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

HEARING

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

OCTOBER 25, 2017

Serial No. 115–68

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
32–978 PDF WASHINGTON : 2018

COMMITTEE ON ENERGY AND COMMERCE

GREG WALDEN, Oregon
Chairman

JOE BARTON, Texas
Vice Chairman
FRED UPTON, Michigan
JOHN SHIMKUS, Illinois
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
GREGG HARPER, Mississippi
LEONARD LANCE, New Jersey
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. MCKINLEY, West Virginia
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
KEVIN CRAMER, North Dakota
TIM WALBERG, Michigan
MIMI WALTERS, California
RYAN A. COSTELLO, Pennsylvania
EARL L. "BUDDY" CARTER, Georgia
JEFF DUNCAN, South Carolina

FRANK PALLONE, JR., New Jersey
Ranking Member
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
GENE GREEN, Texas
DIANA DEGETTE, Colorado
MICHAEL F. DOYLE, Pennsylvania
JANICE D. SCHAKOWSKY, Illinois
G.K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJÁN, New Mexico
PAUL TONKO, New York
YVETTE D. CLARKE, New York
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY, III, Massachusetts
TONY CÁRDENAS, California
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan

C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

[1] Dr. Gottlieb, Dr. McCance-Katz, Dr. Schuchat, and Dr. Volkow submitted a joint written statement.

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

WEDNESDAY, OCTOBER 25, 2017

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

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, Luján, Tonko, Loebsack, Schrader, Kennedy, Cárdenas, 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; Zack 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 Member, Oversight and Investigations; Zach Hunter, Communications Director; 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 Counsel, Health; 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 Direc-

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

Mr. WALDEN. 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.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

OK, 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.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Each day, more than 1,000 people are treated in emergency departments 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've heard the stories of Oregonians who put names and faces to these data points.

Addiction and overdoses are happening at alarming rates in every single community. Scan the headlines on any given day and you'll 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, unable to work, or living as shells of their former selves because of their addiction. It's heartbreaking.

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

From the earliest hearings before our Oversight and Investigations 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 (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. We have held hearings on the growing threat of fentanyl, innovative ideas in the States, and heard directly from more than 50 members—both on and off this committee—just two 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.

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 passed through this committee and signed into law by President Obama has negatively impacted DEA's ability to combat the opioid crisis.

Second, we are also 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'm going to be very blunt: My patience is wearing thin. Our requests for data from the 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 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 Federal Government's shared efforts to address this crisis, allowing us the opportunity to drill deeper to learn about what's working and what's not working. We'll also have an opportunity to discuss how we can better prevent lawful prescription use from spiraling into abuse; and most 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 work 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" effort.

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 need to be open. If there are changes we need to make in the law, 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.

Mr. WALDEN. 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.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

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 Web site 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 con-

trolled 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 prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

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—CMS. Most people access substance abuse treatment through their health insurance coverage-it's 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 Marketplaces, well over a third of the population receives health insurance through the programs that CMS oversees. Medicaid alone is the single largest payer for behavioral health services in the United States. 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. 91 Americans lose their lives to opioid overdose each 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 Brunswick Memorial Funeral Home in East Brunswick, New Jersey, published a blog on the funeral home's Web site 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: "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?'"

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 prescriptions 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 type of efforts and increased funding that Congress must support to respond, and eventually end, this epidemic.

In addition to supporting positive bipartisan laws and increased funding for substance abuse initiatives, Republicans must end their pursuit of taking away health coverage from 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 addiction. 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 six months, DEA just last night sent us their responses to these questions. Of course there are also still many questions in our letters to DEA that remain unanswered. 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.

It is clear, the Nation is in crisis and Congress must do more to address the opioid epidemic. Thank you, I yield back.

Mr. WALDEN. 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, 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, 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, NATIONAL INSTITUTES OF HEALTH; AND NEIL D. DOHERTY, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL OPERATIONS, DIVERSION CONTROL DIVISION, 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, nonabstinence-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 communitywide 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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 two 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.

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, DC, 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.

Mr. WALDEN. 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.

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 medica-

tions 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 joint prepared statement of Dr. Gottlieb, Dr. McCance-Katz, Dr. Schuchat, and Dr. Volkow follows:]

House Committee on Energy and Commerce

Hearing titled, "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"

October 25, 2017

Written testimony on behalf of the following witnesses from the Department of Health and Human Services (HHS):

Elinore McCance-Katz, M.D., Ph.D., Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration, HHS

Anne Schuchat, M.D., Rear Admiral, U.S. Public Health Service; Principal Deputy Director, Centers for Disease Control and Prevention, HHS

Nora Volkow, M.D., Director, National Institutes on Drug Abuse, National Institutes of Health, HHS

Scott Gottlieb, M.D., Commissioner, Food and Drug Administration, HHS

Good morning Chairman Walden, Ranking Member Pallone, and Members of the Committee. Thank you for the opportunity to discuss the opioid crisis in the United States and the Federal response. From the start of his Administration, President Trump has made addressing the opioid epidemic a top priority, and at the Department of Health and Human Services (HHS) we share the President's commitment to bringing an end to this crisis, which is exacting a toll on individuals, families, and communities across the country. The Department has made the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. According the Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. Over the past decade, the U.S. has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Preliminary data for 2016 indicate at least 64,000 drug overdose deaths, the highest number ever recorded in the U.S. Too many of our citizens are being robbed of their God-given potential in the prime of their life.

The opioid epidemic in the U.S. is fundamentally tied to two primary issues. The first issue was the significant rise in opioid analgesic prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but well-intentioned healthcare providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse, addiction, and overdose, such as prescribing at high doses and for longer durations. The second issue is a lack of health system and healthcare provider capacity to identify and engage individuals, and provide them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment (MAT). It is well-documented that the majority of people with opioid addiction in the U.S. do not receive treatment, and even among those who do, many do not receive evidence-based care. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis. Further, there is a need for more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing drugs to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- 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;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- 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.

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. While this statement does not represent an exhaustive list of HHS activities underway, SAMHSA, CDC, NIH, and FDA bring unique expertise and capabilities that enable HHS to take a comprehensive, complementary, and flexible approach to the opioid crisis.

Substance Abuse and Mental Health Services Administration (SAMHSA)
As HHS's lead agency for behavioral health, SAMHSA's core mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA supports a portfolio of activities that address all five prongs of HHS's Opioid Strategy.

Improving Access to Prevention, Treatment, and Recovery Support Services
SAMHSA administers the Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). By providing $485 million to states and U.S. territories in fiscal year (FY) 2017, this program allows states to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder. The President's Budget requests $500 million for this program in FY 2018, the full level authorized by Congress.

The Substance Abuse Prevention and Treatment Block Grant (SABG), first authorized in 1992, is a vital source of funding for states that accounts for approximately 32 percent of total state substance abuse agency funding. For many people seeking to recover from opioid addiction, this public funding represents the only support for treatment. In addition, the block grant's flexible structure enables states to use the funds to address pressing challenges within their communities, such as the opioid crisis.

SAMHSA also has several initiatives aimed specifically at advancing the utilization of MAT for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT-PDOA) program expands MAT access by providing grants to states with the highest rates of treatment admissions for opioid addiction. Twenty-two states are currently funded by MAT-PDOA, and in September 2017, SAMHSA awarded $35

million dollars over three years in additional MAT-PDOA grants to six states.

SAMHSA also provides critical funding for MAT for specific high-risk and vulnerable populations, such as those involved with the criminal justice system and pregnant and postpartum women. SAMHSA's criminal justice grantees can use up to 20 percent of their grant awards for the purchase of FDA-approved medications for treatment of opioid and alcohol addiction. Since 2013, SAMHSA has seen a steady increase in the number of drug courts integrating MAT into their programs with 57 percent of active programs currently integrating MAT.

Under SAMHSA's Pregnant and Postpartum Women's (PPW) program, which serves women with opioid or other substance use disorders who are pregnant and/or newly parenting, grantees are encouraged to ensure access to MAT for opioid addiction, which has been shown to improve birth outcomes. Last month SAMHSA awarded $9.8 million over three years for new State Pilot PPW grants authorized by the Comprehensive Addiction and Recovery Act (CARA, P.L. 114-198) and $49 million over five years in new PPW service grants to support the recovery of pregnant and postpartum women struggling with substance abuse, including opioid addiction.

A well-documented challenge to improving access to opioid use disorder treatment is a lack of providers who can provide MAT. SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Provider's Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides mentoring of newly trained physicians by experienced specialists, maintains a library of evidence-based practice materials, and offers at no cost to the trainee the required DATA 2000 waiver training to enable providers to prescribe buprenorphine for opioid addiction treatment.

SAMHSA regulates opioid treatment programs (OTPs), which dispense methadone and may also dispense and prescribe buprenorphine and administer extended-release naltrexone. In coordination with the Drug Enforcement Administration (DEA) and states, territories, and the District of Columbia, SAMHSA reviews new and renewal applications for OTPs through an accreditation process that ensures programs have sound risk management practices in place and are using evidence-based treatments. SAMHSA also oversees physicians, nurse practitioners (NPs), and physician assistants' (PAs) ability to prescribe buprenorphine in office-based outpatient treatment settings. Last year, SAMHSA published a final rule which allows certain qualified physicians who have obtained a waiver to prescribe buprenorphine for up to 100 patients for at least a year, to now acquire a waiver to treat up to 275 patients. The regulation provides that these licensed physicians can become eligible for the patient limit of 275 either by being board certified in Addiction Medicine or Addiction Psychiatry or by practicing in a qualified practice setting.

These physicians are required to complete a SAMHSA reporting form each year to ensure that physicians prescribing at the new, higher level are in compliance with safe and appropriate prescribing practices. As of September 19th, 3,573 physicians have obtained a waiver to treat up to 275 patients. Most recently, SAMHSA began processing waivers to allow NPs and PAs to prescribe buprenorphine in accordance with the requirements of CARA. As of September 19th, 2,756 NPs and 773 PAs have received a waiver.

SAMHSA also promotes recovery through targeted grants, such as last month's award of $4.6 million over three years in Building Communities of Recovery program grants, created by CARA. The purpose of this program is to mobilize resources within and outside of the recovery community to increase the availability and quality of long-term recovery supports for individuals in or seeking recovery from addiction. These grants are intended to support the development, enhancement, expansion, and delivery of recovery support services as well as promotion of and education about recovery. Programs will be principally governed by people in recovery from substance abuse and addiction who reflect the community served.

Targeting Overdose-Reversing Drugs

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing, through funding and technical assistance, the availability and use of naloxone to reverse overdose. SAMHSA's "Opioid Overdose Prevention Toolkit," first released in 2013, is one of SAMHSA's most downloaded resources. The Toolkit provides information on risks for opioid overdose, recognition of overdose, and how to provide emergency care in an overdose situation. The Toolkit is intended for community members, first responders, prescribers, people who have recovered from an opioid overdose and family members, as well as communities and local governments.

SAMHSA provides a number of funding streams that can be used to expand access to naloxone. States are able to use Opioid STR funds to purchase and distribute naloxone, and some states are also using a portion of their SABG funds for opioid overdose prevention activities.

SAMHSA is currently providing $11 million per year in Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths to 12 states. These grants are also being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as how to purchase and distribute naloxone.

In September 2017, SAMHSA awarded funding for grants authorized by CARA, including almost $46 million over five years to grantees in 22 states to provide resources to first responders and treatment providers who work directly with the populations at highest risk for opioid overdose.

Strengthening Public Health Data and Reporting

SAMHSA's National Survey on Drug Use and Health (NSDUH) provides key national and state level data on a variety of substance use and mental health topics, including

opioid misuse. NSDUH is a vital part of the surveillance effort related to opioids, and the data from NSDUH has been used to track historical and emerging trends in opioid misuse, including geographic and demographic variability.

SAMHSA also works collaboratively with other agencies to better understand the epidemic through sharing of data and assessing the implications of that data and develops publications based on NSDUH and other national surveys and data. Examples of recent SAMHSA publications include: Trends in the Use of Methadone, Buprenorphine, and Extended-release Naltrexone at Substance Abuse Treatment Facilities; Trends in Average Days' Supply of Opioid Medications in Medicaid and Commercial Insurance; and Opioid Prescribing Trends for Adolescents and Young Adults with Commercial Insurance and Medicaid.

Supporting Cutting-Edge Research
SAMHSA is building on existing partnerships with the NIH to improve the research to practice pipeline and is committed to promoting evidence-based practices and service delivery models. The newly formed Office of the Chief Medical Officer and the National Mental Health and Substance Use Policy Laboratory, which were authorized through the 21st Century Cures Act to promote evidence-based practices and service delivery models, will be pivotal to these efforts. Additionally, the National Mental Health and Substance Use Policy Laboratory will assist in addressing the opioid crisis through its evaluation of models that would benefit from further development and through expanding, replicating, or scaling evidence-based practices across wider areas as we seek to increase access to and delivery of the best treatment services for opioid use disorders across America.

Centers for Disease Control and Prevention (CDC)
As the Nation's public health and prevention agency, CDC's expertise and leadership is essential in reversing the opioid epidemic. It was CDC that first identified the increase in opioid overdose deaths in 2004, and since then the agency has applied its scientific expertise to track the epidemic and develop evidence-based prevention strategies. Through various programs and initiatives, CDC supports all five parts of the Secretary's Opioid Strategy:

Strengthening Public Health Data and Reporting
Timely, high-quality data help both public health officials and law enforcement understand the extent of the problem and how it is evolving, develop interventions, focus resources where they are needed most, and evaluate the success of prevention and response efforts. Understanding that data is crucial, CDC is helping states build capacity to monitor the scope of the epidemic and better focus their prevention activities through several programs and activities.

CDC's Overdose Prevention in States (OPIS) provides resources and scientific support to 45 states and Washington, D.C. through three programs. The first two programs, Prescription Drug Overdose: Prevention for States (PfS) and Data-Driven Prevention Initiative (DDPI), provide states with the resources, tools and technical expertise to execute and evaluate prevention strategies to improve safe prescribing practices and prevent prescription drug misuse, abuse, and overdose. States use their funding to

advance prevention in four key areas: 1) Enhancing Prescription Drug Monitoring Programs (PDMP) and leveraging them as public health tools; 2) Improving health system and insurer practices for safer opioid prescribing; 3) Evaluating policies that may have an impact on the opioid epidemic (e.g.. naloxone distribution and Good Samaritan laws); and 4) Quickly responding to emerging and critical needs.

CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program, the third program under OPIS, funds 32 states and Washington, D.C. Started in 2016, ESOOS strives to improve the timeliness of reporting both fatal and non-fatal opioid overdoses and associated risk factors in order to inform public health responses within and across states. What is particularly unique and innovative about this program is the use of emergency department and emergency medical services (EMS) data to track and analyze morbidity data. ESOOS uses this data to establish an early warning system to detect sharp increases (e.g. potential outbreaks) or decreases (e.g. successful intervention efforts) in non-fatal overdoses.

CDC has made progress in improving the timeliness of data reporting and is now releasing quarterly and, as of August 2017, monthly provisional counts of overall drug and opioid overdose deaths in the Vital Statistics Rapid Release (VSRR) series. CDC also relies on its existing infrastructure to monitor rates of new cases of HIV and viral hepatitis in many states. CDC is working with Coroners and Medical examiners to improve both comprehensive toxicology efforts that help with the detection of fentanyl analogs and the capacity for mortality surveillance by identifying ways to help strengthen case management systems to report data more easily and quickly. While CDC has made progress, improvements are needed to build infrastructure (medical examiners, coroners, toxicological testing, additional electronic reporting, etc.). A stronger disease detection system will identify potential problems sooner.

CDC is also tracking opioid use among pregnant and reproductive-aged women and its impact on the mother and newborn as a part of the Treating for Two: Safer Medication Use in Pregnancy initiative. Pilot programs are underway to obtain state-level estimates of NAS to better understand hospital readmissions and long-term adverse outcomes among infants identified with NAS.

In addition to providing funding and technical assistance, CDC conducts epidemiological investigations (Epi-Aids) in states, providing on the ground assistance during a public health crisis. Between 2012 and 2015, Massachusetts experienced a surge of opioid-related deaths, from 698 to 1,747, with over 74 percent of these deaths involving fentanyl. The Massachusetts Department of Public Health (MDPH) called on CDC to help investigate the extent to which illicitly-manufactured fentanyl (IMF) contributed to the surge in opioid-related overdose deaths. CDC worked closely with the MDPH, SAMHSA, and DEA to determine whether IMF mixed with or sold as heroin was the primary cause of the surge of deaths and found that 82 percent of fentanyl-related overdose deaths were suspected to have involved IMF.

To stop the surge, CDC recommended that the MDPH train physicians, treatment

providers, and law enforcement on overdose prevention, screen at-risk people for heroin or fentanyl use, and expand access to naloxone. CDC also recommended outreach to those who experienced an opioid overdose, had a history of substance abuse, or were accessing health programs for active users to link them to treatment and educate them on the dangers of fentanyl.

Often, CDC's work in states leads to further, national initiatives. The 2015 response to an HIV and Hepatitis C (HCV) outbreak in Scott County, Indiana, led to a CDC analysis which identified over 220 U.S. communities that could be especially vulnerable to HIV and HCV outbreaks among persons who inject opioid drugs. One of those states, Tennessee, used CDC's assessment to do further analysis of the state's vulnerabilities. As a result, Tennessee is working to direct its HIV and viral hepatitis resources where they are most needed.

In addition to working with states, a partnership across sectors is necessary. CDC has been working on initiatives with law enforcement agencies, like the DEA, to strengthen public health and law enforcement collaboration on the federal level.

In addition, the Heroin Response Strategy (HRS), funded by the Office of National Drug Control Policy (ONDCP) and deployed in eight High Intensity Drug Trafficking Areas (HIDTAs), covering 20 states, links public health and public safety at the state level. CDC works with the HIDTA directors to sharpen strategic directions, ensure proper coordination and training, support the 20 public health analysts embedded in the program, and improve performance measurement. There is currently a shortage of evidence to guide public health-law enforcement integrated community response, thus as part of the HRS, CDC is launching eight pilot projects across the 20-state initiative to build scientific evidence about what works.

Advancing the Practice of Pain Management

Another of CDC's key focus areas is supplying health care providers with the tools and resources necessary to advance the practice of pain management. In March 2016, CDC released the Guideline for Prescribing Opioids for Chronic Pain, which was developed to help primary care doctors provide safer, more effective care for patients with chronic pain outside of active cancer, palliative, and end-of-life care. The Guideline provides 12 voluntary recommendations for prescribing opioids for patients 18 and older, in primary care settings, based on the most current scientific evidence. This helps patients and physicians better understand and assess risks and benefits of opioid therapy and determine the optimal method for each patient to manage their pain.

CDC has created a number of resources for health care providers to make the Guideline easy to understand and access. Earlier this year, CDC launched the first in a series of interactive, online trainings which provide sample scenarios, feedback, and resources for each recommendation. CDC is also capitalizing on technology to help disseminate the Guideline through the development of an Opioid Guideline Application (mobile app) which contains all of the Guideline recommendations, a morphine milligram equivalent (MME) calculator, and an interactive interviewing feature to help providers prescribe

with confidence. Other materials developed for providers, pharmacists, and patients include graphics, fact sheets, posters, and podcasts, all available on CDC's website.

CDC is also committed to educating consumers about the risks of opioids and the importance of discussing safer, more effective pain management options with their healthcare providers. In September 2017, CDC released the Rx Awareness communications campaign to increase awareness about the risks of prescription opioids and deter inappropriate use. The campaign features real-life accounts of individuals living in recovery, and those who have lost someone to an overdose. CDC is running digital, radio, and out-of-home campaign ads for 14 weeks in select states (KY, MA, NM, and OH) with broader release anticipated in 22 additional OPIS funded states.

Improving Access to Prevention, Treatment, and Recovery Support Services
CDC brings scientific expertise and leverages existing relationships with health systems to link patients who need MAT to the appropriate care. As part of the OPIS effort, several states funded under the PfS program are supporting health system approaches to link patients to treatment and recovery services. For example, states are building systems that facilitate better linkages to treatment, emergency room peer patient navigators, and data dashboards to identify hot spots for treatment needs.

Additionally, CDC is conducting an epidemiologic study to assess what type of MAT (methadone maintenance; buprenorphine; naltrexone) or counseling and other non-medication interventions is most effective, and which contextual, provider, and individual factors influence implementation, prevent relapse, and improve patient wellbeing over a two-year period. This study can help identify who may benefit from which type of treatment to ensure individuals receive the treatment best suited to their needs.

Targeting Overdose-Reversing Drugs
CDC is currently working with SAMHSA to evaluate its Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths program with the goals of describing and understanding the scope and impact of naloxone education and distribution efforts in high-need communities and to identify barriers and potential solutions to increase program effectiveness. Additionally, states funded under OPIS are evaluating practices to improve the distribution and use of overdose reversing drugs and Good Samaritan laws (policies that protect the victim and the bystander from drug possession charges). States utilize CDC data to identify communities experiencing a significant increase in opioid overdose deaths, which helps to inform both the targeted distribution of naloxone and the training of community members, EMS, and law enforcement on naloxone administration.

Supporting Cutting-Edge Research
To better understand the epidemic, identify risk and protective factors, and determine effective interventions, CDC also funds innovative research to prevent misuse and abuse. One CDC funded project at the Carolinas Medical Center in Charlotte, North Carolina, is working to assess and compare changes in prescribing behaviors when providers are presented with electronic alerts on potential misuse or abuse of opioids. This research will inform efforts to improve clinical decision-making. In addition, CDC funds

academic research centers to conduct translational research in order to better understand how to get information into the hands of practitioners. For example, the Johns Hopkins Injury Control Research Center (ICRC) is working to reduce injured patients' risk for opioid misuse through mobile health technology while the West Virginia University (WVU) ICRC was instrumental in the development and implementation of a pilot take-home program for naloxone in rural communities. There were at least 25 overdose reversals in the first nine months of the program in 16 counties. As part of a rapid response project using CDC funds, the WVU ICRC distributed 8,250 naloxone kits to first response agencies and take-home naloxone programs throughout the state in the first half of 2017.

National Institutes of Health (NIH)

NIH is the lead HHS agency providing support for cutting-edge research on pain and opioid misuse, addiction, and overdose. Drug addiction is a complex neurological condition, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the crisis and informing future efforts. Pain is an equally complex condition. To this end, NIH supports a range of activities to advance research on pain and addiction.

Supporting Cutting-Edge Research

Because the most effective way to end opioid misuse and addiction is to prevent it from beginning, NIH is supporting innovative research to better understand what makes an individual vulnerable to opioid misuse. For example, the Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of brain development and child health in the U.S., will help build an evidence base to draw on for a future of precision medicine approaches to prevent opioid addiction.

With the goal of bringing scientific solutions to the opioid crisis, NIH is exploring ways to promote 1) new, innovative medications and technologies to treat opioid addiction and improve overdose prevention and reversal interventions, and 2) safe, effective, non-addictive strategies to manage pain. In April 2017, NIH Director Francis S. Collins, M.D., Ph.D., met with research and development leaders from the world's leading biopharmaceutical companies to discuss new ways for government and industry to work together to address the opioid crisis. NIH continued meetings throughout the summer. As part of these ongoing discussions, NIH participated in a recent meeting with Pharmaceutical CEOs convened by Governor Christie, co-chair of the President's Commission on Combating Drug Addiction and the Opioid Crisis, in Trenton, New Jersey, on September 18th. Some advances NIH is working to promote may occur rapidly, such as improved formulations of existing medications, longer-acting overdose-reversal drugs, and repurposing of treatments approved for other conditions. Others may take longer, such as novel overdose-reversal medications and identifying biomarkers to measure pain in patients. Our goal for these activities is to cut in half the time needed to develop new safe and effective therapeutics to help end the opioid crisis.

NIH will continue to build upon breakthroughs in the treatment of opioid addiction and the reversal of opioid overdose and find ways to advance the development of new products. For example, buprenorphine, one of the three FDA-approved options for MAT treatment, was developed through a partnership between NIH and industry. The intramural program of the National Institute on Drug Abuse (NIDA) conducted the early clinical studies on buprenorphine and then later partnered with industry to develop user-friendly and abuse deterrent formulations. In addition, a NIH public-private partnership helped to develop the only FDA-approved intranasal naloxone product to reverse opioid overdose, an invaluable tool to those on the front lines combating the opioid crisis. In 2013, NIDA funded a biopharmaceutical company for clinical studies to evaluate the pharmacokinetic properties – how much and how rapidly the naloxone is absorbed – of an intranasal formulation. In 2015, the intranasal naloxone was approved by the FDA. With knowledge gained from neuroscience advances, NIH researchers now seek ways to turn the tide in the opioid crisis through a wider range of formulations of existing and new medications, as well as innovative strategies to treat opioid use disorder and prevent and reverse overdose.

NIH is also working toward preventing the most serious health consequences for infants born with NAS. Currently, NIH research aims to determine more precise dosing of buprenorphine in pregnant women, and to reduce the time to develop new treatments. NIH is also launching a new effort on opioid use in pregnancy, to study the effects of medically supervised opioid withdrawal on mother and newborn, and better understand the genetic or epigenetic factors associated with opioid use on neonatal outcomes. NIH will also develop and pilot a common study protocol to generate evidence for best practices in treating newborns with NAS, through a partnership between the NIH Neonatal Research Network and the new IDeA States Pediatric Clinical Trials Network.

NIH researchers are also working to build an understanding of how to effectively integrate prevention and treatment services within healthcare and community systems. For example, NIH is studying strategies to improve the implementation of MAT for people with opioid use disorder in the criminal justice system. This research aims to optimize implementation of evidence-based screening, assessment, and treatment services by juvenile justice agencies and improve coordination with community healthcare providers in a way that promotes long-term recovery from opioid addiction in real-world settings.

Advance the Practice of Pain Management

Our mission to end the opioid crisis will not be successful until we can provide patients with better options for the treatment of pain, which touches 25 million Americans every day. NIH funds a broad range of research on pain, from basic research into the molecular, genetic, and bio-behavioral basis of chronic pain to large-scale clinical studies of potential treatments. NIH funded basic research has identified a myriad of potential targets for future non-addictive therapies. Pathological pain and addiction are classic disorders of brain circuits and the neurotechnologies emanating from the US BRAIN Initiative enable scientists to explore these circuits to advance both diagnostics and therapeutics. Research efforts to understand and alleviate pain depend on better objective

measures of the pain experience for patients. To address this, NIH also supports development of resources to advance the research agenda. One example is the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS provides a rigorously tested patient-reported outcome measurement tool to measure pain, fatigue, physical functioning, and emotional well-being.

NIH works with Federal partners across government to carry out cutting-edge research on pain. Through the Interagency Pain Research Coordinating Committee, NIH developed the Federal Pain Research Strategy, a long-term strategic plan to coordinate and advance the federal research agenda on pain. The Strategy's research priorities include prevention of acute and chronic pain, management of acute pain, transition from acute to chronic pain, and understanding the disparities that influence pain and pain management. Ongoing projects that already are advancing the goals laid out in the Strategy include the NIH-DoD-VA Pain Management Collaboratory program, which recently announced $81 million in research funding to implement cost-effective large-scale clinical research in military and veteran healthcare delivery organizations, focusing on non-pharmacologic approaches to pain management and other comorbid conditions.

Beyond research activities, NIH is engaged in efforts to advance the HHS Opioid Strategy pillar of advancing the practice of pain management. NIH worked with HHS and agencies across government to develop the National Pain Strategy, the government's first broad-ranging effort to improve how pain is perceived, assessed, and treated, which highlights the need for evidence based treatments. NIH is actively working with other Departments and Agencies and external stakeholders to implement the Strategy. In addition, NIH is supporting Centers of Excellence for Pain Education that act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to enhance education about pain and pain care.

Food and Drug Administration (FDA)

FDA, the Agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, is focusing on three broad areas to help address the opioid crisis: lowering overall exposure to opioid drugs and, in turn, reducing the number of new cases of addiction; enabling more opportunities for those currently addicted to opioid drugs to seek MAT that can help them recover; and helping expedite the development of progressively more-effective abuse deterrent formulations of opioid drugs, and better still, non-opioid alternatives for the treatment of pain. To advance these goals, FDA, earlier this year, established an Opioid Policy Steering Committee that brings together the Agency's most senior career leaders to explore and develop additional tools and strategies to confront the opioid crisis.

Support Cutting-Edge Research

Abuse Deterrent Formulations (ADF): FDA's emphasis on assessing the full public health effects of opioids is reflected in the Agency's ongoing work to support the development of forms of prescription opioids that deter abuse. The Agency strongly

supports a transition from the current market dominated by conventional opioids to one in which the majority of opioids have meaningful abuse-deterrent properties. In support of this transition and potential future actions against products without these properties, FDA is focusing its efforts on determining how effective the current abuse deterrent products are in the real world. To assist this effort, the Agency recently gathered independent experts for a scientific workshop to discuss both the existing science and what else is needed to properly assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death. Separately, FDA is working to support generic forms of abuse deterrent opioids by issuing final guidance on their development, in recognition of the important role generic drugs play in the United States.

Alternatives to Opioids for Pain: FDA strongly supports the development of new treatment options for patients in pain, especially treatments that do not have the same addictive features of traditional opioids. To advance both non-addictive and non-pharmacologic treatments for pain, FDA commits to using all of the Agency's authorities. This includes programs such as the Fast Track and Breakthrough Therapy Designations that are intended to facilitate development and to expedite review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. As a part of these efforts, FDA is meeting with innovators who are pursuing non-opioid alternatives for the treatment of pain to provide guidance on their individual products. Agency steps also include a more careful consideration of non-drug alternatives for pain, such as medical devices that can deliver more localized analgesia. FDA is considering how to more closely fit medical device alternatives into a comprehensive approach to the development of treatments for pain.

We know that developing non-opioid and non-addictive pain medicines is challenging for many reasons; therefore, FDA is interested in progressing the entire field of pain drug development. To address the issues related to the trials needed for approval, FDA has participated in a public-private-partnership (PPP) under the Critical Path initiative, the Analgesic Clinical Trial Translation, Innovations, Opportunities, and Networks (ACTTION). The ACTTION PPP is a collaboration among a broad spectrum of national and international groups aimed at advancing the science in this area, including academia, FDA and other government agencies, pharmaceutical and device companies, professional organizations, and patient advocacy groups.

At the same time as we are prioritizing work on non-opioid and non-abusable pain medicines, FDA is also taking new steps to help facilitate the development of medications that can help patients with addiction recover as well as overdose reversal drugs, such as naloxone. FDA is laying the groundwork for naloxone to be available more broadly and is supporting research aimed at encouraging the potential development of over the counter naloxone products.

Advance the Practice of Pain Management

Changes in Prescribing: To reduce the rate of new opioid addiction, we need to decrease overall exposure to opioids. For many people, that first prescription will be for an immediate release (IR) formulation of the drug. Some people will go on to become

addicted and abuse longer-acting formulations that can deliver higher doses, especially when manipulated. Some of these people will eventually move onto street drugs, such as heroin, which are increasingly the low-cost alternative. We know that this route of addiction correlates with exposure. A certain percentage of patients exposed to opioids will go on to develop an addiction to the drugs. One approach to reducing the rate of new addiction, then, is to reduce exposure to prescription opioid drugs. To accomplish this, we need to explore ways to use our regulatory authorities to influence how opioids are prescribed to make sure that only appropriately indicated patients are prescribed opioids, and that the prescriptions are written for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place. We are exploring whether FDA should take additional steps to make sure that general prescribing and the number of opioid doses that an individual patient can be dispensed, is more closely tailored to the medical indication. Among other steps, FDA is soliciting public input on these questions in the form of a public docket that was established the week of September 25.

Expanded Education through Modification of Opioid REMS, and Changes to the Education Blueprint: Since 2012, FDA has required manufacturers of extended-release long-acting opioids to make available educational materials through a Risk Evaluation and Mitigation Strategy (REMS). We know that most of the exposure to opioids is not from extended-release or long-acting formulations, but from IR formulations like hydrocodone and acetaminophen or oxycodone and acetaminophen combinations. In fact, about 90 percent of all opioid prescriptions in the United States are written for IR formulations of these drugs. IR opioid products serve as the gateway for patients and non-patients who may continue to use or misuse these products, which could lead to new addiction. Given this fact, we need to advance policies that rationalize the prescribing and dispensing of IR opioid drugs.

As one step, FDA has determined that a REMS to support education is also necessary for the prescribing of IR opioid products. This regulatory tool is needed to ensure that the benefits of these drugs continue to outweigh the risks of adverse outcomes (addiction, overdose, and death) resulting from inappropriate prescribing, abuse, and misuse, and that providers are properly informed about suitable prescribing and the risks and benefits associated with opioid drugs. FDA has announced its intention to update the existing REMS on extended-release/long-acting opioid analgesics, and for the first time, extend these same regulatory requirements (including prescriber training) to the manufacturers of IR opioid analgesic products. FDA is currently implementing that plan. We have also announced plans to revise the Blueprint used to create education materials to include broader information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). To start this process, the relevant letters, detailing the new requirements, were recently sent to sponsors that manufacture the IR drugs.

In addition to the efforts described above, HHS continues to engage with a broad range of stakeholders – state and local governments, addiction specialists, medical, nursing, dental, and

pharmacy providers, community and faith-based organizations, private-sector partners, community organizations, and law enforcement partners – to share best practices, build collaborations, and identify barriers that could prevent success. We are committed to this fight and will continue to advance a multi-pronged strategy, never forgetting that behind all the statistics are individuals, families, and communities who are being torn apart each day. Our guiding vision must be to improve the lives of all Americans who have been touched by this crisis. That will be the true measure of our success.

Lastly, HHS, through the President's FY 2018 budget, has requested more than $800 million to continue to support the Department's critical opioid investments. We look forward to continuing to work with Congress to identify solutions and to secure the funding needed to turn the tide against the opioid crisis.

Thank you again for inviting SAMHSA, CDC, NIH, and FDA to testify today. We look forward to answering your questions.

Mr. WALDEN. 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 D. 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 phar-

macological 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 second 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:]

Department of Justice

STATEMENT OF

NEIL D. DOHERTY
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL OPERATIONS
DIVERSION CONTROL DIVISION
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

HOUSE ENERGY AND COMMERCE COMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

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

PRESENTED

OCTOBER 25, 2017

Statement of
Neil D. Doherty
Deputy Assistant Administrator
Office of Diversion Control Operations
Diversion Control Division
Drug Enforcement Administration

Before the
Energy and Commerce Committee
U.S. House of Representatives

For a Hearing Entitled
"Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"

October 25, 2017

Chairman Walden, Ranking Member Pallone, and Members of the Committee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the threat posed by the opioid epidemic. The abuse of controlled prescription drugs (CPDs) is inextricably linked with the threat the United States faces from the trafficking of heroin, fentanyl and fentanyl analogues.

Drug overdoses, suffered by family, friends, neighbors and colleagues, are now the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.[1] According to initial estimates provided by the Centers for Disease Control and Prevention (CDC), there were more than 64,000 overdose deaths in 2016, or approximately 175 per day. Over 34,500 (54 percent) of these deaths were caused by opioids. The sharpest increase in drug overdose deaths from 2015 to 2016 was fueled by a surge in fentanyl and fentanyl analogue (synthetic opioids) overdoses.[2]

The misuse of CPDs and the growing use of heroin, fentanyl, and fentanyl analogues are being reported in the United States in unprecedented numbers. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) 2016 National Survey on Drug Use and Health (NSDUH), 6.2 million people over the age of 12 misused psychotherapeutic drugs (e.g., pain relievers, tranquilizers, stimulants, and sedatives) during the past month.[3] This represents 22 percent of the 28.6 million current illicit drug users and is second only to marijuana

[1] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[2] CDC WONDER data, retrieved from the National Institute of Health website; http://www.drugabuse.gov as reported on NIDA's website.
[3] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

(24 million users) in terms of usage.[4] There are more current misusers of psychotherapeutic drugs than current users of cocaine, heroin, and hallucinogens combined.[5]

The increase in the number of people using heroin in recent years – from 373,000 past year users in 2007 to 948,000 in 2016 – is troubling.[6] More alarming is the proliferation of illicit fentanyl and its analogues. DEA investigations reveal that fentanyl and its analogues are being added to heroin and other illicit substances and in many instances pressed into counterfeit tablets resembling CPDs. Because of its high potency, the more fentanyl is introduced to the 11.5 million people that misused a pain reliever in the previous year, there is a likelihood that drug overdoses will continue to climb.[7] Since fentanyl and its analogues can be harmful to public safety personnel who encounter these substances during the course of their daily operations, it is critical they know how to protect themselves. DEA is part of an interagency working group to develop a set of scientific, evidence-based recommendations that first responders can take to protect themselves.

CONTROLLED PRESCRIPTION DRUGS (CPDs)

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.[8] This makes prescription opioid misuse more common than use of any category of illicit drug in the United States except for marijuana. Whereas the vast majority of individuals misusing opioid CPDs do not go on to use heroin, this information provides valuable insight into the role that CPDs play in the opioid epidemic and underscores the need for a robust regulatory program that seeks to stop diversion of CPDs.

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the "street" cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)[9] can be purchased for $5 to $7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for $7 to $10 per tablet on the street. Even stronger prescription drugs are sold for as much as $1 per milligram (mg). For example, 30 mg

[4] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[5] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[6] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

[7] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

[8] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

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

oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost $30 to $40 per tablet on the street. The costs that ensue with greater tolerance make it difficult to purchase these drugs in order to support a developing substance use disorder, particularly when many first obtain these drugs for free from the family medicine cabinet or from friends.

HEROIN

Heroin is transported to the United States predominantly across the Southwest Border (SWB) and is produced with greater sophistication from powerful transnational criminal organizations (TCOs) like the Sinaloa Cartel and New Generation Jalisco Cartel or CJNG. These Mexico-based TCOs are extremely dangerous, violent and continue to be the principal suppliers of heroin to the United States.

Not surprisingly, a small number of people who misuse prescription opioids turn to heroin. Heroin traffickers produce high purity white powder heroin that costs approximately $10 per bag, and usually contains approximately 0.30 grams per bag. This makes heroin significantly less expensive than CPDs. Heroin produces a "high" similar to CPDs and can keep some individuals who are dependent on opioids from experiencing painful withdrawal symptoms. This cycle has been repeatedly observed by law enforcement agencies. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began misusing prescription opioids.[10]

According to reporting by treatment providers, many individuals with serious opioid use disorders will use whichever drug is cheaper and/or available to them at the time.[11] Heroin purity and dosage amounts vary, and heroin is often cut with other substances (e.g., fentanyl and fentanyl analogues). This means that heroin users are at higher risk of unintentional overdose because they cannot predict the dosage of opioid in the product they purchase on the street as heroin.[12] Additionally, varying potencies found in diverted or counterfeit prescription opioids purchased on the street have led to increased unintentional drug overdoses.

A report published by SAMHSA found that four out of five recent new heroin users had previously misused prescription pain relievers.[13] The reasons an individual may shift from one opiate to another vary, but today's heroin is high in purity, less expensive and often easier to obtain than illegal CPDs. High-purity heroin can be smoked or snorted, thereby circumventing a

---

[10] U.S. Department of Justice, Drug Enforcement Administration, 2016 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2016, *available at*: https://www.dea.gov/divisions/hq/2016/hq062716_attach.pdf.

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

[12] Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, Int J Drug Policy, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: Int J Drug Policy, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi: 1016/j drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D., "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, Int J Drug Policy, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

[13] Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Department of Health and Human Services, August 2013, *available at*: https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

barrier to entry (i.e., needle use) and avoiding the stigma associated with injection. However, many who smoke or snort are vulnerable to eventually injecting heroin. Heroin users today tend to be younger and more ethnically and geographically diverse than ever before.[14]

Overdose deaths involving heroin are increasing at an alarming rate, having almost increased more than five-fold since 2010.[15] Today's heroin at the retail level costs less and is more potent than the heroin that DEA encountered two decades ago. It is also not uncommon for heroin users to seek out heroin that dealers claim is "hot," meaning that it is likely cut with fentanyl or its analogues. Users seeking "hot" heroin is an indicator that as higher opioid tolerance levels develop among users, they will continue to seek out more potent forms of opioids.

FENTANYL AND FENTANYL ANALOGUES (SYNTHETIC OPIOIDS)

Fentanyl is a Schedule II controlled substance produced in the United States and used widely in medicine. It is an extremely potent analgesic widely used for anesthesia and also pain control in people with serious pain problems and, in such cases, it is indicated only for use in people who have high opioid tolerance.

Illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped primarily through mail carriers directly to the United States or alternatively shipped directly to transnational criminal organizations ("TCOs") in Mexico, Canada, and the Caribbean. Once in the Western Hemisphere, fentanyl or its analogues are prepared to be mixed into the U.S. heroin supply domestically, or pressed into a pill form, and then moved to the illicit U.S. market where demand for prescription opioids and heroin remain at epidemic proportions. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this market. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 - $5,000 can generate upwards of $1.5 million in revenue on the illicit market.

According to the DEA National Forensic Laboratory Information System ("NFLIS"), from January 2013 through December 2016, over 58,000 fentanyl reports were identified by federal, state and local forensic laboratories.[16] During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,[17] an exponential increase over the past four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a December 2016 Centers for Disease Control Morbidity and Mortality Weekly

[14] Cicero, T., Ellis, M., Surratt, H, Kurtz, S. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, July, 2014.
[15] CDC WONDER data accessed on 10/15/17, as reported at NIDA's website: 3,036 heroin overdoses in 2010; 15,446 overdoses in 2016. https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.
[16] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.
[17] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.

Report, from 2014 to 2015, the death rate from synthetic opioids other than methadone, which include fentanyl, increased 72.2%, from 5,544 (age adjusted rate 1.8) to 9,581 (3.1).[18] Over a two-week period in late March and early April 2016, DEA issued a public safety alert for the Sacramento, California region following an outbreak of overdoses related to counterfeit hydrocodone which had been laced with fentanyl. In all, there were 52 individuals who overdosed, 14 of whom ultimately lost their lives. Additionally, between January and March 2016, nine people died in Pinellas County, Florida from counterfeit Xanax® pills that contained fentanyl. The number of overdose fatalities resulting from fentanyl and fentanyl analogues is under-reported and will increase as postmortem drug testing expands.

DEA RESPONSE TO THE OPIOID EPIDEMIC, HEROIN EPIDEMIC, AND THE THREAT OF FENTANYL AND OTHER SYNTHETIC DRUGS

Effective Outreach

Due to the complexity of DEA's regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its more than 1.7 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by (1) hosting Pharmacy Diversion Awareness Conferences ("PDACs") throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy ("NABP"), American Medical Association ("AMA"), and other groups to address diversion problems and educate the medical community on improving prescribing practices[19]. By the end of October, 2017, DEA will have hosted 97 PDACs in 48 states (including the District of Colombia and Puerto Rico) and will have trained in excess of 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In 2018, DEA will initiate a nationwide program to offer similar training to individual practitioners.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th, pursuant to the Governor's Executive Order in July 2017. As of August 2017, 24 of these 49 states with operational PDMPs require controlled substance

[18] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[19] In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[20] The DEA encourages all practitioners and pharmacists to use their state PDMPs.

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to pain clinics and physicians that are operating unscrupulously and outside of the law, making interconnectivity between PDMPs vital. Federal partners are working to address the interoperability problems. The Office of National Drug Control Policy (ONDCP) and the Bureau of Justice Assistance (BJA) also offer assistance for interstate and state-tribal PDMP linkages. CDC supports 29 states to advance interventions for preventing prescription drug overdoses, through its *Prevention for States* program, which could include activities focused on improving interoperability between PDMPs and Electronic Health Record (EHR) technology and provide real-time provider access. The Indian Health Service (IHS) developed a policy that requires federal IHS facilities to report all controlled substance prescriptions to their respective State PDMPs and requires federal prescribers to check State PDMPs prior to prescribing opioids. Finally, the National Association of Boards of Pharmacy (NABP) hosts NABP Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of PDMP data across state lines to authorized users. The program allows users of participating PDMPs to securely exchange prescription data between certain states. Currently, PDMPs in over 41 states are participating in the program.

Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information (PII) is vital. Unfortunately, access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse use of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the

[20] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20170824.pdf retrieved October 19, 2017.

user for free[21]. These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of October 17, 2017, 2,829 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on April 29, 2017. As a result of all thirteen National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of 8.1 million pounds (4,052 tons) of medications from circulation. The DEA is conducting a Federal Take-Back Day today, October 25, and the fourteenth National Drug Take Back Day is scheduled for October 28, 2017.

DEA'S 360 Strategy

To counter the opioid crisis, DEA initiated and continues to expand upon its 360 Strategy. The strategy leverages existing Federal, State, local, and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and demand reduction. Our enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding the heroin and prescription drug epidemic in our communities. We are also enhancing our diversion control efforts and working with community partners for them to implement evidence-based programs and efforts designed to reduce demand and to prevent the same problems from resurfacing.

As part of the 360 Strategy, DEA recently partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide development of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. The program has reached more than 1.1 million students to date and will run for at least three consecutive school years (through spring 2019) and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

Since its implementation in 2016, the 360 Strategy has been implemented in eight cities– Louisville, Kentucky; St. Louis, Missouri; Pittsburgh, Pennsylvania; Milwaukee, Wisconsin;

[21] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia; and Manchester, New Hampshire. DEA is expanding this program to additional locations including the announcement of Salt Lake City, Utah in September 2017. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

Tactical Diversion Squads

DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the Controlled Substances Act (CSA) and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and present, DEA increased the number of operational TDSs from 37 to 77. In addition, we established two mobile TDS that can deploy quickly to "hot spots" in furtherance of the Diversion Control Division's mission. One mobile TDS was recently deployed to West Virginia and is supporting DEA's offices in Charleston and Clarksburg.

Temporary Scheduling of Synthetic Opioids and New Psychoactive Substances (NPS)

Even though many fentanyl and NPS compounds have been controlled in Schedule I or Schedule II of the CSA, drug traffickers produce and procure new synthetic compounds with relative ease. Over the past several years, DEA has identified hundreds of designer drugs from at least eight different drug classes, including synthetic opioids, the vast majority of which are manufactured in China. DEA continues to utilize its regulatory authority to place many synthetic substances into the CSA pursuant to the aforementioned temporary scheduling authority. Once a substance is temporarily placed in Schedule I, DEA moves towards permanent control by requesting a scientific and medical evaluation and scheduling recommendation from HHS and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, medical examiners, treatment professionals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since January 2011, DEA has utilized this authority on fifteen occasions to place 45 synthetic designer drugs temporarily (emergency control) into Schedule I. This includes the following fentanyl analogues: acetyl fentanyl, butyryl fentanyl, beta-hydroxythiofentanyl, furanyl fentanyl, 4-fluoroisobutyryl fentanyl, and acryl fentanyl. In addition, DEA has published a notice of intent to temporarily control the following three additional fentanyl analogues: methoxyacetyl fentanyl, tetrahydrofuranyl fentanyl, and ortho-fluorofentanyl. In comparison, over the first 25 years (1985-2010) after Congress created this authority, DEA utilized it a total of 13 times to control 25 substances.

However, clandestine chemists continue to develop and synthesize new synthetic drugs. They do this hoping that the new drugs are not covered by any schedule of controlled substances. In fact, when DEA takes an action to temporarily schedule a substance, retailers and traffickers begin selling new versions of their products, which contain new, and they hope unregulated, compounds. In addition, many of these retailers are provided with spurious chemical analyses

that purport to document that the new product line did not contain any controlled substance. Manufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing new synthetic analogue products that are not listed as such in any of the controlled substance schedules.

Significant Enforcement Efforts

The DEA Special Operations Division ("SOD") Heroin/Fentanyl Task Force ("HFTF") Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Custom Enforcement Homeland Security Investigations ("HSI") and Customs and Border Protection ("CBP"); supplemented by the Federal Bureau of Investigation ("FBI") and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the Department of Justice's Organized Crime Drug Enforcement Task Forces ("OCDETF") Fusion Center ("OFC") and Criminal Division, the Department of Defense ("DOD"), Intelligence Community ("IC") and other government entities, and provides field offices (all agencies) with valuable support in their respective investigations.

The HFTF mission aims to:

- Identify, target, and dismantle command and control networks of national and international fentanyl and NPS trafficking organizations.
- Provide case coordination and de-confliction on all domestic and foreign investigations to ensure that multi-jurisdictional, multi-national, and multi-agency investigations and prosecutions have the greatest impact on targeted organizations.
- Provide direct and dynamic operational and investigative support for domestic and foreign field offices for all agencies.
- Identify new foreign and domestic trafficking, manufacturing, importation, production and financial trends utilized by criminal enterprises.
- Analyze raw intelligence and documented evidence from multiple resources to develop actionable leads on viable target(s) involved in possible illicit pill production and/or distribution networks.
- Educate overall awareness, handling, trafficking trends, investigative techniques and safety to domestic and foreign field offices for all law enforcement, DOD, IC and governmental agencies.
- Facilitate, coordinate and educate judicial districts during prosecutions of fentanyl and other NPS related cases.

AlphaBay "Dark Market" Shutdown

In July 2017, the Justice Department announced the seizure of the largest criminal marketplace on the Internet, AlphaBay, which operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities

in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. The interagency investigation into AlphaBay revealed that numerous vendors sold fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

Mexico: Partnership to Reduce Supply of Illicit-Narcotics

DEA, through its partnership with the U.S. Department of State, helps Mexican government officials to improve capacity to interdict and seize illicit-narcotics. DEA routinely engages with Mexico through the bilateral drug policy working group with the Office of the Attorney General (PGR) in Mexico City. These efforts were instrumental in constructive policy changes such as Mexico's decision to schedule the two primary fentanyl precursors, ANPP and NPP in mid-2017.

China: Government Action and Cooperation

DEA, through its leadership here in the United States and its country office in Beijing, has maintained an ongoing relationship with government officials of the People's Republic of China for years, and has been able to leverage this relationship to combat the rising threat from NPS and their precursors. Engagement has been occurring at the leadership level through interagency working groups that operate under the U.S.-China Joint Liaison Group (JLG) framework co-chaired by the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, DEA, and DHS, including the Counternarcotics Working Group led by the Department of Justice, and the Bilateral Drug Intelligence Working Group led by DEA.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls against four fentanyl-class substances: carfentanil; furanyl fentanyl; valeryl fentanyl; and, acryl fentanyl. This announcement was the culmination of ongoing collaboration between DEA and the Government of China, and reaffirms an expanding collaborative commitment to countering illicit fentanyl.

Over the past year, DEA and Chinese officials have met regularly to discuss mutual interests and shared responsibilities in countering the threat from fentanyl class substances. Representatives from the China National Narcotics Laboratory, the Narcotics Control Bureau, and the Ministry of Public Security met with DEA (along with Department of Justice and Department of Homeland Security) officials to exchange information on emerging substances' scientific data, trafficking trends, and sample exchanges. This continued dialogue is anticipated to foster a bilateral information exchange related, but not limited to, the identification of new substances of abuse that may then be considered for national control. The meeting also deepened professional contacts between relevant technical and legal experts.

A key moment in enhanced cooperation on synthetic drugs came in October of 2015, when, following similar discussions, China decided to implement domestic controls on 116 NPS, which included a number of fentanyl analogues, and streamlined its procedures to control

additional substances with no known medicinal use. In total, China has scheduled 138 different NPS, including 128 since October 2015.

Finally, as this threat has increased, law enforcement cooperation at the street level has been very productive, particularly on fentanyl cases. DEA will continue to collaborate with the Government of the People's Republic of China as the threat from fentanyl continues to evolve.

CONCLUSION

The United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of abuse of prescription opioids. DEA's Diversion Control Division will continue to use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. Additionally, DEA expects that demand for opioids will continue to be met in part by Mexican-based TCOs who produce high purity heroin, which is being laced with fentanyl, fentanyl analogues, and other synthetic opioids, and then pressed into counterfeit pills. DEA will continue to address this threat by pursuing the Mexican-based TCOs, which have brought tremendous harm to our communities. Working with DOJ and our interagency partners, DEA will continue to engage our international counterparts, especially China, both multilaterally and bilaterally. We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by controlled prescription drugs, heroin, and fentanyl.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. Thank you very much.

Ms. DEGETTE. Mr. Chairman?

Mr. WALDEN. For what purpose does the gentlelady from Colorado——

Ms. DEGETTE. I have a unanimous consent request.

Mr. WALDEN [continuing]. 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.

Mr. WALDEN. Without objection, those letters will be entered into the record.

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.

Mr. WALDEN. 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. OK. 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 [continuing]. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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 [continuing]. 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 [continuing]. Related to——

Ms. ESHOO [continuing]. 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 weeklong 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.

Mr. WALDEN. 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.

Mr. WALDEN. Without objection.

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

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. OK, 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. OK, 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. OK, methadone.

Dr. MCCANCE-KATZ [continuing]. 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. OK, 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 [continuing]. Can make better determinations.

OK, 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. OK, dependency, what else?

Mr. DOHERTY. Danger for abuse.

Mr. SHIMKUS. Danger for abuse.

OK, 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. Without objection.

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

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 [continuing]. 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.

Mr. WALDEN. 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. OK. 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. OK, 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 over-relying 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. OK.

Dr. GOTTLIEB [continuing]. To perhaps make it more efficient to operate inside those IMFs.

Mrs. BLACKBURN. OK, 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. OK, 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. OK. 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 appears at the conclusion of the hearing.]

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. OK, 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.

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. OK. 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. One week, one month, one 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 while 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. OK. 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. OK.

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. OK.

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.

Ms. DEGETTE. OK. 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, 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. OK, 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. OK. 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-a-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. OK, 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. OK, 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 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 [continuing]. We see very positive results in getting people stably housed.

Ms. MATSUI. OK, thank you very much and I see my time has expired. Thank you.

Mr. WALDEN. 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.

Mr. WALDEN. 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 cutting-edge research that advances our understanding of pain and addiction. What are some examples of recent developments in this area of nonaddictive 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 [continuing]. 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 start-

ing 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.

Mr. WALDEN. 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 clini-

cians 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 DC 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.

Mr. WALDEN. 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. OK. 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. OK? 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.

Mr. WALDEN. Correct.

Mr. WELCH. I will leave it to you.

Mr. WALDEN. 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.

Mr. WALDEN. 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 an 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 one 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 pregraduate 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. OK, 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.

Mr. WALDEN. 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, OK, 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 is 20 percent higher than the number-two state and almost 40 percent higher than the number-three state. It is nearly 2½ 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.

Mr. WALDEN. 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 10 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.

Mr. WALDEN. 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 these, 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. KINZINGER. OK, 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. KINZINGER. 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.

Mr. WALDEN. I thank the gentleman.

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

Mr. LUJÁN. 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. LUJÁN. 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.

Mr. WALDEN. Without objection.

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

Mr. WALDEN. 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 [continuing]. 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 detailed 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—OK, 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.

Mr. WALDEN. I thank the gentleman.

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

Mr. CÁRDENAS. We are both from California.

Mr. WALDEN. Yes, there you go.

Mr. CÁRDENAS. 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. CÁRDENAS. So the answer is no. OK. 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. CÁRDENAS. OK. 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. CÁRDENAS. 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. CÁRDENAS. OK. 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. CÁRDENAS. 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. CÁRDENAS. Will it make it worse; yes or no?

Dr. VOLKOW. Without, it is——

Mr. CÁRDENAS. OK, 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 has a lot of work to do, and with it comes the resources necessary to combat this crisis.

I yield back.

Mr. WALDEN. 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 OK. 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. OK. Did DEA recommend that President Obama veto the bill?

Mr. DOHERTY. No, sir.

Mr. BILIRAKIS. OK. 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. OK. 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.

OK, 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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. OK, my time has actually expired but can Dr. Volkow respond as well?

Mr. WALDEN. 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.

Mr. WALDEN. The gentleman's time has expired.

Mr. JOHNSON. Thank you, Mr. Chairman.

Mr. WALDEN. 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 coprescribing of naloxone. And that is an important best practice, I think, for physicians to take up. And as more physicians are exam-

ining 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.

Mr. WALDEN. 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 half an hour, 45 minutes before 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. OK, 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. OK 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. OK, 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, polycriminal 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.

Mr. WALDEN. The gentleman yields back.

I recognize the gentleman from New York.

Mr. TONKO. Mr. Chair, I ask 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.

Mr. WALDEN. Without objection, they will be entered into the record.

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

Mr. WALDEN. For our witnesses, we probably won't be back for half an hour. So if you want to grab something to eat and whatever else, probably at least a half 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.

[Recess.]

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 9 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 [continuing]. 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. OK, 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 nonpharmacological 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 nonpharmaceutical treatment of pain.

Mr. BURGESS. Without objection, so ordered.

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

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. OK, 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. OK.

Dr. SCHUCHAT [continuing]. 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 ap-

proving 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. OK.

Dr. SCHUCHAT. We need better prescribing.

Mr. CARTER. OK, 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 "OK, 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. OK, 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. OK, 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. OK.

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. OK, 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 appears at the conclusion of the hearing.]

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. OK so if you flip that 80 percent figure, that means that 20 percent of the facilities are not licensed or certified.

OK, 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. OK. 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 Web site 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. OK, 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. OK and what is SAMHSA's role in overseeing or regulating sober homes?

Dr. MCCANCE-KATZ. We have no authority over sober homes.

Mrs. WALTERS. OK. 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. OK. 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 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, reconnected 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 appears at the conclusion of the hearing.]

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 committee is adjourned.

[Whereupon, at 3:26 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

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

I also appreciate all of the witnesses here for coming before our committee and sharing their agency's efforts to fight the opioid crisis at the Federal level.

The Health Subcommittee recently heard from more than 50 members on how the opioid epidemic is affecting their communities. The opioid crisis has touched every corner of American society—no one is immune from this heartbreaking problem. Just this month, our North Texas community lost a young man in his mid-20s from a suspected overdose. This young man, who was the son of one of my daughter's closest friends, had his whole life ahead of him. Too many American families have been devastated by this epidemic. The statistics on this issue are shocking, particularly as we consider that 91 Americans die every day from an opioid overdose, and in 2016 alone, drug overdoses claimed more American lives than the entire Vietnam War.

The debate around pain medication is not a new issue for our committee. In fact, one of the first Energy and Commerce Committee hearings I participated in more than a decade ago focused on physicians' treatment of pain. However, at the time, we were concerned that physicians were not treating pain adequately. Today, we are hearing about a much different situation.

As we consider solutions critical to stemming the opioid crisis, we must strike a careful balance before casting blame. It bothers me when I hear doctors placed at fault for this epidemic. Physicians are our allies, not our adversaries, in this battle against the opioid epidemic. In fact, a caring doctor on the front line can do more to stem this problem than any Federal Government action.

PREPARED STATEMENT OF HON. STEVE SCALISE

Opioid abuse is a major crisis in this country. We've all heard stories from families back home in our districts as this horrible epidemic has swept through communities across America.

Despite everyone's best efforts, the troubling statistics continue to rise. Louisiana was one of many States that experienced double-digit increases in the percentage of opioid related deaths in recent years. Last year there were more opioid related deaths in southeast Louisiana than car crash fatalities.

There is no silver bullet to this problem which is what makes the committee's work so important. Today's hearing will allow us to measure how well recent reforms passed in Congress are being implemented, and tell us what more we can be doing in our fight against opioid abuse.

I want to thank Chairman Walden for allowing the full committee a chance to be a part of today's hearing, and I look forward to working with all of my colleagues to address our country's opioid crisis.

APTA
American Physical Therapy Association

OFFICIAL STATEMENT

1111 North Fairfax Street
Alexandria, VA 22314-1488
703 684 2782
703 684 7343 fax
www.apta.org

Statement for the Record

American Physical Therapy Association

House Energy & Commerce Committee
"Federal Efforts to Combat the Opioid Crisis:
A Status Update on CARA and Other Initiatives"

October 25, 2017

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to submit comments to the House Energy and Commerce Committee as it strives to address the concerns relating to pharmacological pain management.

Physical therapists play an important role in managing acute and chronic pain by administering treatments that include strengthening and flexibility exercises, manual therapy, posture awareness, and body mechanics instruction. Nonpharmacological therapies, such as physical therapy, offer an alternative to opioids and other pharmacologics for pain by helping patients improve their function and range of motion, and understand the underlying causes of their pain.

APTA seeks to fight the opioid epidemic and positively influence public health and well-being by enhancing prescriber, patient, and policymaker understanding of safe and effective pain management through interdisciplinary care that improves movement and function. We actively work to enhance awareness of and access to pain management options that best suit patients' needs, goals, and desires, which can ultimately play a major role in turning around our nation's opioid epidemic. APTA has taken an active role in combating opioid addiction by promoting physical therapy as a viable alternative to opioids to manage acute and chronic pain. As part of this effort, last year APTA launched the #ChoosePT campaign to educate consumers on the unique role physical therapy plays in the treatment of pain. For more information about the campaign, please see: http://www.moveforwardpt.com/Default.aspx.

As Congress continues to explore ways to address the crisis, APTA is pleased to make the following recommendations:

Recognition and Promotion of Effective Nonpharmacological Pain Management Treatments

In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines for prescribing opioids for chronic pain. The CDC made clear within its guidelines that there are better, safer ways to treat chronic pain than the use of opioids, specifically stating that many nonpharmacological therapies, including physical therapy, can ameliorate chronic pain. It is important for stakeholders to be able to recognize physical therapy as a nonpharmacological option that is considered a safe and effective treatment for pain.

Accordingly, as Congress develops policies and practices for combating drug addiction, with a particular focus on the opioid epidemic, ***APTA recommends that Congress more effectively promote the different types of nonpharmacological treatments that are effective for the treatment of pain and put forth recommendations related to such.***

Advancement of Safe and Effective Interdisciplinary, Nonpharmacological Pain Management Care Models

Pain management often needs a comprehensive, integrative approach that focuses on nonpharmacological, interdisciplinary interventions. Successful interdisciplinary pain management models encompass multiple disciplines—including physical therapy, nursing, pharmacy, primary care, and behavioral health—that encourage providers to work as a unified team in the delivery of care. Better supporting the development of and access to interdisciplinary, comprehensive pain management models that evaluate and treat the different factors influencing the presence of pain will only serve to enhance the effectiveness, efficiency, and safety of care delivered to patients with pain.

Accordingly, as Congress develops policies and practices for addressing the opioid epidemic, ***APTA recommends that Congress prioritize the evaluation, development, and improvement of interdisciplinary pain management models that are safe and effective for the treatment of chronic pain.***

Clinician and Patient Education

APTA strongly believes that dissemination of information and education about valuable alternatives to opioids for the treatment of pain, such as physical therapy, will help to move this nation forward in its efforts to improve pain management and promote safe opioid prescribing. Clinicians must be equipped with the knowledge and resources necessary to be able to evaluate treatment options for a patient's pain, both pharmacological and nonpharmacological, and provide a well-informed recommendation on the best treatment for pain management, specific to the needs of the patient.

Patients often do not have the knowledge or opportunity to engage in informed, shared decision-making about the different treatment possibilities for their acute or chronic pain. They desire results and rely on the wisdom of their health care providers to offer them the best treatment option. If clinicians have not been educated on pain management solutions other than over-the-counter or prescription medications, and how such options may suit patients' needs, then alternative treatments such as physical therapy will neither be discussed nor offered to patients. This not only places patients at a significant

disadvantage during the course of treatment but, at the same time, encourages overuse of opioids to treat pain.

The message that successful pain management requires the use of nonpharmacological therapies must be conveyed and reinforced to clinicians, as well as to patients, payers, and the general public. As discussions evolve related to what federal efforts should be undertaken to address the opioid epidemic, ***APTA recommends that Congress provide resources to support training and education to prescribers and others who are directly involved in the management or support of patients with pain, on the value of nonpharmacological treatments and how to recognize when such therapy options are the safer, more effective option for the patient's condition.***

Additionally, educating patients on how to manage their pain is a key component to effectively reducing pain intensity and interference. As patients acquire information related to the management of their condition, their sense of empowerment grows. Being empowered by their health care providers can help patients actively manage their pain, resulting in improved outcomes and reduced costs of care. To support the promotion of patient empowerment and self-reliance, however, clinicians must be educated on the methods by which they can empower their patients. ***APTA urges Congress to recognize the benefits of patient empowerment as it relates to pain management, and the methods and materials most effective in educating clinicians on patient empowerment.***

Eliminating Barriers to Nonpharmacological Pain Management Treatments
As the health care industry moves forward, it is imperative that patients have direct access to nonpharmacological pain management treatments, including physical therapy, as well as interdisciplinary pain management models. Given that the CDC has concluded there is insufficient evidence that opioid use alone improves functional outcomes for those in pain, we recommend that if a clinician prescribes an opioid for pain, then the clinician also refer a patient to physical therapy. Research has demonstrated that when a patient in pain receives early access to a physical therapist, the patient experiences improved functional outcomes, and there is a significant reduction in overall costs.

Unfortunately, barriers to nonpharmacological pain management treatments continue to persist. For example, many insurers continue to promote the use of medications while restricting access to safer, more cost-effective nonpharmacological therapies. Other barriers include patient attitudes toward pharmacological and nonpharmacological therapies, gaps in clinician knowledge, high copayments, and time and visit limits. Until such barriers are addressed, access to nonpharmacological therapies will continue to remain limited, and opioids will remain a go-to quick fix for pain despite their dangerous side effects and, in some instances, long-term ineffectiveness. Moreover, reducing the number of barriers to nonpharmacological treatments will help to inform the design of effective strategies for increasing use of these treatments. There must be a commitment to ensuring that patients have access to the appropriate therapy for pain management and treatment. ***APTA strongly encourages Congress to examine and resolve the existing barriers to nonpharmacological treatments, including interdisciplinary pain management models of care.***

We appreciate the opportunity to provide comments and look forward to partnering with Congress, as well as with the greater community, in a joint effort to improve the safety and quality of care for patients. Should you have any questions regarding our comments, please contact Kara Gainer, director of regulatory affairs, at karagainer@apta.org or 703/706-8547. Thank you for your consideration.

MARSHA BLACKBURN
7TH DISTRICT, TENNESSEE

DEPUTY WHIP

COMMITTEE ON
ENERGY AND COMMERCE

Congress of the United States
House of Representatives
Washington, DC 20515–4207

WASHINGTON OFFICE:
2266 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
TELEPHONE: (202) 225-2811

DISTRICT OFFICES:
305 PUBLIC SQUARE, SUITE 212
FRANKLIN, TN 37064
TELEPHONE: (615) 591-5181

128 N. 2ND STREET, SUITE 202
CLARKSVILLE, TN 37040
TELEPHONE: (931) 503-0381

October 24, 2017

Acting Secretary Eric Hargan
United States Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Acting Administrator Robert Patterson
United States Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Dear Acting Secretary Hargan and Acting Administrator Patterson:

Recent press reports related to the opioid epidemic have raised questions regarding the effects of the Ensuring Patient Access and Effective Drug Enforcement Act (P.L. 114-145), signed into law in April 2016. As a Member of Congress whose district and state has been heavily impacted by the opioid epidemic, I am deeply concerned about the issues raised in these reports and write to request information from your agencies detailing the impact of the law.

The House Energy and Commerce Committee, on which I serve, has continued its work to address this crisis. It is critical that we have a full accounting of the effects of laws passed in recent years in order to inform our decision making going forward.

As you are aware, P.L. 114-145 requires the HHS Secretary to coordinate with the DEA Administrator and other officials from related departments and agencies to submit a report to Congress that: details the effects of the law; notes significant barriers to improved enforcement and appropriate and safe clinical care of patients; and identifies ways to improve both Congress' access to information gleaned from data on opioid prescription and distribution and states' prescription drug monitoring programs that collect this data.

The law states that the report is due one year following enactment, which occurred on April 19, 2016. At this time, six months after the deadline established in the law, no such report has been submitted to Congress. This missed deadline is unacceptable.

HHS and DEA must act swiftly to submit this report to the appropriate committees in the House of Representatives and Senate and should include information about the law's impact on agencies' efforts to prevent diversion and stop the flow of prescription opioids into our communities.

Sincerely,

Marsha Blackburn
Member of Congress

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

Statement

of the

American Hospital Association

for the

Committee on Energy and Commerce

of the

United States House of Representatives

"Federal Efforts to Combat the Opioid Crisis:
A Status Update on CARA and Other Initiatives"

October 25, 2017

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit testimony on solutions to address the opioid crisis. We thank you for convening the leadership of key agencies of the Department of Health and Human Services to examine the opioid crisis and the role of federal agencies in responding.

Every day, hospitals witness the devastating effects of the opioid epidemic on the patients and communities we serve. While prescription opioids can be a safe and necessary element of pain management, they also carry serious risks of harm because of the potential for misuse, addiction, overdose and death. The Centers for Disease Control and Prevention (CDC) reported that more than 14,000 people died from overdoses involving prescription opioids in 2014. In 2015, mental health and substance use disorders together were the leading cause of disease burden in the United States, surpassing cancer and cardiovascular disease, according to an infographic

published in the Journal of the American Medical Association. A June 2017 report from the Agency for Health Care Research and Quality found that opioid-related hospital stays increased by 75 percent for women and 55 percent for men between 2005 and 2014, while opioid-related emergency department visits doubled for both men and women.

America's hospitals and health systems play a distinct role in helping to address the opioid epidemic. Our members are working to end this epidemic, employing a multitude of strategies to fight this serious public health problem. They are implementing standard protocols for prescribing opioids, educating clinicians, promoting the use of state prescription drug monitoring programs, offering treatment and referrals to patients, implementing alternative ways to address pain management, and safeguarding prescription medicines from diversion.

At the same time, hospitals recognize that the medical community cannot end the opioid epidemic alone. Success will require sustained collaboration between private and public entities. As one example of such collaboration, last year, the AHA and CDC created a patient education resource on prescription opioids. Developed with input from CDC subject matter experts and hospital clinical and behavioral health leaders, the document provides evidence-based information about the risks and side effects of opioids. Our resource, distributed to all member hospitals and health systems and available through the AHA's website, is designed to facilitate discussions between health care providers and patients about the risks of, and alternatives to, opioids. In addition, the resource includes recommendations on the proper storage of opioids and disposal of unused opioids.

Hospitals and health systems recognize the essential role of federal resources in this effort. The AHA applauds the leadership of the members of the Committee in enacting the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, and we continue to support full funding and implementation of these laws. We urge you to assess the progress made to date in implementing their provisions, especially those related to expanding treatment, promoting education and training, reducing stigma and enforcing parity. The AHA further urges the Committee to support additional federal initiatives that promote access to comprehensive treatment for opioid-dependent patients and the allocation of adequate resources for such treatment, appropriate data sharing, prescriber education and parity enforcement.

RECOMMENDATIONS

We would like to offer the following actions the government could take to help stem the tide of the opioid epidemic.

First, the AHA continues to urge Congress to eliminate barriers to treatment created by the Medicaid Institutions for Mental Disease (IMD) exclusion, which prohibits federal financial participation for inpatient care for individuals age 21-64 provided in an IMD with more than 16 beds. If the exclusion were eliminated, IMDs could expand access to services for patients with substance use disorders. This would be particularly helpful in improving access to treatment for those with severe or more complex substance use disorders (SUDs), reducing wait times for treatment, and possibly reducing boarding of patients with substance use and mental health disorders who would benefit from inpatient treatment.

Second, we urge the Committee to support amending 42 CFR Part 2, which governs the confidentiality of SUD patient records and impedes the sharing of patient information necessary for delivering the most efficient and effective care. The AHA supports legislation to fully align the Part 2 regulation with the Health Insurance Portability and Accountability Act (HIPAA) regulation as the best way to eliminate these barriers. Recent revisions made by the Substance Abuse and Mental Health Services Administration (SAMHSA) to the Part 2 regulations do little to eliminate existing barriers. In fact, complete alignment of Part 2 and HIPAA will require statutory changes, and we urge the Committee to support legislation necessary to achieve this outcome. Applying the same requirements to all patient information – whether behavioral or medical – would support the appropriate information sharing essential for clinical care coordination and population health improvement, while safeguarding patient information from unwarranted disclosure.

Third, the AHA encourages the Committee to enhance access to Medication Assisted Treatment (MAT). A recent report from the National Academies of Sciences, Engineering and Medicine underscores the gaps in the availability of MAT. The AHA has supported efforts to increase patient limits for buprenorphine prescribing. We agree that the federal government should continue to incentivize adequate access to MAT, and we urge the Committee to identify ways to increase the number of providers with specialty training as well. Among the key challenges for hospitals and health systems is finding physicians and psychiatrists with certifications in addiction medicine who can help oversee MAT services, directing evidenced-based medicine and serving as a resource for other clinicians, psychiatrists and staff.

Fourth, the AHA believes that fully employing and connecting prescription drug monitoring programs (PDMPs) – statewide electronic databases that collect designated data on substances dispensed in the state – will bolster federal efforts to combat the opioid epidemic. The AHA supports strengthening PDMPs and ensuring that PDMP information is shared across state lines. The federal government should seek ways to maximize their capacity to help clinicians avoid unnecessary or potentially harmful opioid prescriptions. We understand that most PDMPs already engage in some level of information sharing, especially with their neighboring states. In addition to enhancing these efforts, the potential exists to use certified electronic health records (EHRs) to improve knowledge about a patient's active and prior medications. We urge the Committee to find ways to support the inclusion of PDMP information in the certified EHR in a timely and efficient manner that is easy for clinicians to use in the course of their clinical workflow.

Fifth, the AHA strongly supports prescriber education through medical and dental school training, as well as continuing medical education, and has worked to disseminate information to hospitals on opioid prescribing guidelines, such as the CDC guidelines for chronic pain. We also have committed to continue sharing successful hospital practices related to education, prescriber monitoring and alternatives to pain management. We plan to release a toolkit later this fall with additional information and resources for hospitals. While the AHA supports increased prescriber education initiatives, we caution that mandatory requirements can have unintended consequences.

Finally, the AHA applauds the Committee's record of commitment to improving enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA). Our members and the patients they serve continue to face obstacles in securing coverage and payment as intended by federal mental health and substance use disorder parity laws. We agree that more must be done to enhance parity compliance, including ensuring that parity provisions in the 21st Century Cures Act are fully implemented. New guidance for health plans, improved transparency of benefit information, and additional parity compliance analysis tools can all support better adherence to MHPAEA provisions. All federal agencies, and especially the Department of Labor, must make parity enforcement a priority.

CONCLUSION

The AHA thanks you again for your ongoing efforts to address the opioid crisis. Our member hospitals and health systems stand ready to work with you to improve the health of all our communities.

Testimony
From The
Protecting Access to Pain Relief (PAPR) Coalition
House Committee on Energy and Commerce
October 25, 2017

The Protecting Access to Pain Relief (PAPR) Coalition is pleased to submit this testimony in response to the House Energy and Commerce Subcommittee on Health's hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Updated on CARA and Other Initiatives."

The PAPR Coalition is a multi-stakeholder group of 16 public health organizations able to collectively reach out to millions of medical professionals, people living with pain, patients managing chronic disease, and concerned citizens whose mission is to advocate for public policy that supports continued access to and choice of appropriate over-the-counter (OTC) pain relief. Our list of members and other information can be found at our website www.paprcoalition.com. The PAPR Coalition remains dedicated to ensuring patients' access to the OTC pain relief they need as a part of their care regimen while continuing its efforts to educate the public about the appropriate use of acetaminophen and ensure patient safety by promoting the use of non-opioid pain relief options.

Currently, over 100 million Americans suffer from chronic pain; that is more than the number of patients suffering from diabetes, stroke, coronary artery disease and cancer combined.[1] Because of its near ubiquity nationwide, pain presents a significant public health problem in the U.S. An Institute of Medicine report found that pain costs our society at least $560-$635 billion annually (equal to about $2,000 per person) in lost wages and compensation for disability days.[2] In addition, the costs of care associated with chronic pain, which include diagnostic tests, physical

[1] AAPM Facts and Figures on Pain. *The American Academy of Pain Medicine*. http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer.
[2] Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011.

therapy, medications, and medication management, can be extremely burdensome on both patients and the healthcare system as a whole. A 2015 study of a large U.S. health integrated delivery system found that treating chronic pain costs approximately $32,000 per patient per year, with an annual average of nearly 19 outpatient visits and five imaging tests per patient.[3]

Within these overall expenditures, the total cost of medication prescribed for pain is enormous, with one study indicating $17.8 billion in total annual spending on prescription medication for pain that includes analgesics, nonsteroidal inflammatory drugs (NSAIDs), opioids, muscle relaxants, and topical products.[4] Further, over a seven-year period the number of outpatient visits made for chronic pain increased by three percentage points, indicating that diagnoses of chronic pain requiring some form of medication-based treatment will likely continue to increase over time.[5]

OTC pain medication, specifically acetaminophen, is often a medically necessary and cost effective way for patients to manage pain. There are approximately 120 million adults in the U.S. have a health condition for which NSAIDs and certain other pain medications are contraindicated. These patients rely on acetaminophen for pain relief.

Therefore, in addition to lower costs, for many patients, OTC pain relief, and specifically acetaminophen, represents the safest medically recommended means of alleviating pain caused by illnesses and co-morbidities ranging from osteoporosis to end-stage renal disease. Moreover, access to non-opioid therapies for pain are more important than ever. The opioid epidemic is still flourishing nationwide. Opioid overdose alone led to the death of more than 500,000 people in the U.S. from 2000 through 2015, and in 2014 alone almost 2 million Americans abused or were dependent on opioids for pain relief.[6] Increased availability of these potentially harmful medications has fueled this epidemic. Nearly 250 million prescriptions for

---

[3] Park PW et al. Cost burden of chronic pain patients in a large integrated delivery system in the United States. *Pain Practice*. November 2016. 16(8):1001-1011.
[4] Rasu RS et al. Cost of pain medication to treat adult patients with nonmalignant chronic pain in the United States. *Journal of Managed Care & Specialty Pharmacy*. September 2014. 20(9):921-928.
[5] Ibid.
[6] "Opioid Overdose: Understanding the Epidemic." Centers for Disease Control and Prevention (CDC). 30 Aug. 2017. https://www.cdc.gov/drugoverdose/epidemic/index.html.

opioid medication were written in 2014 alone, with significant differences in the numbers of prescriptions written across geographic areas and states that make public health responses to these issues difficult.[7] Thus, in the U.S., addictive opioid medications have become the *de facto* first-line treatment for chronic pain rather than a possible secondary option carefully considered by a patient and his or her healthcare team.

The opioid crisis provides another reason for policy makers to ensure that patients have full access to all appropriate doses of OTC acetaminophen. While any medication is only a part of the total balanced approach to pain management, the Coalition believes that any attempt to curtail access to these safe and effective pain relief options would be a detriment to the vast number of patients whose chronic pain may be effectively managed through OTC and other non-opioid medications. In addition, the Coalition believes policy makers should take additional steps to educate prescribers, other health providers, and professionals and patients about the value of OTC pain medication while ensuring these products are used safely.

The PAPR Coalition strongly supports efforts by Congress to empower federal agencies, such as the FDA, the NIH, the CDC, and the Office of National Drug Control Policy (ONDCP), to responsibly and constructively address not only access to important OTC pain relief therapies but also promote provider and patient education to ensure that patients are using safe and effective pain relief while avoiding the strong potential for misuse and abuse associated with opioids. More specifically, the PAPR Coalition looks forward to working with policy makers and external stakeholders to pursue specific policy objectives including:

- Improving public health by ensuring patients have full access to OTC pain relief therapies, including maximum strength acetaminophen;

- Partnering with external stakeholders, including the FDA and NIH, to ensure the safe use of pain medications, including OTC pain medications, through patient and provider education and other informational activities;

[7] "Opioid Overdose: Prescription Opioids." Centers for Disease Control and Prevention (CDC). 30 Aug. 2017. https://www.cdc.gov/drugoverdose/opioids/prescribed.html.

- Promoting the use of non-pharmacologic and non-addictive pharmacologic pain relief options, including OTC pain relief, to ensure patients are not harmed through dependency on opioid and other potentially addictive pain relief options;

- Incorporating the patient experience and patient preference information into the FDA's decision-making regarding policies related to current and future OTC pain relief therapies.

As new efforts are being developed to combat the opioid crisis while increasing patient health and quality of life, the PAPR Coalition is dedicated to working with other interested stakeholders and Congress to help educate patients and their physicians about the need for access to safe and dependable treatment options for the millions of Americans who suffer from chronic pain.

If you have any further questions about the Coalition, please email Michael Werner (michael.werner@hklaw.com) or Joel Roberson (joel.roberson@hklaw.com).

ASAM American Society *of* Addiction Medicine

October 25, 2017

The Honorable Greg Walden
U.S. House of Representatives
2185 Rayburn HOB
Washington, D.C. 20515

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon HOB
Washington D.C. 20515

Dear Chairman Walden and Ranking Member Pallone,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 5,100 physicians and aligned health professionals who specialize in the treatment and prevention of addiction, thank you for the opportunity to provide comments and recommendations as the House Energy and Commerce Committee considers next steps in combatting the opioid epidemic.

ASAM agrees that our nation is in a crisis. Opioid overdoses and deaths continue to devastate families and communities across the country, and it is imperative that Congress take action to increase access to evidence-based addiction treatment and recovery support services, as well as take steps to enhance prevention and early intervention efforts.

ASAM appreciates the work the Committee has done to combat the opioid epidemic. The Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act have made a valuable impact in increasing access to addiction treatment and recovery services and growing the treatment workforce. However, there is much more work to be done. The Centers for Disease Control and Prevention's (CDC) provisional count of drug overdose deaths reports a 21% increase in drug overdose deaths between 2016 and 2017, largely due to the increase prevalence of potent synthetic opioids such as fentanyl.

Respectfully, ASAM offers the following recommendations for the Committee's consideration as it works to develop strategies and craft legislation to combat the opioid epidemic.

Growing the Treatment Workforce

The current addiction treatment gap will never be closed with the current addiction treatment workforce. There are simply too few physicians and

11400 Rockville Pike Suite 200 Rockville, MD 20852
Phone: 301-656-3920 | Fax: 301.656.3815
www.ASAM.org

ASAM American Society *of* Addiction Medicine

other clinicians with the requisite training to meet the treatment needs of the estimated 19.4 million Americans suffering from untreated substance use disorders. To make a meaningful and sustainable impact on the current opioid overdose epidemic, and to stave off future epidemics related to other addictive substances such as cocaine, benzodiazepines or methamphetamine, it is imperative that our nation invest in training opportunities for clinicians seeking to specialize in addiction treatment.

- ASAM urges the Committee to take up H.R. 3692, the Addiction Treatment Access Improvement Act, introduced by Rep. Paul Tonko (NY-20) and Rep. Ben Ray Lujan (NM-03). This legislation would codify the 275-patient limit for addiction specialist physicians who treat patients in the office setting with FDA-approved Schedule III-V narcotic medications, eliminate the sunset date for nurse practitioners' and physician assistants' prescribing authority, and expand the definition of 'qualifying practitioner' to include nurse anesthetists, clinical nurse specialists, and nurse midwives.

- Congress should fully appropriate $10 million in funding for Section 9022 of the 21st Century Cures Act, which authorizes the Secretary to establish a training demonstration program within the Health Resources and Services Administration (HRSA) to award grants for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings.

- ASAM supports the proposal currently being finalized by Rep. Hal Rogers (KY-05) and Rep. Katherine Clark (MA-05) to authorize loan repayment for health professionals who specialize in addiction treatment and recommends the Committee take it up as soon as possible.

Opioid Prescriber Education

ASAM supports mandatory prescriber education on safe prescribing practices and the recognition and treatment of addiction for all health professionals registered with the Drug Enforcement Administration (DEA) to prescribe controlled substances. Thus, ASAM urges the Committee take up H.R. 4075, the Improved Addiction Education Act, introduced by Rep. Brian Fitzpatrick (PA-08), Rep. Thomas MacArthur (NJ-03), Rep. Donald Norcross (NJ-01), and Rep. Ann Kuster (NH-02). This legislation would establish guidelines for the content and certification of courses on safe prescribing and identifying patients with addiction and require that clinicians who prescribe Schedule II or III drugs demonstrate they have completed a certified course on the issue. This mandated education on safe prescribing and addiction is critical, and ASAM stands ready to support the Committee in this effort.

CARA Implementation

1. **The Pain Management Best Practices Inter-Agency Task Force**

ASAM American Society *of* Addiction Medicine

ASAM commends the Department of Health and Human Services (HHS) for accepting nominations for the Task Force on Pain Management. The Task Force was authorized in Section 101 of CARA to review research and best practices and recommend strategies to combat the opioid epidemic. ASAM urges HHS to swiftly convene the Task Force and include an addiction specialist as a member of the Task Force. ASAM submitted a letter of support for the nomination of addiction specialist Dr. James Murphy and believes his work on the front lines of the opioid addiction epidemic will serve as an invaluable asset to the Task Force.

2. **Improving Access to Overdose Treatment**

Section 107 of CARA authorizes HHS to award grants to addiction treatment programs to expand access to drugs or devices for opioid overdose reversal. ASAM commends the Substance Abuse and Mental Health Services Administration (SAMHSA) for expeditiously awarding these grants and is looking forward to seeing grantees develop protocols to connect patients who have experienced a drug overdose with appropriate treatment. ASAM urges Congress to inquire about the results of these grant programs upon their completion, so that lessons learned about effective ways to connect patients who have experienced an overdose to treatment can be shared.

3. **Improving Treatment for Pregnant and Postpartum Women**

ASAM commends SAMHSA and the Center for Substance Abuse Treatment (CSAT) for issuing grants under Section 501 of CARA to improve addiction treatment for pregnant and postpartum women. Pregnant and postpartum women face numerous additional barriers that inhibit their ability to access the addiction treatment they need. Thus, these grants have a particularly valuable impact in ensuring that pregnant and postpartum women have access to the appropriate levels of care.

Patient Brokering

ASAM shares the Committee's concerns about predatory marketing campaigns that advertise non-medical, non-evidence-based addiction treatment. These campaigns take advantage of patients who are often desperate to find treatment for their addiction and are not aware of what is or is not evidence-based addiction treatment. ASAM stands ready to work with the Committee to develop strategies to ensure that patients can access high quality, evidence-based care.

Thank you again for your continued attention to this pressing public health crisis. ASAM looks forward to continuing to work with the Committee to expand access to high-quality addiction treatment and expand evidence-based prevention practices.

Sincerely,

[redacted]

Kelly Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

ICA
International Chiropractors Association
6400 Arlington Blvd.
Suite 800
Falls Church, VA 22042
(703) 528-5000
(703) 528-5023 FAX
www.chiropractic.org

October 25, 2017

Written Testimony to the Record
Hearing: Federal Efforts to Combat the Opioid Epidemic:
A Status Update on CARA and Other Initiatives
Energy and Commerce Committee
U.S. House of Representatives

Chairman Walden, Ranking Member Pallone, and Members of the Committee, as the Executive Director of the International Chiropractic Association, I am providing information to the Committee that I believe will be helpful as you address the current state of the opioid epidemic, pain management, and addiction recovery in our nation. I ask that this information be included in the hearing record and shared with all Committee members.

Chiropractic is a non-invasive, drugless form of health care that seeks to maximize the body's capacity to heal itself by restoring the structural balance and integrity of the human spine and remove any interference to the vitally important nerves it houses. It is estimated that over one million chiropractic adjustments are provided every day around the world. There is a significant body of peer-reviewed scientific evidence that supports the benefits of chiropractic care, particularly for management of conditions that present the symptom of pain. The evidence is clear, chiropractic care is safe, effective, and often offers significant cost-savings opportunities.

The International Chiropractors Association (ICA) is the world's oldest, continually operating international chiropractic professional organization representing practitioners, students, chiropractic assistants, educators, and lay persons world-wide. The ICA was founded in 1926 in Davenport, Iowa by Dr. B. J. Palmer. We are dedicated to the growth and development of the chiropractic profession based on Dr. Palmer's commitment to professional and clinical excellence and, the fundamental principle of chiropractic as a unique, separate, distinct, and drugless health care profession.

To receive the doctor of chiropractic (DC) degree, candidates must complete extensive undergraduate prerequisites and several years of graduate-level instruction and internship at an accredited chiropractic institution. Comprehensive knowledge of all systems of the body and diagnostic procedures enable the DC to thoroughly evaluate a patient, address disorders relating to the spine and determine the need for referral to another health care provider. The practice of chiropractic is recognized and regulated in over 52 countries; and doctors of chiropractic are licensed in all 50 states, the District of Columbia. Puerto Rico, and the Virgin Islands. There are more than 75,000 doctors of chiropractic in active practice and more than 10,000 students currently enrolled in chiropractic education in the United States.

The anatomical focus of the DC on the human spine has created the perception of the DC as just a back doctor. Although this perception is not entirely incorrect, it is very much incomplete. Doctors of chiropractic are a highly appropriate resource in matters of work-place safety, stress management, fall risk assessment and injury prevention, postural correction, and lifestyle and wellness counseling. Chiropractic care is a tremendous tool for opioid avoidance which continues to be under-utilized in the federal response to the opioid epidemic. If we as a nation are to accurately address the quandary we

find ourselves in, it is important to address the root cause of the problem, the over reliance of prescription drugs for the management of pain and the resulting addiction crisis. There are a host of non-drug options to treat pain including chiropractic. It is also important to recognize that the solution to drug addiction is not shifting patients from addiction to opioids legal (such as oxycodone) or illegal (such as heroin) to another medication (such as methadone); but to move towards recovery from addiction. Swapping one drug for another does not eliminate the risk of preventable deaths from accidental overdose or adverse reaction to drugs or drug interactions.

For decades the ICA and members of the complementary and integrative health community have worked across the levels of government to improve the health care system, and the quality of health care by being included in federal programs, advisory bodies, and to have greater research resources. There are a host of surveys that underscore that chiropractic and other complementary approaches are what Americans desire to utilize.

Numerous task forces, practice guidelines from professional organizations and governmental agencies, the Joint Commission and the former Surgeon General's Turn the Tide Campaign recommend non-pharmacological approaches to pain.

Moving Beyond Medications is a new campaign that International Chiropractors Association as a member of the Integrative Health Policy Consortium (IHPC), and the Academic Consortium for Integrative Medicine and Health, and others recommend to promote non-pharmacological approaches as first line pain treatment, with opioids considered only if these and non-opioid treatments are ineffective.

The Pocket Guide is attached to this testimony expands on these recommendations to help primary care clinicians and their patients with this approach. Further information about the evidence-base for non-pharmacological approaches is available at the Academic Consortium's website- *https://www.imconsortium.org/*

ICA's Vice President, Dr. Stephen Welsh observed, "To solve the opioid epidemic, public policy makers and the entire medical system need to rethink the inclusion of and access to chiropractic, not as an afterthought, but as a first line referral. Congress and both state and federal policy makers need to embrace the true value that chiropractic and other complementary and integrative approaches provide and to enable open access to those services, before a prescription for an opioid is written. All citizens, especially veterans, active duty military members and their families, should be able to seek chiropractic care without a physician referral, as a first line of care."

Cost Savings: An NIH-funded study published in 2016 reports back pain is the most common Social Security Disability Insurance (SSDI) program qualifying diagnoses and accounts for 30.5% of program participants and 40% of the growth in the SSDI enrollment since 1996. Researchers reviewed Medicare data found that the per-capita supply of doctors of chiropractic and spending on chiropractic adjustive care were strongly inversely correlated with the percentage of younger Medicare beneficiaries obtaining an opioid prescription.

There are multiple evaluations pointing to both the significant benefit and the cost savings of chiropractic care. They include:

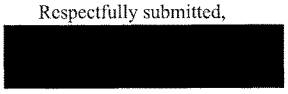
- The doctor of chiropractic as the primary care provider resulted in a 52 percent reduction in pharmaceutical costs, 43 percent decrease in hospital admissions, and 43 percent fewer outpatient surgeries and procedures. This was the finding in a four-year study begun in 1999 of DCs in a primary care role in a large Chicago HMO.
- Twenty-five percent reduction in backpain related costs associated when chiropractic was utilized as well as lower overall total annual health care costs. These were the findings in a 4-year retrospective review of claims from 1.7 million health plan members in an HMO insurance plan.
- A 2001 analysis of chiropractic utilization cost savings in Medicare found a lower overall payment for Medicare Services -$4,426 versus $8103.
- A study in the Ontario health System (Canada) indicated that greater chiropractic coverage would result in increased visits, but also net savings in both direct and indirect costs for Ontario's health system between $380 and 770 million.
- A 1997 review of health insurance payments and patient utilization episodes for common lumbar and low back conditions in over 6,100 patients who first visited doctors of chiropractic or medical doctors. Chiropractic care was more satisfying and 50 percent lower costs ($518 versus $1020).
- A 2011 comparison of provider types and management costs for complicated and uncomplicated low back pain for North Carolina teacher and state employees found that while there were more provider claims for doctors of chiropractic that the cost was 30 to 50 % less than either physical therapist or medical doctors.

Further analysis in Workman's Compensation data include:

- In a 2003 Texas analysis: The lower back injury claims cost average is $15,884. The claim costs average decreases to $12,202 when the worker receives at least 75% of their care from a doctor of chiropractic. When 90% of the care is provided by a chiropractor, the average cost declines to $7,632.
- A 2002 Florida analysis of workers' compensation claims from 1994-1999 found that the average total cost for low-back cases treated medically was $16,998 while chiropractic care was only $7,309. Patients treated primarily by chiropractors were found to reach maximum improvement almost 28 days sooner that if treated by a medical doctor.

The ICA appreciates this opportunity to share this information and perspective. We stand ready to answer any questions or provide additional information the Committee or staff may find helpful.

Respectfully submitted,



Ronald M. Hendrickson
Executive Director

cc: Members, House Energy and Commerce Committee

MOVINGBEYONDMEDICATIONS

Non-Pharmacological Approaches to Pain Management and Well-Being

In response to the current public health crisis of opioid abuse, overdose, and death, many organizations have issued guidelines and recommendations for treating pain, including the former Surgeon General's "Turn the Tide" campaign. Similar to other guidelines, this campaign recommends non-pharmacological approaches as first line pain treatment, with opioids to be considered only if these and non-opioid pharmacological treatments are ineffective. This document expands upon those recommendations to help primary care clinicians and their patients with this approach.

1 Assess Patient's Pain and Well-Being

- Perform a thorough assessment of the patient's pain condition, treatments, lifestyle and overall health status
- Ask the patient to describe the pain, including word descriptors, location, duration, aggravating and alleviating factors, intensity, and functional impact
- Ask about the patient's psychological status (e.g., depression, anxiety, ineffective coping styles), nutritional health, sleep pattern, and social and environmental contributors to the pain experience

2 Set Goals Jointly with the Patient

- Ask the patient what he or she would like to do, if pain treatment is successful
- Jointly decide on 2-3 SMART (Specific, Measurable, Attainable, Relevant, Time Bound) goals as measures of progress. Set goals for outcomes important to patient, not for pain intensity alone

3 Educate the Patient about Integrative Pain Management Options

- Describe evidence-informed non-pharmacological and self-care approaches to managing pain and promoting wellness, including but not limited to:
- Acupuncture
- Chiropractic, Osteopathic and Myofascial Manipulation, Massage Therapy, and Physical Therapy
- Cognitive Behavioral Therapy, Stress Management, and other psychological therapies
- Mind-Body Approaches, Meditation, Biofeedback, Guided Imagery
- Yoga, Tai Chi, and other movement therapies

4 Develop a Treatment Plan with the Patient; Assess Potential Challenges

- Based on your clinical assessment and discussion with the patient, develop a treatment plan
- Discuss potential challenges, and ways to overcome them, with the patient
- Reinforce that 1) chronic pain is a complex problem with no simple solutions; 2) each patient's path is a little different and you will be there to support your patient along their path, 3) just as the tide causes all boats to rise, getting healthier overall helps all medical conditions improve--even chronic pain
- Obtain patient's commitment to carry out the treatment plan

5 Follow Up, Troubleshoot and Modify Treatment Plan as Needed

- See the patient regularly; assess progress toward identified goals at each appointment
- Encourage changes they have made and urge them to continue the good work
- Problem-solve to help overcome barriers to treatment plan adherence
- Modify treatment plan to maximize progress toward goals

Resources for Information on Nonpharmacological Approaches to Pain Management and Wellbeing

ACADEMIC COLLABORATIVE FOR INTEGRATIVE HEALTH
The Collaborative
www.integrativehealth.org

ACADEMIC CONSORTIUM FOR INTEGRATIVE MEDICINE & HEALTH
www.imconsortium.org

AIHM
Academy of Integrative Health & Medicine
www.aihm.org

INTEGRATIVE HEALTH POLICY CONSORTIUM
www.ihpc.org

House Energy & Commerce Committee

Hearing on:

"Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"

On behalf of the Peace Officers Research Association of California ("PORAC"), I appreciate this opportunity to provide the Committee with testimony on the toll the opioid abuse epidemic is taking on our local communities and the dangers that law enforcement agencies face in our fight against this deadly scourge.

We commend Congress for taking action to address this multifaceted problem with the passage of the Comprehensive Addiction and Recovery Act (CARA) last year. CARA supports education, prevention, treatment, and recovery efforts to address the epidemic and aims to help those addicted to opioids get and stay well. And while this legislation is an important step in the fight against opioid abuse, its impact may not be fully realized for some time and we must not grow complacent after its passage. Rather, based on what PORAC members are experiencing in the communities they serve, we encourage Congress to double-down on its efforts to eradicate this deadly epidemic.

PORAC is our nation's largest statewide association representing public safety personnel. As the organization's president, it is my distinct privilege to represent over 70,000 members of the public safety community. Our members serve in California and include active, retired, and reserve municipal police officers and sheriff's deputies as well as correctional and probation officers, airport police, and officers in other statewide groups. PORAC is dedicated to empowering and representing the interests of rank-and-file peace officers and to protecting the rights of the men and women who on a daily basis keep our nation's communities safe.

Police and public safety personnel do much more than safeguard our communities from crime. As funding and programming for community health initiatives continue to decline, law enforcement has stepped up to fill the void. In many instances, local police are the first to respond to crisis calls relating to drug use, mental illness, and other health matters.[1]

Good policing, therefore, has expanded beyond securing just the physical safety and well-being of our communities. Law enforcement is on the front lines combatting the opioid abuse epidemic, and it is my hope this Committee takes note of this new role being taken on by peace officers across the country .

[1] It is not uncommon for law enforcement to be called to a scene of a drug overdose and have to administer overdose reversal drugs. *See generally*, http://stopoverdose.org/.

4010 Truxel Road • Sacramento, CA 95834-3725 • (916) 928-3777 • FAX (916) 928-3760 • (800) 937-6722

I. The Economics and Origins of Heroin and Opioid Abuse

Heroin and opioids have historically been available to American citizens and law enforcement has consistently worked to combat the abuse and illegal trafficking of those substances. Over the past several years, opioid abuse has increased dramatically throughout the nation. According to data from the Center for Disease Control and Prevention ("CDC"), for example, drug overdose deaths in 2016 most likely exceeded 64,000, an increase of 22% percent from the previous year—the largest annual increase ever recorded.[2] These figures are deeply troubling and should inspire lawmakers and law enforcement to reinforce their collaborative efforts.

There are multiple factors at play in this trend. But chief among them is the price competitiveness of heroin and other opioids vis-à-vis other illegal substances, including cocaine and methamphetamines. This is unsurprising. The ebbs and flows of specific illegal drugs are often linked to cyclical patterns based on supply and price competitiveness.

There is an interesting additional factor at play in the case of opioids: legality. Since legitimate medical treatment can often involve opioids without running afoul of the law, opioid addiction and abuse – in contrast to the use of other drugs – can be the result of a legitimate medical use. Our local law enforcement has noticed that pharmaceutical opioids, including drugs such as Vicodin or Percocet, are often a source of experimentation for young people. In many instances, youth experiment at parties with an opioid stolen from a family member's prescription and once hooked, eventually shift to cheaper tar heroin sold on the streets.

Street heroin is commonly laced with fentanyl, a highly addictive and dangerous synthetic opiate that many have attributed to the increase in overdoses and heroin deaths. drug overdoses involving fentanyl have increased by 540% in the past three years, rising from 3,000 to 20,000 deaths from 2013 to 2016.[3] The increase in incidence of fentanyl use has presented new, potentially lethal challenges for police and public safety personnel -- which I discuss in greater detail below.

California law enforcement has seen a rise in the trafficking of street heroin by Mexican drug cartels. California's Central Valley, for example, is a primary destination and distribution point for heroin once it crosses the border from Mexico. From the Central Valley, the drug is moved north and east: to northern California and to other states. Local law enforcement is collaborating with federal authorities to halt the ever-increasing flow of heroin into our country.

[2] Katz, Josh. "Fentanyl Overtakes Heroin as Leading Cause of U.S. Drug Deaths." The New York Times, 2 Sept. 2017, www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html.
[3] *Id.*

However, it is not an easy task – a task made more difficult by the cuts to both local and federal law enforcement budgets that limit the ability of law enforcement to engage in effective community policing.

II. The Growing Health Risks Facing Law Enforcement

As noted above, law enforcement has been encountering more and more drugs that contain fentanyl, which can be more than 50 times as potent as heroin. Because of fentanyl's potency—and because law enforcement must respond to drug overdoses with increasing regularity—it represents an unusual health hazard for police and public safety personnel.[4]

The Drug Enforcement Agency (DEA) this past summer issued an urgent warning to law enforcement and first responders that contained the following cautionary language: "Since fentanyl can be ingested orally, inhaled through the nose or mouth, or absorbed through the skin or eyes, any substance suspected to contain fentanyl should be treated with extreme caution as exposure to a small amount can lead to significant health-related complications, respiratory depression, or death."[5]

The DEA's alert came after multiple incidents of officers unknowingly came into contact with the drug and suffered serious reactions. In May of this year, for example, a police officer in Ohio wiped a trace of white powder off of his shirt after searching a car containing drugs. The white powder turned out to be fentanyl, and an hour later he lost consciousness only to be saved by four doses of naloxone.[6] It should be noted that our canine partners are also at risk of ingesting, inhaling, or absorbing (through their paws) the drug and obviously have a much lower tolerance than humans.

PORAC is encouraged by the DEA's focus on educating law enforcement and the public about the lethality of fentanyl and, in turn, the dangers it poses to police and public safety personnel who while carrying out their duties come into contact with the drug.

---

[4] Sarah Zhang, *Fentanyl is So Deadline That It's Changing How First Responders Do Their Jobs*, The Atlantic (May 15, 2017), https://www.theatlantic.com/health/archive/2017/05/fentanyl-first-responders/526389/.

[5] For Fentanyl: A briefing Guide for First Responders, see https://www.dea.gov/druginfo/Fentanyl_BriefingGuideforFirstResponders_June2017.pdf

[6] Megan Cerullo, *Ohio police officer accidentally overdoses on fentanyl by brushing it off shirt after drug bust*, New York Daily News (May 16, 2017), http://www.nydailynews.com/news/crime/ohio-police-officer-accidentally-overdoses-fentanyl-article-1.3170821.

III. Opioid Abuse and Criminal Justice

In California and across the nation, there has been a big push to enact sentencing reform in light of rising prison costs and over-crowding. For drug crimes in particular, the sentencing reform movement has tended to discourage incarceration and instead focus on the benefits of rehabilitation and treatment.

PORAC recognizes that our state and federal jails and prisons are seriously overcrowded and believes it is imperative that we fix this problem. To be effective, sentencing reform must adjust sentencing practices in a meaningful way that keeps our communities safe. With regard to opioid abuse, this means that sentencing reforms must be paired with well-supported and effective social services.

California's experience has been instructive in this regard.[7] Of particular relevance is the state's most recent sentencing reform initiative, Proposition 47, which California voters approved on November 4, 2014.

Historically, when an individual was arrested in California for possession of narcotics such as cocaine, heroin, or methamphetamine he or she was charged with a felony (and the charge could not be reduced to a misdemeanor). Proposition 47 reclassified many "non-serious" and "non-violent" property and drug felonies, including possession of heroin for personal use, as misdemeanors.[8]

Problematically, Proposition 47 took prison "off the table" for those charged with drug possession, but failed to fill that void with sufficient social services. So, while the number of individuals that are being charged with misdemeanor possession of heroin and other illegal drugs continues to increase, there is no place to send these people for treatment for drug addiction.

There are not enough beds in rehabilitation facilities or enough providers of social services in the state of California to support addicts. Furthermore, given the toothless nature of our state's criminal laws since passage of Proposition 47, it is also difficult to ensure an

[7] California has had a circuitous path to sentencing reform and many of those efforts have been blamed for present day overcrowding. This has included the 1993 "Three Strikes" sentencing law, when California went "tough on crime." Similarly, California law enforcement has been on the front lines in dealing with the fallout since 2011 from AB109 "prison realignment," which diverted low-level offenders from state prisons to local county jails, and placed an enormous financial and administrative burden on local law enforcement. Specifically, AB109 prison realignment "altered both sentencing and post-prison supervision for the newly statutorily classified "non-serious, non-violent, non-sex" offenders." *See generally* California's "Three Strikes" Sentencing Law, http://www.courts.ca.gov/20142.htm; Stanford Law School, California Realignment, *available at* http://www.law.stanford.edu/organizations/programs-and-centers/stanford-criminal-justice-center-cjc/californiarealignment.

[8] For the text of Proposition 47, *see* http://vig.cdn.sos.ca.gov/2014/general/pdf/text-of-proposed-laws1.pdf#prop47; *see also* Attorney General of California, Official Title and Summary of Proposition 47, *available at* http://vig.cdn.sos.ca.gov/2014/general/pdf/proposition-47-title-summary-analysis.pdf.

individual provided a spot in a rehabilitation facility actually receives treatment. This is very problematic given how hard it is to break any drug addiction, and opioid addiction in particular. Unfortunately, without treatment, many addicts are turning to crime to fund their drug habits. In fact, California law enforcement has already begun noting an uptick in the number of property crimes since passage of Proposition 47.[9]

III. Policy Solutions

The escalation of opioid abuse is very real. Tackling the opioid epidemic will be difficult. PORAC supports rational and meaningful policy reforms that consider the views of all stakeholders and encourages lawmakers to consider the following policy solutions.

First, PORAC urges Congress to work to seal our borders to prevent the entry of illegal drugs from abroad. People choose heroin because it is plentiful and cheap. Smart security and customs policy can change this reality, and when it does, it is very likely that heroin's street popularity will decline—helping to reduce the supply and to mitigate the trend of opioid addicts transitioning to heroin.

Second, PORAC believes it is imperative lawmakers enact laws to ensure that opioid pharmaceuticals are being prescribed in a safe manner. Irresponsible prescribing practices are exacerbating this epidemic. Every day, our rank-and-file officers are trying to work with and help people whose addictions to heroin began with access to legally prescribed opiates. It is time for policymakers to cut this "access point" by meaningfully regulating medical prescribing practices and pain clinics while also promoting systems to monitor prescription use and identify fraudulent prescriptions.

Third, PORAC exhorts lawmakers to fully fund community policing efforts and social services programs. Without sufficient funding, local police cannot protect citizens and social service providers cannot help address addiction and other health concerns that are often closely connected with criminal justice.

Fourth, PORAC encourages policymakers in Congress and at the federal agencies to recognize the health risks posed to law enforcement by fentanyl and provide appropriate resources and materials to mitigate these risks. For instance, PORAC urges the Food and Drug Administration to consider developing guidance similar to what the DEA has produced in order to educate first responders about the dangers of fentanyl.

---

[9] For example, according to the most recent crime statistics provided by the City of Sacramento Police Department to the FBI for inclusion in their federally mandated Uniform Crime Report, between January-October 2015, in Sacramento the number of burglaries increased by 16.16%, larceny by 2.56%, and motor vehicle theft by 27.39% as compared to the data from January-October 2014. *See also* City of Sacramento, Sacramento Year-to-Date Crime Statistics, *available at* http://data.cityofsacramento.org/datastreams/92971/sacramento-year-to-date-crime-statistics/.

Fifth, PORAC urges Congress to carefully review and consider the forthcoming recommendations of the newly-formed President's Commission on Combatting Drug Addiction and the Opioid Crisis. PORAC looks forward to the Commission's report and believes it can help to guide the development of public policy.

IV. Conclusion

On behalf of PORAC, I thank the members of this Committee for again providing us the opportunity to share our views. Members may note I provided similar testimony to this Committee when it examined the opioid crisis nearly two years ago. Unfortunately, since that time , the problem has only worsened in many areas of the country.

PORAC asks federal lawmakers to learn from California and to continue to discuss the various proposals relating to the heroin epidemic with law enforcement – with the women and men who keep our communities safe from crime every day and who are often front line providers of health services. We stand ready and willing to work with members of the Committee, and with Congress to ensure that federal policy relating to opioid abuse is effective.

[redacted]

Mike Durant
President, Peace Officers Research Association of California

4010 Truxel Road • Sacramento, CA 95834-3725 • (916) 928-3777 • FAX (916) 928-3760 • (800) 937-6722

STATEMENT

of the

American Medical Association

for the Record

House Committee on Energy and Commerce

RE: Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives

October 25, 2017

Division of Legislative Counsel
(202) 789-7426

Statement

For the Record

of the

American Medical Association

to the

House Committee on Energy and Commerce

RE: Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives

October 25, 2017

The American Medical Association (AMA) recognizes the need for continued and increased physician leadership, a greater emphasis on overdose prevention and treatment, and the need to coordinate and amplify the efforts and best practices already occurring across the country. Much more work remains to reverse the nation's opioid epidemic and the AMA, our partners on the AMA Opioid Task Force, and physicians across the country are committed to doing what is necessary to end the epidemic. It is clear, however, that the nation's opioid-related overdose and death epidemic will not end until there is a national commitment to ensure that patients receive comprehensive, multimodal pain care and access to treatment for substance use disorders and that the necessary resources are available to meet those goals.

The AMA continues efforts to urge physicians to use prescription drug monitoring programs (PDMPs), make judicious prescribing decisions, enhance their education, and co-prescribe naloxone, and the statistics show that some positive changes are occurring:

- Between 2012 and 2016 the number of opioid prescriptions decreased every year by a total of more than 43 million—a 16.9 percent decrease. Every state saw a decrease.
- From 2014-2016, the number of health care professionals registered with their state's PDMP increased 180 percent to more than 1.3 million.
- In 2016, physicians and other health care professionals used PDMPs 136.1 million times, at 121 percent increase since 2014.
- In 2015 and 2016, 118,550 physicians completed courses on opioid prescribing, pain management, addiction and related areas.
- In the first two months of 2017, 32,659 naloxone prescriptions were dispensed, an increase of 340 percent from the 2016.

On each of these measures, there has been progress. Yet these efforts are not enough. The number of overdose deaths continues to rise.

The two most important metrics that must drive public policy remain improved patient outcomes and reduced opioid-related overdose and death. Central to improving outcomes on these measures is access to and support for treatment for both non-opioid pain care and comprehensive treatment for substance use disorders.

We applaud the committee's hard work on the Comprehensive Addiction and Recovery Act (CARA) and appreciate that Congress provided funding for grants to states for opioid treatment and other programs as part of the 21st Century Cures Act. However, more resources are needed, especially for treatment programs. Right now, only a small percentage of individuals who need substance use disorder treatment programs have access to them. We urge Congress to fully fund CARA and make additional investments to increase desperately needed treatment capacity.

We are confident that progress in areas such as PDMP use, education, and naloxone access will continue. More than 10,000 physicians became certified to treat patients with buprenorphine in the last year alone. These steps will help but, alone, they will not be enough. Further action is needed by Congress and the Administration to turn the tide on this epidemic. The President's Commission on Combating Drug Addiction and the Opioid Crisis has already identified several critical actions that must be taken.

First, waive Medicaid's 16-bed federal limit to treat patients with a substance use disorder. The AMA strongly supports the Commission's recommendation to "rapidly increase treatment capacity" and to "grant waiver approvals for all 50 states to quickly eliminate barriers to treatment resulting from the federal Institutes for Mental Diseases (IMD) exclusion within the Medicaid program." Given that only about 10 percent of the nearly two million patients with a substance use disorder can access treatment, it is essential that treatment capacity be increased as expeditiously as possible. Removing the 16-bed IMD exclusion is an important first step to increasing physicians' ability to care for patients with an opioid use disorder.

Second, suspend federal regulatory and other barriers to providing buprenorphine. The AMA supports eliminating the requirement for obtaining a special federal waiver to prescribe buprenorphine for the treatment of opioid use disorder. Even though the regulatory approach has eased somewhat over the past year, there still are considerable barriers in place. Removing the federal waiver requirement will give many more patients new access to treatment from physicians and other qualified health care professionals. The safety and effectiveness of medication assisted treatment (MAT) is well-established, and we need to do all we can to encourage more qualified clinicians to care for patients with an opioid use disorder.

Third, direct the Attorney General to enforce existing substance use disorder parity laws. We strongly agree with the recommendation to "enforce the Mental Health Parity and Addiction Equity Act." This can be done at both the state and federal levels, but America's patients also need your leadership to encourage health insurance companies and pharmacy benefit managers to end the type of prior authorization, step therapy, and fail first protocols that only serve as barriers to MAT and multimodal pain care. Some payers already have taken positive steps to remove some barriers, but this epidemic requires all payers to work with us to ensure access to care.

There are additional steps that we believe should also be taken to further efforts to address the current crisis:

Support implementation of the National Pain Strategy (NPS). The NPS was published in 2016 but little progress has been made on implementing its core elements to improve the state of pain care in the nation. The AMA believes that—along with comprehensive treatment of opioid use disorder—the capability to deliver multidisciplinary treatment of pain is also necessary to reverse the nation's opioid overdose and death epidemic. The NPS calls for developing a system of patient-centered integrated pain management practices based on a biopsychosocial model of care that enables health professionals and patients to access the full spectrum of pain treatment options, and it also calls for taking steps to reduce barriers to and improve the quality of pain care for vulnerable, stigmatized and underserved populations. NPS implementation will change the paradigm for treating pain and ensure that physicians can recommend all pain management modalities to patients and know that insurance plans will cover those

treatments. When payers use high deductibles, yearly limits on treatments such as physical therapy, and prior authorization to delay or deny care, patients often are left with few non-opioid pain treatments. In addition, employers need to recognize that patients may require time away from work to participate in therapeutic modalities so that opioid analgesics are not the only affordable option.

Encourage electronic prescribing of controlled substances (EPCS). Drug Enforcement Administration requirements for biometric devices limit user-friendly consumer electronics already found in physicians' offices, such as fingerprint readers on laptop computers and mobile phones, from being utilized for two-factor authentication in EPCS. This and other rules contribute to cumbersome workflows and applications which are an impediment to physician EPCS uptake. Encouraging EPCS uptake and interoperability of PDMP databases and electronic health records would improve the integration of controlled substance use data into practice workflows and clinical decision-making.

Improve access to Naloxone. If it were not for expanded use of naloxone, there would likely be tens of thousands more deaths from opioid-related overdoses. State policies have helped spur widespread access, but the AMA remains concerned that some patients may not be able to access this life-saving opioid antidote medication due to its high cost. The AMA urges manufacturers and health insurers to help ensure that first responders, community-based organizations, family members and patients can readily access and administer naloxone.

Strengthen state-based PDMPs. Physicians' consultation of these databases has increased from 61 million queries in 2014 to more than 136 million in 2016. PDMPs are now functional in almost every state, and most state PDMPs can share data. To expand the use of these clinical support tools, the AMA urges increased research and funding to help integrate PDMPs into electronic health records and physician workflow in a meaningful, user-friendly manner. In addition, the AMA supports efforts to identify best practices in PDMP use and implementation for others to learn from and potentially emulate.

Integrate opioid epidemic solutions into federal payment programs. Federal payment and delivery system reforms provide opportunities to better support and incentivize clinicians who enhance their education on pain management and safe prescribing, become certified to prescribe buprenorphine, co-prescribe naloxone, utilize PDMP data in clinical practice, and coordinate treatment and support services for patients experiencing pain and/or addiction. The AMA recommends that, as they design new payment models, health programs such as Medicare and Medicaid prioritize innovative approaches to preventing and treating pain and addiction.

Support state-based innovations. In the past 2-3 years, several hundred new policies have been enacted at the state and local levels to address the opioid epidemic. The AMA strongly urges that efforts be undertaken to fully evaluate how these new laws and policies affect access to treatment for opioid use disorder, impact pain care, or might be associated with unintended consequences. As the nation's opioid epidemic is increasingly fueled by heroin and fentanyl and other illicit, synthetic derivatives, the AMA urges the Commission to take a hard look at how public policies focusing on opioid supply need to be balanced by policies that offer a measure of hope to those individuals and families already affected by this epidemic.

Support continued Medicaid coverage for treatment of opioid use disorders and pain management. The Medicaid expansion under the Affordable Care Act has been a path to treatment for hundreds of thousands of individuals with opioid use disorders. Such treatment must be sustained in any future health system reform legislation or regulation. In addition, Medicaid also provides insurance coverage that is critical to treatment of acute pain so that it does not become chronic pain, as well as treatment of mental health issues that people with opioid use disorders often have.

Thank you for the opportunity to present these views. The AMA looks forward to working with the Committee, Congress as a whole, and the Administration to turn the tide of this epidemic.

Leaders in Multidisciplinary Care Since 1988

October 18, 2017

The Honorable Orrin Hatch
United States Senate
Washington, DC

Dear Senator Hatch:

I am writing on behalf of the Academy of Integrative Pain Management (AIPM; formerly the American Academy of Pain Management) to thank you for your remarks on the Senate floor, in the wake of the recent reporting from *60 Minutes* and *The Washington Post*, regarding the Ensuring Patient Access and Effective Drug Enforcement Act. As you know, the American Academy of Pain Management signed on to a letter supporting passage of this legislation in 2015. We remain in support of the provisions of this legislation.

Our concern in 2015 was that the US Drug Enforcement Administration (DEA) was making use of its power to impose immediate suspension orders on drug distributors in such a way that access to necessary medications was threatened for many people with legitimate prescriptions for documented chronic pain. In attempt to stem the flow of opioid medications that were being misused and abused primarily by people who did not have a legitimate medical need for them, DEA chose to adopt the most adversarial position possible, issuing immediate suspension orders that summarily closed medication distribution warehouses. While this action might have cut off access for people who abused the medications, unfortunately, it also cut off access for people using the medications appropriately in ways that improved their quality of life. In short, DEA's actions could have affected a person with Stage IV cancer to the same extent as they could have affected someone intent on crushing and injecting medications with the intent of "getting high". We felt that some balance in enforcement actions needed to be struck, and that the Ensuring Patient Access and Effective Drug Enforcement Act did just that.

Since the passage of this act, we have been heartened by the increased level of cooperation between DEA and the companies it regulates. Working together with manufacturers and distributors in a less adversarial manner, DEA has played a role in eliminating the vast majority of "pill mill" activity supported by distribution of suspicious opioid orders. This also has resulted in ensuring access to vital medications for those people with pain who need them. This improved balance in enforcement activity is, we believe, appropriate and necessary.

We oppose efforts to repeal the provisions of this act in response to news reports that rely largely on the opinions of disaffected former DEA staff, without attempting to present the views of other former

8700 Monrovia St., Suite 310, Lenexa, KS 66215
T: 209-533-9744 F: 209-533-9750 E: aapm@aapainmanage.org W: www.aapainmanage.org

DEA staff who wrote the very language at question in this legislation. Achieving balance should be the goal in many aspects of our nation's current opioid overdose epidemic: balance in the ways we treat pain so as to reduce unnecessary opioid exposures, balance in efforts to address both the supply of abused drugs and the demand for them, and balance in law enforcement efforts so that the needs of people with pain are protected while access is denied for those without a legitimate medical need. The Ensuring Patient Access and Effective Drug Enforcement Act provides this last type of balance, and it should not be repealed.

We encourage Congress to take a more reasonable, measured, and balanced approach to the issue of this act's impact on the ability of DEA to effectively enforce the Controlled Substances Act. We encourage the relevant committees of jurisdiction in the House and the Senate to hold hearings at which current DEA staff are asked about the extent to which this law hampers their ability to act in cases of extreme and imminent danger to American citizens. We hope that these hearings would also enable the committees to hear from drug manufacturers, distributors, prescribers, dispensers, and patients, all of whom can explain the impact of DEA practices before and after passage of this act. If these hearings reveal a real pattern of ineffective enforcement due to the provisions of this law, then the committees can act in a measured and balanced manner to remedy the problems without completely invalidating the law.

Again, thank you for standing up for the needs of people with pain and the clinicians who care for them. We stand ready to help in not only this regard, but also with opportunities to improve the care of people with pain by expanding access to non-pharmacological treatments for pain, including integrative and complementary medicine treatments.

Sincerely yours,

Robert Twillman, Ph.D., FAPM
Executive Director

ADA American Dental Association®

STATEMENT OF THE

AMERICAN DENTAL ASSOCIATION
TO THE
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

ON

FEDERAL EFFORTS TO COMBAT THE OPIOID CRISIS

SUBMITTED BY

THE AMERICAN DENTAL ASSOCIATION

October 25, 2017

Washington Office: 1111 14th Street NW Washington DC 20005 (202) 898-2400

The American Dental Association is pleased to submit this statement for the record for the House Committee on Energy and Commerce's hearing on "Federal Efforts to Combat the Opioid Crisis," held October 25, 2017.

The American Dental Association recommends that the federal response to the opioid crisis begin to address the nuances of managing acute pain following one-time surgical procedures, such as a wisdom tooth extraction. We also recommend that any prescriber education opportunities be coordinated with professional societies and administered by an accredited continuing education provider—and that the coursework be dually recognized for state licensure purposes.

The misuse and abuse of opioid pain relievers—such as Vicodin® and Percocet®—has reached epidemic proportions. As the sixth most frequent prescribers of these potentially addictive pain medications, dentists are well positioned to help keep them from becoming a source of harm.

The federal government has invested considerable time and resources to raise professional awareness about the opioid epidemic and encourage more judicious prescribing of opioid pain medications. Our main criticism is that the federal response has not sufficiently distinguished pain management in dentistry from pain management in medicine, specifically when it comes to managing acute pain versus chronic pain. For that reason, it has not been particularly useful for dentists.

For example, the highly touted Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain does not address the particulars of managing acute pain following a one-time surgery. In fact, the document expressly states, "Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline."

Another example is the Food and Drug Administration's Risk Evaluation and Mitigation Strategy for Extended Release and Long Acting Opioid Analgesics. The goal of the REMS has been to reduce inappropriate prescribing, misuse, and abuse of long acting opioids. While long acting opioids can be useful in managing chronic pain, there is rarely, if ever, a need to manage chronic pain following a one-time dental surgery (e.g., wisdom tooth extraction, etc.), much less to prescribe a long acting opioid.

We would like to iterate that dentists have benefited from some federal activities, such as the Substance Abuse and Mental Health Services Administration's Providers' Clinical Support System for Opioid Therapies.

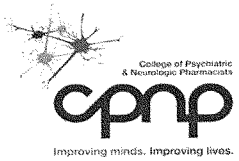
Thanks, in part, to a grant from SAMHSA and the American Academy of Addiction Psychiatry, the ADA has been able to offer free continuing education webinars covering the latest pain management techniques to help prevent opioid abuse. The webinars are tailored to illustrate the way acute dental pain can be managed safely using IR/SA opioids. Plus, the ADA Continuing Education Recognition Program credential provides a sound basis for state regulatory agencies to accept the CE credit for licensure.

Also, the National Institute of Dental and Craniofacial Research is currently investigating the biological triggers of dental pain and novel ways to alleviate it using non-narcotic therapies. NIDCR is also studying dentists' knowledge of opioid abuse and what leads them to prescribe opioids in the first place. Together, the findings will enable us to target our education and outreach messages to dentists and, ideally, lead them to use non-narcotic pain relievers as the first-line therapy for acute pain management.

We were pleased by a recent statement from FDA Commissioner Scott Gottlieb suggesting that the agency will be revisiting its risk management program to ensure opioid prescribing is better tailored to the medical indication. We hope this is an indication that federal agencies are beginning to appreciate that acute pain is managed differently from chronic pain.

Again, the American Dental Association recommends that the federal government's opioid prescriber education and outreach efforts begin addressing the nuances of managing acute pain following one-time surgical procedures, such as a wisdom tooth extraction. We also recommend that any prescriber education opportunities be coordinated with professional societies and administered by an accredited continuing education provider—and that the coursework be dually recognized for state licensure purposes.

We would like to thank the committee for this opportunity to submit this statement for the record. We share your commitment to ending this tragic and entirely preventable public health crisis, and we are committed to working with you to do just that.



October 25, 2017

American Pharmacists Association (APhA), Academy of Managed Care Pharmacy (AMCP), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP), College of Psychiatric and Neurologic Pharmacists (CPNP), National Association of State Pharmacy Associations (NASPA) and National Community Pharmacists Association (NCPA)

STATEMENT FOR THE RECORD

TO THE HOUSE ENERGY & COMMERCE COMMITTEE HEARING: "FEDERAL EFFORTS TO COMBAT THE OPIOID CRISIS: A STATUS UPDATE ON CARA AND OTHER INITIATIVES"

On behalf of the American Pharmacists Association ("APhA"), Academy of Managed Care Pharmacy ("AMCP"), American Society of Consultant Pharmacists ("ASCP"), American Society of Health-System Pharmacists ("ASHP"), College of Psychiatric and Neurologic Pharmacists ("CPNP"), National Alliance of State Pharmacy Associations ("NASPA") and National Community Pharmacists Association ("NCPA"), we appreciate the opportunity to provide our perspective regarding federal efforts to combat the opioid crisis.

Our organizations view medication-assisted treatment (MAT) as an important component of a multipronged approach to addressing opioid abuse and improving treatment. We applaud efforts to expand access to MAT, such as increasing Drug Addiction Treatment Act (DATA)-waivered physician's prescribing caps and allowing nurse practitioners (NPs) and physician assistants (PAs) to obtain a DATA waiver. To further expand access to MAT, we urge the Committee to pass legislation that allows pharmacists to obtain a DATA waiver. H.R. 3991, the

Expanded Access to Opioid Abuse Treatment Act of 2017, a recently introduced bill, enables pharmacists to obtain a DATA waiver in the same manner as PAs and NPs.

Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.[1,2] Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. In addition, pharmacists are mid-level practitioners like PAs and NPs, and six states allow pharmacists to prescribe Schedule II-V controlled substances under a collaborative practice agreement.[3,4] Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are unable to meaningfully expand access to MAT because they are not eligible for a DATA waiver.

When pharmacists partner with physicians and other health care professionals to provide MAT, they can streamline care and improve outcomes. Pharmacists' responsibilities may include treatment plan development, dispensing, patient communication, care coordination, and adherence monitoring and improvement activities, among others. Allowing pharmacists to obtain a DATA-waiver will increase patients' access to MAT and address treatment gaps.

Pharmacists are often an underutilized health care resource despite their medication expertise and accessibility. Pharmacists today graduate with a Doctorate of Pharmacy degree, which requires six to eight years of higher education to complete, and have more medication-related training than any other health care professional. We thank you for the opportunity to provide our recommendation regarding an important opportunity to increase patients' access to substance use treatment programs by utilizing pharmacists.

---

[1] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192., available at: http://www.japha.org/article/S1544-3191(15)30041-8/abstract

[2] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321, available at: https://www.ncbi.nlm.nih.gov/pubmed/11847954

[3] *See* Drug Enforcement Agency, Mid-Level Practitioners Authorization by State, available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf, last accessed: October 18, 2017.

[4] *See* Centers for Disease Control and Prevention (2017), *Advancing Team-Based Care Through Collaborative Practice Agreements,* available at: https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf (last accessed: August 14, 2017).

Statement of J. Paul Molloy, CEO
Oxford House, Inc. – the umbrella nonprofit for the
National Network of 2,259 Oxford Houses

House Energy and Commerce Committee
Health Subcommittee

October 25, 2017

Mr. Chairman, I am pleased to re-connect with this Committee to bring you up-to-date about the progress Oxford House™ has made following enactment of §2036 of PL 100-690 the 1988 Anti-Drug Abuse Act [42 USC 300x-25]. I appeared as a witness before this Committee in August 1988 along with three residents of local cluster of 13 Oxford Houses. Following that testimony, the Congress added §2936 to the Anti-Drug Abuse Act and that provision served as a catalyst for expanding the local network of 13 Oxford Houses into the national network of more than 2,250 Oxford Houses spread throughout the country. Together, these Oxford Houses have 17,890 recovery beds but many more Oxford Houses are needed. I would also note that Oxford House is the only recovery program listed on the federal government's National Registry of Evidence-based Programs and Practices (NREPP).

I would like to briefly discuss the Oxford House program and its emphasis on long-term recovery without relapse. Recovery requires more than short-term treatment and/or medication; while these may both be necessary, long-term sustained recovery requires behavior change and that takes time. I urge this Committee to address this part of the recovery process along with the critical early stages of recovery. Supporting long-term recovery options like the Oxford House program cost little but minimal support can save lives and reduce the much higher costs of repeated treatment episodes.

The Treatment Episode Data Set [TEDS] maintained by the federal government shows that 15% of those in treatment have had five previous treatment episodes. The average number of times through treatment is more than three. The idea that "relapse is part of the disease" has become a slogan or mantra for the treatment industry. Oxford House shows that recovery without relapse can be the norm rather than the exception.

Each Oxford House is a rented ordinary single-family home that is self-run and self-supported by the House residents. Oxford House, Inc. [OHI] is the nonprofit, 502[c][3] umbrella organization that provides groups of six or more recovering individuals a charter that permits each group to operate using the organization's time-test system of operation. There is no charge for the charter but the group must agree to abide by the terms of the charter to remain an Oxford House. The charter requires that the residents run the House democratically, each pay an equal

share of rent and household expenses and immediately expel any resident who relapses.

Oxford Houses permit recovering individuals to live together as long as they want in order to maintain long-term recovery. The self-run, self-supported aspect of the program permits Oxford Houses to expand to meet the need. OHI owns no property; the grants it receives supports providing technical assistance to help start new Oxford Houses and teach residents the system of operation. OHI also sponsors an annual convention. The 2017 convention, held in Washington, DC, over Labor Day weekend, attracted over 1,200 Oxford House residents and alumni. Portions of the program were broadcast on C-Span2 and are available on that site.

The 1988 Anti-Drug Abuse Act served as a catalyst for national expansion of Oxford Houses by providing the means for recovering individuals to organize and help themselves to transition from active addiction to comfortable sobriety. The underlying question is whether it can be expanded enough to significantly mitigate the current opioid epidemic and its terrible cost. Like every other proposal Oxford House is not a magic bullet. The decline in alcoholism and drug addiction can occur with a cultural shift from promotion of instant gratification to one that focuses on personal and civic responsibility. However, greatly expanding the number of Oxford Houses can significantly help change our current culture by providing both symbolic and real opportunity for addicts to develop long-term recovery. Without massive expansion of Oxford Houses, long-term recovery without relapse will be thwarted.

Public money and more teachers of the Oxford House system of operation can once again serve as a catalyst for squarely addressing the most effective way to make recovery without relapse the norm rather than the exception. Small start-up loans and training residents of new Oxford Houses has proven to be effective in creating the existing national network of 2,256 Oxford Houses. Both can be expanded at low cost but such expansion should utilize the existing alcoholism and drug addiction infrastructure. State incentive payments can achieve that outcome.

When the 1988 Act became law, many felt that the revolving loan provision would be a total failure. How could anyone expect newly recovering alcoholics and drug addicts to repay a start-up loan of $4,000? Experience has shown those fears were unfounded. In state after state, newly recovering alcoholics and drug addicts have in fact repaid start-up loans so other houses could be started. For example, in Oregon the 180 Oxford Houses have borrowed $720,000 from the revolving loan fund. Repayment has been on schedule with each house repaying $170 for 23 month and a final repayment of $90 in month 24. In other words, the original $100,000 revolving loan fund has been turned over more than 7 times. In North Carolina the 244 Oxford Houses have borrowed $976,000 turning over the original $100,000 almost ten times.

The $4,000 loan amount is set as a cap in the 1988 law and if inflation [CPI] were applied it would now be $8,345. The proposed amendment suggests changing the cap to $6,000, which does not fully account for inflation but OHI experience has shown it would work well for starting a new Oxford House. The amendment also readjusts the repayment time from 24 months to 36 months to enable house to repay on the existing $170 a month repayment schedule. The importance that the start-up fund is a revolving loan fund cannot be overstated. The revolving nature of the fund inspires houses to repay so that other recovering alcoholics and drug addicts can enjoy what they have – a functional Oxford House.

I have attached a draft of the proposed changes in PL 100-690 – the 1988 Anti-Drug Abuse Act. I hope this committee will include those changes as part of any legislative effort to mitigate the current opioid epidemic. I have also attached a brief summary entitled "Saving Money-Saving Lives" showing where Oxford Houses are already established and helping individuals achieve long-term recovery without relapse year after year.

STATEMENT FOR THE RECORD

Submitted to the
House Energy and Commerce Committee

Federal Efforts to Combat the Opioid Crisis

October 25, 2017

America's Health Insurance Plans
601 Pennsylvania Avenue, NW
Suite 500, South Building
Washington, D.C. 20004

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for consumers.

We appreciate this opportunity to comment on issues surrounding the pervasive opioid crisis. Opioid misuse and addiction is an urgent public health crisis in America, now the number one cause of death for those under 50 years old. The consequences are profound, impacting individuals and families no matter where they live, how much they earn, or how young or old they are. The impact is broad, affecting social services, the health care system, communities, and the economy.

As leaders of America's health insurance providers, we have seen the tragic consequences of the opioid crisis. It has harmed our members and their families, and it has weakened our communities. We share the committee's commitment to reducing the number of addictive substances in American communities, and to dramatically reducing the chronic condition of addiction.

On October 20, AHIP and a panel of health plan leaders – including chief executive officers, chief medical officers, and physician executives from AHIP member companies – participated in a public meeting held by the President's Commission on Combating Drug Addiction and the Opioid Crisis. Our industry delivered a clear message: the health plan community is committed and taking concrete steps to stem the opioid crisis and effectively treat drug addiction.

While testifying before the President's Commission, our members highlighted important examples of a comprehensive, integrated approach to reduce the use of opioids and cover and provide treatments and services that include both physical and behavioral health. They presented strategies such as non-opioid pain alternatives, medical management techniques, and provider training that they are using on the front lines to combat the opioid crisis. They also described cutting edge data analytic tools that are being used to identify at-risk individuals and inform future treatment efforts. Additionally, plans highlighted areas of potential improvement including privacy reform (42 CFR Part 2) to improve appropriate access to patient information regarding opioid use and the shortage of providers who are trained to provide medication-assisted treatment (MAT).

Our members' leadership in addressing the opioid crisis is further demonstrated by a new effort we announced last week – the Safe, Transparent Opioid Prescribing (STOP) Initiative – to support the

widespread adoption of clinical guidelines for pain care and opioid prescribing. The STOP Initiative begins with a robust, evidence-based methodology that health plans can use to measure how care provider practices compare to the Centers for Disease Control and Prevention's (CDC) Guidelines for Prescribing Opioids for Chronic Pain. This measurement will help health plans and care providers collaborate to improve adherence with the CDC guidelines, significantly improving patient safety and reducing the risk of opioid misuse. The STOP Initiative establishes an industry-wide approach to measuring performance against the CDC guidelines, tracking and reducing the number of opioid prescriptions.

Our members recognize that collaboration among all stakeholders is essential to achieving progress in the opioid crisis. Accordingly, health plans are actively engaged with social services agencies, state Medicaid programs, health care providers, pharmacists, and pharmaceutical companies to advance solutions. Health plans have been working closely with federal, state, and health care leaders to find other safer, more effective ways to treat chronic pain; understand the crisis and develop strategies to address it; understand prescribing patterns and how they may affect dependence and addiction; and ensure patients struggling with addiction get the treatment and support needed for recovery.

Our statement focuses on: (1) effective strategies that health plans are developing and deploying to combat the opioid epidemic; (2) our members' commitment to mental health parity and substance use treatment; and (3) our recommendations for improving federal and state efforts to address the opioid crisis.

Health Plans are Combating the Opioid Epidemic

This is a crisis we need to solve, and health plans are working hard to be part of the solution. Health plans are embracing a comprehensive approach to tackling opioid misuse and addiction, while ensuring access to effective treatment for patients. Health plans cover multi-faceted, effective approaches to pain management that include evidence-based treatments, more cautious opioid prescribing, and careful patient monitoring. By combining education, prevention, behavioral health care, and evidence-based treatment, health plans are making real progress in addressing addiction and improving the health and well-being of families and communities.

Health plans have robust checks and balances in place to ensure that patients get the right medication in the right dosages for their conditions. These checks and balances include:

- Building high quality networks with quality doctors, pharmacies and facilities;

- Utilizing a sequenced approach, which guides patients through evidence-based pain management before prescribing an opioid;

- Requiring prior authorization for opioids, so health plans' clinical experts can work with doctors to ensure adherence to evidence and offer the most effective treatments; and

- When an opioid is prescribed, using the lowest dosage and shortest duration to effectively treat the individual's pain.

Health plans also analyze their data to identify potentially harmful prescribing patterns that trigger further review. When signs of fraud or abuse are detected, health plans investigate and work with law enforcement to stop it.

Health plans have a unique view of how health care works, and how patients experience coverage and care. With that unique insight, they continue to expand and refine a comprehensive, multi-faceted approach to preventing and managing opioid misuse and related conditions, including:

- Education: Developing community-wide consumer education campaigns to increase awareness of opioid abuse and misuse, consisting of marketing outreach, dedicated websites, school curriculum and related documentaries.

- Partnering with Providers: Working closely with – and often directly employing – physicians, nurses, and pain management experts to ensure their members receive the safest, most proven, and most effective approaches to pain care. Their case management programs provide ongoing services, support, and education to prevent and treat people with, or at risk of developing, opioid and other substance use disorders, as well as their caregivers and families. Health plans also develop an appropriate network of facilities and providers, identify centers of excellence, and collaborate with providers and emergency departments to facilitate appropriate triage and care coordination.

- CDC Guidelines: Utilizing and promoting the CDC's guidelines for prescribing opioids for chronic pain to encourage non-opioid pain care, cautious prescribing of opioids, and

improved outcomes.[1] The CDC recommendations include prescribing the lowest possible dose and shortest duration effective for each patient, and close patient monitoring.

- Medical Management: Pursuing effective provider incentive structures to protect patient safety and affordability. These structures include medical management techniques, such as step therapy, prior authorization, and quantity limits consistent with best practices. Medical management is particularly beneficial when there is wide variation in practice and the potential for overuse or misuse of services.

- Physician-Pharmacist Coordination: Facilitating coordination between physicians and pharmacies for patients who receive prescriptions from multiple providers and who may also be prescribed medications that have dangerous reactions with narcotic medications such as muscle relaxants or benzodiazepines.

- Data Analytics: Leveraging data analytics to monitor pharmacy claims for prescription patterns that indicate someone at high risk of potential overuse or misuse. This includes information sharing among Medicare Part D plans when beneficiaries who have been identified as potential over-users of opioids move from one Part D plan to another.

- Support Programs: Engaging patients and providing them with support programs, such as substance use disorder coaching, Pharmacy Home programs to coordinate care and medication access, outreach to prescribers, and alerts to pharmacies.

- Medication-Assisted Treatment: Improving access to evidence-based medication assisted treatment (MAT) to help a person overcome their substance use disorder, along with treatment services such as counseling, peer support services, and community-based support groups. AHIP and our members support the Substance Abuse and Mental Health Services Administration's (SAMHSA) goal of increasing patient access to qualified practitioners waivered to prescribe Food and Drug Administration (FDA) approved controlled substances for use in maintenance and withdrawal MAT.

- Services for High-Risk Patients: Working with state and federal partners to promote rapid and effective access to evidence-based treatment for populations at increased risk of overdose and death, such as individuals re-entering the community after serving prison time. Efforts

[1] https://www.cdc.gov/drugoverdose/prescribing/guideline

may include pre-release of Medicaid enrollment, enhanced care coordination efforts to ensure linkage to community-treatment providers, and recovery services to support stability during the transition home.

Health Plans are Committed to Mental Health Parity and Substance Abuse Treatment

We fully agree that those who are struggling with an opioid use disorder need to have timely access to support for recovery and treatment. Health insurance providers offer services to members that include – in addition to MAT, as we discussed above – cognitive behavioral health counseling and recovery support. Because individuals struggling with addiction often have other chronic medical and behavioral health conditions, we strongly believe that these services must be customized and coordinated to ensure the best possible opportunity for recovery.

We support the protections established by the federal Mental Health Parity and Addiction Equity Act (MHPAEA), and health insurance providers have been working diligently to implement them. However, mental health parity still faces many issues. For example, the mechanisms to measure quality in mental health are much less developed than those that exist for medical or surgical care. There are no validated standards, certifications or accreditations for behavioral health facilities. Federal rules limit providers' ability to share substance use information, hindering efforts to support an individual through recovery. Laws and regulations that apply to mental health and substance use disorder treatment are subject to multiple jurisdictions and interpretations, making it difficult to comply with federal and state requirements.

To help improve mental health parity and treatment for those with a substance use disorder, we recommend two actions to modernize federal laws and guidelines: (1) modernizing existing regulations (42 C.F.R. Part 2) to allow providers to confidentially share information about a patient's substance use disorder diagnosis and treatment, for the purpose of improving access to treatment, enhancing treatment quality, and strengthening care coordination; and (2) encouraging the Department of Labor and the Department of Health and Human Services to provide guidance to states regarding mental health benefits and parity and to expand awareness regarding federal jurisdiction and state roles. This will help ensure clarity on which rules and guidelines govern, and also assure that federal and state guidelines do not conflict regarding mental health parity.

Recommendations to Improve Federal and State Efforts to Address the Opioid Crisis

To continue to address this issue, and to create an open dialogue with our members on effective solutions, AHIP has sponsored an opioid working group, which meets regularly. This group represents plans across the country that serve millions of consumers in every insurance market, from large national providers to small, Medicaid-only plans. It is led by health plan physicians, pharmacists, and policy experts who share their expertise on the most effective strategies to address this public health crisis.

While health plans are working collaboratively across their communities to make real, measurable progress in addressing opioid misuse and addiction, there is no question that more must be done. To effectively solve the crisis, all stakeholders must do their part. Federal and State policymakers can be important conduits to drive collaboration between public and private stakeholders, and prioritize and promote best practice policy solutions. Based on feedback from AHIP's opioid working group, we recommend federal and state policymakers focus on the following:

- Expanding access to evidence-based MAT and recovery services, including related efforts to expand and strengthen the workforce and infrastructure. Unfortunately, the demand for these treatment services currently exceeds the supply, in part due to the process for providers to be certified to prescribe MAT and a shortage of behavioral health professionals generally. This also includes allowing for access to MAT in correctional facilities and upon reentry into society.

- Prioritizing research on pain and substance use disorder treatment to better evaluate effectiveness and impact on outcomes. This includes developing best practices and validated, evidence-based criteria for establishing "centers of excellence" in pain management and substance use disorder treatment.

- Improving the completeness, workflow integration, and interoperability of state prescription drug monitoring programs (PDMPs), and ensuring plan access.

- Adopting a comprehensive opioid management program in Medicaid and other state-run health programs, and allowing for greater flexibility in opioid management program approaches in these programs.

- Encouraging integration of primary and behavioral health care, including modernizing 42 C.F.R. Part 2 regulations – as we recommend above – to allow for the confidential sharing of information on substance use diagnoses to improve access, quality, and care coordination.

- Assessing the available evidence and potential consequences of incentivizing abuse-deterrent opioid formulations, and how they may factor into prevention and treatment for patients and the potential to significantly increase costs without reducing the risk of abuse or addiction.

Conclusion

We are committed to helping America overcome the opioid addiction epidemic. But no one entity can overcome this crisis alone. If we are to succeed, we must all come together – including federal and state leaders, physicians and health care systems, health insurance providers and community organizations, employers, and pharmaceutical manufacturers and distributors. Each of us offers an important perspective into the health care system and the patient experience. We welcome opportunities to collaborate with other stakeholders to find solutions that provide patients with pathways to healing, without increasing their risk of addiction.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 17, 2017

The Honorable Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Thank you for appearing before the Committee on Energy and Commerce on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

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

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

Food and Drug Administration responses to Questions for the Record
Committee on Energy and Commerce
October 25, 2017 hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"

The Honorable Michael C. Burgess

1. **As we continue to treat those addicted to opioids, we must also prevent new patients from abusing pain medication, which often leads to addiction. Opioids with abuse-deterrent formulations (ADFs) help deter opioid misuse. Do you agree that abuse-deterrent technology has a role to play in addressing the opioid crisis?**

As we continue to confront the staggering human and economic toll from opioid abuse and addiction, we are focused on taking actions that reduce the scope of new addiction by decreasing unnecessary exposure to opioids. At the same time, we also must take steps to help those with acute and chronic pain who need access to medicines, including opioids, get access to improved alternatives. Until we are able to find new non-opioid forms of pain management for those who need treatment for pain, it is critical that we also continue to promote the development of opioids that are harder to manipulate and abuse, and take steps to encourage their use over opioids that do not offer any form of abuse deterrence.

2. **The FDA's Opioid Action Plan calls for accelerating prescribers' uptake of opioids with abuse-deterrent formulations. Impediments such as prior authorization, formulary placement, non-medical switching and "fail first" policies can prevent patients from accessing abuse-deterrent formulations and are counterproductive to addressing opioid abuse prevention. Several states such as West Virginia, Massachusetts, Florida, Maryland, and Maine, have recognized the benefits of abuse-deterrent opioids and passed laws to remove formulary barriers to these drugs.**

   a. **What is the federal government doing to ensure that providers have access to abuse-deterrent products when appropriate?**

   FDA supports the development of opioid drugs that have progressively more-effective abuse-deterrent formulations to reduce the opportunity for manipulation and abuse, and is taking a number of new steps to advance the opportunity for abuse deterrent formulations of opioid drugs to become a more viable alternative to formulations that are more prone to manipulation and subsequent abuse. Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit.

   Recognizing the importance of generic drugs to ensure patient access, FDA also must lay out a viable path for the entry of generic versions of abuse deterrent drugs. The Agency recently issued a final guidance to assist industry in their development of generic versions of

approved ADF opioids. This guidance includes new recommendations about the type of studies companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. We are also taking additional steps beyond the new guidance to help developers of generic ADFs navigate the regulatory path to market as quickly as possible and make the review process more efficient and predictable. For example, we are developing appropriate, improved testing methodologies for evaluating complex features like abuse deterrence for both brand name (innovator) and generic opioid drug products. In addition, we are also taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids.

b. Should all patients have access to abuse-deterrent technology at parity with other opioids?

Although insurance companies and other payors often rely in part on FDA's approval of medications in making their coverage decisions, the Agency does not have authority to intervene in such decisions.

The Honorable Joe Barton

1. **The techniques for managing acute pain are different from the techniques for managing chronic pain. In fact, some specialties, like dentistry, rarely (if ever) have to treat patients for chronic pain. Even the types of opioids that would be prescribed—long acting versus short acting—are different. The CDC guideline and the current FDA REMS strategy have both focused on managing chronic pain, but what are you doing to help promote more judicious prescribing among those who are not in the business of managing chronic pain?**

To reduce the rate of new opioid addiction, we need to decrease overall exposure to opioids for both acute and chronic pain. This means using our regulatory authorities to address how opioids are prescribed. We need to make sure that only appropriately indicated patients are prescribed opioids, and that the prescriptions are written for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place.

Given what we already know about the scope of current prescribing, and the subsequent patterns of abuse, it is clear that there should be fewer prescriptions being written for opioids. When opioids are prescribed, more of these prescriptions should be written for shorter durations of use. I believe there are still too many thirty-day prescriptions being written for conditions like dental procedures or minor surgery, which should require very short-term use, if they require an opioid prescription at all. Therefore, we are exploring whether FDA should take additional steps to make sure that general prescribing, and the number of opioid doses that an individual patient can be dispensed, is more closely tailored to the medical indication.

Among other steps, FDA is soliciting public input on these questions. The Agency is exploring whether and how it should use its authorities to better address issues related to prescribing and dispensing, as part of the HHS Opioid Strategy to advance the practice of pain management.

2. What are you doing to promote the delivery of preventive services that help to control acute pain and stop such pain from becoming chronic?

As part of the HHS Opioid Strategy to support cutting-edge research on pain and addiction and to advance the practice of pain management, FDA is committed to working with sponsors and with researchers who are developing non-opioid and non-addictive pain medications to bring these new options to patients as expeditiously as possible. FDA has a number of programs, such as Fast Track and Breakthrough Therapy Designation, which are intended to facilitate the development and review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. Novel non-opioid medications with the potential to provide effective pain relief, and that satisfy the applicable legal criteria, may be appropriate candidates for such programs. We have issued Fast Track Designation for more than 30 non-opioid analgesics and Breakthrough Therapy Designation for 12 non-opioid analgesics.

<u>The Honorable Gus Bilirakis</u>

1. Many patients who suffer from opioid addiction also have other co-morbidities that require the use of other medications and medical devices. As a result, care coordination can play a major role in helping stem drug abuse but also promote basic medical safety.

a. In what ways is data currently being used to advance this end?

FDA collects post-market safety data that can include information about other medications patients may be using along with the drug in question, and this information may be used to better educate patients and providers about the benefits and risks of using a drug in combination with another drug. As an example of ongoing data collection, FDA has required post-marketing studies of the holders of new drug applications for extended-release and long-acting (ER/LA) opioid analgesics. These NDA holders are currently conducting a series of ten observational studies and one clinical trial to provide data to better understand the risks of misuse, abuse, addiction, overdose, and death associated with long-term opioid analgesic use in patients prescribed ER/LA opioid analgesics. Risk factors for these adverse outcomes, which can include co-morbidities and other prescribed medications, will also be examined in these studies. FDA expects to have the data from these studies and trial by early or mid-2020.

b. In what role can interoperability of medical devices and the systems to which they report play in increasing safety and efficiency in patient care?

The ability of devices to communicate effectively with other devices while providing clear and useful information to users is a major component of device safety and efficiency of patient care. Interoperability in healthcare has the potential to encourage innovation and facilitate new models of health care delivery by promoting the availability and sharing of information across systems even when products from different manufacturers are used. Interoperable devices can improve patient care, reduce errors and adverse events, and encourage innovation. FDA supports interoperability when data can be exchanged between devices safely and securely.

FDA recently issued a guidance document titled "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices" that outlines our current thinking on how device manufacturers should consider interoperability when designing a device. With respect to interoperability, we recommend device developers consider the type of data being exchanged, anticipated users, how to mitigate any risks identified, how best to label a device intended to be used in an interoperable setting, how to verify and validate data exchanges work correctly, how to label an interoperable device, and the use of standards. FDA has a robust standards program that has supported the use of standards related to interoperability. In 2013, we recognized an initial set of standards manufacturers could use to improve patient care by making sure devices work well together. We have since recognized additional standards related to interoperability and encourage their development and use.

More broadly, FDA is participating in the development of the National Evaluation System for health Technology (abbreviated as NEST), which will link various sources of data collected as part of routine clinical care—including data from electronic health records, medical claims, and medical device registries—to improve the quantity and quality of information that can be used to support decision-making by a variety of medical device users and evaluators. FDA can use such information to support decisions related to marketing and surveillance of medical devices; insurance companies can use such information to support coverage and payment decisions; hospitals can use such information to support quality improvement activities; and device manufacturers can use such information to support a new or revised indication for a new or existing product. NEST will support interoperability by harmonizing data that are collected from devices and data about how devices are used.

2. **Many patients who suffer from opioid addiction also have other co-morbidities that require the use of other medications and medical devices. As a result, care coordination can play a major role in helping stem drug abuse but also promote basic medical safety.**

   a. **In what ways is data currently being used to advance this end?**

      See response to 1a

   b. **In what role can interoperability of medical devices and the systems to which they report play in increasing safety and efficiency in patient care?**

See response to 1b

3. **Last August, FDA authored a blog post titled: "FDA Supports Greater Access to Naloxone to Help Reduce Opioid Overdose Deaths." Can you provide this Committee with an update on the development of an over-the-counter version of naloxone?**

Prevention and treatment of opioid overdose is an urgent public health priority, and FDA recognizes the need to improve access to naloxone for the emergency treatment of known or suspected overdoses until emergency medical help arrives. As part of the HHS Opioid Strategy, the Agency is focusing on: 1) expanding the utilization of naloxone; 2) accelerating the development and availability of new naloxone formulations and user friendly products; and 3) identifying and disseminating the best practice naloxone delivery models and strategies. FDA is reviewing options, including over-the-counter (OTC) availability, to make naloxone more accessible to treat opioid overdoses, building on the Agency's recent approval of intranasal naloxone. To lay the groundwork for naloxone to be available more broadly, FDA is supporting research to facilitate the development of labeling for a potential OTC version of naloxone aimed at encouraging manufacturers to develop OTC naloxone products. In addition, FDA has contacted every maker of an approved naloxone product and offered to meet with them to discuss the OTC process, and several have taken us up on this offer.

<u>The Honorable Chris Collins</u>

1. **The opioid epidemic is a serious public health crisis, but the FDA has not prioritized non- opioid pain medications in the same way as antibiotics to treat drug-resistant bacteria. The Generating Antibiotic Incentives Now (GAIN) Act passed in 2012 to spur the development of new antibiotics to fight drug-resistant bacteria in hospitals and communities gave the FDA a path to qualify infectious disease products for Fast Track Designation and Priority Review. In 2013, the CDC estimated that 23,000 die each year due to resistant infections. In 2015, a total of 33,091 persons in the United States died from drug overdoses involving opioids and yet similar actions have not been taken.**

   a. **Has the agency considered taking the same approach with the opioid epidemic?**

FDA is committed to working with sponsors and with researchers who are developing non-opioid and non-addictive pain medications to bring these new options to patients as expeditiously as possible. FDA has a number of programs, such as Fast Track and Breakthrough Therapy Designation, which are intended to facilitate the development and review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. Novel non-opioid medications with the potential to provide effective pain relief, and that satisfy the applicable required criteria, may be appropriate candidates for such programs. We have issued Fast Track Designation for more than 30 non-opioid analgesics and Breakthrough Therapy Designation for 12 non-opioid analgesics.

2. **The opioid epidemic is a serious public health crisis, but the FDA has not prioritized non- opioid pain medications in the same way as antibiotics to treat drug-resistant bacteria. The Generating Antibiotic Incentives Now (GAIN) Act passed in 2012 to spur the development of new antibiotics to fight drug-resistant bacteria in hospitals and communities gave the FDA a path to qualify infectious disease products for Fast Track Designation and Priority Review. In 2013, the CDC estimated that 23,000 die each year due to resistant infections. In 2015, a total of 33,091 persons in the United States died from drug overdoses involving opioids and yet similar actions have not been taken. Has the agency considered taking the same approach with the opioid epidemic?**

See response to 1

The Honorable David McKinley

1. **Police, fire fighters, and other emergency personnel are the first to arrive on an opioids-related scene. These professionals are there to protect us, but they are at risk of being exposed to potent opioids and their synthetic analogues, such as fentanyl and carfentanyl. What's being done to protect these first responders, what more can be done, and what do you need from Congress?**

FDA recognizes the need to improve access to naloxone for the emergency treatment of known or suspected overdoses and accidental exposure until emergency medical help arrives. The Agency is focusing on: 1) expanding the utilization of naloxone; 2) accelerating the development and availability of new naloxone formulations and user friendly products; and 3) identifying and disseminating the best practice naloxone delivery models and strategies. FDA is reviewing options, including over-the-counter (OTC) availability, to make naloxone more accessible to treat opioid overdoses, building on the Agency's recent approval of intranasal naloxone. FDA is facilitating the development of labeling for a potential OTC version of naloxone, which is currently only available by prescription.

To help facilitate the potential availability of OTC naloxone, FDA has developed a draft model naloxone drug facts label (DFL) and an accompanying simple pictogram that would be placed next to the DFL to correspond with the DFL directions, and FDA has initiated label comprehension testing to determine whether consumers can easily understand the information. This study is currently ongoing.

In addition, HHS contributed to the development of the Fentanyl Safety Guidance for First Responders that was released in Fall 2017, which is available here: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final%20STANDARD%20size%20of%20Fentanyl%20Safety%20Recommendations%20for%20First%20Respond....pdf.*

2. **Dr. Gottlieb, your testimony describes significant efforts by the FDA to address the opioid crisis in the US, including encouraging use of non-addictive forms of pain management. Yet, the FDA announced in a press release dated January 14, 2014 that the agency would take regulatory action to restrict access to OTC acetaminophen to prevent inadvertent overdose, despite the fact that half of Americans are contraindicated for non- steroidal anti-inflammatory drugs (NSAIDs) and may only take acetaminophen. Given the need to respond to the opioid crisis with non-addictive treatment options for patients, does FDA still intend to take regulatory action limiting access to OTC acetaminophen?**

Yes, FDA remains focused on helping to ensure safe use of acetaminophen in adults and children. To achieve this goal, FDA is working on a proposed rule intended to reduce the recommended daily adult dose of acetaminophen in OTC pain relief products consistent with the previous action for prescription combination drug products containing acetaminophen to a dose that is still effective for pain relief, but will reduce the likelihood of liver damage. Acetaminophen is currently the most common cause of drug-induced liver injury in the US.

FDA also is working on a proposed rule addressing acetaminophen dosing instructions in the labeling of OTC acetaminophen products for children that are based upon weight as well as age to reduce unintentional overdose. FDA has previously issued guidance recommending that the concentration of single-ingredient liquid acetaminophen products used in children be standardized to reduce dosing errors and to require warning statements on the labels of acetaminophen-containing prescription drugs to let consumers know that rare but serious skin reactions may occur with acetaminophen. In addition, manufacturers of OTC acetaminophen-containing products have voluntarily implemented safety-related changes to their labeling.

While working on rulemaking on these issues, FDA has provided public advisories and guidance to industry to make the public and drug manufacturers aware of the risks discussed above. FDA has also worked to educate consumers about the risks of taking multiple acetaminophen-containing products at the same time.

3. **Dr. Gottlieb, as you know, over-the-counter (OTC) pain relievers taken as directed provide a safe and non-addictive alternative to the use of opioids. Advocates for patients that can only take acetaminophen to manage pain and for whom non-steroidal anti-inflammatory drugs (NSAIDs) are contraindicated are aware of the importance of balancing the need for OTC pain relief options with education on safe use of these medications and awareness of all pharmacologic and nonpharmacologic pain relief options as part of their pain management plan. What is the FDA currently doing to educate both providers and patients living with pain about the safe use of OTC pain relief options, as well as other safe and effective pain management options, and to make these materials easily accessible and interpretable by these populations?**

FDA supports expanded availability of safe nonprescription pain relievers as alternatives to opioids. Beginning with the labels of products that contain these pain relievers which clearly lay out their efficacy, FDA works both to inform the public of information on safe use of currently available nonprescription pain relievers, and to support industry efforts to develop new and improved OTC pain relievers.

FDA continually monitors safety reports and medical literature pertaining to OTC pain medicines; meets frequently with sponsors of current and potential OTC pain relievers to give these manufacturers advice and support for development programs for new and improved OTC pain relievers; and routinely updates Drug Facts labeling and issues communications to providers and consumers on important safety topics.

4. **As you know, over-the-counter (OTC) pain relievers can serve as safe and non-addictive alternatives to opioids. It's important that patients are aware of all options as part of their pain management plan. What is the FDA currently doing to educate both providers and patients about the safe use of OTC pain relief options, as well as other safe and effective pain management options, and to make these materials easily accessible and interpretable by these populations?**

See response to 3

5. **Your testimony describes significant efforts by the FDA to address the opioid crisis in the US, including encouraging use of non-addictive forms of pain management. Yet, the FDA announced in a press release dated January 14, 2014 that the agency would take regulatory action to restrict access to OTC acetaminophen to prevent inadvertent overdose, despite the fact that half of Americans are contraindicated for non-steroidal anti-inflammatory drugs (NSAIDs) and may only take acetaminophen. Given the need to respond to the opioid crisis with non-addictive treatment options for patients, does FDA still intend to take regulatory action limiting access to OTC acetaminophen?**

See response to 2

<u>The Honorable Buddy Carter</u>

On June 13th, the FDA put out a release titled "Statement from FDA Commissioner Scott Gottlieb, M.D. – FDA is taking new steps to help assess opioid drugs with abuse-deterrent properties." This is part of their commitment to take actions on opioids.

1. **The FDA released a statement in June focusing on ways to deter opioid abuse and in that announcement. What are you doing to pursue those actions and combat opioid abuse?**

FDA continues to have an important role to play in addressing this crisis under the five-point HHS Opioid Strategy. Among other efforts, some of the steps we are initially focused on relate to three broad areas. First, lowering overall exposure to opioid drugs and, in turn, reducing the number of new cases of addiction. Second, enabling more opportunities for those currently addicted to opioid drugs to seek medication-assisted treatment (MAT) – the use of medication combined with counseling and behavioral therapies – that can help them recover. And third, helping to expedite the development of progressively more-effective abuse deterrent formulations of opioid drugs, and better still, non-opioid alternatives for the treatment of pain. Some examples of the actions FDA is taking to address the crisis include:

We are committed to making sure that FDA's decisions to approve new opioid drugs, as well as decisions related to how we evaluate the post-market safety of currently marketed medicines, are made within a benefit-risk framework that considers not only the outcomes of opioids when used as prescribed, but also the public health effects of the inappropriate use of these drugs.

FDA supports the development of opioid drugs that have progressively more-effective abuse-deterrent formulations to reduce the opportunity for manipulation and abuse, and is taking a number of new steps to advance the opportunity for abuse deterrent formulations of opioid drugs to become a more viable alternative to formulations that are more prone to manipulation and subsequent abuse. Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit.

FDA is committed to using all of the Agency's authorities to advance both non-addictive and non-pharmacologic treatments for pain,. This includes programs such as the Fast Track and Breakthrough Designations that are intended to facilitate development and to expedite review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. We are working to provide additional guidance to innovators who are pursuing non-opioid alternatives for the treatment of pain. Our steps also include a more careful consideration of non-drug alternatives for pain, such as medical devices that can deliver more localized analgesia.

To reduce the rate of new opioid addiction, we need to decrease overall exposure to opioids. This means using our regulatory authorities to address how opioids are prescribed. We need to make sure that only appropriately indicated patients are prescribed opioids, and that the prescriptions are written for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place. We are exploring whether FDA should take additional steps to make sure that general prescribing, and the number of opioid doses that an individual patient can be dispensed, is more closely tailored to the medical indication.

FDA is updating the existing Risk Evaluation and Mitigation Strategy (REMS) on extended release opioid analgesics, and for the first time, extending these same regulatory requirements (including prescriber training) to the manufacturers of IR opioid analgesic products. The new,

updated REMS will include modifications to FDA's existing Blueprint for prescriber education to broaden information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic).

FDA's Opioid Policy Steering Committee is also considering whether there are circumstances when FDA should require some form of mandatory education for health care professionals, and how the agency would pursue such a goal, and the agency has issued a public notice to solicit input on a detailed series of questions related to these goals.

2. You announced that you would be engaging with "external thought leaders." What were the results of that meeting?

The public workshop held on July 10-11, 2017, involved discussion on a central question related to opioid medications with abuse-deterrent properties: do we have the right information to determine whether these products are having their intended impact on limiting abuse and helping to curb the epidemic? We recognize that the science of abuse deterrence is relatively new. Both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. That is why we are also focusing our efforts on determining how effective the current abuse-deterrent products are in the real-world setting and better understanding the attitudes and beliefs of health care professionals and those who are prescribed these products. While these innovative formulations are designed to make it harder for people to manipulate the opioid drug so they cannot be abused, it is important that prescribers and patients understand that these drugs are not "abuse-proof," and they do not prevent addiction, overdose, or death. To address these issues, among other steps, we are currently conducting a study to evaluate whether the nomenclature we use to describe these drugs, by labeling them "abuse deterrent," is accurately conveying their benefits.

<u>The Honorable Ryan Costello</u>

1. What effect will increased patient access to medical technologies have on limiting long-term opioid therapies?

Medical devices have a potential role both in pain management and in treating opioid use disorders. Depending on the cause of the pain, FDA-approved or cleared devices may offer an alternative or adjunct to treatment with opioids or other analgesics, and FDA encourages physicians to consider the needs of the patient and whether an appropriate device should be used as part of a patient's treatment plan.

FDA is committed to working with clinical investigators and companies to bring novel technologies to market for the treatment of pain as an alternative to opioids or to treat opioid use disorder.

2. **What are the current policies of CMS, Tricare, and commercial insurance carriers when evaluating surgical procedures and medical technologies? Is opioid use reduction part of that evaluation process?**

FDA defers to CMS.

3. **What statutes exist that require clarity and transparency into the levels of evidence required for positive payer policies for medical technologies, surgical procedures, and medical interventions? Can statutes be developed and implemented that would standardize these requirements?**

FDA defers to CMS.

The Honorable Pete Olson

1. **Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)? Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?**

FDA defers to SAMHSA or other components of HHS.

The Honorable Bill Johnson

1. **Innovative non-opioid treatments for pain are being developed that can prevent addiction before it starts. How is the FDA working to accelerate approval of such treatments? How can we better align the approval process with federal reimbursement policies for approved innovative medications and devices, so that once new treatments are approved, patients are not barred from accessing them because they are not covered by Medicare?**

FDA is committed to working with sponsors and with researchers who are developing non-opioid and non-addictive pain medications to bring these new options to patients as expeditiously as possible. FDA has a number of programs, such as Fast Track and Breakthrough Therapy Designation, which are intended to facilitate the development and review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. Novel non-opioid medications with the potential to provide effective pain relief, and that satisfy the applicable legal criteria, may be appropriate candidates for such programs. We have issued Fast Track Designation for more than 30 non-opioid analgesics and Breakthrough Therapy Designation for 12 non-opioid analgesics.

Although insurance companies and other payors often rely in part on FDA's approval of medications in making their coverage decisions, the Agency does not have authority to intervene in such decisions.

2. **You've been supportive of abuse-deterrent technologies as one means of deterring early users from progressing to more dangerous methods of consuming prescription drugs, and CARA encouraged FDA to enhance development and approval of abuse-deterrent formulations. However, even though 60% of all branded, extended-release, long-acting opioids have an abuse-deterrent formulation, virtually all of those prescriptions involve one specific opioid product – Oxycodone. When will the FDA update its existing Branded Guidance and publish product guidance for Generic abuse-deterrent formulations to incentivize additional product designs and generics, which may be as effective and less costly?**

Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit. But to transition this market more quickly to the ADFs, and consider permanently withdrawing the older formulations that lack abuse-deterrent features in the event these products were judged to be less safe – there are a number of factors we must consider. One of the factors that the FDA would consider relates to generic access. We must have the potential to improve access to the newer formulations, for appropriately selected and monitored patients, through the introduction of generic competitors or else the market could be left without sufficient supplies to meet market demand.

In order to support this transition and encourage advancements in this area, in November 2017, the FDA issued a final guidance to assist industry in their development of generic versions of approved ADF opioids. This guidance (available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM492172.pdf*) includes new recommendations about the type of studies companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart.

The final guidance for industry entitled "Abuse-Deterrent Opioids — Evaluation and Labeling" was issued in April 2015 *(http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf)*. We periodically assess the need for updated or revised guidance for industry and may update this guidance in the future if appropriate.

3. **Dr. Gottlieb, I introduced legislation, with my colleague on this committee Doris Matsui, to address teen abuse of DXM, the active ingredient in most cough medicines, by prohibiting sales to people under 18. Will you commit to working with us to advance this policy?**

HHS will be happy to provide technical assistance on the bill if requested.

The Honorable Richard Hudson

1. **FDA has proposed streamlining of the drug approval process for discovery in the area of Pain Management. What efficiencies could be gained by a standardized data and analytics platform that was the same as the submission standard?**

The availability of a standardized data and analytics platform could make analyses more efficient, but the review of data is not often a limiting factor in the drug approval process. Such standardization would improve the ability to look at data across different products to look for similarities and differences that may have clinical relevance.

The Honorable Susan Brooks

1. **I have heard you say that preventing drug use before it begins is the is the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?**

FDA defers to SAMHSA or other components of HHS.

The Honorable Ben Ray Lujan

Addressing the opioid epidemic is going to require a multi-faceted approach. We cannot cure opioid addiction through law enforcement or treatment alone. We must also work to address the problem at the start. This means we should also be adopting policies and practices to reduce the amount of opioids that are available in circulation, and educating health care providers on opioids, pain management, and non-opioid pain alternatives.

Approximately 80 percent of the legal global opioid supply is consumed in the United States. Based on 2015 sales, the top five opioid products were made by Purdue Pharma, Johnson & Johnson, Insys Therapeutics, Mylan and Depomed, according to sales. A 2016 survey by the National Safety Council revealed that about 99 percent of physicians exceed the recommended three-day dosage limit, with a quarter of them writing prescriptions for a full month and thus overprescribing these types of medications.

Members of this Committee have called for additional prescriber education and training to this effect and I want to learn more about what role FDA and DEA can play in this process.

1. **Dr. Gottlieb, you recently announced that the FDA is taking the step to require immediate release opioid formulations be subject to the more stringent Risk Evaluation and Mitigation Strategy (REMS) program that extended release and long-acting opioid**

formulations are subject to today. The REMS for these products requires that training be available to health care providers. Will you walk us through the REMS requirements for these products, and specifically discuss the training that is available to health care practitioners under the REMS?

Since 2012, manufacturers of extended release and long-acting (ER/LA) opioid analgesics have been subject to a REMS, which requires, as its primary component, that training be made available to prescribers of those products. To meet this requirement, the sponsors of the ER/LA opioid analgesics have been providing unrestricted grants to accredited continuing education providers for the development of education courses for health care professionals based on content outlined by FDA, which the agency calls the "Blueprint." FDA is now extending these REMS requirements to the immediate release (IR) manufacturers.

While some of the ER/LA manufacturers also make IR opioids, this action will greatly expand the number of products covered by the REMS. The existing REMS currently includes 64 ER/LA opioid analgesic products. Once the action is finalized, an additional 277 IR opioid analgesics will be subject to these REMS requirements.

In addition to expanding the REMS to include IR products, FDA is modifying the content of the educational "Blueprint" required under the REMS. The agency is adding content on pain management, including non-opioid alternatives. This includes principles related to the acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). The revised Blueprint will also cover information about the safe use of opioids, and basic information about addiction medicine and opioid use disorders.

For the first time, this training will also be made available to other health care professionals who are involved in the management of patients with pain, including nurses and pharmacists, which is in addition to prescribers of opioid analgesics. FDA believes that all health care professionals involved in the management of patients with pain should be educated about the safe use of opioids so that when they write or dispense a prescription for an opioid analgesic, or monitor patients receiving an opioid analgesic, they can help ensure that the product is properly indicated for the patient and used under appropriate clinical care.

2. **Is training under the REMS mandatory for health care practitioners today?**

Currently, this training is not mandatory for health care practitioners.

3. **Can you give us a sense of how many health care practitioners have voluntarily participated in the training available under the REMS?**

As of 2/28/2017[1] there have been 430,859 health care practitioner participants in the training available under the ER/LA REMS. Of these participants, 208,040 completed all components of an educational activity and met the education provider's criteria for passing. Of the participants who completed all components of an education activity and met the education provider's criteria for passing, 88,316 were individual clinician participants who were registered with the DEA to prescribe schedule II and/or III controlled substances and who wrote at least one ER/LA opioid prescription in the past year.

4. **I understand that FDA is considering whether mandatory education might be appropriate. Dr. Gottlieb, what are your thoughts on mandatory training? Is this something that you would support, and if so, how would FDA operationalize such a requirement?**

FDA's Opioid Policy Steering Committee is considering whether there are circumstances when FDA should require some form of mandatory education for health care professionals, and how the agency would pursue such a goal. The agency's purpose is to reduce overall exposure to opioids by making certain that prescribing doctors are properly informed about appropriate prescribing recommendations, that providers understand how to identify the risk of abuse in individual patients, and know how to get addicted patients into treatment. The agency has issued a public notice to solicit input on a detailed series of questions related to these goals. FDA has also been scheduling meetings with provider organizations and sponsors engaged in dispensing drugs – including health systems and pharmacy chains, in an effort to solicit additional input on new strategies.

In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. The New York Times reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The Times and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long- term investments in prevention, treatment, recovery, and monitoring.

The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.

---

[1] Quarterly update data is unaudited and provided by CE providers directly to the REMS Program Companies (RPC). Collection and reporting of participants and completers is not required by the REMS Implementation Guidelines.

5. Commissioner Gottlieb, do you have all of the tools you need to stop the opioid epidemic?

FDA intends to take whatever steps we can, under our existing legal authorities, to ensure that exposure to opioids is occurring under appropriate clinical circumstances, and for appropriate patients.

6. Commissioner Gottlieb, given the 31 percent cuts to FDA in the President's budget proposal, what programs relating to the opioid epidemic will be cut? Which programs would have been expanded that will now not be?

FDA is committed to addressing the opioids crisis using all available tools and strategies, and will continue to work with Congress to ensure we have adequate resources to carry out our mission.

Opioid addiction is not a new problem. Misuse of and addiction to pharmaceuticals has existed for centuries, ever since morphine was heralded in the 1850s as a solution to our opium addiction problem– until it, in turn, morphine became a larger problem, as did heroin, and then methadone. Today, we understand the importance of pain relieving agents, but as my constituents continue to perish at alarming rates due to these drugs, we need to be working together to address the crisis. The public and private sectors can and should work together to swiftly address the opioid epidemic. The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science that is necessary to helping the FDA accomplish its mission. The Foundation was created by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to address regulatory science challenges of the 21st century. The central focus of the Foundation is to assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the agency's ability to protect and promote the health of the American public.

7. Understanding what we know now about this issue, what further information or support do you need from pharmaceutical manufacturers to more aggressively combat this crisis?

FDA is committed to working in partnership with industry to ensure that exposure to opioids is occurring under only appropriate clinical circumstances, and for appropriate patients. As described in the response to question 1, FDA has notified manufacturers of immediate-release opioids that they will be subject to the same REMS requirements that currently apply to extended release/long-acting opioids, including that training be made available to prescribers of these products. IR manufacturers will be required to inform prescribers and other health care providers involved in the treatment and monitoring of patients with pain

(e.g., pharmacists, nurses) of the existence of the REMS and the need to successfully complete the necessary training.

In addition, there is a critical need to encourage the development of novel treatments for chronic pain, including non-opioid alternatives, as well as new and innovative treatments for substance use disorders in order to augment our currently limited treatments. Encouraging the development of these products requires both scientific and translational development. FDA has previously, and is currently, working in these areas, including through our participation in the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership (PPP) and other PPP and consortia initiatives in a wide variety of areas relevant to pain treatment, opioids, substance use treatment, drug safety, and accelerated drug development.

8. **How are you engaging the Reagan-Udall Foundation to develop effective, innovative regulatory responses to the opioid crisis?**

FDA's partnership with the Reagan-Udall Foundation for the FDA has focused on a number of key initiatives, including the Innovation in Medical Evidence Development and Surveillance (IMEDS) Program and the Expanded Access Navigator tool. We look forward to continuing this partnership to advance FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century.

There are multiple forms of opioid painkillers, including abuse-deterrent formulations (ADFs) and extended-release/long-acting (ER/LA) formulations. Now, in addition to expanding the REMS to include immediate-release (IR) products, FDA is modifying the content of the educational "Blueprint" required under the REMS. The agency is adding content on pain management, including non-opioid alternatives. The content includes principles related to the acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). The revised Blueprint will also cover information about the safe use of opioids, and basic information about addiction medicine and opioid use disorders.

But education alone will not be enough. Patients need to be able to access effective products without the risk of addiction. Non-opioid pain alternatives include biologics in the pipeline, such as fasinumab (an NGF antibody for osteoarthritis and chronic lower back pain, in Phase 3 development by Regeneron) and tanezumab (an NGF antibody for osteoarthritis and chronic lower back pain, in Phase 3 development by Pfizer and Eli Lilly). Tanezumab is the first NGF inhibitor to receive Fast Track designation from the FDA.

9. **How will you be working with the Centers for Medicare and Medicaid Services, Indian Health Services, and the Department of Veterans Affairs to arrange for inclusion in the relevant reimbursement schedules of biologics as non-opioid pain alternatives?**

Although insurance companies and other payors often rely in part on FDA's approval of medications in making their coverage decisions, the Agency does not have authority to intervene in such decisions. We defer to CMS for further information on this topic.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 17, 2017

The Honorable Elinore McCance-Katz
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. McCance-Katz:

Thank you for appearing before the Committee on Energy and Commerce on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

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

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

House Committee on Energy and Commerce Hearing: Federal Efforts to Combat the Opioid Crisis

October 25, 2017

Questions for the Record – SAMHSA

The Honorable Michael C. Burgess

1. CARA requires that resources be put in place to assist women and children affected by opioid addiction. What is SAMHSA doing to address opioid addiction in pregnancy and neonatal abstinence syndrome?

Response:
Congress passed the Protecting Our Infants Act of 2015, the purpose of which is to address opioid use by pregnant women and resultant consequences to newborn infants. The Act tasked the Department of Health and Human Services to produce a three-part report to include: 1) a review of gaps, overlap, or duplication regarding prenatal opioid use and neonatal abstinence syndrome (NAS); 2) state of the science and clinical practice; 3) and a strategy and set of recommendations. On January 17, 2017, SAMHSA provided the report to Congress. HHS has convened a department-wide workgroup that is developing an implementation plan based on the strategy that will support decision-making by departmental leadership with regard to specific agency priorities.

In addition, SAMHSA is developing *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*. This Guidance will outline the optimal management of pregnant and parenting women with an opioid use disorder (OUD) and their infants based on the recommendations of experts. This Guidance will help healthcare professionals determine the most clinically appropriate action for a particular circumstance, with the expectation that the healthcare professionals will make individualized treatment decisions. A cornerstone of the Guidance is that a healthy pregnancy results in a healthy infant and mother.

In Fiscal Year 2017, SAMHSA awarded 19 new grants for residential treatment centers for pregnant and parenting women. There are currently a total of 29 grantees receiving a total of $16 million. These programs provide comprehensive services to women with substance use disorders and their families. Treatment is required to include access to medications for women who are opioid dependent.

As a result of CARA, SAMHSA also awarded three new State Pilot Grants for Pregnant and Post-Partum Women (PPW). The goal of the PPW pilot is to expand outpatient services for pregnant and postpartum women and their families with substance use disorder, including OUD and/or co-occurring substance use and mental disorders at the community-level.

SAMHSA and the Administration for Children and Families (ACF) jointly fund the National Center on Substance Abuse and Child Welfare (NCSACW), a national resource center providing

information, expert consultation, training and technical assistance to child welfare, dependency court and substance abuse treatment professionals to improve the safety, permanency, wellbeing, and recovery outcomes for children, parents, and families. The NCSACW also makes available webinars, assessment instruments, training and program toolkits, resource lists, and other publications.

With SAMHSA and ACF support during 2017, NCSACW conducted 12 presentations and 11 web-based trainings/virtual meetings on opioids. During its September 2017 webinar, "Supporting Families Affected by Opioid and Other Substance Use Disorders, Child Abuse and Prevention Act, Plan of Safe Care," over 1,200 individuals attended. In addition, during the same period NCSACW received and responded to over 300 opioid-related technical assistance requests; produced and disseminated the Policy Academy brief, *Improving Outcomes for Pregnant and Postpartum Women with Opioid Use Disorders and Their Infants, Families, and Caregivers*; and developed a web-based directory of resources on best practices for the treatment of opioid use disorders and neonatal abstinence syndrome.

2. **Effective treatment options are key to helping solve the opioid crisis and many for-profit type entities have entered the treatment and recovery space. Are we doing enough to ensure quality among treatment and recovery centers? What more can we do to help those seeking help better find and compare the quality of treatment options?**

Response:
SAMHSA is committed to promoting effective practice across the behavioral health service system. Improving access to medication-assisted treatment remains a central part of SAMHSA's efforts to improve practice in the treatment of opioid use disorder. A number of SAMHSA's programs have this as a primary goal and a number of other related programs with a broader focus, such as drug courts, have also made use of medication assisted treatment a priority.

SAMHSA requires the use of evidence-based practices (EBPs) in its grant programs, including the recent State Targeted Response to the Opioid Crises Grant program authorized by the 21st Century Cures Act. Grant project officers ensure that EBPs are used by the grantees that they oversee and help programs address implementation issues by linking them to training or technical assistance.

To assist individuals seeking help for opioid use disorders, SAMHSA has supported a number of shared decision-making tools for consumers of treatment and recovery support services. Shared decision-making is an emerging best practice in behavioral and physical health that aims to help people in treatment and recovery have informed, meaningful, and collaborative discussions with providers about their health care services. It involves tools and resources that offer objective information. People in treatment and recovery can then weigh that information against their personal preferences and values. Shared decision-making tools empower people who are seeking treatment or in recovery to work together with their service providers and be active in their own treatment.

In 2016, SAMHSA released *Decisions in Recovery: Treatment for Opioid Use Disorder*, an innovative decision support tool for people in or seeking recovery from opioid use disorder, as well as for treatment providers. Consumers who use this tool learn about medication assisted treatment, how to be better positioned to compare treatment options and decide which is the best option for their recovery, and how to discuss preferences with a treatment provider.

SAMHSA continues to explore additional opportunities to share and disseminate these tools.

The Honorable Greg Walden

1. The Comprehensive Addiction and Recovery Act of 2016 (CARA), which was signed into law over a year ago, empowered the Secretary of Health and Human Services to determine methods by which office-based opioid addiction treatment practitioners provide all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder. Similarly, CARA provides the Secretary with the authority to ensure that such practitioners are trained in evidence-based practices such as detoxification, relapse prevention and the use of all FDA-approved medications for the treatment of opioid use disorders.

Please tell us what progress you have taken to implement these reforms to opioid addiction treatment. When do you expect SAMHSA to fulfill its requirement to ensure providers are educating on the full range of requirements in CARA? Finally, does SAMHSA have a timeline on when it will notify existing waivered providers on the requirements of CARA to offer all FDA-approved medications to patients seeking treatment?

Response:
SAMHSA held a meeting for all of the eligible training providers in September 2016. At that meeting, the group agreed to a revised curriculum with a new set of learning objectives that is in line with section 303 of CARA and includes information on the use of all FDA-approved medications. SAMHSA's training program, the Providers' Clinical Support System-Medication Assisted Treatment, completed its update of the online and live courses to be compliant with section 303 in November 2017. Now that TIP 63: *Medications for Opioid Use Disorders,* has been released, SAMHSA will ensure that currently waivered practitioners receive the TIP which includes information about the appropriate use of all FDA-approved medications for the treatment of opioid use disorders consistent with the requirements of CARA. At the same time, providers that do not work in SAMHSA regulated Opioid Treatment Programs are still not permitted by law to prescribe or dispense methadone for opioid use disorder treatment under the Controlled Substances Act.

2. CARA and CURES provided significant funding for states to expand substance use disorder treatment, through grants administered by SAMHSA. In addition, CARA required grantees to submit data that will be posted online and easily searchable. Can you provide us with a status update on those requirements?

Response:
All CARA program grants that were appropriated funding for Fiscal Year 2017 have been awarded. Funding opportunities for each of the programs required specific data elements to be collected.

Grantees for the First Responders - Comprehensive Addiction and Recovery Act Cooperative Agreement will respond to the following measures:

1. The number of first responders and members of other key community sectors equipped with a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;
2. The number of opioid and heroin overdoses reversed by first responders and members of other key community sectors receiving training and supplies of a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;
3. The number of responses to requests for services by the entity or sub-grantee, to opioid and heroin overdose; and
4. The extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions.

The Improving Access to Overdose (OD) Treatment grantee will respond to the following measures.

1. Total amount of OD Treatment Access grant funds spent on purchase of FDA-approved overdose reversal drugs.
2. Number of health care providers and pharmacists trained on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.
3. Total amount of OD Treatment Access grant funds spent on co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.
4. Number of patients who have experienced a drug overdose that are connected with appropriate treatment, including medication assisted treatment and appropriate counseling and behavioral therapies.

a. **What accountability measures is SAMHSA requiring of states to make sure that the grant monies are spent wisely?**

Response:
All SAMHSA grantees are required to report data to SAMHSA on a regular basis regarding their program's progress. Each program is required to report both output and outcome measures demonstrating project progress. These measures may include, but are not limited to:

1. Number of people served;
2. Abstinence from substance use;
3. Employment status;
4. Housing status;

5. Criminal justice involvement; and
6. Retention in treatment.

b. **How do we know if states are spending money on people who are most likely to respond to treatment?**

Response:
The State Targeted Response to the Opioid Crisis Grant provides states and jurisdictions with the flexibility to provide opioid use disorder treatment services in a variety of clinical settings. States were required to develop a strategic plan targeting geographic regions and populations that were most in need and to report the data that lead them to select those areas and populations in the application and in a strategic plan. The plans are monitored by grant project officers on regular monthly calls and by submission of progress reports by states twice per year.

States' and jurisdictions' administrative rules require substance use disorder treatment providers to utilize standardized assessment instruments to determine if a person meets the criteria for an opioid use disorder. The states and jurisdictions and their respective sub-recipients, i.e., community- and faith-based organizations, are required to implement or expand access to clinically appropriate evidence-based medications and services for persons with an opioid use disorder, including the use of FDA-approved medications designed for the treatment of an opioid use disorder. States and jurisdictions and their respective grant sub-recipients must also provide appropriate psychosocial intervention and recovery support services for persons in early recovery.

c. **Is there a formal risk assessment that states must use to make sure the monies are targeting the people who are most likely to benefit from such treatment programs?**

Response:
The State Targeted Response to the Opioid Crisis Grant requires states and jurisdictions to develop a needs assessment using statewide epidemiologic data. The needs assessments identify: (1) geographic areas within a state or jurisdiction where opioid misuse and related harms are most prevalent; (2) the number and location of opioid use disorder treatment providers in a state or jurisdiction; and (3) existing activities and services and their funding sources in a state or jurisdiction that address opioid use prevention, treatment and recovery activities and gaps in such activities and services.

Further, the State Targeted Response to the Opioid Crisis Grant requires states and jurisdictions to develop comprehensive strategic plans to address the gaps in prevention, treatment and recovery services identified in their respective needs assessments. The states and jurisdictions prepared and submitted their respective needs assessments on or before July 31, 2017, and their respective strategic plans on or before August 30, 2017.

The plans are monitored by grant project officers on regular monthly calls and by submission of progress reports by states twice per year. Reports on the first six month progress were due December 15, 2017.

The Honorable Markwayne Mullin

1. Preliminary estimates from the CDC show that 64,000 Americans died from opioid overdoses last year. Another 50,000 or 60,000 of our fellow citizens will die from medical conditions closely related to opioid abuse like HIV/AIDS, Hepatitis C and cirrhosis. Yesterday, I became the lead sponsor of Rep. Tim Murphy's bill, the Overdose Prevention and Patient Safety Act, which would make it easier to share addiction medical records in care coordination settings. Do you believe 42 CFR Part 2 is an impediment to addressing our nation's opioid crisis?

Response:
The federal regulations at 42 C.F.R. Part 2 (Part 2) allow substance use disorder (SUD) patient information to be shared among providers in certain circumstances. For example, a patient can give written consent to authorize the sharing of his or her SUD treatment record with any treating provider. Also, Part 2 typically does not apply to entire hospitals, emergency rooms (ER)/departments, or trauma centers, which would usually be considered general medical facilities. Accordingly, Part 2 is not an impediment to the sharing of SUD treatment records among providers in these settings, where the HIPAA Privacy Rule would continue to apply. With regard to general medical facilities or staff within such facilities, Part 2 applies only to an identified unit in the facility to the extent that the unit holds itself out as providing and provides SUD services, or to staff within the facility whose primary function is the provision of SUD services and who are identified as providers of such services. When Part 2 applies, it allows sharing without a patient's consent in medical emergencies, such as opioid overdoses. The Part 2 medical emergency exception allows a patient's SUD information to be shared with other medical personnel when there is a bona fide medical emergency in which the patient's consent cannot be obtained. The determination of whether a medical emergency exists is made by the treating/disclosing provider. Information disclosed by a Part 2 program during a medical emergency can be further shared with medical providers as needed (i.e., re-disclosed) in order to diagnose or treat the patient during the emergency.

At the same time, there are statutory limitations related to sharing protected SUD patient information absent written consent, and the exceptions to the consent requirements are limited. The statute has been an impediment to sharing addiction records in care coordination settings. Within the constraints of the statute, SAMHSA has been working diligently to issue clarifications and education providers about what information sharing is permissible under both the statute and the regulation.

As required by the 21st Century Cures Act (section 11002), SAMHSA held a public meeting on January 31, 2018, to obtain input about the impact of Part 2 on "patient care, health outcomes, and patient privacy." The information gathered during this Part 2 public meeting can help policymakers better assess what changes can and should be made under current regulations or whether statutory changes are required to accomplish such objectives.

i. If yes – Are you supportive of a legislative fix like my bill (HR 3545) that would align Part 2 with HIPAA?

Response:
While the Administration has not taken a position on this bill HHS remains happy to provide technical assistance on any legislation if desired. SAMHSA supports further consideration of the benefits of aligning Part 2 with HIPAA.

ii. If no – why do you support a separate privacy rule for patients with addictions?

Response:
N/A

b. The President's Opioid Commission and the Former CDC Administrator Tom Frieden have highlighted a need to fix Part 2. What have your agencies heard in the numerous round table discussions held across the country? Can any of you address this problem internally?

Response:
SAMHSA acknowledges concerns expressed by stakeholders. SAMHSA regularly responds to inquiries and participates in calls with stakeholders who both generally favor and are critical of Part 2. While SAMHSA does not provide legal advice, the Agency strives to understand stakeholder concerns about Part 2 implementation and regulatory requirements. SAMHSA staff often discuss the rule with stakeholders and potential approaches to such issues as data sharing by all-payer claims databases, use of electronic health records, responding to medical emergencies, research and many other topics.

In addition to such discussions with stakeholders, SAMSHA also received numerous public comments on Part 2 as part of the notice-and-comment rulemaking process including:

- During a June 2014 listening session (May 12, 2014, 79 FR 26929; https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations);
- Following publication of a notice of proposed rulemaking in February, 2016 (Feb. 9, 2016; 81 FR 6987); and
- Following publication of a supplemental notice of proposed rulemaking (82 FR 5485) in January 2017.

In compliance with the 21st Century Cures Act, SAMHSA hosted a listening session on January 31, 2018.

c. Part 2 is cited as the reason why most states are not sharing data or not tracking outcomes in regards to treatment. What guidance can be given to states to measure outcomes but protect patient information?

Response:
Part 2 does not preclude sharing of Part 2 data for purposes of research, audit, or evaluation. The final 2017 Part 2 rule allows a Part 2 program or other lawful holder of patient identifying information to disclose Part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule, 45 CFR Part 46). In the final rule, SAMHSA expanded permissible data linkages to enable researchers holding Part 2 data to link to data sets from federal and non-federal data repositories. Similarly, Part 2 permits a Part 2 program or other lawful holder to disclose patient identifying information to certain persons for audit or evaluation purposes, if certain requirements are met. Thus, states can measure outcomes while protecting patient information by conducting research based on client outcome measures as well as evaluating outcomes of patients utilizing the current Part 2 provisions related to these areas.

d. Does anyone have a sense of the potential savings for Medicare and Medicaid if we are able to amend Part 2?

Response:
To SAMHSA's knowledge, there is no independent, peer-reviewed research concerning the costs of Part 2 to Medicare and Medicaid. As noted in the final 2017 rule, SAMHSA has used HIPAA costs as a proxy for estimating the regulatory impact of Part 2. SAMHSA therefore cannot specifically quantify the estimated savings or costs to these programs, were Part 2 to be amended.

e. If we are able to save money via care coordination, shouldn't we be able to adequately fund treatment programs back in the states?

Response:
Care coordination is an effective way to identify patients with high service utilization or clinical risks and to address these needs and risks through increased support from specialized doctors or a care manager/coach that collaboratively assist in the management of disease. Care coordination provides benefits for the individual's health status, as well as in managing foreseeable and expensive costs related to crisis and emergency needs, while supporting the individual with the provision of lower-cost alternative care. Care coordination is promising, but there is insufficient data to know if the savings generated would provide significant reinvestment opportunities. Better health at a lower cost has been a long-standing goal of health care systems. Coordinated care may provide some system savings that could be reintroduced into state and community systems to meet emerging funding needs. Currently, disclosing information related to treatment-related activities such as care coordination requires written consent under Part 2. SAMHSA supports further consideration of the benefits of aligning Part 2 with HIPAA.

2. According to the CDC, Native Americans have the highest rates of both opioid overdose deaths as well as HCV-related deaths. Does your department engage with these populations around risk factors associated with opioid abuse, including the spread of infectious diseases such as HIV and HCV?

Response:
SAMHSA is committed to addressing the behavioral health needs of the nation, including American Indians and Alaska Natives (AI/AN). In response to behavioral health and related issues faced by AI/ANs, SAMHSA established the Office of Tribal Affairs and Policy to improve the Agency's response and coordination of resources for these populations. SAMHSA has improved access to prevention resources for AI/ANs that address behavioral health-related risks for tribal communities. These resources include behavioral health information specifically for tribal communities, as well as funding opportunities that allow tribes to address targeted substances of abuse.

For example, the Tribal Behavioral Health Grant program (also called TBHG or Native Connections) focuses on preventing and reducing suicidal behavior and substance abuse and promoting mental health among Native young people. Among other actions, each TBHG grantee assesses their substance abuse, suicide, and other mental health needs and develops a targeted plan for addressing them. Based on the tribal grantee's assessment, the targeted substance(s) of abuse may include opioids, alcohol, methamphetamines, and/or other drugs. There are similar opportunities to address opioids through other substance abuse prevention grants for which tribal entities are eligible. In addition, SAMHSA-supported resources such as the "Risk and Protective Factors for Substance Abuse and/or Mental Health Problems Among Alaska Native and Native American Populations" publication identify specific risk and protective factors based on published studies that assist in developing targeted tribal programming for Alaska Natives.

Mental and substance use disorders can contribute to the risk for HIV/AIDS and viral hepatitis. As a result, SAMHSA supports efforts such as the HIV Capacity Building Initiative, Minority AIDS Initiative Continuum of Care, and Targeted Capacity Expansion-HIV Program. Tribal communities have been supported through some of these efforts which allow for HIV testing (and pre- and post-test counseling), referrals for treatment, integration of medical HIV/AIDS and behavioral health care, and testing for other infectious diseases such as hepatitis C. SAMHSA also developed an information resource called "Hepatitis C/HIV in Native American Populations" and distributed it widely to elevate the awareness of tribal communities on these risks, actions they can take, and funds available through the agency.

3. **Do you currently have the ability to help tribal and public health systems develop programs to alert providers of care for opioid abuse to also test for concomitant infectious diseases and provide a pathway to treatment? Are you engaging in these activities currently, if so, can you please elaborate on these efforts and provide any findings on the results?**

Response:

Yes, SAMHSA has the ability to help tribal and public health systems develop programs. Specifically, SAMHSA addresses the risks for HIV/AIDS and viral hepatitis by supporting grants that improve coordination of mental and substance use disorder treatment, including HIV testing with pre- and post-test counseling and referrals for treatment; integrated medical, HIV/AIDS, and behavioral health care; and testing for other infectious diseases. Examples of funded tribal projects include the following grants:

- Native American Health Center's Ekwahness ("To Hold Tightly")
- Salish Kootenai College Integrative Community Empowerment
- College of the Muscogee Nation's Guarding the Future

Currently, SAMHSA administers the "Minority AIDS Initiative Continuum of Care Pilot - Integration of HIV Prevention and Medical Care into Mental Health and Substance Abuse Treatment" program. This program supports projects that coordinate and integrate services through the co-location of behavioral health treatment and HIV medical care including American Indians and Alaska Natives. The focus is on substance abuse treatment programs and community mental health programs that can co-locate and fully integrate HIV prevention and medical care services within them.

In Fiscal Year 2017, SAMHSA announced the "First Responders - Comprehensive Addiction and Recovery Act Cooperative Agreement" program. SAMHSA awarded over $11 million over four years to 21 grantees to train and provide resources for first responders and members of other key community sectors on carrying and administering an FDA-approved product for emergency treatment of known or suspected opioid overdose. States and tribal entities (American Indian and Alaska Native tribes, tribal organizations, and consortia of tribes or tribal organizations) were eligible to apply. The tribal entities receiving a grant were the Choctaw Nation of Oklahoma, White Earth Band of Chippewa Indians, Lac Du Flambeau Band of Lake Superior Chippewa Indians, and the Cherokee Nation.

4. How could we strengthen our public health system infrastructure to better respond to the opioid epidemic and its long term health consequences?

Response:
The opioid epidemic has had a significant impact on the nation and tribal communities. According to SAMHSA's 2016 National Survey on Drug Use and Health report, which provides national and state-level data on the use of tobacco, alcohol, illicit drugs (including non-medical use of prescription drugs) and mental health in the United States, 11.8 million people in the U.S. aged 12 or older misused opioids in the past year and 948,000 reported using heroin. Within this number, 63,000 American Indians and Alaska Natives aged 12 and older reported misusing opioids and 5,000 aged 12 and older reported using heroin. In 2015 and 2016, illicit drug use was higher among American Indians and Alaska Natives as compared to the total U.S. population.

In FY 2017, the Department of Health and Human Services announced that $485 million would be awarded to states and territories to combat opioid addiction through the State Targeted Response (STR) to the Opioid Crisis Grant program. The STR program is administered by

SAMHSA and aims to: increase access to treatment; reduce unmet treatment needs; and reduce opioid overdose related deaths through the provision of prevention, treatment, and recovery activities for opioid use disorder, including prescription opioids, as well as illicit drugs such as heroin. By statute, tribes were not directly eligible for an STR grant, and SAMHSA can encourage but not compel states to include tribes in their STR plans.

The Honorable Gus Bilirakis

1. As more treatments for diseases transition from more expensive care settings like inpatient to out-patient facilities and even to the home, what is the importance of being able to treat addiction in a home setting versus a traditional methadone clinic?

Response:
Treatment of addiction is increasingly accessible and affordable for individuals in an outpatient or intensive outpatient setting versus a more expensive and confining inpatient or residential setting. Outpatient treatment services include the availability of safe and effective medication-assisted treatment programs for patients with opioid use disorders, using methadone, buprenorphine, or naltrexone, in combination with evidence-based addiction counseling and related services and supports. For some people who are stable or for whom the risk of complications is low, treatment that does not require regular attendance at a facility may be the most appropriate because convenience of treatment often improves adherence. Having more options that can address the variety of patient needs improves outcomes. The Drug Addiction Treatment Act of 2000 (DATA 2000) enabled buprenorphine to be prescribed or administered to a patient on an outpatient basis by a physician, nurse practitioner, or physician assistant with a certain type of waiver. Patients who are treated by providers with waivers are not required to attend a program daily, as is generally the practice when a patient begins methadone treatment in an Opioid Treatment Program. Another treatment option that is becoming increasingly popular is the use of extended-release injectable naltrexone, which is administered as a once a month injection by a physician for individuals to prevent relapse to opioid dependence, after the patient has completed opioid detoxification. This medication also has the advantage of not requiring that a patient be able to attend a daily or weekly treatment program. In addition, in May, 2016, the Food and Drug Administration approved the first buprenorphine implant for the maintenance treatment of opioid dependence. This medication is designed to provide a constant, low-level dose of buprenorphine for six months in a patient who is already stable on low-to-moderate doses of other forms of buprenorphine, as part of a complete treatment program. In November, 2017 the Food and Drug Administration also approved the first once-monthly injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder in adult patients who have initiated treatment with a transmucosal (absorbed through mucus membrane) buprenorphine-containing product. This product provides a new treatment option for patients in recovery for whom the once-monthly injection may be more appropriate than other forms of buprenorphine, as it may reduce the burden of taking medication daily as prescribed (medical adherence).

2. **Currently there isn't a clear standard for medication assisted treatment (or MAT) prescribing, and we've heard reports of an increasing number of rogue actors offering MAT. In many cases these "pop up clinics" actively recruit vulnerable client populations and provide substandard services with minimal oversight. While we support consumer choice and market competition, we also want to balance this with consumer safeguards to ensure that this problem improves, not worsens, and that bad actors are not rewarded via federal dollars. Additionally, questions have been raised as to whether states are requiring evidence-based practices be used in the STR grant program. What is SAMHSA doing to ensure rogue actors are not the recipient of federal dollars and evidence-based practices are being used so that funds expended go to providing the best possible treatment and recovery services?**

Response:
SAMHSA regulates Opioid Treatment Programs through an initial certification process and ongoing accreditation oversight. SAMHSA also manages the DATA 2000 waiver program for physicians, physician assistants, and nurse practitioners that provide office-based prescribing of certain FDA-approved medications for opioid use disorder. In addition to management and oversight of STR Grantees (as described above), SAMHSA is providing ongoing technical assistance (TA) to all grantees using conferences, webinars, learning collaboratives, and the $12 million Opioid State Targeted Response TA program. Evidence-based MAT prescribing, supported by a variety of SAMHSA tools and resources, is an essential aspect of this TA.

SAMHSA required states to identify the evidence-based practice that they intended to use in their initial application for STR funds and in their strategic plans submitted in August of 2017. Grant project officers have monthly calls with each state to discuss progress on implementation of their plans and any concerns that either the state or SAMHSA has with progress. Grant project officers are also making site visits to states to meet with state staff and providers and patients to understand the implementation process on the ground. States are required to report twice a year on a set of questions including the numbers of people that received specific services. Additionally, the program is being evaluated by an external evaluator. The evaluation includes an assessment of use of evidence-based practices.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides other supports in addition to treatment. The fact sheet is on SAMHSA's website: https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf.

The Honorable Chris Collins

1. Despite the staggering overdose reports from my district's coroners and the CDC, opioids are still primarily used for the treatment of pain. It is estimated that around 250

million Schedule II prescriptions are filled across the country each year. However, there are other effective options for pain management. For example, several academic peer-reviewed journals have found that states that have legalized the use of marijuana for medical purposes had significantly lower state-level opioid overdose mortality rates...and found that it was an effective form of pain management. Alternatively, anesthesia is utilized in various surgical and non-surgical procedures to improve perioperative *[preoperative, intraoperative, and postoperative]* pain control while minimizing systemic opioid consumption.

a. **Under the Opioid State Targeted Response (STR) grants, are states using funds to educate physicians and providers on utilizing non-opiate treatment for pain?**

Response:
The State Targeted Response to the Opioid Crisis Grant program provides states and jurisdictions with the flexibility to obligate and expend funds to train substance use and mental health care practitioners on topics such as best practices for prescribing opioids, pain management, recognizing potential cases of substance use disorder, referral of patients to treatment programs, and overdose prevention, including the Centers for Disease Control and Prevention's (CDC) Guidelines for Prescribing Opioids (https://www.cdc.gov/drugoverdose/prescribing/guideline.html) to train practitioners.
The Opioid STR Mid- and End-Year Reports do not capture any information regarding the use of non-opioids for the treatment of chronic pain or training focused on the use of non-opioids for the treatment of pain. The states and jurisdictions also have the flexibility to train opioid use disorder prevention and treatment providers, such as physicians, nurses, nurse practitioners, physicians assistants, counselors, social workers, care coordinators, and cases managers. SAMHSA's Opioid Overdose Prevention Toolkit (https://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf) must be used when developing training to address opioid overdose, as well as CDC's Guidelines for Prescribing Opioids..

2. CARA established the Pain Management Best Practices Inter-Agency Task Force to provide advice and recommendations for development of best practices for pain management and prescribing pain medication. The Task Force is also expected to develop a strategy for disseminating such best practices to relevant federal agencies [the Department of Veterans Affairs, Department of Defense, and Department of Health and Human Services] and the general public.

a. What is the current status of the nominations process? As this is an advisory committee, to what degree do you expect providers to adopt these practices? Please explain.

Response:
The deadline for nominations to serve on the Task Force closed on September 27, 2017; HHS is currently in the process of reviewing all applications, and it is anticipated that decisions will be made soon. Once selections have been made and agreements to serve have been secured, the Task Force membership roster will be announced on the HHS webpage, https://www.hhs.gov/ash/advisory-committees/pain/index.html.

The Task Force is required to propose updates to best practices and recommendations on addressing gaps or inconsistencies between best practices for pain management (including chronic and acute pain) developed or adopted by Federal agencies. The proposed updates and recommendations will be submitted to relevant Federal agencies and the general public to consider.

3. Under CARA's Opioid State Targeted Response grants, states would distribute funds using a strategic planning process and upon which states were required to submit a needs and capacity assessment to SAMHSA. The use would go to nine allowable activities.

Is this information and distribution of funds collected in a database? If so, can you please describe how you can utilize this data in further identifying gaps in prevention, treatment, and recovery?

Response:
States were required to submit both a needs assessment and strategic plan describing how needs would best be addressed in each state. Once the funds were released to the states, the states determined how to further allocate the funding. States identify who is funded in their bi-annual reports, and the data is compiled in SAMHSA's online block grant application system (WebBGAS) available for further review.

4. Under Section 303 of the Comprehensive Addiction and Recovery Act, eligible physician assistants and nurse practitioners can receive a waiver to prescribe drugs for maintenance or detoxification treatment (i.e. buprenorphine) for 30 or less patients that the total number applicable to the qualifying practitioner. The cap can be raised to 100 after the prescriber has been waivered for one year. As this program has gotten off the ground, we are starting to hear from some practitioners working in addiction clinics that may quickly reach the 30 patient limit, and clinics in areas that have a challenging time finding waivered practitioners may have to turn away patients who are seeking treatment for opioid addiction.

Is raising the cap beyond Section 303 something Congress or HHS should consider raising? Why or why not?

Response:
SAMHSA began processing waiver applications for mid-level practitioners in February 2017, and it is preparing a report, as required by CARA, that addresses, among other issues, whether there is a need for the Secretary to increase or decrease the number of patients a practitioner with a waiver may treat. That report is due in July 2019. SAMHSA will continue to implement the provisions of CARA and looks forward to receiving input from stakeholders regarding this matter, which will inform the July 2019 report.

The Honorable Tim Walberg

1. Section 102 of CARA provides for a National Awareness Campaign to educate both parents and youth. We need to ensure that we are doing all we can to protect the next generation with robust prevention programming messages to serve as a counterweight to the proliferation of pro-drug messaging in the media today. However, the Awareness Campaign has yet to be funded – or even really acknowledged. An awareness campaign is desperately needed.

What is the status of implementing Section 102 of CARA?

Response:
The office of the Assistant Secretary of Public Affairs (ASPA) is coordinating the National Awareness Campaign. There are three components of this Campaign. The Campaign will help to educate Americans across the lifespan to:

- Understand their roles in the opioid crisis;
- Adopt behaviors to prevent opioid medication-sharing; and
- Engage in safe storage and disposal practices.

2. What is SAMHA's plan for implementing the National Awareness Campaign?

Response:
SAMHSA's component is still under development.

The Honorable David McKinley

1. Police, fire fighters, and other emergency personnel are the first to arrive on an opioids related scene. These professionals are there to protect us, but they are at risk of being exposed to potent opioids and their synthetic analogues, such as fentanyl and carfentanyl. What's being done to protect these first responders, what more can be done, and what do you need from Congress?

Response:
SAMHSA acknowledges the importance of protecting our first responders who are out in the field saving lives, but may be at risk of exposure to opioids and/or its analogues. SAMHSA administers the Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO) and

- https://www.dea.gov/druginfo/Fentanyl_BriefingGuideforFirstResponders_June2017.pdf

2. Fentanyl: Preventing Occupational Exposure to Emergency Responders, Protecting Workers at Risk (August 30, 2017)
   - https://www.cdc.gov/niosh/topics/fentanyl/risk.html

It is also important that all first responders have easy access to naloxone not just for preventing the death of the individuals they serve in the community, but for preventing the death of their first responder colleagues as well. This goes hand-in-hand with training of first responders on information such as the nature of the opioids involved, the safe handling of these drugs and how to protect oneself (e.g. having access and utilizing personal protective equipment), the signs and symptoms of an overdose, how to administer naloxone, and the possibility of administering more than one or two doses.

2. The 21st Century Cures Act passed last year provided nearly $1 billion in funding designated predominantly to expand treatment for opioid use disorders through the State Targeted Response grant program. We appreciate HHS releasing the first round of $485 million in funding this year, but were surprised that West Virginia was not awarded funding in the first round of $144.1 million additional funding. Specifically, SAMHSA awarded $9.8 million over three years for a new State Pilot Pregnant and Postpartum Women's (PPW) program. We received notice from the West Virginia Department of Health and Human Resources (DHHR) that they applied for this funding and were denied.

a. What determinants are taken into consideration when allocating certain dollar amounts?

Response:
Each grant has its own set of evaluation criteria, which are used to review applications. These evaluation criteria are listed in each funding opportunity announcement and includes Statement of Need; Proposed Approach; Staff, Management, and Relevant Experience; and Data Collection and Performance Measurement. The STR formula consisted of two elements: treatment gap and number of drug poisoning deaths. The treatment gap is weighed at 70 percent; the mortality figure is given at 30 percent weight.

b. Does a state with a higher level of deaths receive more funding or preference than a state with a lower level of deaths?

Response:
Whether an applicant is successful for any of the non-formula based grants under the programs authorized by CARA is based on the particular need for funding as articulated in the responses by the applicant to the Funding Opportunity Announcement and that application then is scored by a peer review panel. SAMHSA provides non-formula based grants to the applicants with the highest scores with the funding available to SAMSA by Congress. The STR formula consisted of two elements: treatment gap and number of drug poisoning deaths. The treatment gap is weighted at 70 percent; the mortality figure is given a 30 percent weight. Each state receives a

proportional share of the funding based on the state's proportional share of the national numbers for the measures listed above.

c. If so, then why was West Virginia's application declined?

Response:
Applications submitted by entities from West Virginia for additional discretionary funding did not score high enough in the peer review process to receive a competitive award.

d. What can they and similar entities in their situation do in the future to strengthen their application?

Summary statements will be sent to each applicant detailing the peer reviewer response to the application. The summary statements for each applicant will include a narrative describing the strengths and weaknesses for each evaluation criteria section of the application. This will help inform the applicant on ways to improve their submissions. The summary statements for the First Responders and State Pilot Grant for Treatment of Pregnant and Post-Partum Women have been completed and released to organizations. The summary statements for Building Communities of Recovery and Services Grant Program for Residential Treatment for Pregnant and Post-Partum Women are in the process of being written.

3. In addition, I have heard that some states have not fully released STR funding which has created obstacles for rural communities to combat the opioid crisis directly. What barriers are preventing the use of this grant money and what is HHS doing to address these barriers? What can be done to expedite getting these dollars into the communities that need them most?

Response:
SAMHSA released the FY 2017 State Targeted Response (STR) to the Opioid Crisis Grant Notices of Award on April 27, 2017, and the funds were available for distribution on May 1, 2017. Most states' administrative rules required the Opioid STR recipients to follow their respective procurement rules applicable to federal funds. As a result, some states experienced delays in making Opioid STR funds available to sub-recipients, i.e., community-and faith-based organizations approved by the states to provide opioid use disorder prevention, treatment and recovery services. All states have subsequently fulfilled their respective procurement processes and opioid funds are being made available to sub-recipients.

4. What is being done to address difficulties that individuals have accessing treatment for opioid use disorder, especially in rural and underserved communities? How should we address the lack of treatment providers with addiction treatment skills?

Response:
One way SAMHSA addresses the lack of treatment providers is by is working with the Health Resources and Services Administration and other operating divisions within HHS and across the federal government to expand access via telehealth. We are in the process of developing a use case that explains how telehealth can be used to provide MAT in rural areas.

SAMHSA is also developing an Extension for Community Healthcare Outcomes (ECHO) pilot to examine how additional training and mentoring impact physician practice change (e.g. treating more patients with opioid use disorders). Project ECHO is a model developed by the University of New Mexico to expand medical knowledge and get best practice care to those who need it. Multipoint videoconferencing is used to provide didactic and case-based learning to health professionals more effectively developing capacity to safely and effectively treat individuals with a substance use disorder (SUD). Many waivered providers do not prescribe because they do not feel competent to treat a complex condition like opioid use disorder. This method has been shown to help providers in rural areas provide care that is comparable to specialty care for other complex conditions. More than half of the states are using their Opioid STR funding to create ECHO programs to support rural providers. States are also setting up hub and spoke systems modeled on the state of Vermont program. In this model, patients are stabilized in a specialty care setting (hub) and once on a stable dose of medication they are referred to a primary care provider (spoke) who can manage the medication. If the primary care provider has questions or concerns, s/he can reach out to the hub provider for guidance and support.

In addition, SAMHSA's Addiction Technology Transfer Center (ATTC) Program develops and strengthens the specialized behavioral healthcare and primary healthcare workforce that provides SUD treatment and recovery support services. The ATTCs deploy a variety of methods to accelerate the adoption and implementation of evidence-based and promising SUD treatment and recovery-oriented practices and services by heightening the awareness, knowledge, and skills of the workforce addressing the needs of people with substance use or other co-occurring health disorders; and fostering regional and national alliances among culturally diverse practitioners, researchers, policy makers, funders, and the recovery community.

The ATTC grantees work directly with SAMHSA on activities aimed at improving the quality and effectiveness of treatment and recovery, and work directly with providers of clinical and recovery services, and others that influence the delivery of services, to improve the quality of workforce training and service delivery across the nation and in rural and underserved communities. The ATTC program supports Opioid Treatment Programs to develop their workforce capacity. Project ECHO (mentioned above) is an example of a technology that the ATTC's use to improve the skills of treatment providers and increase access to SUD care.

SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Providers' Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides mentoring of newly trained physicians by experienced specialists, maintains a library of evidence-based practice materials, and offers at no cost to the trainee the required DATA 2000 waiver training to enable

providers to prescribe buprenorphine for opioid addiction treatment. SAMHSA recently awarded a grant to provide technical assistance and training related to prevention, treatment and recovery from opioid use disorder to states and communities on individual needs within these jurisdictions as a means to better assure the use of evidence based practices and to expand the healthcare workforce providing treatment for opioid addiction.

The Honorable Pete Olson

1. Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)?

Response:
The FY 2017 appropriations act did not provide funds to SAMHSA to carry out the PDMP provisions of CARA.

2. Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?

Response:
States have multiple potential sources of funds to improve their PDMPs. Many specialty addiction care providers still do not participate in electronic data transfer as they do not have electronic health records. This may impact workflows and information sharing and impede the integration of care.

The Honorable Bill Johnson

1. Community-based organizations like Field of Hope are on the front lines of the opioid epidemic. CARA included numerous grant programs and funding sources to address addiction treatment, but it does not seem to have trickled down to the front-line providers. What is SAMHSA doing to ensure that grant funding aimed at substance abuse benefits on-the- ground providers, and are there ways we could improve in that area?

Response:
SAMHSA carries out its role through a variety of mechanisms, including administering grant programs (e.g. drug court grants, pregnant and postpartum women treatment grants, youth and family treatment grants); convening policy academies and expert meetings; providing training and technical assistance to the field; and developing and disseminating information resources.

SAMHSA's criminal justice programs recognized that drug court professionals needed enhanced awareness and skills in understanding and connecting clients with medication assisted treatment (MAT). SAMHSA responded by increasing the amount of grant dollars grantees can allocate towards MAT and provided a grantee training on how to implement MAT. As a result of these and other efforts, 57 percent of SAMHSA's criminal justice programs have integrated MAT into their programming.

Also, the Building Communities of Recovery grants were awarded to eight organizations in Fiscal Year 2017. The purpose of this new CARA-funded program is to mobilize resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery support from substance abuse and addiction. These grants support the development, enhancement, expansion and delivery of recovery support services.

Additionally, in Fiscal Year 2017, SAMHSA funded:

- Nineteen new residential treatment programs for pregnant and postpartum women and their families with substance use disorder (SUD) and/or co-occurring substance use and mental disorders at the community-level.
- Three new state programs to primarily expand outpatient services for pregnant and postpartum women and their families with SUD and/or co-occurring substance use and mental disorders at the community-level.
- Twelve new state youth treatment grants with a requirement to expand the number of treatment providers to serve youth with SUD and/or co-occurring substance use and mental disorders.
- Seventy five criminal justice grants to organizations to provide treatment to individuals involved in the criminal justice system.

The Honorable Susan Brooks

1. I have heard you say that preventing drug use before it begins is this the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

Response:
Characteristics of successful prevention intervention programs are represented in the National Institute on Drug Abuse's Preventing Drug Use among Children and Adolescents: A Research-Based Guide for Parents, Educators, and Community Leaders (2nd ed.). Sixteen prevention principles are presented to assist parents, educators, and community leaders to think about, plan for, and deliver research-based drug abuse prevention programs at the community level. The areas addressed include, but are not limited to: risk factors and protective factors, prevention planning, and prevention program delivery. The core elements of effective research-based programs include: Structure – how each program is organized and constructed; Content – how the information, skills, and strategies are presented; and Delivery – how the program is selected or adapted and implemented, as well as how it is evaluated in a specific community. When adapting programs to match community needs, it is important to retain these core elements to ensure the most effective parts of the program stay intact. SAMHSA promotes the use of its Strategic Prevention Framework, a planning process, as a comprehensive guide to plan, implement, and evaluate prevention programs.

Successful implementation strategies take time and resources. The essential challenge is to ensure that the incentives, structures, and operations at the systems, organizational, and

practitioner level are consistent with each other and aligned in a way that supports the desired practitioner behavior. In "Implementation Research: A Synthesis of the Literature," researchers found that well planned and carefully executed implementation strategies can be used to improve services at the practitioner level, organizational level, and national level. In the programs that were examined, the core implementation components involved: careful selection; staff training, coaching, and performance evaluation; program evaluation and facilitative administration; and methods for systems interventions.

With regard to barriers to program implementation, one of the biggest challenges to the field is the ability to take effective programs and replicate them with fidelity across the country. In the Institute of Medicine's "Strategies for Scaling Effective Family-Focused Preventive Interventions to Promote Children's Cognitive, Affective, and Behavioral Health (workshop summary)," barriers identified to scaling up research-based programs include: lack of demand for the programs, insufficient organizational capacity, lack of sustainable funding, and factors other than evidence from research that influence decision making around whether or not to implement a particular program. The potential for many evidence-based interventions is not fully realized when interventions are not implemented with quality, or that quality is not sustained over time. Scaling up a program can also be hampered by an over-reliance on program developers who do not have the expertise or time to scale-up and disseminate their programs, and rigid adherence to the programs which may need to be adapted to specific populations or organizations.

2. Substance use disorder confidentiality regulations limit the use and disclosure of patients' addiction records from certain treatment programs. I've heard from health providers that separating a patient's addiction record from the rest of his or her medical record may hinder the delivery of receiving safe, effective, and coordinated treatment.

a. In the context of the opioid crisis, do you believe it is important that a patient's provider has access to his or her substance use disorder record?

Response:
Yes, it is important that a patient's provider have access to the patient's substance use disorder treatment record as the health and safety of the patient should be the first priority of all providers. While SAMHSA has undertaken efforts to facilitate information exchange by revising its regulations related to confidentiality of substance use disorder treatment records (42 CFR Part 2), the current statute can be an obstacle to a providers' ability to access their patients' records and Part 2 is not completely aligned with HIPAA.

b. Do you think a patient whose doctor doesn't know that he or she is in recovery from an opioid addiction is getting the best evidence-based care?

Response:
SAMHSA believes strongly that patients who have received or are receiving treatment for a substance use disorder benefit from receiving integrated, coordinated care. Accordingly,

SAMHSA's 2017 and 2018 final Part 2 rules reflect the agency's efforts to balance the need for integrated care with the need to ensure patients receiving diagnosis, treatment and referral for treatment for substance use disorders also understand how and by whom their part 2 patient identifying information is used. Part 2 permits patients to consent in writing to sharing information with their treating providers. Indeed, the final 2017 rule makes this process easier than previously was the case by permitting the use of a general designation (i.e., the patient can choose to share their Part 2 information with "all of my current treating providers"). SAMHSA encourages Part 2 programs and patients to discuss the benefits patients may obtain from coordinated care which, in turn, is best facilitated by permitting their health care providers to receive part 2 information. Moreover, during a medical emergency when prior patient consent cannot be obtained, a Part 2 program also may disclose information needed to respond to that emergency (42 CFR 2.51 - Medical emergencies.)

c. There is a lot of talk about mental health and addiction parity. Do you think it's parity for a substance use record to be treated differently from a mental health or HIV record? Can the same quality care be given when a provider does not know that their patient is being treated for an addiction?

Response:
SAMHSA supports further consideration of the benefits of aligning the statute governing Part 2 with HIPAA to ensure parity.

The Honorable Richard Hudson

1. Many people coming out of the correctional system have had problems with opioids and represent some of those at highest risk for overdose and death. What is SAMHSA doing to address this?

Response:
SAMHSA's role in the criminal justice system is to bring about strategic linkages between community-based behavioral health providers, the criminal justice system, and community correctional health programs; promote effective diversion and reentry programs; and foster policy development at the intersection of behavioral health and justice issues. Recognizing that individuals leaving the correctional system have a high risk for overdose and death, SAMHSA encourages drug courts and offender reentry program grantees to spend up to 20 percent of their annual grant award to pay for Food and Drug Administration-approved medications for treatment or substance use disorders.

Offender reentry program grants are also required to develop and implement an overdose prevention program as part of their service delivery for soon-to-be released offenders and those recently released from a correctional setting. These grantees collaborate with community corrections programs, law enforcement, and judges on the program. The opioid overdose prevention programs must include an educational component, which includes SAMHSA's

Opioid Overdose Prevention Toolkit (https://www.samhsa.gov/capt/tools-learning-resources/opioid-overdose-prevention-toolkit).

SAMHSA also provides training on how to implement opioid overdose prevention programs and medication assisted treatment programs for its criminal justice grants through webinars, on-site technical assistance, trainings, grantee meetings and conferences.

The Honorable Ben Ray Lujan

1. While the funding provided by the 21st Century Cures Act was extremely welcome in my state, we still need to do more to expand treatment capacity. For many of my constituents it often feels like we are trying to hold back the ocean armed with a tablespoon. Listen to a few lines from a letter I received just a few days ago from a distraught father in my district:

"As a responsible parent, I must inform my daughter about the dangers of pills and opioids because, statistically speaking, she's more likely to die from an overdose than anything else. So how do I begin to explain how we got here? How do I explain that Congress, the President, and even the DEA are ignoring the issue, and things are getting worse? This isn't hyperbole: overdoses are killing far more Americans than gun homicides and opioids in particular are killing more people than cocaine, meth, or any other illegal narcotic. And I am now in the impossible position of having to explain all of this to my daughter."

So while the funding provided in Cures was a first step, we must do more. What the advocates and planners in our states and cities need is certainty. They can't hope to hire new staff or spend money on infrastructure if they don't think funding is going to last for more than 2 years. As a result, I've heard from my community that money has gone toward short-term and stopgap measures. Measures that do little to reassure parents in Santa Fe or in other parts of my state that Congress understands their concerns and that we are providing real help for a very real problem.

We all know that short-term solutions aren't enough to seriously address this epidemic. We need to seriously invest time and money into combatting this crisis in our communities, and we need to do so in a way that builds in stability and allows our communities to do long term planning.

a. Assistant Secretary McCance-Katz are you aware of which, if any, states have used the funding passed in 21st Century Cures to expand physical infrastructure or undertake strategic planning that goes beyond the 2 year funding window passed in 21st Century Cures?

Response:
The State Targeted Response to the Opioid Crisis Grant (STR) requires states to prepare and submit needs assessments and strategic plans. The assessments were submitted on or before July

31, 2017, and the strategic plans were submitted on or before August 3, 2017. States recognize that the 2-year funding authorized by section 1003 of the 21st Century Cures Act will assist states in addressing some of their emergent needs regarding prevention, treatment and recovery support services for persons with opioid use disorders. The STR grants allow a very small portion of grant funds to be used to renovate or alter existing facilities, building new facilities is not an allowable expense.

2. I think we need to do more to build long-term capacity to address this epidemic. That is why I have introduced the Opioid and Heroin Abuse Crisis Investment Act to extend the 21st Century Cures funding for an additional five-years – a timeframe that allows for long-term planning and more than stopgap measures. I'd welcome my colleagues support on this effort and hope that we can work together in a bipartisan fashion to find creative ways to get more support to those in need.

The Comprehensive Addiction and Recovery Act (CARA) made critical strides in the fight against the opioid epidemic. This committee worked to help expand access to vital addiction treatment options including medication assisted treatment (MAT). CARA allowed Nurse
Practitioners (NPs) and Physician Assistants (PAs) to prescribe MAT in accordance with state law. I supported that effort and I think we can build on that work.

Congressman Tonko and I recently introduced legislation to do just that. Current law sunsets the authority for NPs and PAs – our bill makes it permanent. The legislation also recognized the integral role played by Advanced Practice Registered Nurses (APRNs) in health care teams all across the country, but especially in rural states like New Mexico where thousands of families depend on APRNs for so much of their routine health care. We especially need to make it easier for pregnant and postpartum women struggling with addiction to get help.

Allowing all APRNs, including Certified Nurse Midwives, to prescribe and refer to MAT will expand access for addicted New Mexicans and Americans across the country.

a. What is SAMHSA doing to ensure medication assisted treatment is easily accessible to all who need the help?

Response:
SAMHSA develops and publishes documents to educate providers and patients regarding FDA approved medications for the treatment of substance use disorders. SAMHSA further provides education including DATA waiver training and mentoring to providers through its Providers' Clinical Support System on the use of medication-assisted treatment in providing care to populations affected by substance use disorders. SAMHSA has a treatment locator to help patients locate Opioid Treatment Programs and Drug Addiction Treatment Act waivered providers on its website. SAMHSA works in partnership with DEA and State Opioid Treatment Authorities to administer technical assistance to providers establishing new treatment programs. SAMHSA offers the State Targeted Response Grants, Medication Assisted Treatment-Prescription Drug Opioid Addiction grants, and Block grants which are all sources of funding for

medication assisted treatment. Finally, SAMHSA processes all applications for new providers regulated by the Agency as expediently as possible.

b. How would expanding who can prescribe medication assisted treatment impact access in rural areas like parts of New Mexico?

Response:
Expanding prescribing authority to qualified providers may have a positive impact on access to care in all geographic settings, but could be especially helpful in rural areas that do not have as many physicians as NPs, PAs and other non-physician providers.

3. Assistant Secretary McCance-Katz: We appreciate all of the work your agency has been doing to provide block grants to our communities back home. I recently had the opportunity to visit with a recovery center in Española, New Mexico. During this visit I was surprised to learn that rural treatment centers are not always considered eligible for grant funding because of certain grantee requirements – even as rural regions in the US are getting hit harder!

I'd like to share a specific example from Hoy Recovery. Recently, a Center for Substance Abuse Treatment Targeted Capacity Expansion grant became available. The grant would have been ideal for this center except New Mexico was disqualified because the grant required a substantial increase in admissions to Medication Assisted Treatment.

New Mexico was not able to demonstrate increased use MAT because we didn't have the workforce capacity and needed assistance to expand – the exact thing the grant would have provided.

Another example: There was a recent Office of Minority Health grant that Hoy also applied for. However, the evaluation requirements called for a greater number of patients served than they, as a small, rural community, could produce.

While I understand the importance of targeting funding to the largest number of people possible, many of the communities that need help the most are much smaller than 100,000 people.

a. How does SAMHSA justify requiring proof of capacity expansion for grants intended to help organizations expand capacity?

Response:
SAMHSA did not receive an application for a Targeted Capacity Expansion Medication Assisted Treatment Prescription Drug and Opioid Addiction grant from New Mexico. SAMHSA does allow applicants for this program to spend funds on infrastructure development to begin developing capability not just to expand capacity.

SAMHSA did not define eligibility for this program. Eligibility was articulated in the FY 2017 Omnibus, which required that eligibility for MAT-PDOA be limited to the states with the highest

rates of admissions, including those that had demonstrated a dramatic increase in admissions for the treatment of opioid use disorder. As identified by SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2014, 17 states were eligible to apply. New Mexico was not one of the 17 states with the highest rates of primary treatment admissions for heroin and opioids per capita, and therefore was not eligible to apply for a MAT-PDOA grant in FY 2017.

b. What can we tell our constituents who live in small, rural communities that are ineligible for more funding simply because they are small?

Response
SAMHSA does not restrict eligibility on its community-based grants based on size. All applications are accepted from all communities. SAMHSA has funded and continues to fund small, rural communities.

c. Has SAMHSA produced any materials that explore barriers and restrictions for funding of rural communities?

Response:
While smaller, rural communities are not restricted from applying for funding opportunities, SAMHSA recognizes they may face challenges in developing and submitting all required application materials, especially the first time. For this reason, SAMHSA hosts applicant webinars to walk potential applicants through the entire process, including application and registration processes, requirements and validations, and the post-submission process. Recordings of the webinars are generally posted on the SAMHSA website as well for those unable to join at the scheduled times. Certain grant programs have also included program specific webinars and FAQs for potential applicants. As well, each funding opportunity announcement includes staff contacts at SAMHSA whom applicants can reach out to with programmatic or financial questions.

4. In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. The New York Times reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The Times and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long-term investments in prevention, treatment, recovery, and monitoring.

The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a
95 percent hit.

a. Assistant Secretary McCance-Katz, do you have all of the tools you need to stop the opioid epidemic?

Response:
HHS is currently reviewing the need for additional resources and authorities to address the opioid epidemic in order to ensure a coordinated response by the Department in partnership with other areas of the Federal Government.

b. Given the 10 percent cuts to SAMHSA in the President's budget proposal, what programs relating to the opioid epidemic will be cut? Which programs would have been expanded that will now not be?

Response:
The Substance Abuse Treatment appropriation was preserved in its entirety. Additionally, all programs in the Substance Abuse Prevention appropriation specifically related to opioids were also preserved in their entireties in the Fiscal Year 2018 President's Budget.

The Honorable Paul Tonko

1. With the passage of CARA, PAs and NPs can receive a waiver to prescribe buprenorphine after completing 24 hours of education. This 24 hour requirement is viewed by many healthcare providers as a barrier to care, given that many qualified PAs or NPs will have difficulty completing this requirement, and especially given the fact that physicians are only required to complete eight hours. Do you have any data that justifies the differences in requirement for this waiver, and are changes to this requirement something that you think the Department should consider?

Response:
The 24-hour training requirement is a congressional mandate under CARA. SAMHSA does not have any data to justify the difference in the requirement or evidence that the additional hours of training are a significant burden to mid-level providers.

2. In order to receive a waiver to prescribe buprenorphine, PAs and NPs are currently required to have their supervising or collaborating physician be "waiver eligible." This requirement has the potential to restrict access to treatment for those suffering from opioid addiction. The Secretary HHS has the ability to allow PAs and NPs that work in collaboration with a physician to obtain waivers, even if that collaborating physician is not a waiver-qualified provider. Are changes to this requirement something that you think the Department should consider?

Response:

The Secretary has regulatory authority over the requirements that must be satisfied to qualify as a "qualifying other practitioner," and this authority includes the authority over the "collaborating or supervising physician requirement" under 21 USC 823(g)(2)(G)(iv)(III).

In addition, some states have laws that require nurse practitioners or physician's assistants to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician. Twenty-eight states require some degree of collaboration or supervision of nurse practitioners by physicians.[1] The regulations regarding what physician assistants (PAs) can prescribe vary by state; in 44 states and the District of Columbia PAs can prescribe all FDA-approved medication-assisted medications, while 5 states allow them to prescribe only buprenorphine and naltrexone, and Kentucky allows them to prescribe only naltrexone.[2] PAs generally practice under physician supervision. SAMHSA began processing waiver applications for mid-level practitioners in February 2017 and it is preparing a report, as required by CARA, informed by input from stakeholders.

3. Can you briefly discuss your experience with expanding MAT in jails and prisons in Rhode Island, and how SAMHSA and this Administration could help support and expand these innovative approaches?

Rhode Island has implemented a program in which individuals incarcerated are screened for opioid use disorder and evaluated to determine medical needs related to this condition. If a person is already receiving medication assisted treatment for an opioid use disorder, this is continued. If a person is opioid-addicted and at risk for withdrawal they are offered medical treatment including initiation of medication assisted treatment (for those with short sentences). For those who are near release and have a history of opioid use disorder and are not on medication assisted treatment; they are offered the opportunity to begin treatment prior to leaving the Dept. of Corrections. All of those with opioid use disorder are connected to ongoing outpatient treatment prior to leaving and naloxone is also offered on release. This program has been well accepted by inmates and staff alike and Rhode Island is seeing success in assuring ongoing care for this population which is at high risk for overdose death on leaving jail or prison without medication assisted treatment and clinical follow up.

Response:
SAMHSA's criminal justice programs focus on developing systemic and strategic linkages between community-based behavioral health providers, the criminal justice system, and community correctional health programs to promote effective diversion and reentry programs; and foster policy development at the intersection of behavioral health and justice issues.

Recognizing that individuals leaving the correctional system have a high risk for overdose and death, SAMHSA encourages drug courts and reentry grants to spend up to 20 percent of their

[1] https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment
[2] https://www.aapa.org/wp-content/uploads/2017/03/f-833-4-8256527_dk6DMjRR_Prescribing_IB_2017_FINAL.pdf

annual grant award to pay for Food and Drug Administration-approved medications for medication assisted treatment. Reentry grants have been required to provide a plan and implement an overdose prevention program as part of their service delivery for soon-to-be released offenders and those recently released from a correctional setting. These grantees collaborate with community corrections programs, law enforcement, and judges to develop and implement an opioid overdose prevention program. The opioid overdose prevention programs must include an educational component, which includes SAMHSA's Opioid Overdose Prevention Toolkit (https://www.samhsa.gov/capt/tools-learning-resources/opioid-overdose-prevention-toolkit).

SAMHSA provides training on how to implement opioid overdose prevention programs and medication assisted treatment programs for its criminal justice grantees through webinars, on-site technical assistance, trainings, grantee meetings and conferences.
SAMHSA is aware of several department of corrections programs (Rhode Island, Pennsylvania, Massachusetts, Kentucky) who have developed MAT programming, including all three FDA approved medications, with the purpose of improving outcomes and success rates after the individual is released to the community. SAMHSA grantees, regional administrators, and community partners are key links in working with the Department of Corrections to ensure there is a continuum of care, accountability, and support as individuals' transition from incarceration to the community.

The Honorable Frank Pallone, Jr.

1. With 90 percent of addictions beginning in the teenage years, we know there is a critical need for effective drug prevention programming, especially during this current opioid crisis. In the past decade, our national prevention infrastructure has been decimated (including the elimination of funding for the National Youth Anti-Drug Media Campaign) and our ability to educate young people and prevent more teens from becoming addicted is hobbled. We need prevention messages to serve as a counterweight to the proliferation of pro-drug messaging in the media today.

In order to convey the risk of opioid and other drug abuse and reverse the stark addiction and overdose trends that are creating heartbreak in families across the country, investment in prevention messaging is crucial. Regarding Section 102 in CARA- the National Awareness Campaigns provision, can you please tell us what the status of implementation and investment is? What do the various agencies plan to do to move forward with this provision and how can we help?

Response:
The Office of the Assistant Secretary of Public Affairs (ASPA) is coordinating the National Awareness Campaign. There are three components of this Campaign. The Campaign will help to educate Americans across the lifespan to:

- Understand their roles in the opioid crisis;
- Adopt behaviors to prevent opioid medication-sharing; and

- Engage in safe storage and disposal practices.

In addition, the Centers for Disease Control and Prevention (CDC) released the Rx Awareness communications campaign publicly in September. The campaign features real-life accounts of individuals living in recovery from opioid use disorder, and those who have lost someone to a prescription drug overdose. The campaign will increase awareness and knowledge among Americans about the risks of prescription opioids and deter inappropriate use.

2. Press coverage of the response to the epidemic often focuses on expanding access to treatment and increasing the availability of naloxone. However, those are two elements that must fit into a larger, more comprehensive response.

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

Response:
To fully address the opioid crisis, our nation must prevent people from developing a problem by reducing use of opioids and stopping misuse before it develops into a disease state. If an individual does develop an opioid use disorder (OUD), service systems must make sure the individual has access to evidence-based treatment and recovery support services. HHS' five point opioid strategy is designed to cover the entire spectrum and includes:

1) Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response;
2) Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain while also reducing inappropriate use of opioids and related harms;
3) Improve access to addiction prevention, treatment, and recovery support services;
4) Target the availability and distribution of overdose-reversing drugs to ensure broad availability of these medications to people likely to experience or respond to an overdose; and
5) Support cutting-edge research to advance understanding of pain and addiction, lead to the development of new prevention interventions and treatments, and identify effective public health interventions to reduce opioid-related harms.

3. Dr. Volkow and Dr. McCance-Katz I would like to ask you a few questions related to treatment approaches for opioid use disorder. I have been particularly struck by stories of individuals with opioid use disorder and families who have been targeted and referred to low quality and non-evidence-based treatment services. As I'm sure you're aware, in many cases, this has led to tragic consequences upon leaving such programs.

a. Dr. Volkow and Dr. McCance-Katz – I understand that the evidence is clear that medication assisted treatment is the gold standard of opioid use disorder treatment. What are some of the barriers of widespread uptake for this treatment approach?

Response:
The biggest barrier is access to providers who can prescribe or administer the medications. There are not enough providers who are willing and able to treat patients with opioid use disorder. As of April 13, 2018, there are 1,585 Opioid Treatment Programs and over 49,000 waivered prescribers many of whom never prescribe MAT or do not prescribe to their patient limit[3] there is an inadequate supply of providers who can treat individuals with OUD. While any licensed prescriber can administer Vivitrol, the requirement to be medically withdrawn from opioids prior to its administration means that it can be difficult to initiate in an outpatient setting.

The second barrier is knowledge and attitudes. Many parents of young adults report multiple admissions into short term residential treatment settings for their children without ever having been told about medication. Patients and families may not know about medication as an option and medication free treatment programs often do not raise it as a possibility because of misperceptions about utilizing medication to treat certain substance use disorders.

Patients receiving MAT may face discrimination in many systems including in the work place, in criminal justice settings, in child protective settings and others that discourage or mandate that patients not take medication for their OUD.

Finally, difficulty accessing medication by reason of insurer requirements such as prior authorizations and cost can be a barrier for some people.

b. What is the difference between this and other chronic conditions as far as uptake of evidence-based medical care? And could you dispel some of the stigma that exists about the use of medications to treat this chronic condition that doesn't exist for the use of medications to treat like diabetes or heart disease?

Response:
Approximately 20 percent of individuals with opioid use disorder receive treatment for this condition. Fewer than half of private-sector treatment programs offer medications for opioid use disorders. Thus, uptake of treatment and evidence based care is much less than it is for other conditions. SAMHSA continues to work to dispel the stigma regarding use of medications to treat opioid use disorder, but in many communities stigma is ingrained at levels from family members to providers and government officials. More work needs to be done to ensure that patients can access evidence-based care.

c. What are you doing to increase awareness among the general public and the medical community about these evidence-based approaches to opioid use disorder?

Response:
SAMHSA produces a number of publications and tools, and delivers technical assistance for providers and laypersons to increase awareness of medication-assisted treatment (MATx App, PCSS-MAT, toolkits, continuing medical education).

[3] Drug Alcohol Depend. 2017 Dec 1;181:213-218. doi: 10.1016/j.drugalcdep.2017.10.002. Epub 2017 Oct 18.

As required by CARA, SAMHSA is developing a Toolkit for Improving Practice (TIP) replacing two TIPs on medications to treat opioid use disorder (TIP 40, "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction"; and TIP 43, "Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs") with a single TIP that covers all approved medications.

SAMHSA also works with professional associations and consumer groups to inform members and the general public about the evidence for medication assisted treatment.

4. According to SAMHSA's annual survey on drug use and health, in 2016, there were approximately 21 million Americans aged 12 years or older that need substance abuse treatment, however, only around 11 percent or 2.2 million of these individuals received treatment.

a. What are some of the barriers that exists for individuals receiving treatment for their opioid use disorder?

Response:
There were about 2.1 million people with active opioid use disorder in 2016 and about 20 percent of them received some type of treatment. Most people do not seek out care. For those that do, the primary barrier is access to care. In many locations there is no provider, or there are waiting lists to receive treatment. For some people, barriers are resources to pay for treatment or transportation to treatment programs, or other obligations like family and work that make it hard to find time to go through the process of becoming eligible for treatment.

SAMHSA is encouraged by the efforts in some states to reach out to people with opioid use disorder in emergency departments and in community settings to try to engage them in seeking care. Some state programs are guaranteeing immediate access to treatment for people with opioid use disorder who ask community outreach workers, first responders or others for care.

b. I understand that approximately 96% of those who need substance abuse treatment do not believe they need treatment. How can we further increase the likelihood that those with substance abuse disorders understand the need for and their ability to acquire substance abuse treatment?

Response:
Training providers to recognize, screen for, and treat substance use disorders, particularly in primary and general medical settings will assist in identifying more patients with substance use disorder and getting them into appropriate treatment programs.

However, many people with substance use disorders do not access healthcare services of any kind. Many communities are using people in recovery to conduct outreach and engagement activities to encourage more people to enter treatment. These efforts are taking place in emergency departments, in community settings like homeless shelters or areas where people who use drugs may congregate, and in other settings like fire and police stations. In addition,

SAMHSA's Screening, Brief Intervention, and Referral to Treatment (SBIRT) grants encourage the participation of Employee Assistance Programs (EAPs) to provide early identification and support of those with substance use disorders. Currently, an SBIRT grantee is has a targeted initiative to utilize SBIRT in EAPs.

In order to get individuals with substance use disorders to understand that they need help and that help is available, their perceptions about the need for and the benefit of receiving treatment must change. SAMHSA works to increase availability of gender-specific and culturally-appropriate education, prevention, and early interventions, which includes strategies for outreach and engagement. SAMHSA recognizes the importance of providing outreach and other engagement strategies to increase participation in and access to treatment for diverse populations; thus, there is standard language regarding this in SAMHSA's funding opportunity announcements.

5. Dr. McCance-Katz, I am interested in learning more about efforts to expand the substance abuse treatment workforce. I am pleased that Congress and the Obama Administration were able to take steps to expand the workforce and efforts to expand access to buprenorphine by better utilization of the existing health care workforce.

However, we continue to hear that workforce shortages are limiting access to substance abuse treatment.

a. Could you briefly describe the current supply of the substance abuse treatment workforce and how that matches up with the demand for substance use disorder treatment services?

Response:
Many reports have documented the supply and distribution of professionals who oversee the care of persons with substance use and mental disorders. Each report had unique methodologies and occupations that were included. Data exists for psychiatrists, psychologists, advance practice nurses, social workers, licensed professional counselors (substance use disorder and mental health) and other counselors, marriage and family therapists, school psychologists, and to some limited extent on prevention specialists, peer recovery specialists, and psychiatric aides. Information on Drug Addiction Treatment Act 2000 waivered prescribers is also available.

Methodologies used to measure future demand vary, leading to mixed conclusions. However, most studies anticipate worker shortages. With a few exceptions, southern states and several mid-west states have the greatest deficits in psychologists, counselors and social workers. (2013, Health Resources and Services Administration "The U.S. Health Workforce Chart book. Part IV: Behavioral and Allied Health).

The Rural Health Research Center Data Brief (Supply and Distribution of the Behavioral Health Workforce in Rural America, 2016) describes non-metropolitan counties without behavioral health providers, and the large percentage of counties without any of these professionals (psychiatrists - 65 percent; psychologists - 47 percent; psychiatric nurse practitioners - 81 percent).

A report by the SAMHSA Addiction Technology Transfer Centers, "Vital Signs: Taking the Pulse of the Addiction Treatment Workforce, A National Report" (2012, Ryan, Murphy, Krom) reported that annual turnover of direct care staff newly hired in the previous 12 months was 52 percent, and the previous 12-month turnover for all staff (new and more than 12 months) was 18.5 percent. The report concluded that high turnover rates add to provider training and recruitment costs and could threaten the quality of care received by clients entering treatment. Retention of staff is an important consideration impacting supply and distribution of staff.

SAMHSA and the Health Resources and Services Administration implement congressionally mandated programs to address workforce shortages. All of the programs aim to provide training fellowships/scholarships and loan repayment programs to students pursuing health professions, some that are specific to behavioral health and others that are for primary health care providers who could provide care in an integrated health care setting. These programs are all primarily aimed at addressing the supply and distribution issues. The Minority Fellowship Program managed by SAMHSA also addresses the supply issue for Fellows working with underserved populations.

As we learn to more effectively engage people in treatment and begin to better address barriers to care, such as stigma and misunderstanding, fragmentation of services, and insurance limitations, the need for a qualified and stable workforce will grow.

b. Could you talk about some of the barriers that prevent students and health care providers from pursuing careers in the treatment of substance use disorder specifically and behavioral health more generally?

Response:
There are several barriers that, combined, make it difficult to encourage students and health care professionals to become behavioral health (substance use and mental health treatment) providers.

1. Stigma – There remains a great deal of stigma toward individuals with substance use and mental disorders. There is still the idea that individuals with behavioral health conditions can "pull themselves up by their bootstraps" and not a very good understanding that these are neurobiological disorders.
2. As with other chronic disorders, it can be frustrating to see the struggles and not the success in treatment in many instances.
3. Reimbursement – In comparison to many other fields in health care – professionals who treat behavioral health conditions do not make as much money as their counterparts who treat physical health conditions and are not reimbursed at the same rates for comparable work, a factor that likely drives much of the field's challenges around workforce turnover.

c. What can we do to encourage more health professional students and health care providers to pursue these type of careers?

Response:

1. Encourage opportunities to meet with observe and interact with persons in successful sustained recovery.
2. Encourage opportunities to have rotations in behavioral health treatment settings.
3. Loan repayment programs for persons that work in behavioral health.
4. Consider the incorporation education about treatment of behavioral health conditions in undergraduate and graduate medical education curriculum as well as in the curricula of other healthcare professions (nurses, nurse practitioners, physician assistants, pharmacists, psychologists, social workers, medical assistants, etc.).
5. Encourage the modernization of behavioral health treatment facilities through technology, telemedicine follow up and use of interactive applications that engage persons over time.
6. Education to "normalize" these brain disorders. These are physical disorders of the brain not "mental disorders."
7. Examine issues regarding professional re-imbursement.
8. Foster greater integration and coordination with broader health systems so that behavioral health generally and substance use disorder in particular, begin to be viewed as standard components of health care systems.

6. Much of the discussion last year in the lead up to the passage of CARA focused on the overprescribing of prescription drugs. As the epidemic has continued to evolve, we understand that heroin and synthetic opioids like carfentinil are playing an increasing role in overdose deaths across the country. I'm interested in learning more about how this evolution in the epidemic is changing our response.

a. How is the increased use of heroin and increase in synthetics, such as carfentinil affecting our response?

Response:
SAMHSA is updating its publications on addressing opioid overdose awareness and response to ensure first responders and laypersons are aware of the nuances between traditional opioids and synthetics such as carfentanil.

SAMHSA's grantees are providing additional patient education on the potential for synthetics infiltrating other opioids.

Further, treatment programs are beginning to administer greater patient education and dissemination of naloxone products within treatment programs. In addition, NIDA is funding research to address the issue that multiple doses of naloxone are sometimes needed to revive individuals who have taken high-potency, synthetic opioids like fentanyl and carfentanil. In the future, stronger formulations of naloxone would help to ensure that overdoses from powerful synthetic opioids can be effectively reversed when administered in time.

The great risks associated with fentanyl and its analogues create greater urgency to ensure people are able to access medication assisted treatment in a timely manner, leading to more efforts to engage patients in emergency departments, community settings where people use, and needle exchange programs. SAMHSA is working with states to ensure programs are able to triage patients and provide immediate access to care for people with opioid use disorder, particularly those that use illicit opioids.

b. How has this change affected our response?

Response:
We know that many people will need multiple doses of naloxone in order to be revived, so we are training first responders about the changes that are occurring. We also know that fentanyl analogues can and are being combined with drugs other than opioids, so we are warning first responders that people known to use other drugs may still have overdosed on fentanyl. This is important for first responders both in terms of how they approach the patient but also in terms of their own safety.

Finally, because the risk of death is so high, we are working with states to increase their outreach and engagement activities to get active users into treatment quickly and ensure that treatment is available to people at high risk on demand. We are providing training and technical assistance to states on implementing outreach models and changing treatment practices to permit triage and rapid admission instead of lengthy admissions processes that create bottlenecks in access to care.

c. Are there specific approaches that we should be considering to combat this change in the epidemic?

Response:
Yes, those approaches include:

1. Ensuring adequate availability of naloxone;
2. Beginning treatment when people are in emergency departments or other parts of a hospital for opioid use related causes (infections, overdose, etc.) or are otherwise identified as having an OUD;
3. Access to treatment on demand through active community outreach by peer counselors or via drop in centers at fire (e.g., Safe Stations) and police stations (e.g. Angel Initiative/PAARI); and
4. Ensuring access to medication assisted treatment rather than relying on detoxification and/or residential treatment which are less effective and associated with an elevated risk of overdose if medication is not provided post-detoxification (extended-release naloxone may be used following completion of detoxification) or as part of residential treatment, including as part of continuing outpatient treatment: Opioid use disorder is a chronic disease that requires ongoing disease/recovery management and is not appropriately treated through short episodes of detoxification episodes or inpatient/residential treatment.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 17, 2017

Dr. Anne Schuchat
Principal Deputy Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Schuchat:

Thank you for appearing before the Committee on Energy and Commerce on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

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

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

CDC QFRs
Energy and Commerce Committee
Hearing
Federal Efforts to Combat the Opioid Crisis: A Status Update
on CARA and Other Initiatives
October 25, 2017

Questions for the Record
Dr. Anne Schuchat, Principal Deputy Director, CDC

The Honorable Michael C. Burgess

1. **The CDC has spoken about the "hidden causalities" of the opioid epidemic in regards to the rise of infectious diseases due to injection drug use. What further can be done to reduce the harms and health care costs associated with the crisis?**

   Answer:

   A comprehensive, multi-sectoral approach is needed to prevent infectious diseases attributed to opioid use disorder which includes:
   - Collaboration at the community level between public health, law enforcement, healthcare, education, substance use treatment providers, housing services, and faith-based stakeholders.
   - Coordination across multiple levels of the U.S. health care system.
   - Implementation of tailored community-based prevention services which include, but are not limited to, testing and treatment for infectious diseases including HIV, hepatitis B, and hepatitis C; provision and disposal of sterile injection equipment (where legal and consonant with community support); provision of naloxone and overdose prevention training; and provision of or referral to addiction treatment and mental health services, including medication-assisted treatment.

   Does the agency have appropriate authorities to respond to the rise of these infectious diseases?

   Answer:

   Authorities granted to CDC under the Public Health Service Act (PHSA) allow for wide-ranging prevention and response activities. Additionally, the Department of Health and Human Services is undergoing a department-wide process to identify what authorities or changes in statute would be helpful to combat the opioid crisis.

2. **The Washington Post has reported on the "rampant spread of Hepatitis C" due to the opioid abuse epidemic. Are we doing a sufficient job identifying those with HCV or HBV and linking them to care?**

   Answer:
   Rates of viral hepatitis have risen steadily, tripling between 2010–2015, mirroring the opioid crisis with young, white Americans in rural communities hit the hardest—but, few communities in the nation have been spared. Currently, only about half of people living with HCV and HBV know they are infected. Because of this and other obstacles, hundreds of thousands of Americans with viral hepatitis who would benefit from treatment have not yet received it.

   CDC's infectious disease programs provide an established, nationwide network asset that can be strengthened to prevent transmission of infectious diseases and link drug users to care. CDC's viral hepatitis disease monitoring activities is limited to 14 U.S. states.

3. **The CDC estimated that the total "economic burden" of opioid abuse is $78.5 billion per year—given the increases in Hepatitis and HIV associated with addiction does this number include concomitant infectious diseases of abusers and then others infected, as well as long term treatment?**

   Answer:

   The 18-month study from which this cost estimate arose calculates overall healthcare costs for those with substance use disorder but does not does not fully capture the economic burden of infectious disease stemming from the opioid crisis. To estimate the lifetime burden from infectious diseases, additional analyses of healthcare costs of heroin use, HIV, and viral hepatitis treatment, and productivity and quality of lives lost to opioid use disorders would be required.

4. **We know that having a better understanding of the epidemic, including where it's hitting Americans the hardest, and why, is essential to building upon and improving the current federal government response. How can we improve the timeliness of data on opioid use and abuse while also maintaining quality of data?**

   Answer:

   The timeliness of mortality data reporting in general has improved significantly over the past few years with over 50 percent of deaths now being reported to CDC within 10 days of the death. However, deaths involving drugs continue to be among the slowest deaths to be reported. A recent CDC analysis of the timeliness by cause of death showed that, on average,

over 80 percent of all deaths had been sent to CDC within 13 weeks (about three months) of the death, but less than 40 percent of drug overdose deaths had been sent. This is due largely to the need for toxicology testing. For drug overdose deaths, an important component of data quality is accurate reporting of the specific drugs involved on the death certificate and this is dependent on toxicology and medical examiner and coroner capacity. The single most important thing that could be done to improve the timeliness of data on opioid involved death reporting would be to improve the timeliness of conducting toxicology testing. To do this, it is necessary to strengthen the capacity within offices of medical examiners and coroners, and forensic toxicology labs. The major limiting factors in reducing the drug death data reporting lag are the timeliness and variability of death investigation in offices of medical examiners and coroners, and toxicology practices across the country. Medical examiners and corners rely on ancillary tests, specifically toxicology, to determine the cause of death. Many of the state labs that provide postmortem forensic services to the medical examiner and coroner community are under-resourced and have long delays. In addition, many rural counties must transport decedents long distances to the nearest regional site and incur additional costs for coroner and law enforcement personnel who attend the autopsies. Support for these labs and other capability enhancements could help, along with increased support for medical examiners and coroners to address the timeliness, quality, and reporting process for postmortem toxicology results.

Greater Standardization of Procedures is also necessary. Performance of state vital records vary significantly across the country. It is important to establish and implement minimum performance standards in improving the timeliness and quality of mortality vital statistics and a process for ensuring that states sustain themselves at that minimum level. CDC is partnering with the Public Health Accreditation Board to currently beta test draft performance standards for improving the timeliness and quality of mortality statistics. In addition, collaboration with the ME/C community is needed to develop death scene investigation protocols for drug overdose deaths as well as standard practices for ME/C and has a real impact on their practice.

Finally, it is important to enhance the Workforce.

Beyond providing resources to strengthen death investigation and toxicology, Medical Examiners and Coroner offices need more resources, including trained personnel, especially trained medicolegal death investigators and forensic pathologists, to meet the increasing demands from the increased number of drug overdose deaths.

To create a more comprehensive picture of opioid overdose deaths to inform prevention and response efforts, CDC is also working to build state capacity and to provide scientific expertise to assist states in improving the timeliness of data for both fatal and non-fatal overdoses through CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program. In its first programmatic year, CDC funded 12 states to: 1) Improve the timeliness of reporting of nonfatal opioid overdoses using Emergency Department (ED) and Emergency Medical Services (EMS) data; 2) Improve the timeliness of reporting of fatal opioid overdoses and associated risk

factors so that these data can be used to inform public health response tactics within and across states; and 3) Disseminate findings to stakeholders to support prevention efforts. With the increase in funds appropriated to CDC in Fiscal Year 2017, CDC was able to expand the ESOOS program to fund an additional 20 states and Washington, D.C. (for a total of 32 states and Washington, D.C.). CDC also was able to provide supplemental funds to all ESOOS-funded states, with the expectation that a minimum of 60 percent of the supplemental funds were to go to medical examiners/coroners to primarily support comprehensive toxicology testing of opioid-involved deaths. One particularly novel and innovative component of this program is the use of emergency department (ED) and emergency medical services (EMS) data to track and analyze nonfatal overdose data. These data aid states in identifying "hot spots" or areas with emerging drug overdose clusters so prevention efforts can be targeted quickly.

ESOOS-funded states leverage CDC's National Violent Death Reporting System (NVDRS) platform to collect data on all unintentional or undetermined intent opioid overdose deaths under a module entitled the State Unintentional Drug Overdose Reporting System (SUDORS), which uniquely captures detailed information on toxicology, death scene investigations, and other risk factors that may be associated with a fatal overdose. For instance, SUDORS data have identified and tracked large increases in fentanyl analog deaths driven by carfentanil within one state's borders. Early findings from these data, again, reinforce the need and urgency for more timely and comprehensive toxicology testing.

CDC published a *MMWR* Early Release and a Vital Signs report in March using ESOOS data which will be the timeliest data CDC has published to date on drug overdoses- approximately within 2 months of publication.

CDC, in partnership with March of Dimes, is working to protect mothers and babies though a pilot project in Illinois, New Mexico, and Vermont to explore approaches for improving the speed and accuracy of surveillance of Neonatal Abstinence Syndrome (NAS). Data report there is about one baby born every 25 minutes affected by opioid withdrawal. Surveillance of NAS is important to inform a public health response that can quickly identify areas of need and target interventions to improve outcomes for these babies by connecting mothers to services and care. These pilot projects are also evaluating the health services needed through their first birthday, which will help prepare the health system to care for these babies.

The Honorable Joe Barton

1. **The techniques for managing acute pain are different from the techniques for managing chronic pain. In fact, some specialties, like dentistry, rarely (if ever) have to treat patients for chronic pain. Even the types of opioids that would be prescribed—long acting versus short acting—are different. The CDC guideline and the current FDA REMS strategy have both focused on managing chronic pain, but what are you doing to help promote more judicious prescribing among those who are not in the business of managing chronic pain?**

Answer:

Although the CDC Guideline focuses on the use of opioids to treat chronic pain, it does provide some guidance in the treatment of acute pain. Recommendation 6 in the Guideline states that long-term opioid use often begins with acute pain treatment, and when treating acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed. More than a few days of exposure to opioids can significantly increase hazards and increase the likelihood of dependence.

In addition, the CDC has released several resources for patients for the treatment of acute pain. These include:

- *What You Need to Know* outlines the differences between acute and chronic pain and also the facts that a patient needs to know when prescribed opioids for acute pain management.
- *Get the Facts* is an infographic that highlights important information about acute pain management for common conditions and injuries.
- *Opioid Overdose Tip card* is about preventing an overdose generally. It is also featured on our acute pain materials tab on the CDC website.
- Clinician Commitment Poster to Patient Prescription Safety [PDF – 2 MB] also addresses acute pain.
- Continuing Medical Education credits are being offered to healthcare providers for the training on the opioid guidelines.

The National Safety Council is also sponsoring a systematic review of the evidence related to the management of acute musculoskeletal pain. The evidence review is currently underway by McMaster University and is expected to be completed by December 2018. A full guideline will follow, developed jointly by the American College of Physicians and American Academy of Family Physicians. A CDC representative serves on the technical review advisory panel for this effort.

2. **What are you doing to promote the delivery of preventive services that help to control acute pain and stop such pain from becoming chronic?**

Answer:

CDC's Guideline provides guidance for the treatment of acute pain (see Recommendation 6 described in the above response to question #1). In addition, CDC will serve on the technical review advisory committee for an acute pain guideline (see NSC work described above in the response to question #1). We also have released several communications materials

(referenced in the above question) that are supporting the delivery of preventive services. Finally, CDC's work through our funded states encourages the uptake and implementation of the CDC Guideline, which includes recommendations regarding acute pain management with opioids.

The Honorable Gus Bilirakis

I recently learned about a new initiative from the health insurance industry called the STOP Initiative that will help plans measure how individual providers in their networks are adhering to CDC guidelines for prescribing opioids for chronic pain using claims data to quantitatively track from results. It is my understanding that this is the first industry-wide initiative that will help to measure these guidelines.

1. **Can you please describe these measures and what they seek to do?**

Answer:

America's Health Insurance Plans (AHIP) launched its Safe, Transparent Opioid Prescribing (STOP) Initiative, which is designed to support widespread adoption of clinical guidelines for pain care and opioid prescribing. The STOP Measure will be shared widely with health plans and initial results will be gathered throughout the coming months. As experience is gained, the initial version of the measure will be updated, revised, and validated. As part of the overall STOP Initiative, AHIP and an opioid work group will continue to introduce best practices as the health care industry works together to combat the opioid epidemic.

The CDC was not engaged in the development of these measures included in STOP. However, CDC was made aware of these efforts by individuals representing AHIP. Based on information shared by AHIP with CDC, the four measures include: 1) Percentage of immediate-release opioids versus percentage of long-acting/extended-release opioids; 2) Percentage of opioids prescribed concurrently with benzodiazepines; 3) When and how often urine drug tests are performed for patients on opioid therapy; and 4) Dosage and days supply of opioid prescriptions. CDC perceives these four measures to correspond broadly to a few of the 12 recommendations enumerated in the CDC Guideline. An initial assessment is that use of these measures may hold potential to track concordance with elements of the CDC Guideline at minimum. This voluntary initiative was launched on October 19, 2017, so it is too early to see the results.

2. **From your perspective, do you think this type of initiative is something that will help move the needle on the opioid epidemic?**

Answer:

While CDC cannot speak to the efficacy of this effort in particular given our cursory knowledge of this initiative, CDC is supportive of the development and use of measures to assess and encourage adherence to clinical recommendations, as well as to promote quality improvement efforts. Certain insurers are developing similar measures. CDC has been considering how to assist in coordination of this effort so that consistent measures can be developed. AHIP, as the association of some individual insurers/plans across the nation, is heading in this direction, which is noteworthy.

3. **Do you think more efforts like this are needed to generate tangible results when it comes to adoption of these guidelines?**

Answer:

CDC is supportive of a comprehensive approach to operationalize and evaluate the recommendations contained in the Guideline to change the culture of clinical practice. One means for doing so is with efforts like the STOP Initiative. Under the STOP Initiative, AHIP has launched the STOP Measure, an evidence-based methodology health plans can use to measure how provider practices compare to the Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain. This measurement aims to help health plans and providers collaborate to improve adherence with the CDC guidelines, thereby improving patient safety and reducing the risk of opioid misuse. CDC is supportive of the development and use of measures to assess and encourage adherence to clinical recommendations, as well as to promote quality improvement efforts.

To encourage uptake and use of the Guideline, CDC developed a comprehensive implementation plan to move science into action. Since health care systems have the potential to improve pain management including safer use of opioids through guideline concordant care on a broad scale, CDC engaged external stakeholders to develop Quality Improvement (QI) measures based on the Guideline. These are voluntary QI measures intended to support practice improvement for primary care practices by tracking opioid prescribing and providing feedback to clinicians through a data dashboard. CDC is recruiting large health care systems in which to pilot implementation of the QI measures, track their progress, and to be part of a 12-month Opioid QI Collaborative.

CDC's QI-related work is one component of its overarching Guideline implementation strategy. Broadly stated, CDC's Guideline implementation effort is comprised of the following: 1) Communication and Dissemination; 2) Clinical education and training; 3) Insurer and Pharmacy Benefit Manager Strategies; and 4) Health System Strategies.

Another way to improve uptake is to integrate the guideline into electronic health records (EHRs) or clinical decision support tools. CDC is collaborating with the Office of the National Coordinator to integrate Guideline recommendations, such as alerts for Morphine Milligram Equivalent (MME) thresholds, defaults on prescribing amounts for the initiation of opioids and

prompts to check the PDMP, into EHRs. This work was piloted in three hospital systems (Yale New Haven Hospital, Carolinas Medical Group, and Houston Medical) and is currently being evaluated. The Carolinas HealthCare System successfully built an EHR alert to address opioid prescribing by providing critical information at the point of care. The following five objective criteria available in the EHR were programmed to "trigger" the alert: three or more prescriptions for an opioid in past 30 days; two or more onsite administration of opioids in past 30 days; current prescription with 50 percent or more remaining ("early refills"); previous presentation for opioid overdose; and positive blood alcohol content or toxicology screen for cocaine or marijuana.

The Honorable Chris Collins

1. **As PDMPs have evolved in recent years, incorporating PDMP data into a prescriber or pharmacist's clinical workflow seems to be the key to ensuring that the data is used effectively while also increasing efficiency and saving time for providers. What are the barriers currently preventing more states from incorporating PDMP data into clinical workflow?**

   Answer:

   Two main barriers are the costs and the lack of capacity (skilled staff) to implement the software.

   A PDMP must also be easy to access, and the data must be accurate and timely.
   The most helpful, and arguably the most important, feature of a PDMP-EHR integration platform is ensuring that patient data is displayed in a simple and organized manner. Clinicians do not want the PDMP data to be a simple laundry list of prescriptions that are not necessarily itemized by date. A well-built PDMP-EHR integrated platform provides the clinician/end user with PDMP data within clinical workflow in an easily accessible and readable format. Another helpful feature are the flags/alerts. Integrated PDMP-EHR platforms that provide clinicians/end users with easily accessible and organized data presented in clear manner with guideline concordant alerts/flags would facilitate increased PDMP use and informed clinical decision making.

2. **We know that the "moment of clarity" when a patient realizes they need to go into treatment can be short-lived, and having resources in place to immediately connect patients to treatment is critical to the chances of recovery. When a PDMP does indicate a patient has been "doctor shopping" and potentially has a substance use disorder, what policies are in place to direct them to treatment if they wish to go? If none exist, how could we help encourage them to access treatment at that time?**

Answer:

CDC's Prevention for States (PfS) program requires states to implement community-based or insurer interventions. In addition, states have the option to undertake evaluations of state policies or a rapid response project to address the rapidly changing epidemic.

The best practices CDC has seen thus far are strategies to encourage referrals at the site of overdose reversal treatment and directing them to services.

States have taken these opportunities to implement a variety of initiatives that support individuals suffering from substance use disorder and encourage them to access treatment. One example is the work of Maryland's PfS team. Maryland has a community-based intervention, the Overdose Survivors Outreach Program (OSOP), that enhances the hospital Screening, Brief Intervention, Referral to Treatment (SBIRT) model in six Baltimore city hospitals by adding community peer outreach post-discharge. These peer recovery specialists will conduct outreach to overdose survivors from 4 hospitals that have implemented SBIRT. In addition, some PDMP platforms are developing tools that integrate the CDC guidelines into their platforms. These platforms create easy-to read reports for clinicians to use to assess patients risk factors and needs. In addition, these platforms are integrating alerts for patients in need of MAT treatment to local MAT treatment facilities.

3. **Some states such as Massachusetts have started using data as a weapon in the fight against opioids. They are combining data from prescription records, death records, medical examiners... even prisons. For example, they found that a person who is released from jail in Massachusetts has a 56 times greater chance of dying from an overdose than the average person. They are using that information to make better policy decisions, as well as to identify specific individuals who are in need of services. States are supposed to be the laboratories of democracy. What has the CDC learned from states in their use of data analytics? Is there a plan to use data to fight the opioid crisis?**

Answer:

Strengthening our understanding of the crisis through better public health data and reporting is an HHS priority and included in the Department's 5-point strategy to combat the opioid epidemic. Surveillance and data are key components in informing a public health response to the opioid epidemic and can come from multiple sources, such as a PDMP, vital records, or emergency departments. Linking and analyzing data from these sources can help provide the best understanding of how the opioid crisis is affecting states.

One means to shore up state capacity and to provide the needed level of scientific expertise to assist states in these efforts has been the creation of CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program. In its first programmatic year (2016), CDC funded 12 states to: 1) Improve the timeliness of reporting of nonfatal opioid overdoses using Emergency Department

(ED) and Emergency Medical Services (EMS) data; 2) Improve the timeliness of reporting of fatal opioid overdoses and associated risk factors so that these data can be used to inform public health response tactics within and across states; and 3) Disseminate findings to stakeholders to support prevention efforts.

The program collects data on fatal opioid overdoses through the State Unintentional Drug Overdose Reporting System (SUDORS), which uniquely captures detailed information on toxicology, death scene investigations, and other risk factors that may be associated with a fatal overdose. For instance, SUDORS data have identified and tracked large increases in fentanyl analog deaths driven by carfentanil within one state's borders. Early findings from these data reinforce the need and urgency for more timely and comprehensive toxicology testing.

ESOOS also improves innovative strategies around morbidity data, using EMS and ED data to provide a comprehensive picture around non-fatal opioid overdoses. The use of this data can act as an early warning system to detect sharp increases or decreases in overdoses. In addition, this data can help inform where more resources, such as naloxone or treatment capacity, are needed.

The initial cohort of 12 states began program implementation on September 1, 2016, and CDC will rapidly disseminate findings as states provide data. The first report of ESOOS mortality data, "Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700—10 States, July—December 2016," was published as a *Morbidity and Mortality Weekly Report (MMWR)* Early Release on October 27, 2017. States completed data reports by August 31, 2017, and CDC published it less than two months later.

With the increase in funds appropriated to CDC in Fiscal Year 2017, CDC expanded the ESOOS program to fund an additional 20 states and Washington, D.C., for a total of 32 states plus D.C. CDC also was able to provide supplemental funds to all ESOOS-funded states, with the expectation that a minimum of 60 percent of the supplemental funds were to go to medical examiners/coroners to primarily support comprehensive toxicology testing of opioid-involved deaths.

States are also leveraging PDMP data to inform public health prevention responses around safer prescribing. Linking PDMP data to an electronic health record can help facilitate safer prescribing at the point of care. In addition, PDMP data can also help identify high prescribing counties or localities in need of provider education, specifically academic detailing.

In addition to more timely data, the ability to leverage data sources across agencies is beneficial in creating a full picture of the opioid overdose crisis. CDC is working with DEA to find ways to use law enforcement data to improve public health interventions. For example, DEA data available through the National Forensic Laboratory Information System (NFLIS), were used during a 2015 Epidemiological Assistance, or Epi Aid, in which CDC scientists responded to a request from the state of Ohio to assist in examining the ongoing increase in unintentional

fentanyl-related overdose deaths in their state, elucidate the population most at risk, and inform their public health response. In part, the Epi Aid explored whether changes in law enforcement fentanyl drug reports (from NFLIS) could be used to estimate trends in fentanyl-related mortality. In analyzing data on fentanyl drug reports and fentanyl-related deaths, it was found that changes in reported fentanyl drug reports were predictive of changes in fentanyl-related deaths in Ohio, especially in 2014 as the epidemic began.

States are at the forefront of using data to understand Neonatal Abstinence Syndrome (NAS). CDC, in partnership with March of Dimes, is working to protect mothers and babies through a pilot project in Illinois, New Mexico, and Vermont to explore ways to estimate the prevalence of NAS and support infants affected by NAS in the first year of life. Surveillance of NAS is important to inform a public health response that can quickly identify areas of need and target interventions to improve outcomes for these babies by connecting mothers to services and care. These pilot projects are also evaluating the health services needed through their first birthday, which will help prepare the health system to care for these babies. CDC, in partnership with March of Dimes, is supporting the Tennessee Department of Health in first look at the impact NAS may have on educational needs and services for children in the United States. It links Tennessee Medicaid (TennCare) and birth certificate data to Tennessee Department of Education data tracking special education outcomes during early childhood (3–8 years of age). Preliminary findings indicate children with a history of NAS were significantly more likely to: 1) be referred for evaluation of an educational disability, 2) meet criteria for a disability, and 3) receive therapies or services.

The Honorable Buddy Carter

1. **What type of education is available, or should be available, to providers on evidence based prescribing and clinical strategies for abuse-deterrent opioids and understanding when to prescribe immediate release (IR), extended release (ER), and long-acting (LA) opioids?**

Answer:

The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain addressed the use of abuse deterrent opioids, noting that "As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (190), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations." At this time, there is limited evidence to support use of specific

abuse deterrent opioids. Better evidence of benefits of abuse deterrent opioids is needed to inform education and training for providers.

For extended-release/long acting (ER/LA) opioids, multiple trainings have been made available as part of FDA's Risk Evaluation and Mitigation Strategy (REMS) for ER/LA Opioid Analgesics, approved in 2012. These trainings were provided using unrestricted funds from opioid manufacturers. One example of a high-quality training produced for this REMS was Boston University's SCOPE of Pain.

CDC offers free continuing education training on opioid prescribing for providers, including a webinar series and interactive online modules. A lecture on "Dosing and Titrating Opioids" in the webinar series addresses appropriate use of IR and ER/LA opioids. Other content in the webinar series and online modules addresses related topics including how to assess when benefits of opioids are likely to outweigh risks, nonopioid treatments for pain, and how to communicate with patients about opioid use.

The Honorable Pete Olson

1. **Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)? Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?**

Answer:

CDC did not receive any funding through CARA. While CDC does fund states for improvements to PDMPs via the Overdose Prevention in States program, this was not through CARA.

Funding to states is critical to enhance PDMPs, which includes making them real-time, actively managed, and easy to use and access.

2. **How does CDC work with federal partners, specifically law enforcement and public safety partners such as the DEA and ONDCP?**

Answer:

CDC works closely with our Federal partners including the DEA and ONDCP to combat the opioid epidemic. CDC embedded a public health analyst within DEA for one year to better inform collaborative efforts and to assist in learning the cultures of each field, which can help increase communication across agencies. Within this personnel exchange, it was particularly useful to learn of and share information about the data sources that each agency uses. As a result of this personnel exchange, DEA and CDC established a data-sharing request process for

National Forensic Laboratory Information System (NFLIS). Although DEA publishes annual and semi-annual NLFIS reports to its website for public viewing, prior to this agreement, the sharing of raw data with CDC had been inconsistent DEA and CDC are currently in the process of establishing a formal data and information-sharing agreement. CDC and DEA are working together to find ways to use law enforcement data to improve public health interventions. DEA data systems, such as NFLIS, can act as an early warning system for potential outbreaks or sharp increases in overdoses.

As an example, NFLIS data were used during a 2015 Epidemiological Assistance, or Epi Aid, where CDC scientists responded to a request from the state of Ohio to assist in examining the ongoing increase in unintentional fentanyl-related overdose deaths in their state. In part, the Epi Aid explored whether changes in reported fentanyl drug-seizure rates (from NFLIS) could be used to estimate trends in fentanyl-related mortality. In analyzing data on fentanyl-related seizures and fentanyl-related deaths, it was found that changes in reported fentanyl-seizures were predictive of changes in fentanyl-related deaths in Ohio, especially in 2014 as the epidemic began.

CDC also works with ONDCP to address the regional nature of the opioid epidemic by collaborating on the Heroin Response Strategy (HRS) under the High Intensity Drug Trafficking Areas (HIDTAs) program, which is funded by ONDCP. The HIDTA HRS leverages strategic partnerships to target the organizations and individuals trafficking deadly drugs like heroin and illicit fentanyl so that overdoses are reduced and lives are saved. The HRS currently coordinates the efforts of 10 regional HIDTAs across 22 states. The HIDTA HRS is a collaborative public health/public safety model focused on coordinated data-driven approaches to reduce opioid overdose deaths.

CDC scientists, working with HIDTA law enforcement experts, manage project planning and development for the HRS, which includes:

- Program and communications systems
- Program evaluation
- Initiative-wide project implementation
- Regional coordination of Public Health Analysts

In addition, CDC partners with the HIDTAs to manage the Public Health and Public Safety Network, which includes a public health analyst (PHA) and a drug intelligence officer (DIO) in each of the 22 states the HIDTA HRS covers. PHAs work collaboratively across sectors and agencies within each state to gather, analyze, and distribute drug-related public health data; develop and support data-driven policy and programming initiatives; facilitate interagency collaboration; and advance efforts in surveillance, treatment and prevention initiatives within their state. They bring a public health perspective to law enforcement efforts, and enhance public health efforts with law enforcement intelligence and relevant data.

One of the projects conducted under the HIDTA HRS is the Good Samaritan Project, which assesses law enforcement knowledge of and perspective about Good Samaritan laws (laws that offer legal protection to people who give reasonable assistance to those who are, or who they believe to be, injured, ill, in peril, or otherwise incapacitated) within their state, which is one of the strategies implemented as means to prevent drug overdose fatalities.

Also, in support of this work, CDC has partnered with ONDCP to invest $2 million to support the piloting of community-level initiatives to further efforts to address the opioid epidemic in partnership with regional HIDTA programs. Under this initiative, 13 grants have been awarded in 10 different states to support implementation of innovative strategies within a targeted geographic area with the aim of building the evidence base for response activities that other communities can employ.

Projects address topics such as post-overdose strategies to link people to care using patient navigators and recovery coaches; justice-involved populations and access to MAT; pre-arrest diversion; buprenorphine induction in the ED; neo-natal abstinence syndrome; and adverse child experiences.

The Honorable Susan Brooks

1. **I have heard you say that preventing drug use before it begins is the most cost effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?**

Answer:

To respond to and curtail the opioid crisis, CDC applies scientific expertise and centers activities on surveillance and implementation of public health strategies, which includes addressing inappropriate prescribing of opioids as a key driver of the current epidemic. Given the levers that exist at the state-level, through its Overdose Prevention in States effort across three programs, CDC is partnering with 45 states and Washington, D.C., to provide resources and scientific expertise to maximize those levers with a specific focus on using data to drive action and preventing people from getting addicted in the first place through safer prescribing. Some of the key prevention aspects of our program are:

1. maximizing the use of state Prescription Drug Monitoring Programs as both a public health surveillance and clinical decision support tool;

2. implementing community and insurer interventions to have the biggest impact on populations;

3. evaluating state-level policies in place to continue to build the evidence base for strategies that hold promise. Underlying success in these endeavors is strong collaboration across different entities within the state to support a multi-sector response to this complex issue.

Through these efforts, CDC has established strong partnerships with public health entities in the vast majority of states. In CDC's estimation, however, the next critical step to address existing barriers is to establish and strengthen efforts at the local level as well. CDC has learned from our funded states that the manifestation of the epidemic differs within different regions of the same state. While in some regions overdoses from prescription opioids are the primary concern, in others it is overdoses from illicit opioids. Given this, a suite of resources and response interventions applicable at a local level are needed. CDC currently is in the initial stages of developing a suite of interventions that localities can choose from to quickly implement a response based on the needs presented. CDC is partnering with the National Association of County and City Health Officials (NACCHO) to assess resources available, develop tools that address gaps, and to evaluate implementation of these strategies at the local level. In addition, CDC is working closely with HIDTA partners in 22 states to implement and evaluate pilot projects across a variety of communities to grow the evidence base about what works in real-world settings. Ongoing gaps that exist include tailoring local interventions that yield efficacy within the context of rural and tribal communities in particular. Both communities possess underlying challenges that are distinct from other regions; therefore, the need exists to assess and promote tailored public health response strategies to benefit these populations. In addition, an important component of prevention should be primary prevention among youth to stop the trajectory toward use in adulthood. CDC data suggest that the middle- school years present a strong opportunity for intervention. While it can be difficult to bridge education and public health agencies, CDC has experience in successfully supporting these connections to address health risks And works to implement health education, youth development, and screening and referral activities in schools to address high-risk behaviors such as substance use.

Finally, CDC is collaborating with other components of HHS and with other Federal agencies to prevent drug use before it begins by addressing pain management. CDC is working on the HHS National Pain Strategy (NPS) Implementation Steering Committee, which is working to improve pain management in the U.S. using the strategies laid out in the NPS.

The Honorable Markwayne

1. **According to the CDC, Native Americans have the highest rates of both opioid overdose deaths as well as HCV-related deaths. Does your department engage with these populations around risk factors associated with opioid abuse, including the spread of infectious diseases such as HIV and HCV? Do you currently have the ability to help tribal and public health systems develop programs to alert providers of care for opioid abuse to also test for concomitant infectious diseases and provide a pathway to treatment? Are you engaging in these activities currently, if so, can you please elaborate on these efforts and provide any**

findings on the results? How could we strengthen the our public health system infrastructure to better respond to the opioid epidemic and its long term health consequences?

Answer:

CDC collaborates with states, counties, local, and tribal communities, as well as with the Indian Health Service (IHS), to prevent opioid overdoses and related harms. CDC has the ability to support tribal health programs via CDC's work with U.S. states. CDC does not currently directly fund tribal governments; however, funding awards for CDC's HIV prevention efforts stipulate that states must address and collaborate with tribal communities in their jurisdictions.

CDC is working with IHS on an analysis of existing data sources that may inform IHS about regions and counties at potential risk for spread of HIV and HCV infection associated with injection drug use, in order to identify priority localities for HIV and HCV prevention and harm-reduction interventions. CDC is also providing technical assistance to the Cherokee Nation to optimize care and move toward eliminating HCV among American Indians in the Cherokee Nation Health System. This includes supporting the planning, implementation, monitoring, and evaluation of efforts to bring together a coalition of public health, clinical care, and academic medicine partners. Successful completion will not only improve the health of the Cherokee Nation, but also inform similar programs to move toward eliminating HCV infection in other American Indian and non-American Indian populations. In 2015, a five-fold increase in testing occurred, from 3,337 persons initially tested to 16,772 in the Cherokee nation. Additionally, screening for Hepatitis C virus in the Indian Health Service, reports an increase in testing from 8% to 33 percent nationwide among American Indian/Alaskan Native populations between 2012 and 2015.

The Honorable Gregg Harper

1. **CDC recently launched a communications campaign. Can you tell us about the campaign and how it is being rolled out?**

Answer:

CDC publically released the Rx Awareness communications campaign in September. The campaign features real-life accounts of individuals living in recovery from opioid use disorder, and those who have lost someone to a prescription drug overdose. The campaign will increase awareness and knowledge among Americans about the risks of prescription opioids and deter inappropriate use. CDC is running digital, radio, and out-of-home campaign ads for 14 weeks in select states (OH, KY, MA, and NM) with broader release anticipated in 22 additional states funded through CDC's Opioid Prevention in States effort.

The Honorable Leonard Lance

1. **Can you tell us about CDC's opioid surveillance programs, especially in regards to fentanyl? How has CDC improved the timeliness of reporting? What gaps remain in data collection capabilities and how is CDC working to bridge those gaps?**

Answer:

CDC now funds the Enhanced State Opioid Overdose Surveillance (ESOOS) program in 32 states and Washington D.C. In its first programmatic year, CDC funded 12 states to: 1) Improve the timeliness of reporting of nonfatal opioid overdoses using Emergency Department (ED) and Emergency Medical Services (EMS) data; 2) Improve the timeliness of reporting of fatal opioid overdoses and associated risk factors so that these data can be used to inform public health response tactics within and across states; and 3) Disseminate findings to stakeholders to support prevention efforts.

The program collects data on fatal opioid overdoses through the State Unintentional Drug Overdose Reporting System (SUDORS), which uniquely captures detailed information on toxicology, death scene investigations, and other risk factors that may be associated with a fatal overdose. For instance, SUDORS data have identified and tracked large increases in fentanyl analog deaths driven by carfentanil within one state's borders. Early findings from these data reinforce the need and urgency for more timely and comprehensive toxicology testing.

ESOOS also improves innovative strategies around morbidity data, using EMS and ED data to provide a comprehensive picture around non-fatal opioid overdoses. The use of this data can act as an early warning system to detect sharp increases or decreases in overdoses. In addition, this data can help inform where more resources, such as naloxone or treatment capacity, are needed. CDC released a *Vital Signs* in March, which will publish CDC's most timely data on drug overdoses given the near real-time reporting of this system.

The initial cohort of 12 states began program implementation on September 1, 2016, and CDC will rapidly disseminate findings as states provide data. The first report of ESOOS mortality data, "Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700—10 States, July—December 2016," was published as a *Morbidity and Mortality Weekly Report (MMWR)* Early Release on October 27, 2017. States completed data reports by August 31, 2017, and CDC published it less than two months later. CDC published a *Vital Signs* report and *MMWR* Early Release in March 2018, which will include the timely data on drug overdoses given the near real-time reporting of this system.

With the increase in funds appropriated to CDC in Fiscal Year 2017, CDC was able to expand the ESOOS program to fund an additional 20 states and Washington, D.C. CDC also was able to provide supplemental funds to all ESOOS-funded states, with the expectation that a minimum of 60% of the supplemental funds were to go to medical examiners/coroners to primarily

support comprehensive toxicology testing of opioid-involved deaths. With the increase in funds appropriated to CDC in Fiscal Year 2018, CDC anticipates scaling up funding and technical support to enhance surveillance within all 50 states to improve the timeliness and comprehensiveness of fatal and nonfatal opioid overdose reporting.

In terms of gaps, it is necessary to strengthen the Mortality Data Infrastructure (IT Systems). When a drug overdose death occurs, multiple data requestors ask toxicology and ME/C offices to provide data using tools that are not integrated with the laboratory information systems and case management systems that they use every day. This puts significant burden on these offices and contributes to the lag in the data. CDC will work closely with the Association of State Crime Lab Directors, Society of Forensic Toxicologists, and National Association of Medical Examiners to help enhance their capabilities so that they can help provide the data. Support is needed to enhance the Interoperability of medical examiner/coroner case management systems and state electronic death reporting systems to improve timeliness and data quality.

The Honorable Morgan Griffith

1. **Prescription drug monitoring programs (PDMPs) are an invaluable tool for preventing "doctor shopping" and diversion of opioid medications. We know that PDMPs are regulated differently from state to state in terms of when/if a provider is required to check them, what information is included in a PDMP, and who has access to this information. Some states also have agreements in place to allow access between their respective PDMPs across state lines. What are ways in which PDMPs can be better utilized to identify instances of addiction to opioids and prevent overdoses? What can be done to improve PDMP sharing across state lines?**

   Answer:

   The opioid crisis manifests differently in communities and states. To the extent that states have access to more data, including data that are more timely as well as data from other states, the better they are able to inform and tailor their response.

   PDMPs are a promising tool to address the epidemic and prevent opioid misuse, abuse, and overdose. Their utility as a public health resource and tool can be maximized through various means. For one, they can provide essential information to a clinician at the point of care as they are making that critical treatment decisions for their patient. This is what we mean when we say that PDMPs are a clinical decision-making tool. Just like any other part of a patient's medical history, the PDMP provides essential information to inform decisions about care.

Another public health application is the use of PDMP data to inform strategic prevention programming and resource allocation. This is what we mean when we talk about the PDMP as a public health surveillance tool. PDMPs can tell us where prescribing is problematic, where we need to focus prescriber education efforts, and where overdoses may be more likely to occur so that we can ensure availability of naloxone and use health systems to connect people to treatment and care.

PDMPs can also act as part of an early warning system to detect increases in prescribing in certain communities. Analyzing de-identified PDMP data by geographic area, whether that be county, zip code, etc. can show trends in medical and non-medical use of prescription drugs.

Ensuring that these public health applications of the PDMP are maximized is a key and required component under our Prevention for States program and the enhanced component of our Data-Driven Prevention Initiative program.

Every state PDMP operates differently, so the challenges and barriers for each state will differ. Some states may be precluded from sharing data from a legislative or regulatory perspective. Other may have difficulties from a resource perspective, particularly if there are costs associated with data sharing and prove prohibitive to a state. Others may have technical challenges, such as integrating PDMPs with EHRs. Finally, some states may have a different agency housing a PDMP, requiring MOUs to share data with public health entities.

Some of these challenges can continue to be addressed by the provision of technical assistance and resources from the federal level. Illinois will soon be implementing guideline concordant enhancements to their integrated PDMP-EHR integrations that provides flags based on the active cumulative Morphine Milligram Equivalent (MME). There will be flags based on ≥ 50 MME and ≥ 90 MME. The PDMP will also provide resources such as links to the CDC's prescribing guideline provider tools and resources based on the MME flags. These changes/enhancements were a result of TA provided by the Illinois CDC PfS state support team.

In addition, the Illinois CDC PfS state support team has been working to provide technical assistance around the PfS second required strategy of implementing initiatives in the community and/or health systems. Through the CDC PfS team's monthly calls and site visit, the CDC and Illinois have developed and disseminated Illinois Prescription Monitoring Program County Profiles.

CDC is also working with funded states for PDMP and EHR (electronic health record) integration. This step is critical for ensuring the information from PDMPs are a part of clinical workflow and easy for providers to check while seeing patients.

2. **We often hear that not enough states are sharing PDMP data with other states. However, my understanding is that 45 states are now actively sharing PDMP data. For states that are not, the barriers are primarily at the state legislative level and not technological. What are your views on the current state of interstate data sharing? Do you think that states have been**

doing a better job in recent years of sharing data with their neighboring states (at a minimum) to prevent doctor shopping?

Answer:

States have made important strides to share data to prevent doctor shopping, inform strategic prevention programming and resource allocation, and understand regional trends in opioid prescribing to better inform physicians about their own prescribing patterns. Ensuring that these public health applications of the PDMP are maximized is a key and required component under our Prevention for States program and the enhanced component of our Data-Driven Prevention Initiative program. CDC also provides important technical assistance through its grantee communities of practice, which allows peer-to-peer learning so that states can share best practices, lessons learned, and key successes in addressing challenges that may be similar among states.

States have been working to share PDMP data via data hubs such as the RxCheck and PMPi. As of now, 48 states and Washington, D.C. are exchanging data via either the PMPi or the RxCheck.

The Honorable Ben Ray Lujan

1. **In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. The New York Times reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The Times and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long-term investments in prevention, treatment, recovery, and monitoring. The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.**

a. **Deputy Director Schuchat, do you have all of the tools you need to stop the opioid epidemic?**

Answer:

CDC received an increase in appropriation in both fiscal years 2016 and 2017 for opioid overdose prevention activities. With that funding, CDC is now able to fund 45 states and Washington, D.C. to implement prevention activities and to collect data on fatal and non-fatal overdoses. CDC is committed to continuing prevention activities with the resources we are appropriated.

b. Given the 17 percent cuts to CDC in the President's budget proposal, what programs relating to the opioid epidemic will be cut? Which programs would have been expanded that will now not be?

Answer:

CDC appreciates Congress's support and investment of our opioid prevention work. CDC is committed to continuing opioid overdose prevention and will continue to work with states in their overdose prevention programs and surveillance.

The Honorable Paul Tonko

1. Does the CDC have any data that specifically details overdose death rates or incidence for individuals leaving jail or prison? If not, is there a way for CDC to obtain this data?

Answer:

CDC does not have systematic access to data on overdoses for all individuals leaving jail or prison, but the Enhanced State Opioid Overdose Surveillance program, which seeks to improve the timeliness of data collection on fatal and non-fatal opioid overdoses, does capture some information on justice-involved populations. The State Unintentional Drug Overdose Reporting System (SUDORS), which uniquely captures detailed information on toxicology, death scene investigations, and other risk factors that may be associated with a fatal overdose, does collect information on recent release from an institution for all opioid overdose deaths. "Jail, prison, or detention facility" is one of the options for institutions. To qualify as a recent release, the decedent had to have spent one or more nights in the institution, within a month prior to death. SUDORS also captures information about deaths that occurred while the decedent was in custody, which could have been under arrest, in jail/prison, in a psychiatric institution, etc. This information could be used to track what proportion of opioid overdose decedents had recently been incarcerated, and what proportion died while incarcerated.

While CDC does not collect data related to individuals leaving jail or prison, in 2015, the Massachusetts Department of Public Health (MDPH) requested CDC's assistance with an epidemiological investigation (Epi-Aid). Massachusetts had experienced a surge of opioid-related deaths, from 698 in 2012 to 1,747 in 2015, and over 74 percent of the drug overdose deaths involved fentanyl. The key goal of the investigation was to understand the extent to which the sharply increasing supply of illicitly-made fentanyl (IMF) in Massachusetts from 2013 through 2015 contributed to the surge in opioid-related overdose deaths. CDC worked closely with the MDPH, SAMHSA, and DEA to determine that illicitly-made fentanyl mixed with or sold as heroin was primarily responsible for the surge of deaths from 2014 to 2015. Eight out of ten fentanyl-related overdose deaths were suspected to involve illicitly-made fentanyl. Using the data obtained in the investigation, CDC provided recommendations for the MDPH related to

screening people for heroin and/or fentanyl use, expanding access to naloxone and providing training for overdose prevention, and implementing messaging and education around the dangers of fentanyl, especially in the cases of people who had recently been released from prison.

Given the specific needs of justice-involved individuals as particularly vulnerable demographic, CDC has partnered with the National Governors Association (NGA) to assess different strategies and programs underway within states to address opioid use disorder while individuals are incarcerated and following their release. More specifically, NGA convened a Learning Lab for interested states to attend and learn about programs and strategies within a peer state to provide Medication-Assisted Treatment (MAT) and other services for justice-involved populations. In addition, NGA hosted a webinar to educate leadership within states about the efficacy of MAT and to highlight other innovative strategies that states can employ to prevent opioid misuse, abuse, and overdoes specific to this target population.

The Honorable Frank Pallone, Jr.

1. **With 90 percent of addictions beginning in the teenage years, we know there is a critical need for effective drug prevention programming, especially during this current opioid crisis. In the past decade, our national prevention infrastructure has been decimated (including the elimination of funding for the National Youth Anti-Drug Media Campaign) and our ability to educate young people and prevent more teens from becoming addicted is hobbled. We need prevention messages to serve as a counterweight to the proliferation of pro-drug messaging in the media today. In order to convey the risk of opioid and other drug abuse and reverse the stark addiction and overdose trends that are creating heartbreak in families across the country, investment in prevention messaging is crucial. Regarding Section 102 in CARA- the National Awareness Campaigns provision, can you please tell us what the status of implementation and investment is? What do the various agencies plan to do to move forward with this provision and how can we help?**

Answer:

Although CDC did not receive any funding to implement provisions in CARA, CDC has developed the Rx Awareness communications campaign which was released publicly in September. The campaign features real-life accounts of individuals living in recovery from opioid use disorder, and those who have lost someone to a prescription drug overdose. The campaign will increase awareness and knowledge among Americans about the risks of prescription opioids and deter inappropriate use. CDC is running digital, radio, and out-of-home campaign ads for 14 weeks in select states (OH, KY, MA, and NM) with broader release anticipated in 22 additional states funded through the CDC Opioid Prevention in States effort.

2. **I would like to thank all of the witnesses for joining us. I am particularly interested in learning more about CDC efforts to improve the timeliness and comprehensiveness of the data available about the epidemic.**

a. **Can you tell us about CDC's surveillance programs?**

Answer:
CDC's surveillance programs strengthen our understanding of the crisis through better public health data and reporting which is a component of HHS's 5-point strategy to combat the opioid epidemic.

The National Vital Statistics System (NVSS) is one of oldest and most critical surveillance systems at CDC for monitoring the impact (measured in lives lost) of the opioid epidemic. Through the NVSS data on all births, deaths, and fetal deaths are sent to the National Center for Health Statistics (NCHS), which has contracts with all 57 vital records jurisdictions to provide these data. From these data, CDC compiles annual national statistical data files and publishes a variety of reports. Annual mortality data are currently available through 2015 and 2016 data will be release before the end of the year. To address a need for even more timely data NCHS now releases quarterly provisional estimates based on a current flow of vital statistics data from the states vital records offices. To address specific request for timely information of drug overdose death, CDC recently began releasing monthly provisional drug overdose counts that provide the most timely information available on the overall numbers of drug overdose deaths and death involving specific drugs and drug classes by state.

In addition, CDC has launched the Enhanced State Opioid Overdose Surveillance (ESOOS) program. In its first programmatic year, CDC funded 12 states to: 1) Improve the timeliness of reporting of nonfatal opioid overdoses using Emergency Department (ED) and Emergency Medical Services (EMS) data; 2) Improve the timeliness of reporting of fatal opioid overdoses and associated risk factors so that these data can be used to inform public health response tactics within and across states; and 3) Disseminate findings to stakeholders to support prevention efforts.

The program collects data on fatal opioid overdoses through the State Unintentional Drug Overdose Reporting System (SUDORS), which uniquely captures detailed information on toxicology, death scene investigations, and other risk factors that may be associated with a fatal overdose. For instance, SUDORS data have identified and tracked large increases in fentanyl analog deaths driven by carfentanil within one state's borders. Early findings from these data reinforce the need and urgency for more timely and comprehensive toxicology testing.

ESOOS also improves innovative strategies around morbidity data, using EMS and ED data to provide a comprehensive picture around non-fatal opioid overdoses. The use of this data can act as an early warning system to detect sharp increases or decreases in overdoses. In addition, this data can help inform where more resources, such as naloxone or treatment capacity, are needed.

The initial cohort of 12 states began program implementation on September 1, 2016, and CDC will rapidly disseminate findings as states provide data. The first report of ESOOS mortality data, "Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700—10 States, July—December 2016," was published as a *Morbidity and Mortality Weekly Report (MMWR)* Early Release on October 27, 2017. States completed data reports by August 31, 2017, and CDC published it within two months.

With the increase in funds appropriated to CDC in Fiscal Year 2017, CDC was able to expand the ESOOS program to fund an additional 20 states and Washington, D.C. (for a total of 32 states and Washington, D.C.) CDC also was able to provide supplemental funds to all ESOOS-funded states, with the expectation that a minimum of 60 percent of the supplemental funds were to go to medical examiners/coroners to primarily support comprehensive toxicology testing of opioid-involved deaths.

States are at the forefront of protecting mothers and babies by using data to understand Neonatal Abstinence Syndrome (NAS). With support from CDC and in partnership with March of Dimes, Illinois, New Mexico, and Vermont to explore approaches for improving the speed and accuracy of surveillance of Neonatal Abstinence Syndrome (NAS). Surveillance of NAS is important to inform a public health response that can quickly identify areas of need and target interventions to improve outcomes for these babies by connecting mothers to services and care. These pilot projects are also evaluating the health services needed through their first birthday, which will help prepare the health system to care for these babies.

CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) in 51 jurisdictions (47 states, the District of Columbia, New York City, Puerto Rico, and the Great Plains Tribal Chairmen's Health Board) collects state-specific, population-based data from women during the postpartum period on maternal attitudes and experiences before, during, and shortly after pregnancy. CDC is supporting 6 states (AK, ME, NM, NY, PA, WV) to collect supplemental data on maternal substance use through the PRAMS.

b. How has CDC improved the timeliness of reporting?

Answer:

Timeliness of mortality reporting has improved significantly over the past several years. In 2010, only about 7% of deaths were reported to CDC within 10 days of the death. This percentage has increased steadily over the past few years and today over 50% of deaths nationally are reported to CDC within 10 days. The introduction of electronic death registration (EDR) systems in most states has been a significant catalyst for these improvements and CDC has been actively involved in encouraging states to implement these systems and has funded special projects in many states to enhance and maximize these systems with specific timeliness

goals. As current EDR systems age resources will be needed to maintain and upgrade aging systems if improvements in timeliness are to be sustained.

Capitalizing on the significant improvements in the timeliness of deaths being reported by the states, CDC launched the Vital Statistics Rapid Release (VSRR) program in 2015 with the first release of quarterly provisional mortality estimates, which included national estimates of overall drug overdose death rates. In August of 2017, the VSRR program was expanded to include monthly provisional counts of drug overdose deaths and death involving specific drugs and drug classes by state. The most recent monthly provisional report was released on November 13, 2017, and includes counts of drug overdose deaths through April 2017.

Reliable provisional estimates of death rates and counts for many causes of death can be released 3 months after the death occurred, but due to the additional time needed for toxicology drug overdose deaths are among the last reported to CDC, which means that reliable provisional rates and counts for these deaths can only be released 6 to 9 months after the death occurred. CDC is working closely with the state vital records offices and the ME/Coroner community on efforts to help minimize the time needed to report drug overdose deaths, including efforts to better integrate ME/Coroner case management systems with state EDRS.

c. What gaps remain in data collection capabilities, including the effect of some of the surveillance programs not being implemented in all 50 states and DC, and how is CDC working to bridge those gaps?

Answer:

CDC's surveillance programs strengthen our understanding of the crisis through better public health data and reporting which is a component of HHS's 5-point strategy to combat the opioid epidemic. Though timely, high-quality data are critical to support a multi-sector response to the opioid epidemic, states remain at differing capacity with regard to opioid overdose surveillance.

One means to shore up state capacity and to provide the needed level of scientific expertise to assist states in these efforts has been the creation of CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program. In its first programmatic year, CDC funded 12 states to: 1) Improve the timeliness of reporting of nonfatal opioid overdoses using Emergency Department (ED) and Emergency Medical Services (EMS) data; 2) Improve the timeliness of reporting of fatal opioid overdoses and associated risk factors so that these data can be used to inform public health response tactics within and across states; and 3) Disseminate findings to stakeholders to support prevention efforts.

The initial cohort of 12 states began program implementation on September 1, 2016, and CDC will rapidly disseminate findings as states provide data. The first report of ESOOS mortality data, "Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700—10 States, July—December

2016," was published as a *Morbidity and Mortality Weekly Report (MMWR)* Early Release on October 27, 2017. States completed data reports by August 31, 2017, and CDC published it within two months.

With the increase in funds appropriated to CDC in Fiscal Year 2017, CDC was able to expand the ESOOS program to fund an additional 20 states and Washington, D.C. CDC also was able to provide supplemental funds to all ESOOS-funded states, with the expectation that a minimum of 60 percent of the supplemental funds received were to directly support comprehensive testing within each state.

CDC is now funding 32 states and Washington, D.C. under the ESOOS program.

3. **Adverse effects and accidental overdoses from opioids have had a huge impact on our nation, however, there are also downstream health consequences of opioid use, especially IV opioid or heroin use, such as HIV, Hepatitis B and Hepatitis C that also affects our nation's health. In 2015, there was an outbreak of HIV in a small town in Indiana, where nearly 200 individuals became infected with HIV due to injection of oxymorphone. I was particularly struck by statements from public health officials in a recent article in Politico. According to that article, health officials believe that the 2015 outbreak in Scott County is a harbinger of things to come as abuse of – painkillers, heroin, fentanyl, and other drugs – rages on. According to the Director of Public Health in Alaska, "[t]he nightmare that wakes me up at 3 a.m. is a Scott County – level HIV outbreak happening here in Alaska."**

a. **Dr. Schuchat, do you share these concerns about the risk of additional infectious disease outbreaks as a result of the opioid abuse epidemic?**

Answer:

The threefold increase in hepatitis C between 2010 and 2015and the 2015 HIV outbreak in Indiana are powerful evidence that persons who inject drugs are at high risk for both HIV and viral hepatitis, and that these infections can gain ground at any time unless the nation remains vigilant about prevention, testing, care.

b. **What are we currently doing to monitor and prevent these infections from IV drug use?**

Answer:

Last year, tens of thousands of viral hepatitis, HIV, and endocarditis (heart valve) infections occurred in the nation due to injection drug use. CDC is working to prevent these infections by:

- Using data to monitor emerging trends and direct prevention activities;

- Providing up-to-date scientific information and strengthening state, local, and tribal capacity to respond and prevent injection drug use-associated infectious diseases;
- Working with providers, health systems, and payers to implement effective prevention programs; and,
- Coordinating with public safety and community-based partners to rapidly link people to effective infectious disease (and substance use) treatment

c. What suggestions do you have for improving prevention strategies?

Answer:

CDC aims to strengthen our understanding of the crisis through better public health data and reporting which is a component of HHS's 5-point strategy to combat the opioid epidemic. A comprehensive, multi-sectoral approach is needed to prevent infectious diseases attributed to opioid use disorder which includes:

- Collaboration at the community level between public health, law enforcement, healthcare, education, substance abuse treatment providers, housing services, and faith-based stakeholders.
- Coordination across multiple levels of the U.S. health care system.
- Implementation of tailored community-based prevention services which include, but are not limited to, testing and treatment for HIV, viral hepatitis, and endocarditis, provision and disposal of sterile injection equipment (where legal and consonant with community support), provision of naloxone and overdose prevention training, and provision of or referral to addiction and mental health services, including medication-assisted treatment.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 17, 2017

Dr. Nora Volkow
Director
National Institute on Drug Abuse
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Volkow:

Thank you for appearing before the Committee on Energy and Commerce on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

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

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
FEDERAL EFFORTS TO COMBAT THE OPIOID CRISIS: A STATUS UPDATE ON CARA AND OTHER INITIATIVES

WEDNESDAY, OCTOBER 25, 2017

Questions for the Record – Dr. Volkov

The Honorable Fred Upton

1. The 21st Century Cures Act promoted the importance of advancing precision medicine. NIH Director Francis Collins previously discussed the importance of knowing what medications work for what patients, in what doses, and at what times. How can advances in precision medicine be used to assess risks associated with opioid use disorder and identify the most clinically appropriate treatments? What is the NIH doing to improve awareness of the treatment options for opioid use disorder and examining efficacy of different treatments?

The 21st Century Cures Act provides support for the National Institute of Health's (NIH's) Precision Medicine Initiative (PMI) and the *All of Us* Research Program, which seeks to extend precision medicine to all diseases by building a national research cohort of one million or more U.S. participants.[1] This resource holds promise for understanding the lifestyle, environmental, and biological – including genetic – factors that may influence risk for addiction and treatment response to develop tailored therapies based on an individual's unique risk factors. Medical information related to substance use disorders (SUDs) may be subject to additional confidentiality protection under 42 CFR Part 2. In order to ensure that the *All of Us* cohort will be able to incorporate SUD treatment information, the National Institute on Drug Abuse (NIDA) program staff have been working closely with *All of Us* program staff to ensure that data that are subject to 42 CFR Part 2 can be incorporated into this resource.

Accelerating scientific research to address the ongoing opioid crisis is a top priority for NIH. To this end, NIDA has been part of a trans-NIH group coordinating with *All of Us* across all scientific domains, including *Mental Health & Addiction* and *Sensory, Pain & Neurologic*, with the long-term goal of creating precision approaches for both pain and opioid addiction treatment.

In order to improve awareness of effective treatments for opioid use disorder, NIDA has published the report *Medications to Treat Opioid Addiction*[2], providing a comprehensive overview of the current state of the science related to pharmacological treatments for

[1] https://allofus.nih.gov/about/about-all-us-research-program
[2] https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview

opioid use disorder (OUD). NIDA has also published data briefs to concisely present the evidence on the effective treatment options for opioid use disorder, including *Effective Treatments for Opioid Addiction*[3] and *Treating Opioid Use Disorder During Pregnancy*.[4]

Toward the goal of examining relative treatment efficacy of existing medications for OUD, the results of a NIDA-funded comparative effectiveness study are expected to be published in November 2017 in *The Lancet* comparing buprenorphine/naloxone and extended release naltrexone (XR-NTX). These results will complement findings from a smaller Norwegian study comparing outcomes for patients taking buprenorphine/naloxone and those on XR-NTX.[5]

2. A recent study estimated that over half of the opioid prescriptions in the United States went to individuals with depression, anxiety and other mood disorders. According to the study, "after controlling for a wide array of other demographic and clinical risk factors…having a mental health disorder [like depression or anxiety disorder] is associated with increased opioid use." Is it common for individuals with no prior history of substance abuse or comorbid psychiatric conditions to develop opioid use disorder? What research has the NIH performed to look into the possible connection between taking prescription opioids and the co-occurrence of opioid use disorder and mental health problems like depression or anxiety disorder?

Many individuals who develop opioid use disorder do not have a prior history of mental illness or substance use disorder. However, mental illness can contribute to the development of substance use disorders, and vice versa, and the same risk factors can impact both mental health and substance use. Because mood disorders increase vulnerability to drug use and addiction, the diagnosis and treatment of the mood disorder can reduce the risk of subsequent drug use. Because the inverse may also be true, the diagnosis and treatment of drug use disorders may reduce the risk of developing other mental illnesses and, if they do occur, lessen their severity or make them more amenable to effective treatment. Detailed information on the link between mental illness and substance use disorders is available in the NIDA Research Report entitled *Comorbidity: Addiction and Other Mental Illnesses*.[6]

It is important to note that many childhood risk factors for substance use also increase risk for other psychiatric and behavioral problems, including conduct disorder,

---

[3] https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction

[4] https://www.drugabuse.gov/publications/treating-opioid-use-disorder-during-pregnancy/treating-opioid-use-disorder-during-pregnancy

[5] Tanum, L., et al. (2017). "The Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial." JAMA psychiatry.

[6] NIDA Research Report: *Comorbidity: Addiction and Other Mental Illnesses*. Available at: https://www.drugabuse.gov/sites/default/files/rrcomorbidity.pdf

depression, and delinquency.[7] Shared genetic or biological risk factors may contribute to the emergence of mental illness and substance use, and symptoms of one may influence the development of the other. Prevention interventions often target these shared risk factors and have been shown to reduce risk for both substance use and addiction, as well as a range of behavioral health problems.[8]

NIDA, along with multiple NIH Institutes, Offices, and Centers, in partnership with the Centers for Disease Control and Prevention (CDC), is currently funding the Adolescent Brain Cognitive Development (ABCD) Study which is the largest long-term study of brain development and child health in the U.S, and the longitudinal nature of the study will help answer these questions. Because the ABCD Study is also collecting information about youth substance use, mental health, physical health, brain development, as well as cognitive and academic performance, scientists will be able to gain new insight into the connection between mental health and substance use disorders.

The Honorable Bill Johnson

1. The NIH has launched some initiatives to improve pain management education in medical, nursing, pharmaceutical, and dental schools. Can you give an update on the efforts of the Centers of Excellence in Pain Education (CoEPEs)?

The NIH Pain Consortium's Centers of Excellence in Pain Education (CoEPEs) program was first funded in the spring of 2012. NIH is currently funding 11 academic institutions in the US that act as hubs for the development, evaluation and distribution of pain curriculum resources for medical, dental, nursing, pharmacy and other health professional schools to enhance and improve how health care professionals are taught about pain and its treatment. Case-based scenarios form the backbone of the curriculum resources and 11 modules contain interactive digital elements to guide learners through with questions and answers, videos, and problem solving. There are currently six published case studies with five additional cases in the final stages of production. The CoEPEs facilities are now working on putting together proposals for eleven additional case studies for 2018.

The CoEPE modules are available through the NIH Pain Consortium Webpage (https://painconsortium.nih.gov/Funding_Research/CoEPEs). Further, the Department of Health and Human Services (DHHS) National Pain Strategy (NPS) provider education

---

[7] National Research Council (US) and Institute of Medicine (US) Committee on the Prevention of Mental Disorders and Substance Abuse Among Children, Youth, and Young Adults: Research Advances and Promising Interventions; O'Connell ME, Boat T, Warner KE, editors. Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities. Washington (DC): National Academies Press (US); 2009. Available from: https://www.ncbi.nlm.nih.gov/books/NBK32775/ doi: 10.17226/1248

[8] NIDA. Principles of Substance Abuse Prevention for Early Childhood. 2016. Available from: https://www.drugabuse.gov/publications/principles-substance-abuse-prevention-early-childhood/index.

effort, which is in the process of implementation, proposes to use the CoEPEs as the basis of a larger national pain education effort.

2. Alternative, non-addictive analgesics could prevent addiction before it starts. I understand that NIH is conducting research into potential opioid alternatives. Can you talk about the work being done and how it might help combat the opioid crisis?

In 2016 NIH spent $483 million on pain research ranging from cell and molecular mechanisms of acute and chronic pain to safe, effective therapy development, to large scale clinical trials. The portfolio includes many projects that address the pressing need to develop new non-opioid, non-addictive pain treatments. Studies range from early-stage drug target discovery focused on molecular pathways of pain signaling including exploration of receptors and channels as potential non-addictive analgesic targets to testing in behavioral models. A number of targets identified through NIH basic science research, such as the nerve growth factor receptor and pain-related ion channels, are now being pursued in industry sponsored clinical trials of non-addictive treatments.

NIH is developing opioids with reduced risk of addiction and misuse. NIH-supported investigators are developing new compounds that exhibit novel properties as a result of their combined activity at different opioid receptors (mu, delta, and kappa). Compounds with combined activity at the mu and delta receptors or at all three receptors can induce strong analgesia without producing tolerance or dependence in animal models. In addition, discovery of adjunct medications that can be combined with opioids to reduce the needed dose, promise to result in lower potential for dependence and addiction. Innovative methods are being explored for drug delivery to increase specificity and efficacy and to reduce analgesic side effects, as well as modified formulations to enhance delivery.

NIH supports an initiative called the Blueprint Neurotherapeutics Program for small molecule drug discovery and development. For example, the National Institute of Neurological Disorders and Stroke (NINDS) funds studies through this program that aims to develop non-addictive kappa opioid receptor antagonists for migraine and a safe, non-opioid analgesic that can be taken orally to reduce diabetic nerve pain.

Other non-pharmacological approaches show promise for pain management. A tissue–based tool for screening potential migraine drugs is under development and a library of small molecules is being leveraged to screen for candidates for optimization as analgesics. Tissue engineering and regeneration to create tissue scaffolding and microenvironments to promote wound healing and joint cartilage and intervertebral disc replacements is being applied to relieve pain. Neural stimulation technologies for chronic intractable pain are being improved. For example, wearable ultrasound devices and implantable micro-stimulators are being tested for peripheral and central nervous system targets to relieve pain.

Evaluation and dissemination of complementary and integrative health approaches are a crucial component of quality pain management. NIH supported studies include

mechanism-based clinical studies on cognitive behavior therapy, exercise, yoga, acupuncture, massage and fitness, and mindfulness practices that are important components of the NIH federal pain research portfolio.

The Honorable Chris Collins

1. Despite the staggering overdose reports from my district's coroners and the CDC, opioids are still primarily used for the treatment of pain. It is estimated that around 250 million Schedule II prescriptions are filled across the country each year. However, there are other effective options for pain management. For example, several academic peer-reviewed journals have found that states that have legalized the use of marijuana for medical purposes had significantly lower state-level opioid overdose mortality rates...and found that it was an effective form of pain management. Alternatively, anesthesia is utilized in various surgical and non-surgical procedures to improve perioperative [preoperative, intraoperative, and postoperative] pain control while minimizing systemic opioid consumption.

a. Under the Opioid State Targeted Response (STR) grants, are states using funds to educate physicians and providers on utilizing non-opiate treatment for pain?

(SAMHSA Primary)

2. CARA established the Pain Management Best Practices Inter-Agency Task Force to provide advice and recommendations for development of best practices for pain management and prescribing pain medication. The Task Force is also expected to develop a strategy for disseminating such best practices to relevant federal agencies [the Department of Veterans Affairs, Department of Defense, and Department of Health and Human Services] and the general public.
a. What is the current status of the nominations process? As this is an advisory committee, to what degree do you expect providers to adopt these practices? Please explain.

The Pain Management Best Practices Inter-Agency Task Force is being established by the Secretary of the Department of Health and Human Services in cooperation with the Secretary of Veterans Affairs and Secretary of Defense. The Office of the Assistant Secretary for Health (OASH) released a call for nominations for individuals to serve on the Task Force through the Federal Register on August 28, 2017. It is our understanding that the Office received hundreds of applications from qualified individuals, reflecting the high-level of interest in serving and indicating the significant attention directed to the task force. A careful and comprehensive tiered evaluation process was established for selection of the candidates. The breadth and quality of expertise of the nominees ensures that the membership requirements for balance and knowledge as outlined in CARA will be met. It is our understanding that OASH expects to complete the selection and approval process by the end of 2017 and to convene the first meeting of the committee early in 2018.

The pain and opioid crises have highlighted the important role of this task force and generated intense interest in the committee's role and potential impact on pain management, including opioid prescribing practices. The committee can draw from the 2016 National Pain

Strategy which outlined a comprehensive program for pain management in the United States. Providers, especially those in primary care where most pain patients seek care, clearly are seeking better and more comprehensive clinical practice guidance for their patients with unmet needs for pain relief. It is expected therefore, that the task force recommendations will be disseminated and implemented broadly by the pain care community.

3. NIDA's Principles of Drug Addiction Treatment was created to address addiction to a wide variety of drugs, including nicotine, alcohol, and prescription drugs. It was first printed in October 1999 and revised in December 2012.

(a) Considering that robust new research has been published since that time, does NIDA have plans to produce a fourth edition?

(b) It has come to my attention that this document is not utilized by all healthcare providers and families with afflicted loved ones across the country. What can NIDA or Congress do to ensure that these types of resources are available to all stakeholders?

NIDA is currently in the process of creating a Principles of Opioid Addiction Treatment guide, summarizing the current state of the science on medications and evidence-supported behavioral therapies for opioid use disorder. It is expected to be completed by the fall of 2018. To ensure that information on evidence-based treatment is available to all stakeholders, NIDA also recently developed a Research Report on Medications for Opioid Addiction[9] (released May 2017) and brief fact sheets for policymakers, healthcare providers, and other stakeholders on the state of the science of medications for opioid addiction.[10] NIDA, along with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and SAMHSA, also helped support the development of the American Society of Addiction Medicine's *ASAM Standards of Care*, which was released in 2014.

The Honorable Buddy Carter

1. NIH is currently undertaking a public-private initiative to develop new non-opioid therapies. That initiative is designed to bring to market less-addictive options for patients. 1. Dr. Volkow, I know that NIH is currently working on a public-private initiative. What do you currently have in the pipeline as non-addictive alternatives?

Addressing the opioid crisis is a top priority for the Trump Administration and the Department of Health and Human Services, including the National Institutes of Health (NIH). NIH supports a broad portfolio of research to develop and test strategies for the prevention and treatments of opioid use disorder (OUD). In addition, NIH is exploring a public-private collaborative research initiative to address the opioid crisis. The initial plan for this initiative was recently described by Drs. Collins and Volkow in the New England Journal of Medicine and includes three major areas for advancement: (1) *safe, more effective, and non-addictive strategies* for chronic pain management to prevent

[9] https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview

[10] https://www.drugabuse.gov/publications/finder/t/902/policy-briefs

misuse of and addiction to prescription opioids; (2) *new and innovative opioid addiction treatments* to reduce drug use and support recovery; and (3) *overdose reversal interventions* to reduce mortality and promote access to treatment.[11]

To identify the scientific strategies with the greatest potential, NIH brought together innovative experts from government, industry, and academia for a series of three cutting-edge science meetings. Plans are underway to develop a draft strategy for collaborative activities including major goals of the initiative, action steps, key partners, deliverables, timeline, and resources (in-kind and financial costs) to fully carry out the proposed action steps. The Foundation for the National Institutes of Health will solicit input on the final draft from participants including Federal partners as well as other relevant stakeholders. Upon final approval of the plan, it will be posted on the NIH website at: https://www.nih.gov/opioid-crisis

In 2016 NIH spent $483 million on pain research ranging from cell and molecular mechanisms of acute and chronic pain to safe, effective therapy development, to large scale clinical trials. The portfolio includes many projects that address the pressing need to develop new non-opioid, non-addictive pain treatments. Studies range from early-stage drug target discovery focused on molecular pathways of pain signaling including exploration of receptors and channels as potential non-addictive analgesic targets to testing in behavioral models. A number of targets identified NIH basic science, such as the nerve growth factor receptor and pain-related ion channels, are now being pursued in industry sponsored clinical trials of non-addictive treatments.

NIH is developing opioids with reduced risk of addiction and abuse. NIH-supported investigators are developing new compounds that exhibit novel properties as a result of their combined activity at different opioid receptors (mu, delta, and kappa). Compounds with combined activity at the mu and delta receptors or at all three receptors can induce strong analgesia without producing tolerance or dependence in animal models. In addition, discovery of adjunct medications that can be combined with opioids to reduce the needed dose, promise to result in lower potential for dependence and addiction. Innovative methods are being explored for drug delivery to increase specificity and efficacy and to reduce analgesic side effects, as well as modified formulations to enhance delivery.

NIH supports an initiative called the Blueprint Neurotherapeutics Program for small molecule drug discovery and development. For example, the National Institute of Neurological Disorders and Stroke (NINDS) funds studies through this program that aim to develop non-addictive kappa opioid receptor antagonists for migraine and a safe, non-opioid analgesic that can be taken orally to reduce diabetic nerve pain.[12]

---

[11] Volkow, N. D. and F. S. Collins (2017). "The Role of Science in Addressing the Opioid Crisis." New England Journal of Medicine 377(4): 391-394.

[12] https://projectreporter.nih.gov/project_info_description.cfm?aid=9325694&icde=36528658&ddparam=&ddvalue=&ddsub=&cr=3&csb=default&cs=ASC&pball=

Other non-pharmacological approaches show promise for pain management. For example, new molecules are being developed as analgesics and new tissue-based engineering tools are being used to develop microenvironments that promote wound healing. Additionally, joint cartilage and intervertebral disc replacements are being applied to relieve pain and neural stimulation technologies are being improved for chronic pain. For example, wearable ultrasound devices and implantable micro-stimulators are being tested for peripheral and central nervous system targets to relieve pain.

Evaluation and dissemination of complementary and integrative health approaches are a crucial component of quality pain management. NIH supported studies include mechanism-based clinical studies on cognitive behavior therapy, exercise, yoga, acupuncture, massage and fitness, and mindfulness practices that are important components of the NIH federal pain research portfolio.

2. Who are you currently working with and what's the timeline? Does there need to be a legislative fix to speed these alternatives to market?

To fight the opioid crisis, an all hands-on deck strategy is needed. NIH is enlisting partners across government and the private sector to develop scientific solutions to this public health crisis. NIH is currently in the process of partnering with pharmaceutical companies, but the list of partners is not yet finalized. Regarding any legislative fixes, the Department of Health and Human Services is undergoing a department-wide process to identify what authorities or changes in statute would be helpful.

The Honorable Susan Brooks

1. I have heard you say that preventing drug use before it begins is the is the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

The National Institute on Drug Abuse (NIDA) continues to fund a robust prevention portfolio that builds upon solid epidemiological findings and insights from genetics and neuroscience research, applying this knowledge to develop effective strategies to prevent initiation of drug use and escalation of use to addiction among youth. Highly effective evidence-based drug use prevention interventions and drug addiction treatment approaches have been developed and tested. These are well detailed in the Surgeon General's Report on Alcohol, Drugs and Health.[13] NIH's current prevention portfolio encompasses a broad range of research to (1) increase our understanding of the factors – including genetic, psychological, and environmental – that enhance or mitigate an

[13] Surgeon General's Report on Alcohol, Drugs, and Health. 2016. at https://addiction.surgeongeneral.gov/

individual's risk for drug use and substance use disorders; and (2) develop and testing intervention strategies targeted to high-risk populations.

For example, KEEP SAFE is a family-based and skill-focused program designed to prevent substance use and other related health risking behaviors among youth in foster care. Research indicated that the intervention significantly reduced substance use in foster youth at 18 months post-baseline and that the intervention influenced substance use through two processes: youths' improved quality of relationships with caregivers at 6 months post-baseline and fewer associations with deviant peers at 12 months post-baseline. This suggests that these two processes may be important targets in substance use prevention programs for foster youth.

Broad adoption of evidence-based prevention interventions has been limited due to implementation challenges that span financial, regulatory, geographic, attitudinal, and logistical issues. Ongoing research is working to develop strategies to translate evidence-based practices in a way that confers population-level impact,[14] including for developing implementation capacity, and implementation and sustainability of evidence-based practices across systems and settings. For example:

- Organizational and system supports for evidence-based implementation
- Work-force development and training
- Ongoing fidelity monitoring
- Continuous quality improvement
- Financing

In addition, NIH supports basic research to understand the impact of drug use during adolescence on brain development. Adolescence is a period of intense brain and cognitive development. During this time, one's environments, experiences, and exposures shape brain structure and function, and ultimately adult identity. Brain research, particularly in the last decade, has opened new windows to understanding the adolescent brain, but there is much we still do not know about the normal trajectory of brain development during adolescence and the many experiences that may enhance or disrupt it, such as substance use. To address this gap, NIH, in partnership with the Centers for Disease Control and Prevention (CDC), is funding the landmark Adolescent Brain Cognitive Development (ABCD) Study[15], a multi-site, longitudinal investigation of 10,000 children from ages nine and ten into early adulthood. As of October 2017, over 6,500 youth have enrolled in the study. The actionable information coming out of this study will be a foundation upon which to develop and refine substance use prevention and treatment as well as other health promotion interventions that are rooted in a deep understanding of the neurobiological and psychosocial factors that influence adolescent health and wellness to optimize the wellbeing and success of our Nation's children.

---

[14] Spoth R, Rohrbach LA, Greenberg M, et al. Addressing core challenges for the next generation of type 2 translation research and systems: the translation science to population impact (TSci Impact) framework. Prev Sci 2013;14:319-51.

[15] http://abcdstudy.org/index.html

In particular, more research is needed to improve strategies for prevention of risky drug use among those aged 18-30, and to develop evidence-based strategies for the prevention of opioid misuse that preserve access to effective pain management. In addition, more research is needed to develop strategies for transforming health systems and other public and private service platforms for successful integration of sustainable, evidence based drug use prevention interventions.

Finally, NIH would like to note that this year, a new study called the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) will evaluate treatment options and improve clinical care of infants with Neonatal Abstinence Syndrome (NAS)/NOWS. The study is a collaboration between the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's (NICHD's) Neonatal Research Network (which has 30 years of experience in conducting clinical trials with newborns) and the new IDeA States Pediatric Clinical Trials Network (within the NIH Office of the Director's Environmental Influences on Child Health Outcomes (ECHO) Program), with sites located in rural and medically underserved communities. This joint research effort will use the reach of both networks to assess the prevalence of NAS, understand current approaches to managing NOWS cases (including non-pharmacological approaches), and develop protocols for conducting large scale studies across the country to inform clinical care for affected infants.

2. Please describe the NIDA-supported research that is investigating how to improve access to treatment for incarcerated individuals. How is NIDA working with state and local communities on this particular problem?

NIDA's Juvenile Justice Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS) cooperative was established in 2013 and is composed of six research centers and one coordinating center. The main study is a randomized trial that involves 36 sites in seven states and aims to test the effectiveness of two implementation strategies for promoting system-wide change to improve the continuum of substance use services for juvenile offenders under community supervision.[16] JJ-TRIALS has led to the development of the Juvenile Justice Behavioral Health Services Cascade, a framework for measurement of unmet substance use treatment needs that can be used to identify services delivery needs and develop strategies to address them.[17]

Beyond juvenile populations, NIDA currently is funding research to test the feasibility and utility of depot formulations of buprenorphine and naltrexone to prevent relapse to

[16] Knight DK, Belenko S, Wiley T, et al. Juvenile Justice—Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS): a cluster randomized trial targeting system-wide improvement in substance use services. Implementation Science : IS 2016;11:57.

[17] Belenko S, Knight D, Wasserman GA, et al. The Juvenile Justice Behavioral Health Services Cascade: A new framework for measuring unmet substance use treatment services needs among adolescent offenders. Journal of Substance Abuse Treatment; 74:80-91.

opioid use and recidivism in incarcerated opioid-dependent individuals.[18] Barriers to care also are being investigated, with research specific to the difficulties that justice-involved veterans have in accessing medications for Opioid Use Disorder (OUD)[19] and development of eLearning tools to improve attitudes toward medications in drug and felony courts.[20]

The period of transition from incarceration to community living can cause disruption in care for substance use disorders and for associated health conditions such as HIV and Hepatitis C. NIDA funds research to identify barriers and facilitators of linkage to care following incarceration, along with research to develop interventions to improve care continuity, reduce overdose risk, and identify factors specific to vulnerable sub-populations. This research includes:

- Development of an intervention to support initiation of buprenorphine or methadone treatment following release from incarceration[21,22];
- Evaluation of pre-release initiation of extended-release naltrexone (XR-NTX) followed by post-release home visits for XR-NTX injection delivery[23];
- Development of a program to optimize HIV treatment outcomes for women under community correctional supervision[24]; and
- Development and testing of behavioral interventions to reduce risky behaviors and improve treatment adherence post-release.[25,26]

3. In your opinion, what are the most pressing gaps in data collection that must be addressed in order to stem the tide on this crisis? We hear a lot about the underreporting of overdose deaths – what are the contributing factors that lead to underreporting and inaccurate reporting and what is NIDA doing to address that?

(CDC Primary)

---

[18] 4U01DA034743-04–DEPOT PHARMACOTHERAPIES FOR OPIOID-DEPENDENT OFFENDERS: OUTCOMES AND COSTS
[19] 1R21DA041489-01A1–IMPROVING ACCESS TO PHARMACOTHERAPY FOR OPIOID USE DISORDER AMONG JUSTICE INVOLVED VETERANS
[20] 5R34DA038799-03–FACILITATING MAT ACCEPTANCE & IMPLEMENTATION IN PROBLEM SOLVING & FELONY COURTS
[21] 5K23DA034541-06–BUPRENORPHINE FACILITATED ACCESS AND SUPPORTIVE TREATMENT IN FORMER INMATES
[22] 5K24DA022112-10–HIV AND ADDICTIONS AMONG CRIMINAL JUSTICE-INVOLVED POPULATIONS
[23] 5R01DA040636-02– LONG-ACTING NALTREXONE FOR PRE-RELEASE PRISONERS: A RANDOMIZED TRIAL OF MOBILE TREATMENT
[24] 4K23DA033858-05– EVALUATING AND IMPROVING HIV OUTCOMES IN COMMUNITY-BASED WOMEN WHO INTERFACE WITH
[25] 5R01DA025885-09–SUSTAINABLE HIV RISK REDUCTION STRATEGIES FOR CJ SYSTEMS
[26] 1R36DA043393-01A1– ADDRESSING OVERDOSE RISK AMONG RECENTLY INCARCERATED PEOPLE LIVING WITH HIV/AIDS

4. Please describe any current or planned programs in which NIDA would collaborate with state governments to scale-up evidence-based research in prevention or treatment.

NIDA-funded researchers are partnering with states to examine the strategies that are being used to increase access to opioid use disorder medications through the SAMHSA State Targeted Response to the Opioid Crisis Grants that were funded through the 21st Century Cures Act. Five NIDA-funded research projects will help evaluate:

- The creation and deployment of the Patient Decision Aid for Medication-Assisted Treatment (PtDA- MAT), a patient-centered decision tool to promote the use of medications, assess patient values and preferences, and incorporates scientific evidence to increase patients' understanding of possible medication risks, benefits, alternatives, and their associated outcomes.[27]
- The Recovery Initiation and Management after Overdose (RIMO) protocol for individuals who are revived from an opioid overdose. The protocol is initiated within a week of nonfatal overdose and includes assertive recovery supports and facilitates linkage with evidence-based treatment for OUD using medications.[28]
- Planned Outreach, Intervention, Naloxone, and Treatment (POINT), an emergency department-based outreach program for engaging opioid overdose survivors in Indiana with treatment. Recovery coaches are deployed to emergency departments to assist patients with accessing medication-assisted treatment after discharge from the emergency department.[29]
- A Rhode Island initiative is focused on expanding the medication assisted treatment workforce by developing and testing a pharmacist-delivered intervention for the management of patients who are stable on medications. This model will also be refined and tested to provide continuity in medication assisted treatment for patients who are being released from incarceration.[30]
- The Hub & Spoke model for provision of medication assisted treatment in primary care settings. This model is being tested in Washington state with a study that focuses on adults with OUD who are covered by Medicaid.[31]

In addition, NIDA has partnered with states and several other federal agencies to address the opioid crisis in rural U.S. regions, issuing funding opportunities to help communities

[27] https://projectreporter.nih.gov/project_info_description.cfm?aid=9513338&icde=36846083&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=
[28] https://projectreporter.nih.gov/project_info_description.cfm?aid=9511074&icde=36846131&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=
[29] https://projectreporter.nih.gov/project_info_description.cfm?aid=9513197&icde=36846207&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=
[30] https://projectreporter.nih.gov/project_info_description.cfm?aid=9513201&icde=36846245&ddparam=&ddvalue=&ddsub=&cr=4&csb=default&cs=ASC&pball=
[31] https://projectreporter.nih.gov/project_info_description.cfm?aid=9513139&icde=36846292&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=

develop ways to comprehensively prevent and treat Substance Use Disorder (SUD), overdoses, and infectious disease transmission related to injection drug use. These projects support the work of state and local communities in developing best-practice responses that rural public health systems can implement. The grants are co-funded by the Appalachian Regional Commission, the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Honorable Ben Ray Lujan

In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. The New York Times reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The Times and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long- term investments in prevention, treatment, recovery, and monitoring.

The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.

1. Director Volkow, do you have all of the tools you need to stop the opioid epidemic?

To fight the opioid crisis, an all hands-on deck approach is needed. NIH is enlisting partners across government and the private sector to deliver scientific solutions to this public health crisis. Regarding tools we may need, the Department of Health and Human Services is undergoing a department-wide process to identify what authorities or changes in statute would be helpful.

2. Given the 19 percent cuts to NIH in the President's budget proposal, what programs relating to the opioid epidemic will be cut? Which programs would have been expanded that will now not be?

Addressing the opioid crisis is a top priority for the Department of Health and Human Services, including NIH. We will prioritize research to develop solutions for this crisis and strive to accelerate progress as quickly as available resources will allow.

The Honorable Frank Pallone, Jr.

1. Dr. Volkow and Dr. McCance-Katz I would like to ask you a few questions related to treatment approaches for opioid use disorder. I have been particularly struck by stories of individuals with opioid use disorder and families who have been targeted and referred to low quality and non-evidence-based treatment services. As I'm sure you're aware, in many cases, this has led to tragic consequences upon leaving such programs.

(a) Dr. Volkow and Dr. McCance-Katz – I understand that the evidence is clear that medication-assisted treatment is the gold standard of opioid use disorder treatment. What are some of the barriers of widespread uptake for this treatment approach?

(b) What is the difference between this and other chronic conditions as far as uptake of evidence-based medical care? And could you dispel some of the stigma that exists about the use of medications to treat this chronic condition that doesn't exist for the use of medications to treat like diabetes or heart disease?

(c) What are you doing to increase awareness among the general public and the medical community about these evidence-based approaches to opioid use disorder?

(a) Medication-Assisted Treatment (MAT) has been adopted in less than half of private-sector treatment programs, and even in programs that do offer MAT, only 34.4 percent of patients with opioid use disorder (OUD) receive it.[32] The barriers are many, including a limited number of trained prescribers and settings in which people with OUD can obtain treatment; negative attitudes and misunderstandings about MAT held by the public, providers, and patients; and policy and regulatory barriers. Although there are currently over 45,000 DEA-registered Data Waive practitioners and over 1,600 DEA-registered narcotic treatment programs throughout the U.S., those are mainly focused on highly-populated, metropolitan areas and limited access still exists in more scarcely-populated areas of the country.

In the past, the only medication available to treat opioid addiction was methadone and it was available only through opioid treatment programs, which were separate from the rest of healthcare. With the approval of buprenorphine in 2002 and then naltrexone in 2010, MAT became available from office-based physicians. However, clinicians may administer buprenorphine only if they hold special waivers. There remains a shortage of qualified, waivered physicians able to deliver buprenorphine.

For decades, a common concern was that maintenance therapy (methadone and, more recently, buprenorphine) "substitutes one addiction with another," a legacy of older, 12-step models of recovery that avoided all use of medications. Despite common myths, when someone is treated with methadone or buprenorphine the dosage of medication used does not produce euphoria, it helps to control cravings and withdrawal symptoms in

[32] Knudsen HK, Abraham AJ, Roman PM. Adoption and implementation of medications in addiction treatment programs. *J Addict Med.* 2011;5(1):21-27. doi:10.1097/ADM.0b013e3181d41ddb.

opioid-dependent patients, thus enabling them to function at work, in family life and relationships, and participate in treatment. These medications restore balance to the brain circuits that have been dysregulated by addiction, allowing the patient's brain to heal while they work towards recovery. Unfortunately, provider skepticism still contributes to low adoption of MAT; this skepticism also contributes to systematic prescription of inadequate doses or inadequate duration of treatment.[33]

Other impediments have to do with public and private insurance coverage. Most commercial insurance plans cover some opioid-addiction medications—most commonly buprenorphine—and Medicaid can cover buprenorphine and methadone in every state. However, even when MAT is covered, insurers (including Medicaid programs or their managed-care organizations) may impose limits on dosages prescribed, annual or lifetime medication limits, initial authorization and reauthorization requirements, minimal counseling coverage, and "fail first" criteria requiring that other therapies be attempted first.[34] These structural impediments synergize with attitudinal ones, for instance by encouraging insufficient dosing/duration, which causes treatment to fail, which leads to a perception that MAT is not effective. Also, few private insurance plans cover extended-release naltrexone, and most do not cover methadone provided through opioid treatment programs.

(b) Although cost of medication may sometimes constitute impediments to obtaining high-quality treatment for other diseases, no other common, devastating health condition has so many barriers to care that in one way or another come down to stigma—against the disease and against the idea of treating it as a medical condition. Abundant research has made clear that MAT, when delivered at a clinically appropriate dose, reduces illicit opioid use, risk of relapse and overdose, risk of infectious disease transmission, and associated criminality.

(c) To dispel misconceptions about MAT and educate the public and providers about MAT's effectiveness in treating OUD, the National Institute on Drug Abuse (NIDA) has produced a range of web-based materials on MAT including a Research Report on Medications for Opioid Use Disorder[35] (released May 2017) and brief fact sheets for policymakers, healthcare providers, and other stakeholders on the state of the science of medications for opioid addiction.[36] NIDA has also published extensively on the need for expanded access to MAT in professional publications and the popular press. NIDA has also partnered with other federal agencies to promote access to MAT, for instance the 2016 Surgeon General's Report on Alcohol, Drugs, and Health, and SAMHSA's upcoming Principles of Mental Health and Substance Use Disorder Treatment for Criminal Justice Populations.

---

[33] http://www.nejm.org/doi/ref/10.1056/NEJMp1402780#t=references

[34] Clark RE, Baxter JD. Responses of state Medicaid programs to buprenorphine diversion: doing more harm than good? JAMA Intern Med 2013;173:1571-1572.

[35] https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview

[36] https://www.drugabuse.gov/publications/finder/t/902/policy-briefs

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 17, 2017

Mr. Neil Doherty
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Doherty:

Thank you for appearing before the Subcommittee on Health on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

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

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

MAY 07 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Neil Doherty, Deputy Assistant Administrator of the Office of Diversion Control for the Drug Enforcement Administration, before the House Committee on Energy and Commerce on October 25, 2017, at a hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives." We hope that this information is of assistance to the Committee.

Please do not hesitate to contact this office if we can be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Prim Escalona

Prim F. Escalona
Principal Deputy Assistant Attorney General

Enclosure
cc: The Honorable Frank Pallone
Ranking Minority Member

QUESTIONS FOR THE RECORD

NEIL DOHERTY
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION
DEPARTMENT OF JUSTICE

HOUSE COMMITTEE ON ENERGY AND COMMERCE

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

OCTOBER 25, 2017

Questions Posed by Representative Adam Kinzinger

1. With respect to Prescription Drug Monitoring Programs, what issues should we be aware of regarding PDMP access by law enforcement personnel?

RESPONSE: As you know, prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and, where permitted, law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. The Drug Enforcement Administration (DEA) strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th state to have an operational PDMP, pursuant to the Governor's Executive Order in July 2017. As of January 2018, 40 of these 49 states with operational PDMPs require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[1] The DEA encourages all practitioners and pharmacists to use their state PDMPs.

PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion. Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information (PII) is vital. Access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data. These requirements can hinder DEA's investigations of those who are operating outside of the Controlled

[1] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf retrieved March 6, 2018.

Substances Act (CSA) and may affect DEA's ability to effectively protect the public health and safety.

Questions Posed by Representative Bill Flores

2. A serious problem in the opioid epidemic is synthetic drugs. The DEA released its 2017 National Drug Threat Assessment Monday. One of the findings was, and I quote, "Overdose deaths, already at high levels, continue to rise. The increased mixing of heroin with analogues of the highly-potent synthetic opioid fentanyl and other synthetic opioids has exacerbated this situation."

   Our colleague, Mr. Katko of New York, testified before this committee earlier this month about a bill he has that help protect our communities from synthetics and analogues. Now, there is still work to be done on his proposal – which has passed the Judiciary Committee, I should note.

   - Mr. Doherty, has the DEA focused any attention on providing technical comments on the Katko bill, titled the Stop the Importation and Trafficking of Synthetic Analogues Act – or SITSA for short?

   RESPONSE: Yes. The Department of Justice (the Department) and DEA have provided extensive technical assistance on SITSA to both the House and the Senate. The Department and DEA welcome any additional tools that Congress can provide to assist DEA in combating the opioid epidemic. In the interim, DEA will continue to utilize all available tools, including temporary scheduling of substances as authorized by 21 USC 811(h). In fact, on November 9, 2017, the Department and DEA announced that we intended to take immediate action against the flow of illicit fentanyl analogues into this country and the alarming increase in overdose deaths linked to synthetic opioids by scheduling all fentanyl-related substances on an emergency basis. The "notice of intent" was published in the Federal Register on December 29, 2017. The final order was published in the Federal Register on February 6, 2018, and made effective on that date. Pursuant to this final order, anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This critical scheduling action will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances.

3. Are there tools that the DEA has requested from Congress to help combat synthetics?

   RESPONSE: DEA and the Department have provided technical assistance to both the House and Senate regarding SITSA, which would be a useful tool to combat the proliferation of synthetic analougues. As mentioned in the response to the previous question, DEA continues to utilize its regulatory authority to place many synthetic substances into Schedule I of the CSA pursuant to the aforementioned temporary scheduling authority.

4. I understand law enforcement desires additional scheduling authorities, while researchers have concerns with how this may unintentionally impact the scientific community's ability to study compounds for groundbreaking medications.

    - Is there a way we can strike a balance of scheduling these rapidly-multiplying analogues in a timelier manner while also protecting the important work being done by scientific researchers?

RESPONSE: The introduction of new drugs of abuse is causing unprecedented harm to our communities and scheduling is an important tool DEA uses to protect the public from the trafficking and diversion of these harmful substances. It bears repeating that scheduling does not prevent DEA-registered researchers from conducting research on the substances. DEA agrees that it is important for the research community to have access to these novel psychoactive substances and DEA strongly supports research with controlled substances, including those in schedule I of the CSA. This research informs regulatory and policy decisions. Indeed, the process of drug scheduling requires the Department of Health and Human Services (HHS) to evaluate the research and provide DEA with a binding recommendation regarding the control of a substance. The scientific evidence remains critical to both the drug scheduling and the approval process. As a provider of this binding control recommendation and a primary source for funding, HHS should continue to maintain a robust role. The procedures that must be followed to apply for a DEA registration to conduct research with a schedule I controlled substance are set forth in 21 C.F.R. 1301.18.

DEA has taken steps to simplify the research application process, including the introduction of a new electronic system through which applications can be submitted, and will continue to work with the research community to ensure applications are processed in a timely manner. DEA has granted every application received for bona fide research with a schedule I controlled substance, and as of March 18, 2018 there are 601 DEA-registered schedule I researchers.

DEA worked with the Department to provide formal technical assistance on SITSA. During that time, DEA and HHS engaged extensively in order to understand its concerns related to permanent scheduling and research under SITSA.

Questions Posed by Representative Chris Collins

5. As PDMPs have evolved in recent years, incorporating PDMP data into a prescriber or pharmacist's clinical workflow seems to be the key to ensuring that the data is used effectively while also increasing efficiency and saving time for providers. What are the barriers currently preventing more states from incorporating PDMP data into clinical workflow?

RESPONSE: DEA agrees that integrating PDMP data into electronic health records to better inform the prescriber and pharmacist before a prescription

is dispensed is a best practice. However, DEA is not aware of barriers that are currently preventing states from incorporating PDMP data into clinical workflow and respecfully defers to HHS.

6. We know that the "moment of clarity" when a patient realizes they need to go into treatment can be short-lived, and having resources in place to immediately connect patients to treatment is critical to the chances of recovery. When a PDMP does indicate a patient has been "doctor shopping" and potentially has a substance use disorder, what policies are in place to direct them to treatment if they wish to go? If none exist, how could we help encourage them to access treatment at that time?

RESPONSE: DEA is not aware of any policies aimed at directing patients to treatment and would respectfully defer to the Bureau of Justice Assistance (BJA) or HHS. Although there are no policies mandating referral to treatment, DEA is not aware of anything to prohibit health professionals who currently have access to PDMP information to engage in intervention and referral to treatment. DEA defers to the Substance Abuse and Mental Health Services Administration (SAMHSA) to explore the expanding practice of screening, brief intervention, and referral to treatment among health professionals. Additionally, DEA plays a role in supporting effective drug treatment of persons with opioid use disorders through providing waivers and certifications to physicians, physician assistants, and nurse practitioners to dispense/administer medications approved by the U.S. Food and Drug Administration (FDA) for addiction treatment – buprenorphine, naltrexone, and methadone in certain settings.

7. a. Some states such as Massachusetts have started using data as a weapon in the fight against opioids. They are combining data from prescription records, death records, medical examiners... even prisons. For example, they found that a person who is released from jail in Massachusetts has a 56 times greater chance of dying from an overdose than the average person. They are using that information to make better policy decisions, as well as to identify specific individuals who are in need of services. States are supposed to be the laboratories of democracy. What has the CDC learned from states in their use of data analytics?

RESPONSE: DEA respectfully defers to the Centers for Disease Control and Prevention (CDC) for a response.

b. Is there a plan to use data to fight the opioid crisis?

RESPONSE: DEA uses data when pursuing actions against those who violate the CSA. For example, the Automation of Reports and Consolidated Orders System (ARCOS) is the electronic system in which manufacturers and distributors report the manufacture, sale, purchase, loss, or other disposition of certain controlled substances. ARCOS is an important tool in both DEA's law enforcement mission and its regulatory mission. DEA field elements use ARCOS to assist investigators with accountability audits during onsite regulatory investigations and also to review

and verify specific registrant's activities and reporting accuracy. A unit within the Diversion Control Division's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution created by the CSA. This unit performs quality control reviews of ARCOS data and then uses validated ARCOS data to detect anomalies and identify leads. This unit is now proactively preparing reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil, and regulatory investigations. DEA shares ARCOS data with its federal, state, local, and tribal law enforcement and regulatory counterparts who have a need to know and are operating in coordination with DEA for investigative purposes. In addition to ARCOS data, DEA registrants are required under current regulations to report the theft or significant loss of controlled substances. Each report is fully investigated and this data also informs DEA's decision making and resource prioritization.

In addition to data that is collected by DEA pursuant to the CSA, we are also engaging with both federal and state partners on data sharing agreements to enhance our efforts. DEA is currently working with a coalition of States Attorneys General (Coalition) to develop an information-sharing agreement in support of ongoing investigations that the Coalition has initiated. This information sharing agreement will include the sharing of ARCOS data with States and in return, those States who can, will share data from PDMPs in support of active DEA investigations. DEA has also been working with HHS on an information sharing agreement. HHS's Office of Inspector General (OIG) has been sharing with DEA information from HHS's OIG analytics for the Medicare Program. DEA has already received data from HHS regarding the Part D prescription program that is being utilized alongside additional data in support of ongoing matters.

Finally, in line with the Department's Opioid Fraud and Abuse Detection Unit (a Department pilot program announced in August, 2017), the Department, DEA, Federal Bureau of Investigation (FBI), and counterparts at HHS are utilizing advanced data-analytics to combat the opioid crisis. As part of this program, the Department has dedicated experienced prosecutors for a three-year term in twelve districts, who will focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense opioids for illegitimate purposes.

Questions Posed by Representative Buddy Carter

8. Under CARA, prescribers can write up to three 30-day prescriptions without any refills. You can look into how pharmacists could play a larger role and ways to address prescriber behavior.

   Additionally, you can ask questions about limiting prescriptions for acute pain needs, such as dental work or minor surgeries with the possibility for a limited refill.

   Mr. Doherty, under CARA, prescribers were allowed to write up to three 30-day

prescriptions for a patient but no refills. While CARA took some great steps forward, I think it's worth taking another look at its progress and ways to improve the program. One area I'd like to raise would be limiting prescriptions for acute pain procedures and needs. As a pharmacist, I've seen people come in with 30 day prescriptions for minor dental procedures. Have you looked in to that possibility and what would be the DEA's outlook on such a move?

RESPONSE: DEA has reviewed CARA and could not locate a provision authorizing prescribers to write up to three 30-day prescriptions for a patient with no refills. The question may be referring to a final rule on the "Issuance of Multiple Prescriptions for Schedule II Controlled Substances," which DEA published in the Federal Register on November 19, 2007. (72 FR 64929) This rule allowed prescribers to issue three sequential prescriptions at one time for a schedule II controlled substance, effectively allowing a patient to be issued prescriptions for a 90-day supply of controlled substances. 21 C.F.R. 1306(b). DEA does not dictate what quantities of controlled substances constitute a 30-day supply, as DEA does not regulate the practice of medicine.

With regard to limiting prescriptions for acute pain, DEA notes that the CDC published guidance to prescribers suggesting that three days or less of an opioid medication will often be sufficient for acute pain. DEA does not dictate the amount of a controlled substance that a prescriber should authorize as these clinical decisions are the direct result of the doctor's clinical training and the result of his/her evaluation of the patient's particular needs.

Finally, DEA provided technical assistance on the provision in CARA that authorized prescribers and patients to request a partial fill of a prescription for a schedule II controlled substances. This provision authorizes a patient or practitioner to request that the pharmacist only dispense a portion of the quantity prescribed, and he/she may request the remainder of the quantity prescribed to be dispensed within 30 days. This provision was intended to reduce the amount of unused and unwanted opioids outside of the drug supply chain, i.e., in people's homes.

9. Would the DEA be willing to look at reducing the number of prescriptions for opioids and allowing for one, limited refill of the prescription? I believe it could help to reduce the amount in circulation as well as address some of these accessibility needs we've brought up through take-back programs.

RESPONSE: It is not clear how authorizing one limited refill of a schedule II controlled substance would result in a reduction in the number of prescriptions written and the amount of controlled substances in circulation. The refilling of a prescription for a controlled substance listed in schedule II is prohibited under Federal law. 21 USC §829(a).

10. October 28th is the 14th National Drug Take-Back Day. During your tenure in the state legislature, you helped create the program that turned in 9,630 pounds of unwanted

medications during the April drive in Georgia.

- How would the DEA approach a national mail-in take-back program across the country? What sort of security concerns and guidelines would need to be addressed to make it effective?

RESPONSE: A mail in take-back program is one of several acceptable options authorized under current DEA regulations. 21 C.F.R. 1317.70. On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet. According to the 2016 National Survey on Drug Use and Health, approximately half of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or received it free from a friend or relative. These regulations provide a safe and legal method for the public to dispose of unused or expired controlled prescription drugs (CPDs). As of January 9, 2018, a total of 3,214 DEA registrants have become "authorized collectors."

11. On top of those concerns, would a nominal fee paid by the patient be able to cover the costs of such a program?

RESPONSE: Per 21 C.F.R. 1317.70(c), "collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free)" for the collection of controlled substances via mail. Collectors set their own fee should they choose to do so. It should be noted that 21 C.F.R. 1317.70(c)(4) states that "the cost of shipping the package shall be postage paid."

Questions Posed by Representative Pete Olson

12. Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)? Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?

RESPONSE: DEA does not have grant making authority and is therefore unaware of how much funding has been allocated to state prescription drug monitoring programs as a result of CARA.

Questions Posed by Representative Susan Brooks

13. I have heard you say that preventing drug use before it begins is the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

RESPONSE: It is true that preventing drug use before it starts is the most cost-effective way to reduce drug use and its related consequences. Interventions that prevent substance misuse and substance use disorders can yield a greater economic return than the services that treat them. For instance, a study of prevention programs estimated that every dollar spent on effective, school-based programs to delay onset of use of alcohol, tobacco, and illegal drugs may save an estimated $18 in costs related to problems later in life such as lost productivity and diminished quality of life.[2]

Effective research-based programs share the following core elements: structure—how each program is organized and constructed; content—how the information, skills, and strategies are presented; and delivery—how the program is selected or adapted and implemented, as well as how it is evaluated in a specific community. When adapting programs to match community needs, it is important to retain these core elements to ensure that the most effective parts of the program stay intact.[3]

While it is important to note that prevention strategies must be tailored to the individual setting, thereby avoiding a "cookie-cutter" approach, successful prevention approaches share a variety of characteristics. For instance, they are data-driven, in that data is compiled and used to guide all prevention-related decisions, from determining which drug abuse issues to address to choosing the most appropriate way to address those problems. Also, they focus on population-level change, which means implementing multiple strategies that address the identified risk and protective factors related to drug abuse in a given community. Furthermore, they are comprehensive, combining a variety of strategies rather than relying on a singular strategy. Lastly, they rely on a team approach. An effective prevention approach needs – and greatly benefits from – the participation of diverse partners. These individuals and institutions may change over time, but the need for prevention partners is constant.[4]

Besides a lack of resources, which continues to be a significant barrier to implementing prevention and intervention programs throughout the government, other barriers include insufficient training and technical assistance opportunities

---

[2] Miller, T., & Hendrie, D. (2008). Substance abuse prevention dollars and cents: A cost-benefit analysis. (DHHS-Pub. No. (SMA) 07-4298). Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention.)

[3] www.drugabuse.gov/publications/preventing-drug-abuse-among-children-adolescents-in-brief/chapter-3-applying-prevention-principles-to-drug-abuse-prevention-programs/what-are

[4] www.samhsa.gov/capt/applying-strategic-prevention-framework

for community coalitions and others across the nation working to prevent drug abuse, workforce shortages in the drug abuse prevention field, a lack of conformity to implementing evidence-based programs as designed, and apathy about drug abuse prevention in general.

Questions Posed by Representative Markwayne Mullin

14. I introduced H.R.3528, the Every Prescription Conveyed Securely Act, with Katherine Clark (D-MA), to require e-prescribing of controlled substances (EPCS) under Medicare Part D. As you may know, the President's Commission on Opioids recommended that the use of e- prescribing of opioids should be encouraged. Since the DEA relaxed its prohibition of e-prescribing for controlled substances in 2010, e-prescribing has expanded for Medicare beneficiaries and six states have mandated its use specifically for controlled substances.

    Does the DEA have a position on this legislation? Please explain the DEA's position and any concerns it may have with EPCS.

    RESPONSE: Thank you for your work on this important issue. The Administration has not taken a position on this legislation. DEA supports the e-prescribing of controlled substances through its issuance of an interim final rule on EPCS, which was published in the Federal Register in March 2010. This rule clarifies the criteria by which DEA-registered practitioners may electronically issue controlled-substance prescriptions and by which DEA-registered pharmacies may receive and archive those prescriptions. It also creates an authentication procedure to ensure the prescriptions are not forgeries. The goal of this interim rule is to reduce the number of errors caused by illegible written prescriptions and help hospitals integrate prescription records into other medical files. As a result of this interim final rule, DEA received a number of comments and subsequently has met with stakeholders as it drafts a final rule. DEA will continue to work towards the publication of this final rule.

Questions Posed by Representative Ben Ray Lujan

15. In the U.S., we still have too few locations to drop off unwanted and expired medication – some of which can be dangerously addictive or fatally lethal in even small doses – like fentanyl. According to the 2017 National Drug Threat Assessment, in 2015, over half of people who misused prescription pain relievers, like opioids, got them from a friend or relative while roughly 34% got them from one doctor.

    - Administrator Doherty, what is the DEA doing to combat the misuse of pain relievers that are given by, bought from, or stolen from family friends?

    RESPONSE: On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies,

mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related SUDs, and promotes awareness that according to the 2016 National Survey on Drug Use and Health, one source of these drugs is often the home medicine cabinet, as approximately half of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free. These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of January 9, 2018, a total of 3,214 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on April 25, 2018. As a result of all fifteen National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of nearly 10 million pounds (4.98 tons) of medications from circulation. The sixteenth National Drug Take Back Day is scheduled for October 2018.

Education is a key piece of combatting the opioid epidemic, including the misuse of pain relievers that are given by, bought from, or stolen from family friends. DEA initiated and continues to expand upon its 360 Strategy. The strategy leverages existing Federal, state, local, and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and demand reduction. Our enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding the heroin and prescription drug epidemic in our communities. We are also enhancing our diversion control efforts and working with community partners for them to implement evidence-based programs and efforts designed to reduce demand and to prevent the same problems from resurfacing.

As part of the 360 Strategy, DEA has partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide development of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. The program has reached more than 1.1 million students to date, will run for at least three consecutive school years (through spring 2019), and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

Since launching the 360 Strategy in 2016, it has been implemented in eight cities: Louisville, Kentucky; St. Louis, Missouri; Pittsburgh, Pennsylvania; Milwaukee, Wisconsin; Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia; and Manchester, New Hampshire. DEA is expanding this program to additional locations including the announcement of the Salt Lake City, Utah location in September 2017. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

16. What is the DEA doing to make it harder to misuse of prescription drugs attained directly from doctors?

RESPONSE: DEA cannot control if ultimate users will misuse prescription drugs obtained directly from doctors. With that said, DEA works to prevent the diversion of controlled prescription drugs from doctors. DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and the present, DEA increased the number of operational TDSs from 37 to 77. In addition, we established two mobile TDSs that can deploy quickly to "hot spots" in furtherance of the Diversion Control Division's mission.

Additionally, please see the discussion of DEA's National "Take-Back" Initiative discussed above in response to question 1. This program, along with the authorized disposal methods in the Secure and Responsible Drug Disposal Act of 2010 and 21 C.F.R. 1317, is intended to reduce the amount of unwanted and unused controlled prescription drugs in peoples' homes such that they cannot be misused by the ultimate user or others.

17. I'm aware of private sector organizations such as CVS and Walgreens that are working diligently to provide more drop-off locations in their stores and local communities. What would it take to have drop-off locations for controlled substances in every community in the United States? What is the public sector doing to aid the private sector in these efforts?

RESPONSE: The DEA cannot mandate nor does it offer an incentive to a DEA-registered pharmacy, hospital or clinic to become an "authorized collector" pursuant to the September 2014 final order that establishes rules for this activity. DEA strongly encourages its approximately 90,000 registrants in these classes to consider becoming authorized collectors so that families have safe and convenient opportunities to dispose of unused and unwanted controlled prescription drugs 365 days per year.

The GAO recently studied this issue in its report entitled, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs* (GAO-18-25, published October 12, 2017).

18. Addressing the opioid epidemic is going to require a multi-faceted approach. We cannot cure opioid addiction through law enforcement or treatment alone. We must also work to address the problem at the start. This means we should also be adopting policies and practices to reduce the amount of opioids that are available in circulation, and educating health care providers on opioids, pain management, and non-opioid pain alternatives.

Approximately 80 percent of the legal global opioid supply is consumed in the United States. Based on 2015 sales, the top five opioid products were made by Purdue Pharma, Johnson & Johnson, Insys Therapeutics, Mylan and Depomed, according to sales. A 2016 survey by the National Safety Council revealed that about 99 percent of physicians exceed the recommended three-day dosage limit, with a quarter of them writing prescriptions for a full month and thus overprescribing these types of medications.

Members of this Committee have called for additional prescriber education and training to this effect and I want to learn more about what role FDA and DEA can play in this process.

- Mr. Doherty, as you know, a number of stakeholders have called for mandatory prescriber training on opioids to be a requirement of DEA registration. What role do you see prescriber education playing in addressing the opioid crisis, and what role has, or can, DEA play in ensuring health care practitioners are properly informed about the benefits and risks of opioids and the role appropriate prescribing can play in addressing the opioid epidemic?

RESPONSE: DEA believes that all entities in the controlled prescription drug supply chain benefit from having the most information possible regarding the benefits and risks of opioids, as well as the role that appropriate prescribing can play in addressing the opioid epidemic. DEA supports the CDC's *Guideline for Prescribing Opioids for Chronic Pain.* DEA is encouraged to see that the total prescriptions dispensed for the opioid analgesic class has trended downward from a high of approximately 290 million prescriptions in 2014 to approximately 240 million prescriptions in 2017.[5]

Additionally, in 2018, DEA has initiated a nationwide program to offer training to individual practitioners on the important role they play in preventing diversion of these controlled substances. This program will be modeled after, and will follow upon, the success of the 97 Pharmacy Diversion Awareness Conferences that DEA held throughout the country, culminating in October 2017. DEA trained over 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled.

[5] Information obtained by DEA pursuant to its contract with Quintiles IMS Health's for statistical information from its National Prescription Audit database. Information obtained on 12/6/17.

19. In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. *The New York Times* reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The *Times* and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long- term investments in prevention, treatment, recovery, and monitoring.
The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.

    - Deputy Assistant Administrator Doherty, do you have all of the tools you need to stop the opioid epidemic?

RESPONSE: With four out of five new heroin initiates reporting that they previously misused prescription pain relievers,[6] the efforts of DEA's Diversion Control Division have never been more critical. The DEA has a wide array of tools to ensure its more than 1.7 million registrants are in compliance with the CSA. These include outreach to industry, medication disposal, regulatory oversight, administrative actions, civil penalties, and criminal charges, among others. DEA has and will continue to use all available tools to combat the opioid epidemic.

Outreach to Industry

Due to the complexity of DEA's regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its more than 1.7 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by: (1) hosting Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy (NABP), American Medical Association (AMA), and Federation of State Medical Boards (FSMB), and other groups to address diversion problems and educate the medical community on improving prescribing practices.[7] As of November 2017, DEA will have hosted 100 PDACs in all 50 states (as well as the District of Colombia and Puerto

[6] Substance Abuse and Mental Health Services Administration. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Department of Health and Human Services, August 2013. *available at:* https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

[7] In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

Rico) resulting in the training of more than 13,300 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In May 2018, DEA plans to initiate a nationwide program to offer similar training to individual practitioners.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail-back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related SUDs, and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free[8]. These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of November 30, 2017, 2,948 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on April 25, 2018, which collected another record-setting 949,046 pounds—474.5 tons—of potentially dangerous expired, unused, and unwanted prescription drugs for disposal at more than 5,800 collection sites. As a result of all 15 National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed nearly 10 million pounds (4,982 tons) of medications from circulation. The sixteenth National Drug Take Back Day is scheduled for October 2018.

Prescription Drug Monitoring Programs

PDMPs are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th state to have an operational PDMP, pursuant to the Governor's Executive Order in July 2017. As of August 2017, 24 of

[8] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

these 49 states with operational PDMPs require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[9] DEA encourages all practitioners and pharmacists to use their state PDMPs.

Production Quotas for Schedule II Opioids

The Diversion Control Division is responsible for setting Aggregate Production Quotas (APQs) every year. These APQs are the "total quantity of each basic class of controlled substance listed in schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. The APQs are determined after consideration of certain statutory factors, described in 21 C.F.R. § 1303.11 (b), which include:

1. **Total net disposal (e.g. domestic sales, exports, waste) of the substance by all manufacturers during the current and two preceding years;**
2. **Trends in the national rate of net disposal of the substance; total actual (or estimated) inventories of the substance and of all substances manufactured from that substance, and trends in inventory accumulation;**
3. **Projected demand as indicated by procurement quotas requested in accordance with DEA regulations; and**
4. **Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.**

Since 2014, DEA has observed a decline in prescriptions written for certain schedule II opioids. These declines have led to overall reductions in licit demand which, in turn, have directly impacted the factors DEA considers when establishing the APQs for schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous years' (2016) level. The 2018 APQs result in a nearly 20 percent reduction from the 2017 levels. These reductions include the aforementioned opioids, as well as oxymorphone, codeine, and meperidine. These decreases can be attributed to local, state, and federal agencies creating new partnerships, enforcing current regulations, and issuing updated guidance documents, including the Centers for Disease Control and Prevention's 2016 publication entitled, *CDC Guideline for Prescribing Opioids for Chronic Pain.* In addition, we are

[9] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20170824.pdf retrieved October 19, 2017.

encouraged that more states have enacted and enforced laws mandating the use of prescription drug monitoring programs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

DEA'S 360 Strategy and Operation Prevention

To counter the opioid crisis, DEA continues to expand its 360 Strategy, a comprehensive three-pronged approach tackling the cycle of violence and addiction generated by the link between drug cartels, violent gangs, and the rising problem of prescription opioid misuse and heroin use in U.S. cities. The 360 Strategy features: coordinated law enforcement actions against drug cartels and heroin traffickers in specific communities; diversion actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners; and community outreach through local partnerships that empower communities to take back affected neighborhoods after enforcement actions and prevent the same problems from cropping up again. In 2016, DEA implemented its strategy in: Louisville, Kentucky; Milwaukee, Wisconsin; St. Louis, Missouri and Pittsburgh, Pennsylvania. In 2017, DEA implemented its strategy in Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia and Manchester, New Hampshire. In 2018, DEA is implementing this program in Salt Lake City, Utah; Northern and Southern New Jersey; and Philadelphia, Pennsylvania.

As part of the 360 Strategy, DEA has partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide development of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. The program has reached more than 1.1 million students to date, will run for at least three consecutive school years (through spring 2019), and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

Significant Enforcement Efforts

In addition to the actions of the Diversion Division, DEA continues to aggressively combat the opioid epidemic through a variety of enforcement and partnership efforts. The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Customs

Enforcement, Homeland Security Investigations (HSI) and Customs and Border Protection (CBP); supplemented by the FBI and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department's Criminal Division, the Department of Defense (DOD), the Intelligence Community (IC), and other government entities, and provides field offices from all agencies with valuable support in their respective investigations.

These relationships have led to several large enforcement actions, including two separate OCDETF investigations centered in North Dakota and Southern Mississippi that resulted in the first-ever indictments in September 2017 of two Chinese nationals responsible for the manufacturing, importation, and distribution of fentanyl in the United States. In addition, SOD played an integral role in the July 2017 seizure of the largest criminal marketplace on the Internet, AlphaBay, which operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. Multiple OCDETF interagency investigations into AlphaBay revealed that numerous vendors sold fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

Automated Reporting and Consolidated Orders System (ARCOS) Data

DEA's Diversion Control Division has also taken numerous steps to examine sales and monitoring processes. For example, Diversion Control utilizes various reports and records to monitor trends or determine anomalous transactions, which can then be developed into investigative leads. A unit within the Diversion Control's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit is now proactively preparing quarterly threat assessment reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil and regulatory investigations. DEA is working collaboratively with a coalition of States Attorneys General to provide non-public, law enforcement sensitive ARCOS data to support their active investigations against certain manufacturers and distributors.

Diversion Enforcement Actions

DEA uses a wide array of diversion enforcement tools to ensure its more than 1.7 million registrants are in compliance with the CSA. These include administrative actions, civil penalties, and criminal charges. Within DEA's administrative authorities, there are multiple actions that may lead to an individual or entity having

a registration revoked, which include orders to show cause (OTSC), immediate suspension orders (ISO), and voluntary surrenders. Upon a registrant surrendering a registration for cause, or DEA obtaining a suspension/revocation of the registration, the registrant can no longer dispense, prescribe or administer controlled substances, which DEA deems to be a success. Since FY 2011, these combined actions result in an average of roughly 980 registration revocations per year. Of the total registration revocations, ISOs have historically made up a small portion, averaging less than three percent annually. Additionally, combined ISO and OTSC actions in 2017 more than doubled since 2014.

Working with the United States Attorneys' Offices, DEA has pursued civil actions against some of the nation's largest drug distributors. Over the last decade, opioid distributors nationwide have paid nearly $390 million in civil penalties and DEA has entered into Memoranda of Agreement (MOAs) with the distributors to ensure their future compliance. In Fiscal Year 2017, distributors paid more than $194 million in civil penalties, which is more than the previous seven years combined (close to $148 million).

Since 2010, DEA has re-prioritized its criminal investigators and embedded them with diversion investigators into enforcement groups called tactical diversion squads (TDS). TDSs investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and present, DEA increased the number of operational TDSs from 37 to 77. In addition, DEA established two mobile TDS groups that can deploy quickly to "hot spots" in furtherance of the Diversion Control Program's mission. For example, one mobile TDS team recently deployed to Charleston and Clarksburg, West Virginia. Each of these groups focuses primarily on criminal enforcement and the results of their work often lead DEA registrants to surrender their DEA registration for cause. Over the last seven years, these TDS groups have initiated an average of more than 1,500 cases per year and made an average of more than 2,000 arrests per year.

Supporting Effective Drug Treatment

Additionally, DEA plays a role in supporting effective drug treatment of persons with opioid use disorders through providing waivers and certifications to physicians, physician assistants, and nurse practitioners to dispense/administer medications approved by the FDA for addiction treatment – buprenorphine, naltrexone, and methadone in certain settings.

20. How will the DEA allocate its 3.7 percent boost in funding in the President's budget proposal to fight the opioid epidemic?

RESPONSE: DEA appreciates the U.S. House of Representatives mark of the FY 2018 budget, which is consistent with the President's budget request. DEA has developed proposals that identify priorities that focus on anticipated program needs and that will allow DEA to continue to target the most significant drug trafficking threats including CPOTs, PTOs, and other significant DTOs. The FY 2018 President's Budget request will provide DEA resources to build upon our success and to continue to address the scourge of heroin and controlled prescription drug abuse. Enhancement requests include the following:

1. **<u>Heroin Enforcement:</u> $8.5 million in support of coordinated Law Enforcement actions that aim to sever the ties between cartels and the violent gangs which supply deadly opioids to our communities.**

2. **<u>Transnational Organized Crime</u>: $6.5 million for investigative activities focusing on the TCOs responsible for large quantities of drugs arriving in U.S. cities. DEA will enhance overseas investigative capabilities and the Sensitive Investigative Units (SIU) Program.**

3. **<u>Violent and Gun-Related Crime Reduction Task Force:</u> $5.9 million to tackle the violence generated by drug cartels and street gangs. DEA appreciates the U.S. House of Representatives mark of the FY2018 budget, which is consistent with the President's budget request. This request includes $21 million to combat the opioid epidemic and violent crime (10 agents) in support of the disruption and dismantlement of the individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA.**

4. **<u>Opioid Training, Enforcement, and Drug Disposal:</u> $20 million in support of actions against individuals and organizations operating outside the law. Additionally, long-term education and training engagements with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners will be conducted.**

5. **<u>Diversion Investigators and Tactical Diversion Squads:</u> $9.4 million will provide 55 positions (to include 10 Special Agents and 28 Diversion Investigators) to create new and enhance current Diversion Groups while solidifying existing TDSs to conduct criminal enforcement activities involved in diversion schemes (i.e. pill mills, prescription forgery rings, and rogue internet pharmacies).**

21. Opioid addiction is not a new problem. Misuse of and addiction to pharmaceuticals has existed for centuries, ever since morphine was heralded in the 1850s as a solution to our opium addiction problem– until it, in turn, morphine became a larger problem, as did heroin, and then methadone. Today, we understand the importance of pain relieving agents, but as my constituents continue to perish at alarming rates due to these drugs, we need to be working together to address the crisis. The public and private sectors can and should work together to swiftly address the opioid epidemic. The Reagan-Udall

Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science that is necessary to helping the FDA accomplish its mission. The Foundation was created by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to address regulatory science challenges of the 21st century. The central focus of the Foundation is to assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the agency's ability to protect and promote the health of the American public.

- Understanding what we know now about this issue, what further information or support do you need from pharmaceutical manufacturers to more aggressively combat this crisis?

RESPONSE: As the U.S. Food and Drug Administration (FDA) is the agency with a regulatory obligation to ensure that only safe and effective drugs are approved for marketing in the United States, DEA respectfully defers to the FDA on what additional measures pharmaceutical manufacturers should take to address the opioid epidemic.

22. Stopping the flow of opioids into the U.S. will require a decrease in demand. People who are at highest risk of overdose use prescription opioids nonmedically for 200 or more days a year. These highest-risk users are approximately four times more likely than the average user to buy the drugs from a dealer or other stranger. From a supply perspective, the ways for illicit opioids and heroin to enter the U.S. are ever-changing and creative, driven by the rise of e-commerce and outpacing our current abilities to monitor what enters across our borders.

Opioids and heroin illicitly enter the U.S. through the U.S. Postal Service and traditional drug smuggling channels. Illicit synthetics are largely manufactured in China and smuggled into the United States via traditional channels and through the U.S. Postal Service. Fentanyl is a synthetic opioid that Americans can order online through illicit drug marketplaces. Online ordering of counterfeit prescription drugs is possible via e-commerce websites and through dark web markets on the Tor network. Because fentanyl is potent, it is easy to hide in letters and small packages that are sent by post. Overseas labs in China are mass-producing fentanyl and fentanyl-related compounds and marketing them to drug trafficking groups in Mexico, Canada, and the United States. Mexico often serves as a transshipment point for fentanyls shipped from China. In 2017, fentanyl is being trafficked through Mexico into the U.S. alongside heroin and cocaine, though it is largely produced in Asia. Customs and Border Protection officers search packages entering the U.S. through the John F. Kennedy International Airport mail center for fentanyl and other synthetic opioids using an old X-ray machine, a borrowed handheld laser that can peek into packages, and a dog trained to detect fentanyl. In fiscal year 2016, the CBP team at JFK airport seized seven fentanyl packages. This year, they have seized 64 as of September 17, 2017.

Not all illicit synthetics enter the U.S. from other countries. A DEA intelligence brief

published in July 2016 noted that people within the U.S. are also making and selling fentanyl pills. In January 2016, DEA agents seized 6,000 fentanyl pills made to look like oxycodone from a dealer who was manufacturing them in his New York residence. A similar pill pressing operation was discovered in Los Angeles in March 2016.

Heroin consumed in the U.S. comes mainly from Afghanistan and Mexico, according to the UN's International Narcotics Control Board (INCB). As much as 94 percent of the heroin entering America comes from Mexico, estimated William R. Brownfield, assistant secretary of the Bureau of International Narcotics and Law Enforcement Affairs.

- Why can't the U.S. stop and dramatically reduce trafficking of opioids and heroin into the U.S.?

RESPONSE: DEA is diligently working by taking a whole of government approach with our federal partners to reduce the trafficking of opioids and heroin into the United States. There are many current initiatives aimed at combatting this problem, some of which are listed below.

Significant Enforcement Efforts

The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Customs Enforcement Homeland Security Investigations (HSI) and Customs and Border Protection (CBP); supplemented by the FBI and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department's Criminal Division, the Department of Defense (DOD), the Intelligence Community (IC) and other government entities, and provides field offices from all agencies with valuable support in their respective investigations.

The HFTF mission aims to:

- **Identify, target, and dismantle command and control networks of national and international fentanyl and New Psychoactive Substances (NPS) trafficking organizations.**
- **Provide case coordination and de-confliction on all domestic and foreign investigations to ensure that multi-jurisdictional, multi-national, and multi-agency investigations and prosecutions have the greatest impact on targeted organizations.**
- **Provide direct and dynamic operational and investigative support for domestic and foreign field offices for all agencies.**
- **Identify new foreign and domestic trafficking, manufacturing, importation, production and financial trends utilized by criminal enterprises.**
- **Analyze raw intelligence and documented evidence from multiple resources**

to develop actionable leads on viable target(s) involved in possible illicit pill production and/or distribution networks.

- Educate overall awareness, handling, trafficking trends, investigative techniques and safety to domestic and foreign field offices for all law enforcement, DOD, IC and governmental agencies.
- Facilitate, coordinate and educate judicial districts during prosecutions of fentanyl and other NPS related cases.

AlphaBay "Dark Market" Shutdown

In July 2017, the Department announced the seizure of the largest criminal marketplace on the Internet, AlphaBay, which operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. Multiple OCDETF interagency investigations into AlphaBay revealed that numerous vendors sold fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

Mexico: Partnership to Reduce Supply of Illicit-Narcotics

DEA, through its partnership with the U.S. Department of State, helps Mexican government officials to improve capacity to interdict and seize illicit narcotics. DEA routinely engages with Mexico through the bilateral drug policy working group with the Office of the Attorney General (PGR) in Mexico City. These efforts were instrumental in constructive policy changes such as Mexico's decision to schedule the two primary fentanyl precursors, ANPP and NPP in mid-2017.

China: Government Action and Cooperation

DEA, through its leadership in the United States and its country office in Beijing, has maintained an ongoing relationship with government officials of the People's Republic of China for years, and has been able to leverage this relationship to combat the rising threat from NPSs and their precursors. Engagement has been occurring at the leadership level through interagency working groups that operate under the U.S.-China Joint Liaison Group (JLG) framework co-chaired by the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, DEA, and DHS, including the Counternarcotics Working Group led by the Department of Justice, and the Bilateral Drug Intelligence Working Group led by DEA.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls against four fentanyl-class substances: carfentanil;

furanyl fentanyl; valeryl fentanyl; and, acryl fentanyl. This announcement was the culmination of ongoing collaboration between DEA and the Government of China, and reaffirms an expanding collaborative commitment to countering illicit fentanyl.

Over the past year, DEA and Chinese officials have met regularly to discuss mutual interests and shared responsibilities in countering the threat from fentanyl class substances. Representatives from the China National Narcotics Laboratory, the Narcotics Control Bureau, and the Ministry of Public Security met with DEA (along with Department of Justice and Department of Homeland Security) officials to exchange information on emerging substances' scientific data, trafficking trends, and sample exchanges. This continued dialogue is anticipated to foster a bilateral information exchange related, but not limited to, the identification of new substances of abuse that may then be considered for national control. The meeting also deepened professional contacts between relevant technical and legal experts.

A key moment in enhanced cooperation on synthetic drugs came in October 2015, when, following similar discussions, China decided to implement domestic controls on 116 NPS, which included a number of fentanyl analogues, and streamlined its procedures to control additional substances with no known medicinal use. In total, China has scheduled 138 different NPS, including 128 since October 2015.

Finally, as this threat has increased, law enforcement cooperation at the street level has been very productive, particularly on fentanyl cases. DEA will continue to collaborate with the Government of the People's Republic of China as the threat from fentanyl continues to evolve.

Class Wide Scheduling of Fentanyls

As stated in previous responses, the Department of Justice and DEA announced on November 9, 2017, that DEA intended to take immediate action against the flow of illicit fentanyl analogues into this country and the alarming increase in overdose deaths linked to synthetic opioids by scheduling all fentanyl-related substances on an emergency basis. The "notice of intent" was published in the Federal Register on December 29, 2017. The final order was published in the Federal Register on February 6, 2018, and made effective on that date. Pursuant to this final order, anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This scheduling action will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances.

23. If Congress was to allow for international drug importation writ large, does that have the potential to impact either positively or negatively the ability for nefarious actors to increase illegal opioid trafficking in the US?

RESPONSE: Any such authorization would require changes to the CSA and DEA

is not in a position to comment on a hypothetical issue without knowing how Congress might seek to make those statutory changes. DEA notes that its mission is to enforce the controlled substances laws and regulations of the United States, which would include preventing the importation and distribution of illegal drugs, as well as preventing the diversion of controlled prescription drugs from the legitimate drug supply chain. DEA is willing to review any draft legislation proposed by Congress on this matter.

○