why DEA decided to do that, if they felt like that was needed.

According to DEA's history, quota history, it is not until 2016 and 2017 that DEA announced that the quotas for oxycodone, hydrocodone, and morphine, and fentanyl would be reduced. And if you don't know that question, if you could get it back to us why all of a sudden they waited until 2016 and 2017 to do that.

And I understand the DEA has the authority to revise their quota at any during the year in response to change in sales, new manufacturers entering the market, new product development, or product recalls.

Does DEA have the authority to revise the quota of controlled substance in response to patterns of abuse, or misuse, or increase diversion?

Mr. Doherty. Again, sir, not under my direct purview but I do know, generally speaking, that that authority does rest with DEA, as well as decreasing quota when requested by a registrant.

Mr. Green. Okay. Well, Mr. Chairman, I would hope we could get -- if you could have somebody who has that information to get to the committee. And if we have to send a letter, hopefully the committee would send that.

Mr. Chairman, before I yield back, when we did the Affordable Care Act, it is crucial to address the opioid crisis. And what we did with the Affordable Care Act, prior to the ACA there was 34 percent of individual market policies did not cover substance use treatment. Now all health care policies that are sold in marketplaces must include these services for substance use disorders. And repealing the mental health and substance use disorder coverage provisions of the ACA will remove at least $5.5 billion annually from the treatment of low-income people with mental and substance use disorders.

In my early days as a probate lawyer, I also did mental health. And so often, back in the 1980s and even the 1990s, we did not have a place where people would go. And most insurance policies in Texas, in their State, did not cover mental health, unless you were very wealthy.

And so that is why the ACA was changed, to do that. And as I recall, for mental health and substance abuse, Medicaid is probably still the biggest provider in the country. And so by cutting Medicaid, it is making it even more of a problem.

And I know I am running 17 minutes -- 17 seconds over my time but I run through the 3 minutes. So, I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman is correct to observe the chair has been very indulgent with letting people go over because this is an important topic.

And I am also going to yield myself a time for redirect. I want to ask a couple of additional questions on the PDMD programs.

This committee authorized NASPER, probably in 2005. It has been funded. In this year's Labor/HHS appropriations bill as passed by the house in September, there was an amendment offered and accepted by your chairman that funded, for the first time, the NASPER program, which I think is terribly important.

In my home community, an obituary in the paper the other day of a young man in the mid-20s was the child of a woman who

was my daughter's best friend -- my sister's best friend in high school. And it was quite a shock to the community. And you ask questions and it comes out that it probably was opiate-related and probably was a rather substantial number of pills that this young man was given his last physician visit.

So it bothers me that we have the data and Mr. Doherty, this probably for you. I realize it is not law enforcement data but I will even broaden it for anyone. The information is now there. It is being collected in a prescription drug monitoring program. There has to be some sort of algorithm and a red flag go up, even de-identified patient data, to help identify a hot spot, either a pharmacy -- so much of the PDMP program is provider-directed but it seems like it could also be pharmacy-directed as well.

You identify a hot spot. Here is one prescriber where more pills are going out the door than any other prescriber in town or here is a pharmacy where more are filled. Is there any way to create that nexus so that at least there is the reason to do a little bit more investigation?

De-identify the patient data. I am not trying to out the patient who has a problem but where are these facilities where the difficulty is occurring?

Mr. Doherty. Sir, thank you for that question. And in terms of data analytics, such as a PDMP, DEA supports them and

DEA supports law enforcement access to them.

Unfortunately, sir, the 49 states that currently have PDMPs have a varying degree of access. Some require a court order. DEA advocates for law enforcement access, obviously with the PII, personal identification information, in mind and we feel it is a vital tool for law enforcement to do as you said, sir, to identify hot spots and to further our criminal investigations and take action against registrants operating outside the law.

As I said, 49 states have them; 41, to my knowledge, re connected through a program called InterConnect. We think that is a positive step as well. However, as I stated before, the degree of access varies. It varies quite a bit, sir.

Mr. Burgess. I think going forward that is something that we do have to keep in mind. There has to be a way to identify these places where problems are occurring and at least have a chance for intervention.

Dr. McCance-Katz, you and I talked briefly before the hearing started. You know I am not a fan of needle exchange programs but let me just ask you this.

There is technology where a syringe and needle can only be used one time. Retractable Technologies, in my district, has developed such a syringe. You push the plunger all the way in and the needle retracts up into the barrel and you cannot retrieve the needle without destroying the device.

I don't know whether that is something that SAMHSA has looked at but in the needle exchange programs, as they exist, I would at least like the assurance that it is a true single-use device that is being dispensed in a needle exchange program.

Dr. McCance-Katz. Well, what I believe to be the case, sir, is that the Federal Government, our funds do not go to purchase syringe equipment of any kind. What funds can be used for are things like support staff within a program that does syringe exchange, mainly to help people get to treatment.

So we do not have any authority over that and are not involved in that.

Mr. Burgess. To get the continuing medical education I required for my license this year, I took your online SAMHSA-sponsored opioid abuse. I took two of the three modules. And thank you for having it online. Thank you for having it at a price I could afford.

But one of the harm-reduction strategies that they talk about in this SAMHSA-authorized product out of Harvard Medical School is our needle exchange programs. And again, I am not a fan of that. But if we are involved in that, I really think the effort should be that they be a single-use device and this retractable technology is FDA approved. It has been around for a while. It has never been widely used because they are a little bit more expensive. But if we are going to the trouble to do harm

reduction, I think that is a type of harm reduction I would like to see.

Dr. McCance-Katz. I think that is a very good suggestion. And I actually, since you bring that up, I will take it back to our staff at SAMHSA and we will look at that course you are talking about.

Mr. Burgess. Thank you. I am not trying to be the Chamber of Commerce guy for Retractable Technologies, but they do have a good product.

I want to thank all of you. This has been a lengthy but I think important and informative hearing. I know I have gotten a lot of information. This coupled with the 50 members that we heard from 2 weeks' ago with the individual opiate problems they have in their district, I hope will form the nidus of the ability to come together on some things. We obviously have a problem that needs to be fixed. We have heard it expressed passionately several times today.

Dr. Gottlieb, I do have one question for the record that I am going to submit to you in writing because it was so technically complicated, I didn't think I could do it justice by reading it to you. But it is an important question and it deals with distribution of counterfeit products. And again, I will submit that in writing because we have gone significantly overtime.

Seeing that there are no further members wishing to ask

questions, I do want to thank all of our witnesses for being here today.

We have received outside feedback from a number of organizations and I would like to submit statements from the following for the record: The American Medical Association, the Academy of Integrated Pain Management, the American Dental Association, the American Society of Addiction Medicine, Medication Assisted Treatment Coalition, International Chiropractors Association, Oxford Housing Incorporated, American Association of Nurse Anesthetists, Protecting Access to Pain Relief, and America's Health Insurance Plans.

Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 11**********

Mr. Burgess. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record and I ask the witnesses to submit their response within 10 business days upon receipt of the questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 3:26 p.m., the subcommittee was adjourned.]