

FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS

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

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FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS

TUESDAY, MARCH 21, 2017

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

The subcommittee met, pursuant to call, at 10:20 a.m., in Room 2123 Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, Griffith, Barton, Burgess, Brooks, Collins, Walberg, Walters, Costello, Carter, Bilirakis, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Peters, and Pallone (ex officio).

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Elena Brennan, Legislative Clerk, Oversight and Investigations; Adam Buckalew, Professional Staff Member, Health; Karen Christian, General Counsel; Zachary Dareshori, Staff Assistant; Jordan Davis, Director of Policy and External Affairs; Paige Decker, Executive Assistant and Committee Clerk; Scott Dziengelski, Policy Coordinator, Oversight and Investigations; Britany Havens, Professional Staff, Oversight and Investigations; Alex Miller, Video Production Aide and Press Assistant; David Schaub, Detailee, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Hamlin Wade, Special Advisor for External Affairs; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Counsel, Health; Christopher Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Staff Assistant; Kevin McAloon, Minority Professional Staff Member; Jon Monger, Minority Counsel; Dino Papanastasiou, Minority GAO Detailee; and C.J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Good morning. Welcome to this hearing called “Fentanyl: The Next Wave of the Opioid Crisis.”

America is in a full-on opioid crisis. About two decades ago, it started with the over prescribing of opioid drugs and then shifted more to heroin. Today, the subcommittee examines the next wave of the opioid crisis, an even more dangerous threat on our streets—fentanyl.

Fentanyl is made in the lab and for many years it has been a powerful pain medicine used by patients with cancer or for those with extreme pain.

I might add to this, I remember when I was injured in Iraq a few years ago, battlefield medicine meant in recovery they gave me lots of fentanyl patches, and I know what it is like to have the reaction to that.

It is 50 times more potent than heroin and 100 times more potent than morphine. Now illicit fentanyl has become a potent additive to heroin, cocaine, or even counterfeit prescription drugs.

This is the way the drug dealers increase profits: Stretch out their supply and expand the number of addicts by juicing the potency of heroin or other street drugs, sort of what people have done with MSG in foods.

Users often don't even know that fentanyl is in the heroin. The fentanyl crisis is exceptionally dangerous because of its high potency and the speed with which it reaches the brain. Just 2 milligrams of fentanyl can kill, whether swallowed, inhaled, or absorbed through skin.

To appreciate how small an amount 2 milligrams is: A sweetener packet that you see at your restaurant table is about 1,000 milligrams. Two milligrams of fentanyl can kill you.

Those suffering from an overdose involving fentanyl may require both higher doses and multiple administrations of naloxone to reverse the overdose and to become stabilized. Even the police and first responders are at risk from inadvertently touching or inhaling fentanyl powder at a crime scene or helping an overdose victim.

In March 2015, the Drug Enforcement Administration, or DEA, issued a nationwide alert on fentanyl as a threat to health and public safety.

A year later, the DEA sent another alert, calling the spike in fentanyl seizures an unprecedented threat. Customs and Border Protection data shows an 83-fold increase in the amount of fentanyl seized in 3 years.

An added challenge is that there are many chemical variations of fentanyl, commonly referred to as analogues. There are about 30 known analogues.

However, only 19 of these analogues are controlled substances under Federal law. Since 2013, fentanyl overdoses and deaths have surged with no end in sight. Fentanyl and its analogues have contributed to at least 5,000 overdose deaths in the United States, including the death of music star Prince last year. In my district alone, fentanyl-related deaths have exploded since 2014.

Last year, 86 people in Westmoreland County died from drug overdoses linked at least in part to fentanyl, and even these statistics seriously undercut the fentanyl threat nationally because most States and localities are not testing or tracking fentanyl in drug overdose cases. So we are flying blind.

At this rate, the capacity of law enforcement and the healthcare system will be overwhelmed. China is the primary source of fentanyl, and there are thousands of labs making illicit pure fentanyl as well as the source of ingredients or precursors needed to manufacture fentanyl.

Traffickers ship these ingredients to secret labs in Mexico run by drug cartels and then smuggle pounds of fentanyl over the Southwest border through our porous borders, launching it through catapults or drones and into the U.S.

Chinese labs are also a primary source for fentanyl ordered on the open internet and on the dark web. Pure fentanyl is delivered through the mail or air express carriers.

Finally, China is the main source of pill presses that can make thousands of pills an hour to support fentanyl press mill operations. I might add here I am pleased that China is saying that they are taking some action in helping to reduce this and we look forward to working with them because it is so deadly.

The fentanyl problem is spreading and going to get worse because the money and profit is enormous. According to the data from the DEA, a kilogram of heroin can be purchased for roughly \$6,000 and sold wholesale for \$80,000.

However, a kilogram of pure fentanyl can be purchased for less than \$5,000 and is so potent that it can be stretched into 16 to 24 kilograms of product when using cutting agents such as talcum powder or caffeine.

Therefore, while each kilogram of fentanyl can be sold wholesale for \$80,000, it can result in a total profit in the neighborhood of \$1.6 million. That is about 20 times more profit.

We need a Federal strategy dedicated to combating fentanyl as the clear and present danger it presents to our national security and public health.

We welcome our panel of witnesses today. We salute you for your work, thank you for appearing today, and look forward to working together to stop the spread of this epidemic.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

America is in a full-on opioid crisis. About two decades ago, it started with the overprescribing of opioid drugs and then shifted more to heroin. Today the subcommittee examines the next wave of the opioid crisis, an even more dangerous threat on our streets—fentanyl.

The surge of fentanyl is having a dramatic and deadly effect on our communities. We all see the headlines—these are our neighbors, our families, our friends. We need an “all hands on deck approach” to fight this problem, which will involve not just the Federal Government, but States, localities, and even international partners.

Fentanyl is made in a lab. For many years, it has been a powerful pain medicine used by patients with cancer or for those with extreme pain. It is about 50 times more potent than heroin and 100 times more potent than morphine.

Now illicit fentanyl has become the MSG of narcotics, a potent additive to heroin, cocaine, or even counterfeit prescription drugs. This is the way the drug dealers increase profits, stretch out their supply, and expand the number of addicts by juicing the potency of heroin or other street drugs. Users often don’t even know that fentanyl is in the drugs they are buying.

The fentanyl crisis is exceptionally dangerous because of its high potency and the speed with which it reaches the brain. Just 2 milligrams of fentanyl can kill, whether swallowed, inhaled, or absorbed through skin. To appreciate how small an amount 2 milligrams is, a sweetener packet at a restaurant table contains 1,000 milligrams.

Those suffering from an overdose involving fentanyl may require both higher doses and multiple administrations of naloxone to reverse the overdose and to become stabilized. Even the police and first responders are at risk from inadvertently touching or inhaling fentanyl powder at a crime scene or helping an overdose victim.

An added challenge is that there are many chemical variations of fentanyl—commonly referred to as analogues. There are about 30 known analogues, however only 19 of these analogues are controlled substances under Federal law.

Since 2013, fentanyl overdoses and deaths have surged with no end in sight. Fentanyl and its analogues have contributed to at least 5,000 overdose deaths in the United States, including the death of music star Prince last year. In my district alone, fentanyl-related deaths have exploded since 2014. Last year, 86 people in Westmoreland County died from drug overdoses linked at least in part to fentanyl. Even these statistics seriously undercount the fentanyl threat nationally because most States and localities are not testing or tracking fentanyl in drug overdose cases. At this rate, the capacity of law enforcement and the healthcare system will be overwhelmed.

China is the primary source of fentanyl. There are thousands of labs making illicit pure fentanyl as well as the source of ingredients or precursors needed to manufacture fentanyl. Traffickers ship these ingredients to secret labs in Mexico run by drug cartels and then smuggle pounds of fentanyl over the southwest border into the U.S. Chinese labs are also a primary source for pure fentanyl ordered on the open internet and on the dark web and delivered through the mail or air express carriers. Finally, China is the main source of pill presses that can make thousands of pills an hour to support fentanyl press mill operations.

The fentanyl problem is spreading and going to get worse because the money and profit is enormous. According to data from the DEA, a kilogram of heroin can be purchased for roughly \$6,000 and sold wholesale for \$80,000. However, a kilogram of pure fentanyl can be purchased for less than \$5,000 and is so potent that it can be stretched into 16 to 24 kilograms of product when using cutting agents such as talcum powder or caffeine. Each kilogram of cut fentanyl can be sold wholesale for \$80,000, resulting in a total profit in the neighborhood of \$1.6 million. That is about 20 times more profit than heroin.

We need a Federal strategy dedicated to combatting fentanyl as the clear and present danger it presents to our national security and public health.

We welcome our panel of witnesses today. We salute you for your work, thank you for appearing today, and look forward to working together to stop the spread of this epidemic.

Mr. MURPHY. Now I recognize my friend from Colorado, Ms. DeGette.

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

Ms. DEGETTE. Thank you so much, Mr. Chairman.

Every day somewhere in this country there is a news account about how opiate addiction has wrecked a small town or family. Personal stories about Americans who have become addicted to pain pills and then they get hooked on heroin.

These are heartbreaking stories about Americans dying and leaving loved ones, often their children, to pick up the pieces. The opioid epidemic is unprecedented and it is escalating, and I think we all agree that we need a comprehensive strategy to confront it.

In 2015, more than 33,000 Americans died of an overdose involving a prescription or illicit opioid and more than 2 million people had an opioid use disorder.

Fentanyl is, of course, an even deadlier layer to this crisis. It can be up to 50 times more potent than heroin and a 100 times more potent than morphine. It's lethal at even the tiniest amounts and anyone exposed to it can be—can have its detriments.

You know, illicit fentanyl is not a new problem. What is new, though, is its growing prevalence. Since 2010, that number covered by American law enforcement nationwide has risen twentyfold, from 640 samples tested to 13,000 samples tested in 2015, according to information from the DEA.

U.S. law enforcement, as the chairman said, believes China is the primary source of illicit fentanyl and precursor chemicals. Chinese producers ship fentanyl or chemicals to make it directly into the United States.

Precursor chemicals, or finished fentanyl, is shipped to Mexico and Canada where it is trafficked across our borders in pure form or is mixed with other illicit drugs like heroin.

Today, we want to ask the panel some tough questions about law enforcement and diplomatic efforts to stem the tide of fentanyl flowing from China and whether they are sufficient.

We are also going to ask which vectors drug traffickers use to ship this drug into our country, like express consignment carriers and international mail.

I think this is another important step that this subcommittee had been taking to address the opioid epidemic, and for the record I want to continue this bipartisan work.

That said, Mr. Chairman, I also think we need to find a way to address the treatment side of this epidemic and this is, sadly, where I have significant differences with my majority colleagues.

Passage of the Affordable Care Act, as you know, has led to nearly 20 million Americans gaining healthcare coverage. In addition, the ACA has enabled Governors to expand the Medicaid services they offer, which was critical in States that were overwhelmed by the opioid epidemic.

Studies estimate that, since 2014, 1.6 million uninsured Americans gained access to substance abuse treatment across the 31 States like mine that expanded Medicaid coverage.

This is particularly important for hard-hit States like Kentucky, where one study reports that residents saw a 700 percent increase in Medicaid beneficiaries seeking treatment for substance use.

Two weeks ago, the majority rushed through this committee a bill to repeal the ACA that many believe will threaten the progress that Medicaid expansion has made in getting people suffering from addiction into treatment.

In its assessment of that bill last week, the Congressional Budget Office said that millions of Americans—24 million of them—will lose health coverage.

Many of those will be people currently receiving Medicaid assistance which include people receiving treatment for opioid addiction.

In January, healthcare experts from Harvard and NYU wrote and op-ed for the Hill about how repealing the ACA would reverse important public health gains. They focused primarily on my baby, the 21st Century Cures Act which I did with Fred Upton and all of this whole committee. We approved it unanimously.

But it really—we can have a whole hearing just about how badly the GOP's ACA repeal bill will hamper the progress that we just passed in 21st Century Cures.

I just want to draw attention to one part of this op-ed, though, where they authors wrote “repealing the ACA and its behavioral health provisions would have stark effects on those with behavioral health illnesses. We estimate that approximately 1,253,000 people with serious mental disorders and about 2.8 million Americans with a substance abuse disorder of whom about 222,000 have an opioid disorder would lose some or all of their insurance coverage.”

The end of the day, we don't know what kind of bill is going to reach the president's desk. But if we really want to address the opioid crisis, I suggest that we don't pass this very poorly thought out piece of legislation.

I yield back.

Mr. MURPHY. Gentlelady yields back.

I now recognize the chairman of the full committee, Mr. Walden, for 5 minutes.

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

Mr. WALDEN. I thank the gentleman and I thank you for holding this very important hearing.

The opioid crisis, as we know, has touched every corner of our Nation. Just like my colleagues, I have met with community leaders, physicians, first responders, law enforcement and families on this issue.

Each have shared their heartbreaking stories on the effects of this crisis in our communities. You see, addiction doesn't understand politics. It doesn't understand income. It doesn't understand race or where someone's from. It is an equal opportunity destroyer. This crisis has hit close to home for all of us.

Last Congress, this committee worked in a bipartisan way to advance sweeping legislation to fight the Nation's opioid epidemic. It was an effort that actually began in this subcommittee, which held a series of hearings that examined the growing problems of prescription drug and heroin abuse.

We should be proud of those efforts but as we will discuss today there is a new threat emerging. Last year, there were encouraging reports that showed that the number of prescriptions for opioids in the United States had finally declined. That was good news. For the first time in 20 years that had happened. Yet, we saw the number of opioid-related overdoses and overdose-related deaths continuing to surge upward and we ask why.

That is why we are having the hearing today. Emerging data strongly suggests the main driver is fentanyl and its chemical variations. Fentanyl essentially represents a third wave in the Nation's ongoing opioid crisis. It is why we are here.

Fentanyl is a more challenging threat within the opioid crisis in comparison to threats of prescription opioids and heroin. The fentanyl threat is multifaceted. It's been produced as a legitimate pain medication by drug companies for decades but it is also produced illicitly in black market operations in China.

Illicit fentanyl is hard to detect and, unlike prescription pain killers, it is not primarily diverted from the legitimate market nor is it strictly comparable to the black market of heroin. It can be purchased over the internet openly or on the dark web.

Precursor chemicals used to make fentanyl are produced in China and shipped to clandestine labs in Mexico. Drug cartels are smuggling massive amounts of fentanyl with other narcotics from Mexico across the Southwest border.

Drug traffickers in the United States not only are getting deliveries of fentanyl from China through the mail or express carriers but they are also getting direct or indirect shipments from China

of pill presses that can make thousands of pills an hour to fuel their operations and distribution networks into our towns, our communities, and the lives of our citizens.

Pure fentanyl is not considered a replacement drug for OxyContin or heroin. It is too potent. Just 2 to 3 milligrams can kill an individual, and has.

More often than not, it is added in to heroin, cocaine, or counterfeit drugs to boost the potency and increase the likelihood of addiction. What's even scarier is people taking these drugs may not even know that they are taking fentanyl, let alone what it is.

Fentanyl makes the deadly threat of opioid abuse even deadlier. In 2014 and 2015 in my home State of Oregon, a reported 49 people died from fentanyl. The number of deaths from fentanyl appears to be rising, and that is just what we know.

As we work to combat this quickly evolving public health threat, there is an important question to be asked—how can we fight this threat when we don't even know how quickly it is spreading.

Combating this growing multi-faceted fentanyl threat will require more than drug control strategies aimed at opioid overprescribing and heroin.

Fentanyl is a global problem that requires an urgent response. I commend the efforts of our Government, ONDCP, DEA, and the State Department particularly for their success in gaining cooperation with China and the United Nations. We need to continue and support this international engagement to be successful.

Like our work on the opioid epidemic last Congress, combating fentanyl truly requires an all-hands-on-deck effort. We need to think outside the box to find ways to stop the surge of the fentanyl crisis, and I look forward to your testimony and working with all of you to solve this problem.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

The opioid crisis has touched every corner of our Nation. Just like my colleagues, I have met with community leaders, physicians, first responders, law enforcement, and families on this issue. Each have shared heartbreaking stories on the effects of this crisis in our communities. You see, addiction doesn't understand politics. It doesn't understand income, race, or where someone is from. It is an equal opportunity destroyer. This crisis has hit close to home for each of us.

Last Congress, this committee worked in a bipartisan way to advance sweeping legislation to fight the Nation's opioid epidemic. It was an effort that actually began in this subcommittee, which held a series of hearings that examined the growing problems of prescription drug and heroin abuse. We should be proud of those efforts. But as we will discuss today, there is a new threat emerging.

Last year, there were encouraging reports that showed that the number of prescriptions for opioids in the United States finally declined—for the first time in 20 years. Yet, we saw the number of opioid-related overdoses and overdoserelated deaths continuing to surge upward. Why?

Emerging data strongly suggest the main driver is fentanyl, and its chemical variations. Fentanyl essentially represents a third wave in the Nation's ongoing opioid crisis. It's why we are here today.

Fentanyl is a more challenging threat within the opioid crisis, in comparison to the threats of prescription opioids and heroin. The fentanyl threat is multi-faceted. It has been produced as a legitimate pain medication by drug companies for decades. But it is also produced illicitly in black market operations in China. Illicit fentanyl is hard to detect, and unlike prescription painkillers it is not primarily diverted from the legitimate market. Nor is it strictly comparable to the black market of heroin. It can be purchased over the internet openly, or on the dark web. Precursor chemicals used to make fentanyl are produced in China, and shipped to clan-

destine labs in Mexico. Drug cartels are smuggling massive amounts of fentanyl with other narcotics from Mexico across the Southwest border. Drug traffickers in the U.S. not only are getting deliveries of fentanyl from China through the mail or air express carriers, but they are also getting direct or indirect shipments from China of pill presses that can make thousands of pills an hour to fuel their operations and distribution networks into our towns and communities.

Pure fentanyl is not considered a replacement drug for OxyContin or heroin. It is too potent. Just 2 to 3 milligrams can kill an individual. More often than not, it is added into heroin, cocaine, or counterfeit drugs to boost the potency and increase the likelihood of addiction. What's even scarier is people taking these drugs may not even know that they are taking fentanyl, let alone what it is.

Fentanyl makes the deadly threat of opioid abuse even deadlier. In 2014 and 2015 in my home State of Oregon, a reported 49 people died from fentanyl. The number of deaths from fentanyl appears to be rising, and that's just what we know. As we work to combat this quickly evolving public health threat, there's an important question to be asked. How can we fight this threat when we don't even know how quickly it is spreading?

Combating this growing, multi-faceted fentanyl threat will require more than the drug-control strategies aimed at opioid overprescribing and heroin. Fentanyl is a global problem that requires an urgent response. I commend the efforts of our Government, ONDCP, DEA, and the State Department, particularly, for their success in gaining cooperation with China and the United Nations. We need to continue and support this international engagement to be successful. Like our work on the opioid epidemic last Congress, combating fentanyl truly requires an allhands-on-deck effort.

We need to think outside the box to find ways to stop the surge of the fentanyl crisis. I look forward to your testimony, and working with all of you to solve this problem.

Mr. WALDEN. And I yield the balance of my time to the gentleman, the chairman of the Health Subcommittee, Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman, and thank you, Mr. Chairman, for holding the hearing.

I want to thank the DEA. Mr. Milione, I think you have been in to my office to talk about this issue in the past one on one. It is of concern to me.

You know, I have been on the Health Subcommittee long enough that in 2005 we were having a hearing about why doctors weren't prescribing adequately for pain, and now the past two Congresses we have been concerned about the appearance of the opioid epidemic.

Fentanyl is not a new product. It has been around for some time. But on the other hand, the analogues of fentanyl are relatively new and it is the fueling of the illicit trade with the ability to get things over the internet, which I think has been probably been the crux of this problem.

We do have problems with the overseas market with the way the supply comes in to our country.

So I hope that we can hear some insight this morning on perhaps some additional things that might be done to stop that flow.

Thank you, Mr. Chairman, and I will yield back—yield back to the gentleman from Oregon, who then yields back, correct?

Mr. MURPHY. Thank you. The gentleman's time has expired.

I recognize the ranking member of the committee, Mr. Pallone, for 5 minutes.

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

Mr. PALLONE. Thank you, Mr. Chairman.

The opioid epidemic in our country continues to grow at an alarming rate. In 2015, more than 33,000 Americans died of an opioid overdose and more than 2 million individuals have an opioid use disorder. According to the Center for Disease Control, 91 Americans die every day from an opioid overdose.

Today we are focusing on fentanyl, a powerful synthetic opioid that is 50 times more potent than heroin and up to a hundred times more potent than morphine.

Because of its potency, fentanyl is a dangerous substitute for heroin and it results in frequent overdoses that can cause respiratory depression and even death.

The number of overdose deaths is rapidly increasing and the death rate from synthetic opioids other than methadone increased by 72 percent from 2014 to 2015.

This substantial increase in the death rate from synthetic opioids is largely attributable to the increased availability of illicit fentanyl.

I want to thank our witnesses today for their testimony and work on this very important issue. Fentanyl is dangerous not only to users but also to our law enforcement and public health officials on the front lines of this epidemic and I look forward to working together to explore ways that we can better confront the supply of the fentanyl now plaguing our communities.

I also would like to talk today about the treatment side of the opioid epidemic. Just two weeks ago committee Republicans rushed Trumpcare through the committee, a bill which repeals the Affordable Care Act. The ACA has been instrumental in addressing the current opioid crisis and, inexcusably, Trumpcare would only exacerbate the crisis.

Thanks to Medicaid expansion under the ACA, 1.6 million people with substance use disorders now can receive the treatment they need in the 31 States and Washington, DC, that expanded the program.

But Trumpcare effectively ends Medicaid expansion in 2020. According to the CBO, Trumpcare also cuts \$880 billion in Federal outlays for Medicaid over the next 10 years, which will severely undermine our efforts to fight the opioid crisis.

These drastic cuts in Medicaid made possible by Republican plans to end Medicaid expansion in the CAPTA program will ration care for millions of Americans including the rationing of substance abuse treatment.

Trumpcare also repeals the central health benefits for Medicaid expansion enrollees at the end of 2019. States would no longer have to offer benefits like substance abuse, mental health services or prescription drugs to millions of Americans who rely on such care.

Repealing the essential benefits packages effectively repeals the mental and substance use disorder coverage provisions of the ACA and would remove approximately \$5.5 billion annually from the treatment of low-income people with mental and substance use disorders.

Repeal will take away care from those who are actively seeking treatment and preventive services and we simply cannot afford to eliminate this care in what is oftentimes a life and death situation.

Trumpcare threatens access to lifesaving treatment for more than 1 million people with opioid disorders.

Our hearing today explores the fentanyl problem. However, I would argue that this issue is a part of a much wider opioid problem that we are battling.

To address this properly, we must make sure Americans with substance abuse disorders can access effective treatment.

And so, Mr. Chairman, I want to work with you to confront fentanyl and the larger opioid problem. However, in my opinion, repealing the ACA and cutting Medicaid by nearly a trillion dollars over the next 10 years will do nothing but undermine our efforts to treat Americans who are suffering from opioid addiction. We will not be able to arrest our way out of this problem.

Without adequate treatment options for those suffering from an opioid addiction, this problem will only worsen and so will the deaths and destruction we have seen play out across the United States.

I don't know if anybody wants my extra minute. If not, I will yield back.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Mr. Chairman, the opioid epidemic in our country continues to grow at an alarming rate. In 2015, more than 33,000 Americans died of an opioid overdose, and more than 2 million individuals had an opioid use disorder. According to the Center for Disease Control, 91 Americans die every day from an opioid overdose.

Today we are focusing on fentanyl, a powerful synthetic opioid that is 50 times more potent than heroin and up to 100 times more potent than morphine.

Because of its potency, fentanyl is a dangerous substitute for heroin and results in frequent overdoses that can cause respiratory depression and even death. The number of overdose deaths is rapidly increasing.

The death rate from synthetic opioids, other than methadone, increased by 72 percent from 2014 to 2015. This substantial increase in the death rate from synthetic opioids is largely attributable to the increased availability of illicit fentanyl.

I want to thank our witnesses today for their testimony and work on this very important issue. Fentanyl is dangerous not only to users, but also to our law enforcement and public health officials on the front lines of this epidemic.

And I look forward to working together to explore ways that we can better confront the supply of the fentanyl now plaguing our communities.

I would also like to talk today about the treatment side of the opioid epidemic.

Just two weeks ago, committee Republicans rushed TrumpCare through the committee, a bill which repeals the Affordable Care Act. The ACA has been instrumental in addressing the current opioid crisis, and, inexcusably, TrumpCare would only exacerbate the crisis.

Thanks to Medicaid Expansion under the ACA, 1.6 million people with substance use disorders now can receive the treatment they need in the 31 States and Washington, DC, that expanded the program. TrumpCare effectively ends Medicaid Expansion in 2020.

According to the Congressional Budget Office, TrumpCare also cuts \$880 billion in Federal outlays for Medicaid over the next 10 years, which will severely undermine our efforts to fight the opioid crisis. These drastic cuts in Medicaid, made possible by Republican plans to end Medicaid Expansion and to cap the program, will ration care for millions of Americans, including the rationing of substance abuse treatment.

TrumpCare also repeals Essential Health Benefits for Medicaid expansion enrollees at the end of 2019. States would no longer have to offer benefits like substance abuse, mental health services or prescription drugs to millions of Americans who rely on such care.

Repealing the mental and substance use disorder coverage provisions of the ACA would remove approximately \$5.5 billion annually from the treatment of low income people with mental and substance use disorders.

Repeal will take away care from those who are actively seeking treatment and preventive services. We simply cannot afford to eliminate this care in what is oftentimes a life and death situation. TrumpCare, threatens access to life-saving treatment for more than one million people with opioid disorders.

Our hearing today explores the fentanyl problem. However, I would argue that this issue is a part of a much wider opioid problem we are battling. To address this problem, we must make sure Americans with substance abuse disorders can access effective treatment.

Mr. Chairman, I want to work with you to confront fentanyl and the larger opioid problem. However, repealing the ACA and cutting Medicaid by nearly a trillion dollars over the next 10 years, will do nothing but undermine our efforts to treat Americans who are suffering from an opioid addiction.

We will not be able to arrest our way out of this problem. Without adequate treatment options for those suffering from an opioid addiction, this problem will only worsen, and so will the deaths and destruction we have seen play out across the U.S.

Thank you, and I yield back.

Mr. MURPHY. I thank the gentleman. Yields back.

For a minute, I want to offer for the record, if unanimous consent, an article from the Washington Post called “Where opiates killed the most people in 2015.” It has interesting maps of where these occur throughout the country.

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

Mr. MURPHY. For example, synthetic opioid rates in Ohio, West Virginia, and Kentucky, and pockets in New Hampshire, Massachusetts, Rhode Island, and other aspects, which kind of tell us that there is not one opiate epidemic but several, and no silver bullet.

We are going to have to make sure whatever this committee does and finds today from our esteemed witnesses, we are going to have to work in a way to give flexibility—maximum flexibility to States to work this out.

I ask unanimous consent that the Members’ written opening statements be introduced in the record, and without objection those documents will be entered in the record.

Now I’d like to introduce our panel of Federal witnesses for today’s hearing. We will start with Mr. Kemp Chester, Acting Deputy Director in the Office of National Drug Control Policy; Mr. Louis Milione, assistant administrator at the Diversion Control Division within the Drug Enforcement Administration, or DEA; Mr. Matthew Allen, Assistant Director of Homeland Security Investigative Programs at the U.S. Immigration and Customs Enforcement Division within the Department of Homeland Security, or DHS; the Honorable William Brownfield, Assistant Secretary of State, International Narcotics and Law Enforcement Affairs of the U.S. Department of State; Dr. Debra Houry, Director, National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention; and Dr. Wilson Compton, Deputy Director at the National Institute on Drug Abuse within the National Institutes of Health.

I want to thank all our witnesses today for being here and providing testimony. We look forward to a very productive hearing.

Let me charge you with this, though, which I usually don’t do. More people are dying of drug overdose deaths than of guns.

We have reached the point where more people are dying of drug overdose deaths than deaths in the entire Vietnam War, almost in a per-year basis.

What you are going to tell us today is falling on ears that are open to anything you can offer us. The families in America—and you have heard the stories, impassioned stories from Members here—stories of the deep concerns of the number of the deaths, the devastation in communities—what you’re saying here is extremely important.

So we look forward to hearing from you on this growing threat of fentanyl- and opioid-related deaths.

So as you are aware, this committee is holding an investigative hearing, and when doing so it is our practice of taking testimony under oath.

Do any of you have any objection to giving testimony under oath? Seeing no objections, the Chair then advises you are under the rules of the House and rules of the committee. You’re entitled to be advised by counsel.

Do any of you desire to be advised by counsel during your testimony today? Seeing none, in that case, will you all please rise and raise your right hand and I’ll swear you in.

[Witnesses sworn.]

Thank you. You are all sworn in. You are now under oath and subject to the penalties set forth in Title 18 Section 1001, the United States Code.

I will call upon you each to give a 5-minute summary of your written statement. Just watch the lights there and you’ll have a sense of that.

I’ll begin with Mr. Chester. You are recognized for 5 minutes.

STATEMENTS OF KEMP L. CHESTER, ACTING DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; LOUIS J. MILIONE, ASSISTANT ADMINISTRATOR, DIVERSION CONTROL DIVISION, DRUG ENFORCEMENT ADMINISTRATION; MATTHEW C. ALLEN, ASSISTANT DIRECTOR, HOMELAND SECURITY INVESTIGATIVE PROGRAMS, HOMELAND SECURITY INVESTIGATIONS, IMMIGRATION AND CUSTOMS ENFORCEMENT, DEPARTMENT OF HOMELAND SECURITY; WILLIAM R. BROWNFIELD, ASSISTANT SECRETARY OF STATE FOR INTERNATIONAL NARCOTICS AND LAW ENFORCEMENT AFFAIRS, DEPARTMENT OF STATE; DEBRA HOURS, M.D., DIRECTOR, NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL, CENTERS FOR DISEASE CONTROL AND PREVENTION; WILSON M. COMPTON, M.D., DEPUTY DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF KEMP L. CHESTER

Mr. CHESTER. Chairman Murphy, Ranking Member DeGette and members of the subcommittee, thank you for inviting me and my interagency colleagues to discuss the public health and public safety issues surrounding the opioid epidemic, particularly that of illicit fentanyl and what the Federal Government is doing to address this problem.

I appreciate the committee’s strong support of our work to reduce drug use and its consequences. I currently serve as the acting director of the Office of National Drug Control Policy, which crafts

the president's drug control policy and oversees all Federal Government counter drug activities and related funding.

This is a critical mission because, as you are aware, more than 52,000 Americans died from a drug overdose in 2015. That's an average of 144 per day with 91 of those deaths involving opioids such as prescription pain medications, heroin and illicit fentanyl.

Overdoses involving opioids have nearly quadrupled since 2000 and between 2013 and 2015 the number of deaths involving synthetic opioids other than methadone, a statistical category that includes fentanyl, has more than tripled, reaching nearly 10,000 in 2015, and this number is likely low because not every overdose death investigation looks for fentanyl.

The majority of the illicit fentanyl in the U.S. is smuggled in after being produced in Mexico or China. Both heroin and clandestinely produced fentanyl can be manufactured, packaged and smuggled by the same drug trafficking organization.

The reemergence of illicit fentanyl represents a complex problem. It is considerably more powerful than heroin, its precursor chemicals are not fully controlled in other countries.

It's being added into the heroin supply or pressed into counterfeit prescription opioid pain pills, meaning users are often unaware they are taking fentanyl, and because of its potency it can be shipped in small packages and transactions then involve relatively low dollar amounts, making it much harder to detect.

First responders and police officers report that they need to use much more than the standard dose of naloxone to reverse an overdose caused by fentanyl, which strains resources.

We also have a limited capacity to treat those who habitually use illicit opioids. Only one in nine people in the U.S. who need treatment are receiving it, and we have seen outbreaks in many States where fentanyl, carfentanil and other fentanyl analogues have played a role in the wave of overdose deaths that devastate communities.

In short, illicit fentanyl is exacerbating an already challenging problem that the Federal Government is working extremely hard to address.

The reality of this epidemic has led us to adopt new ways of addressing drug use and trafficking. That's why the heart of our effort is the partnership between public health and law enforcement, some of whom are represented here today, to help address the problem in communities across the country.

We are also working with our State Department colleagues to engage foreign partners to prevent illicit drugs from being manufactured and trafficked into the United States.

In terms of public health, we are working to prevent new initiates to drug use by encouraging prescriber and public education, encouraging prescribers to use the CDC's guidelines and their State prescription drug monitoring programs and emphasizing prevention efforts to deter drug use initiation, including ONDCP's Drug-Free Communities Program. We are also working to expand access to treatment including evidence-based medication assisted treatment for opioid use disorder and help people sustain long-term recovery.

In this regard, we deeply appreciate Congress' support for treatment expansion through the funds authorized under the 21st Century Cures Act.

Another critical innovation is that we are helping to build new partnerships between local law enforcement partners and the public health community to end this crisis and to establish routine cooperation between the Federal Government and the State, Tribal, and local levels.

In terms of reducing the availability of these drugs in the United States, the Federal Government's efforts are centered on stopping illicit drugs before they cross our borders and dismantling the organization that traffic drugs into and through our communities.

Within ONDCP, the National Heroin Coordination Group was created in October 2015 in partnership with the National Security Council to synchronize Federal Government efforts to reduce the availability of heroin and illicit fentanyl across the country and address gaps in redundancies in department and agency activities through its interagency-coordinated Heroin Availability Reduction Plan, which addresses heroin and fentanyl as a single problem set.

ONDCP also funds the High-Intensity Drug Trafficking Areas program that coordinates anti-trafficking efforts and intelligence across State, local, Tribal, and Federal law enforcement communities, and in 2015, ONDCP developed the Heroin HIDTA Response Strategy, a coordinated effort across 20 States and the District of Columbia in response to the heroin and fentanyl crisis.

And internationally we are working with foreign partners like Mexico, China and Canada to reduce the supply of illicit fentanyl, its precursors and its analogues into and across North America.

While we are working diligently to turn the tide on this epidemic, and perhaps are making some progress, we continue to work through numerous challenges such as detecting illicit fentanyl at our borders and in our mail and parcel system, working with our international partners to reduce the manufacturing and trafficking of heroin and fentanyl, and finding and disrupting the internet marketplaces where illicit fentanyl is purchased and delivered.

Mr. MURPHY. Could you finish up because we are——

Mr. CHESTER. Yes, sir.

As the Federal Government works to reduce the size of the opioid-using population through prevention and treatment and reduce the availability of these drugs in our communities, your support for these efforts is critical to our success.

Thank you, and I look forward to answering your questions.

[The prepared statement of Mr. Chester follows:]



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

**“Fentanyl: The Next Wave
of the Opioid Crisis”**

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

Tuesday, March 21, 2017
10:15 a.m.
2123 Rayburn House Office Building

Statement of:
Kemp L. Chester
Acting Director of National Drug Control Policy

Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for inviting me to discuss the public health and public safety issues resulting from the opioid epidemic – and illicit fentanyl in particular.

Background

In 2015, more than 52,000 Americans, or approximately 144 people each day, died from a drug overdose. Opioids – a category of drugs that includes heroin, prescription pain medicines like oxycodone, and fentanyl – are having a considerable impact on public health and public safety in communities across the United States. Of the overdose deaths in 2015, 63 percent (33,091) involved an opioid, 47 percent (24,508) involved prescription pain medicines, and 25 percent (12,990) involved heroin.¹

The threat posed by heroin has continued to grow dramatically over the past several years – between 2007 and 2015, deaths involving heroin have risen 441 percent, from 2,402 to 12,990,² and since 2013, available public health data indicate fentanyl-laced heroin has been increasingly involved in these deaths. In 2015, 9,580 drug overdose deaths involved synthetic opioids other than methadone (a statistical category that is dominated by fentanyl), up from 3,105 such deaths in 2013, a 209 percent increase. Even with this substantial increase, it is likely that overdose deaths involving opioids like fentanyl are undercounted – of deaths where drug overdose is cited as the underlying cause, approximately one-fifth of the death certificates do not list the specific drug(s) involved in the fatal overdose.³

Fentanyl is a powerful Schedule II synthetic opioid approved in a variety of products for indications including the treatment of breakthrough cancer pain in opioid-tolerant patients and anesthesia.⁴ Pharmaceutically produced fentanyl comes in patches, lozenges, tablets, and liquid. Conversely, illicitly produced fentanyl is mixed with powder heroin to increase its effects, with diluents and sold by itself as “synthetic heroin,” or pressed into pill form and sold as commonly misuse prescription opioids, with or without the buyer’s knowledge.⁵

Public health and law enforcement officials nationwide believe that the emergence of fentanyl in the illegal drug market is compounding our country’s current opioid crisis by fueling the high mortality rate we are seeing. It is important to note that law enforcement officials do not believe our Nation’s fentanyl problem originates from diversion from licit sources, but rather from clandestinely produced fentanyl that is mixed with heroin or pressed into tablets intended to mimic the appearance of prescription opioid medications such as oxycodone or hydrocodone. Mexico and China are the two largest sources of illicit fentanyl smuggling to the United States.⁶

¹ An opioid-related death may involve more than one type of opioid.

² CDC National Center for Health Statistics. (2016). Multiple Cause of Death, 1999-2015 (WONDER Online Database). Available at: <http://wonder.cdc.gov/mcd-icd10.html>.

³ Trinidad, James P., Margaret Warner, Brigham A., Bastian, Arialdi M. Miniño, and Holly Hedegaard. (Dec 20 2016). Using Literal Text From the Death Certificate to Enhance Mortality Statistics: Characterizing Drug Involvement in Deaths. National Vital Statistics Report. Volume 65, Number 9.

⁴ Available at: <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

⁵ DEA. Strategic Intelligence Section. 2016 National Heroin Threat Assessment. DEA-DCT-DIR-031-16.

⁶ DEA. Counterfeit Prescription Pills Containing Fentanyls: A Global Threat. DEA-DCT-DIB-021-16, July 2016.

Due to similarities in production, trafficking, and consumption, it is important that we address concerns regarding heroin and illicit fentanyl together within the broader context of the opioid crisis. The same drug trafficking organization can manufacture and package both heroin and clandestinely produced fentanyl. These organizations likely use the same supply routes and distribution methods for both drugs. Moreover, both heroin and fentanyl belong to the same class of opioid drugs that produce similar effects on the body, and the available epidemiological data indicate that the people using and overdosing on fentanyl are very similar to those using heroin. As a result, drug trafficking organizations may see the heroin user population as a ready-made customer base for illicit fentanyl. Furthermore, addressing both drugs together allows us the ability to confront the heroin crisis without inadvertently compounding and accelerating illicit fentanyl use. If we drastically and quickly reduce the availability of heroin, thereby increasing its price, without simultaneously addressing illicit fentanyl availability, we risk driving people to use illicit fentanyl, which could create a potentially more deadly opioid drug threat.^{7,8}

Federal Response

The combination of increased availability and purity with low prices for both heroin and illicit fentanyl has led to a complex national security, law enforcement, and public health issue that demands significant effort, creativity, and interagency coordination and collaboration. As a result, the Office of National Drug Control Policy (ONDCP) is facilitating the Federal response to this problem with a comprehensive approach that includes preventing initiates to drug use, providing evidence-based treatment for substance abuse, and drastically reducing the availability of illicit drugs through international engagement and law enforcement efforts.

Prevention, Treatment, and Recovery Efforts. One element of the Federal Government's approach is a public health effort to address the use of and consequences from heroin and illicit fentanyl. Collaboration with states, local governments, tribes, and non-governmental organizations is central to these efforts. A number of activities bridge the public health and public safety sectors to respond effectively to the opioid crisis: primary prevention; prescriber and public education; monitoring programs; safe prescription drug disposal; overdose reversal; medication-assisted treatment; and recovery support services.

Primary prevention – Preventing drug use before it starts is critical. Very few individual use heroin or fentanyl without first misusing prescription drugs or using drugs such as cocaine or methamphetamine.⁹ Research has shown that evidence-based primary prevention programs are

⁷ NIH Development, Infectious Diseases and Drug Monitoring Centre. 2014 National Report to the EMCDDA by the REITOX National Focal Point. Tallinn, Estonia.

⁸ European Monitoring Centre for Drugs and Drug Addiction. Fentanyl in Europe EMCDDA Trendspotter Study: Report from an EMCDDA expert meeting 9 to 10 October 2012. Lisbon, Portugal.

⁹ Muhuri PK, Gfroerer JC, Davies MC. SAMHSA. (Aug 2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States. CBHSQ Data Review. Available at: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>.

effective at reducing prescription opioid misuse among youth and young adults.¹⁰ The Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration, within the Department of Health and Human Services (HHS), support grants to states for evidence-based prevention aimed at this key demographic group.

Prescriber and public education – Educating the public, prescribers, pharmacists, and other health professionals about the risks associated with opioid medications remains a priority. In addition, the new prescribing guidelines for opioid therapy for chronic pain (e.g., those released by CDC, Department of Veterans Affairs (VA), and Department of Defense) include a number of recommendations that reflect an understanding of the risks associated with opioid therapy and the importance of considering nonpharmacologic therapy and other risk mitigation strategies.¹¹ Four out of five recent heroin initiates used opioid medications non-medically prior to initiating heroin use.¹² And, while heroin and illicit fentanyl have been involved in a rapidly increasing percentage of opioid overdose deaths, opioid medications are still involved in about half of all U.S. opioid-related deaths,¹³ and the number of people misusing prescription opioids remains much larger than heroin – over 12 million people according to the 2015 National Survey on Drug Use and Health.¹⁴ To be successful in reducing the initiation of heroin and illicit fentanyl use, we must reduce the numbers of new initiates of misuse of opioids. As such, ONDCP works with public and private partners, including parents, to increase awareness, knowledge, training, and education efforts about prescribing practices, addiction, and opioid medications.

Monitoring programs – Prescription Drug Monitoring Programs (PDMPs) are state-operated automated databases that track controlled prescription medications issued to patients. Prescribers, pharmacists, and others, depending on state law, have access to these databases that can help with medication interaction reconciliation or indicate whether more than one doctor is prescribing the same medicine. Currently, all states but Missouri have implemented PDMPs. In addition, at the Federal level, the VA and the Centers for Medicare and Medicaid Services in HHS both have policies in place to help monitor prescription and use of controlled prescription drugs.

Safe prescription drug disposal – Research indicates that 54 percent of those who use opioid medications non-medically obtained those drugs from friends or family.¹⁵ It is important

¹⁰ Spoth R I, Trudeau L, Shin C, Ralston E, Redmond C, Greenberg M, Feinberg M. (2103). Longitudinal effects of universal preventive intervention on prescription drug misuse: three randomized controlled trials with late adolescents and young adults. *Am J Public Health*. 03(4):665-72. DOI: 10.2105/AJPH.2012.301209. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3673263/>.

¹¹ Available at: CDC: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> and VA/DoD: <http://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG021517clean.pdf>.

¹² Pradip et al. (2013). SAMHSA. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the U.S. Center for behavioral Health Statistics and Quality Data Review. Available at: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm>.

¹³ CDC. (2016). Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; Available at <http://wonder.cdc.gov>.

¹⁴ SAMHSA. Center for Behavioral Health Statistics & Quality. National Survey on Drug Use and Health, 2015.

¹⁵ SAMHSA. Center for Behavioral Health Statistics & Quality. National Survey on Drug Use and Health, 2014 and 2015.

to create opportunities for individuals to dispose of unwanted controlled substance prescription medications safely. In 2010, the Controlled Substances Act was amended to permit safer drug disposal, including disposal sites at pharmacies and law enforcement agencies, mail back programs, and drug deactivation products, and in 2014, the Drug Enforcement Administration (DEA) issued new rules governing the secure disposal of prescription controlled substances. As of 2016, the DEA had collected approximately 7.2 million pounds of unwanted prescription medicines through its take-back efforts. The VA also provides disposal options.

Opioid overdose reversal – Naloxone is a prescription medicine that reverses opioid overdoses by blocking opioids from attaching to receptors in the body. While naloxone itself has been in approved for use for decades, it has become a widely used to counteract drug overdose and prevent deaths. In some instances, first responders report that they need to use up to six times the standard dose of naloxone to reverse an overdose caused by fentanyl, which strains resources. The Federal Government is working to expand access to and use of naloxone, and in recent years, police and fire department personnel across the country have been trained and equipped with the drug because timely administration enables a person having an overdose to be transported to an emergency department for immediate care and, if available, treatment. Similar efforts have been made to expand access to and training on the use of naloxone for potential bystanders who may be able to prevent, recognize, and respond to an overdose.

Medication-assisted treatment (MAT) – Food and Drug Administration-approved medications are the standard of care for opioid abuse treatment. These medications include buprenorphine, methadone, and injectable naltrexone. Research shows the increased effectiveness of treatment involving use of these medications in conjunction with psychosocial services for those with opioid addiction over approaches that do not include them. When used with recovery support services, the use of MAT in the treatment of opioid abuse reduces opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission; improves social functioning and treatment retention;^{16,17,18} and improves the outcomes of babies born to women with opioid addiction.¹⁹ Nevertheless, only about 22 percent of people with an opioid use disorder receive specialty treatment,²⁰ and the Federal Government has taken a number of steps to expand access through increased ability to prescribe (including new MAT prescribing privileges for Nurse Practitioners and Physicians Assistants) the medications necessary to facilitate treatment and stable long-term recovery.

Recovery support services – Recovery support services have become the glue that holds together many of our public health efforts. When offered through recovery community organizations – these services can be provided before, during, after, and, in some cases, in lieu of

¹⁶ RP Mattick et al. (2009). Cochrane Database of Systematic Reviews.

¹⁷ RP Mattick et al. (2014). Cochrane Database of Systematic Reviews.

¹⁸ Schwartz, R.P. et al. (2013). Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009. *Am J Public Health*. 103(5):917-22.

¹⁹ American College of Obstetricians and Gynecologists & American Society of Addiction Medicine. (2012). Opioid Abuse, Dependence, and Addiction in Pregnancy. Committee Opinion Number 524. (Reaffirmed in 2016).

²⁰ Unpublished Tabulations from SAMHSA. Center for Behavioral Health Statistics & Quality. National Survey on Drug Use and Health, 2011-2014.

specialty treatment. Recovery support services are based primarily on shared experience of addiction and recovery and only secondarily on training. Peer recovery support services can be seen as a bridge between formal systems, such as hospitals, specialty substance abuse treatment providers, drug courts, or correctional institutions and natural supports in the community, such as mutual aid groups,²¹ family, church, temple, mosque, or other faith groups.

Availability Reduction: The National Heroin Coordination Group. In November 2015, ONDCP, in coordination with the National Security Council (NSC), established the National Heroin Coordination Group (NHCG) to form the hub of a network of interagency partners to leverage agency authorities and resources and synchronize their activities against the heroin and illicit fentanyl supply chains to the United States. When not serving as Acting Director of ONDCP, I am Associate Director of ONDCP in charge of the NHCG. Like ONDCP, the NHCG is uniquely positioned to identify gaps and redundancies in U.S. efforts, while also focusing on directly connecting actions taken on the front end of the supply chain with effects on the domestic market and user population.

Early in its existence, the NHCG, in close coordination with Federal departments and agencies, developed the Heroin Availability Reduction Plan (HARP) to bring together and synchronize the strategies and partnerships at the Federal, state, local, and tribal levels to reduce availability of heroin and illicit fentanyl. As I stated earlier, the heroin and illicit fentanyl crisis is a complex problem with many moving parts throughout the Federal Government. The HARP provides the structure for consistent and clear communication so we can examine the effectiveness of existing efforts and identify gaps and redundancies in government efforts to address this ever-evolving crisis. The close coordination of multi-agency, multi-jurisdictional actions, including investigations and prosecutions, against the organizations manufacturing and distributing heroin and illicit fentanyl directly contribute to our overall goal of reducing the availability of these drugs in the United States.

The HARP deliberately focuses on measuring effects, not simply performance. Law enforcement efforts to disrupt the supply of heroin and illicit fentanyl – from manufacture, through transport, and to sale – are having some impact on availability in the U.S. market. However, in focusing our attention on the connection between actions on the front end of the supply chain with the effects on the domestic market and user population, we can assess the strength of that impact on use, overdose, and mortality rates and its long-term sustainability.

Effective implementation of the HARP brings many important stakeholders to the table, and it has been crucial to our better understanding and vigorous identification of the heroin and illicit fentanyl crisis and its rapid growth, and has allowed the Federal Government to focus on those aspects of the problem that will bring the greatest results.

The NHCG hosts monthly coordination meetings to facilitate and drive discussion and data sharing, which allows for Federal law enforcement engagement and open dialogue with the public health community across the United States. Notably, on public health community calls,

²¹ Examples of mutual aid groups include Alcoholics Anonymous, Narcotics Anonymous, SMART Recovery, LifeRing Recovery, and Woman for Sobriety.

Federal and state public health professionals share near-real-time overdose data with each other and with law enforcement, which provides a critical early warning window for other stakeholders and helps inform our understanding of the problem. In a recent session, one state reported for the first time that fentanyl caused more overdose deaths than heroin. While this information points to an alarming shift, our early access to this information will be used to alert and help prepare Federal and state public health and law enforcement professionals in other states for this change in the trafficking and use environment. Absent these coordination meetings, we would have to rely on annual mortality data sets and lose valuable time as we work to simultaneously reduce the number of people who use these substances and disrupt the heroin and illicit fentanyl supply chain.

As a result of HARP implementation, the NHCG, and consequently the Federal Government, is better informed and more prepared to work to reduce overall heroin and illicit fentanyl availability. Because of our ability to share information and coordinate activities among all relevant actors across the Federal Government:

- We can discover, identify, and disseminate information about the rapid changes to various fentanyl-family drugs. For example, when carfentanil, a powerful fentanyl-family drug used as a large animal tranquilizer, entered the illicit market and caused several multiple death overdose outbreaks, we were able to recognize and respond to its emergence.
- We have been able to focus efforts to identify the source of production of fentanyl and fentanyl analogues. Compared to heroin, which is derived from a plant that can be tested to determine geographical origin, fentanyl is synthesized from chemicals in a laboratory, making identification of its manufacturing origin extraordinarily difficult.
- Agencies are sharing important information to help law enforcement detect fentanyl in the field, including technology that is available or under development, as well as improving the efficacy of training techniques for canine teams to assist in fentanyl detection.
- Agencies are successfully coordinating efforts to detect packages at international mail facilities, looking for illicit fentanyl shipments originating abroad.
- Federal health agencies are more directly engaging in collaborative efforts with Federal law enforcement agencies to share information, collaborate on a comprehensive response, and discuss strategies to effectively address the evolving opioid epidemic.
- The NHCG worked with the HHS and CDC's National Institute for Occupational Safety and Health to produce science-based handling instructions for fentanyl and disseminated those instructions to Federal agents and local police to better protect law enforcement and first responders from potential fentanyl exposure.

Interagency Partnerships. The challenging and complex nature of the heroin and illicit fentanyl problem not only demands increased collaboration and coordination among Federal agencies, including those here today, but also enhanced partnerships at the state, local, and tribal levels where the crisis is felt most deeply. Moreover, state, local, and tribal partners often have demonstrated an enormous amount of energy and innovation, which are key to addressing the problem nationwide. Cooperation and communication among Federal, state, local, and tribal partners provides greater situational awareness for a more comprehensive understanding of changes in the domestic environment.

There are a number of efforts across the Federal Government that enhance collaboration and coordination. For example, ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program is a locally-based program that responds to the drug trafficking issues facing specific areas of the country. Law enforcement agencies at all levels of government share information and implement coordinated enforcement activities; enhance intelligence sharing among Federal, state, local, and tribal law enforcement agencies; provide reliable intelligence to law enforcement agencies to develop effective enforcement strategies and operations; and support coordinated law enforcement strategies to maximize available resources and reduce the supply of illegal drugs.

In August 2015, ONDCP committed \$2.5 million in HIDTA funds to develop a Heroin Response Strategy to respond to the Nation's opioid/heroin/fentanyl epidemic. This unprecedented project combines prevention, education, intelligence, and enforcement resources to address the heroin and fentanyl threat across 17 states and the District of Columbia. The effort is carried out through a unique partnership of seven regional HIDTAs – Appalachia, Michigan, New England, New York/New Jersey, Ohio, Philadelphia/Camden, and Washington/Baltimore. The HIDTA Heroin Response Strategy is fostering a collaborative network of public health-public safety partnerships, sharing best practices, innovative pilots, and identifying new opportunities to leverage resources.

International Engagement. International engagement with Mexico, Canada, and China, as well as multilateral bodies responsible for international control of these substances and their precursor chemicals, are essential to addressing this crisis at the very front end of the supply chain.

U.S.-Mexico engagement regarding heroin and illicit fentanyl is robust. The At a high-level bilateral security meeting in October 2015, discussed heroin as the first agenda topic, which included the importance of increased poppy eradication efforts by the Government of Mexico, as well as drug interdiction, clandestine laboratory destruction, and disruption of precursor chemical trafficking. As the illicit opioid crisis has evolved, illicit fentanyl has become a key part of that discussion.

In early March 2016, the ONDCP Director and the Assistant Secretary of State for International Narcotics and Law Enforcement Affairs traveled back to Mexico, specifically to engage on heroin and illicit fentanyl issues and to impress upon our Mexican partners the urgency with which the United States is addressing this problem. We met with the Mexican Attorney General, as well as senior officers from the Mexican Army, the Mexican Navy, and the Secretariat of the Government, the agencies that lead Mexico's efforts to disrupt the production

of heroin and illicit fentanyl, including poppy eradication and the identification and neutralization of production laboratories.

In June 2016, the leaders of the United States, Mexico, and Canada participated in the North American Leader's Summit where U.S. concerns about heroin and illicit fentanyl were specifically raised. The annual trilateral meeting resulted in the first-ever North American Drug Dialogue (NADD), subsequently held in October 2016 and focused on the opioid crisis, with particular attention paid to heroin and illicit fentanyl. The parties shared information on best practices, data gathering methodologies, and avenues for further trilateral lines of cooperation, including public health efforts. As a follow up, the United States recently hosted a NADD technical workshop here in Washington where we met with the Mexican and Canadian delegations at the White House for four days of information exchange that included heroin and illicit fentanyl, resulting in a list of tangible deliverables for all three countries to address the issue.

We have also had successes in our work with the People's Republic of China. After the United States raised the need for better regulation of Chinese chemical and pharmaceutical industries at a number of high-level engagements, including the Strategic and Economic Dialogue and the Law Enforcement Joint Liaison Group, China responded to U.S. requests to schedule certain fentanyl analogues and other new psychoactive substances by domestically controlling 116 of such substances in 2015. As a result of our joint cooperation, on March 1, 2017 China domestically controlled another four critical fentanyl analogues, including carfentanil, a particularly lethal analogue of fentanyl. These decisions by the Chinese Government to strengthen controls over these substances could have a positive impact in reducing their availability in the United States and other countries.

Federal law enforcement agencies are aggressively addressing the heroin and illicit fentanyl issue both here and abroad. The Federal Bureau of Investigation, Immigration and Customs Enforcement, and DEA have co-located Special Agents with international partners in Mexico and China to assist in criminal investigations targeting drug trafficking organizations and to help their international counterparts develop capacity to conduct the full range of narcotics interdiction activities within their countries to target both heroin and illicit fentanyl. Federal law enforcement agencies, in conjunction with the Department of State, are working with the countries who supply illicit fentanyl, and the precursor chemicals used in its manufacture, to stem the flow of these dangerous chemicals to the Western Hemisphere.

We have also worked aggressively through the United Nations to strengthen international controls against illicit fentanyl-family drugs and the precursor chemicals used by criminals to produce them. On March 16, 2017 in response to an official request from the United States, the United Nations Commission on Narcotic Drugs (CND) voted unanimously to schedule the two chemicals most commonly used to produce illicit fentanyl products – N-Phenethyl-Piperidone (NPP) and 4-Anilino-N-Phenethyl-Piperidine (ANPP) – for international control under the 1988 UN Drug Convention. This decision by the CND will require governments to establish controls over the production and transport of these chemicals and make it considerably more difficult for drug traffickers to access them. Also earlier this month, Secretary of State Rex

Tillerson issued a formal request to the UN Secretary General to expedite the process of controlling carfentanil – a powerful fentanyl analogue responsible for hundreds of U.S. overdose deaths in 2016 – under the UN Single Convention on Narcotic Drugs.

Challenges Ahead

While we have worked to combat the opioid crisis, including the exponential risk that illicit fentanyl presents, and laid a firm foundation for future efforts, we must do more. The complex and ever-evolving nature of the illicit fentanyl problem continues to be a threat to our Nation. Through our efforts thus far in facilitating efforts across the interagency, we have identified gaps in our knowledge, data, and abilities, and now we are working to close them.

Our capability to detect illicit fentanyl at our borders remains limited, as does our ability to effectively interdict at our airfreight package locations. Our Mexican partners could increase their efforts in opium poppy eradication and clandestine laboratory identification and neutralization. And, we must continue to work with the Government of China to better regulate and control their chemical and pharmaceutical industries, both licit and illicit. We also need to better understand the true extent of illicit fentanyl deaths in the United States. For example, as I stated earlier, although it is abundantly clear that the number of overdose deaths involving fentanyl nationwide has increased dramatically, it is likely that the overdose numbers underreport the actual number of such deaths. This is because the ability to detect fentanyl or fentanyl analogues in overdose victims, and the standard inclusion of these drugs in overdose death toxicology screening, varies widely among our Nation's medical examiners and coroners. In localities where detailed toxicology screening is being performed, information suggests there are increasing numbers of overdoses involving these drugs.

We look forward to continuing our work with Federal, state, local, and tribal government partners, as well as our international counterparts and non-governmental organizations, to address these challenges.

Conclusion

The opioid epidemic, initially fueled by prescription opioid misuse and enhanced by the availability of low cost high potency heroin and deadly fentanyl-family drugs, is a public health and public safety crisis. Addressing the problem requires attention and resources dedicated not only to substance abuse prevention and treatment strategies and recovery support services, but also to reducing the availability of these drugs. Our coordination thus far has afforded us a glimpse into how law enforcement officials, Federal, state, and local, are increasingly becoming public health partners, helping those with an opioid addiction to obtain treatment for their disease, and identified how we need to continue our efforts to make the greatest possible gains in this deadly crisis.

ONDCP will continue to work with our international partners, Federal departments and agencies, regional HIDTA programs, and our partners at the state, local, and tribal levels to

reduce heroin and illicit fentanyl production and trafficking and the profound effect these dangerous drugs are having in our communities.

Thank you for the opportunity to testify today and for your commitment to this important issue. I look forward to answering any questions you may have.

Mr. MURPHY. Thank you, Mr. Chester.

Mr. Milione, you're recognized for 5 minutes.

STATEMENT OF LOUIS MILIONE

Mr. MILIONE. Thank you, Committee Chair Murphy, Ranking Member DeGette, distinguished members of the subcommittee.

I want to put these overdose death numbers in some context. So spring is here today and major league baseball will kick off their season next month.

Picture the MLB stadium in any of your respective cities. The more than 52,000 Americans we lost in 2015 to drug overdoses would overflow any of those MLB stadiums, bar none.

I'm sure we all agree that this is an unimaginable tragedy. To the DEA, the fentanyl threat and the broader opioid epidemic are the number-one drug threats facing our country.

With illicitly produced fentanyl, you have substances many times more potent than heroin, sold as heroin, mixed with heroin and, increasingly, pressed into pill form before being sold by criminal networks on our streets as prescription pain killers.

There are five pills that represent five counterfeit pain killers. Based on laboratory analysis of the thousands of seized counterfeit pills, one of every five will contain three times the lethal amount of fentanyl—lethal at 2 milligrams, as was mentioned earlier. To the unsuspecting user, death is lurking in just one of these pills.

Sadly, but not unexpectedly, Mexican cartels are exploiting the opioid use epidemic and aggressively purchasing illicitly produced fentanyl from China, shipping it to Mexico, mixing it with heroin and other substances and shipping it back into the United States through established distribution networks where it is sold in our communities.

Illicitly made fentanyl is also being shipped from China into Canada for distribution across our northern border. It's also being shipped directly from China into the United States for domestic distribution cells.

Why are they doing this? Greed and a complete disregard for human life. There is a massive profit potential with fentanyl. One kilogram of pure fentanyl costs approximately in China about \$3,500.

If you project that kilogram of fentanyl all the way through the supply chain to the distribution level, that \$3,500 kilogram will potentially yield millions of dollars in revenue.

For the DEA and broader U.S. Government to deal successfully with this threat we need a balanced holistic approach that attacks supply and reduces demand. Most importantly, we must be proactive.

We need to use any and all available investigative techniques to identify, infiltrate, indict, capture and convict all members of these criminal organizations both domestic and foreign.

With 221 domestic offices in 21 field divisions and 92 foreign offices in 70 countries, DEA, working with our Federal, State, local, international partners is well positioned to engage in this fight.

Throughout DEA's proud history, our greatest successes have come from our collaborative efforts with the U.S. interagency and

our foreign counterparts. Our approach to this threat is no different.

We have had success and we will continue to have successes against members of these fentanyl manufacturing and distribution networks. But here is the most frustrating part.

Foreign-based fentanyl manufacturers and the domestic Pied Pipers of this poison often operate with impunity because they exploit loopholes in the analogue provisions of the Controlled Substances Act and capitalize on the lengthy resource-intensive reactive process required to temporarily or permanently schedule these dangerous substances.

As we speak, criminal chemists in foreign countries are tweaking the molecular structure of different fentanyl analogues, keeping the same dangerous pharmacologic properties as the controlled substances but helping the manufacturers and distributors avoid criminal exposure because of an altered molecular structure.

Since July of 2015, DEA has emergency scheduled five illicitly produced fentanyls. Four are currently in process. We are tracking 19 more.

Scheduling actions are critically important, but they are reactive, resource-intensive processes. We will continue to do everything we can on the scheduling front, but in the short-term, this esteemed body could provide DEA and our law enforcement partners immediate relief by placing the identified fentanyls and the other dangerous synthetic substances into Schedule I.

This would allow us to keep these drugs out of country and bring to justice the egregious domestic and foreign traffickers preying on our youth and flooding our country with these dangerous drugs.

I would like to end with two opposite but interconnected images—sunlight and shadows. DEA will always operate in the sunlight. We will always follow the rule of law. We will work to reduce demand with our community outreach and prevention efforts throughout the country.

But we have to also operate in the shadows. We need to infiltrate these secretive, dangerous transnational criminal organizations, whether they are here in the United States or in foreign countries.

We need to develop and collect the necessary evidence to bring those that exploit human frailty for profit out from the shadows and into the sunlight of our transparent judicial system for prosecution in the U.S.

The brave men and women of DEA will continue to do the necessarily difficult and dangerous work to address this threat.

Thank you for the opportunity to appear before you and I look forward to answering any of your questions.

[The prepared statement of Mr. Milione follows:]



Department of Justice

STATEMENT OF

LOUIS J. MILIONE
ASSISTANT ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

“FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS”

PRESENTED

MARCH 21, 2017

**Statement of
Louis Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration
Before the
Subcommittee on Oversight and Investigations
Energy and Commerce Committee
United States House of Representatives
March 21, 2017**

INTRODUCTION

Chairman Murphy, Vice Chairman Griffith, Ranking Member DeGette, and Members of the Oversight and Investigations Subcommittee: 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 dangerous synthetic drugs.

DEA has become increasingly alarmed over the proliferation of illicit fentanyl and its analogues, which have been added to heroin and other illicit substances and have also been encountered as counterfeit tablets resembling controlled prescription drugs (CPDs). Fentanyl and fentanyl analogues are potent synthetic opioids which present a serious risk of overdose and death by those who misuse these substances. The 2015 market for misused prescription pain relievers was 12.5 million people¹, and if illicit fentanyl is introduced into even a small portion of that overall market, there is a likelihood that overdoses will increase. In addition, this drug can be absorbed through the skin or inhaled, which makes it particularly dangerous for public safety personnel who encounter the substance during the course of their daily operations. Fentanyl and fentanyl analogues represent the deadly convergence of the synthetic drug threat and current national opioid epidemic.

On a broader scale, synthetic designer drugs, also known as New Psychoactive Substances (NPS), refer to man-made substances designed to mimic the effects of known licit and illicit controlled substances; these substances are oftentimes unscheduled and unregulated. There are a variety of synthetic designer drugs, which are categorized based on the types of controlled substances they are intended to mimic: cannabinoids, cathinones, and hallucinogens known as phenethylamines. The two most commonly used categories of synthetic designer drugs in the United States are synthetic cannabinoids and synthetic cathinones. NPS continue to pose a nationwide threat to the United States and related overdoses and deaths continue to occur.

¹ Center for Behavioral Health Statistics and Quality. (2016). *Results from the 2015 National Survey on Drug Use and Health*. Table 1.27A. Retrieved from <http://www.samhsa.gov/data/>

SYNTHETIC DESIGNER DRUGS OVERVIEW*Fentanyl and Its 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 that case, it is indicated only for use in people who are opioid tolerant.

According to DEA investigations, illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped through mail carriers directly to the United States or alternatively shipped directly to transnational criminal organizations (TCOs) in Mexico, Canada, and the Caribbean. Once there, 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, a total of 50,440 fentanyl reports were identified by Federal, State and local forensic laboratories. During 2016, there were 28,751 fentanyl reports compared to 1,041 reports in 2013, a substantial 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 and Prevention Morbidity and Mortality Weekly Report, from 2014 to 2015, the death rate from synthetic opioids other than methadone, which includes fentanyl, increased by 72.2%, from 5,544 (age adjusted rate 1.8 per 100,000) to 9,581 (3.1 per 100,000). 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.

In 2015, about 3.8 million Americans age 12 or older reported misusing prescription pain relievers within the past month². This makes nonmedical prescription opioid misuse more

² Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from <http://www.samhsa.gov/data/>

common than use of any category of illicit drug in the United States except for marijuana. The illicit market for prescription drugs is considerable in size, which significantly increases the risk that fentanyl or fentanyl analogue-laced counterfeit pills will cause more overdoses across the nation as they are more readily produced by drug trafficking organizations.

CURRENT CHALLENGES

Traffickers Adapting to the Law

Even though many fentanyl-related and NPS compounds have been controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA), entrepreneurs procure new synthetic compounds with relative ease. Over the past several years, DEA has identified numerous fentanyl class substances and hundreds of designer drugs from at least eight different drug classes, the vast majority of which are manufactured in China.

In fact, when DEA takes an action to temporarily schedule a substance, retailers begin selling new versions of their products with new, unregulated compounds in them. Manufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new products that are not listed as such in any of the controlled substance schedules.

Fentanyl, Fentanyl Analogues and the Internet

The tools needed to manufacture counterfeit pills containing fentanyl or fentanyl analogues are available online and are relatively inexpensive compared to other forms of drug production, contributing to its unique level of threat. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. Illicit fentanyl and fentanyl analogues are available for purchase online from anonymous darknet markets and even overtly-operated websites. Industrial pill press machines are also widely available on the open Internet.

Use of Freight Forwarders

Traffickers often use freight forwarders to mail fentanyl and fentanyl analogues from China. Several DEA investigations have revealed that the original supplier will provide the package to a freight forwarding company or individual, who transfers it to another freight forwarder, who then takes custody and presents the package to customs for export. The combination of a chain of freight forwarders and multiple transfers of custody makes it difficult for law enforcement to track these packages. Often, the package will intentionally have missing, incomplete, and/or inaccurate information.

Prosecutions Pursuant to the Analogue Act

A designer drug, including fentanyl analogues, may be a “controlled substance analogue” pursuant to the CSA if it meets the criteria of substantial similarity of chemical structure and effect on the central nervous system. Even if a particular substance is widely regarded as a “controlled substance analogue” under the CSA, each criminal prosecution must establish that

fact anew. The primary challenge to preventing the distribution and use of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is treated as a Schedule I controlled substance only once proven to meet the definition of a controlled substance analogue; prosecutors must also prove that the substance was intended for human consumption. Accordingly, each prosecution requires expert testimony even if the same substance is involved.

In addition, without establishment and inclusion of specific sentencing equivalencies in the U.S. Sentencing Guidelines, prosecutors must produce evidence addressing the factors identified in the relevant guidelines. As a result, prosecutors typically call two expert witnesses to testify at every sentencing hearing to demonstrate that the substances in question fall within guideline definitions, a time consuming, resource intensive, and inefficient process. This in turn raises concern that different courts could reach different sentencing results for the same substance, potentially resulting in disparate sentences for similarly situated offenders.

The above considerations, along with the increasing volume and variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Analogue Act a cumbersome and resource-intensive tool to prevent manufacturing, trafficking, and abuse of designer drugs. That said, agents, chemists, and prosecutors have worked together tirelessly to make the Analogue Act work, with many successful prosecutions to show for it. The Synthetic Drug Abuse Prevention Act of 2012 (SDAPA) approach to control specific, known, synthetic substances in some instances by description of chemical characteristics, was a swift and effective contribution to the overall effort to combat the designer drug threat.³ DEA will continue to identify ways to better combat the designer drug threat.

The Drug Control Process under the CSA

The CSA provides the Attorney General (delegated to the DEA Administrator) with a mechanism to bring new drugs of abuse under CSA control and subject them to a regulatory scheme to protect the public. Through an interagency process, determinations about placement in the CSA are dictated by the following eight enumerated scientific factors:⁴ the state of current scientific knowledge about the substance; its pharmacological effect; its risk to the public health; its psychic or psychological dependence liability; whether the substance is an immediate precursor of a controlled substance; its actual or relative potential for abuse; its history or current pattern of abuse and its scope; and the scope, duration, and significance of abuse. In this process, the Secretary for the Department of Health and Human Services (HHS) is responsible for any scientific and medical considerations about a substance and a recommendation made by the Secretary is considered by the DEA Administrator along with other relevant facts to determine whether there is substantial evidence to warrant control. These scheduling evaluations by both HHS and DEA require extensive scientific, medical, law enforcement and other data. The acquisition of this data is often an arduous and time consuming process. The

³ P.L. 112-144 – Food and Drug Administration Safety and Innovation Act, Subtitle D, Section 1151, titled “Synthetic Drug Abuse and Prevention Act of 2012.

⁴ The eight factors are enumerated in 21 U.S.C. § 811(c).

public continues to be impacted adversely while these data are being obtained in support of control under the CSA.

In circumstances when the DEA Administrator concludes that control of a substance is necessary to avoid an “imminent hazard to public safety,” the DEA Administrator may initiate temporary control of that substance for a period of two years, subject to possible extension for up to one year,⁵ during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.⁶

DEA believes a coordinated response by public health and law enforcement and other stakeholders remains the most effective response to this problem. Further, DEA will continue to share information and engage stakeholders to decrease the demand for illicit fentanyl, fentanyl analogues, and other synthetic substances encountered on the illicit market.

DEA RESPONSE TO THE THREAT OF FENTANYL AND OTHER SYNTHETIC DRUGS

Scheduling by Administrative Rulemaking: Temporary Control

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 March 2011, DEA has utilized this authority on twelve occasions to place 37 synthetic designer drugs into Schedule I, including four fentanyl analogues, acetyl fentanyl, butyryl fentanyl beta-hydroxythiofentanyl, and furanylfentanyl. 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.

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 and U.S. Customs and Border Protection ; supplemented by the Federal Bureau of Investigation and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the Organized Crime Drug Enforcement Task Forces (OCDETF) Fusion Center (OFC), the

⁵ The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).

⁶ Temporary control of a substance may be extended for a period of 1 year if DEA receives the Secretary’s scientific and medical evaluation and scheduling recommendation within the 2-year temporary control period.

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.

China: Government Action and Cooperation

Through both DEA leadership and its country office in Beijing, DEA has maintained an ongoing relationship with People's Republic of China Government Officials for years, and has been able to leverage this relationship to combat the rising threat from NPS. Engagement has been occurring at the leadership level through interagency working groups that operate under the U.S.-China Joint Liaison Group framework, the Counternarcotics Working Group led by the Department of Justice, and the Bilateral Intelligence Working Group led by DEA.

Recently, China's National Narcotics Control Commission announced that scheduling controls against four fentanyl-class substances, carfentanil, furanyl fentanyl, valeryl fentanyl, and acryl fentanyl, would begin on March 1, 2017. This announcement was the culmination of ongoing collaboration between DEA and the Government of China, in large part through the U.S.-China Joint Liaison Group framework, and reaffirms the shared commitment to countering illicit fentanyl.

Over the past several months, DEA and Chinese officials 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 officials to exchange information on emerging substances' scientific data, trafficking trends, and sample exchanges. This dialogue resulted in improved methods for identifying and submitting deadly substances for government control.

Additionally, in October of 2015, following similar discussions through the 2015 U.S. Joint Liaison Group fall meetings, China decided to implement domestic controls on 116 NPS, which included multiple fentanyl analogues.

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 and NPS continues to evolve.

North American Dialogue on Drug Policy (NADD)

DEA is working with the Office of National Drug Control Policy (ONDCP) and the Department of State to enhance coordination with Canada and Mexico to combat the opioid crisis through the North American Dialogue on Drug Policy (NADD). Through the inaugural trilateral meeting in October 2016 and March 2017 technical workshops, DEA has shared best practices and methodology on identifying the sources of heroin and fentanyl in North America and combatting criminal distribution networks. DEA will continue to work with Canada and Mexico to convene experts in these fields so that our three countries can better prevent the production and movement of drugs in and through our countries.

DEA'S 360 STRATEGY

DEA is implementing its 360 Strategy to address the opioid, heroin, and violent crime crisis. The strategy leverages existing federal, state, local and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and community relations. The strategy is founded upon our continued enforcement activities directed at the violent street gangs responsible for feeding the heroin and prescription drug abuse epidemic in our communities.

While law enforcement plays a central role in the 360 Strategy, enforcement actions alone are not enough to make lasting changes in our communities. The 360 Strategy, therefore, also focuses on preventing diversion by providing education and training within the pharmaceutical community and pursuing those practitioners who are operating outside of the law. The final component of the strategy is a community effort designed to maximize all available resources to help communities turn around the recurring problems that have historically allowed the drug and violent crime problems to resurface after enforcement operations.

Following is a summary of the three key facets of the 360 Strategy.

Enforcement: A Commitment to Stopping Violence Associated with Drug Trafficking

The enforcement component of the strategy is built around Rolling Thunder, a DEA-led OCEETF-supported law enforcement initiative that targets the link between the cartels and violent gangs – these two elements have become the “New Face of Violent Crime.” To execute the enforcement, DEA continues to rely upon all of its resources, including its Task Force Officers from local and state partners in the area.

The 360 Strategy aims to address the increased violence and drug trafficking on American streets. In the past, DEA would put its emphasis on working toward the Mexico-based organizations pushing drugs into the United States. As part of Rolling Thunder, DEA Agents actively work to shut down the violent street gangs that regulate the drug trafficking business through the barrel of a gun.

Diversion: Enlisting DEA's Registrant Population in the Fight Against Opioid Abuse

As stated above, the nonmedical abuse of prescription opioids is a strong risk factor for heroin use. The 1.6 million registrants who represent manufacturers, wholesale distributors, dispensers, and prescribers are key partners in our efforts to reduce opioid abuse.

DEA continues to engage with industry, practitioners, and government health organizations to facilitate an honest and frank discussion about the CPD abuse contributing to the current heroin epidemic. Additionally, DEA is studying ways, in collaboration with public health partners, to improve access to information that will help identify the nature of the drug abuse problem plaguing a particular area.

Further, DEA will remain vigilant in identifying and pursuing prescribers and other registrants operating outside of the law. This process will be enhanced locally through the use of tactical diversion squads (TDS), which can mobilize to address regional or local issues, and additional diversion investigators.

Community: Leaving something lasting and positive in the communities we serve

After an enforcement operation targeting violent criminals, there is an opportunity for a prepared community to take advantage of the space and time created to better itself and prevent new traffickers from moving in.

This program enables communities to achieve long-term solutions by addressing not only the immediate drug trafficking problems, but also the underlying conditions that allow drug trafficking, drug use and related violence to flourish. DEA will not only work with federal, state and local agencies to bring greater enforcement resources to bear, but also marshal community groups and their resources to identify local drug abuse problems, barriers to dealing with those problems and treatment solutions. DEA will also partner with other federal agencies and sources of expertise and funding to broaden the resources available to the community.

The 360 Strategy has been implemented in the following cities –Pittsburgh, Pennsylvania; St. Louis, Missouri; Milwaukee, Wisconsin; Louisville, Kentucky; Manchester, New Hampshire; Charleston, West Virginia. Additionally, DEA plans to implement the 360 Strategy in Albuquerque, New Mexico and Dayton, Ohio.

CONCLUSION

Illicit fentanyl and fentanyl analogues will remain an extremely dangerous public safety threat while the current production of non-pharmaceutical fentanyl continues. Fentanyl poses not only a threat to users, but also to law enforcement personnel and postal service employees as minute amounts of the drug are lethal and can be inadvertently inhaled or absorbed through the skin. Although many drug users avoid fentanyl, still others actively seek it out for its strong and

intense high. In 2015 traffickers expanded the historical fentanyl markets as evidenced by a massive surge in the production of counterfeit tablets containing the drug, and by manipulating it to appear as black tar heroin. The illicit fentanyl market will continue to expand in the future as new fentanyl products attract additional users.

Illicit fentanyl and fentanyl analogues will continue to pose a nationwide threat to the United States and overdoses and deaths will continue to occur. These substances are inexpensive and widely available, making them accessible to anyone who wants to use the drugs. In addition, traffickers will continue pressing these substances into counterfeit prescription pills, to expand their market to an unsuspecting user base. These characteristics make illicit fentanyl and fentanyl analogues a valuable commodity to traffickers, since traffickers modify and disguise them as traditional drugs. Traffickers will continue to avoid scheduling actions by modifying the chemical formulas to create new, unregulated and unscheduled drugs. In addition, traffickers may continue to distribute popular substances regardless of their status under the Controlled Substances Act.

DEA will continue to address these threats by pursuing the Mexican-based TCOs that have caused tremendous harm to our communities. Additionally, DEA's Diversion Control Division will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. We look forward to continuing to work with Congress to find legislative solutions needed to address the threat posed by illicit fentanyl, fentanyl analogues, and other synthetic substances encountered on the illicit market. s.

Mr. MURPHY. Thank you, Mr. Milione.
Now, Mr. Allen, you're recognized for 5 minutes.

STATEMENT OF MATTHEW C. ALLEN

Mr. ALLEN. Chairman Murphy, Ranking Member DeGette and distinguished members, thank you for the opportunity to appear before you today to discuss the heroin and fentanyl crisis in the United States and the efforts of U.S. Immigration and Customs Enforcement to target, investigate, disrupt, and dismantle and bring to justice the criminal elements responsible for manufacturing, smuggling, and distribution of dangerous opioid.

As the largest investigative agency within DHS, ICE Homeland Security Investigations investigates and enforces more than 400 Federal criminal statutes.

HSI special agents use their authority to investigate all types of cross-border criminal activity and work in close coordination with U.S. Customs and Border Protection and the Drug Enforcement Administration in a unified effort with both domestic and international law enforcement partners to target transnational criminal organizations that are supplying heroin and fentanyl to the United States.

Today, I would like to highlight our efforts to reduce the supply of heroin and fentanyl to the U.S. and the operational challenges that we encounter.

The United States, as you have heard already, is in the midst of a fentanyl crisis that is multifaceted and deadly. Fentanyl is a Schedule II synthetic opioid used medically for severe pain relief and it is 50 to 100 times more potent than morphine.

United States law enforcement has identified two primary sources of the U.S. illicit fentanyl threat—China and Mexico. China is a global supplier of illicit fentanyl and Chinese laboratories openly sell fentanyl.

In China, criminal chemists work around their government's control efforts by modifying chemical structures to create substances referred to as analogues not recognized as illicit in China but having the same deadly effects.

Although there is ongoing collaboration with China, the lack of current Chinese laws that prohibit analogue manufacturing or export is one of the challenges we face in stemming the flow of illicit fentanyl from China.

Mexican drug cartels also obtain illicit fentanyl and precursor materials required to manufacture fentanyl-related substances from China and primarily use fentanyl as an adulterant in heroin that is produced in Mexico.

The cartels have discovered that manufacturing fentanyl is much more cost effective, efficient and draws less law enforcement attention than cultivating opium poppies to produce heroin.

Fentanyl seized at our U.S. Southwest border is typically 5 to 10 percent in purity. Once illicit fentanyl is distributed in local American drug markets, many people who use drugs, whether heroin or prescription pain pills, are unaware of the presence of more potent fentanyl in their narcotic.

As fentanyl used in suspected heroin or counterfeit pills is more potent than the drugs they resemble, it readily leads to overdosing

and this is often how law enforcement first learns that fentanyl or an analogue has been introduced into a local drug market.

The addictive nature and demand for opioids paired with the low cost and high potency of fentanyl used in counterfeit opioid production has led TCOs to compete for a portion of the illicit U.S. drug market.

Illicit fentanyl is not only dangerous for people who abuse drugs but also for law enforcement, public health workers and first responders who could unknowingly come into contact with it.

Accidental skin contact or inhalation of the substance during law enforcement activity or during field testing of the substance is one of the biggest dangers and challenges we face in law enforcement.

In response to the dramatic increase in the availability of opioids, the Office of National Drug Control Policy, in close coordination with other Federal departments and agencies, developed a Heroin Availability Reduction Plan to reduce the supply of heroin and illicit fentanyl in the United States.

ICE has been supporting HARP since its inception. We are targeting supply chain networks, coordinating with domestic and international partners and providing field training to highlight officer safety and collaboration efforts.

ICE is also fully engaged with the DEA Special Operations Division and the CBP National Targeting Center to identify shipment routes, targeting parcels that may contain heroin, illicit fentanyl and fentanyl-related substances and manufacturing materials that go into making pills in the United States, fully exploiting financial and other investigative analyses along the way.

ICE is committed to battling the U.S. heroin and illicit fentanyl crisis that demands urgent and immediate action across law enforcement interagency lines in conjunction with experts in the scientific, medical and public health communities.

Thank you for the opportunity to appear before you today and I look forward to your questions.

[The prepared statement of Mr. Allen follows:]



U.S. Immigration and Customs Enforcement

STATEMENT

OF

MATTHEW C. ALLEN
ASSISTANT DIRECTOR
HOMELAND SECURITY INVESTIGATIVE PROGRAMS
HOMELAND SECURITY INVESTIGATIONS

U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
DEPARTMENT OF HOMELAND SECURITY

REGARDING A HEARING ON

"Fentanyl: The Next Wave of the Opioid Crisis"

BEFORE THE

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

Tuesday, March 21, 2017
2123 Rayburn House Office Building

Chairman Murphy, Ranking Member DeGette, and distinguished members:

Thank you for the opportunity to appear before you today to discuss the heroin and fentanyl crisis in the United States and the efforts of U.S. Immigration and Customs Enforcement (ICE) to target, investigate, disrupt, dismantle and bring to justice the criminal elements responsible for the manufacturing, smuggling, and distribution of dangerous opioids.

As the largest investigative agency within the U.S. Department of Homeland Security (DHS), ICE Homeland Security Investigations (HSI) investigates and enforces more than 400 federal criminal statutes to include the Immigration and Nationality Act (Title 8), U.S. customs laws (Title 19), general federal crimes (Title 18), and the Controlled Substances Act (Title 21). HSI special agents use this authority to investigate all types of cross-border criminal activity and work in close coordination with U.S. Customs and Border Protection (CBP) and the Drug Enforcement Administration (DEA) in a unified effort with both domestic and international law enforcement partners, to target Transnational Criminal Organizations (TCOs) that are supplying heroin and fentanyl to the United States.

Today, I would like to highlight our efforts to reduce the supply of heroin and fentanyl to the United States and the operational challenges we encounter.

Introduction to Fentanyl

Before we can discuss illicit fentanyl targeting and supply reduction, we need to understand what fentanyl is and how it is produced.

The United States is in the midst of an illicit fentanyl crisis that is multi-faceted and deadly. Fentanyl is a Schedule II synthetic opioid, used medically for severe pain relief in patients that are already opioid tolerant, and it is 50-100 times more potent than morphine. For reference, as little as two milligrams of pure fentanyl can be fatal. Based on investigations, United States law enforcement has identified two primary sources of the U.S. illicit fentanyl threat: China and Mexico.

China is a global supplier of illicit fentanyl and the precursor chemicals used to manufacture the drug. Additionally, Chinese laboratories openly sell fentanyl, to include fentanyl analogues, and other fentanyl-related substances. In China, criminal chemists work around their government's control efforts by modifying chemical structures ever so slightly to create substances not recognized as illicit in China but having the same deadly effects. Although there is ongoing collaboration with China, the lack of current Chinese laws that prohibit analogue manufacturing or export is one of the challenges we face in stemming the flow of illicit fentanyl from China.

China-sourced illicit fentanyl is primarily used by counterfeit tableting organizations in Mexico and the United States that focus on supplying people who misuse prescription pain pills. Counterfeit tablet suppliers often purchase powdered fentanyl through the anonymity of the internet and can access open source and dark web marketplaces for the tools needed for

manufacturing. Fentanyl, pill presses and binding agents are then shipped into the United States primarily via international mail services and express consignment couriers. Illicit fentanyl products attributed to China are generally unadulterated.

Mexican drug cartels also obtain illicit fentanyl and precursor materials required to manufacture fentanyl-related substances from China and primarily use fentanyl as an adulterant in heroin that is produced in Mexico. The cartels have discovered that manufacturing fentanyl is much more cost effective, efficient, and draws less law enforcement attention than cultivating opium poppies to produce heroin. Because of the potency of fentanyl, only microgram quantities are needed to produce an effect. Fentanyl can be diluted and adulterated with other agents to produce dozens of kilograms of heroin-like substitute and can be added to heroin to create a synergistic effect. The adulterated heroin can sell at the traditional heroin street price or much higher if it is advertised as having a stronger effect. When smuggled adulterated heroin is discovered and seized by law enforcement, it has a much lower cost of replacement to the organization. Fentanyl seized at our Southwest Border Region is typically 5-10 percent in purity with the balance being diluents, such as dipyrone, mannitol or lactose.

Once illicit fentanyl is distributed in local American drug markets, many people who use drugs (whether heroin or prescription pain pills) are unaware of the presence of the more potent fentanyl in their narcotic. As fentanyl used in suspected heroin or counterfeit pills is more potent than the drugs they resemble, it readily leads to overdosing. Alternatively, the improper mixing of fentanyl can easily lead to batches of pills with a higher concentration of fentanyl, what is known as “hot spots”, leading to overdose and death. These batches may then be distributed within a specific geographic area and result in an increased number of overdose occurrences and deaths in that area. This is often how law enforcement learns that fentanyl or an analogue has been introduced into a local drug market.

The addictive nature and demand for opioids paired with the low cost/high potency of fentanyl used in counterfeit opioid production has led TCOs to compete for a portion of the U.S. illicit drug market.

ICE’s Efforts to Reduce the Supply of Fentanyl

In accordance with the President’s February 9, 2017, Executive Order on Enforcing Federal Law with Respect to Transnational Criminal Organizations and Preventing International Trafficking, HSI will be working to reduce the supply of Fentanyl.

Heroin Availability Reduction Plan

In response to the dramatic increase in the availability of opioids, the Office of National Drug Control Policy (ONDCP), in close coordination with Federal departments and agencies, developed the Heroin Availability Reduction Plan (HARP) to reduce the supply of heroin and illicit fentanyl in the United States market through supply chain disruption and in detection and intelligence collection as outlined in the plan’s strategy. ICE has been involved in supporting the HARP since its inception.

Pursuant to the HARP, ICE is targeting supply chain networks, coordinating with domestic and international partners, and providing field training to highlight officer safety, trends, and collaboration benefits.

In support of the detection and analysis effort, ICE is fully engaged with the DEA Special Operations Division (SOD) and the CBP National Targeting Center, to identify shipment routes; targeting parcels that may contain heroin, illicit fentanyl, fentanyl-related substances and manufacturing materials; and fully exploiting financial and investigative analyses.

ICE Lines of Effort

Network Identification

The DEA's Special Operations Division (SOD) Heroin and Fentanyl Task Force (HFTF) is supported by ICE, CBP, DEA, and several other federal agencies. The SOD-led, interagency task force exploits electronic communications to proactively identify, disrupt, and dismantle the production, transportation, and financial networks behind the heroin and illicit fentanyl distribution organizations that impact the United States.

The HFTF focuses on the collaborative authorities and efforts of each invested agency's resources, in order to better share and deconflict information. The HFTF works together to target international and domestic organizations by proactively working with field office. The taskforce also assists in coordinating and linking investigations from the street level dealer to the international source of supply.

ICE supports field investigations related to heroin and illicit fentanyl and the overdoses that occur as a result of use. ICE and the HFTF are currently coordinating with the Department of Justice's Organized Crime Drug Enforcement Task Force (OCDETF) Program, its Fusion Center and ONDCP's High Intensity Drug Trafficking Area (HIDTA) taskforces to exploit communication data and social media information that are associated with reports of overdoses within a geographical area. This is in direct support of the OCDETF National Heroin Strategy. Coordination with OCDETF and HIDTA has proven helpful in multi-jurisdictional investigations and in their successful prosecutions.

HSI special agents actively pursue the financial networks used to sustain the heroin and illicit fentanyl trade. As with sources of supply, the financial methods used by smugglers and traffickers have also adapted with current trends. The wholesalers and end users utilize Money Service Businesses (MSBs), Bank to Bank wire transfers, PayPal, and virtual currencies (such as Bitcoin), to name a few, to successfully finance the supply chain and remit illicit proceeds. ICE continues to engage financial industry partners, specifically MSBs, to better identify the movement of illicit proceeds tied to fentanyl.

ICE recognizes that the private sector represents America's first line of defense against money laundering. Through our Illicit Finance and Proceeds of Crime Unit (IFPCU), ICE

partners with the U.S. financial industry, along with state and federal agencies, to combat financial and trade crimes associated with heroin and fentanyl smuggling and distribution.

In targeting virtual currency transactions of heroin and illicit fentanyl, ICE uses blockchain analysis to track transactions between criminal parties. Blockchain is a digital ledger in which transactions made in bitcoin or another cryptocurrency are recorded chronologically and publically. ICE has seen a substantial increase in cases in which private parties are acting as money service businesses to exchange digital currencies into fiat currency to enjoy the illicit proceeds of narcotics smuggling. The IFPCU also utilizes resources provided by the Treasury Executive Office for Asset Forfeiture's Third-Party Money Laundering Initiative to support complex financial investigations. ICE's Bulk Cash Smuggling Center also supports investigations through counter money laundering efforts that target TCOs that supply heroin and fentanyl.

The sources, brokers, and U.S. distributors of heroin and illicit fentanyl often communicate via dark web marketplaces, internet chat rooms, Peer to Peer applications, emails, skype, or other means of electronic communication. ICE's Cyber Division further exploits these methods of communication in furtherance of field initiated criminal investigations. Moving forward, ICE's Cyber Division will focus on exploiting the digital footprints left by the criminal parties. These exploitations will provide additional investigative avenues and exponentially increase targetable data points.

ICE has seen heroin and illicit fentanyl supply chains that are not only engaged in the importation of raw powder from foreign sources and counterfeit pills but also in the importation of the precursor chemicals used to produce finished product in the United States. The flow continues to transit through postal systems, express consignment couriers, and land borders. The finished product appearance can vary based on demand and the target market. In addition to the chemicals and/or binding agents, regional distributors often procure pill making implements (pill presses, fillers, cleaners and dyes) to effectively produce finished product clandestinely. ICE currently works with DEA, CBP, and United States Postal Inspection Service (USPIS) to target and investigate these precursor and manufacturing imports.

Support to CBP Targeting and Interdiction

Every day, CBP's National Targeting Center (NTC) works quickly and quietly to identify people and products that pose potential threats to our nation's security, and to stop them from entering the United States. The NTC employs highly skilled targeting specialists using state-of-the-art technologies to identify high-risk people and cargo in the air, land, and sea environments that enter and leave the United States. The NTC carefully targets and coordinates examination of shipments and travelers who may be associated to transnational criminal organizations and/or the smuggling of heroin and fentanyl.

ICE participates at CBP's NTC through the National Targeting Center – Investigations (NTC-I) program, which leverages intelligence gathered during ICE investigations and exploits it using CBP holdings to target the flow of drugs into the United States. The NTC-I works to share information between CBP and ICE entities world-wide.

NTC-I conducts post seizure analysis based on ICE seizures in the field and CBP seizures at the ports of entry. The analysis is critical to identifying networks that transport heroin and illicit fentanyl-related substances into and throughout the United States. A key component of the post seizure analysis is the financial investigation. The NTC-I focuses on the financial element of the smuggling organization by exploiting information gathered from multiple financial databases.

The NTC-I works closely with CBP to target illicit shipments imported into the United States from abroad for interdiction at international mail facilities. CBP works to target parcels based on numerous characteristics and provides investigative information on past seizures and active smuggling networks to aid in the targeting effort. Partnering with express consignment couriers has proven valuable in identifying additional data sets for targeting and exploitation.

The recent partnership and consistent collaboration between ICE, CBP, USFIS, and DEA has greatly contributed to the success in combatting illicit shipments of heroin and fentanyl-related substances. Sources in China frequently utilize the international mail services to ship fentanyl in small parcels to avoid detection by CBP. The NTC-I leverages the working relationship with USFIS target these shipments for interdiction at U.S. airport hubs and local post offices. The NTC-I has been instrumental in coordinating interdiction and extended border searches on illicit fentanyl-related shipments leading to multiple seizures in the United States and abroad.

International Partners and Cooperation

ICE works closely with our domestic and international law enforcement partners to disrupt and dismantle transnational criminal organizations.

ICE, in support of DEA and the Department of State, has met with law enforcement counterparts from China, Mexico, and South American countries for the purposes of sharing targeting information regarding known sources of heroin, illicit fentanyl, and precursor supply, for interdiction and effective organization dismantlement.

We have traveled with DEA and CBP to China in pursuit of the successful identification and nomination of fentanyl Consolidated Priority Organization Targets (CPOTs) on several occasions, have hosted China counterparts in the United States at the Special Operations Division, and will return to China for continued coordination in April.

CPOT is the command and control element of a major transnational criminal organization and/or money laundering enterprise that significantly impacts the United States illicit drug supply and is designated by the Attorney General and Organized Crime Drug Enforcement Task Force (OCDETF) member agencies. CPOTs represent the "most wanted" transnational criminal and money laundering organizations.

The successful identification and nominations of heroin and illicit fentanyl CPOT targets provide a first step into the designation of fentanyl "kingpins" under the Foreign Narcotics

Kingpin Designation Act, and the ultimate imposition of economic sanctions against CPOTs and their business networks through the Department of Treasury's Office of Foreign Assets Control (OFAC).

ICE has also met with Canadian officials to share trends and targeting strategy in fentanyl-related investigations. Like the United States, our Canadian counterparts have expressed that a fentanyl crisis is also occurring within Canada. ICE has traveled with DEA to Canada on at least three (3) occasions to compare heroin and fentanyl trends, case models, and known targetable data sources. Further, command and control structures, communications, distribution routes, and the logistical movement of fentanyl-related shipments have been shared.

Officer Safety

Illicit fentanyl is not only dangerous for people who use drugs, but for law enforcement, public health workers and first responders who could unknowingly come into contact with it in its different forms. Working dogs are also at risk of exposure.

Law enforcement is presented with several challenges when dealing with fentanyl. Accidentally inhaling the substance during law enforcement activity or during field testing of the substance is one of the biggest dangers with fentanyl. A secondary safety threat, the absorption through the skin, may also produce a response; however, severity of skin absorption for most forms of illicit fentanyl is debated in the scientific and medical communities. In either exposure case adverse health effects can include disorientation, coughing, sedation, respiratory distress or cardiac arrest

Field testing proves to be difficult, because fentanyl is not one of the classic drugs that are familiar to law enforcement. Undercover activities and controlled purchases are also risky, as many regional distributors themselves are unaware of the presence of fentanyl in their heroin product. This leads narcotics officers to believe they are conducting a controlled purchase of heroin or cocaine, when in fact, they may be purchasing illicit fentanyl. Additionally, delays in laboratory testing due to drug seizure volumes are also problematic in quickly identifying fentanyl.

Naloxone is an antidote for opioid overdoses, including those caused by fentanyl. When quickly and properly administered, it can restore normal breathing and consciousness to individuals experiencing an opioid overdose/accidental exposure.

ICE is currently in the process of obtaining and distributing naloxone kits and other Personal Protective Equipment (PPE) to trained special agents in order to prevent fentanyl overdose exposure to law enforcement and is working to develop interim guidance and policy on the handling and transporting of fentanyl evidence.

CONCLUSION

Thank you again for the opportunity to appear before you today and for your continued support of ICE and its law enforcement mission. ICE is committed to battling the U.S. heroin and illicit fentanyl crisis through the various efforts I have discussed today. I would like to reiterate that this problem set is an epidemic that demands urgent and immediate action across law enforcement interagency lines in conjunction with experts in the scientific, medical, and public health communities. I appreciate your interest in this important issue and look forward to your questions.

Mr. MURPHY. Thank you very much.
Now, Mr. Brownfield, you are recognized for 5 minutes. Make sure your microphone is on, please.

STATEMENT OF WILLIAM R. BROWNFIELD

Mr. BROWNFIELD. Thank you, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee. Thank you for the opportunity to appear before you today.

The broad interagency panel here today demonstrates that this is a health issue, a law enforcement issue and an international issue.

This opioid crisis is perhaps our worst drug crisis in 30 years. It kills tens of thousands of our fellow citizens every year. Illicit fentanyl is responsible for many of those deaths and virtually all of that fentanyl is sourced from abroad through foreign drug trafficking organizations.

To solve the problem, we must cut off international supply. That is where my INL bureau comes into play.

Our strategy is three-part—work the neighbors, work China, work the United Nations. First, we realize that most illicit opioids reaching the United States enter through Mexico and Canada.

Mexico produces more than 80 percent of the heroin consumed in the U.S. and Mexican heroin trafficking networks introduce fentanyl into the supply chain.

Since the start of Merida Initiative cooperation in 2008, we have developed a close relationship with Mexican Federal law enforcement. We have delivered hundreds of millions of dollars in border inspection and law enforcement equipment, training and capacity building and intelligence exchange.

Mexico invests \$20 for every one of ours. Mexico has increased efforts to eradicate opium poppies and we recently agreed to expand those efforts further.

Canada is suffering its own opioid crisis, although most of its heroin comes from Afghanistan. We coordinate closely with Canada to address a shared crisis, ensuring both governments have statutory authority to address the problem and sharing real-time law enforcement intelligence.

And all three governments cooperate through the new North American Drug Dialogue where we share information on narcotics research, exchange best practices and develop actions to protect our citizens.

Second, we have expanded cooperation with China, a major fentanyl source country. In 2015, China moved to regulate 116 new synthetic drugs and on March 1st of this year it added four critical fentanyl analogues to its domestic control including carfentanil, sometimes described as fentanyl on steroids—100 times more potent than fentanyl.

We asked China to do more, but I acknowledge these steps by the Chinese Government. They improve our ability to track and control fentanyl and other synthetic drugs entering the United States.

We are also using, targeting and sanctions programs like the narcotics reward and drug kingpin authorities to target fentanyl traffickers.

For nearly 20 years, the U.S. and China have coordinated law enforcement policy through the U.S.-China Joint Liaison Group on Law Enforcement and that dialogue produces valuable cooperation.

Third and finally, we are working through the U.N. system to regulate dangerous opioids and precursors throughout the world. I was in Vienna last week for the annual meeting on the Commission on Narcotic Drugs, the governing body for all U.N. drug policy.

By a vote of 51 to 0, the CND approved our proposal to regulate two essential fentanyl precursors. The entire process took four months rather than the normal 2 years, and while the regulation will not stop illicit fentanyl production, it will be more difficult for criminals to obtain the chemicals needed to make it and easier for countries to prosecute them.

We also support programs by the U.N.'s drug control organization, UNODC, to eliminate opium poppy cultivation and heroin production in Afghanistan, Mexico, Colombia and Guatemala.

Mr. Chairman, members of the committee, we have an international strategy. We are committed to that strategy. We welcome ideas to improve that strategy.

I have learned two lessons in 25 years engagement in international drug policy. First, it takes decades to get into a drug crisis and will take years of patient persistent effort to get out. Second, no strategy is so perfect it cannot be improved.

Thank you, Mr. Chairman. I look forward to the committee's suggestions.

[The prepared statement of Mr. Brownfield follows:]



Prepared Statement of:
Ambassador William R. Brownfield
Assistant Secretary of State for
International Narcotics and Law Enforcement Affairs

Hearing before the:
House Committee on Energy and Commerce
Oversight and Investigations Subcommittee
“Fentanyl: The Next Wave of the Opioid Crisis”

March 21, 2017

Chairman Murphy, Ranking Member DeGette, distinguished Members of the Subcommittee: thank you for the opportunity to appear before you today to discuss the Department of State's work to combat illicit fentanyl, heroin, and synthetic opioids driving the current national opioid epidemic. I am also pleased to be joined today by colleagues from across the U.S. government. Together, we bring to the table a variety of tools driven by a common goal – ending a health epidemic that has already taken thousands of lives and torn apart families and communities around the United States and the world. This is the most serious U.S. drugs crisis since the cocaine boom of the 1980s, and the first time we have seen a surge in opioid abuse since the post-WW II period when morphine originally destined for the battlefield found its way onto the illicit drug market in the United States. The current crisis, however, is fueled by the supply of illicit drugs sourced from abroad. Ending this crisis, therefore, depends on reducing this supply, the focus of the Department of State's efforts, together with robust demand reduction efforts here in the United States.

Reducing the availability of foreign-produced illicit drugs in the United States, whether it is heroin, fentanyl, or other illicit drugs, is part of the Department of State's comprehensive approach to protecting national security. It is our mission to prevent and disrupt the flow of these substances, cutting off crime, including drug trafficking, at its source. The Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL), which I have the honor to lead, safeguards American communities by combating all manner of international crime, including drug trafficking, through robust bilateral programs and multilateral engagement. These efforts strengthen the capacity of foreign partners and build multilateral support for international action to fight crime more effectively. The President's February 9 Executive Order on Enforcing Federal Law with Respect to Transnational Criminal Organizations (TCO) and Preventing International Trafficking will enhance our ability to do this.

The illicit manufacture of fentanyl is fueling today's drug trade because it is highly profitable – it is inexpensive to produce and can be incorporated into heroin or other drugs, pressed into pills, or sold on its own. In order to achieve similar effects to that of heroin in the human body, fentanyl and its analogues require much smaller doses. It is largely sourced in China and brought in through a variety of routes including by small mail order packages shipped directly into the United States or smuggled across our borders. In accordance with the 2016 National Drug Threat Assessment and based on seizure data from the U.S. Drug Enforcement Administration (DEA), we suspect that Mexico may be operating as a transit country, whereby illicit fentanyl is shipped from China to Mexico, where

traffickers lace it into heroin or press it into fake prescription pills, which are then sold in the United States. There is also evidence to suggest that fentanyl synthesis may be occurring on some scale in Mexico.

Internationally, we are not alone in this crisis. Canada, and some countries, such as Estonia, are experiencing similar challenges related to illicit fentanyl. Canada confirms that its illicit fentanyl is being sourced from China as well. INL is combatting this global crisis through bilateral and multilateral channels, primarily with Mexico, Canada, and China, as well as through international action to stem the flow of illicit fentanyl, its analogues, and the precursor chemicals needed to produce them.

Bilateral Priorities

Mexico

Due to the prevalence of drug trafficking in Mexico, our partnership with our southern neighbor has never been more vital in the fight to combat illicit fentanyl, heroin, and synthetic drugs. Since 2008, under the Merida Initiative, the \$1.9 billion appropriated for International Narcotics Control and Law Enforcement (INCLE) funding has provided training, equipment, and technical assistance to complement Mexico's much larger investment in building the capacity of Mexican institutions to counter organized crime, uphold the rule of law, and protect our shared border from the movement of illicit drugs, money, and goods. This includes fixed and mobile non-intrusive inspection equipment and related detection devices provided at Mexico's border crossings, checkpoints, and ports-of-entry. Strengthening Mexican capacity to interdict drugs, dismantle criminal organizations, and disrupt their proceeds protects Americans. Under Merida, INL works closely with the DEA to train and equip Mexican law enforcement officials to identify and safely dismantle clandestine drug laboratories that make heroin, methamphetamine, and other synthetic or semi-synthetic drugs destined for U.S. communities. This includes a recent agreement through DEA to train and equip specialized law enforcement responders on the scheduling, classification, safe detection, and handling of fentanyl and its precursor chemicals. Our programs also strengthen the intelligence analysis and investigative capabilities of Mexican agencies to carry out complex investigations against organized crime groups involved in drug trafficking and the fentanyl trade. As a result of these efforts, cooperation between the United States and Mexico on this issue remains strong.

China

Since China has been determined as a source country, the Department of State continues to advance cooperation with China to address illicit fentanyl, including through the U.S.-China Joint Liaison Group on Law Enforcement Cooperation (JLG), the United States' primary law enforcement dialogue with China. During the fall 2016 meetings of the JLG, the United States requested that Chinese authorities consider a list of chemical substances for scheduling, prioritizing fentanyl precursors and a number of analogues.

The Chinese agreed to consider fast-tracking the request, if the U.S. would prioritize the substances that were of highest priority for our government. In the context of the JLG, the United States strongly prioritized fentanyl analogues among a broader list of substances we hoped to see domestically controlled in China. As a result of this collaboration, China announced that, as of March 1, it domestically controlled four critical fentanyl analogues, including carfentanil, a particularly lethal analogue of fentanyl. By controlling the most critical analogues of fentanyl, China has demonstrated its willingness to take on the illicit fentanyl market, reducing the supply of these analogues to the United States and saving U.S. lives.

Afghanistan

Although Afghan-produced heroin currently accounts for a very small percentage of the U.S. market, Afghanistan remains the source of nearly 80 percent of the world's illicit opiate supply. Canada estimates over 90 percent of its domestic heroin market is traced to Afghanistan, demonstrating the ability of traffickers to supply North America, and while Mexico is currently the predominant source of heroin in the United States, source countries have changed multiple times since DEA began tracking in 1977. U.S. support for Afghanistan's efforts to reduce illicit opioid supplies remains critical to combat use and related criminality in the Homeland, and cut off funding which fuels the insurgency in Afghanistan. INL's efforts in Afghanistan support a coordinated and comprehensive approach that balances supply and demand reduction interventions, including interdiction, eradication, public information, and prevention efforts. Interdiction efforts over the past year have been particularly productive, with two specialized units supported by the United States successfully—and increasingly independently—carrying out high-profile arrests and dozens of airmobile operations neutralizing heroin and morphine laboratories. While reports of seizures in a combat environment are subject to imprecision, these units are responsible for seizing or destroying roughly ten percent of Afghanistan's annual

opium production in 2016—more than 100 metric tons of opium, morphine, and heroin, 160 tons of hashish — with a cumulative value of over \$200 million denied to narco-traffickers and insurgent leaders which threaten U.S. interests. While most Afghanistan-sourced heroin is destined for Europe, Asia and Africa, not the United States, these efforts are integral to the U.S. commitment targeting the world heroin trade. Afghanistan is not a source country for fentanyl.

Multilateral Priorities

International Control

Recognizing that the unregulated purchase of chemical precursors helps fuel illicit fentanyl manufacturing, one of INL's pivotal efforts has been to help establish controls of the production and trafficking of two primary fentanyl precursors, 4-anilino-N-phenethyl-piperidine (ANPP) and N-Phenethyl-4-piperidinone (NPP). These two precursors are controlled in the United States, but not internationally, meaning countries are not required to regulate their production for legitimate purposes. It is currently legal in many countries that have not domestically controlled these precursors to purchase and ship them, making them easily available for use in the illicit manufacture of fentanyl. INL, the Office of National Drug Control Policy (ONDCP), and DEA contributed to the collaborative process that led State to request the UN Secretary-General to initiate the process to control these chemical precursors under the United Nations Convention against Illicit Traffic in Narcotics Drugs and Psychotropic Substances (1988 Convention). Adding these precursors to the 1988 Convention will make it more difficult for traffickers to access them for illicit purposes, because international control will require that individual countries regulate production. International control will not prohibit their legitimate use in producing fentanyl in the United States or other countries for critical pain management purposes.

Working within our treaty obligations, we accelerated the process for international control of these harmful substances which traditionally requires 1-2 years from the time a member state makes the request to five months. In October 2016, we notified the United Nations' International Narcotics Control Board (INCB) that we will lose thousands of lives if we fail to internationally control these substances. The INCB responded efficiently and completed the required scientific reviews in less than four months. On March 16, 2017 the UN Commission on Narcotic Drugs accepted the recommendation of the INCB and voted in favor of controlling these substances. All UN member states now have 180 days to bring these precursors under their regulatory control system. The control of fentanyl precursors will disrupt the fentanyl supply chain of traffickers

and will save American lives. But this vote will not just save lives potentially lost to fentanyl. It is our hope and intention to use this model of accelerated review to prompt quicker international action to control the 700+ synthetic and New Psychoactive Substances that currently exist on drug markets today, an impact that would fundamentally change and make relevant international action.

The United States is also requesting international control of carfentanil, a particularly lethal fentanyl analogue that is being laced into heroin or sold by itself and trafficked in the United States. We are hopeful that the World Health Organization will follow the INCB's example and recommend the substance for control at the next United Nations drug meeting in March 2018.

North American Dialogue on Drug Policy (NADD)

Another critical angle of our diplomacy to stop illicit fentanyl is our trilateral work with our neighbors Canada and Mexico. INL and ONDCP inaugurated the NADD in October 2016 and since then have met regularly at all levels to focus predominantly on combatting the opioid crisis across North America. The NADD facilitates North American cooperation against common drug threats, including by advancing (1) information sharing on the results of research and analysis of heroin, fentanyl, methamphetamines, and chemical precursors; (2) exchanging evidence-based best practices related to reducing opioid harms; and (3) coordinating messaging to countries outside of North America that are impacting the illicit opioid threat in our continent. Discussions together cover a wide range of topics including best practices in prevention and treatment; trends in the trafficking of heroin, fentanyl, methamphetamine, and drug chemical precursors; and distribution networks in each country and across our borders. This trilateral engagement furthers cooperation between our three governments.

Regional Programming with UN Office on Drugs and Crime (UNODC)

Additionally, through technical assistance to the UN Office on Drugs and Crime (UNODC) in Southeast Asia, INL is funding capacity building programs to assist officials in better identifying trafficking of chemical precursors, including fentanyl chemical precursors, at land borders. The UNODC program is also providing training to international law enforcement officials in key countries to raise awareness about fentanyl.

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee, addressing this international crisis is a work in progress and far from an easy objective to achieve. However, the clear purpose that drives our engagement on the world stage is the health and security of our citizens; a goal of critical importance that cannot be overstated. While the task at hand is incredibly challenging, our significant partnerships including with Mexico, Canada, and China and efforts within the UN system, represent the most effective and pragmatic approaches to countering this threat. Working together in unison as a government, and as an international community, we are curbing the impact of this crisis, and will continue to double down on these efforts as we address this threat to the United States.

Mr. MURPHY. Thank you.

Dr. Houry, you are recognized for 5 minutes.

STATEMENT OF DEBRA HOURY

Dr. HOURY. Chairman Murphy, Ranking Member DeGette, I would like to thank you for inviting me here today to discuss this very important issue.

As the director of the National Center for Injury Prevention and Control at the CDC, I would also like to thank the committee for your continued interest in the prevention of opioid misuse and prevention and overdose.

As an emergency physician, I have seen first hand this devastation all over the country. Drug overdose deaths in the United States have nearly tripled in the last 15 years. In 2015, there were approximately 52,000 drug overdose deaths and of those 63 percent involved an opioid.

The large increase in deaths seem to be primarily driven from heroin and synthetic opioids such as fentanyl. fentanyl is an opioid analgesic 80 times more potent than morphine and is almost administered in hospital settings for painful conditions.

Illegally manufactured fentanyl can be mixed with or sold as heroin and is fast acting. Overdoses can occur in seconds after consumption and an overdose from fentanyl is much more difficult to reverse because it is so powerful.

The rate of drug overdose deaths involving fentanyl more than doubled from 2013 to '14, and some States have seen the dramatic effect of this drug much more so than others.

For example, Massachusetts experienced a surge of opioid-related deaths from 698 in 2012 to 1,747 in 2015. To examine this increase, the Massachusetts Department of Public Health requested CDC's assistance in an epidemiological investigation, or Epi-Aid.

CDC determined that over 74 percent of the recent drug overdose deaths involve fentanyl and recommended conducting outreach to high risk groups such as people with substance abuse problems recently released from incarceration.

The rise in fentanyl, heroin and prescription drug overdoses are not unrelated. In Ohio, CDC found that approximately 62 percent of fentanyl and heroin overdose deaths were preceded by at least one opioid prescription during the 7 years prior to death and one in five people who died from a fentanyl overdose had an opioid prescribed to them at the time of their death.

CDC is committed to three strategies that comprehensively protect the public's health and prevents all opioid misuse and overdose deaths.

The first approach is improving data quality and timeliness to better track trends, identify communities at risk and evaluate prevention strategies.

CDC funds 12 States to improve tracking and reporting of illicit opioid overdoses including fentanyl. Improved surveillance is crucial for States to facilitate faster identification in response to spikes in overdoses, leading to quicker, more tailored interventions.

The second approach is supporting States in their efforts to implement effective solutions and interventions. CDC has funded 44

states and Washington, DC, for prevention efforts and surveillance activities.

For example, we have funded Ohio to use their prescription drug monitoring program to identify high-risk patients and they have achieved full data integration with Kroger Pharmacies as part of their integration with electronic health records.

Our third approach is to equip health care providers with the data and tools needed to improve the safety of their patients. To aid primary care providers and evidence-based prescribing practices, CDC developed and published the CDC guideline for prescribing opioids for chronic pain.

In addition to the critical partnership with States, CDC knows this epidemic requires partnerships across sectors and we've been working side by side with law enforcement. We are working with the Drug Enforcement Agency to implement prevention strategies and have initiated a personnel exchange.

The heroin response strategy, which is funded by ONDCP and deployed in eight high-intensity drug trafficking areas, sets out to link public health and public safety. CDC is working to coordinate public health workers on the ground. Successfully addressing this problem requires focused efforts in prevention. All three components—law enforcement, treatment and prevention—must work together to reverse this dangerous threat. We each have a critical role to play. Without effectively preventing more Americans from developing opioid use disorder in the first place we will never get ahead of the problem. Without prevention, more Americans will require treatment, often for the rest of their lives, and more will overdose.

Thank you again for the opportunity to be here with you today and for your continued support of CDC's work in protecting the public's health. I look forward to your questions.

[The prepared statement of Dr. Houry follows:]

Testimony of Dr. Debra Houry, Centers for Disease Control and Prevention (CDC)
before the
Energy and Commerce Committee, Oversight and Investigations Subcommittee
Hearing titled, "Fentanyl: The Next Wave of the Opioid Crisis"
March 21, 2017

Chairman Murphy, Ranking Member DeGette, I would like to thank you for inviting me here today to discuss this very important issue. I'd also like to thank the committee for its continued interest in the prevention of opioid misuse and overdose. My name is Dr. Debra Houry, and I am the Director of the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC). The activities related to the prevention of opioid prescription drug overdose and illicit opioid use are under my leadership at CDC. As a trained emergency room physician, I have seen first-hand the terrible toll drug overdoses take on individuals, families, and communities, and I have a personal goal to do everything we can as public health professionals to help reduce that toll. The consequences of opioid addiction are a true epidemic, and I have heard the devastating stories from all over the country, big cities and rural America.

Within HHS, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been leading a targeted and coordinated policy and programmatic effort to reduce opioid misuse, use disorder, and overdose, including fentanyl use and overdose. The effort focuses on strengthening surveillance, improving opioid prescribing practices and the treatment of pain, increasing access to treatment for opioid use disorders, expanding use of naloxone to reverse opioid overdose, and funding and conducting research to better understand the epidemic and identify effective interventions. As part of this effort,

CDC has been instrumental in activities to improve surveillance, improving opioid prescribing practices and the treatment of pain, and conducting critical research to track the epidemic and identify effective public health interventions to reduce the harms of opioid use.

CDC's work is focused in three primary efforts: improving data quality, data timeliness, and tracking trends to monitor the epidemic; strengthening state efforts by scaling up promising and effective public health interventions because states are critical players in preventing prescription drug overdoses; and supplying healthcare providers with data, tools, and guidance for evidence-based decision making that improves population health. Reversing the epidemic requires changing the way opioids are prescribed. CDC is committed to giving providers and health systems the tools and evidence they need to improve how these are used and prescribed. CDC provides critical expertise in the prevention of opioid misuse, use disorder, and overdose deaths.

Drug overdose deaths in the United States have nearly tripled in the last 15 years. In 2015, there were more than 52,000 drug overdose deaths, and of those, 63 percent involved a prescription or illicit opioid.¹ In 2015, more than two million people age 12 and older had an opioid use disorder related to prescription opioids and nearly 600,000 had a heroin use disorder.² More than 1,000 people are treated in emergency departments each day for not using prescription opioids as directed.³ Although prescription opioids were driving the increase in overdose deaths for many years, more recently, the

¹ Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm6550e1>.

² https://www.cdc.gov/drugoverdose/pdf/guideline_infographic-a.pdf

³ Substance Abuse and Mental Health Services Administration. Highlights of the 2011 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. The DAWN Report. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2013. Available from URL: <http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm>

large increase in overdose deaths has been due mainly to increases in heroin and synthetic opioid (other than methadone) overdose deaths, not prescription opioids. Importantly, the available data indicate these increases are largely due to illicitly manufactured fentanyl. Fentanyl is a synthetic and short-acting opioid analgesic that is 80 times more potent than morphine.⁴ Fentanyl is approved in a variety of products for indications including the management of surgical/postoperative pain, as well as severe chronic pain, and breakthrough cancer pain in patients that are already opioid tolerant.⁵ Fentanyl is administered to inpatients intravenously or prescribed in the form of transdermal patches or lozenges,⁶ but illicitly manufactured fentanyl is often made and sold as counterfeit pills or mixed with or sold as heroin.⁷ Fentanyl is fast-acting, so overdoses can occur in seconds to minutes after use instead of the longer time periods commonly associated with overdoses related to other opioid pain relievers and heroin and can be more difficult to reverse than overdose from heroin or other opioids, potentially requiring multiple doses of naloxone.⁸ This makes the introduction of fentanyl to the illicit drug market very concerning. The rate of drug overdose deaths involving fentanyl more than doubled from 2013-2014 and some states have seen the dramatic effect of this drug much more so than others⁹.

⁴ Gladden RM, Martinez P, Seth P. Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths — 27 States, 2013–2014. MMWR 2016; 65(33):837–843

⁵ Peterson AB and Gladden RM, Delcher C, Spies E, Garcia-Williams A, Wang Y, Halpin J, Zibbell J, McCarty CL, DeFiore-Hymer J, DiOrio, M, and Goldberger B. Increases in fentanyl-related overdose deaths — Florida and Ohio, 2010–2015(<https://www.cdc.gov/mmwr/volumes/65/wr/mm6533a3.htm>). MMWR 2016; 65(33):844–849.

⁶ <https://www.cdc.gov/drugoverdose/opioids/fentanyl.html>

⁷ Gladden RM, Martinez P, Seth P. Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths — 27 States, 2013–2014. MMWR 2016; 65(33):837–843

⁸ Peng PW, Sandler AN. A review of the use of fentanyl analgesia in the management of acute pain in adults. *Anesthesiology* 1999;90:576–99. <https://www.ncbi.nlm.nih.gov/pubmed/9952166>

⁹ Gladden RM, Martinez P, Seth P. Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths — 27 States, 2013–2014. MMWR 2016; 65(33):837–843

For example, Massachusetts experienced a surge of opioid-related deaths, from 698 in 2012 to 1,747 in 2015¹⁰ and over 74 percent of these drug overdose deaths involved fentanyl. In August of 2015, the Massachusetts Department of Public Health (MDPH) requested an epidemiological investigation (Epi-Aid) from CDC. The goal of the investigation was to understand the extent to which illicitly-made fentanyl (IMF) contributed to the surge in opioid-related overdose deaths because the supply had sharply increased in Massachusetts from 2013 to 2015.¹¹ CDC worked closely with the MDPH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Drug Enforcement Administration (DEA) to determine that illicitly-manufactured fentanyl mixed with or sold as heroin was primarily responsible for the surge of deaths from 2014 to 2015¹². Eighty-two percent of fentanyl-related overdose deaths were suspected to involve illicitly-made fentanyl, four percent were suspected to involve pharmaceutical fentanyl, and the remaining 14 percent lacked sufficient evidence to determine the fentanyl source¹³.

Using the findings from the investigation, CDC provided recommendations for the MDPH related to physicians, treatment providers, and law enforcement for screening at-risk people for heroin or fentanyl use, expanding access to naloxone, and providing training for overdose prevention. Those considered at risk included people in drug treatment facilities, in extended-stay residential treatment, and people who were incarcerated. The recommendations also included actively conducting outreach to high risk

¹⁰ The number of opioid-related overdose deaths in 2015 estimated as of November 2016. For additional information <http://www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-nov-2016-ma-residents.pdf>

¹¹ For additional information <https://emergency.cdc.gov/han/han00384.asp> & <http://www.cdc.gov/drugoverdose/data/fentanyl-le-reports.html>

¹² The number of opioid-related overdose deaths in 2015 estimated as of November 2016. For additional information <http://www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-nov-2016-ma-residents.pdf>

¹³ The number of opioid-related overdose deaths in 2015 estimated as of November 2016. For additional information <http://www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-nov-2016-ma-residents.pdf>

groups, such as people who have experienced an opioid overdose, people with substance use problems recently released from incarceration, or those accessing health programs for active users (e.g., syringe services and naloxone distribution programs) to link them to treatment and implementing messaging and education around the dangers of fentanyl.

In Ohio, there were 84 fentanyl-involved deaths in 2013, which increased to more than 526 in 2014 -- a 500 percent increase.^{14,15} To examine the ongoing increase in fentanyl-related overdose deaths, the Ohio Department of Health (ODoH) also requested CDC's assistance in an Epi-Aid. CDC worked with the ODoH to develop specific recommendations to enhance public health surveillance; continue testing for fentanyl by coroners and medical examiners; target interventions towards identified high-risk groups, including individuals who have recently been released from an institution (either from jail or a hospital) and those with a history of mental illness; ensure first responders have ample supplies of naloxone and understand the need for multiple administration of naloxone for fentanyl cases; and expand the availability of naloxone for high-risk community members.

The rise in fentanyl, heroin, and prescription drug involved overdoses are not unrelated. In Ohio, CDC found that approximately 62 percent of all fentanyl and heroin involved overdose deaths were preceded by at least one opioid prescription from a healthcare provider during the seven years prior to death, and one in ten people who died from a heroin overdose, and one in five people who died from a fentanyl overdose, had an opioid medication prescribed to them at the time of their death. In fact, people who misuse prescription opioids -- that is, use other than as directed by a healthcare provider -- are at an

¹⁴ Peterson AB and Gladden RM, Delcher C, Spies E, Garcia-Williams A, Wang Y, Halpin J, Zibbell J, McCarty CL, DeFiore-Hyrmer J, DiOrto, M, and Goldberger B. Increases in fentanyl-related overdose deaths -- Florida and Ohio, 2010-2015(<https://www.cdc.gov/mmwr/volumes/65/wr/mm6533a3.htm>). MMWR 2016; 65(33):844-849.

¹⁵ Spies E, Peterson AB, Garcia-Williams A, Halpin J, Gladden RM, Zibbell J, McCarty CL. Undetermined risk factors for fentanyl-related overdose deaths -- Ohio, 2015 (EpiAid 2016-003). Trip Report Epi2. http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/Ohio-PDO-EpiAid-Trip-Report_Final-Draft_3_18_2016.pdf?la=en

increased risk for heroin use. Among new heroin users, approximately three out of four report having misused prescription opioids prior to using heroin.¹⁶ In addition, data show that people reporting past-year misuse of opioids were 19 times more likely to initiate heroin use than people who did not report past-year misuse of opioids.¹⁷ There were an estimated 12.5 million people who misused prescription opioids in 2015.¹⁸ While most people who misuse prescription opioids do not go on to use heroin, the small percentage (about four percent) who do account for a majority of people recently initiating heroin use.¹⁹

Some have suggested that policies meant to limit inappropriate opioid prescribing have led to an increase in heroin use by driving people who misuse opioids to heroin.²⁰ Recent research, however, has indicated otherwise. One study found that the shift to heroin use began before the recent uptick in these policies, but that other factors (such as heroin market forces, increased accessibility, reduced price, and high purity of heroin) appear to be major drivers of the recent increases in rates of heroin use.²¹

¹⁶ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6.

¹⁷ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. <http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

¹⁸ Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In NSDUH Series H-41. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012

¹⁹ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. <http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

²⁰ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6.

²¹ Wilson M, Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H. Relationship between Nonmedical Prescription-Opioid Use and Heroin Use. *New England Journal of Medicine*. 2016; 374:154-163. DOI: 10.1056/NEJMra1508490.

CDC is committed to a comprehensive approach that protects the public's health and prevents opioid overdose deaths. We strive to do this by improving data quality and timeliness to better track trends, identify communities at risk, and evaluate prevention strategies; supporting states, localities, and tribes in their efforts to implement effective solutions and interventions; and equipping healthcare providers with data and tools needed to improve the safety of their patients.

To aid primary care providers in proper prescribing practices, CDC developed and published the *CDC Guideline for Prescribing Opioids for Chronic Pain* (Guideline or CDC Guideline). The Guideline is intended to improve the way opioids are prescribed through clinical practice guidelines to ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, have opioid use disorder, or overdose from these drugs. CDC has developed an app available for download to help providers put the Guideline recommendations into clinical practice. The app contains the full Guideline, a morphine milligram equivalent (MME) calculator, and an interactive motivational interviewing feature to help providers prescribe with confidence. In addition, CDC is launching a patient and provider education campaign to raise awareness among providers and patients about the opioid epidemic and the CDC Guideline. While opioids can sometimes be part of pain management, this new guideline aims to improve the safety of prescribing and curtail the harms associated with opioids, including opioid use disorder and overdose.

States are vital in battling this epidemic and, as resources are available, CDC is committed to equipping them with the resources and expertise they need to reverse the epidemic and protect their residents, families, and communities. Since 2014, CDC has invested in prevention efforts and surveillance activities in 44 states and Washington, DC. The most impactful state-level approaches to date have

tackled the epidemic on multiple fronts -- promoting effective PDMPs, leveraging the states' role as a healthcare payer to improve patient safety, and engaging hard-hit communities to focus efforts where the epidemic is the most severe.

CDC funds state health departments to focus on collaboration across sectors, including public health, law enforcement, and substance use services agencies, for a truly comprehensive response. Funded states are also advancing prevention on multiple fronts -- including making PDMPs more timely, easier to use, and able to communicate with the PDMPs of other states; implementing interventions that can be integrated within state Medicaid or Worker's Compensation programs to protect patients at risk; and bringing data-driven prevention to the communities struggling with the highest rates of substance misuse and use disorder and overdose. Critically, states have also been given the flexibility to use the program to respond to emerging crises, like fentanyl, and evaluate existing interventions so they know what works best to reduce overdoses and save lives.

To better understand the increase in heroin and fentanyl use and overdose, we are working with states to improve the collection of data. CDC funds twelve states for the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program to improve tracking and reporting of illicit opioid overdoses, including fentanyl.

The opioid overdose surveillance system allows CDC to monitor changing trends and issues related to this epidemic, such as deaths from heroin containing fentanyl, and to understand how the epidemic evolves over time. CDC is working to improve the quality and timeliness of the surveillance data. The

delay in the collection and analysis of current surveillance data makes it difficult for public health to implement the most timely and effective interventions to reduce fatal and nonfatal opioid overdoses. Health departments and CDC often have to use death certificate data that are 12 to 23 months old and lack critical details on the drugs and circumstances contributing to the overdose. Consequently, these data are not always actionable given the rapid changes in types of opioids involved in overdose deaths.

CDC is implementing several strategies in the 12 funded states for improving surveillance of opioid overdoses. First, we are establishing an early warning system to detect sharp increases or decreases in nonfatal opioid overdoses by publishing, at a minimum, quarterly surveillance reports of emergency department visits and emergency medical services transports involving drug overdoses, opioid overdoses (including fentanyl) and heroin overdoses. We are doing this by leveraging existing national and state surveillance systems to collect new data on opioid overdoses. Second, we plan to collect preliminary information on the number and rate of opioid overdose deaths twice a year at the county level. Funded states are not required to submit data for all counties; they may provide fatal overdose data for a subset of counties. However, 11 of the 12 states are providing data on all opioid overdose deaths in their state. Third, approximately every eight months, we will analyze in-depth information from toxicology tests and death scene investigations of fatal opioid overdoses from deaths certificates and medical examiner reports to identify the specific opioid involved, the route of administration, and whether the opioid was illicitly produced or produced by pharmaceutical companies. The latter will be determined by analyzing evidence from the death scene investigation; a white powder at the scene gives an indication of illicitly manufactured fentanyl, while fentanyl patches would indicate pharmaceutically produced. Additionally, toxicology tests can determine whether fentanyl analogues are present, which also indicates illicitly manufactured fentanyl. The 12 funded states will collect the data and report it to CDC for analysis. The 11 states committed to providing data on all opioid overdose deaths will enter data on toxicology tests

and death scene investigators when conducted by coroner or medical examiners. Finally, approximately every eight months, we plan to provide information on key risk factors contributing to opioid overdose deaths, in order to understand how risk factors vary across communities. We plan to disseminate the data via our website and, depending on availability of funds, by developing data briefs, county maps, and a data dashboard.

Improved surveillance will support states to facilitate faster identification and response to spikes in overdoses leading to quicker, more tailored interventions. CDC is positioned to expand our surveillance of illicit opioids to all 50 states and DC should future opportunities come available.

In addition to the critical partnership with states, CDC believes this epidemic requires a partnership across sectors. As such, we have been working side by side with law enforcement agencies, like the DEA, to determine both risk factors for a fentanyl overdose and an implementation plan for prevention strategies. In fact, CDC is currently engaged in a personnel exchange with DEA: a CDC public health analyst has been embedded with DEA and a DEA analyst has been embedded with CDC. This will help to ensure communication across our agencies and strengthen our on-going collaboration.

In addition, the Heroin Response Strategy (HRS), funded by ONDCP and deployed in eight High Intensity Drug Trafficking Areas (HIDTAs), sets out to link public health and public safety. The HRS covers 20 states, from Georgia up to Maine, and as far west as Michigan. Under the governance of the eight HIDTA directors, CDC will ensure proper coordination, training, and measurable outcomes. CDC supports the training and technical assistance for the 20 public health analysts who are embedded in the

program. As part of the HRS, we are also launching eight pilot projects across the 20-state initiative to better understand what communities can do to prevent opioid overdose deaths. There is a shortage of evidence to guide community response, and CDC's initiative is designed to build scientific evidence about what works. Communities must be equipped with effective action steps in order to respond.

As the type of drugs available continues to change, it is imperative that law enforcement and public health continue to work together to prevent as many deaths as possible. We need a partnership that will focus on utilizing public health to prevent addiction from happening in the first place. Similarly, to successfully address this problem, effective treatment, along with effective prevention, is necessary. Without effective treatment, millions of Americans will continue to suffer from opioid use disorder and remain at high risk for overdose. Only together will all three components, law enforcement, treatment, and prevention, work to impact and reverse the worsening threat. Each has a critical role to play. For prevention, we know that without effectively preventing more Americans from developing opioid use disorder in the first place, we will never get ahead of the problem.

While we work to help the millions of Americans already facing addiction, we need to prevent more Americans from becoming addicted in the first place. Failing this, even more Americans will require treatment.

CDC has built relationships with other critical players in the opioid prevention effort as well as an infrastructure to deploy funds and technical assistance to the states to combat addiction and overdose on the ground where it is happening. As such, we are well positioned to prevent opioid misuse and

overdose through our critical prevention work. We strive to enhance our public health surveillance efforts to detect and speed the response to emerging and changing drug threats.

Second, we aim to connect people to evidence-based treatment at opportune moments, often after they have suffered an overdose. Lessons learned from CDC's work in HIV point to using patient navigators, emergency department and hospital discharge protocols, and police personnel to serve as connectors to help those at high risk of overdose find effective treatment.

Finally, our current relationships have laid the groundwork for continued collaboration with law enforcement. Recently, we have had discussions with DEA about adding a public health component to the DEA 360 cities, and about ways we can share data and collaborate on data dissemination. By working together we can share information and better identify drug traffickers, drug hot spots, and points of intervention.

We all know opioid misuse and overdose is a serious public health issue in the United States. The burden of opioid misuse and overdose affects not only individuals and families, but also communities, employers, the healthcare system, and public and private insurers. Addressing this complex problem requires a multi-faceted approach and collaboration between public health, clinical medicine, and public safety at the Federal, state, local, and tribal levels. But, it can be accomplished—particularly with the ongoing efforts of all of the entities represented here on this panel. CDC is committed to tracking and understanding the epidemic, supporting states working on the front lines of this crisis, and providing healthcare providers with the data, tools, and guidance they need to ensure safe patient care.

Thank you again for the opportunity to be here with you today and for your continued support of our work in protecting the public's health. I look forward to your questions.

Mr. MURPHY. Thank you, Doctor.
Now, Dr. Compton, you're recognized for 5 minutes.

STATEMENT OF WILSON M. COMPTON

Dr. COMPTON. Chairman Murphy, Ranking Member DeGette and members of the subcommittee. Thank you for inviting me to provide an overview of how science can help us address the rise in fentanyl use in overdose deaths.

My name is Dr. Wilson Compton and I'm the deputy director of the National Institute on drug abuse. As a physician and researcher, I've seen first hand the devastating impact of the opioid crisis on families and communities and have conducted numerous studies to better understand trends in opioid use and ways to respond.

What is fentanyl and its relationship to the opioid crisis? Fentanyl's high potency and fat solubility allow it to rapidly enter the brain, leading to a fast onset of effects which increases the risk for addiction and overdose.

The emergence of fentanyl and other even higher potency synthetic opioids creates enormous challenges for controlling supply since very small amounts can cause large-scale damage to users as well as to law enforcement and first responders who may come into contact with the drugs.

Fentanyl is one part of the ongoing opioid overdose epidemic which also includes prescription opioids and heroin. While recent Federal and State efforts have begun to help curb over prescribing of the prescription opioids, overdoses continue to rise mainly due to the rise in heroin in fentanyl-related deaths.

NIDA's efforts in this area are part of the broader initiatives of the Office of National Drug Control Policy and the Department of Health and Human Services.

The population of people using fentanyl largely overlaps with those using heroin and so the strategies being implemented to address the ongoing opioid crisis are expected to help address fentanyl addiction and overdoses.

NIDA, along with FDA, co-chairs the Opioid Subcommittee of the Department of Health and Human Services Behavioral Health Coordinating Council and in this role we help to coordinate inter-agency efforts.

So how is research helping to address the opioid crisis? NIDA has supported the development of the three medications that have been FDA approved to treat opioid addiction. Methadone, buprenorphine and naltrexone all have strong evidence of effectiveness.

Despite this effectiveness, only a fraction of people with opioid use disorders are being treated with these medications due to limited treatment capacity, stigma, lack of provider training and cost.

Therefore, NIDA research is helping to develop strategies to promote wider adoption of these medications in variety of settings. For example, initiating buprenorphine treatment in emergency departments has been shown to help ensure that people who overdose are effectively engaged in ongoing treatment for their underlying opioid use disorder.

Other studies have found that providing interim buprenorphine or methadone while awaiting admission to a treatment program reduces opioid use and increases the likelihood of engaging in treatment.

How can research specifically inform our response to fentanyl? Through NIDA's national drug early warning system, we are supporting research to better understand fentanyl's use patterns and trends in hot spots such as Ohio and New Hampshire.

In the first phase of the New Hampshire study, for example, researchers reported that about one-third of fentanyl users knowingly use the drug and may seek out a certain dealer or product when they hear about overdoses because they think it must be highly potent.

What about overdose treatment? Although naloxone can rapidly reverse an opioid overdose, the current standard dose of naloxone is likely not adequate to reverse some overdoses from high-potency opioids like fentanyl.

In response, we are supporting research to develop new longer lasting naloxone formulations and new administration protocols.

NIDA also supports research on prevention and treatment. For instance, in partnership with the CDC, SAMHSA and the Appalachian Regional Commission, NIDA is testing interventions to address opioid misuse in rural America.

In addition, we are planning a research initiative to study treatment expansion models resulting from the additional resources provided to states via the 21st Century Cures Act.

Research is also underway to develop a vaccine for fentanyl to keep fentanyl from entering the brain, thereby protecting against addiction and overdose.

In summary, over 33,000 deaths for opioid overdoses occurred in 2015 with nearly 10,000 involving synthetic opioids like fentanyl. Science-based solutions are available. The challenge is often in their implementation.

NIDA will continue to work closely with the other Federal agencies, both those that are here today and many others, community organizations and private industry to address these complex challenges.

Thank you. I look forward to your questions.

[The statement of Dr. Compton follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE

Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids

Testimony before the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

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Chairman Murphy, Ranking Member DeGette, and Members of the Committee: thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this important hearing to provide an overview of what we know about the role of fentanyl in the ongoing opioid overdose epidemic and how scientific research can help us address this crisis.

The misuse of and addiction to opioids – including prescription pain medicines, heroin, and synthetic opioids such as fentanyl – is a serious national problem that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention (CDC) recently estimated that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.¹ In 2015, over 33,000 Americans died as a result of an opioid overdose.² That year, an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines (including fentanyl), and 591,000 suffered from a heroin use disorder (not mutually exclusive).³

This issue has become a public health epidemic with devastating consequences including not just increases in opioid abuse and related fatalities from overdoses, but also the rising incidence of neonatal abstinence syndrome due to opioid use during pregnancy, and the increased spread of infectious diseases, including HIV and hepatitis C.⁴⁻⁶ Recent research has also found a significant increase in mid-life mortality in the United States particularly among white Americans with less education. Increasing death rates from drug and alcohol poisonings are believed to have played a significant role in this change.⁷

The Pharmacology of Fentanyl and Other Synthetic Opioids

Prescription opioids, heroin, and synthetic opioid drugs all work through the same mechanism of action. Opioids reduce the perception of pain by binding to opioid receptors, which are found on cells in the brain and in other organs in the body. The binding of these drugs to opioid receptors in reward regions in the brain produces a sense of well-being, while stimulation of opioid receptors in deeper brain regions results in drowsiness and respiratory depression, which can lead to overdose deaths. The presence of opioid receptors in other tissues can lead to side effects such as constipation and cardiac arrhythmias through the same mechanisms that support the use of opioid medications to treat diarrhea and to reduce blood pressure after a heart attack. The effects of opioids typically are mediated by specific subtypes of opioid receptors (mu, delta, and kappa) that are activated by the body's own (endogenous) opioid chemicals (endorphins, enkephalins). With repeated administration of opioid drugs (prescription or illicit), the production of endogenous opioids decreases, which accounts in part for the discomfort that ensues when the drugs are discontinued (*i.e.*, withdrawal).⁸

The rewarding effects of opioids – whether they are medications, heroin, or illicitly produced synthetic opioids – are increased when they are delivered rapidly into the brain, which is why non-medical users often inject them directly into the bloodstream.⁹ Fentanyl, in particular, is highly fat-soluble, which allows it to rapidly enter the brain, leading to a fast onset of effects. This high potency and rapid onset are likely to increase the risk for both addiction and overdose, as well as withdrawal symptoms.¹⁰ In addition, injection use increases the risk for infections and infectious diseases. Another important property of opioid drugs is their tendency, when used repeatedly over time, to induce tolerance. Tolerance occurs when the person no longer responds to the drug as strongly as he or she initially did, thus necessitating a higher dose to achieve the

same effect. The establishment of tolerance results from the desensitization of the brain's natural opioid system, making it less responsive over time.¹¹ Furthermore, the lack of sufficient tolerance contributes to the high risk of overdose during a relapse to opioid use after a period of abstinence whether it is intentional – for example, when a person tries to quit using – or situational – for example, if a person cannot obtain opioid drugs while incarcerated or hospitalized. Users no longer know what dose of the drug they can safely tolerate, resulting in overdoses.

While all of these opioids belong to a single class of drugs, each is associated with distinct risks. The risk of overdose and negative consequences is generally greater with illicit opioids due to the lack of control over the purity of the drug and its potential adulteration with other drugs. All of these factors increase the risk for overdose, since users have no way of assessing the potency of the drug before taking it. In the case of adulteration with highly potent opioids such as fentanyl or carfentanil, this can be particularly deadly.¹²⁻¹⁴ Another contributing factor to the risk of opioid-related mortality is the combined use with benzodiazepines or other respiratory depressants, like some sleeping pills or alcohol.¹⁵

The Role of Fentanyl in the Opioid Crisis

The emergence of illicitly manufactured synthetic opioids including fentanyl, carfentanil, and their analogues represents an escalation of the ongoing opioid overdose epidemic. Fentanyl is a μ -opioid receptor agonist that is 80 times more potent than morphine *in vivo*. While fentanyl is available as a prescription – primarily used for anesthesia, treating post-surgical pain, and for the management of pain in opioid-tolerant patients – it is the illicitly manufactured versions that have been largely responsible for the tripling of overdose deaths related to synthetic opioids in

just two years – from 3,105 in 2013 to 9,580 in 2015.² A variety of fentanyl analogues and synthetic opioids are also included in these numbers, such as carfentanil (approximately 10,000 times more potent than morphine), acetyl-fentanyl (about 15 times more potent than morphine), butyrfentanyl (more than 30 times more potent than morphine), U-47700 (about 12 times more potent than morphine), and MT-45 (roughly equivalent potency to morphine), among others.¹⁷

The opioid crisis began in the mid-to late 1990's, following a confluence of events that led to a dramatic increase in opioid prescribing, including: a regulatory, policy and practice focus on opioid medications as the primary treatment for all types of pain;¹⁸ an unfounded concept that opioids prescribed for pain would not lead to addiction;¹⁹ the release of guidelines from the American Pain Society in 1996 encouraging providers to assess pain as “the 5th vital sign” at each clinical encounter; and the initiation of aggressive marketing campaigns by pharmaceutical companies promoting the notion that opioids do not pose significant risk for misuse or addiction and promoting their use as “first-line” treatments for chronic pain.¹⁹⁻²¹

The sale of prescription opioids more than tripled between 1999 and 2011, and this was paralleled by a more than four-fold increase in treatment admissions for opioid abuse and a nearly four-fold increase in overdose deaths related to prescription opioids.²² Federal and state efforts to curb opioid prescribing resulted in a leveling off of prescriptions starting in 2012;²³ however, heroin-related overdose deaths had already begun to rise in 2007 and sharply increased from just over 3,000 in 2010 to nearly 13,000 in 2015.² We now know prescription opioid misuse is a significant risk factor for heroin use; 80 percent of heroin users first misuse prescription opioids.²⁴ While only about four percent of people who misuse prescription opioids initiate heroin use within 5 years,^{24,25} for this subset of people the use of the cheaper, often easier to obtain street opioid is part of the progression of an opioid addiction.²⁶

The opioid overdose epidemic has now further escalated, with the rise in deaths related to illicitly manufactured synthetic opioids. Often, the population of people using and overdosing on fentanyl looks very similar to the population using heroin. However, the drivers of fentanyl use can be complicated as the drug is often sold in counterfeit pills – designed to look like common prescription opioids or benzodiazepines (e.g. Xanax) – or is added as an adulterant to heroin or other drugs, unbeknownst to the user.¹⁴ And there are also market forces supporting the proliferation of higher-potency opioids, as people with opioid addictions develop increasing tolerance to these drugs.²⁷

History of Fentanyl Misuse

The first fentanyl formulation (Sublimaze) received approval by the Food and Drug Administration (FDA) as an intravenous anesthetic in the 1960s. Other formulations, including a transdermal patch, a quick acting lozenge or “lollipop” for breakthrough pain, and dissolving tablet and film, have since received FDA approval.²⁸ Misuse of prescription fentanyl was first described in the mid-1970s among clinicians,²⁹ and continues to be reported among the people misusing prescription opioids.³ More recently, between April 2005 and March 2007 there was an uptick in deaths related to illicitly manufactured fentanyl that was traced to a single laboratory in Mexico. Once the laboratory shut down the rate of overdose declined.³⁰ However, over the last few years there has been a growing production of illicitly manufactured fentanyl, much of which is imported from China, Mexico, and Canada.¹⁴ The increase in illicitly manufactured fentanyl availability in the U.S. is reflected by the substantial increase in seizures of fentanyl by law enforcement which jumped from under 1,000 seizures in 2013 to over 13,000 in 2015.³¹

Research shows that the increasing availability of illicitly manufactured fentanyl closely parallels the increase in synthetic opioid overdose deaths in the U.S.³²

HHS Response and NIDA-Supported Research Related to fentanyl

Within HHS, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been leading a targeted and coordinated policy and programmatic effort to reduce opioid abuse and overdose, including fentanyl use and overdose. The effort focuses on strengthening surveillance, improving opioid prescribing practices and the treatment of pain, increasing access to treatment for opioid addiction, expanding use of naloxone to reverse opioid overdose, and funding and conducting research to better understand the epidemic and identify effective interventions. Under this effort, NIDA is engaged in number critical activities.

NIDA supports the National Drug Early Warning System (NDEWS), which monitors emerging drug use trends to enable health experts, researchers and others to respond quickly to potential outbreaks of illicit drugs. In partnership with the NDEWS, the Northeast Node of the NIDA's Clinical Trials Network (CTN) has been funded to complete a Fentanyl Hot Spot Study in New Hampshire. In 2015, New Hampshire had the highest rate of fentanyl-related deaths in the country and this study is investigating the causes of increased fentanyl use and related deaths in this region.

In the first phase of the study, multiple stakeholders throughout the state, including treatment providers, medical responders, law enforcement, state authorities and policymakers were interviewed about their perspectives on the fentanyl crisis.³³ Many expressed that better user-level data was imperative to answer pointed questions to more accurately inform policy, such as the trajectory of fentanyl use, supply chain, fentanyl-seeking behavior versus accidental

ingestion, value of testing kits, treatment preferences, etc. The researchers reported that, “Some may seek out a certain dealer or product when they hear about overdoses because they think that it must be good stuff.” According to the group leader, only approximately a third of users knowingly use fentanyl, but the number of users is slowly increasing.

The second phase of the study is conducting a rapid epidemiological investigation of fentanyl users’ and first responders’ perspectives, so that real-time data can inform policy in tackling the fentanyl overdose crisis.

Another ongoing NIDA funded study is characterizing the fentanyl crisis in Montgomery County, Ohio – an area experiencing one of the largest surges of illicitly manufactured fentanyl in the country. This study will explore the scope of the fentanyl crisis in this area, collecting data from postmortem toxicology and crime laboratories, and will explore active user knowledge and experiences with fentanyl. Other NIDA funded research is working to develop faster methods for screening for fentanyl and other synthetic opioids to track overdoses through emergency department screening and improve surveillance of the fentanyl threat across the country.

NIDA-supported research is also working to develop new treatments for opioid addiction, including treatments targeting fentanyl specifically. One ongoing NIDA-funded study is in the early stages of developing a vaccine for fentanyl that could prevent this drug from reaching the brain.³⁴

Evidence-Based Approaches

With the emergence of very high potency opioids addressing supply becomes increasingly difficult because the quantities transported may be much lower. Thus, it is critical to address demand reduction through the deployment of evidence-based prevention and

treatment strategies to reduce the number of people developing an opioid addiction and treating the population of Americans who already suffer from this addiction.

Evidence-Based Treatments for Opioid Addiction

Three classes of medications have been approved for the treatment of opioid addiction : (1) agonists, e.g. methadone , which activate opioid receptors; (2) partial agonists, e.g. buprenorphine, which also activate opioid receptors but produce a diminished response; and (3) antagonists, e.g. naltrexone, which block the opioid receptor and interfere with the rewarding effects of opioids.³⁵ These medications represent the first-line treatments for opioid addiction.

The evidence strongly demonstrates that methadone, buprenorphine, and injectable naltrexone (e.g., Vivitrol) all effectively help maintain abstinence from other opioids and reduce opioid abuse-related symptoms. These medications have also been shown to reduce injection drug use and HIV transmission and to be protective against overdose.³⁶⁻⁴⁰ These medications should be administered in the context of behavioral counseling and psychosocial supports to improve outcomes and reduce relapse. Two comprehensive Cochrane reviews, one analyzing data from 11 randomized clinical trials that compared the effectiveness of methadone to placebo, and another analyzing data from 31 trials comparing buprenorphine or methadone treatment to placebo, found that^{38,39}:

- Patients on methadone were over four times more likely to stay in treatment and had 33 percent fewer opioid-positive drug tests compared to patients treated with placebo;
- Methadone treatment significantly improves treatment outcomes alone and when added to counseling; long-term (beyond six months) outcomes are better for patients receiving methadone, regardless of counseling received;

- Buprenorphine treatment significantly decreased the number of opioid-positive drug tests; multiple studies found a 75-80 percent reduction in the number of patients testing positive for opioid use;
- Methadone and buprenorphine are equally effective at reducing symptoms of opioid addiction; no differences were found in opioid-positive drug tests or self-reported heroin use when treating with these medications.

To be clear, the evidence supports long-term maintenance with these medicines in the context of behavioral treatment and recovery support, not short-term detoxification programs aimed at abstinence.⁴¹ Abstinence from all medicines may be a particular patient's goal, and that goal should be discussed between patients and providers. However, the scientific evidence suggests the relapse rates are extremely high when tapering off of these medications, and treatment programs with an abstinence focus generally do not facilitate patients' long-term, stable recovery.^{42,43}

Treatment Challenges

Unfortunately, medications approved for the treatment of opioid abuse are underutilized and often not delivered in an evidence based manner.^{44,45} Fewer than half of private-sector treatment programs offer these medications; and of patients in those programs who might benefit, only a third actually receive it.⁴⁵ Further, many people suffering with opioid addiction do not seek treatment. Identifying the need for and engaging them in treatment is an essential element of addressing the opioid crisis. For example, recent research suggests that initiating patients on buprenorphine following an opioid overdose can increase treatment retention and improve outcomes.⁴⁶ Overcoming the misunderstandings and other barriers that prevent wider adoption of these treatments is crucial for tackling the opioid crisis.

In addition, to achieve positive outcomes, treatments must be delivered with fidelity. To be effective, methadone and buprenorphine must be given at a sufficiently high dose.^{38,39} Some treatment providers wary of using methadone or buprenorphine have prescribed lower doses for short treatment durations, leading to treatment failure and the mistaken conclusion that the medication is ineffective.^{38,47}

As of 2011, more than 22 percent of patients in a methadone treatment programs were receiving less than the minimum recommended dose of methadone.⁴⁸ Interestingly, a recent study identified a genetic variant near the mu opioid receptor gene associated with a higher required dose of methadone (corresponding to a need for about an additional 20 mg per day) in African American patients but not European Americans with this gene variant.⁴⁹ This highlights the need for dosing flexibility to achieve the effective dose for an individual patient. The NIH Precision Medicine Initiative and other ongoing research projects are working to define the genetic, biological, and clinical factors that influence the efficacy of treatment to help clinicians deliver care precisely tailored for a specific patient to improve outcomes.

Research has also shown that tapering off of buprenorphine can present significant risks for relapse.^{43,50} A recent analysis of five studies that examined outcomes following buprenorphine taper found that on average only 18 percent (a range of 10 to 50 percent) of patients remained abstinent one to two months after tapering off of buprenorphine.⁵⁰ In addition, some state programs and insurance providers limit the duration of treatment a patient may receive. There is no evidence base to support this practice, and the available evidence suggests that it poses a significant risk for patient relapse. This is also an important consideration in the context of the two years of funding for the opioid crisis authorized through the 21st Century Cures Act. This funding will be critical for helping states address the ongoing opioid epidemic, however, opioid

addiction is a chronic condition and many patients will need ongoing treatment for many years. It will be important to develop sustainability strategies to ensure that patients do not lose access to these life-saving medications when a particular funding program is discontinued.

While users seeking treatment are on a wait list they generally continue to engage in opioid use and this may contribute to failure to enter treatment when a slot becomes available. Research has shown that providing interim treatment with medications while patients are awaiting admission to a treatment program increases the likelihood that they will engage in treatment. In one study, over 64 percent of study participants receiving interim methadone entered comprehensive care within six months, compared with only 27 percent in the control group, and the group receiving methadone had lower rates of heroin use and criminal behavior.⁵¹ One model for interim treatment with buprenorphine would use urine testing call backs and a special medicine dispensing device to prevent diversion.⁵² Implementation would require a regulatory change because take home buprenorphine is not allowed under interim regulations currently. When this model was tested, patients showed strong adherence to the interim treatment plan and reported strong satisfaction with the treatment. State regulations and payment system issues (bundled payment that does not accommodate billing for interim treatment) are often barriers to this type of program and they are not frequently used.

Fentanyl specific challenges

While specific data on treatment outcomes for patients addicted to fentanyl or other high potency synthetic opioids are not available, the same principles of treatment still apply. In addition, patients regularly using these substances and surviving would be expected to have a strong opioid dependency. At this time we are not sure how many people fit this clinical picture. In this scenario the withdrawal symptoms are likely to be severe, and could lead to life

threatening cardiac arrhythmias and seizures if untreated or if extreme opioid withdrawal is potentiated during overdose reversal.⁵³ There is an urgent need for more research to determine if people using fentanyl or other high potency opioids respond differently to medications for overdose reversal as well as treatment and to determine the most effective approaches for utilizing medications and psychosocial supports in this population.

In general outcomes are better predicted by the strength of the psychosocial supports around patients to support their recovery – educational or job opportunities, supportive friends and family, stable housing, access to child care – than the severity of their addiction. Providing behavioral counseling and wrap around services to address these needs is important for achieving the best outcomes.

Prevention of Opioid Misuse and Addiction

Since the majority of people who develop an opioid addiction begin by misusing prescription opioids, the Department of Health and Human Services (HHS) continues to focus efforts on improving opioid prescribing and preventing the misuse of prescription drugs as the long-run strategy to stop the opioid epidemic. NIDA supports research to understand the impact of federal and state policy changes on rates of opioid abuse and related public health outcomes. This and other federally supported research has demonstrated the efficacy of multiple types of interventions, including:

- Educational initiatives delivered in school and community settings (primary prevention)⁵⁴
- Supporting consistent use of prescription drug monitoring programs (PDMPs)⁵⁵
- Aggressive law enforcement efforts to address doctor shopping and pill mills^{56,57}

- Providing healthcare practitioners with tools for managing pain, including prescribing guidelines and enhanced warnings on drug labels with expanded information for prescribers⁵⁸⁻⁶¹

In states with the most comprehensive initiatives to reduce opioid overprescribing, the results have been encouraging. Washington State's implementation of evidence-based dosing and best-practice guidelines, as well as enhanced funding for the state's PDMP, helped reduce opioid deaths by 27 percent between 2008 and 2012.⁵⁸ In Florida, new restrictions were imposed on pain clinics, new policies were implemented requiring more consistent use of the state PDMP, and the Drug Enforcement Administration (DEA) worked with state law enforcement to conduct widespread raids on pill mills, which resulted in a dramatic decrease in overdose deaths between 2010 and 2012.⁶² These examples show that state and Federal policies can reduce the availability of prescription opioids and related overdose deaths. However, the increasing supply of heroin and illicit fentanyl in the United States is undermining the effects of these improvements. While we have seen a leveling off of overdose deaths related to commonly prescribed opioids over the last few years, overdose deaths related to illicit opioids have risen dramatically during this time.

In early 2016 CDC released guidelines for prescribing opioids for chronic pain.⁶⁰ We believe they represent an important step for improving prescriber education and pain prescribing practices in our nation. NIDA is advancing addiction awareness, prevention, and treatment in primary care practices through seven Centers of Excellence for Pain Education.⁶³ Intended to serve as national models, these centers target physicians-in-training, including medical students and resident physicians in primary care specialties (e.g. internal medicine, family practice, and pediatrics).

Addressing the Public Health Consequences of Opioid Misuse

Other evidence-based strategies can be used to reduce the health harms associated with opioid use, including increasing access to the opioid-overdose-reversal drug naloxone.

Preventing Overdoses with Naloxone

The opioid overdose-reversal drug naloxone can rapidly restore normal respiration to a person who has stopped breathing as a result of an overdose from heroin or prescription opioids. Naloxone is widely used by emergency medical personnel and some other first responders. Beyond first responders, a growing number of communities have established overdose education and naloxone distribution programs that make naloxone more accessible to opioid users and their friends or loved ones, or other potential bystanders, along with brief training in how to use these emergency kits. Such programs have been shown to be effective, as well as cost-effective, ways of saving lives.^{64,65} CDC reported that, as of 2014, more than 152,000 naloxone kits had been distributed to laypersons and more than 26,000 overdoses had been reversed since 1996.⁶⁶ In addition, the majority of states now allow individuals to obtain naloxone from retail pharmacies without a patient-specific prescription.⁶⁷

Two naloxone formulations specifically designed to be administered by family members or caregivers have recently been developed. In 2014 the FDA approved a handheld auto-injector of naloxone, and in late 2015 the FDA approved a user-friendly intranasal formulation that was developed through a NIDA partnership with Lightlake Therapeutics, Inc. (a partner of Adapt Pharma Limited).⁶⁸

The availability of naloxone is critical to reduce opioid-related fatalities.⁶⁹ However, research examining past fentanyl outbreaks shows that higher than typical naloxone doses were

required to reverse fentanyl overdose.⁷⁰ As the use of fentanyl and other highly potent opioids is increasing, it would be prudent to promote the use of naloxone while recognizing that multiple doses may be needed to revive someone experiencing a fentanyl overdose.⁷¹ It is also important for first responders to know that, while fentanyl has a short duration of action (30-90 minutes), it can stay in fat deposits for hours, and patients should be monitored for up to 12 hours after resuscitation.⁷² More research may be needed to develop new naloxone formulations tailored to higher-potency opioids.

Ongoing Opioid-Related Research: Implementation Science

Despite the availability of evidence based treatments for opioid abuse, we have a significant and ongoing treatment gap in our Nation. Among those who need treatment for an addiction, few receive it. In 2014, less than 12 percent of the 21.5 million Americans suffering with addiction received specialty treatment.³ Further, many specialty treatment programs do not provide current evidence based treatments – fewer than half provide access to MAT for opioid use disorders.⁴⁵ In addition, it is clear that preventing drug use before it begins—particularly among young people—is the most cost-effective way to reduce drug use and its consequences.⁷³ Evidence based prevention interventions also remain highly underutilized.

Ongoing NIDA research is working to better understand the barriers to successful and sustainable implementation of evidence based practices and to develop implementation strategies that effectively overcome these barriers. This work also seeks to understand the role environment—be it social, familial, structural, or geographic—plays in preventing opioid use and in the success of prevention and treatment interventions, as well as how to tailor prevention

and treatment interventions to individuals with unique needs, including those in the criminal justice system or with HIV.

Other NIDA supported research is looking at how to improve access to treatment among other high risk populations. For example, patients with opioid addiction are at increased risk of adverse health consequences and often seek medical care in emergency departments (EDs). NIDA is also collaborating with the Baltimore County Health Department on a pilot study to explore the possibility of providing methadone through pharmacies to increase access to treatment in underserved parts of the city. In the pilot, pharmacies would be considered satellite locations of licensed methadone treatment facilities; this model has been used in Pennsylvania and New York. Discussions are underway to explore whether regulatory exceptions can be granted to make this possible. Similarly, ongoing research is examining on the impact of providing opioid addiction treatment within infectious disease clinics. This type of research is essential for translating evidence based strategies into real-world interventions that will reach the greatest number of people and get the most out of limited prevention and treatment resources.

Implementation Research to Address the Opioid Crisis in Rural Communities

Our efforts are also focused on addressing the opioid crisis in the epicenter of the epidemic – Appalachia. NIDA is partnering with the Appalachian Regional Commission (ARC) to fund one-year services planning and needs assessment research grants to provide the foundation for future intervention programs and larger scale research efforts to test interventions to address opioid misuse in rural Appalachia. Four grants were awarded in FY 2016 that will address issues related to injection drug use and associated transmission of infectious disease as well as the coordination of care for prisoners with opioid addiction as they re-enter the community.

A second funding opportunity announcement in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, and ARC was released in October 2016 to support comprehensive, integrated approaches to prevent opioid injection and its consequences, including addiction, overdose, HIV and hepatitis C, as well as sexually transmitted diseases. High rates of injection drug use in Appalachia has led to a rapid increase in the transmission of hepatitis C, raising concern about an outbreak of HIV.⁶ These projects will work with state and local communities to develop best practices that can be implemented by public health systems in the Nation's rural communities including opioid abuse treatment and other strategies to increase the testing and treatment for HIV.

HIV Testing and Treatment

NIDA supported research has helped to develop the seek, test, treat, and retain model of care (STTR) that involves reaching out to high-risk, hard-to-reach drug users who have not been recently tested for HIV; engaging them in HIV testing; engaging those testing positive in antiretroviral therapy; and retaining patients in care. Research has shown that implementation of STTR has the potential to decrease the rate of HIV transmission by half.⁷⁵

Ongoing Opioid-Related Research: Development of Pain Treatments with Reduced Potential for Misuse

NIDA is one of multiple institutes of the NIH supporting research into novel pain treatments with reduced potential for misuse and diversion, including abuse resistant opioid analgesics, non-opioid medication targets, and non-pharmacological treatments. Some of the most promising potential therapies include:

- *Abuse Resistant Opioid Analgesics*: Efforts are underway to identify new opioid pain medicines with reduced misuse, tolerance, and dependence risk, as well as alternative delivery systems and formulations for existing drugs that minimize diversion and misuse (e.g., by preventing tampering) and reduce the risk of overdose deaths. Multiple recent NIH-funded studies have reported progress in the discovery of opioid compounds with selective analgesic effects with reduced respiratory depressive effects and reduced abuse liability.⁷⁶⁻⁷⁸
- *Non-Opioid Medications*: Some non-opioid targets with promising preliminary data include fatty acid binding proteins, the G-protein receptor 55, cannabinoids, and transient receptor potential cation channel A1.
- *Nervous Stimulation Therapies*: Several non-invasive nervous stimulation therapies – including transcranial magnetic stimulation and transcranial direct current stimulation, as well as electrical deep brain stimulation, spinal cord stimulation, and peripheral nerves/tissues stimulation – have shown promise for the treatment of intractable chronic pain. These devices have been approved by the FDA for treatment of other conditions but more research is needed on their effectiveness for pain.
- *Neurofeedback*: Neurofeedback is a novel treatment modality in which patients learn to regulate the activity of specific brain regions by getting feedback from real-time brain imaging. This technique shows promise for altering the perception of pain in healthy adults and chronic pain patients and may also be effective for the treatment of addiction.

Ongoing Opioid-Related Research: Accelerating Development of New Treatments for Addiction

While the three available medications have represented significant advances in the ability to treat opioid use disorders the efficacy of these medications is far from ideal. NIDA is funding research to accelerate development of new treatments. This includes development of non-pharmacological interventions including biologics – such as vaccines, monoclonal antibodies, and bioengineered enzymes designed to prevent a drug from entering the brain – and novel brain stimulation techniques – such as TMS and transcranial direct current stimulation (tDCS), that target brain circuits impaired in addiction with improved specificity and temporal and spatial resolutions, and thus, with less adverse effects. One ongoing NIDA-funded study is in the early stages of developing a vaccine for fentanyl that could prevent this drug from reaching the brain.³⁴

Since the pharmaceutical industry has traditionally made limited investment in the development of medications to treat SUDs, NIDA has focused on forming alliances between strategic partners (pharmaceutical and biotechnology companies as well as academic institutions) with the common goal of advancing medications through the development pipeline toward FDA approval. NIDA conducts research to decrease the risks associated with medications development to make it more appealing for pharmaceutical companies to complete costly phase IIb and III clinical studies. An example of such a project is a partnership with US World Meds, is in late stage development of lofexidine, a medication for the treatment of opioid withdrawal symptoms that might also hold promise for the treatment of other addictions.

Conclusion

NIDA will continue to closely collaborate with other federal agencies and community partners with a strong interest in preserving public health to address the interrelated challenges posed by misuse of prescription opioids, heroin, and synthetic opioids such as fentanyl. We commend the committee for recognizing the serious and growing challenge associated with this exceedingly complex issue. Under the leadership of the Department of Health and Human Services and the Office of National Drug Control Policy, NIDA will continue to support the implementation of the multi-pronged, evidence-based strategies to improve opioid prescribing and pain management, reduce overdose deaths, and increase access to high quality opioid abuse treatment.

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Mr. MURPHY. Thank you, Doctor.

We will now begin with questions. I will recognize myself for 5 minutes.

Mr. Chester, does the ONDCP believe that fentanyl is another wave of the opioid epidemic?

Mr. CHESTER. Yes, sir. It really is two things. I think it is an outgrowth of the heroin crisis, and then once fentanyl has found its way into the supply chain it represents a unique aspect of that particular problem.

Mr. MURPHY. So do we have a strategic plan? Does the Federal Government have a strategic plan to address that unique issue?

Mr. CHESTER. We do. As I mentioned, the Heroin Availability Reduction Plan included both heroin and fentanyl as part of its problem set and that particular plan guides and synchronizes Federal Government activities against the opioid problem set, specifically heroin and fentanyl. Yes, sir.

Mr. MURPHY. Mr. Milione, do you believe that with this unprecedented threat of fentanyl that we have a Federal plan solidly in place as broad as it needs to be?

Mr. MILIONE. I always think there is more to do, based on the level of the threat. Certainly, at DEA it is a priority. We have programs in place to deal with it. But as Ambassador Brownfield said, there is always room for improvement based on the need of the threat.

Mr. MURPHY. Mr. Allen, based on the data that our law enforcement places at international mail facilities at nine different airports in 2015 and 2017, I find it amazing that not one package of fentanyl was detected out of 8,473 that were examined.

Is there more difficulty in coming up with a targeting profile for fentanyl shipments than we know about and what can be done to prove this?

Mr. ALLEN. Detection of fentanyl in—you know, at the land border and in consignment packages and mail is a challenge that we continue to deal with. I think we have better success in certain channels than we do in others. Because Customs and Border Protection gets advanced information from the express consignment companies, their ability to target packages that are inbound to the United States is much better than our ability to target mail that is coming to the United States because the universal postal union that we operate under does not mandate that international shippers including China and others provide advanced information about packages and mail that is coming to the United States.

Mr. MURPHY. So requiring that would help? Would requiring that information help with the postal service?

Mr. ALLEN. Yes, it would.

Mr. MURPHY. Can I also ask where is—who can answer this question? Where is it coming over the border with Mexico? I understand it is places in California and Arizona, am I correct? Do we know specifically?

Mr. ALLEN. The two areas where we've seen it most prevalent is in southern California and southern Arizona. The vast majority has been detected.

Mr. MURPHY. And how do they bring it across the border?

Mr. ALLEN. In personally owned vehicles or on bodies coming—people that are coming as pedestrians across the land border detected at ports of entry.

Mr. MURPHY. People—so people walk across or people who come through—legally through ports of entry and it is either way? Illegal or legal, they're both coming through?

Mr. ALLEN. Legal. Where we are not detecting it is between the ports of entry. We are seeing it come in at designated points of entry and it is being detected and seized and arrests are being made by Customs and Border Protection at ports of entry.

Mr. MURPHY. But in other parts we are not seeing it? They're coming across the border in other places and they're not picked up there?

Mr. ALLEN. On the land border we are not seeing it come between the ports of entry. The other method of it coming into the United States is through express consignment packages and mail, which generally is detected in the interior at express consignment hubs where all consignment packages are cleared by CBP or at international mail facilities that are designated around the United States.

Mr. MURPHY. Thank you.

Dr. Houry, the most recent available data of fentanyl-related overdose deaths come from 2015. Am I correct or do you have more recent data for 2016?

Dr. HOURY. So we have data through 2015 but we've also released a quarterly report for 2016 through the National Center for Health Statistics and that is death data.

I think what is really helpful is, with the funding that we received this past year, we've stood up a surveillance system in 12 States that looks at nonfatal data also. That has been in place for six months.

That allows us to have some DROMIC data from emergency departments to capture more quickly emerging trends.

Mr. MURPHY. With all that, is it—do you think it is still under-reported significantly?

Dr. HOURY. I do think it is significantly under reported because many medical examiners and coroners aren't testing for fentanyl analogues. Up to 20 percent of times, you know, the type of drug is not reported. We are working with AFSO and with the National Association of Medical Examiners to improve death certificate reporting.

Mr. MURPHY. Dr. Compton, in just a few seconds—it is a scientific challenge. Can you explain how it is that fentanyl is more dangerous than other opioids medically?

Dr. COMPTON. Well, the key is through both its strength as well as its fat solubility. So not only is it inherently more potent but it can more rapidly enter the brain where it exerts its respiratory depression, which is what kills people.

Mr. MURPHY. And all right. We will get to more of these but I will go to Ms. DeGette now for 5 minutes. Thank you.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. Milione, as I mentioned in my opening statement, I think we all agree the amount of fentanyl recovered by American law en-

forcement has risen from 640 samples tested to 13,000 samples tested in 2015. Would you agree with that statistic?

Mr. MILIONE. I would, not having them in front of me. But that sounds right.

Ms. DEGETTE. Yes. I mean, it is really raised—going up in crisis proportions, right?

Mr. MILIONE. That's correct.

Ms. DEGETTE. And have arrests for counterfeit pills or sources increased as well?

Mr. MILIONE. I would have to get back to you as far as if there has been an increase. We have been studying—we have been very aggressively investigating these networks.

Ms. DEGETTE. But I think you would agree that the amount of fentanyl recovered has been growing exponentially, right?

Mr. MILIONE. It has.

Ms. DEGETTE. Now, Dr. Compton, I want to ask you, because other opioids sometimes—often lead to fentanyl use some have suggested that to stem the demand for fentanyl we also need to treat opioid addiction because addiction drives the users to seek those other drugs that contain fentanyl. Would you agree?

Dr. COMPTON. Yes. I think the fentanyl issue is most closely related to heroin addiction. So it is the very same people using heroin that seem to have the most trouble with fentanyl.

Ms. DEGETTE. And treatment, as we've learned in many, many hearings in this subcommittee, is an important component in the addiction fight. Is that right?

Dr. COMPTON. Absolutely. We think expanding treatment access is a key component of our—of our attempts to address this.

Ms. DEGETTE. Now, based on—I assume you have had experience with opioids and with heroin. You just can't stop this by arresting people. Would that be fair to say? You have got to also have treatment.

Dr. COMPTON. I think it is either—to point out that it is the combined public health and public safety approaches that look most promising.

So we look at models that include criminal justice systems as well as public health as showing reductions in crime as well as important health outcomes.

Ms. DEGETTE. OK. But health outcomes are a key part of that, right?

Dr. COMPTON. Of course.

Ms. DEGETTE. And so this what I am concerned about. When you're trying to treat opioid addiction, as we have also learned in our many hearings in this subcommittee it is a comprehensive treatment that is very extensive. Wouldn't you agree with that?

Dr. COMPTON. Yes. We have certainly learned that the treatment needs to last quite a long time. It takes people a long time to turn their lives around and recovery is not an instantaneous process.

Ms. DEGETTE. And these drugs, they sometimes change the chemistry of the brain so that you have to have to medication-assisted treatment and other types of tools to be able to treat this. Is that right?

Dr. COMPTON. Yes. NIDA research has certainly demonstrated that.

Ms. DEGETTE. And so in some of these States that have been hit hard with the opioid and fentanyl epidemic, the Medicaid expansion that they have been able to get has been able to help them really target populations for addiction treatment and prevention. Would that be fair to say?

Dr. COMPTON. Certainly treatment expansion is a shared goal for all of us and making sure that the research we support is embedded within the health care system is essential.

Ms. DEGETTE. Now, in the past few years after the passage of the Affordable Care Act Medicaid was now able to pay up to 50 percent of medication treatment in some of these hardest-hit States. Is that right?

Dr. COMPTON. Well, I would really want to refer the specific questions about how Medicaid is funded to the State officials that implement those programs or the CMSes.

Ms. DEGETTE. So you are not familiar about how some States in the last years have been able to increase their treatment?

Dr. COMPTON. I'm certainly familiar with the States' efforts to expand treatment in the last few years.

Ms. DEGETTE. Well, let us talk about Ohio, for example. In Ohio, Republican Governor John Kasich recently said, "Thank God we expanded Medicaid because that Medicaid money is helping to rehab people," and in fact a February 6th, 2017, Pew Report noted that Ohio added 700,000 new Medicaid recipients under its expanded program, and roughly a third were diagnosed with a substance abuse disorder.

According to the CBO, the Republican ACA repeal's proposal would cut \$880 billion in Federal outlays for Medicaid over the next 10 years. Would you disagree with any of those figures?

Dr. COMPTON. Well, certainly, we are interested in research that can look at changes in the health care system. We are partnering with SAMHSA to study the implementation of the 21st Century Cures Act.

Ms. DEGETTE. Right. But would you—would you disagree, for example, that Ohio added 700 [sic] new Medicaid recipients under its expanded program and a third were diagnosed with substance abuse disorders?

Dr. COMPTON. Those figures sound reasonable.

Ms. DEGETTE. OK. So what I'm worried about is probably pretty clear. If you reduce the Medicaid expansion that in States like Ohio, Kentucky, West Virginia, other States that have been hard hit by fentanyl and opioid and heroin that that is also going to reduce the treatment programs we are able to give them.

Thank you, Mr. Chairman.

Mr. MURPHY. You're right. We can't arrest our way out of this. We have to treat it. And just a follow-up to what you're saying: Do we even have enough providers? Does anybody know? We know that half the counties in America don't have psychiatrists, psychologists, social workers. Do we have enough trained drug treatment providers in America?

Dr. COMPTON. We do not have enough to fully meet the needs and they are not evenly spread across the country. So that is why we are engaging in the rural initiative to address the particularly severe shortages in rural areas.

Mr. MURPHY. Thank you very much.

Dr. HOURY. And I would just add to that treatment is important but preventing people from needing addiction services in the first place will also save the health care system a lot of money. So making sure we are using safe prescribing practices is a key component.

Mr. MURPHY. And we'll get to that as well.

Ms. Walters of California is recognized for 5 minutes.

Ms. WALTERS. Thank you, Mr. Chairman.

We have seen the opioid and heroin epidemic ravage every part of our country. Even affluent areas like my home of Orange County, California, are struggling with over 200 deaths per year.

Now we are witnessing a far deadlier iteration, fentanyl-laced drugs. This incredibly powerful pain killer reserved for the most severe and acute pain are being added to heroin, cocaine and counterfeit drugs.

As a mother of four young adults, it breaks my heart every time I see or hear of another life lost. Just last year, a 19-year-old from Orange County overdosed after taking fentanyl-laced cocaine.

This epidemic again hit home when a DEA investigation resulted in four arrests for an alleged fentanyl importation and distribution conspiracy in Long Beach.

The DEA reported that the men had over 30,000 acetyl fentanyl tablets and 13 kilograms of the narcotic.

Mr. Milione, I want to commend your agency for this investigation and keeping this deadly drug off the streets of Orange County.

Mr. Milione, the making and distributing of pills containing fentanyl has been disguised by molding the pills in a wide variety of counterfeit brands and colors. What are the most prevalent pill types being discovered?

Mr. MILIONE. Thank you for the question. It's a pretty broad range but oxycodone—they are going to mimic whatever is popular on the street depending on the market, depending on the area.

So if there is a real market for oxycodone 30s, they'll replicate those. If it is more a powdered substance that they want in a capsule because they'd rather snort the substance, that market will influence how they package it.

Ms. WALTERS. What types of pill making machinery are most commonly associated with these counterfeit drug operations?

Mr. MILIONE. There is a broad range. I mean, anywhere from an inexpensive pill machine to ones that cost \$10,000, \$15,000, \$20,000 that can produce 250,000 pills an hour.

Some of them are handheld that can be very easily used. So it is a broad spectrum there.

Ms. WALTERS. OK. And what are the most likely sources of these counterfeit drugs?

Mr. MILIONE. China is the primary source for the fentanyl. But then, as I said before, going into Mexico and then the networks are shipping the merchandise up into the United States, and what we are seeing more and more is that actually the pills—the counterfeit pills—are being made in the United States at different domestic transportation cells around the country.

Ms. WALTERS. OK. Thank you. And Dr. Houry, we understand that the typical victim of a fentanyl overdose can be extremely

hard to define since it does not follow economic structure or community locales.

What can you tell us about current trends and tendencies?

Dr. HOURY. So you are right, we are seeing this epidemic really increase in all demographics. It's most hardest hit in those 20 to 44 and really that—or 25 to 44 and we are seeing it more in men.

What I think is important, though, is people—like in Rhode Island we saw that a third of the decedents had had a prescription within the past 90 days for an opioid and a third of those had had a high dose of morphine milliequivalent prescription.

So what we had said in the guideline to really be cautious was that people are getting exposed to opioids and then going on to fuel their addiction through heroin and fentanyl.

Ms. WALTERS. OK. Thank you.

And Mr. Chester, in recent months fentanyl was first identified as a major problem in the Northeast, parts of the Midwest and certain States like Florida and Maryland. What do you see as trends or directions of its spread?

Mr. CHESTER. We have begun to see some indications that it has moved west. Obviously, Sacramento, California was the first one. That was about a year ago that we had begun to see it move a little bit farther west.

I think fentanyl found its way into the Northeast simply because it was easier to mix into the powdered white heroin that was popular in the northeast United States.

And so in the western part of the United States we are beginning to see more of the pill form that Mr. Milione was discussing as well.

But fentanyl, even though it began being geographically concentrated in the Northeast, we've seen indicators of areas throughout the United States.

Ms. WALTERS. OK. Thank you. And I yield back the balance of my time.

Mr. MURPHY. Ms. Castor is recognized for 5 minutes.

Ms. CASTOR. Well, thank you, Mr. Chairman, for calling this hearing and thank you to all of our expert witnesses for shining a light on this.

It does feel like we are in the Twilight Zone though because as we are talking about the seriousness of the opioid epidemic we are faced in two days with a vote on a health bill that will recede in this country's responsibility in health services to families who are addicted, who need substance abuse treatment, mental health treatment.

Mr. Chester, you said that only one in nine are receiving treatment who need it. Mr. Milione, you say we have to reduce demand as part of a balanced strategy.

And yet, this GOP health care bill that is coming to the floor will take a hatchet to coverage for millions of Americans plus it will end Medicaid health services as we know it that provide in Florida, in most States, the most important mental health and substance abuse health services.

So this is very important. But, boy, this bill that is coming up for a vote would really take us backwards when we are talking about opioids.

In fact, my—one of my local sheriffs in Pinellas County, which is St. Petersburg and Clearwater, says we cannot and we never will solve this problem at the law enforcement level.

This needs to be treated as an addiction problem—a mental health problem. We may have had great success in beating back the pill mills but all that meant is we are going to see a switch to different drugs and different dealers.

And I wanted to highlight what's happening in West Virginia because it is startling and there is a good investigative reporter that is shining a light on it.

Mr. Milione, according to a December 2016 article in the Charleston Gazette Mail, opioid wholesalers ship mass quantities of opioid medicines that appear to be foreign excess of what certain communities in West Virginia should receive based on sound medical needs.

The article says, “In six years, drug wholesalers showered the State with 780 million hydrocodone and oxycodone pills while 1,728 West Virginians fatally overdosed on those two painkillers. The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia.”

This reporting strongly suggests that West Virginia appears to have been receiving quantities of hydrocodone and oxycodone pills that would clearly be more than what would be medically necessary.

Mr. Milione, are you familiar with some of the reporting which suggests West Virginia may have been grossly oversupplied with dangerous prescription opiates?

Mr. MILIONE. I am.

Ms. CASTOR. I mean, this is really shocking. It would appear that addiction to pain pills can, according to all of the reporting and what you all have testified here today that once you have oxy and hydrocodone that takes over someone's life that that will quickly lead to the user seeking more powerful opiates such as heroine or counterfeit pills, both of which may be adulterated with fentanyl.

Dr. Houry, in your testimony you say reversing epidemic—the epidemic requires changing the way opioids are prescribed. Is it therefore reasonable to assume that addiction to prescription pain medicines have a connection ultimately to the fentanyl problem and the larger opioid epidemic?

Dr. HOURY. Yes. Many of the people who have overdosed on fentanyl have had a opioid prescription at the time of their death. So I believe all of these fentanyl, heroin and prescription opioid overdose deaths are linked.

Ms. CASTOR. And Mr. Milione, MSNBC also ran a story about the substantial influx of opioids into West Virginia. It reported on a small town called Kermit, which I understand only has 392 people.

They reported that Kermit received 9 million hydrocodone pills in 2 years. If this reporting is true, it is hard to believe that we have sufficient systems in place to spot dangerous trends.

Is the DEA familiar with the reports regarding what happened in this small town with the oversupply of addictive pills and what can you tell us about it?

Mr. MILIONE. I am familiar with that report, but we are all—we are familiar that that has happened in many, many locations

across the country. So we have an obligation, obviously, across the whole supply chain from the manufacturers to the distributors.

Ms. CASTOR. What is happening with the wholesalers?

Mr. MILIONE. Well, the wholesalers have to uphold their regulatory obligations and we have taken action recently against the big—two of the big three, McKesson and Cardinal.

Our hope is that their compliance programs, like any good corporate citizens, would work to prevent diversion and they would uphold those obligations. But it is not just the wholesalers. We have to go all the way down the supply chain in order to kind of try to maintain this closed system of distribution.

So it is certainly complex and it is a challenge. But we are well aware of all the issues across the country.

Ms. CASTOR. Thank you. My time has run out.

Mr. MURPHY. Thank you.

Dr. BURGESS, you're recognized for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Milione, let me stay with you if I can, and I don't know if we can get this map of the opiate deaths in 2015 up on the screen. But the map is almost counterintuitive to me. We talk about—that is not the one. It is the total opiate deaths in 2015, just for the purposes of illustration. Thank you.

Almost counterintuitive—six of the States with the lowest numbers—go back one slide, please—six of the States with the lowest numbers, of those six, four are border States—Texas, California, North Dakota, and Montana—which would be counterintuitive if we talk about things that are coming in across the border.

But also if you look at the map, boy, it seems like there is a bullseye on the Midwest, and what are you doing to sort of interrupt those supply chains that seem to have targeted a portion of the country?

Mr. MILIONE. A great question. So you're right, it is transiting in and it is going to—it is not staying at the border where it crosses. It is going to locations around the country.

The Northeast is getting hit. The Midwest is, unfortunately, increasingly getting hit. But now the West is also getting hit.

So what are we doing? Applying law enforcement techniques. We are working with our Federal partners, infiltrating the supply chain but also looking at the distributors and trying to disrupt them with the judicial process.

Mr. BURGESS. Ambassador Brownfield, let me ask you a question and anytime we have a Texan on the panel that is a good thing. So I thank you for being here today.

And just for the record, you are career at the State Department. Is that correct?

Mr. BROWNFIELD. I am, Congressman.

Mr. BURGESS. Well, and thank you for your service to the State Department.

Now, of course, the secretary is in China or has been in China recently. Your testimony today—your written testimony that you provided and your—and your verbal testimony kind of indicated that perhaps things were looking up. Things were—there were positive developments, and I guess I am just not feeling that there are positive developments.

And in fact, Mr. Milione, please don't arrest me but I went online and looked at how to order fentanyl online just while we are sitting here and there are a lot of opportunities and I suspect those opportunities many of them come from Asia or come through China.

Mr. Brownfield, do you—Ambassador Brownfield, do you think we are doing enough to interrupt those?

Mr. BROWNFIELD. Congressman, I will say we are starting very close to point zero in terms of our cooperation with China. We have moved in a positive direction.

We are dealing with a country that has somewhere between 170,000 and 400,000 companies that produce pharmaceuticals somewhere in the People's Republic of China.

As recently as 2 or 3 years ago, there was largely no control over their production whatsoever. Since then, 116 synthetic drugs are now controlled by the Chinese Government and within the last month and a half—literally, within the last month, 4 new ones, including important fentanyl analogies, are now controlled by the Chinese Government.

We have a dialogue. We are talking to one another. Three years ago, their answer was—by the way, is not unusual—around the world was we do not have a fentanyl problem and therefore we are not particularly interested in cooperating with you because it is not being abused in China.

We have gotten beyond that. Are we where we want to be? No, of course not. What you have just proven is we have not yet solved the problem. But are we in fact ahead of where we were 2 or 3 years ago? On that, I say yes.

Mr. BURGESS. Well, and that—I thank you for that effort. I agree with you that is a positive development. But given the distributional aspects on our United States map, is it possible—and, really, it is for anyone on the panel—is it possible to identify from which laboratories or manufacturing houses overseas, which are causing us the greatest problems in these areas that we are seeing on our United States map. Does anyone have an answer for that?

Mr. MILIONE. Congressman, it is a great question, and to build on what Ambassador Brownfield was saying, we have had, on the law enforcement side in China in our Beijing country office tremendous success getting leads from the Chinese of U.S.-based recipients of their fentanyl. That's a huge step forward and allows us now to kind of uncover that network in the United States.

Yes, we have had successes uncovering what those labs are in China and we've been working cooperatively with our law enforcement counterparts over there and we are very pleased with the direction that it is going.

Mr. BURGESS. Well, and just in the limited time I have remaining, Dr. Houry and Dr. Compton, I mean, both of you talked about fentanyl use patterns and I'm a big believer in prescription drug monitoring programs.

Look, I was a physician. It's important to have drugs like fentanyl available. We are grateful for their utility in clinical settings. Clearly, they have to be used appropriately.

But do you have a sense of what I was talking to the DEA and the State Department about—do you have a sense of where the use patterns are occurring?

Is—are you able then to target limited resources so that perhaps an ER can have one of these early intervention programs?

If you're in a hot spot I think that is a good idea. If you're in—out in Lubbock, Texas that might not be as important.

Dr. HOURY. In Ohio we were able to do that. We did an Epi-Aid there and found eight counties that had highest rates. We were able to then, you know, help guide Ohio to where to focus their efforts. And then in Massachusetts we also saw that there was a high rate of overdose deaths in those that were recently incarcerated—about 50 times what we saw in other populations.

So we were able to use the data for that. With prescription drug monitoring programs you can very much see people at risk for opioid use disorder and use that to help link to further—

Mr. BURGESS. Are you?

Dr. HOURY. What we are doing right now is the program has been in place for 2 years and we are in 44 States and getting data that is quicker and better able to be used by States and letting States really focus on evidence-based interventions.

Mr. BURGESS. I am way over time but, honestly, we authorized NASPR back in 2005. It shouldn't be just recently. This should have been an ongoing exercise over the last decade, in my opinion.

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

Mr. MURPHY. The gentleman yields back.

Before I recognize the next one, I want to put together a couple pieces here we just had. So the gentlelady from Florida and Dr. Burgess from Texas talked about these issues.

Kermit, West Virginia—I think that is where you mentioned this tremendous prescription rate—massive amount. I pulled up another chart here of disability rates in the United States and don't you know, Mingo County and those areas in West Virginia are among the highest in the Nation, where Dr. Burgess just pointed out the deaths that are occurring there.

It makes me wonder as you're talking about collecting more data, Dr. Houry, how much more data do you have to have? You're seeing these targeted areas where the amount of prescriptions is way, way out of control.

You can see on that map. This is way out of control and yet—and these deaths are occurring.

So are there any kind of teams, like, going into these places and identifying who's writing these prescriptions and then the deaths that come from this?

Dr. HOURY. Absolutely. We've been sending teams into Ohio, to Massachusetts, to Rhode Island. We've given specific information to the States on how to combat—

Mr. MURPHY. West Virginia?

Dr. HOURY. West Virginia, we've been funding the program. I did the site visit myself out there to West Virginia.

We've been working with each State to look at the prescription drug monitoring programs, and if you look at the guideline, 18 States have now adopted or have implemented aspects of the guideline to help with safer prescribing in their States and we are starting to see significant improvements and you see things like Kentucky through our CDC funding.

Now on our prescription drug-monitoring program it has an alert for if there is high morphine-related equivalence to, again, make sure that people are getting safer prescriptions.

Mr. MURPHY. Thank you.

Ms. Schakowsky, you're recognized for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and I want to thank all of our witnesses. This has been a very important issue because it is an important fight for our communities.

Obviously, the law enforcement piece and figuring out how we can stop the entry into our country of the components of fentanyl—very important.

But I want to say, again, and it is been said many times before, this is also a very serious health issue. And to my Republican colleagues, as we face this vote that is coming up on Thursday we have to recognize the importance of the Medicaid program.

It's the second biggest payer for drug abuse treatment in the United States. It funded, roughly, 25 percent of public and private spending on drug abuse treatment in 2014. We talk about West Virginia.

We are talking about a lot of low-income people and Medicaid is really the source of help for them.

For my home State of Illinois, Medicaid has been absolutely vital to address substance abuse and providing access to treatment.

Medicaid expansion has provided coverage to 650,000 low-income adults in Illinois, nearly one-third of whom have mental health or substance abuse disorders.

That's just the typical percentage all over the country. Without Medicaid, these individuals would be more likely to end up in emergency rooms or jails, which would drive up costs for State and local budgets.

It's also clear that in Illinois we need to be further expanding access to substance abuse treatment and I'm sure that is the case in many other States around the country.

From 2014 to 2015, Illinois saw 120 percent increase in the number of deaths from drug overdoses. And so, you know, yet the Republican Trumpcare proposal would decimate the Medicare program that serves one in four people in Illinois—one in four people in Illinois.

The Republican bill would end Medicaid expansion and pose a drastic per capita cap on funding. I don't want to go more—on more about that because it is been certainly addressed.

Dr. Compton, wouldn't you agree that solving the fentanyl and opioid addiction problem requires that we also ensure that people have access to appropriate substance abuse treatment?

Dr. COMPTON. Certainly given that the underlying issue is an opioid use disorder, treatment is a key component of solving this problem.

Ms. SCHAKOWSKY. Thank you.

And Dr. Houry, in your testimony you stated that "a rise in fentanyl, heroin and prescription drugs involve overseas are not unrelated." I'm sorry—overdoses, not overseas. I'm going to say that again. "The rise in fentanyl, heroin and prescription drug-involved overdoses are not unrelated." Would you agree that in order

to solve the fentanyl crisis we must also address the larger opioid prescription drug epidemic?

Dr. HOURY. Yes. I think a very comprehensive approach is needed and I think prevention is a key aspect of that.

Ms. SCHAKOWSKY. I wanted to also ask Dr. Compton how harmful would it be for a patient with an opioid disorder to have to discontinue his or her substance abuse treatment?

Dr. COMPTON. One of the key predictors of relapse and of recidivism is stopping treatment. So when people stop treatment, particularly abruptly, they're extraordinarily high risk of relapse to their underlying addiction problems as well as criminal behavior and other serious problems.

Ms. SCHAKOWSKY. Thank you.

I'm very concerned. I'm also on the Budget Committee. We know that there has been proposed an 18 percent cut in HHS, \$5.8 billion cut in the National Institutes of Health, which I—my understanding is that you're actually doing some research on—I don't know if the right word is vaccine, but some sort of prevention, something that would—against opioid addiction. Is that true?

Dr. COMPTON. Well, we even have research specifically targeting fentanyl where the development of a vaccine might lead to an approach that could keep the—keep the fentanyl from getting into the brain.

The goal is to keep it in the circulatory system so you get antibodies developed that attach to the fentanyl and keep it out of the brain where it exerts its dangerous effects.

Ms. SCHAKOWSKY. Thank you.

Again, I want to thank all of the people who are here today testifying how you're trying to stop it before it starts and understand all the sources. But I also am interested in the health services.

Thank you. I yield back.

Mr. MURPHY. Gentlelady yields back.

I now recognize the chairman of the committee, Mr. Walden.

Mr. WALDEN. Thank you very much, Mr. Chairman. I want to thank the witnesses again for your learned testimony and your answers to our questions.

The fentanyl threat, Mr. Chester, has been described to us as the third wave of the opioid epidemic. It seems to me that individual States—I've looked at some maps—are seeing different effects, different aspects of the overall epidemic. Some are facing fentanyl head on right now.

Looks like in other areas it hasn't hit or at least not as with the deadly effect. Others are fighting against prescription drug or heroin overdoses.

So I guess my question is, Are we better off to look at this as sort of a State-by-State basis? I realize there are national implications, but it seems like there are some real hot spots in the States.

And so when we think about a strategy here to combat it, should it be multi-headed and look at this opioid epidemic in that way or and look at kind of all-of-the-above or sort of a one-size-fits-all? What, from your experience, would work best?

Mr. CHESTER. Yes, Congressman. So we look at it as a complex national security law enforcement and public health issue at the national level, and then at the State level, there are unique envi-

ronmental factors that cause different manifestations of the opioid problem and as you correctly point out there is fentanyl in some States more than it is in others, there are prescription opioids in others, and in others there is heroin. And in fact we've seen evidence in some places that heroin deaths are the preponderant cause of death, and in other cases fentanyl has surpassed heroin as being the preponderant cause of death.

So in the implementation of our plans we do two things. Number one, we try and respond to unique aspects of that State's environment but also develop a framework to share lessons learned from one State to another.

So things that certain States have found to be successful in dealing with their particular aspect of the problem can be shared with other States who may not be facing that particular problem but may see it in the future.

Mr. WALDEN. All right. Thank you.

And Ambassador Brownfield, first of all, I want to commend the State Department and the good work that you all have done and commend the DEA for your work in helping getting the recommendation of the March 16th effort by the U.N. Commission on Narcotic Drugs in favor of controlling two primary fentanyl precursors.

And I want to thank the Chinese, too. I've met with the ambassador. We've sent them a letter thanking them for their work to shut down some of the facilities.

What do you hope will be the impact from the U.N. recommendation on the fentanyl problem in the U.S.? What can we expect out of that?

Mr. BROWNFIELD. First, at the risk of shameless pandering to you, Congressman, may I thank you for your letter to the ambassador. It makes my job enormously easier when they hear directly from you.

What do we respect from—expect from the CND decision to control the two precursors? First, we have to wait another, roughly, 170 or 168 days before it is fully implemented.

This is a period of time during which the, roughly, 185 member states of the U.N. who are also part of the CND have endorsed or ratified the treaties—have the right to seek an exception.

I do not expect anyone to seek an exception to the ruling, because the vote was unanimous. It was 51 to 0.

When it comes into effect, the countries that produce these two precursors, the two most prevalent precursors in the production of fentanyl in the entire world will be required to control, register, license and verify production of these precursors there. They will—

Mr. WALDEN. And, again, which two countries are those?

Mr. BROWNFIELD. I mean, the two precursors. The most important country is China which, in fact, did support—not only vote for but did support and assist us to some extent in lobbying for the passage.

So what will happen at that point in time is whenever a company, any company in the world, is going to export either of these two precursors, the government of the country where it is produced will be required to notify the national authorities of the country to which it is being exported and it will have to provide the basic data

and information—how much, when, who is the receiving party, route by which it will be shipped.

That then allows the national authority—in this case it might be HSI or ICE or DEA—to determine what is coming in and doing the due diligence to verify this is a legitimate and legal shipment.

This is why I said in my oral statement this is a way to shut down the diversion of legal and illicitly produced fentanyl.

Mr. WALDEN. You know, the State of Oregon and elsewhere tried this with methamphetamine to get at the precursor ingredients and it made a big difference when you put pseudoephedrine behind the counter and required a prescription.

Boy, that just changed the whole dynamic in terms of the individual cooking operations that were polluting homes and killing people.

And so I commend you and the State Department and the governments that were involved for taking this step. We look forward to being partners with you, going forward.

And I yield back the balance of my time.

Mr. MURPHY. Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Sorry about that. Problem with the mic.

Thank you, Mr Chair. I am quite satisfied we are holding this hearing today because it is literally a life-or-death issue for my constituents.

In my hometown of Amsterdam, New York, a small community of about 18,000 people, we had four overdose deaths and another dozen treated overdoses in the month of December alone.

If that rate of carnage were maintained for an entire year, one in every 375 individuals in my hometown would perish. These overdoses were all attributed to fentanyl—one in 375.

When you drive down the interstate in my district, instead of billboards advertising for McDonald's or Taco Bell, you see billboards advising you to call 911 in case of an opioid overdose.

Last year, I had the opportunity to visit a clinic where I witnessed people taking their first steps to recovery aided by a law I helped to pass last year that raised the arbitrary limits on the number of patients a doctor can treat for opioid use disorder.

Bearing witness to these success stories from the recovery community fuels my drive to push for policies that will expand the recovery opportunity for everyone.

That is why I found it astounding that in all of the witnesses' testimony today the word Medicaid was mentioned just twice and both times in the context of prescription drug monitoring programs.

We can talk supply reduction all we want. But you simply cannot talk about a Federal response to the opioid epidemic without talking about Medicaid, which is the largest payer for behavioral health care services in our country.

In New York, Medicaid pays for 38 percent of all medication-assisted treatment for opioid use disorder. In New Jersey, it is 22 percent. Pennsylvania, 29. Indiana, 17. I could go down the list but you get the point.

And as my colleagues have ably pointed out, there is a huge elephant in the room here. The Trumpcare bill this House is being asked to vote on later this week would be the single most dev-

astating piece of legislation to individuals struggling with addiction in our Nation's history.

Trumpcare would eviscerate treatment for individuals who are struggling with opioid addiction by ending the Medicaid expansion, repealing guarantees of mental health and substance use benefits and gutting Medicaid to the tune of \$880 billion over the next 10 years alone.

You don't have to take my word for it. The American Society of Addiction Medicine, a professional society representing over 4,300 professionals in the field of addiction medicine wrote to Congress saying we are concerned that rolling back the Medicaid expansion, certainly sun setting the EHB requirements for Medicaid expansion plans and capping Federal support for Medicaid beneficiaries will reduce coverage for access to addiction treatment services, changes that will be particularly painful in the midst of the ongoing opioid epidemic.

Rolling back the Medicaid expansion and fundamentally changing Medicaid's financing structure to cap spending on health care services will certainly reduce access to evidence-based addiction treatment and reverse much or all progress made on the opioid crisis last year.

The mental health liaison group, an umbrella organizations for groups involved in mental health and substance abuse service wrote, and I quote, "The AHCA would leave without coverage the 1.3 million childless nonpregnant adults with serious mental illness who were able for the first time to gain coverage under Medicaid expansion. It would also leave uncovered the 2.8 million childless nonpregnant adults with substance abuse disorders who gained coverage under expansion for the first time."

Current Ohio Governor, Governor Kasich, "Thank God we expanded Medicaid because that Medicaid money is helping to rehab people."

Former Arizona Governor Jan Brewer, no one's idea of a bleeding heart liberal, wrote, and I quote, "It just really affects our most vulnerable, our elderly, our disabled, our childless adults, our chronically mentally ill, our drug addicted. It will simply devastate their lives and the lives that surround them because they're dealing with an issue which is very expensive to take care of as family with no money."

I could go on but you get the point. I would, Mr. Chair, like to enter into the record this letter from 415 addiction groups nationwide opposing Trumpcare for the devastating impact that Trumpcare would have on treatment for the opioid epidemic.

Mr. MURPHY. Without objection.

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

Mr. TONKO. Thank you, Mr. Chair.

From my vantage point, there is no one outside of a three-block radius of this Capitol Building that thinks that Trumpcare is anything better than a raging dumpster fire.

Certainly, no one thinks this back room bill will improve the lives of those struggling with the disease of addiction.

And with that, Mr. Chair, I yield back.

Mr. MURPHY. Gentleman yields back. I do want to note for the gentleman that the article referenced before—I don't know if you've seen it—from the Washington Post.

There's an important statement that says, the important takeaway is that there is not one opioid epidemic but several.

To policymakers this may mean that solving the problem will similarly require more nuanced vascular solutions than a blanket war on drugs. A strategy to reduce pill overdose in Utah may not have any effect on fentanyl deaths in Massachusetts.

I'm sure we'll go on and—I want to make sure we work together to make sure States have that kind of flexibility to do what they do. So I will continue to work with you on that. Thank you.

I will now recognize Mr. Carter of Georgia, who is himself a pharmacist. Thank you.

Mr. CARTER. Thank you, Mr. Chairman. Thank you all for being here on this—what is obviously a very serious subject. I want to start by talking about the legal, if you will, marketing of fentanyl.

We talked about it some during this hearing. One of the—one of the questions I have, I know—I can't remember who it was that mentioned that you're working with the wholesalers, with Cardinal and McKesson in trying to make sure that they're doing their part and accurately pointed out that you need to follow it all the way through the supply chain.

I can tell you as a practising pharmacist for over 30 years that is very important. We need to make sure that happens.

Have you been in contact with any of the manufacturers—Janssen making Duragesic or Mylan makes a generic—about how much they are able to manufacture and put on the market?

Mr. MILIONE. What we are not seeing is a large-scale widespread diversion of legal fentanyl.

Mr. CARTER. Right.

Mr. MILIONE. It's diverted for personal use mostly. What we are dealing with is clandestinely produced fentanyls. We do have engagement with the manufacturers, obviously, for issues that come up and we are happy to work with them.

Mr. CARTER. That's good, and, you know, that is important for a couple of reasons and I would be remiss if I did not point out that one of the problems we had at the dispensing level is not being able to get enough of the product so that the people who truly needed it—cancer patients and those who were truly in need of it—we would run short on them because they'd put monthly limits on us or something of that sort and we weren't able to get it and that was really a tragedy as well. So I hope we keep that in mind as we go along.

One of the things that I was very involved with as a member of the Georgia State legislature was our yearly update of our dangerous drugs and one of the problems we always had was trying to identify the analogues, and I know that has to be a challenge.

Dr. Houry, that is got to be a challenge here, and one of my other colleagues mentioned about the precursors to it and how we control that. One of the—one of the abused substances that I was always chasing was synthetic marijuana and, you know, and identify it and add it into the—each year into the dangerous drug list and then the next year they'd come out with something else.

I even went as far as to try to identify the molecular structure and say anything with this and still it is just so difficult. Can you—can you address that, sir?

Mr. MILIONE. Sure. I mean, that is—the synthetic threat, outside the fentanyl threat, which is significant, is massive. We have identified about 400 different substances.

It's kind of a misnomer to call it synthetic marijuana. It's a synthetic cannabinoid and then you have the cathinones and then a whole other series of these synthetics.

This is a major problem for us, and the same criminal chemists that are tweaking the molecular structures of fentanyl are doing the same when we schedule those cannabinoids.

Very dangerous—one hit can send someone into a coma or have some kind of violent reaction. It's a big problem for first responders but it is a devastating problem because it is sold legally—

Mr. CARTER. Absolutely, and that is one of the problems we had. We had deaths in my district. We had five deaths in Glyn County because of that. They were buying it at the convenience store.

Mr. MILIONE. We cannot keep up—we cannot keep up pace with the emergency scheduling on the cannabinoid cathinone.

Mr. CARTER. Absolutely. We are just chasing our shadows there.

Mr. MILIONE. Right.

Mr. CARTER. And a couple other things, real quickly.

First of all, from what I'm being told by some of the drug agents, particular in Georgia, part of the problem too is just with marijuana coming over. Some of it is laced with fentanyl. Now, that is a big problem.

Now, full disclosure—I am a big, big opponent to the legalization of marijuana. I think it is just a gateway drug. But nevertheless, that seemed to be a problem, too.

Now, before I run out of time, I want to get to a subject that is very important to me and that is mail order drugs and mail order prescriptions coming through the mail, being delivered to patients' houses. That's where we find out so much.

And listen, Mr. Chairman, one of the biggest culprits—the VA. I am telling you, in Georgia, three out of the five facilities that deliver drugs through the mail are the VA clinics and that is a concern and something we need to address.

We have—we have opioids coming through the mail, being delivered, left on the—on the front porch of someone's home. Not even having it signed for, just leaving a box there.

How much of a problem have you found with what the drugs that are coming through our—through our mail system?

Mr. ALLEN. Well, I don't want to imagine what they—on the VA issue we have a number of open investigations and we are trying to work cooperatively with the compliance departments at the VA nationally, at their headquarters also.

But those are definitely areas of significant concern and I think, you know, that is distinguished from the trafficking of counterfeit drugs that are often moved through the mail.

When Representative Burgess talked about going online, there is just a plethora of online pharmacies that are, you know, appearing to sell legitimate pills when in fact they are counterfeit.

Mr. CARTER. Absolutely.

Mr. ALLEN. Those are moved through the mail system on a daily basis.

Mr. CARTER. And I see I'm out of time. But I do want to say that that is a problem we need to be looking at, Mr. Chairman. This committee and this Congress needs to be looking at mail order prescriptions and what's going through our mail now, and I yield back.

Mr. MURPHY. So let me ask the gentleman, who's a pharmacist, along those lines then. As a pharmacist who will see that perhaps you would be picking up patterns of prescribing it in the community as a pharmacist and you would notice perhaps a massive amount coming through but you would not see that on a mail order system at all? You would be completely blind to that? Am I correct?

Mr. CARTER. You—on a mail order system. In other words, pharmacies that are mailing through, if they're legitimate, they should be keeping records of what's going out, yes.

Mr. MURPHY. Well, I used the example before—the gentlelady from Florida was offering West Virginia, which is ground zero for this.

Mr. CARTER. Absolutely.

Mr. MURPHY. That pharmacy may not necessarily see that people are getting it mailed in from out of the area.

Mr. CARTER. Absolutely, especially if it is more than one. Now, you know, the PBM—excuse me, the PDMPs—sorry—that helps tremendously, especially if we can do it over State lines. That is a tremendous help. We've just recently started that in Georgia.

But Florida is one of the States that is still not doing it, and that is a problem because it is a big problem down there.

Mr. MURPHY. Thank you. Appreciate that.

Mr. CARTER. Thank you, Mr. Chair.

Mr. MURPHY. I recognize the vice chairman of the committee, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman, and I want to thank all of the witnesses for being here today. This is a very serious subject. But I've got to refute some things that I have heard today or at least one in particular.

I think we are comparing apples and oranges when we try to bring in fentanyl and opioid abuse into the debate over whether you want Obamacare, Medicaid expansion or the American Health Care Act, and in fact what I've heard repeatedly is that somehow Medicaid expansion has helped to solve this problem.

But the map of deaths of opioid use that we saw earlier that Dr. Burgess put up—and I've got a paper copy here—shows us that is not the case and I think it is apples and oranges.

I don't think Obamacare caused opioid abuse. I don't think that Obamacare is going to solve it on its own. We are trying to find those answers here today.

I don't think the American Health Care Act is going to be able to solve it in and of itself on its own. But when you look at the States where the deaths are—you know, if you're just going to play games with numbers, the expansion States seem to have more deaths than the nonexpansion States.

Now, do I think that is fair? No, I don't. I think that is horse hockey. But I think that what my colleagues on the other side of

the aisle have said about us causing problems by voting for the American Health Care Act is irrelevant to our discussion today.

So with that being said, Dr. Compton, you mentioned the Appalachian Regional Commission—that you're all working on a project with them. What exactly are you doing? That's my turf, in part.

I represent southwest Virginia, the Appalachian regions of southwest Virginia, which of course border hot spot areas for opioid abuse in Kentucky and West Virginia and it spills over into my district as well.

Dr. COMPTON. Well, I certainly remember a terrific meeting in Wise, Virginia. It's a lovely town. They convened a group from all across the Appalachian region to look at this issue several months ago.

Our initiative with the Appalachian Regional Commission is a grant program to look at demonstration projects to improve the public health infrastructure and determine how good a job that'll do to address the opioid crisis in rural parts of the country, and the Appalachian Regional Commission will be co-funding this along with SAMHSA, the CDC and, of course, NIDA taking the lead on it.

Mr. GRIFFITH. Well, we appreciate it because it is a significant problem and one of the issues there that we have to look at is that whether or not the folks started off because of the—it is a high area for disabilities as well. People have done for years a lot of hard manual work and that they get a prescription and then they get hooked.

Dr. Houry, you indicated in Ohio at least that 62 percent of the people who died from opioid, from heroin or fentanyl had—in the last 7 years had a prescription drug for an opioid. Can you talk more about that?

Dr. HOURY. Sure. We've been seeing this in many States. Like in Rhode Island, a third of the people who had overdosed on fentanyl had had an opioid prescription within three months and a third of those had had a high dose opioid prescription, showing that, you know, people that are on prescription opioids get addicted to opioids and can then go on to overdose from heroin or fentanyl.

Mr. GRIFFITH. And sometimes their prescription runs out but they're hooked and is there some way we can connect the doctors recognizing that maybe their patient has gotten hooked to get them the help?

Because if the prescription just ends and nobody's alerting anybody, aren't those a lot of the folks who are going out and buying it then illegally on the streets somewhere?

Dr. HOURY. Well, and I think that is why we've got our CDC prescribing guideline where we did talk in there about if you have a patient that you suspect opioid use disorder on of the importance of linking them to treatment.

And I think one of the things that I've been really proud about the work CDC is doing is although we are funding the States to do what's most important for the States, each month we do technical assistance calls that help then with their data and provide scientific expertise and where to really focus resources and what are the best evidence-based treatments and then have a convening of all the States to share these best practices that way. As we are

seeing different things emerge in different States we can share those.

I think, you know, data does drive action and I heard us talk about should this be a national or a State approach. New Hampshire was number 20 one year for overdoses. The following year, it was number 5.

So I think we need to give States the flexibility to deal with what's going on in their State, but we need to have that overall approach.

Mr. GRIFFITH. Thank you very much.

Mr. MILIONE—if I said that right, and I apologize if I messed it up—but I would be remiss—while I think that marijuana is a dangerous drug I think your testimony here today indicated that fentanyl was your number-one concern and it is—and it is not your jurisdiction so it is a rhetorical question.

I ask you just to take back why don't we let there be more research on marijuana and its ability to help patients whether it be epilepsy or, in this case, pain? Because while I think it is a dangerous drug, I don't think it is as dangerous as fentanyl and other opioids.

With that, Mr. Chairman, I yield back.

Mr. MILIONE. If I could—if I could say in response to that, we support any approved research along those lines. So we will continue to work with the researchers on those things and we support that.

Mr. GRIFFITH. Well, if I might, Mr. Chairman, it is just the problem is as a Schedule I drug it makes it tougher than it would be if it were Schedule II like fentanyl and other opioids.

Mr. MURPHY. Gentleman yields back.

Now, Mr. Pallone for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

The Affordable Care Act, through the expansion of Medicaid, extended health insurance coverage to hundreds of thousands of Americans in urgent need of treatment for opioid use disorders and I'm concerned that if the money is cut from Medicaid, which is what the CBO says would happen with the Republican bill, patients could lose access to care and this could make the fentanyl problem even worse.

So Dr. Compton, in your testimony you state that, and I quote, "opioid addiction is a chronic condition, and many patients will need ongoing treatment for many years."

What could happen to a patient if their treatment for an opioid addiction was interrupted, for example, because the patient no longer had health care coverage for substance use disorders?

Dr. COMPTON. Well, we do know that when treatment is interrupted or stopped, whether that is intentional or unintentional, the risk of relapse is extraordinary.

Mr. PALLONE. Well, thank you.

Now, some health experts estimate that nearly 1.3 million people are receiving treatment for mental health and substance abuse disorders thanks to Medicaid's expansion. Our efforts to curb the opiate epidemic, I believe, could be severely impacted if those now receiving treatment lose their health insurance.

Should the ACA be repealed, we clearly would expect the opioid crisis, and by extension the fentanyl crisis, to worsen.

So Dr. Compton, again, if people who are currently being treated for an opioid use disorder were to lose coverage, would we expect the numbers of overdoses from opioids including opioid containing fentanyl many increase?

Dr. COMPTON. Well, I hesitate to make a prediction when there are so many factors that can play a role here in terms of how States will respond, how the Medicaid system in general will be organized.

Our goal, of course, at NIH and NIDA is to make sure that the research we support is implemented no matter what the health care system is.

Mr. PALLONE. OK. I just use this State of West Virginia as an example because it was very hard hit by or is very hard hit by the opioid epidemic.

A February 6th article by the Pew Charitable Trust reports that West Virginia in fact has the highest opiate overdose death rate in the Nation.

Let me ask Dr. Houry—I don't know if I'm pronouncing it right there—are you aware that West Virginia has one of the highest death rates from opiate overdoses in the U.S.?

Dr. HOURY. Yes.

Mr. PALLONE. And Dr. Compton, that same Pew article reports that the Medicaid expansion has added 173,000 adults to West Virginia's Medicaid program. West Virginia's Medicaid enrollment is now at 573,000 people, which is about a third of the entire State's population, according to the Pew article.

Dr. Compton, Pew also reported that in 2015, the first year that West Virginia expanded Medicaid, the number of people in treatment for substance abuse jumped from 16,000 to 27,000.

The increased use of Medicaid services for substance abuse would suggest that thousands of West Virginians went without needed treatment service prior to Medicaid's expansion. Would that be a fair assumption, Dr. Compton?

Dr. COMPTON. Well, certainly, when we think about States like West Virginia I would point out that the rural aspects make it very complicated to deliver services.

So I am very proud that we are able to implement this new research program in rural areas.

Mr. PALLONE. And it would appear to me that Medicaid is essential in West Virginia's fight against opioid addiction, which would include the growing problem of fentanyl. I guess my last question, again, Dr. Compton, is if West Virginia were to lose these services would we expect that the opioid and fentanyl problems to worsen, assuming that they were—you know, lost Medicaid coverage—those people?

Dr. COMPTON. Well, I can't speak to the implications of the coverage issues but, certainly, for individuals who are being treated, if you stop their treatment abruptly that could be very deleterious.

Mr. PALLONE. I mean, the problem that I see is that the Republican bill with regard to the expansion eliminates the essential services guarantee and what we have found in the past is a lot of times when you don't have that kind of guarantee the first thing

to go is behavioral services, drug treatment, mental health services, things that are expensive and that many States didn't provide until we said in the Medicaid expansion that they would have to. And I just think that between the cutbacks that would occur, because States would be getting less money, they're going to get less money, they don't necessarily have to cover people depending upon their income, you know, as the—as they reduce the Medicaid expansion population, and then even with the traditional Medicaid or any kind of population if there is no guarantee of essential services then, you know, the first thing that often is cut back is treatment for drugs.

So that is my fear and that is why I think that this is devastating if we are trying to deal with fentanyl and some of these other opiate problems that we have.

So thank you all. Thank you, Mr. Chairman.

Mr. MURPHY. Thank you. The gentleman yields back.

I recognize Mrs. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman, and thanks to everybody on the panel for your incredibly important work.

I must say that fentanyl is not a new problem. I was U.S. Attorney in Southern District of Indiana from '01 to '07. I learned about fentanyl then.

But, yet, we didn't talk about it much the way we focused on methamphetamine and the dangers, for instance, to children, to the environment.

What we are not talking about in the country is the danger. We talk about the overdoses and now seeing the incredible increase in overdoses.

But can we talk a little bit about truly how just dangerous fentanyl is as a product? And I realize that this gets a little dicey because we use it in medical procedures. But I think, having just been with law enforcement and firefighters this past weekend, there are dangers, are there not, Mr. Allen, and that is part of why you're doing training?

And I want to ask you, Mr. Milione, can you talk to us about the dangers of fentanyl and why haven't we, for a long time now, talked about the incredible danger?

Because I don't think addicts and I don't think their families really have understood how incredibly dangerous it is.

Mr. ALLEN. I would say that in the law enforcement community we have been. I would say since the recent surge in fentanyl one of the key things that we have gotten out to the law enforcement community, largely following the lead of DEA, is making awareness to our personnel, to public safety personnel generally, what they could be encountering.

For us operationally it has changed how we do some of our work. One of the investigative techniques that we have done historically is to purchase drugs, whether it is online or domestically and online.

We stopped doing that because of the officer safety concerns that we have that could be inherent to an undercover agent buying drugs or a State and local officer buying drugs and not necessarily knowing what they're purchasing.

There's also a challenge for us from the perspective of field testing. You know, gone are the days, glorified in a lot of television shows, of agents, you know, pulling out a pocket knife and probing a package of suspected drugs and putting that into a test kit.

We, particularly at DHS and within DHS Customs and Border Protection, have taken the lead on trying to examine and explore and field non-intrusive testing that would allow us to go to a place where agents don't have to physically open a package in order to determine what the substance is inside.

Mrs. BROOKS. Mr. Milione, why is there a surge in fentanyl? What is your DEA—and I know you've been at this for a long time—but what would you say is the cause behind the surge that we have been seeing?

Mr. MILIONE. It's free-market principles applied to the convergence of the opioid epidemic with massive profits that can be made, and cartels and criminal groups that are exploiting that, they see the opportunity.

They aggressively market the small amount of fentanyl. They can—they don't have to deal with the massive bulk of heroin and they can get so much more profit out of that. So that is one of the things.

Mrs. BROOKS. But they don't care that it is killing their customers because there are more that just—pipeline?

Mr. MILIONE. In a perverse—in a—I mean, and it is very callous but it is the cost of doing business and I think some of the medical professionals on the panel would say unfortunately there is a perverse, sometimes, reaction when people overdose from high-potency fentanyl. It sometimes attracts more attention to that product.

Mrs. BROOKS. Any idea what the stats are of how many cases we've been charging in the last year or two causing death? Federal cases where we are actually prosecuting drug traffickers for causing death?

Mr. MILIONE. I would have to get back to you with specific statistics. But we are doing more and more of those around the country—death resulting cases, working with the U.S. Attorneys' offices, engaging with the U.S. Attorneys, trying to get them to lean forward and work cooperatively on that. It is definitely what we are focused on.

Mrs. BROOKS. And I guess going to Dr. Houry's comment, is part of the challenge, maybe for a U.S. Attorney, is that coroners are not keeping track of and going into that much detail on the cause of death, which could be a problem, I could see, for a U.S. Attorney, but should we be—should we be asking or requiring coroners to do a better job on that aspect?

Dr. HOURY. I think it is a resource issue for coroners and medical examiners. When you look at the opioid epidemic and the number of deaths that they are now doing cases on, oftentimes they don't have the resources in their community to do that testing for fentanyl or they don't have the labs. They have to send it out, which is additional funding that they need.

Mrs. BROOKS. Besides the labs, what kind of resources would they need to do the testing aside a heroin death or a fentanyl death?

Dr. HOURY. So they would need the lab to distinguish the type of analogue. I think also it is helpful to have the medical examiner through the family history and so forth to determine if this was an unintentional overdose, was this a legal fentanyl where you can see the injection or other paraphernalia associated with it. But I would say it is really the testing for the laboratory and the training as well.

Mrs. BROOKS. Thank you. I yield back.

Mr. MURPHY. Mr. Walberg, you're recognized for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman, and also thank you to the panel. It is clear from your testimony and the questions that you live in a world that is difficult, frustrating, challenging, ugly. But you're doing a great job for us and we appreciate that.

My home State of Michigan shares over 700 miles of land and water border with Canada as part of the longest border in the world.

Mr. Milione, does DEA have precise data on how much fentanyl is coming in directly from Canada?

Mr. MILIONE. We can—we have the data as to what's been seized but that is—there is a certain flaw in that. We don't know exactly what is coming in but we know what we have seized and we can get those statistics to you.

It is imperfect, though, because there are networks that are finding any porous entry to be able to get it in. So—

Mr. WALBERG. Having flown over the entry from Detroit River into Lake Erie and seeing the creative and amazing ways that people will find to cross that water border and seeing the efforts by Customs and Border Patrol as well as ICE and others to interdict that, I would agree with you. It is probably very difficult.

But significant amount coming across?

Mr. MILIONE. Significant in the sense that that is one of our—the main threat streams—China to Canada, Canada across our northern border.

Mr. WALBERG. Mr. Allen, do you have numbers on how much fentanyl ICE has interdicted from Canada and are there hot spots along the northern border?

Mr. ALLEN. What we—what the DHS components, both ICE and CBP, have seized coming from Canada is primarily coming in through consignment and mail, not necessarily along the physical land border with Canada.

Mr. WALBERG. Consignment and mail?

Mr. ALLEN. And mail.

Mr. WALBERG. OK. Mr. Allen, in your written testimony you mention that ISIS met with Canadian officials to share trends and targeting strategies in fentanyl-related investigations.

Can you talk a little bit more about this effort and does your agency intend to expand the coordination with Canada?

Mr. ALLEN. Well, we work along with the Department of State and DEA in that effort. We are meeting with Canadian counterparts, Mexican counterparts and Chinese counterparts, as you have heard today, and I do think that expanding the exchange of information with both source and transit countries is going to be part of how we improve what we do and recognizing that some of the fentanyl that makes its way to the United States either directly

from China or via other places is also in the same stream that makes its way to Canada and Mexico as well.

Mr. WALBERG. I mean, it is great to have a border neighbor that generally we can work pretty well with.

Mr. ALLEN. I would add, you know, one of the things that distinguishes the relationship between the U.S. and Canada and China and Mexico is that the Canadians have come to us and talked about them having a very similar and significant problem that we are.

Mr. WALBERG. I have supported legislation in the last two Congresses introduced by my colleague, Pat Tiberi, called the STOP Act, which, as you know, aims to stop the shipment of synthetic drugs like fentanyl and carfentanil into the U.S.

The bill would require shipments from foreign countries through our postal system to provide electronic advanced data like where it is coming from, who it is going to and what is in it before crossing our borders into the U.S.

Mr. Allen, how would this information help better target illegal drug shipments and keep these dangerous elements out of our communities?

Mr. ALLEN. That would assist primarily Customs and Border Protection, which takes the lead on interdiction, by giving them advanced information that they could use at places like the National Targeting Center to be more effective and more efficient in targeting mail that is coming to the United States.

As we have heard earlier, one of the things that constrains the ability of the—what information the postal—U.S. Postal Service has in advance is the Universal Postal Union and my understanding of the STOP Act is that it would require us to update the UPU through negotiations led by the State Department to provide more and more timely information that would assist CBP in targeting.

Mr. WALBERG. Are there additional steps Congress should consider along with that taking to assist your efforts to identify and stop these shipments?

Mr. ALLEN. None that come to mind.

Mr. WALBERG. Anyone? Thank you, Mr. Chairman. I yield back.

Mr. MURPHY. Now I will recognize another member of the full committee, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you so much, Mr. Chairman. I appreciate it. Thanks for allowing me to ask the questions and I really appreciate the panel being here. This is such a very important issue. It affects all our districts.

Mr. Chester, a lot of people are aware of opioid abuse like OxyContin or heroin but not fentanyl. Is that the case?

And then what are the educational outreach programs currently underway and what resources are available for communities who want to get the message out? I think that is important. If you could answer that question I would appreciate it.

Mr. CHESTER. Yes, Congressman. As I stated earlier, kind of the components of how we are dealing with this comprehensively is to prevent an issue as to drug use, provide treatment for those who are addicted to these drugs and then stop the flow of the drugs coming in to the United States.

In terms of prevention, one of the primary mechanisms that we use in ONDCP is the Drug-Free Communities program. The Drug-Free Communities program, which is funded by ONDCP and is managed by the Substance Abuse and Mental Health Services Administration, is in thousands of communities around the country as a prevention program that is focused on individual needs of individual communities.

Local communities require local solutions and it is a coalition of 12 community members that are focused on the needs of that particular community not only to raise awareness of drug issues but prevent primary drug use or initiation of primary drug use focused on the demographic of about 13 to 17 years old, which is the target demographic for that program. Very effective program.

Mr. BILIRAKIS. It has been effective? OK. Very good.

Mr. Milione and Mr. Allen, as you mentioned earlier, China announced its intention to ban the manufacture and sale of four additional types of fentanyl.

Can you discuss our working relationship with China to prevent entry and sale and are there mechanisms to hold China accountable to its commitment to ban fentanyl?

Mr. MILIONE. Our relationship on the law enforcement working level has been tremendous. Our administrator, Acting Administrator Chuck Rosenberg, was recently in China and met with our counterparts.

As a result of those meetings and shortly thereafter and working with the State Department they agreed to schedule these four—one of them carfentanil, which is 10,000 times more potent than morphine.

These are significant steps. The other positive thing has been, when they initiated investigations in China, there has been real bilateral sharing.

They provided us leads of domestic-based distributors that are—that are ordering fentanyl and that is really helped flush out these networks and now these investigations are ongoing.

So we've been very pleased with the cooperation. We hope it continues and, certainly, it can expand.

Mr. BILIRAKIS. Very good.

Mr. ALLEN. And I would only echo that. The Chinese Government has provided DHS with seizure—information about seizures made in China on their way to the United States and we have been able to use that information to, as Mr. Milione said, identify other individuals and organizations that have received shipments from the same points of origin in China that has allowed us to begin investigation.

Mr. BILIRAKIS. Thank you.

Mr. BROWNFIELD. Finally, Congressman, if I could add one more point from the State Department's side.

Mr. BILIRAKIS. Please go ahead. Please. Please.

Mr. BROWNFIELD. Beginning a little over a year ago, we reached a bilateral understanding with the Chinese Government that they would control the delivery of products from China to the U.S., even if they were not controlled in China if they were controlled in the U.S., in exchange for which we made the same commitment to them.

Now, it is not enforceable in any sort of international organization. But it is an agreement that we reached between ourselves as two governments.

Mr. BILIRAKIS. Thank you.

Dr. Houry, in your testimony you mentioned that CDC is committed to giving providers and health systems the tools they need to improve how opioids are used and prescribed.

Can you discuss these tools and how communities can take advantage of these tools?

Dr. HOURY. Absolutely. We have really had a multi-pronged approach. One is just through education. We have been working with—directly with medical schools and nursing schools on pre-clinical training on effective pain management and safe prescribing practices.

We have also developed seven continuing education webinars that are available for free for providers on our Web site around safe prescribing of opioids, and with the guideline itself—I am a practising physician. I know you have to have something that you can use.

So we have a checklist that is been downloaded more than 25,000 times by providers to use and we also now have a mobile app on our phone around the guideline that has things on motivational interviewing and how do you talk with a patient about these difficult decisions on whether or not to give an opioid, a calculator to help you calculate what's the appropriate and safe dose of an opioid to give.

And we are also—we have piloted a community education program and awareness around the risks of opioids in 10 cities that were hardest hit.

Mr. BILIRAKIS. Very good. I would like to talk to you about possibly coming to my area in Florida, the Tampa Bay area, if you haven't already.

Dr. HOURY. I would welcome that.

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

Mr. MURPHY. Gentleman yields back.

Now, just some closing comments. Ms. DeGette, 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

I just wanted to respond to what our colleague, Mr. Griffith, said about the ACA. Certainly, nobody thinks that the shocking increase in opioid and heroin use is in any way related to the ACA, and we recognize that some of those areas where we do have the Medicaid expansion are the areas which are the red on the map, and that is quite disturbing.

Our point, though, is that, if we hope to treat these folks who are getting addicted to opioids, it is important that they have access to medical treatment, and that is why we are concerned if the Medicaid expansion is retracted, because in those States the Medicaid expansion has helped many people who have—who need to have addiction treatment, which is extensive.

And to that end, I have a letter dated March 20th, 2017, from the Oregon AFSCME which talks about the Medicaid expansion in Oregon and how many people would lose their Medicaid expansion

and their treatment for opioid addiction if the Republican alternative passed this week.

And I would like to ask unanimous consent to put a copy of that letter into the record, Mr. Chairman.

Mr. MURPHY. Without objection.

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

Ms. DEGETTE. Thank you. I yield back.

Mr. MURPHY. Gentlelady yields back.

Just a couple of questions that I have. Mr. Chester, do you have any idea how many Federal agencies are there that deal with substance abuse across all spectrums and all departments?

Mr. CHESTER. I do not have that answer off the top of my head, but I would like to follow up with you, if I can, on that.

[The information follows:]

Office of National Drug Control Policy (ONDCP): There are a total of 13 Federal Departments and 40 independent Federal agencies and department bureaus designated as Drug Control Program agencies that report funding as part of the drug control program. An overview of the support provided to the drug control program by these Departments and agencies is provided in the ONDCP FY 2017 Budget and Performance Summary. In addition, ONDCP works with many other Federal departments and agencies on issues that relate to the development and implementation drug control policies and programs needed to support the National Drug Control Strategy.

Mr. MURPHY. Good. And I know when we asked GAO to do the scenario of mental illness they said at least 112, but it is probably more. They just couldn't figure this out. I don't know how many there are.

I know one of the things this committee did in our mental health bill was tasked the Assistant Secretary of Mental Health and Substance Abuse to coordinate these 112 Federal agencies on efforts in the area of mental illness. Goodness knows how many there are in substance abuse.

And it is a question that I want you all to let us know—I need some answer to—as well as getting back to us that what would you suggest that this administration do in working with Congress to combat this deadly, deadly problem.

I mean, we will have meetings—we will have intense hearings here on things like Ebola, which affects a couple American lives, or on flu, which is thousands of deaths every year.

But we are far past that with fentanyl and opioids and we see towns devastated. And so we do need your suggestions. We want to work together. And I say to my colleague, too, you and I have a shared passion in this area.

It is absolutely unquestionable and this is one we have to be working together. As I said before, there is no silver bullet. States have to handle this a different way.

What was affecting things in West Virginia with perhaps some prescription practices that Ms. Castor pointed out and disability rates and unemployment rates may be very different from Massachusetts or Utah or anywhere else, and I want to make sure States have full flexibility.

So I look forward to saying, let's stay committed to this. We'll get answers to this together.

And I also would ask, Mr. Chester, there is a letter we sent February 23rd, a bipartisan letter with several questions. You may be aware of that.

Any idea when we can expect some answers to that?

Mr. CHESTER. Yes, Congressman. It is in final—the letter is complete. It is in final interagency clearance. We hoped to get it to you this morning, but we will get it to you as soon as possible.

Mr. MURPHY. Thank you. Appreciate that.

Mr. CHESTER. Thank you for the letter.

Mr. MURPHY. Yes. Now, let me just say that in conclusion I want to thank all the witnesses and members that participated in today's hearing and remind members you have 10 business days to submit questions for the record so the witnesses have time to respond to those.

And with that, I again thank the witnesses. This is a very important hearing on a critically important issue for our Nation. We look forward to working with you again until we have this issue addressed.

And with that, this hearing is adjourned.

[Whereupon, at 12:36 p.m., the hearing was adjourned.]

[Material submitted for inclusion in the record follows:]



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 17, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis"

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, March 21, 2017, at 10:15 a.m. in 2123 Rayburn House Office Building, entitled "Fentanyl: The Next Wave of the Opioid Crisis." The United States is experiencing an epidemic of opioid abuse and addiction, with drug overdose deaths increasing over the last two decades and becoming the leading cause of injury death in the U.S. In the early 21st century, overdose deaths primarily involved prescription opioids and then later, around 2005, heroin. Increasingly since 2013, opioid overdose deaths involve fentanyl, the apparent next wave of the opioid epidemic.

This hearing will examine the unique and emerging public health threat of fentanyl, a synthetic opioid. Since 2013, fentanyl and its analogues have contributed to at least 5,000 overdose deaths in the United States. As fentanyl is becoming the leading driver of drug overdose deaths in more states, this hearing will also examine the federal government's strategy to combat the fentanyl threat and how to strengthen the federal response to this crisis.

I. WITNESSES

- Kemp Chester, Acting Deputy Director, Office of National Drug Control Policy (ONDCP);
- Louis Milione, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA);
- William Brownfield, Assistant Secretary of State, International Narcotics and Law Enforcement Affairs, U.S. Department of State;
- Matthew Allen, Assistant Director, Homeland Security Investigative Programs, Homeland Security Investigations, U.S. Immigration and Customs Enforcement, Department of Homeland Security (DHS);
- Debra Houry, M.D., M.P.H., Director, National Center for Injury Prevention and Control, Center for Disease Control and Prevention (CDC); and

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- Wilson Compton, M.D., M.P.E., Deputy Director, National Institute on Drug Abuse (NIDA).

II. BACKGROUND

a. Committee activity on the opioid epidemic

113th and 114th Congresses. The subcommittee held a series of hearings, beginning in April 2014 and continuing into early 2015 that examined the growing problem of prescription drugs and heroin abuse nationwide and evaluated solutions to address the crisis. In the course of these hearings, the subcommittee heard testimony from the federal, state, and local levels, and developed a record demonstrating not only the various factors contributing to the opioid abuse epidemic, but also a number of possible solutions. Solutions presented at these subcommittee hearings helped inform the committee's legislative efforts ultimately enacted into law as part of the Comprehensive Addiction and Recovery Act, followed by authorized funding included in the 21st Century Cures Act.

115th Congress. Earlier this year the committee began focusing on the synthetic opioid, fentanyl, which "has spawned a deadly drug crisis in the United States."¹ On February 23, 2017, the bipartisan leaders of the full committee and the subcommittee sent a letter to the Acting Director of the Office of National Drug Control Policy (ONDCP) seeking details about the fentanyl problem, actions taken, and any strategic plan to address the fentanyl threat.² As of the date of this memorandum, the committee has not yet received a response from ONDCP.

b. Scope of the fentanyl problem

What is fentanyl? Fentanyl is a synthetic (man-made) opioid.³ The drug resembles morphine, but is about 50 times more potent than heroin and 100 times more potent than morphine.⁴ Fentanyl was developed in 1959 and approved by the Food and Drug Administration (FDA) to treat severe pain, especially in patients with cancer and severe diseases. There are two types of fentanyl: 1) *pharmaceutical fentanyl*, which is primarily prescribed to manage acute and chronic pain associated with advanced cancer, and 2) *non-pharmaceutical fentanyl*, which is illicitly manufactured, and is often mixed with heroin and/or cocaine—with or without the user's knowledge—in order to increase the drug's effect.⁵ Available information from multiple

¹ Press Release, U.S. Drug Enforcement Admin., *DEA Warning to Police and Public: Fentanyl Exposure Kills*, June 10, 2016, <https://www.dea.gov/divisions/hq/2016/hq061016.shtml>.

² Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy & Commerce, Hon. Tim Murphy, Chairman, Subcommittee on Oversight and Investigations, & Hon. Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations, to Mr. Kemp Chester, Acting Director, ONDCP (Feb. 23, 2017).

³ Centers for Disease Control & Prevention, *Fentanyl: Incapacitating Agent*, available at https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750022.html (last accessed Mar. 15, 2017).

⁴ Centers for Disease Control & Prevention, *Injury Prevention & Control: Opioid Overdose, Synthetic Opioid Data*, available at <https://www.cdc.gov/drugoverdose/data/fentanyl.html> (last updated Dec. 16, 2016).

⁵ *Id.*

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agencies and companies indicates that the current public health threat of fentanyl is not sourced significantly from the diversion of legitimate fentanyl.

Fentanyl analogues. Besides its high potency, another challenge with fentanyl is the number of analogues, or chemical variations, of the drug. A structural analogue, also known as a chemical analogue or simply an analogue, is a compound having a structure similar to that of another one, but differing slightly in composition. Because the drug is synthetic, and therefore man-made, the drug's chemical composition can be altered slightly to avoid scheduling regulations, yet still maintain its chemical and biological properties. This also makes it harder to detect in comparison to other drugs, such as heroin. As of June 2016, there were 30 known analogues of fentanyl. However, only 19 of these analogues are scheduled as controlled substances. While that number seems small, due to the simplistic nature of only needing to alter a small component of the drug's chemical makeup, there is potentially a far higher number of fentanyl analogues that have yet to be devised and manufactured.⁶

Carfentanil. The most notorious analogue is carfentanil, a drug that is typically used to sedate large animals, such as elephants. According to the Drug Enforcement Administration (DEA), carfentanil is 100 times stronger than fentanyl. This drug is so potent that less than a grain of table salt (0.02 milligrams) can be lethal.⁷ Carfentanil was responsible for an unprecedented 174 overdoses in six days—about seven times the usual rate⁸—and at least eight overdose deaths in the Cincinnati, Ohio area in August 2016.⁹ More recently, an investigation conducted by committee staff found open source websites advertising carfentanil, in addition to other fentanyl products, under the guise of selling “research chemicals.”

Fentanyl as a weapon. In addition to the obvious health concerns that this deadly drug poses, as well as the danger to first responders, concerns have been raised that this drug could be weaponized.¹⁰ This is yet another reason for law enforcement and intelligence agencies to be engaged with the fentanyl issue.

Fentanyl is often hidden and very dangerous. Two milligrams of fentanyl is potentially lethal for a human being, therefore only minute amounts of fentanyl are necessary to produce effects similar to heroin. Since 2013,¹¹ fentanyl and its analogues have contributed to at least

⁶ R.S. Vardanyan and V.J. Hurby, *Fentanyl-related compounds and derivatives: current status and future prospects for pharmaceutical applications*, 6 *Future Medicinal Chemistry* (2014).

⁷ Max Kalinowicz, *10 million lethal doses of carfentanil seized at Mirabel Airport*, GLOBAL NEWS (Jan. 18, 2017), <http://globalnews.ca/news/3190310/10-million-lethal-doses-of-carfentanil-seized-at-mirabel-airport/>.

⁸ Katie Mettier, *This is unprecedented: 174 heroin overdoses in 6 days in Cincinnati*, WASH. POST (Aug. 29, 2016), https://www.washingtonpost.com/news/morning-mix/wp/2016/08/29/this-is-unprecedented-174-heroin-overdoses-in-6-days-in-cincinnati/?utm_term=.22f13b23ea6e. On average, Cincinnati has 4 overdose reports per day, and usually no more than 20 or 25 in a given week.

⁹ Remarks by U.S. Attorney Zachary T. Fardon at Northwestern University Pritzker School of Law (Oct. 20, 2016) available at <https://www.justice.gov/usao-ndil/pr/remarks-us-attorney-zachary-t-fardon-northwestern-university-pritzker-school-law-oct-20>.

¹⁰ Although the hearing and memorandum is focused on fentanyl use as an illicit drug, it should be noted that the National Institute on Occupational Safety and Health (NIOSH) has provided information and recommendations to address “a wide area release of fentanyl as a weapon of terrorism.”

¹¹ Dear Colleague letter from H. Westley Clark, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA) (July 15, 2013) (“Many of you will remember the period

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5,000 overdose deaths in the U.S.¹² The fentanyl crisis is significantly more dangerous than other opioids because of its high potency and the speed with which it reaches the brain. Fentanyl has taken on a silent but deadly characterization because it is most often laced with other drugs such as heroin, cocaine, and counterfeit pills that are advertised to be a more common opioid, such as generic Xanax.¹³ Often times, individuals did not specifically seek out fentanyl and do not know that they are taking something that has fentanyl in it. That danger, combined with the high potency of the drug, creates a high risk of overdose.

Emergency responders have found patients dead before the victim has finished injecting, needles still in hand. The lethality of fentanyl also undermines the effectiveness of evidence-based public health strategies. Fentanyl's rapid effect narrows the window for rescue with the overdose reversal drug, naloxone, and may require both higher doses and multiple administrations to reverse an overdose and stabilize a patient.¹⁴ Fentanyls also pose a "grave threat to law enforcement officials and first responders" since a lethal dose can be accidentally inhaled or absorbed through the skin.¹⁵ An open question is whether an individual's opioid dependency is increased when they take heroin laced with fentanyl versus taking pure heroin, and whether the combination with fentanyl makes opioid addiction even more difficult to treat.

Drug overdose trends. Drug-poisoning (overdose) is now the leading cause of death from injury in the U.S., surpassing motor vehicle accidents, suicide, firearms, and homicide. Deaths from fentanyl and other synthetic opioids are reaching epidemic proportions as well. Nationwide, "[t]he death rate of synthetic opioids other than methadone, which includes drugs such as tramadol and fentanyl, increased by 72.2% from 2014 to 2015, with a total of 9,580 deaths in 2015."¹⁶ As shown in the following table, synthetic opioid death rates (other than methadone) increased across all demographics, regions, and numerous states.¹⁷

from 2005 through 2007 when illicit fentanyl-laced heroin caused a great number of overdose deaths. That was not the first time illicit fentanyl, also called fentanyl analogues, entered the drug market, and likely will not be the last. Recently, small clusters of overdoses and overdose fatalities in a variety of communities, mostly in the eastern United States, have raised alarm. Little is fully known about the situation but it appears fentanyl analogues are involved in at least some of the cases, and may be contaminating both heroin and cocaine.”)

¹² R.A. Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65 *MMWR* 1445 (Dec. 30, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

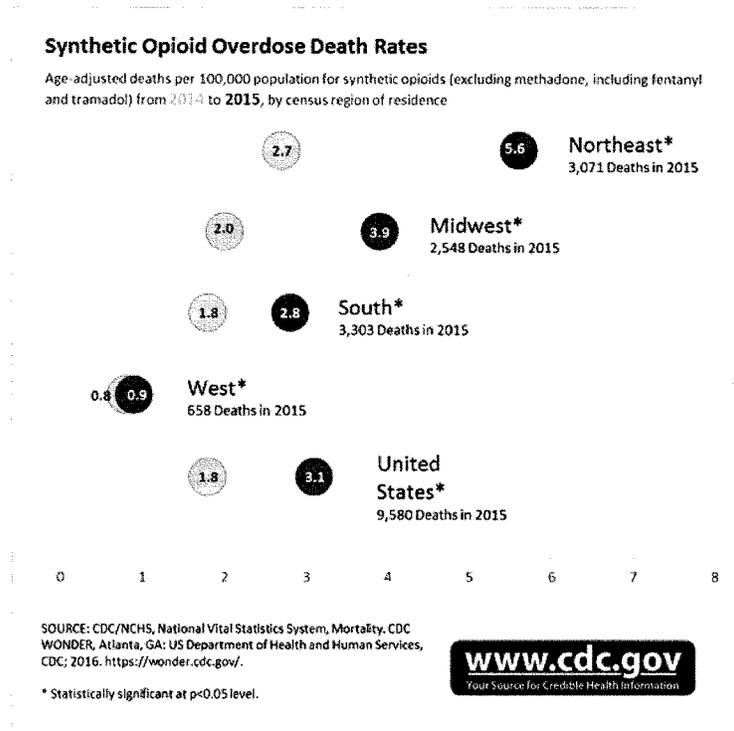
¹³ For example, between January and March 2016, nine people died from counterfeit Xanax pills, a benzodiazepine, containing fentanyl in Pinellas County, Florida. “This demonstrates that though traffickers are interested in expanding the fentanyl market to other counterfeit opioid medications, they are also willing to utilize fentanyls in other non-opiate drugs with exploitable user populations.” Drug Enforcement Admin., *DEA Intelligence Brief, Counterfeit Prescription Pills Containing Fentanyls: A Global Threat*, DEA-DCT-DIB-021016, 6 (July 2016).

¹⁴ In 40 percent of the fentanyl overdose deaths, naloxone was administered. However, when it was not used, it was often because the victim was already deceased by the time first responders arrived. The increased potency of fentanyl in most cases required at least two and sometimes up to six doses of naloxone for a rescue, according to John Halpin, M.D., M.P.H., medical officer with the Division of Unintentional Injury Prevention at CDC. Alison Knopf, *Rx Summit: Fentanyl overdoses outpace heroin*, Behavioral Healthcare Executive, (Mar. 30, 2016), <http://www.behavioral.net/article/rx-summit-fentanyl-overdoses-outpace-heroin>

¹⁵ DEA Intelligence Brief, *supra* note 13, at 2.

¹⁶ Centers for Disease Control & Prevention, *Morbidity and Mortality Weekly Report, Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, (Dec. 16, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

¹⁷ Centers for Disease Control & Prevention, *Injury Prevention & Control: Opioid Overdose, Synthetic Opioid Data*, (Dec. 16, 2016), available at <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.



Limited data on fentanyl overdoses. Unfortunately, definitive national data on fentanyl overdoses is not available. The Centers for Disease Control and Prevention (CDC) is unable to report fentanyl-specific data because fentanyl-related overdose reports are not available in a significant number of states. In addition, there historically has been an 18 to 24 month time lag for CDC to report overdose data, although CDC recently was able to reduce the time lag to 12 months.¹⁸ That said, the CDC has reported to committee staff that there were 11 states with fentanyl-related overdose data from 2013-2015 and 13 states with fentanyl-related overdose data

¹⁸ Email from Staff, Centers for Disease Control & Prevention, to Staff, H. Comm. on Energy & Commerce (Mar. 15, 2017) (“In the past, the 18-24 month delay was due to the pace at which the states can collect, process and report back the data (based on their individual capacity). However, we [CDC] have been working to decrease the “lag” time by providing funding and technical assistance to the states. This year, we [CDC] reported out the 2015 data in December of 2016, so 12 months after the end of the collection period (i.e. the year”).

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from 2015.¹⁹ Because the analysis is considered preliminary and there are key limitations with the state data, CDC advised that additional work is needed before the data can be released to the public.²⁰ Without citing specific statistics, committee staff can confirm that the CDC reported that the preliminary 2016 drug overdose data from a few states showed that fentanyl-related overdose deaths continued to increase.²¹

Due to a lag or lack of knowledge and technology with respect to testing and detection, many municipalities are just beginning to differentiate fentanyl-related deaths from other drug-related overdose deaths. As a result of the data gap, there may be a much higher rate of overdose-related deaths attributable to fentanyl that have not been detected or reported. As a DEA report noted, the deaths related to fentanyl in the U.S. are largely believed to be underestimated due to variations in state reporting techniques and deaths being attributed to heroin or other drugs.²² Test results of illicit drugs also suggest greater fentanyl contamination than assumed. For example, a recent analysis in Canada showed that fentanyl was present in 89 percent of seized counterfeit Oxycontin tablets.²³ Likewise, a supervised injection facility in Vancouver, British Columbia, using a drug checking service over the summer of 2016, found 86 percent of the samples contained fentanyl, many of which were presumed to be methamphetamine, heroin, or cocaine.²⁴

In addition to not having adequate data on the fentanyl threat, unless states and localities make the extra effort of identifying what kind of opioid was the cause of death, they may not get the levels of naloxone that they need.²⁵

The fentanyl threat is spreading. The title of an ABC News article from January 4, 2017, “Fentanyl Deaths Have Spiked Across the US, With No Sign of Slowing Down,”²⁶ summarizes the problem that our country currently faces. Fentanyl is more than an emerging regional problem; in the past 15 months, its presence and danger throughout the nation has greatly escalated. Current statistics from the CDC and other federal entities show data results as of 2015. Yet from January 2016 through March 2017, there has been a significant increase of fentanyl and fentanyl-related overdoses, overdose-related deaths, and arrests. While these incidents have been most prevalent in certain regions of the country, they are not limited to certain localities. For example, two of the largest arrests for fentanyl seized in pill form have occurred in San

¹⁹ Attachment to email from Staff, Centers for Disease Control & Prevention, to Staff, H. Comm. on Energy & Commerce (Feb. 22, 2017).

²⁰ *Id.*

²¹ *Id.*

²² DEA Intelligence Brief, *supra* note 13, at 2.

²³ R.G. Frank and H.A. Pollack, *Addressing the Fentanyl Threat to Public Health*, 376 NEJM 606 (Feb. 22, 2017).

²⁴ Press Release, *86% of drugs checked at Insite contain fentanyl*, Vancouver Coastal Health, Aug. 31, 2016, available at <http://www.vch.ca/about-us/news/news-releases/86-of-drugs-checked-at-insite-contain-fentanyl>!%20.

²⁵ Deanna Allbrittin, *Proposal to track drugs in Indiana overdose deaths*, FOX 59 (Jan. 11, 2017), <http://fox59.com/2017/01/11/proposal-to-track-drugs-in-indiana-overdose-deaths/>.

²⁶ *Id.*

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Francisco in June 2016²⁷ and in Utah in November 2016.²⁸ Further, a man was extradited from Panama to Fargo, North Dakota, in January 2017, to face charges of leading a drug ring and arranging for fentanyl to be brought from China and Canada into Portland, Oregon and Fargo, North Dakota.²⁹

While there have been frightening spikes in overdoses and fentanyl-related overdose deaths throughout Ohio and New England in 2016, there have been significant increases in other areas across the country:

- Sacramento County, California with a reported 52 overdoses, 12 deaths in January 2017;³⁰
- The metropolitan Denver, Colorado area in November 2016 with a reported 31 overdose-related deaths in 4 counties;³¹
- Chicago's Cook County, Illinois with a reported 380 deaths as of early December 2016;³²
- Miami-Dade County, Florida where there have been a reported 228 deaths, triple the 2015 total, and 107 deaths from carfentanil alone as of November 2016;³³ and
- North Carolina, where fentanyl-related overdose deaths increased from 165 in 2014 to 226 in 2015 and to 321 in 2016.³⁴

Fentanyl much more lucrative than heroin. In comparison to heroin, fentanyl is a much more lucrative business for those selling the synthetic drug, including the cartels that are smuggling it into the U.S. For example, a kilogram of heroin purchased from Colombia for roughly \$6,000 can be sold wholesale for \$80,000, according to DEA data. However, a kilogram of pure fentanyl, purchased from China for less than \$5,000, is so potent that it can be stretched

²⁷ 3 Arrested, Accused of Manufacturing Fentanyl-laced Pills Out of SF Sunset District, SAN FRANCISCO KTVU (June 13, 2016), <http://www.ktvu.com/news/158680472-story>.

²⁸ Courtney Tanner, *Thousands of Fentanyl Pills Confiscated in Utah Drug Raid*, SALT LAKE TRIB. (Nov. 22, 2016), <http://www.sltrib.com/news/4623595-155/thousands-of-fentanyl-pills-confiscated-in-utah-drug-raid>.

²⁹ April Baumgarten *Suspected Ringleader In Deadly Fentanyl Case Extradited to North Dakota*, BISMARCK TRIB. (Jan. 26, 2017), http://bismarcktribune.com/news/state-and-regional/suspected-ringleader-in-deadly-fentanyl-case-extradited-to-north-dakota/article_e082cad1-0bad-5974-8480-20c8b1bcf7a8.html.

³⁰ Sarah Heise, *12th Fentanyl Death Reported in Sacramento County; 52 Overdoses Reported in Sacramento County; 2 Deaths in Yolo County*, KCRA (Jan. 26, 2017), <http://www.kcra.com/article/12th-fentanyl-death-reported-in-sacramento-county/6428294>.

³¹ Jennifer Brice *As Fentanyl Overdoses Increase, Officers Get Special Safety Training*, CBS DENVER (Nov. 14, 2016), <http://denver.cbslocal.com/2016/11/14/as-fentanyl-overdoses-increase-officers-get-special-safety-training/>.

³² John Keilman, *Lethal Synthetic 'Super Heroin' Triggers 1st Cook County Overdose Death*, CHICAGO TRIB. (Dec. 9, 2016), <http://www.chicagotribune.com/news/local/breaking/ct-chicago-super-heroin-opioid-analog-deaths-met-20161209-story.html>.

³³ Mike Clary, *South Florida's Opioid Overdose Crisis: At Least 800 Expected to Die by End of 2016*, SUN SENTINEL (Nov. 20, 2016), <http://www.sun-sentinel.com/local/fl-heroin-overdose-epidemic-20161120-story.html>.

³⁴ Pierre Thomas, et al., *Fentanyl Deaths Have Spiked Across the US, With No Sign of Slowing Down*, ABC NEWS (Jan. 4, 2017), <http://abcnews.go.com/US/fentanyl-deaths-spiked-us-sign-slowng/story?id=44554601>.

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into 16 to 24 kilograms when using cutting agents like talcum powder or caffeine. Each kilogram of cut fentanyl can be sold wholesale for \$80,000—for a total profit in the neighborhood of \$1.6 million.³⁵ Because of this profitability, fentanyl is expected to become even more prevalent in the illicit drug market and spread further throughout the U.S. Although there is not comprehensive importation data related to fentanyl, data made available to committee staff substantiate a surge in illicit fentanyl.

c. Source of the Fentanyl Problem

China is a primary source country. According to the DEA, China is the main source of both illicit manufacturing of pure fentanyl as well as the ingredients, also known as precursors, that are being shipped to other countries for manufacturing of fentanyl. Fentanyl is illicitly manufactured in China and either shipped directly into the U.S. or processed at clandestine labs in Mexico and smuggled by drug cartels into the U.S.³⁶ As noted by the DEA, “traffickers usually purchase powdered fentanyl and pill presses from China to create counterfeit pills to supply illicit U.S. drug markets.”³⁷

China has one of the world’s largest chemical industries, with an estimated 160,000 chemical companies producing large quantities of precursor chemicals.³⁸ In response to this problem, the U.S. and Chinese governments have taken steps to address this issue. In October 2015, China added 116 synthetic chemicals, including six fentanyl products, to its list of controlled chemical substances. In February 2017, China agreed to schedule carfentanil and three other fentanyl analogues. At the request of the State Department, the U.N. Commission on Narcotic Drugs moved to control two key fentanyl precursors by adding them to the list of controlled chemicals under the 1988 U.N. Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. On March 16, 2017, the U.N. Commission on Narcotic Drugs accepted the recommendation of the International Narcotics Control Board and voted in favor of controlling these substances.³⁹ All U.N. member states now have 180 days to bring these precursors under their regulatory control system.⁴⁰

Routes of importation into the U.S. According to the DEA, synthetic opioids entering the U.S. travel through three major routes:

³⁵ Azam Ahmed *Drug That Killed Prince Is Making Mexican Cartels Richer, U.S. Says*, N.Y. TIMES (June 9, 2016), <https://www.nytimes.com/2016/06/10/world/americas/drug-that-killed-prince-is-making-mexican-cartels-richer-us-says.html>. A recent case illustrates the high profitability of fentanyl. On December 21, 2016, 55 pounds of fentanyl worth \$1.5 million was recovered in the cab of a tractor trailer truck on Route 34 in Derby, Connecticut. Staff Report, *Derby Police Recover \$1.5 Million Worth of Fentanyl in Route 34 Traffic Stop*, NEWS 8 WTNH (Dec. 22, 2016), <http://wtnh.com/2016/12/21/derby-police-recover-1-5-million-worth-of-fentanyl-in-route-34-traffic-stop/>. This is one of the five largest fentanyl busts in the U.S. to date.

³⁶ DEA Intelligence Brief, *supra* note 13, at 2.

³⁷ *Id.*

³⁸ Letter from Julia Frifield, Assistant Sec’y, Legis. Affairs, U.S. Dep’t of State, to the Hon. Edward J. Markey (May 25, 2016). See also, S. O’Connor, Fentanyl: China’s Deadly Export to the United States, U.S.-China Economic and Security Review Commission Staff Research Report 7 (Feb. 1, 2017) (citing U.S. Dep’t of State, 2014 International Narcotics Control Strategy Report (Mar. 2014)).

³⁹ Email from State Department Bureau of Legislative Affairs to committee staff, (Mar. 16, 2017).

⁴⁰ *Id.*

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- Land/border crossing from Mexico;
- Land/border crossing from Canada; and
- Direct shipments from China (or via re-routed countries) to the U.S. from express consignment, or through international mail.

Illicit synthetic opioids are largely being manufactured in China and smuggled into the U.S. over the Southwest land border and via deliveries by the U.S. Postal Service, foreign mail, or air express consignment carriers. A simple internet search to order these drugs online from Chinese suppliers results in numerous open source e-commerce websites and dark web market options. Users of these sites can remain largely anonymous using currency such as bitcoin. Once the product is purchased, vendors often use discreet or disguised packaging to ship the drug, such as candles, printer accessories, toys, etc. In addition to China being the primary source country, Mexico is a source country for clandestine labs and drug cartels that are purchasing ingredients to manufacture the synthetic drugs themselves. Law enforcement authorities also believe that clandestine fentanyl labs exist in Guatemala and the Dominican Republic.

High-volume seizures on the southwest border. In June 2016, U.S. Customs and Border Protection (CBP) seized almost 200 pounds of fentanyl and other synthetic opioids like fentanyl, the majority of it along the southwest border.⁴¹ This is a 25-fold increase over the eight pounds seized in 2015.⁴² Last fall, federal agents in Mexico discovered 27 kilograms of fentanyl—the dosage equivalent of almost one ton of heroin—on a remote landing strip in the state of Sinaloa. The raid also uncovered about 19,000 tablets of fentanyl marked by traffickers to look like oxycodone. Two men detained in the raid were high-ranking members of the Sinaloa cartel, led by the drug kingpin Joaquín Guzmán Loera, also known as El Chapo.

Customs data on fentanyl-related seizures. CBP seizures of parcels containing fentanyl are increasing. In the fiscal year (FY) 2016 (October 2015–September 2016), CBP intercepted twelve parcels containing fentanyl at John F. Kennedy International Airport in New York. To date in FY 2017 (October 2016 – present), CBP has already intercepted nine parcels containing fentanyl. CBP data also indicates that the agency seized 73 pill press/tablet machines in FY 2014 and FY 2015.⁴³

U.S. Postal Inspection Service seizures data. U.S. Postal Inspection Service (USPIS) data indicates that fentanyl shipments seized in the U.S. originate in a small number of nations, including the U.S. and China. In the period from October 1, 2013 through February 28, 2017 (41 months), the USPIS made 97 seizures of synthetic opioids. During the first five months of FY 2017 (October 1, 2016 – February 28, 2017), USPIS made 14 seizures of synthetic opioids,

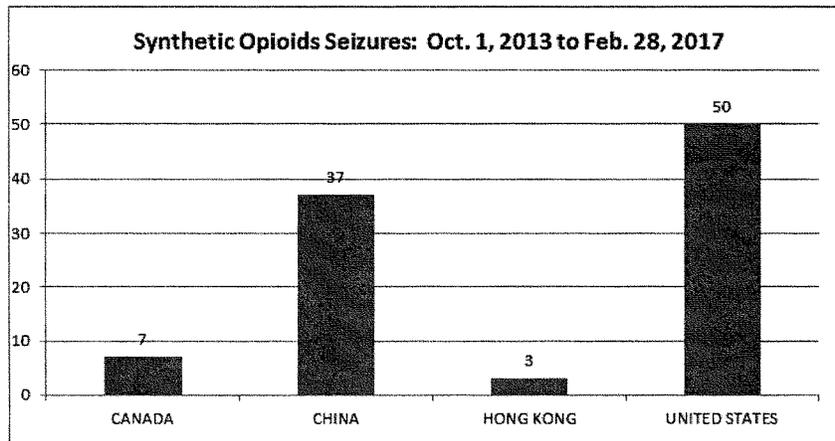
⁴¹ For example, U.S. Border Patrol agents seized 52.69 pounds of fentanyl, along with 38.80 pounds of methamphetamine, and 116.29 pounds of cocaine near San Clemente, California during summer 2016.

⁴² Steven Melendez, *How America Gets Its Deadliest New Drug*, FAST COMPANY (Sept. 9, 2016), <https://www.fastcompany.com/3063518/carfentanil-synthetic-opioids-heroin>.

⁴³ U.S. Customs and Border Protection Response to Senator Wyden's May 20, 2016, Questions at 4 (Attachment to Letter from the Hon. R. Gil Kerlikowske, Commissioner, U.S. Customs & Border Protection, to Hon. Ron Wyden (Aug. 24, 2016)).

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compared to five in the same period last year. Fifty of the seized packages (roughly 51 percent) originated in the U.S., 37 seized packages (roughly 38 percent) came from China, and three seized packages came from Hong Kong. The remainder of the seized packages originated in Canada (roughly seven percent).



Source: U.S. Postal Inspection Service⁴⁴

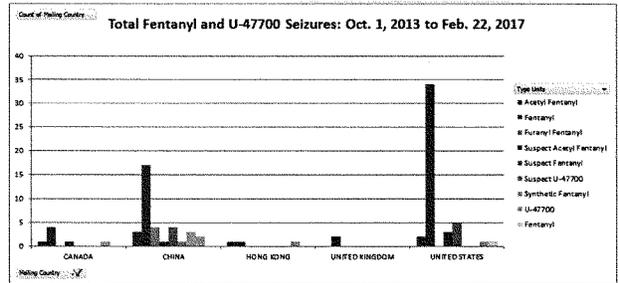
Further, the USPIS data⁴⁵ showed that fentanyl and fentanyl-related products were involved in 86 out of the 93 seizures for the time period from October 2013 to February 2017 as shown in the below chart:

⁴⁴ Attachment to email from Staff, U.S. Postal Service to Staff, H. Comm. on Energy & Commerce (Mar. 8, 2017).

⁴⁵ Attachment to email from USPIS Inspector in Charge to Staff, H. Comm. on Energy & Commerce (February 28, 2017).

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Count of Mailing Country	Acetyl Fentanyl	Fentanyl	Paraanyl Fentanyl	Suspect Acetyl Fentanyl	Suspect Fentanyl	Suspect U-47700	Synthetic Fentanyl	U-47700	Fentanyl	Grand Total
CANADA	1	4			1					7
CHINA	3	17	4		1	4		3	2	35
HONG KONG	1	1							1	3
UNITED KINGDOM	2	2								4
UNITED STATES				3	5				1	11
Grand Total	7	58	4	5	9	1	1	3	5	93



Row Labels	Count of Type Units
FY14	8
FY15	31
FY16	36
FY17	18
Grand Total	93

Source: U.S. Postal Inspection Service

At present, the U.S. Postal Inspection Service reports 29 active synthetic opioid investigations. Of these, 16 (roughly 55 percent) are either confirmed or believed to have a dark-web or an international online vendor nexus.

Regional data on fentanyl imports. State and regional data provide some insight into how fentanyl is imported into the U.S. For example, in July 2016, the local Baltimore/Washington High Intensity Drug Trafficking Area (B/W HIDTA) Office conducted a survey of over 100 health and public safety entities regarding the local fentanyl threat.⁴⁶ On average, respondents estimated that:

- Seventy-one percent of fentanyl is trafficked through traditional drug trafficking organization methods, e.g. personal vehicles, cargo contained within tractor-trailers, and domestic parcels (i.e. both consignment carriers and via U.S. mail);
- Twenty-eight percent of local fentanyl was transported through international packages via mail order from China; and
- One percent of fentanyl was synthesized in local laboratories.⁴⁷

⁴⁶ Briefing by Maryland Governor’s Office of Crime Control & Prevention & Maryland Department of Health & Mental Hygiene for the H. Comm. on Energy & Commerce staff (Mar. 10, 2017).

⁴⁷ *Id.*

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In addition, B/W HIDTA seizure data revealed that from 2015 to 2016, fentanyl seizures increased tenfold.⁴⁸

Blitz operations not finding fentanyl. Although data from CBP, USPIS, and B/W HIDTA indicate that seizures of fentanyl packages are occurring, targeted efforts to find fentanyl parcels have not been successful. Fentanyl was one of the targeted drugs of concern during federal law enforcement blitzes at international mail facilities at nine different U.S. airports from FY 2015 to current date FY 2017. However, not one package of fentanyl was detected out of 8,473 packages examined.⁴⁹

Fentanyl-related counterfeit drug investigations hampered. While the results from the blitz operations suggest more work is needed to develop better targeting intelligence on fentanyl packages, law enforcement faces other challenges with fentanyl-related investigations. Because fentanyl is classified as a controlled substance, law enforcement is further hampered in counterfeit drug cases because they cannot rely on test purchases or undercover buys from pharmaceutical security offices as they do in non-controlled counterfeit drug cases.

Pill presses used to make fentanyl. Illicit pill presses shipped to the U.S. from overseas have been linked to the fentanyl overdose epidemic. As reported by the Salt Lake Tribune, “[d]ealers can buy a pill press and brand-name die molds for little more than \$1,000 and order upward of \$10 million in street value of the drug for a few thousand dollars more. Branded and sold as 30 milligram oxycodone, a single counterfeit pill can fetch over \$30.”⁵⁰

Illegally obtained pill presses allow small-scale milling operations in the U.S. to package between 3,000 and 5,000 pills per hour of illicit fentanyl.⁵¹ For example, in a drug bust of what is believed to be the second-largest distributor of fentanyl in the U.S. in November 2016 in Utah, agents discovered a pill press likely capable of manufacturing several thousand pills per hour.⁵²

The pill presses used to make fentanyl are shipped directly from China or indirectly through other countries such as Canada where pill presses are not regulated. Moreover, such

⁴⁸ *Id.*

⁴⁹ Committee staff tabulation from data provided by U.S. Food & Drug Admin., List of IMF Blitz/Surge Operations (Safeguard and Pangea) from FY '15 (1/01/2014) thru Current Date FY' 17 (2/27/2017) attached to email from Staff, U.S. Food & Drug Admin., to Staff, H. Comm. on Energy & Commerce, (Mar. 9, 2017).

⁵⁰ M. Piper, *Cottonwood Heights man accused of Utah's biggest-ever illicit opioid pill press makes first appearance in court*, SALT LAKE TRIB. (Nov. 23, 2016), <http://www.sltrib.com/home/4625394-155/utah-man-accused-of-making-illicit>.

⁵¹ S. O'Connor, *Fentanyl: China's Deadly Export to the United States*, U.S.-China Economic and Security Review Commission Staff Research Report 6 (Feb. 1, 2017) (citing Commission staff interview with DEA official (Sept. 13, 2016)).

⁵² K. Lockhart, *DEA busts 'catastrophic' pill distribution operation in Cottonwood Heights*, KSL.com (Nov. 22, 2016), <https://www.ksl.com/?sid=42312087&nid=148&title=pollce-discover-major-drug-operation-in-cottonwood-heights>. The video within this article states that the pill press could make up to 7,000 pills per hour. Another pill press found in Sandy City, Utah in June 2016 could also reportedly produce 7,000 pills per hour. Gephardt Daily Staff, *Update: Agents bust massive Cottonwood Heights drug operation; fake fentanyl, other opioids shipped by the millions nationwide*, GEPHARDT DAILY (Nov. 22, 2016), <http://gephardtdaily.com/local/police-national-guard-on-scene-of-pill-making-operation-in-cottonwood-heights/>.

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equipment is only controlled by DEA for DEA registrants. Seizure data from CBP shows China or Hong Kong as the countries of origin in 94 percent of the seizures in FY 2014 and FY 2015.⁵³

ISSUES

The following issues may be examined at the hearing:

- Does the federal government accept that fentanyl presents a unique public health threat and law enforcement challenge that requires a systematic response from the whole-of-federal government?
- What is the structure of the federal response to the fentanyl epidemic?
- What is the current status of the federal response to the fentanyl epidemic?
- How can surveillance of the fentanyl epidemic be improved?
- What additional burdens is the fentanyl epidemic putting on society, the healthcare system, the criminal justice system, the emergency response system, and state budgets?

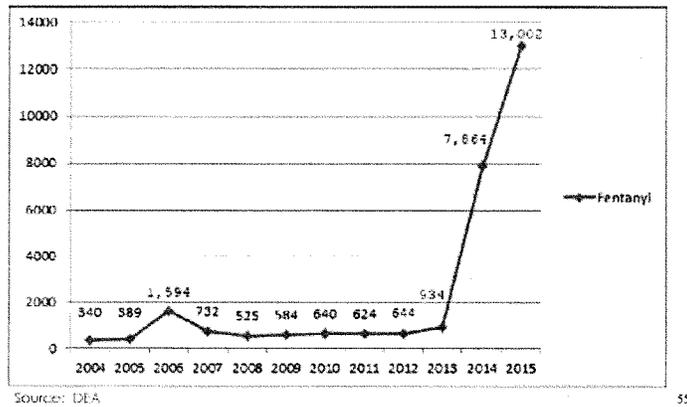
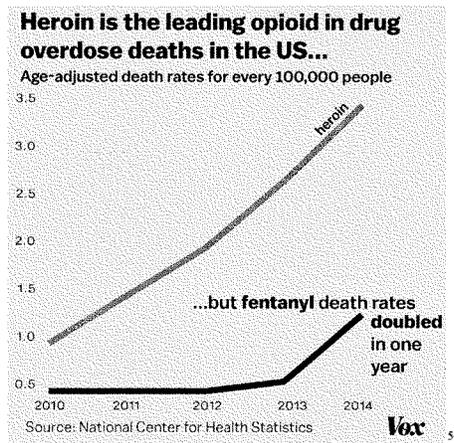
III. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, Brittany Havens, or David Schaub of the committee staff at (202) 225-2927.

⁵³ CBP response to Senator Wyden, *supra* note 42. For the years FY 2014 and 2015 (Oct. 1, 2013 through Sept. 30, 2015), CBP recorded 73 total seizures of illicit pill presses. China was identified as the country of origin for 26 of these seizures (36 percent of the total). By contrast, Hong Kong was the identified origin for 42 seizures (58 percent), while the U.K. (two seizures), India (two seizures) and Taiwan (one seizure) comprised the remainder.

V. APPENDICES

Although there is limited national data on the fentanyl crisis, the two following charts illustrate the surge in the fentanyl problem:



Volume of forensic lab tests showing positive for fentanyl

⁵⁴ Sarah Frostenson, *The Stunning Rise of Deaths from the Pain Drug Fentanyl, In One Chart*, VOX (Dec. 20, 2016), <http://www.vox.com/science-and-health/2016/12/20/14005776/deaths-pain-drug-opioids-fentanyl-chart>.

⁵⁵ *The Fentanyl-Opioid Crisis is a Counterfeiting Crisis*, PHARMACEUTICAL COMMERCE (Oct. 14, 2016), <http://pharmaceuticalcommerce.com/brand-marketing-communications/fentanyl-opioid-crisis-counterfeiting-crisis/>.

The Washington Post

Wonkblog

Where opiates killed the most people in 2015

By Christopher Ingraham December 13, 2016

More than 33,000 people died of opioid overdoses in the United States last year. But speaking of an “opiate epidemic” is in some ways a misnomer. The latest data from the Centers for Disease Control and Prevention show that the country is in fact dealing with multiple opioid epidemics right now — each with a distinct geographic footprint.

The geography of opioid deaths

Starting with the big picture, here’s a map of total opioid death rates by state. County-level data would be preferable, but the CDC suppresses data for many small counties to protect the privacy of the people who live there. The data in this map encompasses everything from heroin to hydrocodone to more powerful synthetic drugs like fentanyl.

Nationally, there are about 10.4 deaths by opioid overdose for every 100,000 people. But as you can see, these deaths aren’t evenly distributed across the country. New England and the Ohio/Kentucky/West Virginia region stand out as two obvious hot spots. Conversely, rates are low in Texas, California, the northern Plains states and Hawaii.

The geography of heroin deaths

Here’s what the distribution of heroin deaths looks like.

Even at the state level the CDC has to suppress some of the data for privacy concerns, mostly in low population states where there are few overall deaths. This map generally follows the contours of the previous one, with a few notable differences: Kentucky stands apart from Ohio and West Virginia for having fewer heroin deaths than its neighbors.

Up in New England, heroin is a much bigger issue in the southern states in that region (Massachusetts and Connecticut in particular) than in places like Maine, Vermont or New Hampshire.

The geography of synthetic opioid deaths

Here's a look at what the CDC classifies as "synthetic opioid" deaths. These are primarily due to substances like fentanyl, the powerful painkiller that's been making headlines lately. But there may be some fatalities from other synthetic opiate products, like tramadol, in here as well. Note that overdose deaths from methadone, a synthetic used to help people quit addictions to other opiate drugs, aren't included here.

The pattern here is markedly different than it is on the heroin map. Synthetic opioid deaths — again, we're primarily talking fentanyl — are almost exclusively an East Coast phenomenon. Nationally, the death rate from synthetic opioids is 3.1 per 100,000. But in Rhode Island, it's 13.2; in Massachusetts, 14.4; and in New Hampshire, which has the highest synthetic opioid death rate in the country, 24.1 out of every 100,000 people died from synthetic opiates in 2015.

Ohio and West Virginia stand out on this map, too.

The geography of 'classic' opioid deaths

Finally, here's a look at deaths from what we might call the "classic" opioid painkillers — substances like hydrocodone and oxycodone. The CDC refers to these as "natural" or "semi-synthetic" opioids, essentially a technical term referring to how similar they are to the chemicals found in natural opium from poppy plants.

These deaths are highly concentrated in two places: West Virginia in the East, and Utah in the West. It's the only category for which certain states, like Massachusetts and Ohio, aren't near the top of the national rankings.

One important thing to keep in mind: In the CDC's data set, these categories aren't mutually exclusive. If a person dies with, say, both fentanyl and heroin in their system, that fatality will show up in the counts for both the heroin and synthetic opiate categories.

Many opioid overdose deaths do involve multiple substances, either combinations of opioids, or opioids in conjunction with things like alcohol, cocaine or other drugs.

The important takeaway here is that there's not just one opiate epidemic but several. For policymakers, this may mean that solving the problem will similarly require a more nuanced basket of solutions than a blanket "war on drugs." A strategy to reduce pill overdoses in Utah may not have any effect on fentanyl deaths in Massachusetts.

And if they aren't careful, certain interventions may actually make the problems worse. One unintended consequence of years of crackdowns on prescription painkillers was a resurgence in the use of heroin, for example.

A table containing the raw data from CDC's WONDER database is below.

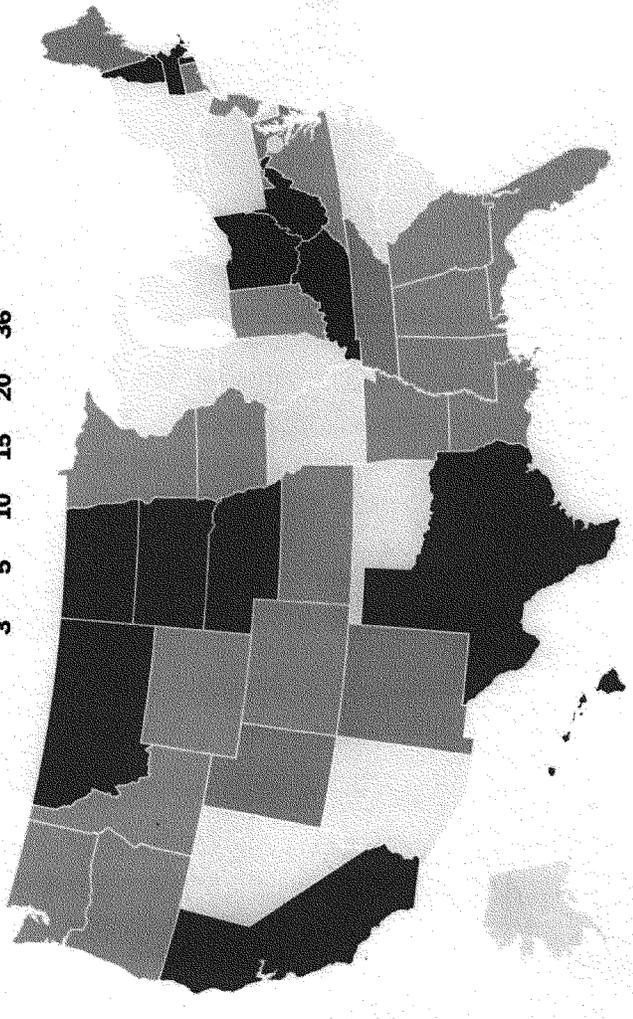
STATE	POPULATION	ALL OPIATE DEATHS	HEROIN DEATHS	SYNTHETIC OPIATE DEATHS	NATURAL OPIATE DEATHS
Alabama	4,858,979	282	111	70	87
Alaska	738,432	86	37	14	51
Arizona	6,828,065	671	247	72	298
Arkansas	2,978,204	203	Suppressed	44	144
California	39,144,818	2018	593	229	1019
Colorado	5,456,574	495	159	64	259
Connecticut	3,590,886	685	390	211	183
Delaware	945,934	133	64	38	36
District of Columbia	672,228	98	67	26	21
Florida	20,271,272	1838	567	610	789
Georgia	10,214,860	858	222	284	435
Hawaii	1,431,603	62	15	13	37
Idaho	1,654,930	90	16	16	51
Illinois	12,859,995	1381	844	278	271
Indiana	6,619,680	536	240	120	147
Iowa	3,123,899	170	45	44	75
Kansas	2,911,641	150	21	36	74
Kentucky	4,425,092	885	310	323	382
Louisiana	4,670,724	287	126	38	108
Maine	1,329,328	238	52	116	102
Maryland	6,006,401	1087	405	357	398
Massachusetts	6,794,422	1550	634	949	225
Michigan	9,922,576	1309	646	457	380
Minnesota	5,489,594	338	115	55	125
Mississippi	2,992,333	150	38	35	73
Missouri	6,083,672	692	303	183	237
Montana	1,032,949	48	Suppressed	Suppressed	26
Nebraska	1,896,190	55	Suppressed	13	30

STATE	POPULATION	ALL OPIATE DEATHS	HEROIN DEATHS	SYNTHETIC OPIATE DEATHS	NATURAL OPIATE DEATHS
Nevada	2,890,845	419	82	32	259
New Hampshire	1,330,608	380	78	285	63
New Jersey	8,958,013	862	508	243	237
New Mexico	2,085,109	351	156	42	160
New York	19,795,791	2166	1058	668	705
North Carolina	10,042,802	1171	393	300	554
North Dakota	756,927	34	Suppressed	Suppressed	15
Ohio	11,613,423	2698	1444	1234	690
Oklahoma	3,911,338	427	36	93	277
Oregon	4,028,977	331	102	34	150
Pennsylvania	12,802,503	1362	663	429	460
Rhode Island	1,056,298	254	45	137	95
South Carolina	4,896,146	554	100	161	322
South Dakota	858,469	27	Suppressed	Suppressed	10
Tennessee	6,600,299	1038	205	251	643
Texas	27,469,114	1287	523	186	473
Utah	2,995,919	448	127	62	357
Vermont	626,042	79	33	33	25
Virginia	8,382,993	820	353	270	276
Washington	7,170,351	692	303	65	261
West Virginia	1,844,128	629	194	217	356
Wisconsin	5,771,337	622	287	112	249
Wyoming	586,107	46	Suppressed	Suppressed	28

Christopher Ingraham writes about politics, drug policy and all things data. He previously worked at the Brook Institution and the Pew Research Center. 🐦 Follow @cingraham

Opioid deaths in 2015

Age-adjusted death rates (per 100,000) for overdose deaths from all opioid drugs

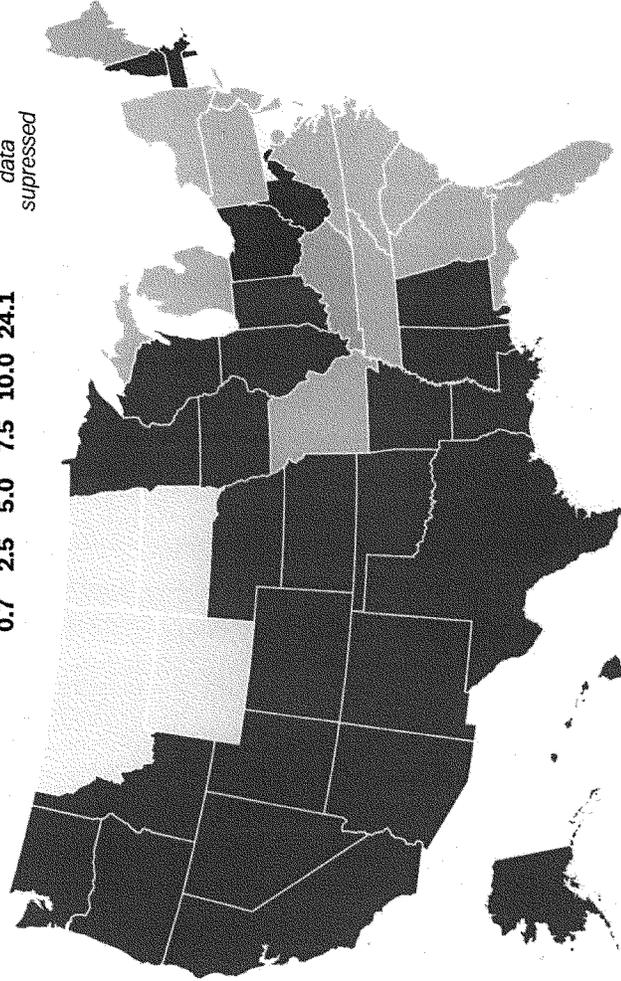
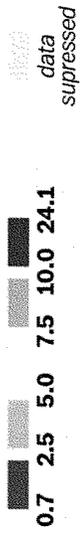


WAPO.ST/WONKBLOG

Source: CDC WONDER

Synthetic opioid deaths in 2015

Age-adjusted synthetic opioid overdose death rate (per 100,000)

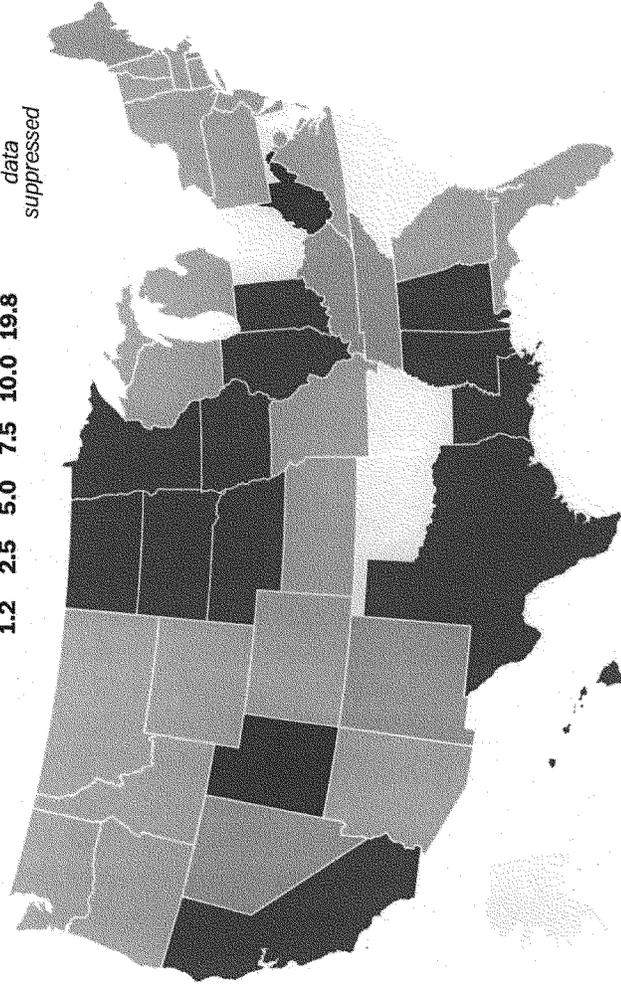


WAPO.ST/WONKBLOG

Source: CDC WONDER

Natural opioid deaths in 2015

Age-adjusted natural overdose death rate (per 100,000)

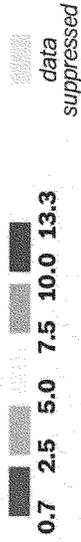


WAPO.ST/WONKBLOG

Source: CDC WONDER

Heroin deaths in 2015

Age-adjusted heroin overdose death rate (per 100,000)



WAPQ.ST/WONKBLOG

Source: CDC WONDER

March 21, 2017

The Honorable Paul Ryan
Speaker of the House
H-232, The Capitol
United States Congress
Washington, DC 20515

The Honorable Nancy Pelosi
Democratic Leader
H-204, The Capitol
United States Congress
Washington, DC 20515

Dear Speaker Ryan and Leader Pelosi,

The undersigned organizations are writing to share our views on the *American Health Care Act* (AHCA) as reported by the Ways and Means and Energy and Commerce committees. We are very concerned that the AHCA's proposed changes to our health care system will result in reductions in health care coverage, particularly for vulnerable populations including those suffering from addiction and mental illness, and we cannot support the bill in its current form.

We collectively represent consumers, families, providers, health care and social service professionals, advocates and allied organizations who are committed to meaningful and comprehensive policies to reduce the toll of substance use disorders and mental illness through prevention, treatment and recovery support services.

More than 20 million Americans currently have health care coverage due to the Affordable Care Act (ACA), including millions of Americans with addiction and mental illness. This coverage is a critical lifeline for these individuals, many of whom were unable to access effective treatment before the ACA's expansion of Medicaid eligibility to low-income adults, and its requirement that Medicaid expansion plans and plans sold in the individual and small group markets provide essential health benefits (EHB) including addiction and mental health treatment services at parity with medical and surgical services.

In the face of the opioid overdose and suicide epidemics, equitable access to a full continuum of mental health and substance use disorder treatment services, including medications to treat addiction and mental illness, must be an essential component of health care coverage. It is also critical that addiction and mental illness be covered on par with other medical conditions consistent with the *Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008* (MHPAEA). The *Affordable Care Act* (ACA) extended the applicability of MHPAEA to the small and individual group market as well as Medicaid expansion plans, which are currently required to offer addiction and mental health services at parity with medical and surgical services. As authors writing in the *New England Journal of Medicine* recently noted, "Repeal of the ACA would dismantle these protections and turn the clock back to a time when most Americans were subject to restrictive and inequitable limits on coverage for medication treatment and other supplementary treatments for opioid use disorder."

We are concerned that rolling back the Medicaid expansion, sunseting the EHB requirements for Medicaid expansion plans, and capping federal support for Medicaid beneficiaries will reduce coverage for and access to addiction and mental health treatment services, changes that will be particularly painful in the midst of the ongoing opioid overdose and suicide epidemics. Moreover, while the AHCA retains the EHB requirements for private plans, it repeals the ACA's actuarial value requirements for those plans. We are concerned that this could result in insurers offering mental health and addiction treatment benefits in name only due to higher costs and/or less robust benefits.

The Medicaid expansion in particular has led to significant increases in coverage and treatment access for persons with addiction and mental illness. In states that expanded Medicaid, the share of people with addiction or mental illness who were hospitalized but uninsured fell from about 20 percent in 2013 to 5 percent by mid-2015, and Medicaid expansion has been associated with an 18.3 percent reduction in unmet need for addiction treatment services among low-income adults. Rolling back the Medicaid expansion and fundamentally

changing Medicaid's financing structure to cap spending on health care services will certainly reduce access to evidence-based treatments and reverse much or all progress made on the opioid crisis last year. Moreover, the loss of Medicaid-covered mental and substance use disorder services for adults would result in more family disruption and out-of-home placements for children, significant trauma which has its own long-term health effects and a further burden on a child welfare system that is struggling to meet the current demand for foster home capacity.

The ACA's Medicaid expansion, EHB requirements for addiction and mental illness treatment coverage, and extension of parity protections to the individual and small group market have surely reduced the burden of the opioid misuse and overdose and suicide epidemics and saved lives. As you consider this legislation, we ask that you ensure addiction and mental health treatment benefits continue to be available to Americans enrolled in the individual, small and large group markets as well as Medicaid plans and that these benefits are compliant with the *Mental Health Parity and Addiction Equity Act*.

Finally, throughout this process, we implore you to keep in mind how your decisions will affect the millions of Americans suffering from addiction and mental illness who may lose their health care coverage entirely or see reductions in benefits that impede access to needed treatment.

Sincerely,

Acadia Healthcare
 Adcare Educational Institute
 Addiction Education Society
 Addiction Haven
 Addiction Resource Council
 Addiction Services Council
 Addiction Policy Forum
 Addiction Treatment Center of New England
 Addictions Connections Resource
 Advocates for Recovery Colorado
 Advocates, Inc.
 Alabama Society of Addiction Medicine
 Alano Club of Portland
 Alcohol & Addictions Resource Center
 Alcohol/Drug Council of North Carolina
 Alternatives Unlimited, Inc.
 Amesbury Psychological Center, Inc.
 American Correctional Association
 American Federation of State, County and Municipal, Employees (AFSCME)
 American Academy of Addiction Psychiatry
 American Academy of Pediatrics
 American Association for Marriage and Family Therapy
 American Association for the Treatment of Opioid Dependence (AATOD)
 American Association of Child & Adolescent Psychiatry
 American Association on Health and Disability
 American Dance Therapy Association
 American Foundation for Suicide Prevention
 American Medical Student Association
 American Nurses Association
 American Public Health Association
 American Psychiatric Association
 American Psychological Association
 American Society of Addiction Medicine

A New PATH
 Anxiety and Depression Association of America
 Arc of South Norfolk, The
 Arise & Flourish
 Arizona's Children Association
 Arizona Council of Human Service Providers
 Arizona Society of Addiction Medicine
 Arkansas Society of Addiction Medicine
 Association for Ambulatory Behavioral Healthcare
 Association for Behavioral Healthcare of Massachusetts
 Association for Community Affiliated Plans
 Association for Community Human Service Agencies
 Association of Asian Pacific Community Health Organizations (AAPCHO)
 Association of Flight Attendants – CWA, AFL-CIO
 Association of Persons Affected by Addiction (APAA)
 Association of Recovery Schools
 Association of Recovery Community Organizations
 Association of Women's Health, Obstetric and Neonatal Nurses
 A Stepping Stone to Success
 Atlantic Prevention Resources, Inc.
 Avanti Wellness
 BAMSI
 Bangor Area Recovery Network, Inc.
 Bay Cove Human Services
 Bay State Community Services, Inc.
 Bazelon Center for Mental Health Law
 Behavioral Health Network, Inc.
 Better Life in Recovery
 Bill Wilson Center
 Boston Alcohol and Substance Abuse Programs, Inc.
 Boston Healthcare for the Homeless
 Boston Public Health Commission
 BreakingTheCycles
 Bridge of Central Massachusetts, Inc., The
 Bridgewell
 Brien Center for Mental Health and Substance Abuse Services, The
 Brookline Community Mental Health Center
 Bullhook Community Health Center, Inc.
 Burke Recovery
 California Consortium of Addiction Programs & Professionals
 California Council of Community Behavioral Health Agencies
 California Society of Addiction Medicine
 Cambridge Health Alliance
 Camelot Care Centers, Inc.
 Cape Cod Healthcare Centers for Behavioral Health
 Capital Area Project Vox
 Casa Esperanza
 Casa Pacifica Centers for Children and Families
 Catholic Charities Family Counseling and Guidance Center
 Catholic Family Center
 Center for Human Development
 Center for Open Recovery
 Center for Recovery and Wellness Resources

Chautauqua Alcoholism and Substance Abuse Council
Chicago Recovering Communities Coalition (CRCC)
Child & Family Services, Inc.
Child and Family Services of New Hampshire
Children's Friend, Inc.
Children's Home Society of Washington
Children's Law Center
Children's Services of Roxbury
CleanSlate
Clergy for a New Drug Policy
Clinical and Support Options, Inc.
Clinical Social Work Association
Coalition of Addiction Students and Professionals Pursuing Advocacy (CASPPA)
Colorado Society of Addiction Medicine
Communities for Recovery
Community Counseling of Bristol County, Inc.
Community-Minded Enterprises
Community Oriented Correctional Health Services (COCHS)
Community Services Institute
Community Solutions
Community Substance Abuse Centers
Connecticut Community for Addiction Recovery (CCAR)
Connecticut Society of Addiction Medicine
Counselors Obediently Preventing Substance Abuse (COPS)
Cutchins Programs for Children and Families
DarJune Recovery Support Services & Café
Dash for Recovery
Davis Direction Foundation - The Zone
DC Fights Back
DC Recovery Community Alliance
Delphi Behavioral Health Group/MHD
Desert Eagle Addiction Recovery
Detroit Recovery Project, Inc.
Dimock Community Health Center
Disability Rights Pennsylvania
Doctors for Recovery
Dorchester Recovery Initiative
Drug and Alcohol Service Providers Organization of Pennsylvania (DASPOP)
Drug Prevention Resources
East Bay Agency for Children
Easy Does It, Inc.
Eating Disorders Coalition
Edinburg Center, The
Eliot Community Human Services
El Paso Alliance
Engaged Recovery Community Services
Faces and Voices of Recovery
Facing Addiction
Family Focused Treatment Association
Family Service Association
Family Service of Greater Boston
FAVOR Greenville
FAVOR Low Country

FAVOR Mississippi Recovery Advocacy Project
FAVOR Pee Dee
FAVOR Tri-County
FED UP! Coalition
Fellowship Foundation Recovery Community Organization
Fenway Health
FHR
Florida Society of Addiction Medicine
Floridians for Recovery
Foundation for Recovery
Friends of Recovery - New York
FSA – Family Service Agency
Futures of Palm Beach
G III Associates
GAAMHA
Gandara Center
Georgia Council on Substance Abuse
Georgia Society of Addiction Medicine
Gosnold on Cape Cod
Granite Pathways
Greater Macomb Project Vox
Greater Philadelphia Association for Recovery Education
Great South Bay Coalition
Greater Cincinnati Recovery Resource Collaborative (GCRRC)
Griffin Recovery Enterprises
Harm Reduction Coalition
High Point Treatment Center
Hillview Mental Health Center, Inc.
Home for Little Wanderers, The
HOPE for New Hampshire Recovery
Hope House Addiction Services
Horizon Health Services
IC&RC
Illinois Association for Behavioral Health
Indiana Society of Addiction Medicine
International Nurses Society on Addictions
Institute for Health and Recovery
Iowa Association of Community Providers
Italian Home for Children, Inc.
Jackson Area Recovery Community
Jewish Family and Children's Services (JF&CS)
Joint Coalition on Health
Jordan's Hope for Recovery
Judge Baker Children's Center
Juneau Recovery Community
Justice Resource Institute (JRI)
Kentucky Society of Addiction Medicine
KEY Program, Inc., The
Kyes 2 a 2nd Chance
Lahey Health Behavioral Services
Lakeshore Foundation
Latah Recovery Center
Legal Action Center

Lifehouse Recovery Connection
 Lifeline Connections
 Long Island Council on Alcoholism and Drug Dependence, Inc.
 Long Island Recovery Association (LIRA)
 Lost Dreams Awaken Center, Inc.
 Lotus Peer Recovery/SoberKerrville
 Lowell Community Health Center, Inc.
 Lowell House, Inc.
 LUK, Inc.
 Madison County Council on Alcoholism & Substance Abuse
 Magnolia Addiction Support
 Maine Alliance for Addiction Recovery
 Mariah's Mission Fund of the Mid-Shor Community Foundation
 Mark Garwood SHARE Foundation
 Martha's Vineyard Community Services
 Maryland-DC Society of Addiction Medicine
 Maryland House Detox
 Maryland Recovery Organization Connecting Communities (M-ROCC)
 Massachusetts Organization for Addiction Recovery (MOAR)
 Massachusetts Society of Addiction Medicine
 McShin Foundation
 Mental Health Association
 Message Carriers of Pennsylvania, Inc.
 MHA of Greater Lowell
 Michigan's Children
 Michigan Recovery Voices
 Michigan Society of Addiction Medicine
 Middlesex Human Service Agency, Inc
 Mid-Michigan Recovery Services, Inc.
 MI-HOPE - Michigan Heroin & Opiate Prevention and Education
 Minnesota Association of Community Mental Health Programs (MACMHP)
 Minnesota Recovery Connection
 Minnesota Society of Addiction Medicine
 Missouri Recovery Network
 MOBER
 Mountain View Prevention Services, Inc.
 NAADAC – the Association for Addiction Professionals
 National Alliance for Medication-Assisted Recovery (NAMA)
 National Alliance on Mental Illness
 National Alliance to Advance Adolescent Health
 National Alliance to End Homelessness
 National Association for Rural Mental Health
 National Association of Addiction Treatment Providers
 National Association of Clinical Nurse Specialists
 National Association of Pediatric Nurse Practitioners
 National Association of State Mental Health Program Directors (NASMHPD)
 National Association for Children's Behavioral Health
 National Association for Rural Mental Health
 National Association of Drug Court Professionals
 National Association of Social Workers (NASW)
 National Association of County Behavioral Health and Developmental Disability Directors
 National Council for Behavioral Health
 National Center on Addiction and Substance Abuse

National Council on Alcoholism and Drug Dependence
 National Council on Alcoholism and Drug Dependence of E. San Gabriel & Pomona Valleys
 National Council on Alcoholism and Drug Dependence--Greater Phoenix
 National Council on Alcoholism and Drug Dependence – Maryland
 National Council on Alcoholism and Drug Dependence – San Diego
 National Council on Alcoholism and Drug Dependence of the San Fernando Valley
 National Council on Alcoholism and Drug Abuse-St. Louis Area
 National Disability Rights Network
 National Federation of Families for Children's Mental Health
 National Health Care for the Homeless Council
 National Safety Council
 Navigate Recovery Gwinnett
 Nevada Society of Addiction Medicine
 New Jersey Association of Mental Health and Addiction Agencies, Inc.
 New Jersey Society of Addiction Medicine
 New Life Counseling & Wellness Center, Inc.
 New Mexico Society of Addiction Medicine
 New York Association of Psychiatric Rehabilitation Services
 New York Society of Addiction Medicine
 New York State Council for Behavioral Health
 NFI Massachusetts, Inc.
 NMSAS Recovery Center
 No Health without Mental Health
 North Charles, Inc.
 North Cottage Program, Inc.
 Northeast Center for Youth and Families, The
 Northern New England Society of Addiction Medicine
 Northern Ohio Recovery Association (NORA)
 Northwest Indian Treatment Center
 North Suffolk Mental Health Association, Inc.
 Northern Rivers Family Services
 North Carolina Society of Addiction Medicine (NCSAM)
 O'Brien House
 Ohio Society of Addiction Medicine (OHSAM)
 Oklahoma Citizen Advocates for Recovery & Treatment Association (OCARTA)
 Old Colony YMCA
 Open Doorway of Cape Cod
 Oregon Recovery High School
 Oregon Society of Addiction Medicine
 Overcoming Addiction Radio
 Partnership for Drug-Free Kids
 Partners in Prevention/National Council on Alcoholism and Drug Dependence of Hudson County, Inc.
 P.E.E.R Wellness Center, Inc.
 PEER360 Recovery Alliance
 Pennsylvania Recovery Organization - Achieving Community Together - (PRO-ACT)
 Pennsylvania Recovery Organizations Alliance (PRO-A)
 Pennsylvania Society of Addiction Medicine
 People Advocating Recovery - PAR
 Phoenix Houses of New England
 Phoenix Multisport Boston
 Pine Street Inn
 Pivot, Alcohol and Substance Abuse Council of Jefferson County, Inc.
 PLR Athens

Pretrial Justice Institute
Prevention Network OCAA
Putnam Family & Community Services, Inc.
RASE Project
REAL- Michigan (Recovery, Education, Advocacy & Leadership)
Recover Project/Western MA Training
Recovery Allies Of West Michigan
RecoveryATX
Recovery Café Seattle
Recovery Community Foundation of Forsyth
Recovery Communities of North Carolina
Recovery Community Of Durham
Recovery Consultants of Atlanta
Recovery Data Solutions
Recovery - Friendly Taos County
Recovery Idaho, Inc.
Recovery is Happening
RecoveryNC (Governors Institute on Substance Abuse)
Recovery Point at HER Place
Recovery Point of Bluefield
Recovery Point of Charleston
Recovery Point of Huntington
Recovery Point of Parkersburg
Recovery Point of West Virginia
Recover Wyoming
reGROUP
Rhode Island Communities for Addiction Recovery Efforts (RICAREs)
Riverside Community Care
Robby's Voice
ROCovery Fitness
Rockland Council on Alcoholism and Other Drug Dependence, Inc.
Sandusky Artisans Recovery Community Center
Sandy Hook Promise
Serenity Sistas
ServiceNet
SMART Recovery
Solano Recovery Project
Solutions Recovery, Inc.
Sonoran Prevention Works
South Arkansas Regional Health Center, Inc
Sound Community Services, Inc.
South Middlesex Opportunity Council, Inc. (SMOC)
South Bay Community Services
South Carolina Society of Addiction Medicine
South Central Human Relations Center
South End Community Health Center
South Shore Mental Health
Spectrum Health Systems, Inc.
SpiritWorks Foundation
Springfield Recovery Community Center
Springs Recovery Connection
SSTAR
STEP Industries

Steppingstone, Incorporated
Student Assistance Services Corp
Substance Use and Mental Health Leadership Council of Rhode Island
Technical Assistance Collaborative, Inc.
Tennessee Society of Addiction Medicine
Texas Society of Addiction Medicine
The Addict's Parents United (TAP United)
The Alliance
The Bridge Foundation
The Bridge Way School
The Campaign for Trauma-Informed Policy and Practice
The Chris Atwood Foundation
The Council on Alcohol and Drug Abuse
The Council on Alcohol & Drug Abuse for Greater New Orleans
The DOOR - DeKalb Open Opportunity for Recovery
The Global Alliance for Behavioral Health and Social Justice
The Kennedy Forum
The Ohana Center
The Recovery Channel
The Rest of Your Life
The Trevor Project
The Village Family Services
The Village Project, Inc.
Tia Hart Recovery Community Program
T.O.R.C.H Inc.
Toward Independent Living and Learning, TILL, Inc.
Treatment Communities of America
Trilogy Recovery Community
Two Guys and a Girl
UMass Memorial Community Healthlink, Inc.
United Methodist Church - General Board of Church and Society
Utah Support Advocates for Recovery Awareness (USARA)
Veterans Inc.
Vermont Council of Developmental and Mental Health Services
Vermont Recovery Network
Victory Programs, Inc.
Vinfen
Virginia Association of Recovery Residences
Voice for Adoption
Voices of Hope for Cecil County
Voices of Recovery San Mateo County
Volunteers of America of Massachusetts, Inc.
WAI-IAM, Inc. and RISE Recovery Community
Walker, Inc.
Washtenaw Recovery Advocacy Project (WRAP)
Washington Federation of State Employees
Washington Recovery Alliance
Washington Society of Addiction Medicine
Watershed Treatment Programs
Wayside Youth & Family Support Network
WEConnect
Wellspring Recovery Services
West Virginia Society of Addiction Medicine

WholeLife Recovery Community/ Arizona Recovery Coalition
Wisconsin Recovery Community Organization (WIRCO)
Wisconsin Society of Addiction Medicine
Wisconsin Voices for Recovery
Wyoming County CARES
Yoga of Recovery
Young Invincibles
Young People in Recovery
Young People in Recovery – Los Angeles
Youth Opportunities Upheld, Inc.
Youth Villages



OREGON AFSCME

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www.oregonafscme.com

March 20, 2017

The Honorable Tim Murphy
Chairman
Oversight and Investigations Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Diana DeGette
Ranking Member
Oversight and Investigations Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Murphy and Ranking Member DeGette:

On behalf of Oregon AFSCME, which represents 25,000 workers, including 1,000 in the behavioral health field, we thank you for holding a hearing in the Subcommittee on Oversight and Investigations on March 21, 2017 to highlight the opioid epidemic. We ask that our letter be made part of the hearing record.

Oregon, like the rest of our nation, is besieged by an opioid epidemic. Prescription and illicit opioids are the main driver of drug overdose deaths. Nationwide, opioids were involved in 33,091 deaths in 2015, including 505 in Oregon. Many individuals develop addictions to prescription drugs then switch to heroin, which can be cheaper and easier to obtain. In Oregon, about 70% of heroin overdoses start with prescription pain pills.

As Congress considers effective ways to help states address this public health crisis that is tearing apart families and communities, we urge you to examine how the American Health Care Act could harm our nation's ability to treat opioid addiction and mental illness.

The Congressional Budget Office estimates that the American Health Care Act will cause as many as 14 million people to become uninsured in 2018 and 24 million by 2026. These millions of Americans will lose access to addiction and mental health treatment, the very services that are needed to help individuals recover from addiction, relapse, trauma and mental illness.

Oregon's Health Authority, has analyzed the impact of this bill on our state. As many as 465,000 Oregonians will lose health coverage between 2018 and 2023, including some 80,000 next year. The fundamental change in Medicaid would threaten low-income working Oregonians and families drastically. Currently, one million Oregonians are covered by Oregon Health Plan, our state's Medicaid program. Enactment of the American Health Care Act will mean that in 2020, 183,000 Oregonians will lose Medicaid coverage and as many as 375,000 by 2026. The Oregon Health Plan, like other expansion Medicaid plans has proved to be a

workhorse when it comes to addressing the needs of Oregonians with mental health and substance use disorders. The loss of this coverage will harm those who have finally gotten access to mental health and addiction treatment, as well as their families.

The American Health Care Act, if enacted, would also shift \$190 million in costs to our state in 2020. The cumulative cost shift would be \$2.6 billion over the next six years. The ramifications of this reduction in federal funds is broad and deep. It will slow economic activity in Oregon, undermine our state budget and risk the loss of more than 23,300 health care jobs, including behavioral health care workers. Oregon, like other states, would be forced to deny access, benefits and services to hundreds of thousands of our most vulnerable residents, or cut state funds for education, public safety, environmental protection or other needed public services, or a combination of all three. These options are untenable and would weaken our efforts to address the opioid epidemic.

As the Committee considers how the federal government responds to the opioid crisis, we urge the Congress not to make it worse by approving the American Health Care Act.



Michael Seville
Executive Director, Oregon AFSCME Council 75

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

April 11, 2017

Mr. Kemp Chester
Acting Deputy Director
Office of National Drug Control Policy
750 17th Street, N.W.
Washington, DC 20006

Dear Mr. Chester:

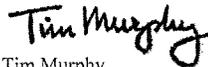
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, March 21, 2017, to testify at the hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, April 25, 2017. Your responses should be mailed to Elena Brennan, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515, and e-mailed in Word format to Elena.Brennan@mail.house.gov.

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

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachment

RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
THE ACTING DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING THE MARCH 21, 2017, HEARING ENTITLED,
“FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS”
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Tim Murphy

- 1. What additional burdens is the fentanyl epidemic putting on society, the healthcare system, the criminal justice system, the emergency response system, and Federal, state, and local budgets?**

ANSWER:

Once illicit fentanyl began to emerge in pockets throughout the country, it became apparent that the United States would be facing challenges on multiple levels and experiencing additional burdens on local, state, tribal, and Federal agencies. Fentanyl outbreaks trigger rapid notification of public health and law enforcement agencies, interviews of patients and their family members to trace and limit further use or distribution of the fentanyl, immediate naloxone resupply and augmentation for emergency medical services (EMS) crews, public health alerts, and an acceleration of naloxone distribution to opioid users and their friends and families. At the Federal level, the Centers for Disease Control and Prevention (CDC), part of the Department of Health and Human Services (HHS), has sent multiple teams to investigate fentanyl-related overdose “outbreaks” in Ohio, Florida, and Massachusetts.^{1,2} This type of response to drug outbreaks is not unprecedented, but the magnitude is indicative of a greater burden than previously seen in the United States in response to earlier fentanyl overdose outbreaks.

Since October 2016, the Office of National Drug Control Policy’s (ONDCP) National Heroin Coordination Group (NHCG) has collaborated with partner states in each of the four major U.S. Census regions to monitor the public health impact of the heroin and fentanyl crises and to identify emerging trends.³ During a recent meeting, it appeared that overdose deaths involving fentanyl may be eclipsing total year-end mortality associated with overdose deaths involving heroin in a growing number of states. As some states reported in subsequent meetings, they are seeing an increase in fentanyl-related overdose deaths, which is presenting new challenges to

¹ Peterson AB, Gladden RM, Delcher C, et al. Increases in Fentanyl-Related Overdose Deaths — Florida and Ohio, 2013–2015. *MMWR Morb Mortal Wkly Rep* 2016; 65:844–849. DOI: <http://dx.doi.org/10.15585/mmwr.mm6533a3>.

² Somerville NJ, O’Donnell J, Gladden RM, et al. Characteristics of Fentanyl Overdose — Massachusetts, 2014–2016. *MMWR Morb Mortal Wkly Rep* 2017; 66:382–386. DOI: <http://dx.doi.org/10.15585/mmwr.mm6614a2>.

³ Partner states that volunteered to participate: Alaska, Arizona, California, Florida, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Ohio, Virginia, Wisconsin, West Virginia, and Utah.

policymakers and public health and safety officials, as well as to the treatment system for people who use drugs.

Beyond the immediate public health and safety risk that a fentanyl outbreak may cause in a local community, there are other, broader challenges that exist at the Federal, state, local, and tribal levels. These include a lack of post-mortem testing standards, a dearth of medical examiners/coroners to conduct timely tests for fentanyl presence, and a lack of sufficient mechanisms to detect drugs coming into the United States.

Since there are no federally-mandated standards for conducting death investigations or nationwide mandatory rules governing the types of toxicology testing and reporting required in death investigations (post-mortem testing standards), we are unable to get an accurate national assessment of the prevalence of fentanyl-involved deaths. For the same reason, local jurisdictions also do not have a clear picture of what is happening in their own communities. With the increase in fentanyl-related deaths, many coroners and medical examiners lack the capacity to conduct thorough post-mortem testing in a timely manner. They also may not have the ability to test for fentanyl or its metabolites. Of the country's approximately 2.6 million deaths each year, medical examiners and coroners investigate approximately 500,000 because the deaths are sudden or unexpected, are suspicious or the result of violence, or the decedent lacked an attending physician. In deaths where a drug overdose is cited as the underlying cause of death, one-fifth of the death certificates in 2014 do not list the specific drug(s) involved.⁴ This lack of testing and information gathered at the time of death further compounds our lack of clear, consistent data.

Detecting illicit fentanyl and its analogues at our borders, seaports, airports, and mail handling facilities is complicated and costly given the small amount of fentanyl necessary to provide similar effects as heroin, and simply put, it is a numbers game. As a synthetic drug, fentanyl is more difficult to detect using traditional detection methods. And, with illicit fentanyl and its analogues now presenting as black tar or white powder heroin in some parts of the country, visual inspections are becoming increasingly unreliable in identifying substances. Given that Mexico and China are the two largest sources of illicit fentanyl smuggled into the United States, detection and interdiction at our nation's land borders, ports, and airports are key. However, because fentanyl can be shipped in such small quantities, it is incredibly difficult to identify amongst the high volume of incoming shipments.

As our law enforcement professionals seek to identify and respond to fentanyl-related incidents, they are confronted by the significant safety risk of coming into physical contact with the drug. To mitigate this risk, ONDCP is working with Federal, state, local, and tribal agencies to establish response protocols and to assist agencies in determining the equipment and procedures necessary to contain fentanyl incidents and protect our law enforcement, medical and rescue personnel. While this effort is ongoing, the NHCg has already worked with HHS and CDC's National Institute for Occupational Safety and Health to produce science-based handling instructions for fentanyl, which were disseminated to Federal agents and local police.

⁴ Warner M, Trinidad JP, Bastian BA, Miniño AM and Hedegaard H. (2016) Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2010-2014. National Vital Statistics Report. 65(10):1-14 (December 20).

2. **Last fall, the Canadian press reported that a type of test strip to indicate the presence of fentanyl was being made widely available for a low price (\$5 Canadian). These kits or test strips were first announced in Vancouver, British Columbia, but later reports have identified them to pharmacies in Winnipeg, Manitoba (the middle of Canada). Yet there appears to be little if any public reaction, response, or similar kits detected or reported in the US. Why is that?**

ANSWER:

To date, the United States has not supported making the testing of illicitly purchased drugs (at times referred to as pill testing, drug checking, or adulterant screening) more accessible. Intrinsicly, the drugs being tested are illegal and their quality and content are suspect and cannot be used "safely."

Our understanding is that the test strips referenced in the question are enzyme immunoassay kits originally developed to test for the presence of fentanyl in urine, which are now being used to test for fentanyl in drug samples diluted in water. As a result, there is not a significant body of scientific evidence to determine if such test kits are accurate, if they can detect the range of fentanyl analogues necessary, or if they are an effective means of protecting users from potential overdose.

3. **Locally, Governor Hogan of Maryland announced a new initiative creating an Opioid Operational Command Center to aid in coordination of resources. How prevalent are such initiatives, and where would they be most needed?**
- a. **Where are you getting the best cooperation from the states?**
 - b. **What advances have these states reported that could/would assist nationwide efforts?**
 - c. **Where would such coordination need improvements?**
 - d. **Would we be better off with state-by-state approach?**

ANSWER:

ONDCP is generally aware of state level efforts to address heroin and illicit fentanyl. For example, Alaska is establishing a multi-agency incident command structure, which among other activities, is working to improve information sharing, such as morbidity and mortality data and arrest information, among Federal and state law enforcement and public health agencies.

However, while ONDCP does not have a comprehensive database of state initiatives related to addressing heroin and illicit fentanyl, through the implementation of the Federal Government's Heroin Availability Response Plan (HARP), the NHCG works with 20 states that volunteered to provide data and discuss their strategies, policies, and actions on reducing the use and availability of heroin and fentanyl. Every month, a different group of states (based on geography) present on their comprehensive efforts and recent trends, which other states can then learn from and tailor their own responses to specific, local needs and challenges. The NHCG has also used information provided by states to inform the nationwide strategy and efforts to address heroin and illicit fentanyl at the Federal level. The communication venues coordinated by the

NHCG show that an all hands approach on both the Federal and state levels are necessary to turn the tide on current heroin and fentanyl trends.

Additionally, in 2015, ONDCP committed \$2.5 million in High Intensity Drug Trafficking Area (HIDTA) program funds to develop the Heroin Response Strategy to respond to the Nation's heroin and opioid epidemic through combined prevention, education, intelligence, and enforcement resources to address this drug threat across 15 states (Connecticut, Delaware, Kentucky, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, and West Virginia) and the District of Columbia. The Heroin Response Strategy brings together public health, law enforcement, and other stakeholders to address the problem comprehensively. The effort is the result of a unique partnership of five regional HIDTA programs – Appalachia, New England, New York/New Jersey, Philadelphia/Camden, and Washington/Baltimore.

In 2016, ONDCP provided \$3.9 million to expand the Heroin Response Strategy to include the Ohio, Michigan, and Atlanta/Carolinas HIDTAs. These HIDTAs encompass five states that have been ravaged by the negative consequences of opioid abuse, and also exhibit drug trafficking patterns that are intrinsically linked with the original 15 states and the District of Columbia of the Heroin Response Strategy.

- 4. In Maryland, among other states, there are growing groups of people who are organized regarding Heroin or Opioid Awareness to help addicts and the citizenry to recognize the threat of fentanyl and fentanyl-laced heroin. What can be learned from their efforts?**
- a. How can they be best supported by networks of local, state, and Federal assistance?**

ANSWER:

We have seen many efforts by groups across the country at all levels of government to increase awareness of illicit fentanyl and its dangers. This approach is part of not only Maryland's strategy,⁵ but also many other states' overdose prevention plans. For example, Massachusetts' plan includes educating parents about signs of addiction.⁶ Parental education can be valuable, as many parents report their inability to recognize addiction and their lack of knowledge of how to help their children if they are using drugs. California has developed a public dashboard on opioids, Utah has launched the "Stop the Opidemic" public awareness campaign, and other states are making their media campaign materials accessible to the public for use in their communities. Many local and national coalitions use their internet sites to provide online information.

Because of the potency of fentanyl and its analogues, as well as the various forms in which it has been encountered, it is critical for the public to learn about the dangers of illicit fentanyl and its analogues, even for experienced opioid users. Law enforcement has encountered fentanyl and its analogues in non-opioid drugs, such as cocaine and methamphetamine, and there have been

⁵ Available at: http://bha.dhmd.maryland.gov/OVERDOSE_PREVENTION/Pages/Index.aspx.

⁶ Available at: <http://www.mass.gov/eohhs/docs/dph/stop-addiction/recommendations-of-the-governors-opioid-working-group.pdf>.

anecdotal reports of fentanyl in marijuana. Fentanyl and its analogues have also been found in high quality counterfeit pills made to mimic prescribed drugs including opioids and benzodiazepines (e.g., Xanax and Valium).

Any educational or public awareness effort must be evidence-based. It also should include mechanisms for evaluation of effectiveness. Efforts should also include information about how to obtain and dispense naloxone, an opioid overdose reversal drug. Furthermore, because of the potency of fentanyl and its analogues, it is important to emphasize that additional doses may be needed to reverse a fentanyl overdose. Lastly, it is imperative that individuals using drugs, or those around them, know that overdose victims need to receive medical care if an overdose is reversed with naloxone.⁷

- 5. We are aware that, on the street, when “word gets out” about a given batch of drugs being potentially deadly, it can conversely attract more customers searching for a greater high. What sources or uses of communication and education are most effective on such a level to provide adequate warnings about lethal dosage?**

ANSWER:

Since opioid tolerance varies from person to person, determining what is a “lethal dose” is not possible. A dose that may cause respiratory depression in an experienced opioid user is likely to be much larger than in an inexperienced user. It will also vary depending on body weight and other metabolic factors. Some analogues are potent enough to cause overdose in any user. Therefore, messaging focused on the lethality of the drug is not recommended.

Messaging should provide an awareness of the presence of illicit fentanyl and its analogues in the community, assistance with the identification of fentanyl, education on the risk of counterfeit pills, and information on the lethality/toxicity in general of the drug(s). These messages are important to convey to the user, health practitioner, and the community at large. This information is particularly important for non-opioid users or pill seekers, who may be unprepared for fentanyl-tainted drugs and are unlikely to know about its potency or the need for naloxone. Messaging delivered from trusted health sources and non-governmental organizations may be better received than from other sources.

- 6. Is there any reason to believe that drug dealers are intentionally selling fatal doses of fentanyl on occasion to get publicity to users about the potency of their drug product?**
- a. Similarly, due to the purity of fentanyl, is there any evidence that suggests drug dealers are intentionally selling products that contain fentanyl to intensify an addict’s addiction?**

ANSWER:

Anecdotally, ONDCP has heard reports that some users and dealers were unaware they were buying or selling heroin laced with fentanyl or fentanyl alone. There are other anecdotal reports that individuals are well aware of what is being sold and what is being purchased. Fentanyl’s

⁷ Available at: <http://www.nopetaskforce.org/overdose.php>.

effects closely resemble those of heroin, but it is much more potent and its duration of action is shorter. The shorter duration of action and the rapid tolerance of the drug requires quicker escalating doses to obtain the same "high."

One state participating in HARP implementation recently stated that individual users are hearing about fentanyl's potency and are affirmatively seeking the more potent drug. There are also reports of individuals seeking to avoid fentanyl, fearing the risk of overdose. The Revere Police Department in Massachusetts has reported users switching to cocaine to attempt to avoid an overdose.

The Honorable Ryan Costello**1. How would you describe the public health and safety threat of illicitly produced fentanyl to communities throughout the nation?****ANSWER:**

More than 52,000 people died from drug overdose in 2015. In 2015, overdose deaths involving a synthetic opioid other than methadone (the medical coding category that includes fentanyl) reached 9,580, an increase of 73 percent over the previous year and had tripled from 3,105 in 2013.⁸ This rapid escalation in deaths involving illicit fentanyl is troubling. Illicit fentanyl also exacerbates our nation's opioid epidemic that was brought on by prescription drug misuse and heroin use, in that it also contributes to addiction, non-fatal overdoses, and opioid-exposed infants who require costly post-natal care and child welfare involvement.

Quantifying the effects of the illicit fentanyl trade on crime, and public safety as a whole, is impossible. Additionally, systemic crime is inherent in drug trafficking, which exists by definition outside the rule of law. Finally, the recent influx of illicit fentanyl draws attention and resources away from other public safety investigations by usurping law enforcement time and resources.

2. Why is the East Coast heroin market more susceptible to the risk of fentanyl overdoses?**ANSWER:**

Historically, the U.S. heroin market has been divided along the Mississippi River, with the Eastern market favoring white powder heroin and the Western market dominated by black tar heroin. Because of the physical appearance of illicit fentanyl, it can be readily mixed with white powder heroin and difficult to detect by visual inspection. As a result, historically, a greater number of fentanyl-related deaths involving synthetic opioids (other than methadone) are seen in the Northeastern and Southern regions of the nation, due to the ease of combining white powder fentanyl with white powder heroin. However, recent evidence shows this paradigm may be shifting.

Law enforcement has encountered illicit fentanyl in other parts of the country in different forms. For example, recently a forensic scientist from Orange County, California, shared detailed photographs of drug evidence showing the many forms of fentanyl and its analogues presented to the laboratory, including fentanyl presented as black tar, white powder, compressed brown or white powders, rocklike substances, oxycodone, alprazolam, and other counterfeit pharmaceutical forms. The most recent evidence (April 2017) presented brown tar heroin containing methamphetamine, acetyl fentanyl, and fentanyl.

Given how increasingly unreliable visual inspection has become in accurately identifying substances, the Orange County Forensic Crime Lab instituted a new process by which all drug

⁸ Centers for Disease Control and Prevention, National Health Statistics. Multiple Cause of Death 1999-2015 on CDC WONDER Online Database released 2016. Extracted by ONDCP from <http://wonder.cdc.gov/medicd10.html>, December 2016.

evidence is forensically tested and, to the extent possible, the results are shared with medical examiners/coroners and prosecutors. The shifting nature of the illicit fentanyl market may necessitate jurisdictions to review and revise their testing protocols to determine the extent of fentanyl and analogues in their communities. As detection methods improve, we will most likely see an increase in deaths attributed to fentanyl-related overdose across the country.

3. What is the appeal of adding fentanyl if it is effectively killing users? Is it less expensive to produce? Does it, in non-lethal quantities, produce a different high?

ANSWER:

Information from the Drug Enforcement Administration (DEA) suggests that illicit fentanyl is substantially more profitable than heroin because of a variety of factors. This was again reiterated at this hearing in the written testimony from DEA Assistant Administrator Louis Milione, where he stated that Mexican traffickers have seized the opportunity to enter the fentanyl market because of its profit potential. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for \$3,000 – \$5000 can generate upwards of \$1.5 million in revenue on the illicit market.⁹

The effects on the body of fentanyl closely resemble those of heroin, but are much more potent and the duration of action is shorter. The shorter duration of action will lead a person with a substance use disorder to take the drug more frequently to maintain ongoing effects. Opioid tolerance varies from person to person; therefore, determining what is a “lethal dose” is not possible. A dose that may cause respiratory depression in an experienced opioid user is likely to be much larger than in an inexperienced user. It will also vary depending on body weight and other metabolic factors.

⁹ Statement of Louis J. Milione, Assistant Administrator, Drug Enforcement Administration before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce “Fentanyl: The Next Wave of the Opioid Crisis” hearing. March 21, 2017, p.2.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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Minority (202) 225-3641

April 11, 2017

Mr. Louis Milione
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Milione:

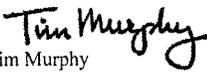
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, March 21, 2017, to testify at the hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis."

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

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachment



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

OCT 24 2017

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
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 Louis Milione, former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Oversight and Investigations, on March 21 2017, for a hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis." We hope that this information is of assistance to the Subcommittee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen E. Boyd".

Stephen E. Boyd
Assistant Attorney General

Enclosure

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

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

Hearing:
“Fentanyl: The Next Wave of the Opioid Crisis”
March 21, 2017

Questions for the Record

The Honorable Tim Murphy

1. **How is fentanyl more of a law enforcement challenge than prescription opioids or heroin?**

Response: Due to the extremely high potency and the techniques used to traffic fentanyl and fentanyl analogues, this group of illicit opioids presents more of a law enforcement challenge than prescription opioids or heroin. There are many fentanyl analogues ranging from 50-100 times the potency of morphine to up to 10,000 morphine’s strength for carfentanil. Not all fentanyl analogues are scheduled in the U.S. Illicit manufacturers are able to chemically modify a scheduled compound to make it an unscheduled one, facilitating distribution until the modified version of the compound is scheduled. Chinese manufacturers are continually introducing new synthetic opioids into the illicit market, impacting the U.S. and other countries where the new compounds are not scheduled.

Another unique challenge associated with the trafficking and misuse of fentanyl and its analogues is their high potency and lethality. Often, neither the trafficker nor the user is able to differentiate between an effective dose and a lethal dose.

2. **Is one of the challenges to combatting fentanyl that it has so many analogues – also known as chemical variations?**

- a. **If so, how does this present a unique challenge to addressing the supply?**

Response: Small variations or modifications to fentanyl’s chemical structure retain and often enhance the opioid effects. DEA continues to respond to the introduction of these chemical variants with available tools such as authorities provided under the Controlled Substance Analogue Enforcement Act (“Analogue Act”) and temporary scheduling authority. Since the temporary scheduling of acetyl fentanyl in July 2015, DEA has used its temporary scheduling authority (sometimes called “emergency” scheduling because it is triggered by an Attorney General finding that temporary scheduling is “necessary to avoid an imminent hazard to the public safety”) five more times to schedule an additional six fentanyl analogues, including the most recent action, to temporarily place Schedule I controls on acryl fentanyl on July 14, 2017. DEA is currently collecting information for potential additional actions. Prior to this series of actions, DEA had last used temporary scheduling authority to schedule fentanyl analogues in the mid-1980s when Congress enacted the Comprehensive Crime Control Act of 1984, which provided DEA with this

authority. In addition to its temporary (emergency) scheduling authority, DEA relies on the Analogue Act to investigate and prosecute those preying on vulnerable populations in advance of finalizing a control action.

3. Are the pill presses that are used in fentanyl trafficking being shipped from China?

Response: India, China, and Germany were the top three countries from which pill presses/encapsulation machines were shipped in 2015 and 2016; however, to the best of DEA's knowledge, illicit operations identified to date in 2017 used presses that had been purchased from China.

a. Are the pill presses being trans-shipped from China through other countries and then to the U.S.?

Response: At present, DEA has no information regarding transshipment of pill presses from China through other countries.

b. Is there a concern about trans-shipment of pill presses through other countries? If so, why?

Response: While DEA is not currently aware of transshipment of pill presses through other countries, we continue to be vigilant in identifying emerging trends that may impact drug trafficking.

4. DEA and DHS have seized numerous pill presses with Chinese sources. They were identified as intentionally mislabeled. However, parts or components to pill presses are also being shipped. What can you tell us about such detections, and cooperation with the Chinese government?

Response: If shipped separately, the parts of a pill press, except for the dies, do not meet the criteria for the criminal offense with respect to counterfeiting equipment under 21 U.S.C. Section 843(a)(5). Nevertheless, depending on the facts and circumstances, it could be an offense of possessing or distributing equipment with the intent to illegally produce a controlled substance (including a counterfeit) under Sections 843(a)(6) or (7). The parts are often mislabeled to avoid law enforcement and reporting requirements. DEA has had discussions regarding pill press regulations with the Chinese government, but they are not regulated in China. However, the Chinese are willing to cooperate with DEA in investigations where crimes can be tracked back to China.

5. While we recognize that most online addresses in the U.S. for supplying fentanyl are either faked or can be altered, there continue to be legitimate (i.e. actual physical) addresses of buildings that are listed on the websites by some fentanyl suppliers. Are these addresses being screened through law enforcement databases – including (if available) the addresses of individuals linked by e-mail to respond to customer questions?

Response: DEA seeks to investigate many leads in tracking down illicit fentanyl suppliers.

a. Do these addresses represent possible drop shipment locations?

Response: DEA is not in a position to speculate on possible links between these locations and illicit fentanyl suppliers.

b. Has this ever been investigated?

Response: As stated above, DEA seeks to investigate many leads in tracking down illicit fentanyl suppliers.

6. The detection and identification of NPP and ANPP, two of the major essential precursors - or ingredients - to making fentanyl, have been debated topics since there are legitimate laboratory and medical uses for these items. What quantities have been noted as going to labs for legitimate purposes, how are they normally ordered or created, and from where?

Response: NPP is a List I chemical controlled by DEA that is used to manufacture fentanyl and is also used in organic synthesis. ANPP is a schedule II controlled substance (an immediate precursor) which is used by the pharmaceutical industry to manufacture fentanyl.

In the U.S., those who wish to “create” (i.e.) or manufacture ANPP and fentanyl would have to obtain a Schedule II manufacturing registration from the DEA. DEA registered manufacturers would then apply for an individual manufacturing quota. The Aggregate Production Quota (APQ) is the total amount of a controlled substance that can be manufactured in a 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 2016 APQ for ANPP was 2,950 kilograms and for fentanyl was 2,300 kilograms. Those wishing to manufacture NPP would obtain List I chemical manufacturing registration from DEA and report their manufacturing activities to DEA on a yearly basis. DEA has not received any such reports.

a. Are other precursors being considered for identification as illegal substances?

Response: DEA actively monitors for precursor modifications through established programs and investigations. As a new chemical or synthetic route is identified, DEA collects information and evaluates the details for a possible chemical control. There is process established under the CSA to regulate a chemical that provides for engagement with the chemical industry. Through our domestic and international chemical control efforts, DEA is able to respond to changes in precursor chemicals to disrupt the clandestine manufacture of controlled substances. In March 2017, DEA with the State Department secured the international control of two fentanyl precursors.

7. A recent drug bust in Chicago discovered that there were almost 200,000 phone calls placed to one phone line in six months, or about 1,000 calls per day. This data helped DEA and local police detect and arrest the offenders. What kinds of similar or other data-sharing and related techniques have been/are available to assist law enforcement?

Response: DEA has established 77 Tactical Diversion Squads (TDS) in 43 states, the District of Columbia and the Caribbean. The TDS groups' primary function is to investigate the diversion of controlled substances from the legal market to the illicit market. TDSs are comprised of DEA Special Agents, Diversion Investigators, State, local, and tribal Task Force Officers, and other federal law enforcement agencies (e.g., HHS-OIG and FBI agents). DEA works very closely with state and local law enforcement agencies across the country in sharing information, data, and resources to help combat the opioid epidemic.

DEA has a number of reporting mechanisms that it can analyze to develop investigative leads. Internally, the Automated Reports and Consolidated Orders System (ARCOS), the Unlawful Medical Products Internet Reporting Entries (UMPIRE), and the 877-RxABUSE hotline are all resources that DEA may rely on to establish leads relating to the potential diversion of controlled substances.

The DEA Analysis and Response Tracking System (DARTS) for DEA users, and the De-confliction and Information Coordination Endeavor (DICE) system for non-DEA users, help support data-sharing and de-confliction efforts to assist law enforcement. These tools allow law enforcement personnel to check if others are gathering the same types of information. These tools maximize coordination and information sharing among law enforcement agencies and allow for immediate field de-confliction, which enhances ongoing investigations and ensures officer safety when "blue-on-blue" investigative actions are uncovered.

8. Since carfentanil is the deadliest of all fentanyl analogues, what can be said about areas where it has been detected consistently?

Response: DEA is unaware of any specific areas where carfentanil has been consistently detected.

a. What about sources and types of production?

Response: Carfentanil is approved by the Food and Drug Administration for use in veterinary medicine and is a Schedule II substance in the United States. From 2014-2016, there have been no U.S. manufacture or imports of veterinary products containing carfentanil. During the same time period, there was no manufacturing of carfentanil for analytical standards, but these analytical standards were imported about 15 times. In 2017, DEA set the APQ at 10 grams and issued manufacturer quotas to three separate companies to manufacture analytical standards. The quantity of the drug needed for legitimate medical use is established by quota, and distributors and users are registered. DEA has not encountered diversion of the lawful carfentanil drug product. Rather, the appearance of the substance on the illicit drug market is through sources of production in Chinese laboratories, where the compounds are produced and then purchased and shipped to the United States from dark web illicit marketplaces.

b. Where have localized spikes in deaths (and in seizures) been most pronounced?

Response: Overall, the drug overdose death rate increased significantly from 12.3 per 100,000 in 2010 to 16.3 in 2015. Death rates have increased in 30 states and Washington, D.C., and have remained stable in 19 states. During 2015, a total of 52,404 persons in the United States died from a drug overdose, an increase from 47,055 in 2014; among these deaths, 33,091

(63.1%) involved an opioid, an increase from 28,647 in 2014. The age-adjusted opioid-involved death rate increased by 15.6%, from 9.0 per 100,000 in 2014 to 10.4 in 2015. According to CDC initial estimates, there were more than 64,000 overdose deaths in 2016, or approximately 175 per day. More than 34,500 (54%) of these deaths were caused by opioids. The sharpest increase in drug overdose deaths was fueled by a surge in fentanyl and fentanyl analogues (synthetic opioids) overdoses, accounting for more than 20,000 (31%) of these deaths.¹

Numerous reports of fentanyl and other synthetic opioid deaths and encounters have originated in the Midwest and Northeast and the issue continues to evolve, affecting new communities across the United States. It is anticipated that these highly addictive and lethal substances are in additional communities and those encounters may be underreported. Drug overdoses are complex events. DEA continues to respond to overdose clusters and work with local, tribal and State public health officials to triangulate information to a specific drug causing the overdose event. In response to these overdoses, DEA has utilized emergency scheduling authority to control numerous fentanyl analogues. As the trend of encountering new synthetic opioids continues, additional and centralized reporting of overdose events would assist DEA in its response time.

Since the demand for fentanyl and fentanyl analogues remains high, DEA continues to engage with foreign counterparts to reduce the supply. DEA has engaged extensively with China and has shared information regarding carfentanil encounters. China's subsequent control of carfentanil on March 1, 2017, was a significant outcome. DEA and the State Department have requested the World Health Organization to review carfentanil for international control in the coming year.

9. Most experts agree that the issue of diverted drugs has lessened in recent years, while the problem of illicit fentanyl has exploded. However, there are several types of prescription fentanyl commonly available (e.g. patches, Actiq lollipops or lozenges) that are still subject to counterfeiting and abuse. Are these types being detected or seized as illegally manufactured, and to what degree?

Response: The diversion of licit fentanyl is not common in comparison to other pharmaceutical controlled substances such as oxycodone and hydrocodone. Furthermore, DEA is not aware at present of the illicit manufacture/counterfeiting of legitimate pharmaceutical fentanyl products, such as patches, Actiq lollipops, or lozenges. However, due to its potency, diverted fentanyl is more likely to cause an overdose than other more commonly diverted prescriptions. Should diversion of licit fentanyl be discovered, DEA will commit the resources necessary to investigate.

Illicitly-produced fentanyl has been detected in counterfeit oxycodone pills, which are being seized at a high rate. This fentanyl powder is sourced from China. North American distributors manufacture the powder into counterfeit prescription pills that are trafficked throughout the continent. The "branding" of the pills to mimic, or look like legitimate prescription pills, has resulted in the drugs being abused by witting and unwitting users.

10. While organized crime cartels and individual internet orders have been defined as principal suppliers of illicit fentanyl, other entities have been identified. For example, biker gangs have been cited as allied with cartels as distributors in some instances,

while significant quantities of heroin mixed with fentanyl have been discovered at dogfighting events. What can you tell us about the detection and prevalence of such alternative drug distributors?

Response: The tools needed to manufacture counterfeit pills containing fentanyls are available online and are relatively inexpensive compared to other forms of drug production, contributing to its unique level of threat. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. Fentanyls are available for purchase online from anonymous dark net marketplaces and even overtly-operated websites. Industrial pill press machines are also widely available on the open internet. An April 2016 online search of auction websites by DEA revealed a wide variety of pill presses for sale. One pill press capable of producing 5,000 pills per hour was priced at \$995, and die molds for oxycodone and Xanax® pills were for sale at \$115 and \$130, respectively. The availability of counterfeit prescription drugs containing fentanyls will continue to grow in the near term. The relative ease and low cost associated with obtaining the drugs and equipment needed to manufacture counterfeit pills containing fentanyls will encourage individuals, as well as large and small DTOs, to move in this direction. Additionally, non-cartel-affiliated individuals may undertake production of counterfeit pills.

11. Regarding the detection of fentanyl pills, what kinds of commonly used techniques (or outputs) have been detected in the seizures of pills in terms of shaping from pill molds, coloring, distribution, and the like?

Response: The source of fentanyl is primarily of non-pharmaceutical origin and has been identified in powder form as well as in solutions and tablets that mimic legitimate pharmaceutical products (i.e., counterfeit tablets). These tablets have imitated oxycodone, hydrocodone, and alprazolam pharmaceutical formulations, leading an end user to believe that the counterfeit product is a legitimate pharmaceutical product.

In 2015, there was a marked surge in the availability of non-pharmaceutical fentanyl pressed into counterfeit prescription opioids such as oxycodone. In many cases, the shape, colorings, and markings are consistent with authentic prescription medications and the presence of fentanyl only becomes known under laboratory analysis. The rise of fentanyl in counterfeit pill form exacerbates the fentanyl epidemic. Prescription pill abuse is less stigmatized than use of illegal drugs and may attract new, inexperienced drug users, thereby creating more fentanyl-dependent individuals.

12. Since the time of China's listing of 116 illegal substances in 2015, where/have there been identification(s) of illegal manufacture and sanctions on Chinese labs?

Response: After China's listing of substances in 2015, DEA has seen a marked decrease in these substances. DEA does not yet know the extent of sanctions placed on Chinese labs. DEA investigations have revealed various Chinese manufacturers who import illegal substances into the U.S. including fentanyl and fentanyl analogues. The Chinese government and DEA have begun coordinated investigations on Chinese manufacturers and labs. On October 17, 2017, DOJ announced indictments against two Chinese nationals and their North America-based traffickers and distributors for separate conspiracies to distribute large quantities of fentanyl and fentanyl analogues and other opiate substances in the United States.

- a. **Has this kind of information been shared with us by the Chinese government, or will it?**

Response: DEA continues to work cooperatively with its Chinese counterparts, which includes the sharing of information related to coordinated investigations and seizures of fentanyl compounds.

13. **Numerous sources state that the current fentanyl crisis is due in most part to illicit shipments and manufacturing. Yet there are several types of diverted fentanyl that have also been created illegally. Can you comment on this type of illegally made/diverted fentanyl?**

Response: DEA's information indicates that fentanyl seizures are suspected to be illicitly manufactured. DEA's review of registered fentanyl manufacturers and distributors indicate it is not generally being diverted from legitimate industry. DEA continues to reassess market vulnerabilities that may allow for fentanyl diversion to fill availability shortfalls.

- a. **How prevalent is this? In other words, is it a significant source of the problem we are seeing right now?**

Response: DEA information indicates that fentanyl diversion occurring from legitimate manufacturers and distributors is not a significant source of the problem. The data indicates that fentanyl seizures are of drugs that have been illicitly manufactured. Findings related to recent fentanyl encounters suggest that fentanyl is being pressed into pills to resemble other drug products. Although diversion of fentanyl for personal use has taken place at very low levels in the past, information from recent fentanyl encounters suggest that illicit, foreign-sourced fentanyl powder is imported and pressed into counterfeit pills in order to resemble other drug products. These counterfeit drugs are passed-off to unknowing users and often contain lethal amounts of fentanyl. There are no indications that counterfeit fentanyl drug products are being encountered on the legitimate drug market.

Illicit fentanyl is being encountered throughout the United States. Encounters at the borders include fentanyl in both powder and counterfeit tablet form or in combination with heroin or in some instances, with cocaine. DEA continues to investigate and disrupt these organizations with our federal, state, and local partners. Significant quantities of the drug have been removed from the streets and DEA will continue to utilize all tools available to disrupt and prosecute those peddling these poisons.

14. **Is the diversion of Buprenorphine a significant factor also driving the opioid epidemic? What data does the DEA have regarding this diversion?**

Response: Buprenorphine is a narcotic drug for which there is a significant demand in illicit channels. Given that buprenorphine is often prescribed to persons who are addicted to narcotics, it is expected that some of the buprenorphine dispensed to patients will be diverted through illegal resale. For this reason, it is controlled and its use as an addiction treatment medicine is highly regulated. However, multiple cross-sectional studies have found that the majority of people who misuse diverted buprenorphine report doing so to "self-treat" for opioid use disorder or opioid

withdrawal symptoms. In addition, buprenorphine is a partial agonist at the μ -opioid receptor, meaning it only partially activates the receptor. It poses a significantly lower risk for overdose than full agonist opioids such as oxycodone or heroin. DEA does not have data that would allow for a precise quantification of such diversion. At the same time, buprenorphine, when properly dispensed as part of an effective addiction treatment program, can be highly beneficial in leading to recovery from opioid addiction.

Buprenorphine as a partial agonist is less likely than other opioids to cause respiratory depression unless it is used in combination with other sedatives. Overdose data suggests it is less of a factor in overdose deaths than other opioids although users in treatment sometimes overdose.

When users withdraw from opioids, especially if they cannot obtain treatment on demand, they often view it acceptable to borrow or illicitly obtain drugs to prevent this withdrawal.ⁱⁱ Demand for buprenorphine as a diverted product may stem from an insufficient provider network for buprenorphine as an addiction treatment medicine.ⁱⁱⁱ To date, fewer than 40,000 providers have taken the training and completed the special certification process to provide buprenorphine through office based treatment and most providers are not working up to capacity. One study in Ohio showed that although 466 providers were listed as offering services, nearly 1 in 5 did not actually provide treatment and more than 40% who accepted patients did not accept insurance. Until this issue is solved, buprenorphine is likely to continue to be diverted for self-treatment, to prevent withdrawal and for non-medical use.

Products combining buprenorphine with naloxone are available to produce withdrawal if patients ingest them by injection. These combination products were intentionally designed to thwart misuse and diversion and appear to be effective at this relative to buprenorphine-only products.^{iv} To decrease diversion for non-medical use, the Centers for Medicare and Medicaid Services and insurers should examine their policies to ensure that patients have access to these buprenorphine formulations and that the products with pure forms of buprenorphine only intended for use under supervised administration or during pregnancy are reserved for such purposes.

New less-divertible products such as buprenorphine implants are also available and may help decrease diversion, however, they require surgery and follow-up removal and are only intended for use in stabilized patients. Policy makers should consider ways to promote their use.

The Honorable Buddy Carter

- 1. In 2010, the Drug Enforcement Administration (DEA) issued an interim final rule (IFR) to allow for the electronic prescribing of controlled substances (EPCS). Since that time, DEA has acknowledged that the IFR does not allow for an unfilled prescription for a Schedule II controlled substance to be transferred or forwarded by a pharmacy to another pharmacy because the first pharmacy, for whatever reason, is unable to fill the prescription. DEA has further stated that the agency plans to address this issue when the agency issues the EPCS final rule. Considering that this unresolved issue is likely leading to delays in patient care and is acting as a barrier to the widespread adoption of EPCS, please provide an update on DEA's progress in issuing the final rule.**

Response: DEA's Interim Final Rule (IFR) on Electronic Prescriptions for Controlled Substances (EPCS) provides practitioners with the option to sign and transmit prescriptions for controlled substances electronically. Pharmacies are permitted to receive and archive electronic prescriptions. In FY 2012, DEA announced the first DEA-approved certification process for EPCS. Through December 31, 2015, DEA approved six different certification processes. The Diversion Control Program (DCP) continues to hold open dialogue with industry stakeholders in order to research, develop and implement EPCS regulations.

As the IFR stated, DEA regulations addressing the transfer of prescriptions are set forth in 21 CFR 1306.25. Consistent with the greater danger to the public health and safety associated with the diversion of Schedule II controlled substances (as compared to schedule III-V controlled substances), DEA regulations have historically not allowed for the transfer of prescriptions for Schedule II controlled substances. Nonetheless, DEA is continuing to evaluate this issue, with input from the regulated industry, to explore the possibility of amending DEA regulations to allow for the transfer of electronic prescriptions of Schedule II controlled substances in a manner consistent with effective safeguards against diversion.

The Honorable Frank Pallone, Jr.

1. According to a December 2016 article in the Charleston Gazette-Mail, opioid wholesalers shipped mass quantities of opioid medicines that appeared to be far in excess of what certain communities in West Virginia should have received based on sound medical needs. The article said:

“In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two pain killers [...] The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia.”

- a. Has DEA been able to examine the veracity of the oversupply assertions laid out in the 2016 article?

Response: Yes.

- b. If DEA has found these assertions to be accurate, what action, if any, has DEA taken on this issue with respect to supply chains into West Virginia? Please include information on any joint effort with other federal, state, or local law enforcement or public health agencies.

Response: DEA currently has two Tactical Diversion Squads (TDS) operating in Charleston, South Carolina, and Clarksburg, West Virginia, which work with state and local law enforcement. DEA established the Clarksburg TDS Group in December 2016 to help address the opioid epidemic within the state of West Virginia. DEA, working with United States Attorneys and the Department of Justice, has taken and continues to pursue criminal, administrative, and civil actions against various bad actors within the closed system of distribution, including, but not limited to, suppliers, doctors and pharmacies. Recently, DEA investigated and civilly settled significant investigations on wholesale distributors, including Amerisource Bergen, Cardinal Health, McKesson and Miami-Luken, which had supplied controlled substances into West Virginia. These settlements levied not only fines, but also imposed significant new reporting requirements on these distributors.

- c. Similarly, has DEA identified specific public safety issues stemming from the possible oversupply of prescription drugs as described in the 2016 Charleston Gazette-Mail reporting?

Response: Yes. DEA recently implemented its 360 Strategy in an effort to combat the nationwide opioid epidemic. This three pronged approach, including increased law enforcement operations to address violent crime, ongoing diversion control efforts, and community outreach is currently being used in West Virginia as a proactive tool to help combat the opioid crisis. Further information on DEA's 360 strategy can be found at: <https://www.dea.gov/prevention/360-strategy/360-strategy.shtml>

- d. What additional insights does DEA have into the alleged practices as indicated in this reporting?

Response: In July 2014, the State of West Virginia passed legislation requiring clinics that treat chronic pain to be licensed by the West Virginia Department of Health. Once licensed, there are additional requirements on the clinics that have significantly reduced diversion of controlled prescription drugs by doctors.

DEA issues quotas to DEA-registered bulk manufacturers and dosage form manufacturers for scientific, research and medical needs in addition to lawful exports and inventory. The databases that are used to justify and verify quota applications are nationally aggregated commercial sales and retail sales data. The regulatory requirements for quota are only at the manufacturers' level and the requirements and regulatory controls of quotas do not extend to the distributor levels. Quotas are not issued to manufacturers based on geographic areas. Sales by manufacturers to distributors are tracked by DEA through the Automated Reports and Consolidated Orders System (ARCOS), but individual distributions are not pre-approved by DEA.

Although the distributors are not covered under the Quota program, they have specific reporting requirements outlined in DEA regulations, including utilizing specific forms and report transactions to ARCOS. In addition, as DEA registrants, they are obliged by the CSA to maintain effective controls against diversion of controlled substances into illicit channels, and DEA regulations require distributors to design and operate a system to detect suspicious orders and to promptly notify DEA of any such orders. DEA has been active in enforcing that provision against national and regional controlled substance distributors.

Manufacturers also distribute the products they make, so they too are under an obligation to detect and notify of suspicious orders. A recent settlement with a large national manufacturer, Mallinckrodt plc, resulted in a civil penalty and an agreement by the company to enhance the monitoring of sales to distributors, as well as to use of available tools within the company to monitor "downstream" orders by customers of distributors who receive Mallinckrodt's drugs.

2. **MSNBC also ran a story about the substantial influx of opioids into West Virginia. More specifically, it reported on the small town of Kermit, with an estimated population of only 392 people. MSNBC reported that one pharmacy in Kermit received 9 million hydrocodone pills in two years. If this reporting is true, I am concerned we do not have sufficient systems in place to identify and respond to such dangerous trends or, if those systems do exist, they may have failed in this case. You indicated during your testimony that DEA is familiar with reports of possible oversupply of these addictive pills in West Virginia.**
 - a. **Is DEA aware of the reports that one pharmacy in Kermit, West Virginia may have received 9 million hydrocodone pills over a two-year period?**

Response: Yes.

- b. **If so, what actions, if any, has DEA taken to date in response to possible oversupply in the Kermit, West Virginia case?**

Response: DEA and its State and local counterparts investigated the referenced pharmacy, which resulted in the pharmacy surrendering its DEA registration "for cause," meaning the pharmacy

voluntarily surrendered its DEA registration as a result of its alleged failure to comply with the Federal requirements pertaining to controlled substances. In addition, several doctors and nurse practitioners associated with the “pill mill” for which the pharmacy had filled prescriptions were federally prosecuted and convicted.

3. **The reports of possible oversupply of addictive opioids into West Virginia may raise additional concerns regarding whether there are systemic weaknesses in our regulatory and enforcement systems that could allow abusive oversupply patterns to go unnoticed or unaddressed.**

- a. **Has DEA identified any systemic failures surrounding the oversupply of opioids in West Virginia?**

Response: DEA has identified the need to carefully scrutinize and analyze data indicating that distributors may be supplying amounts of controlled substances disproportionate to the population size, given that it could be a data point indicative of diversion.

- b. **If yes, what issues did DEA identify? What has DEA concluded were the causes of these issues? What solutions has the DEA identified, and what efforts to date has DEA taken to implement these solutions?**

Response: As part of DEA’s efforts to continue engagement with distributors, DEA conducts annual Distributor Conferences and has initiated quarterly Distributor Initiative meetings that are conducted with specific wholesalers. The purpose of these meetings is to review their data and obligations in handling controlled substances, discuss national trends involving the abuse of pharmaceutical controlled substances, discuss their “due diligence”, and review ARCOS data for sales and purchases of Schedule II and III narcotic controlled substances. DEA also discusses and reviews the law and regulations pertaining to suspicious orders. At the conclusion of the Distributor Initiatives, DEA Headquarters Diversion personnel provide training to the respective field division’s diversion investigators on policy changes, new systems and regulations, and other relevant information.

Additionally, specific to West Virginia, DEA increased personnel in its local field offices, including two TDS. The TDS groups combine DEA resources with those of federal, state, and local law enforcement agencies in an innovative effort to investigate, disrupt and dismantle those suspected of violating the CSA or other appropriate federal, state or local statutes pertaining to the diversion of licit pharmaceutical controlled substances. The TDS groups help coordinate with various judicial districts to maximize the effectiveness of multiple investigations and prosecutions of those involved in the diversion of pharmaceutical controlled substances.

4. **If true, the reported oversupply of these addictive pills to the State of West Virginia raises significant concern that the same problem could be occurring elsewhere.**
- a. **What monitoring systems are in place to detect potential oversupply of prescription drugs nationwide? Do we have a monitoring unit to compare to population size?**

Response: At this time, a single system does not exist to provide total distribution, usage, and prescription monitoring data and to compare that to a state or locality's population.

There are several ways in which DEA is able to monitor suspicious orders. Distributors are required to submit monthly or quarterly reports of their purchases and sales of Schedule II and Schedule III Narcotics to ARCOS. These reports are verified by DEA personnel and can be used as a tool to pinpoint areas throughout the United States in which excessive amounts of pharmaceutical controlled substances are purchased. In addition to these requirements, DEA's Diversion Regulatory Section conducts quarterly Distributors Initiatives. The ARCOS section provides data to support that initiative.

An additional tool DEA may use to further active investigations is the State-run Prescription Monitoring Programs (PMPs). Although access requirements and procedures vary by state, PMP networks can give DEA investigators the ability to access opioids prescriptions written by practitioners within all participating states. The PMPs allow DEA investigators to identify states where excessive amounts of opioids may have been dispensed in their area. Further, as noted above in response to Question 1.d, DEA-registered controlled substance distributors are obliged by the CSA to maintain effective controls against diversion of controlled substances into illicit channels, and DEA regulations require distributors to design and operate a system to detect suspicious orders and to promptly notify DEA of any such orders. DEA has been active in enforcing that provision against national and regional controlled substance distributors.

b. Does DEA have sufficient insight into the supply patterns of other states hard-hit by the opioid epidemic to identify and respond to suspicious patterns occurring elsewhere?

Response: DEA has oversight of regulatory matters under the Diversion Control Division. This oversight allows DEA personnel to conduct field regulatory investigative activities such as periodic scheduled investigations, pre-registration investigations, Order to Show Cause investigations, and theft/loss investigations, among others. The aforementioned investigations are conducted to ensure compliance with the Controlled Substances Act (CSA) and promulgated regulations found in the Code of Federal Regulations. In an effort to gain sufficient insight on areas that may face challenges with excessive opioid distribution, DEA also includes 10 pharmacies per field office as part of its yearly scheduled investigations.

DEA has the authority to reduce quota authorizations to bulk manufacturers and dosage manufacturers when it has been shown through investigations that diversion has occurred within the closed system of distribution as a result of the manufacturer not complying with the rules and regulations outlined in the CSA. However, through various investigations, DEA has determined that many of these incidents of oversupplying areas are the result of a series of primary, secondary, and even tertiary distributors selling and reselling dosage units before supplying the retail pharmacies. Although the DEA-registered distributors are not required to request quota, they are required to report transactions using DEA forms and report to ARCOS. The distributors' activities can be tracked by DEA and these issues can be addressed to each distributor in meetings, such as the Distributor Initiative Briefings. All of these tools allow for DEA to address any substantial issues/areas of concern where diversion is suspected.

ⁱ CDC WONDER data, retrieved from the National Institute of Health website; <http://www.drugabuse.gov> as reported on NIDA's website.

ⁱⁱ Kenney SR1, Anderson BJ2, Bailey GL3, Stein MD4
The relationship between diversion-related attitudes and sharing and selling buprenorphine.
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Congress of the United States
House of Representatives

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April 11, 2017

Mr. Matthew Allen
Assistant Director, Homeland Security Investigative Programs
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Dear Mr. Allen:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, March 21, 2017, to testify at the hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, April 25, 2017. Your responses should be mailed to Elena Brennan, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515, and e-mailed in Word format to Elena.Brennan@mail.house.gov.

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

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachment

Question#:	1
Topic:	Fentanyl Challenges
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How is fentanyl more of a law enforcement challenge than prescription opioids or heroin?

Is one of the challenges to combatting fentanyl that it has so many analogues - also known as chemical variations?

If so, how does this present a unique challenge to addressing the supply?

Response: Fentanyl is a Schedule II synthetic opioid, used medically for severe pain relief and its analgesic effect is 80 times more potent than morphine and 40-50 times stronger than heroin. As little as 2 milligrams of fentanyl can be fatal. Illicitly produced fentanyl is a greater law enforcement challenge than prescription opioids because it can be easily concealed or formulated to mirror other substances, which makes its presence often unknown to the officers who encounter it during the course of their duties. The presence of fentanyl is often only fully detectable using laboratory analysis. Law enforcement officers are less likely to encounter diverted pharmaceutical prescribed fentanyl.

China-sourced illicit fentanyl is primarily used in counterfeit tableting organizations in the United States that aim to supply prescription pill users. Counterfeit tablet suppliers often purchase powdered illicit fentanyl through the anonymity of the internet and can access open internet and darkweb marketplaces for the tools needed for manufacturing. Illicit Fentanyl, pill presses, and binding agents are then shipped into the United States through the mail parcel system and express consignment. The illicit fentanyl obtained directly from China is typically extremely high in purity rates and often unadulterated.

Mexican drug cartels also obtain illicit fentanyl and precursor materials required to manufacture fentanyl-related substances from China and primarily use fentanyl as an adulterant to their heroin products. The cartels have discovered purchasing or manufacturing illicit fentanyl is much more cost effective and efficient than cultivating opium poppies to produce heroin. Because of the potency of fentanyl, only a few micrograms are needed, and it can be diluted and cut with other agents to produce dozens of kilograms of heroin product. The adulterated heroin can sell at the traditional heroin street price or much higher under the advertisement of a stronger euphoric effect. Smuggled adulterated heroin products now have a much lower cost of replacement when discovered and seized by law enforcement. Typically Mexico-supplied fentanyl is under 12 percent pure.

Question#:	1
Topic:	Fentanyl Challenges
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Chinese exporters continue to replace and modify chemical variations in production circulation to circumvent the U.S. Controlled Substances Act and the regulated chemical list within China. This provides obstacles when working to schedule new variations of fentanyl analogues within the United States and China.

To date, the U.S. Customs and Border Protection (CBP), Laboratories and Scientific Services Directorate has detected 14 fentanyl analogues and has intelligence leads on six more fentanyl analogues. When a particular analogue of fentanyl is not specifically regulated by the Controlled Substances Act, U.S. Immigration and Customs Enforcement (ICE) special agents and Assistant U.S. Attorneys are tasked with utilizing the Controlled Substance Analogue Enforcement Act of 1986. This is a nuanced statute that presents significant challenges in the prosecution of individuals involved in the supply and distribution chain.

Question#:	2
Topic:	Trans-shipment
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Are the pill presses that are used in fentanyl trafficking being shipped from China?

Response: Many of the companies that manufacture pill presses are based in China and act as suppliers for third-party online vendors, such as EBay and Amazon. The United States regulates the importation of pill presses, but does little to verify whether the purchaser has a legitimate need and the actual use of pill presses is unregulated. As these items have both licit and illicit uses, whether they are diverted to illicit enterprises or used for illicit purposes depends on the party purchasing the pill press.

Question: Are the pill presses being trans-shipped from China through other countries and then to the U.S.?

Response: CBP is not aware of specific transshipment countries. Regardless of origin, all pill presses entering the United States must be registered with the Drug Enforcement Administration Office of Diversion Control under 21 CFR 1310.05(c).

Question: Is there a concern about trans-shipment of pill presses through other countries? If so, why?

Response: In the United States, pill presses are regulated by the Drug Enforcement Administration (DEA). In countries such as Canada, no registration is required and the machines can be purchased online for \$3,000 to \$10,000. Canada is currently contemplating legislation, Bill C-37, which would require every pill press to be registered with Health Canada and permit officers at the border to detain unregistered pill presses.

Question#:	3
Topic:	India and UK as Original Sources
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Recent reports have reconfirmed earlier analyses that the main source nations of fentanyl have been China, Mexico, and Canada, the two latter countries often as transshipment points. However, several other "southern" nations have been identified, one of these as the principal supplier to a major American city. CBP has even identified India and the U.K. as sources of several port seizures since FY 2015.

Does DHS regard India and the UK as original sources of fentanyl or as transshipment points?

Response: CBP's Office of Intelligence (OI) is not aware of reporting to indicate that India and the UK are original sources of fentanyl or act as transshipment points, nor is it aware of CBP port seizures traced to these countries since Fiscal Year 2015. CBP OI considers Mexico and China as primary source countries for fentanyl flow into the United States. Reporting indicates that relatively larger scale quantities (by weight) of fentanyl primarily enters the United States in privately-owned vehicles from Mexico via the Southwest Border of the United States. In contrast, fentanyl from China and Canada typically enters the United States through express consignment and international mail shipments in relatively smaller quantities (by weight). CBP additionally considers Canada and Mexico as transshipment points for fentanyl, fentanyl analogues and fentanyl precursors bound for the United States from China.

Question#:	4
Topic:	Tracking and Detection Techniques
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: DEA, CBP and other agencies have reported how often the shipments of fentanyl go through multiple carriers and often multiple countries before the products are finally delivered to the U.S. What tracking and/or detection techniques are made available by U.S. Postal Service and major international carriers in order to flag items that are sent to numerous locations in this manner before it arrives?

Response: CBP receives advance electronic data on all international Express Consignments shipments and can effectively target these shipments on arrival in the U.S. In the international mail environment, CBP receives limited and inconsistent data, which makes it extremely difficult to target and track these shipments prior to arrival, and in many cases, even after arrival. In addition, CBP is unable to track fentanyl shipments that go through multiple carriers, and different countries before being delivered to the United States. CBP is working with the United States Postal Service (USPS) to address this issue.

CBP can track and target shipments based on the last movement that is destined to the United States. Most tracking techniques utilize the information provided by the international carriers, including historical information. This information consists of date of shipment arrival, the manifested commodity and declared weight, shipper name and address, consignee name and address of destination. CBP has the ability to flag shipments with similar routing, manifested commodity descriptions, shipping addresses or names, and also by the consignee information.

Question: Have DEA and CBP thought of ways to improve these techniques?

Response: CBP is holding discussions with USPS to address the challenges that currently exist in the targeting and interdiction of international mail shipments. One major challenge is the ability of the USPS to locate the packages upon arrival to the US at the international mail facilities. Another challenge is the quality of the data provided. Information is not always available for the sender, commodity description, or location of arrival, and not covering all packages that arrive.

CBP and DEA have taken a whole of government approach to bring together, contextualize, and synchronize the strategies and partnerships currently taking place at the federal, state, and local levels to identify and reduce illicit fentanyl. Information shared among the partners allows CBP to identify the packages in international mail when the data is available and collaborate directly with the partner to take further action.

Question#:	5
Topic:	Domestic Shipper
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: The U.S. Postal Inspection Service reported to committee staff in February that three of their five fentanyl-related closed cases involved a "domestic shipper" as the source. Are you familiar at all with these cases?

Did these cases involve the same shipper each time?

What can you tell us about the domestic shippers in these cases?

Response: ICE would require additional information relating to the U.S. Postal Inspection Service cases referenced to in order to provide a response.

Generally speaking, however, with respect to ICE investigations, domestic distributors often source fentanyl and fentanyl-related substances from illicit drug market places via the darkweb or Internet, and primarily sell fentanyl in counterfeit opioid tablets. Unlike fentanyl sourced from Mexico, domestic distributors often have no cartel affiliations.

Question#:	6
Topic:	Manifest Data
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Is Homeland Security Investigations ("HSI") using manifest data from the consignment carriers such as Federal Express to develop any leads or patterns about Chinese sources of fentanyl-related shipments?

Freight forwarding of drug shipments may involve bundling or consolidating several kinds of items into one shipment. Is HSI using manifest data from consignment carriers about patterns of freight forwarding?

Would certain patterns of freight forwarding raise a red flag for HSI?

Response: ICE exploits all types of shipping data, including consignment carriers and freight forwarders, to identify trends and target illicit fentanyl shipments.

ICE and CBP analyze advance information to gather, fuse, and assess data from the global supply chain to develop a risk profile and evaluate that risk at the earliest point.

Question#:	7
Topic:	Cooperation with Consignment Carriers
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Has HSI developed a level of cooperation with consignment carriers so that subpoenas or other investigative tools can be expedited to investigate fentanyl-related cases?

What can you tell us about recent and/or significant seizures of illicit opioids and/or related items, e.g. pill presses or component parts, in terms of source countries or entry points into the USA?

Since so much of the source for fentanyl is attributed to China, and many air express or other modes of shipment are relatively small, what has been learned about return or source addresses when illicit drugs have been identified?

Response: ICE has established strong partnerships with consignment carriers such as Federal Express (FedEx), United Parcel Service (UPS), and DHL, primarily in the ICE offices closest geographically to the companies' headquarters or international consignment hubs. For example, ICE HSI Memphis has forged a mutually beneficial working relationship with FedEx World Headquarters that helps to disrupt and dismantle transnational criminal organizations utilizing FedEx services to illegally ship fentanyl, fentanyl-related substances, pill presses, and pill press parts both domestically and internationally. These efforts have allowed ICE and CBP to analyze shipping trends in an effort to better identify and target suspicious shipments. Similarly, relationships have also been forged by ICE HSI Louisville with UPS and by ICE HSI Cincinnati with DHL. This partnership strategy has proven fruitful in the expediting and return of subpoena requests relating to fentanyl investigations.

Recently, DHL supported a request initiated by ICE that resulted in the seizure of 25 kilograms of suspected fentanyl found in several DHL parcel shipments. The parcels originated in China, and were destined for the northeast region of the United States. DHL continues to provide substantial information, which is aiding in the identification of members of a regional or "domestic" fentanyl-supplying organization. ICE currently has multiple ongoing investigations that have resulted in the seizures of pill presses, counterfeit pill press dies, and compound mixers. On a regular basis, pill presses and their component parts destined to locations throughout the nation are seized at the aforementioned express consignment hubs. These seizures are used to generate lead packets that are distributed to the affected ICE offices. As a result of the intelligence received from these seizures, illicit fentanyl tableting operations are often identified.

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In each of these cases, it has been determined that the fentanyl, fentanyl-related substances, and/or pill press items have originated in main land China. Many of the Chinese addresses are those associated with freight forwarding services and not of the manufacturing/supplying organization. Additionally, investigations have revealed that supply organizations utilize freight forwarders that typically have multiple freight consolidators. This provides several layers of anonymity in the shipment process and thwarts law enforcement efforts in identifying the true source address.

Question#:	8
Topic:	Cellulose
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: It has been noted that there are substantial quantities of cellulose that usually or frequently accompany shipments of fentanyl powder for the process of making it into pills. Is law enforcement finding quantities of cellulose in drug distribution cases involving fentanyl?

Should cellulose be tracked?

Response: Microcrystalline cellulose (MC), as well as several other excipients (copovidone, magnesium stearate, etc.) are frequently used in illicit fentanyl and fentanyl-related substance tableting operations. These excipients are almost always found when a tableting operation is discovered. ICE special agents and (CBP) Officers often utilize information contained in manifested shipments of the items to develop actionable leads for dissemination to ICE special agents in the field. Most international distributors of MC accurately manifest their products as MC, which is completely unregulated.

Currently, CBP and ICE are successfully tracking MC and have found it to be beneficial to targeting, interdiction, and enforcement actions.

Question#:	9
Topic:	Testing Strips
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Last fall, the Canadian press reported that a type of test strip to indicate the presence of fentanyl was being made widely available for a low price (\$5 Canadian). These kits or test strips were first announced in Vancouver, British Columbia, but later reports have identified them to pharmacies in Winnipeg, Manitoba (the middle of Canada). Yet there appears to be little if any public reaction, response, or similar kits detected or reported in the US. Why is that?

Response: Within a week of the reports of the market availability of these test strips, sales were stopped over concerns with accuracy and effectiveness of using urine test strips on bulk drug samples. As of this time, we are not aware of any reliable field test kits for the detection of bulk opioids that is currently on the market. ICE is currently working with our U.S. law enforcement counterparts to identify the safest handling methods and best field testing procedures for fentanyl.

Question#:	10
Topic:	Carfentanil
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Given that carfentanil can be lethal to the touch, or even to breathe, what kinds of special precautions are being provided to law enforcement and emergency responders to guard against accidental toxic contact?

Given the extreme deadliness of carfentanil, and its documented use as a chemical weapon, at what point would trafficking in carfentanil be considered a national security issue?

Response: Carfentanil is treated by law enforcement officers in the same respect as other fentanyl-related substances. Proper personal protective equipment, such as masks and gloves, is issued to the field to be utilized when suspected carfentanil is encountered. In an effort to standardize protective procedures, the National Institute for Occupational Safety and Health (NIOSH) recently published standard guidance to prevent occupational exposure to fentanyl for emergency responders. ICE special agents are also being trained in the administration and use of naloxone, which is used to treat overdose symptoms. Law enforcement hazardous material response teams are used for search warrant executions of locations suspected of containing fentanyl-related substances.

ICE remains committed to interdicting, identifying, disrupting, and dismantling organizations that provide fentanyl and related substances such as carfentanil to the United States.

Question#:	11
Topic:	Dark Web Sources
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Many, if not most online orders for fentanyl and its analogues are alleged to be accessed through the dark web, whether it may be "Tor," Silk Road, or other sources. To what extent can patterns and tendencies, such as shipments and receipts, be traced and detected that can assist law enforcement in limiting or shutting down various sites?

Response: Packages of fentanyl and its analogues purchased through the dark web are often small quantities and packaged in a manner that does not alert law enforcement. However, when packages are identified and seized, it is sometimes possible to identify unique characteristics associated with a particular dark web vendor's packaging or shipping methodology. Since these unique characteristics are frequently replicated across multiple packages from the same vendor, it is sometimes possible to document packaging similarities and link associated packages. These similarities can include labeling, packaging, point of origin or ship from location, or deceptive items included within a package. While some of these packaging trends only help law enforcement attribute shipments to a particular vendor who remains unknown, consistent points of origin or shipping locations sometimes contribute to identification of the vendor. Likewise, the same destination address for multiple packages may help to establish a pattern that can assist law enforcement in identifying the purchasers.

Although identifying these patterns and tendencies in packages of fentanyl and its analogues sometimes contributes to the identification and location of dark web vendors and buyers, this normally only has a slight limiting effect on darknet marketplaces. Since these marketplaces have numerous vendors, when one vendor is identified and arrested, another source of supply is readily available on the marketplace. Additionally, because these marketplaces operate with the anonymity and security afforded through encryption software such as Tor or other platforms, identifying the physical location of servers and shutting down the sites is normally very challenging.

Question: How is the dark web more of a law enforcement challenge than rogue Internet pharmacies on the open web?

Response: There are various components of the dark web and related functionality that make it significantly more challenging for law enforcement than rogue Internet pharmacies on the open web, including security and anonymity, cryptocurrencies, and the user community.

1) Security and anonymity:

Question#:	11
Topic:	Dark Web Sources
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

It is normally possible to identify the location of sites hosted on the open web, such as rogue Internet pharmacies, through a variety of law enforcement techniques. However, Tor has implemented security and encryption, ensuring Tor hidden service sites are not readily identifiable, even when sophisticated law enforcement techniques are applied.

Tor and other platforms that provide the ability to host dark websites and connect to the dark web were designed and built with security and anonymity as primary goals. To provide security, all traffic that is routed within the Tor network is encrypted. To provide anonymity, Tor is configured so users never directly connect to the servers hosting the Tor hidden service sites, and the servers hosting the sites never connect directly to the user who is attempting to make a connection. As a result, no identifying Internet protocol address or other information is transmitted when connections are made to a site.

Additionally, because dark websites are normally hosted through companies or individuals that are not compliant with law enforcement, even when the location of a dark website is identified, serving a warrant or court order often presents another set of challenges. Lastly, because encryption is employed for all transmitted data, even when a server location is identified, a Title III intercept is not a viable solution because transmitted data is unreadable.

2) Cryptocurrencies or privacy-focused cryptocurrencies:

Darknet marketplaces require purchasers and vendors to use convertible virtual currencies, primarily bitcoin, or the new generation of privacy-enhancing cryptocurrencies when conducting transactions. Although network analytic investigative tools can assist with identifying and analyzing related transactions on a Bitcoin-type blockchain, attributing transactions to a specific user and identifying a real person or entity as a user is more challenging than with traditional payment methods. Moreover, the new generation of privacy-enhancing cryptocurrencies presents significant challenges to the use of existing network analytic tools. While the United States regulates convertible virtual currency exchangers, hosted wallets, and (for centralized virtual currencies) administrators as money transmitters, with anti-money laundering and countering the financing of terrorism (AML/CFT) obligations under the Bank Secrecy Act, including AML program, transaction monitoring, recordkeeping, and reporting requirements, the general lack of regulation of virtual currency globally exacerbates its risks and presents obstacles to international law enforcement cooperation.

3) User community:

An active user community facilitates the use of both the dark web and virtual currencies for illicit activities. Fora on both the open web and the dark web provide information

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related to dark web activities, including how to download Tor and access the dark web, how to employ encryption, and how to remain anonymous online. Other discussions in these fora include latest trends in drugs, reviews of drugs purchased on the dark web, and information about other items sold through the dark web. Additionally, many users in these fora seek to educate other users by highlighting suspected law enforcement activity on the dark web, encounters with law enforcement related to dark web purchases, and any other information related to notable law enforcement investigations.

Question#:	12
Topic:	Fentanyl from Russian-Speaking Countries
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Some of the committee staff efforts to track down internet suppliers of fentanyl have resulted in connections to Russian language websites, not necessarily China as first assumed. It is also known that the Baltic countries (especially Estonia) have been struggling with outbreaks of illicit fentanyl for years. Have there been any fentanyl seizures in the U.S. that have come from Russian-speaking countries?

Response: ICE is aware of one case being conducted by ICE HSI Boston where an empty parcel from Zaporozhye, Ukraine, was discovered during a search warrant executed at the home of an individual under investigation for selling controlled substances.

It is unknown whether this parcel contained fentanyl or a fentanyl-related substance (FRS). Aside from this case, the National Targeting Center, as the clearinghouse within the Department of Homeland Security responsible for tracking this type of data, is not aware of any fentanyl or FRS seizures occurring at an international mail facility where the product was from a Russian-speaking nation.

Question#:	13
Topic:	Payment Processes
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: There is the old adage 'follow the money' when efforts are made to detect illegal drug suppliers. Bitcoins have been cited as a particular favorite mode of payment for many fentanyl shipments. What efforts have or are currently being made to track these payment processes?

Have new or changing alternatives been detected?

Is ICE seeing any evidence that credit card companies, consignment carriers, or domain registrars are accepting bitcoin as payment?

Response: ICE maintains a proactive approach to virtual currency and recognizes virtual currency may become more mainstream if the technology is embraced globally. Many illicit fentanyl sources operate on the dark web and use bitcoin for financing. ICE's Illicit Finance and Proceeds of Crime Unit conducts outreach to major virtual currency exchangers operating within the United States in order to clarify and emphasize the need for collaborative partnerships. Partnerships between ICE and financial-sector businesses enhance ICE's operational abilities to investigate digital currencies. ICE collaborates with industry leaders to identify and acquire access to the most effective forensic tools available to analyze and identify information through the Bitcoin blockchain, which is a traceable ledger of every Bitcoin transaction ever conducted. Blockchain analytics technology enables investigators to track payments back from the darknet marketplaces, with the goal of identifying the user connected to a specific bitcoin wallet address.

In an effort to enhance user privacy, newer cryptocurrencies use technology that obstructs efforts to trace transactions through a distributed ledger, and present heightened challenges to regulatory and compliance efforts. Privacy-enhancing cryptocurrencies present new challenges for law enforcement to identify the source of transactions utilizing these types of virtual currencies.

ICE is aware that some domain registrars accept bitcoin payment. Although ICE has not experienced major credit card companies accepting bitcoin, it is aware that certain pre-paid credit cards do accept bitcoin.

Question#:	14
Topic:	UPS and FedEx Cooperation
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Some of the illicit fentanyl, and its precursors, is being detected as being sent through American commercial carriers, such as UPS and FedEx. What kind of cooperation have you received from these carriers?

Can they improve their monitoring and cooperation? If so, how?

Response: ICE and CBP work closely with express consignment companies to target contraband, including fentanyl, its precursors, and fentanyl analogues. Both ICE and CBP have an excellent working relationship with the express consignment companies. Efforts continue to foster a continuous improvement environment for monitoring.

Question#:	15
Topic:	Monitoring the Foreign Supply
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Ryan Costello
Committee:	ENERGY & COMMERCE (HOUSE)

Question: As we work towards the implementation of the Comprehensive Addiction and Recovery Act (CARA), how are we also monitoring the foreign supply networks of deadly chemicals fueling the opioid and heroin epidemic, such as those being produced in China?

Response: ICE and CBP work with other U.S. agencies and foreign partners to identify foreign supply networks and seize illicit fentanyl and fentanyl-related substances before they arrive in the United States.

ICE and CBP are exploiting shipment data to better target shipments of suspected deadly chemicals, including working with its Attaché offices in China, Canada, and Mexico to pursue informational leads obtained through seizure analysis and investigative methods. Trends in chemical structure or concealment methods are shared internationally to identify fentanyl organizations, and new manufacturing methods and chemical compounds.

In April 2017, ICE and CBP personnel assigned in Hong Kong, China, worked with Hong Kong Customs and Excise (HKCE) to target parcels suspected of containing fentanyl and other illicit substances that were transhipped from mainland China to Hong Kong and destined for the United States. Based on information provided by ICE and CBP, HKCE was able to seize packages destined to the United States and several other countries that contained fentanyl or other illicit substances.

Question#:	16
Topic:	Mexican Poppy Crops
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Ryan Costello
Committee:	ENERGY & COMMERCE (HOUSE)

Question: You noted in your testimony the influence of poppy cultivation in Mexico, of which the DEA has reported a 50 percent increase. As you know, increased cultivation therefore means increased production and trafficking. What more needs to be done to encourage Mexico's cooperation and willingness to destroy poppy crops? What are the obstacles here?

How are American authorities working with Mexican authorities to counter this threat?

Response: ICE, DEA, and the State Department are working proactively with the Government of Mexico (GoM) to identify and destroy poppy fields identified through investigative means. Mexico's vast geographical terrain and extreme cartel violence provide some obstacles for law enforcement. ICE, DEA, the State Department and the GoM continue to share intelligence and investigate transnational criminal organizations to stop and eradicate poppy crops and prevent other controlled substances from being produced and smuggled into the United States.

Question#:	17
Topic:	Security Loophole
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Ryan Costello
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Currently, over 340 million packages come into the United States through the global postal system, via the United States Postal Service, without advanced electronic manifest data. Do you agree that this is a major security loophole, and a problem that needs to be fixed?

Response: USPS provides CBP all of the advanced electronic data they received for the foreign post operation. The advanced electronic data provided to CBP and all end-users in the system is used to target shipments as appropriate. While CBP would agree that this is an issue that needs to be addressed by USPS, CBP continues to inspect, via x-ray technology, radiation detection, K-9 inspection, and physical examination, all mail that is presented to CBP. CBP currently receives advance electronic data from several countries via the USPS and we are actively targeting shipments.

Question: Would having this data better enable CBP and other agencies to detect and interdict dangerous and deadly drugs?

Response: Obtaining additional data from USPS is very important to CBP.

CBP has limited visibility in the international mail environment, which consists of Letter Class mail, Parcel Mail and E-Packets that originate in China. CBP receives no advanced data on letter class mail and receives limited, inconsistent data for parcels from the following countries: China, Hong Kong, Germany, Canada, Spain, France, Australia, South Korea, Singapore and the United Kingdom. Interdicting and targeting specific shipments creates a challenge, as mail processing at the International Mail Facilities (IMFs) is a manual process, which relies upon an officer's visual and physical inspection of parcels. The USPS is often unable to locate targeted packages because there is no mechanism at the IMFs to ensure the presentation of all targeted shipments.

Ideally, USPS modernization would support leveraging the increasing availability of AED by allowing items identified using a tracking number, such as the one that UPU regulations will soon require to be applied to all small packets containing goods, to be pulled for inspection when they are scanned into the computer system as having arrived at their particular air hubs.

Question: Do you believe foreign posts, like China Post, should be compelled to provide advanced electronic manifest data to the USPS, so the USPS can provide that data to CBP?

Question#:	17
Topic:	Security Loophole
Hearing:	Fentanyl: The Next Wave of the Opioid Crisis
Primary:	The Honorable Ryan Costello
Committee:	ENERGY & COMMERCE (HOUSE)

Response: Through the USPS, CBP has been able to receive advance electronic data from a number of countries on a voluntary basis. China Post is one of the foreign postal operators that voluntarily provides approximately 99 percent of its e-packet data to USPS for review by CBP. Compelling a foreign post to provide electronic data is an approach that may or may not be feasible. CBP believes that we need to work with USPS to develop more bi-lateral agreements with foreign post operators to receive data.

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) 225-2827
Minority (202) 225-3641

April 11, 2017

The Honorable William Brownfield
Assistant Secretary of State
International Narcotics and Law Enforcement Affairs
U.S. Department of State
2201 C Street, N.W.
Washington, DC 20520

Dear Ambassador Brownfield:

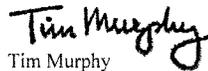
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, March 21, 2017, to testify at the hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, April 25, 2017. Your responses should be mailed to Elena Brennan, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515, and e-mailed in Word format to Elena.Brennan@mail.house.gov.

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

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachment

**Questions for the Record Submitted to
Assistant Secretary Brownfield by
Representative Tim Murphy (#1)
House Energy and Commerce Committee
March 21, 2017**

Question:

Your written testimony notes that China has agreed to domestically control carfentanil. However, your testimony also states that the U.S. is requesting international control of carfentanil. What is the additional benefit of having carfentanil subject to international control in addition to Chinese government control?

Answer:

Reducing the availability of carfentanil is a top priority in combating the opioid epidemic in the United States. Adding it to the international control regime, under the United Nations Single Convention on Narcotic Drugs, will obligate all 193 State Parties to the Convention to institute legislative and administrative measures to monitor and regulate its manufacture and distribution, and to cooperate with other member states to execute the provisions of the Convention. In response to U.S. requests made through the standing bilateral Joint Liaison Group (JLG) on Law Enforcement, since 2015 China has taken action to control domestically more than 120 synthetic drugs. Recently, in March 2017, China announced controls on carfentanil and three other prominent fentanyl analogues.

China's decision to domestically control carfentanil is a welcome measure that should contribute towards preventing its use for illicit purposes.

**Questions for the Record Submitted to
Assistant Secretary Brownfield by
Representative Tim Murphy (#2)
House Energy and Commerce Committee
March 21, 2017**

Question:

Very recently, there was a Global Smart Update from the U.N. Office on Drugs and Crime, centered on fentanyl and its analogues. Are you familiar with this document?

- a. If so, what significant findings does it provide for the U.S. regarding fentanyl?

Answer:

With support from the Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL), the United Nations Office on Drugs and Crime (UNODC) Global Synthetics Monitoring: Analyses, Reporting, and Trends (SMART) Programme publishes bi-annual updates examining patterns and trends of the global synthetic drug situation. The most recent Global SMART Update, *Fentanyl and its analogues – 50 years on*, was published in March 2017 and is available on UNODC's website:

<http://www.unodc.org/unodc/en/scientists/global-smart-update-2017-vol-17.html>.

The March 2017 publication provides a good synopsis of the origins, complexity and controls of fentanyl and its analogues in the opioid market. The report cites

an illicit manufacturing method for fentanyl using the two precursor chemicals, ANPP and NPP. At the United States behest, the 53 members of the Commission on Narcotic Drugs (CND) voted unanimously, at the March 2017 meeting, to control these two chemicals. The report also highlights open source press materials examining the prevalence of illicit fentanyl analogue use globally.

**Questions for the Record Submitted to
Assistant Secretary Brownfield by
Representative Ryan Costello (#1)
House Energy and Commerce Committee
March 21, 2017**

Question:

Currently, over 340 million packages come into the United States through the global postal system, via the United States Postal Service, with advanced electronic manifest data. Do you agree that this is a major security loophole, and a problem that needs to be fixed?

- a. Would having this data better enable CBP and other agencies to detect and interdict dangerous and deadly drugs?

Answer:

Trafficking controlled substances across state lines and through the U.S. Postal Service are serious offenses. The United States government has long recognized that Advance Electronic Information for packages and small packets arriving by international mail is valuable for a variety of customs, law enforcement and security purposes, although the Department of State would defer to U.S. Customs and Border Protection (CBP) on its specific utility for interdicting synthetic opioids and other dangerous drugs.

- b. Do you believe foreign posts, like China Post, should be compelled to provide advanced electronic manifest data to the USPS, so the USPS can provide that data to CBP?

Answer:

The Department of State's Bureau of International Organization Affairs is actively advancing U.S. efforts through the Universal Postal Union (UPU) to promote global electronic exchange of customs data for mail items containing goods. The United States is working with other UPU member countries to secure final approval for a messaging standard for this data and to build capacity to capture and transmit it. The UPU's 192 members agreed to prioritize this U.S.-led objective.

Although postal services worldwide agree on the need to exchange this data, few, if any, foreign postal operators have the ability, resources, or training to exchange item-level data with USPS for their entire postal volume, as opposed to shipments from major commercial mailers.

Since international mail exchange takes place on the basis of reciprocity within the context of a global agreement, unilateral actions could end the ability of Americans to send or receive international mail. Consequently, it is critical that any requirements the U.S. sought to impose on foreign postal operators be

carefully designed to address U.S. law enforcement objectives and the capacity of affected countries to comply.

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April 11, 2017

Dr. Debra Houry
Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Houry:

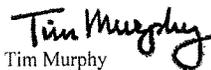
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, March 21, 2017, to testify at the hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis."

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Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing: "Fentanyl: The Next Wave of the Opioid Crisis"
March 21, 2017
Questions for the Record

Questions for the Record for Dr. Debra Houry, Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC)

Chairman Tim Murphy

1. A Huffington Post article in January commented that many hospital Emergency Departments or related hospital sections do not yet test for fentanyl in the systems of potential victims. How prevalent does that situation continue to be, and what steps are being taken to rectify it?

Answer: CDC does not have national data on the percentage of emergency departments that test for fentanyl or fentanyl analogs, but historical reports suggest that many hospitals do not test for synthetic opioids such as fentanyl.ⁱ In the emergency department (ED) setting, where the focus is on immediate resuscitation and restoration of vital signs, knowing the specific form of opioid involved in an overdose has little clinical relevance unless the opioid has a long half-life, such as methadone. Clinical diagnosis of opioid overdose is sufficient to begin appropriate treatment, and naloxone is titrated to whatever level is necessary to achieve an adequate response. A rapid drug screening panel, using immunoassay technology, is often conducted in the ED setting for suspected overdose cases, and is used to provide objective evidence of opioid overdose, but a positive screening test is unlikely to be sent for confirmatory testing which would allow for the specific opioid, such as fentanyl, to be identified. Such testing is expensive, and the results would only be available after the ED patient has been discharged. Some EDs have elected to add a rapid immunoassay test specific to fentanyl into their standard drug screen panel, but many may not be aware of the availability of this rapid test. Furthermore, a rapid fentanyl immunoassay test may or may not detect the various fentanyl analogs now available, leading to false negative results. There are example of hospitals in jurisdictions with high levels of fentanyl use and overdose, such as in Rhode Island, beginning to test for fentanyl.ⁱⁱ

- a. **How does this impact data reporting and collection in hospital settings?**

Answer: Because we do not know the percentage of emergency departments testing for fentanyl and whether this percent is increasing or decreasing over time, it is difficult to assess national trends in fentanyl-related overdoses. This has been a limitation of previous national estimates of fentanyl non-fatal overdoses.ⁱⁱⁱ In April 2017, CDC began to receive preliminary data on emergency department visits related to drug overdoses on a quarterly basis from 11 states^{iv} as part of the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality funding announcement.^v Although the data contain preliminary information on the emergency department visit, analyses will be conducted to estimate how often emergency departments appear to be testing and detecting fentanyl-related overdoses.

- b. **How can we improve data collection and reporting to ensure we are getting complete and accurate information?**

Answer: CDC is addressing the problem in at least two ways. First, CDC is raising awareness about the increasing problem of fentanyl-related overdoses and identifying states and jurisdictions strongly impacted.^{vi} This highlights the importance of responding and tracking nonfatal fentanyl-related overdoses in those jurisdictions. Second, CDC has recommended and is working with 12 states funded through the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality funding announcement to develop rapid methods for identifying drug overdose outbreaks using existing data from emergency department and emergency medical services.^{vii} This project will help assess the current data collected on nonfatal overdoses by emergency departments and identify opportunities to improve surveillance of emergency department visits related to fentanyl-related overdoses.

2. **There is a wide variation in the reporting of overdose statistics from state to state, and even county to county. However, committee staff located a county in Illinois (Will County, in suburban Chicago) that now tracks “Accidental Overdoses” by date of death, cause of death (fentanyl and/or other drugs), and personal demographics like race, sex, and age. How helpful is this for legal and medical entities? If useful, could this reporting format be evaluated for recommendation as a prototype for other communities and states?**

Answer: CDC believes that the information collected in Will County would be extremely helpful if it were collected on all death certificates of drug overdose deaths in the US. It also substantially aligns with current federal efforts to improve and enhance fatal and nonfatal drug overdose data collections. This information is useful to public health, medical, and legal entities, as it helps researchers, investigators, health care providers (for both clinical and behavioral health), and public health practitioners to understand and identify drug use risks, appropriate clinical and behavioral care, and public health interventions.

The US death certificate is designed to collect all of the information on drug overdose deaths being collected by Will County. However, data quality issues, especially with regard to the reporting of specific drugs can be a challenge when interpreting drug overdose statistics.^{viii} After a drug overdose death is investigated, the investigator (usually a medical examiner or coroner) certifies the cause of death (e.g., drug poisoning [overdoses]) and should also include details and circumstances such as the specific drugs contributing to the death (e.g., heroin and cocaine). However, the quality of information regarding specific drugs involved with drug overdoses varies substantially across states and counties. Nationally, drugs are unspecified for approximately 1 in 5 drug overdose deaths in the US. The percent of overdose death certificate data with information on at least one drug varies substantially across states (from 48 percent to nearly 100 percent in 2014).^{ix}

There are multiple national and state efforts underway to address these issues that align with the effort in Will County. Currently, CDC is partnering with the Association of State and Territorial Health Officials (ASTHO) on a project to improve drug specificity on death certificates. This project will gather individual perspectives about the importance of death certificate data in public health practice, the issues affecting the quality of mortality data, and identify potential solutions and benchmark indicators for improved data quality. This project builds on ongoing work by CDC’s National Center for Health Statistics (NCHS) to improve the quality of drug overdose death information. Additionally, NCHS has built text search tools that can be used to identify drug overdose related to specific drugs such as fentanyl.^x Finally, the CDC Enhanced State

Surveillance of Opioid-Involved Morbidity and Mortality announcement funds 12 states to collect complete toxicology findings and death scene evidence collected on all opioid-related overdose deaths starting in July 2016. This will allow the 12 states and CDC to better track drug specific mortality.^{xj}

3. Have new priorities been established to inform or assist the states in distinguishing fentanyl overdoses and deaths from other opioids? If so, where and how are they implemented?

Answer: Yes, and CDC is assisting states in four ways. First, in response to the sharp increases in the supply of illicitly-manufactured fentanyl (IMF) and fentanyl-related drug overdose deaths in 2014, CDC changed its method for calculating overdose deaths related to opioid analgesics to exclude overdose deaths that may have involved IMF.^{xii} The calculation change was widely distributed and is reflected in the current indicators CDC uses to track the progress of its state prevention efforts. Second, CDC was involved in Epidemiological Investigations (*Epi-Aids*) in Ohio and Massachusetts where the broad distribution of IMF is driving increases in opioid-related overdose deaths. Ohio now separately tracks fentanyl-related overdose deaths.^{xiii} In Massachusetts, CDC collaborated with the Massachusetts Department of Health to estimate the percent of fentanyl-related overdose deaths that were suspected to involve IMF versus pharmaceutical fentanyl.^{xiv} In addition to informing targeted prevention efforts in Massachusetts, the methodology can be applied in other states. Third, CDC is partnering with the Association of State and Territorial Health Officials (ASTHO) on a project to improve drug specificity on death certificates. This project will gather individual perspectives about the importance of death certificate data in public health practice, the issues affecting the quality of mortality data, and identify potential solutions and benchmark indicators for improved data quality. This project builds on ongoing work by the National Center for Health Statistics (NCHS), within CDC, to improve the quality of drug overdose death information. Additionally, NCHS has built text search tools that can be used to identify drug overdose related to specific drugs such as fentanyl.^{xv} Finally, the CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality announcement funds 12 states to collect complete toxicology findings and death scene evidence collected on all opioid-related overdose deaths starting in July 2016. This will allow the 12 states and CDC to track fentanyl-related overdose deaths and deaths related to fentanyl analogs such as acetyl fentanyl and carfentanil when coroners and medical examiners test for analogs.^{xvi} In addition, the 12 states may be able to estimate deaths related to IMF using the methodology developed in Massachusetts if sufficient death scene evidence was documented.

4. In your statement, you refer to “effective PDMPs [Prescription Drug Monitoring Programs]” and how you have made them timelier and easier to use in interstate communication. How have you improved or enhanced this process, and can you cite examples?

Answer: CDC has funded 42 states and Washington, D.C., to combat the prescription drug overdose epidemic through state programs. Funded states are using various methods to maximize the effectiveness of their PDMPs. For example, Arizona has upgraded their PDMP software so the time it takes for patient prescription information to be updated in the system has been reduced from 7 days to 1 to 3 days. The reduction in the time between data entry and the system being updated allows prescribers to more accurately calculate a patient’s morphine milligram equivalent (MME) dose, enabling providers to more easily recognize patients who

may be at risk for overdose and provide better care.

Another example is Kentucky. In December 2015, Kentucky began integrating morphine equivalent information into patient PDMP reports. With the help of CDC funding, Kentucky PDMP patient reports now contain an Active Cumulative Morphine Equivalent (ACME) number. If the ACME is 100 or greater, a warning symbol appears along with a note that increased clinical vigilance may be appropriate. This functionality increases a doctor's ability to provide safe and effective care to their patients. Following the enhancement of the PDMP reports, a 2% decrease was seen in high opioid prescribing to adults, and a remarkable 25% reduction in opioid prescribing to youth aged 0-17 between the last quarter of 2015 and the end of the first quarter of 2016.

CDC funds have been used to launch a pilot project in Tennessee and Kentucky to examine the added value of interstate PDMP data sharing. The project will assess the extent to which data sharing across states enhances each state's ability to identify and respond effectively to high-risk patients.

5. **One response given in localities is that the need and availability of Naloxone is ever-present. Given the unknown need for quantities on hand for paramedics, etc., since there can be no set amount to counteract a given overdose – how can this need be effectively addressed?**

Answer: There are two factors to ensure that adequate naloxone will be available to responders to manage overdose, particularly in locations where fentanyl is present. The first is to ensure limited supplies of naloxone are prioritized to locations where they are most needed, and the second is to consider making higher dose formulations of naloxone available to responders. Improved surveillance can assist with the first goal, which is best served by a combination of data from public health and public safety. Monitoring of ED and EMS data for spikes in overdose and spikes in naloxone administrations can help to identify hotspots where naloxone resources can be directed, along with data from public safety, which identifies changes in the illicit drug market. Due to the recognition that multiple administrations of naloxone are often necessary to revive a fentanyl overdose in the field,^{xvii} the FDA has recently convened an Advisory Committee to assess the most appropriate doses of naloxone that should be made available for use in the field, as well as criteria for assessing the most appropriate dose to utilize in advance of an overdose event.^{xviii}

- a. **The state of Virginia has even gone so far as to mandate its access to all state residents. How has this type of response helped the crisis?**

Answer: HHS and international health organizations recommend providing naloxone kits to laypersons who use opioids, who might witness an opioid overdose, to patients in substance use treatment programs, to persons leaving prison and jail, and as a component of responsible opioid prescribing.^{xix} An interrupted time series analysis during 2002–2009 found that opioid overdose death rates were reduced in Massachusetts communities where overdose education and nasal naloxone distribution was implemented.^{xx} One strategy to improve access and distribution of naloxone to community members is to implement a Standing Order for naloxone. This strategy has been recently implemented in Virginia, and allows pharmacists in Virginia to recommend and dispense naloxone to

those deemed to be at significant risk of opioid overdose, without a prescription from a physician. The strategy has been implemented in a number of other states, and has been demonstrated to increase the availability and use of naloxone among community members.^{xxx}

6. In your written testimony you state that CDC has funded 12 states for Enhanced State Surveillance of Opioid-Involved Mortality. What are the criteria for funding for these states?

Answer: The criteria for funding states for the Enhanced State Surveillance of Opioid-Involved Mortality was based on a competitive application process where states were scored based on their burden and their ability to:

- a) Increase the timeliness of aggregate nonfatal opioid overdose reporting.
- b) Increase the timeliness of fatal opioid overdose and associated risk factor reporting.
- c) Disseminate surveillance findings to key stakeholders working to prevent or respond to opioid overdoses.

The number of states funded was based on the appropriation for the activity.

7. Your written testimony mentions that CDC is connected to 44 states at present regarding prevention efforts and surveillance activities, with the goal of expanding to all 50 states. What can you tell us about the six states not yet connected, and what hurdles need to be cleared to achieve their involvement?

Answer: The six states that are not yet supported directly by CDC funds are: Florida, Texas, Iowa, Mississippi, North Dakota, and Wyoming. Although these states do not currently receive funding, we provide non-monetary programmatic resources (that are available to any state) upon request. Examples include CDC's Opioid Indicators Toolkit and recordings of technical assistance webinars and training events. By providing these resources, our goal is to ensure all states have and can utilize the Indicators Toolkit, and recordings of technical assistance webinars and training events.

We also plan to work directly with the six states by inviting them to CDC-funded opioid overdose training academies, which are designed to: 1) include state teams comprised of key players, such as the governor's office, public health, Medicaid, law enforcement, treatment providers, and health systems leaders; 2) teach best practices related to partnerships, data systems, and evidence-based interventions; and 3) develop a state plan that includes key agencies and most impactful interventions. These academies have been very successful in the past when executed with a partner who can ensure that the right state-level leaders come to the training and can offer follow-up assistance afterwards. Both the National Governors Association and the National Network of Public Health Institutes could potentially offer these trainings in conjunction with CDC.

8. How can real-time monitoring of the fentanyl threat be expanded?

**Please note this question is from NIDA's QFRs, but is best addressed by CDC. CDC's response is below.*

Answer: A top priority in stopping the fentanyl epidemic is to create a national surveillance system that will give a full picture of the epidemic in real-time. We are currently funding 12 states under the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program to improve tracking and reporting of illicit opioid overdoses, including fentanyl, as part of this surveillance system. It allows CDC to monitor changing trends and issues related to this epidemic, such as deaths from heroin containing illicitly manufactured fentanyl, and to understand how the epidemic evolves over time. If the program was expanded to all 50 states, we could have a true national snapshot of nonfatal and fatal opioid-involved overdoses. This could give us more timely information on geographic areas experiencing sharp increases so we could respond more quickly with responses tailored to that outbreak. It could also give us information on decreases of overdoses which would help us rapidly identify successful intervention efforts.

The Honorable Buddy Carter

1. **The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 was signed into law on April 19, 2016. This Act requires a report to Congress not later than one year after enactment identifying among other things, obstacles to legitimate patient access to controlled substances, and how collaboration among federal, state, and local law enforcement agencies and industry can benefit patients and prevent diversion and abuse of controlled substances. HHS is tasked with submitting the report to Congress in coordination and collaboration with a number of other federal agencies, including the Drug Enforcement Administration. Please provide us with an update of the status of the report.**

Answer: This is outside of CDC's purview; however, HHS will follow up with your office for a response.

ⁱ For additional information https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html .

ⁱⁱ For additional information <http://www.providencejournal.com/news/20170404/as-overdoses-surge-many-ri-hospitals-start-testing-for-fentanyl-in-ers> .

ⁱⁱⁱ For additional information https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html .

^{iv} Although 12 states are funded through the ESOOS program, only 11 states are submitting ED data. States have the option to submit ED or EMS data or both. Ten of the 12 states are submitting both ED and EMS data. Oklahoma is not submitting ED data, and Missouri is not submitting EMS data.

^v For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{vi} For additional information <https://emergency.cdc.gov/han/han00384.asp> and

<https://www.cdc.gov/mmwr/volumes/65/wr/mm6533a2.htm> .

^{vii} For additional information <https://emergency.cdc.gov/han/han00395.asp>,

<https://emergency.cdc.gov/han/han00384.asp> , <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> and

<https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{viii} For additional information <http://www.cste.org/blogpost/1084057/246934/Announcing-New-Recommendations-for-Epidemiologists-to-Improve-Reporting-of-Drug-Overdose-Deaths-on-Death-Certificates> .

^{ix} For additional information https://www.cdc.gov/nchs/data/health_policy/unspecified_drugs_by_state_2013-2014.pdf and <http://s3.documentcloud.org/documents/1151267/heroin-project-2014-study-on-overdose-deaths.pdf> .

^x For additional information https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf and https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_09.pdf .

^{xi} For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> .

^{xii} For additional information <https://www.cdc.gov/drugoverdose/data/analysis.html> .

^{xiii} For additional information <https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf?la=en> .

^{xiv} For additional information <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> .

^{xv} For additional information https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf and https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_09.pdf.

^{xvi} For additional information <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html>.

^{xvii} For additional information <https://www.cdc.gov/mmwr/volumes/66/wr/mm6614a2.htm> and <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6234a5.htm>.

^{xviii} For additional information <https://www.fda.gov/AdvisoryCommittees/Calendar/ucm516000.htm>

^{xix} For additional information <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm>, <https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>, and http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/ and <https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf>.

^{xx} Additional information available at <http://www.bmj.com/content/346/bmj.f174.long>

^{xxi} Davis, CS et al, Legal Changes to increase access to naloxone for opioid overdose reversal in the U.S., Drug and Alcohol Dependence, 2015 Dec 1;157:112-20 <https://www.ncbi.nlm.nih.gov/pubmed/26507172>

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April 11, 2017

Dr. Wilson Compton
Deputy Director
National Institute on Drug Abuse
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Compton:

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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing: "Fentanyl: The Next Wave of the Opioid Crisis"
March 21, 2017

Questions for the Record for Dr. Wilson Compton, Deputy Director, National Institute on
Drug Abuse (NIDA), National Institutes of Health

Questions from Chairman Tim Murphy

1. **Question:** Last fall, the Canadian press reported that a type of test strip to indicate the presence of fentanyl was being made widely available for a low price (\$5 Canadian). These kits or test strips were first announced in Vancouver, British Columbia, but later reports have identified them to pharmacies in Winnipeg, Manitoba (the middle of Canada). Yet there appears to be little if any public reaction, response, or similar kits detected or reported in the US.
 - a. Does NIDA have any familiarity with these test kits?
 - b. Is NIDA supporting research into these types of test kits?

Answer: Our understanding is that these test strips are enzyme immunoassay kits originally developed to test for the presence of fentanyl in urine that are being used to test for fentanyl in drug samples diluted in water. These kits are available for sale in the United States as well, from [Diagnostic Automation/Cortez Diagnostics Inc.](#), [Confirm Biosciences](#), and [NarcoCheck](#), and are sensitive to a variety of newer fentanyl analogs. At this time, there are no NIDA projects researching the adaptation of these kits to identify fentanyl in drug samples.

2. **Question:** What challenges does fentanyl present in a treatment setting and how does that compare to treating a patient that is addicted to opioids or heroin?

Answer: The high potency of fentanyl and its rapid onset of effects are likely to increase the risk for overdose, as well as for addiction and for withdrawal symptoms. Thus, fentanyl users may be more likely to have severe opioid use disorders, compared with users of other types of opioids, but the treatment strategy is the same. It is also important to note that most individuals who illicitly use fentanyl also use other opioids; polydrug use is very common. Furthermore, users may be unaware that fentanyl was in the substances that they consumed.

Medication-assisted treatment (MAT) is the standard of care. Evidence strongly demonstrates that methadone, buprenorphine, and injectable extended-release naltrexone all effectively help maintain abstinence from other opioids and reduce opioid use disorder symptoms. These medications should be administered in the context of drug use monitoring along with appropriate counseling and psychosocial supports to improve

outcomes and reduce the potential for relapse. However, there have been few cases of illicitly manufactured fentanyl users treated with MAT, and given that fentanyl use may lead to a more severe opioid use disorder, higher doses may be required to restore balance to the brain circuits impaired in these patients and to support recovery.

3. Question: How could the NIDA-funded National Drug Early Warning System be used to enhance fentanyl surveillance?

Answer: The NIDA-funded National Drug Early Warning System (NDEWS) uses multiple sources of data to monitor fentanyl use and informs our understanding of the extent of the problem. NDEWS is a unique approach to understanding drug use (including fentanyl) patterns and trends in sentinel communities and across the nation. This program identifies emerging issues and disseminates information to a broad range of stakeholders. Key components of NDEWS include:

- a. leveraging existing data from law enforcement, public health, and research sources to monitor indicators of drug use, availability and consequences, in combination with novel data available via the internet and media;
- b. establishing collaborations with researchers in local communities to produce annual Sentinel Community Site Drug Use Patterns and Trends Reports and serving as contacts for emerging issues through the year. For example, [NDEWS Sentinel Community Site Advance Report 2016: Selected Findings for Heroin, Fentanyl, and Methamphetamine](#)
- c. an open virtual NDEWS Network of more than 1,500 members, including researchers, practitioners, and concerned citizens, providing the opportunity for NDEWS to share information and query the Network about emerging drug trends, and for Network participants to alert others to significant drug-related issues in their areas as they arise, query each other about what they have seen, and exchange scientific information and resources;
- d. the ability to conduct a limited number of “hot spot” studies in collaboration with local researchers to obtain more detailed information on emerging issues, including analysis of existing bio-specimens for the detection of drug metabolites—for example, [New Hampshire HotSpot Report: The Increase in Fentanyl Overdoses \(2016\)](#);
- e. the dissemination of information through several mechanisms including project website, annual Sentinel Community Site reports, special reports addressing priority topics and a webinar series addressing timely drug topics.

4. Question: How can real-time monitoring of the fentanyl threat be expanded?

This question is best addressed by CDC. Please see their QFRs for a response.

5. Question: Is NIDA supporting any research on understanding the differences between fentanyl analogues and their responsiveness to naloxone?

Answer: While no NIDA projects are currently researching the efficacy of naloxone for treating overdoses related to fentanyl analogues, the National Institutes of Health (NIH), of which NIDA is a component, has just launched an Opioid Research Initiative to target research advances toward an end to the opioid crisis. Overdose Treatment Options is one of the three key pillars of this Initiative (along with Pain Management and Opioid Addiction Treatment), which will focus on developing new stronger, longer-acting antagonists to address the higher-potency synthetic opioids and reduce opioid overdose mortality.

6. Question: Is NIDA supporting any behavioral research on effective prevention messaging?

Answer: NIDA is not currently supporting projects on prevention messaging that address fentanyl specifically, or opioids more broadly. The prevention messaging grants that NIDA supports primarily address tobacco, alcohol and marijuana use. However, NIDA is supporting a research study that is exploring the acceptability and feasibility of using social media-based interventions for opioid misuse and overdose prevention among patients on chronic opioid therapy ([5R21DA039458-02](#)).

7. Question: Is NIDA supporting any research on the development of a low-cost rapid field test to detect the presence of fentanyl?

Answer: As noted in our response to question 1, NIDA is not currently funding any research to develop a field test for detecting fentanyl in drug samples. However, we are funding a project to develop a more rapid test for screening biosamples (e.g. blood or urine). Routine drug screens in hospitals often fail to detect synthetic drugs, so clinicians might be unaware of what caused an overdose. Mass spectrometry has the potential to be a useful tool to detect synthetic drugs, but it is rarely used at the point of care due to the complexity of conducting the analyses. A NIDA-funded study (DA043037)¹ is addressing this issue by exploring the use of “paper spray” mass spectrometry, which simplifies the testing process to make it more feasible in healthcare settings or potentially for emergency responders in the field. Researchers are developing and testing a disposable paper spray cartridge, which automates the preparation of the sample for testing. If the technology becomes widely used, the timely information on synthetic drug usage has the potential to improve the quality of care, and will be very useful for monitoring and surveillance of the fentanyl threat across the country.

8. Question: The trends in medical prescriptions for fentanyl and related opioids are decreasing. Is NIDA supporting research to evaluate what programs have been effective in these areas?

Answer: Federal and state efforts have begun to curb the rate of opioid prescribing in the last few years. In states with the most comprehensive initiatives to reduce opioid

overprescribing, the results have been encouraging. The state of Washington's implementation of evidence-based dosing and best-practice guidelines, as well as enhanced funding for the state's Prescription Drug Monitoring Program (PDMP), helped reduce opioid deaths by 27 percent between 2008 and 2012.² In Florida, new restrictions were imposed on pain clinics, new policies were implemented requiring more consistent use of the state PDMP, and the Drug Enforcement Administration (DEA) worked with state law enforcement to conduct widespread raids on pill mills, which resulted in a dramatic decrease in opioid prescribing and in overdose deaths between 2010 and 2012.³ These examples show that state and federal policies can reduce the availability of prescription opioids and related overdose deaths. NIDA is currently funding work to further explore the effectiveness of policies and programs intended to reduce opioid prescriptions, which includes research on:

- The impact of opioid prescribing practices on clinical outcomes⁴
- The impact of PDMP use on opioid prescribing and related health outcomes⁵
- Improving data extraction from PDMPs to identify patients who are doctor shopping⁶
- The impact of clinical guidelines and training on opioid prescribing and health outcomes⁷

9. Question: What has research shown about what is driving the increasing rates of heroin use?

Answer: Heroin produces its effects through the same opioid receptors as prescription pain relievers do, and research has shown that increases in heroin use have largely been driven by the increase in misuse of prescription opioids. Between 1999 and 2011 there was a fourfold increase in opioid prescribing that was paralleled by increases in prescription opioid misuse, addiction, and overdose.⁸ While only about 1-3 percent of people who misuse prescription opioids transition to heroin in any given year,^{9,10} 80 percent of heroin users today initiated opioid misuse with prescription opioids.⁹ Those who transition to heroin are likely to use multiple other drugs and to have severe prescription opioid use disorders, suggesting that the transition to heroin is part of a broad drug misuse pattern.

Increases in heroin use may also be driven by increases in heroin availability and purity, along with its relatively low cost.⁸ Mexican potential pure heroin production increased from an estimated eight metric tons in 2005 to 70 metric tons in 2015—more than a 10-fold increase. Domination of the U.S. market by Mexican and Colombian heroin sources, along with technology transfer between these suppliers, has increased the availability of easily injectable, white powder heroin.¹¹ In a recent survey of patients receiving treatment for opioid use disorder, accessibility was one of the main factors identified in the decision to start using heroin.¹² While some have speculated that regulatory changes aimed to restrict prescription opioid availability have led to increased heroin use, this was not the primary driver as heroin use began to rise before these policy shifts.⁸

10. Question: Does fentanyl adulteration of heroin and other drugs of abuse raise concerns about increases in the rates of addiction and overdoses?

Answer: Yes. Fentanyl taken alone or in combination with other drugs exhibits properties that are associated with a heightened risk of addiction and overdose. Fentanyl is extremely fat-soluble, so it crosses the blood-brain barrier very rapidly and exerts potent subjective effects within seconds.¹³ Faster euphoric effects are associated with increased addictive potential of drugs.¹⁴ Fentanyl also quickly and potently reduces the rate of breathing, and circumstances surrounding fentanyl overdose—including lack of fentanyl metabolism and death with the needle still in the vein—indicate that such overdoses can occur very quickly.^{15,16} Acute chest wall rigidity caused by IV fentanyl use could also contribute to heightened risk of rapid overdose death. A recent study of injection drug use determined that fentanyl injections had twice the overdose risk of heroin injections, and eight times the overdose risk of injections of common prescription opioids, such as oxycodone.¹⁷ This increase in overdose risk is exacerbated by the fact that drugs sold as heroin or counterfeit pills may be cut with variable amounts of fentanyl, and a person may not even know that they're being exposed to this potent and dangerous opioid.¹⁵

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