

# OVERSIGHT OF FEDERAL EFFORTS TO COMBAT THE SPREAD OF ILLICIT FENTANYL

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

FIRST SESSION

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## **OVERSIGHT OF FEDERAL EFFORTS TO COMBAT THE SPREAD OF ILLICIT FENTANYL**

**TUESDAY, JULY 16, 2019**

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

The subcommittee met, pursuant to call, at 10:04 a.m., in the John D. Dingell Room 2123 Rayburn House Office Building, Hon. Diana DeGette [chairwoman of the subcommittee] presiding.

Members present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Sarbanes, Tonko, Peters, Pallone (ex officio), Guthrie (subcommittee ranking member), McKinley, Griffith, Brooks, Mullin, Duncan, and Walden (ex officio).

Staff present: Mohammad Aslami, Counsel; Joe Banez, Professional Staff Member; Kevin Barstow, Chief Oversight Counsel; Jeffrey C. Carroll, Staff Director; Manmeet Dhindsa, Counsel; Tiffany Guarascio, Deputy Staff Director; Chris Knauer, Oversight Staff Director; Jourdan Lewis, Policy Analyst; Kevin McAloon, Professional Staff Member; Benjamin Tabor, Staff Assistant; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Mike Bloomquist, Minority Staff Director; Adam Buckalew, Minority Director of Coalitions and Deputy Chief Counsel, Health; Jordan Davis, Minority Senior Advisor; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Brannon Rains, Minority Legislative Clerk; and Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations.

Ms. DEGETTE. The Subcommittee on Oversight and Investigations will now come to order. Today, the Subcommittee on Oversight and Investigations is holding a hearing entitled “Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl.”

The purpose of today’s hearing is to examine the increasing threat posed by fentanyl and the Federal Government’s coordination and response.

The Chair now recognizes herself for purposes of an opening statement.

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

Today, we are once again here to discuss the opioid crisis, an epidemic that this country has been battling for years. Previously, this committee has taken numerous actions to investigate the origins

and elements of the crisis and help bring relief to those who are suffering.

Today's hearing will examine the growing threat of synthetic opioids, which experts have called the third wave of the opioid epidemic.

Our communities have already been ravaged by prescription opioids and then heroin. Now, unfortunately, we are seeing significant increases in overdose deaths involving synthetic opioids like fentanyl, including in my home state of Colorado.

Fentanyl is extremely dangerous. It is 50 times more powerful than heroin, 100 times more powerful than morphine, and it is responsible for a number of growing overdose deaths in America.

Fentanyl is also cheap and it's easy to produce, giving a high return for those who seek to profit from the destruction that it causes. Fentanyl can be used on its own or can be mixed with other drugs.

Alarmingly, even amateur chemists can produce this highly dangerous drug with minimal resources and experience. It is often made overseas, likely in China, then shipped either directly to users in the United States or through intermediaries in other countries like Mexico.

It can be bought anonymously on the dark web, and because it is so potent, small but deadly quantities of the drug can be shipped in packages via the U.S. mail or in private consignment carriers.

Today, we have before us six agencies who play important roles in fighting the proliferation of fentanyl. Each is responsible for a piece of this effort, from guarding the border, to taking down drug trafficking organizations, to protecting the legitimate drug supply.

These agencies will provide us with their assessment of how we got here, where the fentanyl threat stands right now, and how it has changed in recent months.

And I want to thank each one of our witnesses for coming today.

The purpose is to examine the state of fentanyl, but also our government's response to it. The threat is serious and evolving, and our response must be equally committed and adaptable.

These agencies have experience enforcing our nation's drug laws, gathering intelligence against traffickers, and arresting powerful criminals, and we are thankful for their efforts.

But fentanyl represents a unique problem, so these agencies need to develop new ways of attacking it. Because we have seen the opioid crisis evolve and take different forms, we also need to anticipate how fentanyl trends are likely to continue to change.

I am interested to hear all of our witnesses' perspectives on this and how we can get ahead of the evolving threat so we are not caught flat-footed like we have been before, unfortunately.

I am struck by the diverse missions of this panel. It is not every day that we have a hearing with the U.S. Postal Service and the DEA on the same panel.

Every one of these witnesses represents just a piece of the puzzle, which means that we cannot succeed unless everybody comes together. The crisis is going to require a massive coordinated effort to overcome.

We, frankly, need a national strategy on fentanyl response, and I don't mean just a white paper document or a task force report.

I mean we need a coherent practical plan for how we are going to beat this problem. For example, the Office of National Drug Control Policy is supposed to formulate a strategy, bring all of the agencies together, and see to it that the strategy is implemented effectively.

Are you coordinating the efforts of these agencies, and if so, how? Your mission is now more important than ever, so we will be looking to you for leadership and vision.

DEA, you are on the front lines and often develop important leads for targeting drugs. Is that information being regularly shared with CBP so that it can adequately target fentanyl shipments when they come into the U.S.?

FDA, suddenly, you are in the middle of this fight because fentanyl is increasingly being mixed with other drugs, including counterfeit prescription drugs.

How are you coordinating with law enforcement to protect the drug supply?

These are just a few of the questions we will explore today. If we are going to solve this problem, we need better cooperation across agencies, and we need to think differently than we have on past drug epidemics.

Finally, this hearing is just one piece of oversight. This subcommittee will stay on this issue and ensure progress is being made so, as so frequently happens, unfortunately, we are not back next year talking about the same problems.

Again, I thank the witnesses for their service on this critical issue and for coming here today, all in one panel.

[The prepared statement of Ms. DeGette follows:]

#### PREPARED STATEMENT OF HON. DIANA DEGETTE

Today, we are here once again to discuss the opioid crisis, an epidemic this country has been battling for years.

Previously, this Committee has taken numerous actions to investigate the origins and elements of the crisis and help bring relief to those who are suffering.

Today's hearing will examine the growing threat of synthetic opioids, which experts have called the "third wave" of the opioid epidemic.

Our communities have already been ravaged by prescription opioids and then heroin. Now, we are seeing significant increases in overdose deaths involving synthetic opioids such as fentanyl, including in my home state of Colorado.

Fentanyl is exceedingly dangerous. It is 50 times more powerful than heroin, 100 times more powerful than morphine, and it is responsible for a growing amount of overdose deaths in America.

Fentanyl is also cheap and easy to produce, giving a high return for those who seek to profit from the destruction it causes. Fentanyl can be used on its own or can be mixed with other drugs. Alarming, even amateur chemists can produce this highly dangerous drug with minimal resources and expertise.

It is often made overseas, likely in China, then shipped either directly to users in the United States or through intermediaries in other countries such as Mexico.

It can be bought anonymously on the Dark Web, and because it is so potent, small but deadly quantities of the drug can be shipped in packages via the U.S. Mail or private consignment carriers.

Today, we have before us six agencies who play important roles in fighting the proliferation of fentanyl. Each of them is responsible for a piece of this effort—from guarding the border, to taking down drug trafficking organizations, to protecting the legitimate drug supply.

These agencies will provide us with their assessment of how we got here, where the fentanyl threat stands now, and how it has changed in recent months.

The purpose of today's hearing is to examine the state of fentanyl, but also our government's response to it. The threat is serious and evolving, and our response must be equally committed and adaptable.

These agencies have experience enforcing our nation's drug laws, gathering intelligence against traffickers, and arresting powerful criminals. And we are thankful for their efforts. But fentanyl represents a unique problem, so these agencies need to develop new ways of attacking it.

Because we have seen the opioid crisis evolve and take different forms, we also need to anticipate how fentanyl trends are likely to continue to change. I am interested to hear these witnesses' perspectives on how we can get ahead of this evolving threat, so we are not caught flat-footed.

As I look at the witness panel, I am struck by their diverse missions. It is not every day that we have a hearing with the U.S. Postal Service and the DEA on the same witness panel.

Each of you represents only a piece of this puzzle, which means we cannot succeed unless all of you come together. This crisis is going to require a massive, coordinated effort to overcome.

We need a national strategy on our fentanyl response. And I don't just mean a white paper document or a task force report. I mean we need a coherent, practical plan for how we are going to beat this problem.

For example, the Office of National Drug Control Policy (ONDCP) is supposed to formulate a strategy, bring all the agencies together, and see to it that the strategy is implemented effectively. Are you coordinating the efforts of these agencies, and if so, how? Your mission is now more important than ever, so we will be looking to you for leadership and vision.

DEA, you are on the front lines and often develop important leads for targeting drugs. Is that information being regularly shared with CBP so it can adequately target fentanyl shipments when they come into the U.S.?

FDA, you are suddenly in the middle of this fight because fentanyl is increasingly being mixed with other drugs, including counterfeit prescription drugs. How are you coordinating with law enforcement to protect the drug supply?

These are just a few of the questions we will explore today. If we are going to solve this problem, we need better cooperation across agencies, and we need to think differently than we have on past drug epidemics.

Finally, this hearing is just one piece of our oversight. This Subcommittee will stay on this issue and ensure progress is being made so that we are not back here again next year talking about the same problems.

I thank the witnesses for their service on this critical issue, and for being here today.

MS. DEGETTE. And now I recognize the ranking member of the subcommittee, Mr. Guthrie, for five minutes for an opening statement.

**OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY**

Mr. GUTHRIE. Thank you, Chair DeGette, for holding this important hearing.

The Energy and Commerce Committee has been steadfast in its efforts to help combat the opioid crisis with both investigations and legislation.

Whether it was the committee's investigations into opioid distributors, patient brokering, or major opioid manufacturers, we have continued to ask questions and demand answers for the American people.

When it comes to legislation, this committee led the way on passage of the 21st Century CURES Act, the Comprehensive Addiction and Recovery Act, and the SUPPORT Act for patients in communities.

I was proud to work with these three landmark bills which are advancing treatment and recovery initiatives, improving preven-

tion, protecting communities, and bolstering our efforts to fight deadly illicit synthetic drugs like fentanyl.

Fentanyl is a synthetic opioid that is 80 to 100 times stronger than morphine and 50 times more potent than heroin. For many years, pharmaceutical fentanyl has been utilized as a powerful pain medicine to treat severe pain such as advanced cancer pain commonly used in the form of a patch on the skin or a lollipop.

But pharmaceutical fentanyl is not why we are here today. We are here today because of concerns over illicit or illegally manufactured fentanyl. The fentanyl crisis is particularly dangerous because of its high potency, and the small amount required to potentially cause an overdose.

It has become a powerful additive to drugs such as heroin, cocaine, or counterfeit pills with or without the user's knowledge.

According to the CDC, in 2017 there were more than 28,000 deaths involving synthetic opioids in the United States, which is more deaths than from any other type of opioid.

Further, overdose death rates from synthetic opioids increased all across all demographics, county urbanization levels, and numerous states.

A little bit of fentanyl goes a long way, which makes it harder for law enforcement to track where and how fentanyl is being purchased. Fentanyl can be purchased on the internet both in open source and on the dark web, and can be purchased pseudo anonymously using bitcoin or crypto currency.

In addition to being smuggled across our borders, fentanyl can be mailed in small quantities through the Postal Service or express consignment carriers and, therefore, has a higher likelihood of coming into the United States undetected.

These circumstances require a much different approach to intelligence, interdiction, and law enforcement compared to methods that may be better suited for what might be considered a more common drug smuggling operation.

The threat is real, and it has been growing over the past few years. According to Customs and Border Protection data, in fiscal year 2015, 70 pounds of fentanyl were seized in the United States.

In comparison, for fiscal year 2018, more than 2,000 pounds of fentanyl was seized. Further, for fiscal year 2019 to date, there have been 17,003 pounds of fentanyl seized, which is enough fentanyl for more than 600 million lethal doses of fentanyl, and we still have four more months of data to count before we know the total for this year.

I want to acknowledge some of the efforts and accomplishments of this administration, including but not limited to HHS establishing an interdepartmental substance use disorder coordinating committee, China pledging to add fentanyl to its list of controlled substances, increasing shipment tracking responsibilities and coordination among multiple entities, and disruption efforts which has taken down an entire online black market.

While we are already seeing new tools and resources provided and utilized as a result of this committee and the administration's work, the threat still exists, and our work is not done.

I want to thank all the witnesses for being here today. I look forward to hearing from all of you about successes we have had in

combating our nation's fentanyl threat but also how the threat has changed, what challenges remain, and what more we in Congress can do to be partners in this fight.

I yield back.

[The prepared statement of Mr. Guthrie follows:]

#### PREPARED STATEMENT OF HON. BRETT GUTHRIE

Thank you, Chair DeGette, for holding this important hearing.

The Energy and Commerce Committee has been steadfast in its efforts to help combat the opioid crisis, with both investigations and legislation. Whether it was the Committee's investigations into opioid distributors, patient brokering, or the major opioid manufacturers—we've continued to ask questions and demand answers for the American public.

When it comes to legislation, this Committee lead the way on passage of the 21st Century Cures Act, the Comprehensive Addiction and Recovery Act, and the SUPPORT for Patients and Communities Act. I was proud to work on these three landmark bills, which are advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering our efforts to fight deadly illicit synthetic drugs like fentanyl.

Fentanyl is a synthetic opioid that is 80 to 100 times stronger than morphine and 50 times more potent than heroin. For many years, pharmaceutical fentanyl has been utilized as a powerful pain medicine to treat severe pain, such as advanced cancer pain, commonly used in the form of a patch on the skin or a "lollipop." But pharmaceutical fentanyl is not why we're here today—we're here today because of concerns over illicit, or illegally manufactured, fentanyl.

The fentanyl crisis is particularly dangerous because of its high potency and the small amount required to potentially cause an overdose. It has become a powerful additive to drugs such as heroin, cocaine, or counterfeit pills—with or without the user's knowledge. According to the CDC, in 2017 there were more than 28,000 deaths involving synthetic opioids in the United States—which is more deaths than from any other type of opioid. Further, overdose death rates from synthetic opioids increased across all demographics, county urbanization levels, and numerous states.

A little bit of fentanyl goes a long way—which makes it harder for law enforcement to track where and how fentanyl is being purchased. Fentanyl can be purchased on the internet—both in the open source and on the dark web—and can be purchased pseudo-anonymously using bitcoin or crypto currency.

In addition to being smuggled across our borders, fentanyl can be mailed in small quantities through the postal service or express consignment carriers, and therefore has a higher likelihood of coming into the United States undetected. These circumstances require a much different approach to intelligence, interdiction, and law enforcement compared to methods that may be better suited for what might be considered a more common drug smuggling operation.

The threat is real and has been growing over the past few years. According to Customs and Border Protection data, in fiscal year 2015, 70 pounds of fentanyl were seized in the United States. In comparison, for fiscal year 2018, more than 2,000 pounds of fentanyl were seized. Further, for fiscal year 2019 to date, there have been 1,703 pounds of fentanyl seized. That is enough fentanyl for more than 600 million lethal doses of fentanyl, and we still have four more months of data to account for before we will know the total for this year.

I want to acknowledge some of the efforts and accomplishments of this Administration, including but not limited to HHS establishing an interdepartmental substance use disorder coordinating committee; China pledging to add fentanyl to its list of controlled substances; increasing shipment-tracking responsibilities and coordination among multiple entities; and disruption efforts such as taking down an entire online black market. While we are already seeing new tools and resources provided and utilized as a result of this Committee and the Administration's work—the threat still exists, and our work is not done.

I want to thank all of the witnesses for being here today. I look forward to hearing from all of you about successes we have had in combatting our nation's fentanyl threat, but also how the threat has changed, what challenges remain, and what more we, in Congress, can do to be partners in this fight.

Ms. DEGETTE. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for five minutes for purposes of an opening statement.



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

Mr. PALLONE. Thank you, Madam Chair.

This committee has held many hearings on the opioid crisis over the last several years, and with each hearing it seems the challenge to combat the crisis grows even more daunting.

While opioid prescribing rates appears to have gone down, overdose deaths continue to climb. Communities all around the country are still suffering from this epidemic, now largely at the hands of heroin, increasingly fentanyl.

Fentanyl is a deadly synthetic drug that is 50 times more powerful than heroin. Because it's relatively easy to make and so potent, it is tragically leading to large increases in overdose deaths.

We have all heard the terrible numbers that tell the story. In 2017, there were over 47,000 opioid overdose deaths. Twenty-eight thousand of those deaths involve synthetic opioids such as fentanyl.

My home state of New Jersey, for example, has seen a ten-fold increase in deaths involving fentanyl in the last several years, and fentanyl represents the third wave, as the chairwoman said, in the opioid crisis.

After the country was inundated with prescription opioids, prescribing rates went down. But many of those who were already addicted then turned to heroin, and now the trend is shifting towards synthetic opioids like fentanyl, which pose a unique threat.

These drugs are manufactured overseas in countries like China, oftentimes in clandestine labs. These drugs are then shipped into the U.S. often in small quantities that are difficult to detect.

And to make matters worse, we are now seeing fentanyl increasingly mixed into other drugs like cocaine, methamphetamine, and even counterfeit prescription drugs like Oxycodone.

This means that many unsuspecting people are dying at the hands of fentanyl when they didn't even realize they were taking it, and this drug represents an unprecedented threat to the U.S. and we have to do everything we can to stop this flow into our communities.

Today, we are hearing from the key law enforcement and regulatory agencies on the front line of this battle. Each agency plays a critical part and has decades of experience in this fight.

The problem, however, is that fentanyl is unlike any drug crisis we have faced before. All of these factors point to one conclusion. We have to think differently about how to counter the spread of fentanyl. The old approaches simply will not suffice.

Finally, we have repeatedly heard from experts that we cannot arrest our way out of the opioid crisis and fentanyl is no different. Evidence-based treatment is the best hope for those suffering from addiction and we must support programs that provide that help.

So today's hearing focuses on how to stop the flow in fentanyl but this is by no means the end of the conversation. I am committed to providing Americans suffering from opioid use disorder access to the quality treatment they need, and this committee will continue to shine a spotlight on this crisis to help identify solutions including in the treatment and public health arenas.

[The prepared statement of Mr. Pallone follows:]

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

This Committee has held many hearings on the opioid crisis over the last several years, and with each hearing it seems the challenge to combat the crisis grows even more daunting.

While opioid prescribing rates appear to have gone down, overdose deaths continue to climb. Communities all around the country are still suffering from this epidemic, now largely at the hands of heroin and increasingly, fentanyl.

Fentanyl is a deadly synthetic drug that is 50 times more powerful than heroin. Because it is relatively easy to make and so potent, it is tragically leading to large increases in overdose deaths.

We have all heard the terrible numbers that tell this story. In 2017, there were over 47,000 opioid overdose deaths, 28,000 of those deaths involved synthetic opioids such as fentanyl. My home state of New Jersey, for example, has seen a tenfold increase in deaths involving fentanyl in the last several years.

Fentanyl represents the third “wave” in the opioid crisis. After the country was inundated with prescription opioids, prescribing rates went down—but many of those who were already addicted then turned to heroin.

Now the trend is shifting toward synthetic opioids like fentanyl, which poses a unique threat. These drugs are manufactured overseas in countries like China, oftentimes in clandestine labs. These drugs are then shipped into the United States, often in small quantities that are difficult to detect.

To make matters worse, we are now seeing fentanyl increasingly mixed into other drugs like cocaine, methamphetamine, and even counterfeit prescription drugs like oxycodone. This means that many unsuspecting people are dying at the hands of fentanyl when they didn’t even realize they were taking it.

This drug represents an unprecedented threat to the United States—and we must do everything we can to stop its flow into our communities.

Today we will hear from the key law enforcement and regulatory agencies on the front lines of this battle. Each agency plays a critical part and has decades of experience in this fight. The problem, however, is that fentanyl is unlike any drug crisis we have faced before.

Just about everything about this threat is new: how easily it can be produced and sold, where it can be made, how it can be trafficked into our country, how difficult it is to detect—and of course, how deadly it is.

All of these factors point to one conclusion—we have to think differently about how to counter the spread of fentanyl. The old approaches simply will not suffice.

We need to hear from the agencies about how they are adapting to this new and evolving threat, how they are thinking of new ways to attack this problem, and especially, how they are collaborating.

The fentanyl threat is so unprecedented, and so challenging, that no single agency can tackle it on its own. They must all work together.

You simply cannot let turf wars or the competition for bringing cases stop you from cooperating with one another to help solve this problem. The stakes are too high.

Finally, we have repeatedly heard from experts that we cannot arrest our way out of the opioid crisis, and fentanyl is no different. Evidence-based treatment is the best hope for those suffering from addiction, and we must support programs that provide that help.

Today’s hearing focuses on how to stop the flow of fentanyl, but this is by no means the end of the conversation. I am committed to providing Americans suffering from opioid use disorder access to the quality treatment they need. This Committee will continue to shine a spotlight on this crisis to help identify solutions, including in the treatment and public health arenas.

I yield back.

Mr. PALLONE. I have about two minutes left, and I’d like to yield that now to the gentlewoman from New Hampshire, Ms. Kuster.

Ms. KUSTER. Thank you, Chairman Pallone.

We have seen the opioid crisis evolve and take many different forms, as you described. But no community in this country has been spared. New England and New Hampshire, in particular, have been devastated by this crisis.

In my home state, while we have seen the rate of prescription opioid and heroin overdose deaths decline, the rate of fentanyl—involved overdoses has not subsided.

With the help of a coordinated approach at the local level, the hub and spoke model ensures that every Granite Stater has nearby access to treatment and recovery services.

But this does not solve the supply problem. We know all too well that newer, stronger, and deadlier analogs of fentanyl continue to proliferate and challenge our ability to prevent needless premature deaths.

I look forward to the hearing. I look forward to your testimony and I thank the gentlewoman chairing this subcommittee and the chair of the committee for their attention to this crisis.

Thank you. I yield back.

Mr. PALLONE. Thank you. I have about a minute. I don't know if anybody else wants the time. If not, I will yield back, Madam Chair.

Ms. DEGETTE. The gentleman yields back.

The Chair now recognizes the ranking member of the full committee, Mr. Walden, for five minutes for purposes of an opening statement.

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

Mr. WALDEN. Good morning, Madam Chair, and thank you for holding this really, really important hearing on getting illicit fentanyl off our streets.

As you've heard, fentanyl is so deadly a piece of it, the size of a few grains of salt, can kill you. It reportedly led to 49 deaths in Oregon in 2017. So, ridding our communities of fentanyl is a key piece of combating the opioid crisis in Oregon and across the country.

Illicit fentanyl is a tremendously difficult and dynamic problem. It is hard to detect and is highly potent and lucrative enough to be sent in small envelopes or packages, and while the heroin market was monopolized by large criminal groups, this fentanyl wave—it is harder to police.

It is coming almost entirely from the black market on the dark web and clandestine labs in China and Mexico with many mid-level and small operators in addition to drug smuggling operations like the cartels.

This subcommittee last held an oversight hearing on illicit fentanyl back in March of 2017. The need for fentanyl focused action was clear then.

Two years later, there are numerous significant accomplishments. Last year the committee worked in a bipartisan way to enact the SUPPORT Act to bolster the fight against opioids such as fentanyl. This law has helped provide advanced electronic data of international mail shipments to help target and intercept illicit fentanyl.

This act also provided the FDA with a new tool for deterring imports of illicit fentanyl. As you'll recall, Dr. Burgess went up to a mail distribution facility in New Jersey and learned a lot and brought that back to us.

The Trump administration has spurred improved actions in the fentanyl fight. Our nation is getting at least some improved level of cooperation from the Chinese government on class-based scheduling, which helps remove an incentive for traffickers to introduce new substances in the fentanyl family for the purpose of evading controls.

President Trump deserves credit for moving this bold proposal based on the longstanding work of the White House Office on National Drug Control Policy, the DEA, and the State Department.

President Xi of China deserves some credit for agreeing to a commitment to crack down on fentanyl as a class. We'd like to see more there.

While it's too soon to assess the impact, early indications are at least encouraging. And since February of 2018, DEA has imposed emergency scheduling of fentanyl-related substances, but we need to work with DEA and other federal agencies to find the best approach to make this scheduling permanent.

The Stop Importation and Trafficking of Synthetic Analogs, or SITSA, Act, which would have given law enforcement additional tools they need to get illicit drugs such as fentanyl off our streets without compromising important public health and research protections, that was included in our House-passed version of the SUPPORT Act but, sadly, was not included in the final package that became law.

Mr. Katko of New York, he sponsored this legislation. It would be a good place to start again and we should make it law.

On July of 2017, the Department of Justice announced the seizure of AlphaBay. That's the largest criminal marketplace on the dark web and a major source of fentanyl linked to overdose deaths.

The AlphaBay takedown was an international operation led by the U.S. Both DEA and CBP recently made the largest seizures of fentanyl in U.S. history and we thank you for that. Federal agents working with local police seized 50 kilos of fentanyl precursor in 2017.

For the first time the Justice Department announced indictments of Chinese nationals for conspiracies to distribute large quantities of fentanyl and fentanyl analogs.

May of '19, a dark net drug dealer was indicted for selling fentanyl online, thanks to Homeland Security's investigations, a year-long nationwide undercover action, and under agreement with the U.S. Postal Service, China Post is providing advanced electronic data on parcels mailed to the U.S.

FDA and CBP signed an agreement in April of 2019 to maximize inspection detection capabilities to products such as fentanyl from entering the United States.

So, we salute these important federal workers and agencies for their work. But we know big challenges remain. More work is needed to get better cooperation from Mexico's law enforcement authorities.

We need to remain vigilant with China on its fentanyl commitment. Much more needs to be done to collect better data on fentanyl trafficking and to improve data sharing and we want to hear more on strategy to disrupt fentanyl trafficking.

We will be asking questions how we can strengthen our efforts on what this committee can provide. The SUPPORT Act was a great start, but it is not enough.

And Madam Chair, I would remind you we posted our final oversight investigations report on the committee's Web site and sent everybody a letter at the beginning of the year.

There were some important recommendations there I hope we can eventually get to.

Before I conclude, I want to take a moment to recognize Michael Gray. He is father of Amanda Beatrice Rose Gray. Amanda died of an overdose of pure fentanyl in January of 2018—pure fentanyl.

Michael has been a tireless advocate fighting against the opioid epidemic and fentanyl. His efforts informed our work in the last Congress. He was incredibly helpful in that, and let us remember as the face of this crisis his daughter, and we thank you for being here and we thank you for your work.

Madam Chair, in conclusion, the Actus Foundation—we have a letter we would like entered into the record that we previewed with you.

[The prepared statement of Mr. Walden follows:]

#### PREPARED STATEMENT OF HON. GREG WALDEN

Chair DeGette, thank you for holding this hearing on getting illicit fentanyl off our streets.

Fentanyl is so deadly that a piece the size of a few grains of salt can kill you, and reportedly led to 49 deaths in Oregon in 2017. Ridding our communities of fentanyl is a key piece of combating the opioid crisis in Oregon and across the country.

Illicit fentanyl is a tremendously difficult and dynamic problem. It is hard to detect, highly potent, and lucrative enough to be sent in small envelopes or packages. While the heroin market was monopolized by large criminal groups, this fentanyl wave is harder to police. It is coming almost entirely from the black market on the dark web and clandestine labs in China and Mexico with many mid-level and small operators, in addition to drug smuggling operations like the cartels.

This Subcommittee last held an oversight hearing on illicit fentanyl in March 2017. The need then for fentanyl-focused action was clear.

Two years later, there are numerous significant accomplishments.

Last year, this Committee worked in a bipartisan way to enact the SUPPORT Act to bolster the fight against opioids such as fentanyl. This law helped provide advance electronic data of international mail shipments to help target and intercept illicit fentanyl. This Act also provided the FDA with a new tool for deterring imports of illicit fentanyl.

The Trump Administration has spurred important actions in the fentanyl fight. Our nation is getting cooperation from China on class-based scheduling, which helps remove an incentive for traffickers to introduce new substances in the fentanyl family for the purpose of evading controls. President Trump deserves credit for moving this bold proposal, based on the longstanding work of the White House Office on National Drug Control Policy, the DEA, and the State Department. President Xi of China deserves credit for agreeing to a commitment to crack down on fentanyl as a class. While it is too soon to assess the impact, early indications seem encouraging.

Since February 2018, DEA has imposed emergency scheduling of fentanyl-related substances. We need to work with DEA and other federal agencies to find the best approach to make this scheduling permanent. The Stop the Importation & Trafficking of Synthetic Analogues (SITSA) Act, which would have given law enforcement additional tools they need to help get illicit synthetic drugs, like fentanyl, off our streets without compromising important public health and research protections was included in the House-passed version of the SUPPORT Act, but ultimately not included in the final package that became law. Mr. Katko's legislation is a good place to start.

In July 2017, the Department of Justice announced the seizure of AlphaBay, the largest criminal marketplace on the dark web, and a major source of fentanyl linked

to overdose deaths. The AlphaBay takedown was an international operation led by the U.S.

Both DEA and CBP recently made the largest seizures of fentanyl in U.S. history. Federal agents working with local police seized 50 kilos of a fentanyl precursor in May 2017, apparently one of the largest, if not the largest, seizure of a precursor in the U.S.

For the first time, the Justice Department announced indictments of Chinese nationals for conspiracies to distribute large quantities of fentanyl and fentanyl analogs.

In May 2019, a darknet drug dealer was indicted for selling fentanyl online, thanks to Homeland Security Investigations' yearlong nationwide undercover actions to target vendors of illicit goods on the dark web.

Under an agreement with the U.S. Postal Service, China Post is providing advanced electronic data on parcels mailed to the U.S.

FDA and CBP signed an agreement in April 2019 to maximize inspection and detection capabilities to products such as fentanyl from entering the U.S.

We salute the federal agencies for this work, but big challenges remain. More work is needed to get better cooperation from Mexico's law enforcement authorities. We need to remain vigilant with China on its fentanyl commitment. Much more needs to be done to collect better data on fentanyl trafficking and to improve data-sharing. We want to hear more on a strategy to disrupt fentanyl trafficking. We will be asking questions on how we can strengthen our efforts, and what help this Committee can provide.

The SUPPORT Act was a great start. Let's continue our bipartisan legislative efforts to combat this crisis.

I look forward to the testimony and thank our witnesses for being here today.

Ms. DEGETTE. Without objection, and I would add my thanks to you, Mr. Gray, for all of your tireless work.

Mr. WALDEN. Thank you, Madam Chair.

Ms. DEGETTE. The gentleman yields back, and I now ask unanimous consent that the Members' written opening statements be made part of the record.

Without objection, so ordered.

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

Ms. DEGETTE. I would now like to introduce our panel of witnesses for today's hearing.

Mr. Kemp L. Chester, Assistant Director of the National Opioids and Synthetics Coordination Group, the White House Office of National Drug Control Policy. Welcome.

Mr. Matthew Donahue, Regional Director, North and Central Americas Operation Division, Drug Enforcement Administration at the U.S. Department of Justice.

Mr. Thomas F. Overacker, Executive Director, Office of Field Operations, Custom and Border Protection at the U.S. Department of Homeland Security.

Mr. Gary R. Barksdale, Chief Postal Inspector at the U.S. Postal Service,

Mr. David A. Prince, Deputy Assistant Director, Transnational Organized Crime, Homeland Security Investigation, Immigration and Customs Enforcement at the U.S. Department of Homeland Security.

Carol Cave, Director of the Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration at the Department of Health and Human Services.

Thank you all for appearing in front of the subcommittee today. You are aware the committee is holding an investigative hearing and, when doing so, has had the practice of taking testimony under oath.

Do any of you have any objections to testifying under oath?

Let the record reflect that the witnesses have responded no. The Chair then advises you under the rules of the House and the rules of the committee you're entitled to be accompanied by counsel.

Do any of you desire to be accompanied by counsel today?

Let the record reflect the witnesses have responded no. If you would, please rise and raise your right hand so you may be sworn in.

[Witnesses were sworn.]

Ms. DEGETTE. You may be seated.

Let the record reflect the witnesses have now responded affirmatively and you are now under oath and subject to the penalties set forth in Title 18 Section 1001 of the U.S. Code.

The Chair will now recognize the witnesses for five minutes summary of their written statements. In front of each of you is a microphone and a series of lights. The light turns yellow when you have a minute left and it turns red to indicate that your time has come to an end.

And so let's start with you, Mr. Chester. You are now recognized for five minutes.

**STATEMENTS OF KEMP CHESTER, ASSISTANT DIRECTOR OF THE NATIONAL OPIOIDS AND SYNTHETICS COORDINATION GROUP, WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY; MATTHEW DONAHUE, REGIONAL DIRECTOR NORTH AND CENTRAL AMERICAS, OPERATION DIVISION, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE; THOMAS F. OVERACKER, EXECUTIVE DIRECTOR, OFFICE OF FIELD OPERATIONS, CUSTOMS AND BORDER PROTECTION, U.S. DEPARTMENT OF HOMELAND SECURITY; GARY R. BARKSDALE, CHIEF POSTAL INSPECTOR, U.S. POSTAL SERVICE; DAVID A. PRINCE, DEPUTY ASSISTANT DIRECTOR, TRANSNATIONAL ORGANIZED CRIME, HOMELAND SECURITY INVESTIGATIONS, IMMIGRATION AND CUSTOMS ENFORCEMENT, U.S. DEPARTMENT OF HOMELAND SECURITY; CAROL CAVE, DIRECTOR, OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **STATEMENT OF KEMP L. CHESTER**

Mr. CHESTER. Chairwoman DeGette, Ranking Member Guthrie, members of the subcommittee, thank you for inviting me to testify today on this critical issue.

The Office of National Drug Control Policy, under the leadership of Director Jim Carroll, leads the development of the administration's national drug control strategy and oversees its implementation.

The 2019 strategy is a comprehensive plan to address the president's top drug priority—the current opioid crisis—also focusing on the emergence of even newer synthetic opioids and other emerging crises such as methamphetamine use and the increase in cocaine availability.

As part of the executive office of the president, ONDCP is uniquely positioned and has played an integral in coordinating a

comprehensive approach to drug policy development and implementation.

It has facilitated successful interagency collaboration, coordination, and problem resolution on myriad drug policy issues.

To that end, ONDCP has led countless interagency efforts directly related to the illicit opioid problem set. ONDCP established the National Heroin Coordination Group, recently renamed the National Opioids and Synthetics Coordination Group, in the fall of 2015 to apply new thinking to the heroin and fentanyl problem and develop a novel approach to addressing it.

We worked collaboratively with the interagency in 2016 to develop and issue the Heroin Availability Reduction Plan, or HARP, to guide and synchronize interagency activities against the available of heroin, fentanyl, and fentanyl analogs.

To this day, the HARP is the one document that brings together, contextualizes, and synchronizes the Federal Government, activities at the federal, state, local, and tribal levels as well as in the international domain.

Ten times every month our opioids and synthetics coordination group leads video teleconferences at all levels of classification and nationwide webinars where departments, agencies, state, local, and tribal officials and key embassies share information and synchronized efforts based upon a common understanding of the strategic trends related to the opioid problem set.

This level of direct leadership has been instrumental in developing a better understanding of the crisis at all levels as well as serving as the driver for collaboration and tangible results both domestically and with international partners.

Based upon our in-depth understanding of the opioid crisis, key issues such as the challenges of fentanyl detection, safe fentanyl handling, and the need for innovative public health approaches were brought to the forefront and are currently being addressed.

Our partnership with the U.S. Postal Inspection Service has increased interagency understanding of the international and domestic mail flow into the United States, and U.S. vulnerabilities in disrupting the fentanyl and synthetic opioid supply chain.

Our collaboration with the FBI-led Joint Criminal Opioid and Darknet Enforcement, or J-CODE, team, U.S. Customs and Border Protection's National Targeting Center, and our management of key international relationships with Mexico, Canada, China, Afghanistan, and others have brought tangible results in disrupting the flow of these dangerous drugs across our borders.

For example, because of the interagency focus on disruptive the fentanyl supply chain, in the spring of 2017 CBP began to imprint odor of fentanyl on all narcotics detection K9s, and now more than 450 dogs are trained addressing a critical vulnerability in our detection capability.

As the fentanyl threat grew in 2016 and 2017, the lack of good scientific information concerning the threat of fentanyl exposure had a chilling effect on U.S. law enforcement and our first responders.

ONDCP initiated an interagency working group to develop and publish the fentanyl safe handling recommendations, and shortly thereafter CBP released a companion roll call video in use today.



ONDCP is leading an interagency process with the Departments of Justice and Health and Human Services to schedule fentanyl analogs before the temporary action expires while providing a framework to address the dynamic illicit drug market in a more comprehensive manner and making all of these substances available to the research community.

The national drug control strategy states, quote, “While confronting today’s drug crisis to arrest its growth and reduce its effects, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the 21st century,” closed quote.

The men and women of ONDCP are doing just that. I would like to thank this committee and your House colleagues for your foresight and leadership in addressing this critical national security, law enforcement, and public health challenge.

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

[The prepared statement of Mr. Chester follows:]



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

## **“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

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

Tuesday, July 16, 2019  
10:00 a.m.

2123 Rayburn House Office Building

Statement of  
Kemp L. Chester  
Assistant Director of the National Opioids and Synthetics Coordination Group  
Office of National Drug Control Policy

Chairwoman DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for inviting me to testify today on the growing threat of fentanyl in the United States.

More than 70,200 Americans died from a drug overdose in 2017,<sup>1</sup> with 41 percent (28,466) of these deaths involving a synthetic opioid other than methadone (SOOTM). This is a statistical category that primarily includes illicitly produced synthetic opioids<sup>2</sup> like fentanyl and its analogues, as well as non-fentanyl synthetic opioids like the U-series drugs. As we have seen for the past several years, these synthetic drugs have been the principal driver of the historically high number of overdose deaths that our Nation has suffered during the opioid crisis.

Fentanyl is a rapid-acting Schedule II opioid analgesic intended for use in treating acute pain in trauma settings, chronic pain, anesthesia, and end-of-life palliative care, and it has helped thousands of Americans manage their pain effectively. Fentanyl was first synthesized in 1959, and the key intermediates in its early preparation were benzylfentanyl and norfentanyl. Several fentanyl-related substances with accepted medical or veterinary uses, like carfentanil, sufentanil, and thiafentanil, are also Schedule II controlled substances.

In the 1980s, a new approach to the synthesis of fentanyl was discovered using N-phenethyl-4-piperidone (NPP) and 4-anilino-N-phenethylpiperidine (4-ANPP) as the key intermediates in fentanyl synthesis. Because of the outsized role that illicitly produced fentanyl was playing in America's opioid crisis, in March 2017, under United States leadership, the international community placed strict controls on these two precursor chemicals to prevent the widespread proliferation of illicitly produced fentanyl, principally trafficked from China.

According to the Drug Enforcement Administration (DEA), national law enforcement reports of illicit fentanyl seized remained steady from 2001 to 2005, followed by a noticeable increase in 2006, which was attributable to a single fentanyl lab in Mexico. Following the seizure of that lab, fentanyl reports continued to remain steady until significant increases occurred from 2014 through 2017. In 2017, more than 83,400 domestic drug seizures submitted for forensic testing involved fentanyl or fentanyl analogues.<sup>3</sup> This represents nearly twice the number of such submissions in 2016 and a nearly five-fold increase since 2015.<sup>4</sup> While fentanyl seizures are most typically in a powder, salt, or rock-like form, seized quantities of fentanyl and fentanyl analogue capsules, tablets, and liquid have also increased dramatically alongside solid kilogram forms in recent years.<sup>5</sup>

In 2018, at least 318,634 tablets and capsules seized within the United States were subjected to DEA laboratory testing, according to DEA's STARLiMS forensic drug chemistry database. Of those, approximately 108,015, or 34 percent, were determined to contain fentanyl or a fentanyl analogue as its primary drug, with or without other illicit drugs and non-narcotic substances.<sup>6</sup> This represents nearly five times the number of fentanyl and fentanyl analogue-containing tablets and capsules analyzed by DEA's laboratories in 2016.

During this same period, Customs and Border Protection (CBP) experienced a similar proliferation of the entire range of fentanyl-related substances and other synthetic opioids. Between 2012 and early 2016, CBP encountered seven new fentanyl analogues, and then encountered 12 new fentanyl analogues during a 261-day span in late 2016 and 2017. The time between CBP encounters with new non-fentanyl opioids averaged six months from 2012 to 2016, but in 2017 CBP encountered five new non-fentanyl opioids in a 150-day span. However, the most drastic increase in CBP laboratory encounters were fentanyl-related substances that had the

fentanyl skeleton but had molecular deletions, rather than the additions or substitutions that were employed to create analogues, and whose illicit use was not yet known. Between 2009 and 2016, CBP had encountered two of these substances 44 months apart, but in 2017 CBP encountered six of these new substances in one 276-day period. In total, from 2016 to 2018, CBP encountered either a new fentanyl analogue, a non-fentanyl opioid, or a fentanyl substance utilizing a molecular deletion nearly every single month (33 total).<sup>7</sup>

Further complicating our understanding of this dynamic environment are inconsistencies in toxicology practices in drug death investigations across the country, which makes a full understanding of the true impact of these new and emerging substances elusive. According to the Centers for Disease Control and Prevention, 28,466 of all drug overdose deaths in 2017 involved synthetic opioids, including pharmaceutical and illicit fentanyl. From 2016 to 2017, synthetic opioids-involved overdose death rates increased 45.2 percent.<sup>8</sup> However, limited available data at the state level, due to varied capability and capacity of coroners and medical examiners in some localities to perform toxicology screenings, suggests that the death toll due to fentanyl analogues is even higher. For example, in Florida in 2017, 1,685 deaths involved a fentanyl analogue, with the most common analogues being carfentanil (637), furanyl fentanyl (365), and cyclopropyl fentanyl (210).<sup>9</sup> In Maine, in the first six months of 2018, fentanyl analogues were involved in 37 deaths, with acetyl fentanyl and methoxyacetyl fentanyl being the most common.<sup>10</sup> In Ohio, between January and February of 2017 alone, 48 percent (135) of all drug deaths involved acryl fentanyl, 31 percent (87) involved furanyl fentanyl, and eight percent (22) involved carfentanil.<sup>11</sup> The demand for, and the quantity of, illicit fentanyl and fentanyl analogues in the United States market are both increasing, and they continue to have a devastating effect on the health and safety of America's communities.<sup>12</sup>

In keeping with its statutory responsibility to advise the President on drug policy issues and advance the President's drug control policies, the Office of National Drug Control Policy (ONDCP), under the leadership of the Director James Carroll, coordinates 16 Federal drug control agencies and other interagency partners in the development of the Administration's *National Drug Control Strategy* (herein referred to as the *Strategy*) and oversees its implementation. The 2019 *Strategy* is focused on, "saving American lives and setting our Nation on a path to being stronger, healthier, and drug-free."<sup>13</sup> It is a comprehensive plan to address the President's top drug priority, the current opioid crisis, while also focusing on the greater availability of synthetic drugs and other emerging crises such as increased methamphetamine use and cocaine availability.

In addition to addressing the President's top drug priority through *Strategy* implementation and oversight, ONDCP has been focusing on opioids and fentanyl for several years. In collaboration with the National Security Council (NSC), ONDCP established the National Heroin Coordination Group (NHCG) within ONDCP in the fall of 2015. This small group serves "as the hub of a network of colleagues and partnerships across the interagency community who can leverage their home agency authorities and resources to disrupt the global heroin supply chain." It was formed to apply new thinking to the heroin/fentanyl problem and develop a novel approach to addressing it, with an initial focus on Mexico and heroin, but also including China as a source of precursor chemicals and fentanyl. The NHCG began work on October 26, 2015 composed of ONDCP staff specializing in research and data, state, local, and tribal affairs, and source country and global drug flows, along with interagency detailees from the military services, a former Federal prosecutor from the Department of Justice (DOJ), an experienced Special Agent from the Federal Bureau of Investigation (FBI), and a research

pharmacologist from the Drug Enforcement Administration (DEA). Over the past several years, a CBP chemist, a U.S. Postal Inspection Service (USPIS) senior investigator, and public health experts have been added to the staff of ONDCP.

In 2015 the NHCG was given 90 days to develop “a Heroin Availability Reduction Plan (HARP) of actions, goals, and measures to provide a roadmap to guide and synchronize the interagency activities against [the heroin supply].” An NSC Interagency Policy Committee (IPC)<sup>14</sup> approved the formation of the NHCG and the development of the HARP on November 24, 2015. After interagency development and coordination was completed, the HARP was elevated to a Deputies Committee and approved on June 22, 2016. The HARP thus became the single document to bring together, contextualize, and synchronize current and planned heroin and fentanyl availability reduction activities at the Federal, state, local, and tribal levels, as well as in the international domain.

As part of its initial planning for the HARP, the NHCG made a critical decision that the HARP would deliberately conflate heroin and fentanyl into a single problem set, for several reasons. In line with the understanding of the threat at the time, traffickers were adding fentanyl as an adulterant to boost the effect of heroin or mixing it with diluents to create and sell the product as synthetic heroin, likely utilizing the same supply chains and distribution mechanisms for both drugs. In addition, heroin and fentanyl belong to the same class of opioids and create a similar effect in the user, often making their user populations one and the same. Finally, addressing both drugs as a single problem set provided the ability to address the heroin crisis without inadvertently compounding the fentanyl one. Addressing both heroin and fentanyl in a singular fashion was intended to minimize the chance of accelerating the growth of exclusive fentanyl use by addressing it as part of the larger heroin problem.

To fully align ONDCP with its most recent reauthorization bill and the 2019 *Strategy*, in February 2019, Director Carroll announced an internal transformation. The NHCG was renamed the National Opioids and Synthetics Coordination Group (NOSCG),<sup>15</sup> and NOSCG assumed added responsibility, in coordination with ONDCP's Public Health, Education and Treatment team, for public health actions required to address the opioid epidemic and for the Nation's response to synthetic drugs, such as methamphetamine. ONDCP, in collaboration with the NSC and the Domestic Policy Council, are conducting meetings to facilitate routine interaction, information sharing, and problem resolution across the Federal interagency with a focus on tangible and demonstrable outcomes to successfully implement the HARP and the 2019 *Strategy*.

Over the past several years, ONDCP and the NOSCG have led or co-chaired countless interagency meetings directly related to the heroin and fentanyl problem. Some have been focused on bilateral and trilateral leadership summits and meetings in which heroin and fentanyl were top agenda items, such as: the North American Leaders Summit (NALS) for the leaders of the United States, Canada, and Mexico; the North American Drug Dialogue (NADD); and the U.S.-Mexico Security Cooperation Group (SCG). Others have focused on U.S. capacity, capabilities, and interagency actions to address the flow of fentanyl, fentanyl analogues, and other synthetic opioids from source and transit countries to include canine detection, trafficking patterns and internet sales, and safe handling.

In addition these interagency meetings, since the start of HARP implementation in the late summer of 2016, the NOSCG has driven daily mechanisms for information sharing, gap identification, and strategy coordination by conducting routine weekly and monthly meetings to focus efforts and facilitate information sharing among Federal, state, local, and tribal agencies.



Every month, the NOSC leads a secret-level video teleconference with Federal drug enforcement agencies for updates on the progress of Federal law enforcement actions focused on the heroin and fentanyl problem, as well as candid discussions of current and planned activities. Participants use this meeting to discuss major operational efforts, successes, lessons learned, and broader strategic-level trends relevant to HARP implementation.<sup>16</sup>

To focus on disrupting the flow of illicit fentanyl and synthetic opioids originating from China, every month the NOSC hosts the Synthetics Opioids Working Group (SOWG) with U.S. Embassy Beijing to serve as the principal forum for information sharing and coordination among ONDCP, NSC, the Department of State (DOS), and the Embassy regarding U.S.-China bilateral counternarcotic priorities. The SOWG played a key role in President Trump's meetings with President Xi Jinping at the 2018 G20 in Buenos Aires, Argentina, which led to China's announcement of class scheduling of all fentanyl-related substances,<sup>17</sup> and at the 2019 G20 in Osaka, Japan.

Each month, the NOSC co-leads an interagency working group with U.S. Embassy Mexico City, which includes DEA headquarters, U.S. Northern Command, and the DOS Bureaus of Western Hemisphere Affairs and International Narcotics and Law Enforcement Affairs (INL). It is the most effective tool for synchronizing policy formulation and implementation between Mission Mexico and the NOSC where the Federal Government speaks with one voice and maintains critical security relationships with our Mexican partners.

The NOSC also leads monthly nationwide webinars to address strategic level trends and to link actions and plans at the Federal level with those taking place at the state level and below. During these meetings, which focus on a different census region each month, state, local, and tribal officials provide updates on the trends they are seeing, the actions they are taking in

response, and planned activities pertinent to achieving the HARP's strategic end state of reducing the number of Americans dying from opioid overdose. One of the more tangible benefits of this forum has been allowing states to posture themselves for the illicit opioid crisis as it develops in their state or region.

In addition, the NOSCG and CBP Laboratories and Scientific Services (LSS) co-chair the monthly *Scientific Trends Open Network Exchange (STONE) Call* to share trend data and information among forensic scientists, medical examiners, coroners, intelligence analysts, and members of the law enforcement community on newly identified substances seized by CBP.

Every week, ONDCP's Office of Intelligence leads a weekly Top Secret/Sensitive Compartmentalized Information (TS-SCI) video teleconference, the principal forum for information sharing and coordination within the Intelligence Community (IC) for addressing the opioid epidemic and increasing cocaine consumption in our Nation. It has occurred weekly since November 2015, with more than 20 outstations to synchronize IC and law enforcement intelligence collection, analysis, and production efforts to support implementation of the HARP with the IC.<sup>18</sup>

During the first year of HARP implementation, the NOSCG identified the need for the United States Postal Inspection Service (USPIS) to be a part of the Federal opioid interdiction effort. This need was further amplified in the *President's Commission on Combating Drug Addiction and the Opioid Crisis*, *President Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand*, and ultimately in the 2019 *Strategy*. As with all synthetic drugs, fentanyl and its analogues are difficult to detect, as they can be ordered over the internet in small amounts and at low dollar figures by any individual who wants them, and they can be sent directly to the buyer. The detection of high-purity fentanyl shipped directly into the United

States through international mail or express consignment services presents a unique challenge and illustrates the evolution of the drug trade from largely plant-based substances. Moreover, the incredibly high volume of mail combined with the ability to ship fentanyl in very small quantities, along with the relative lack of robust screening technology and detection capabilities, make detecting and seizing these drugs as they move through the mail system monumentally difficult.

The inclusion of the USPIS in HARP implementation efforts has increased interagency understanding of the international and domestic mail flow into the United States and the vulnerabilities it represents in our ability to disrupt the fentanyl, fentanyl analogue, and synthetic opioid supply chain. The USPIS's active participation in HARP implementation actions has ensured prompt collaboration with the Federal Bureau of Investigation's (FBI)-led Joint Criminal Opioid and Darknet Enforcement (J-CODE) team, CBP's National Targeting Center (NTC), and numerous ONDCP led international engagements with Mexico, Canada, China, Australia, and the United Kingdom.

One of the gaps that was quickly identified was the lack of canine fentanyl detection capacity at ports of entry and international mail facilities. Previous generations of drug detection dogs were trained to detect the major plant-based drugs such as heroin, cocaine, and marijuana. Because of the interagency focus on disrupting the fentanyl supply chain, in June of 2017 CBP ran tests to determine if narcotics detection canines were capable of being trained to alert to the presence of fentanyl. The pilot program was very successful, so a train-the-trainer initiative began whereby canine trainers in various field locations began imprinting the odor of fentanyl on all narcotics detection canines within the CBP Office of Field Operations (OFO). By March of 2018, over 450 existing OFO drug dog teams had been trained and all new OFO drug dog

teams are being trained to detect fentanyl and various fentanyl analogues. These dog teams work at most major ports of entry, including international mail facilities and express consignment hubs, and along the Southwest land border.

Better detection capabilities using technical instrumentation at our borders, express carrier consignment facilities, and international mail facilities also is necessary to interdict shipments of fentanyl and other synthetic opioids before they enter the U.S. supply chain. ONDCP has worked with CBP on implementing the International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology (INTERDICT) Act, augmenting CBP's chemical identification equipment and scientific support for border encounters of fentanyl and fentanyl analogues. In October 2018, CBP's LSS stood up the 24/7 Narcotics Reachback Center (NRC) to assist officers and agents in the field, and the NRC now provides scientific support for analyses of unknown chemical substances using spectral interpretation from CBP presumptive field screening devices. CBP is in the process of upgrading its IT support to transfer data more expeditiously to handle the anticipated increased volume of spectral interpretation submissions.

In February 2019, the Department of Homeland Security's Science and Technology Directorate collaborated with ONDCP, USPIS, and CBP to launch the Opioid Detection Challenge seeking novel plans for rapid, nonintrusive detection tools that will help find illicit opioids trafficked through the mail system.<sup>19</sup> Last month, ONDCP announced the eight finalists in the first stage of the Challenge.<sup>20</sup>

As the fentanyl threats grew in 2016-2017, the challenge of a widespread misperception surrounding fentanyl handling among law enforcement and first responders developed. Fentanyl can be lethal; however, the lack of good scientific information concerning fentanyl exposure had

a chilling effect on U.S. law enforcement interdiction efforts. In collaboration with ONDCP, the NSC led an interagency working group (IWG) to develop the *Fentanyl Safety Recommendations for First Responders*,<sup>21</sup> released on November 1, 2017, as part of *The President's Commission on Combating Drug Addiction and the Opioid Crisis* <sup>22</sup> final report. Shortly after, CBP led an effort to produce a companion video *Fentanyl: The Real Deal*; both are available on the ONDCP webpage and have been circulated to Federal, state, tribal, and local law enforcement. The *Recommendations* and the video contain practical, science-based handling information developed by Federal environmental and workplace safety, emergency response, medical, health, and law enforcement experts and in consultation with and supported by national stakeholder organizations.

To undercut the operations of fentanyl traffickers, we brought together resources from DOJ, Department of Homeland Security, US Attorneys, IC, and Department of the Treasury to bring targeted sanctions against fentanyl traffickers who operate in China, India, the United Arab Emirates, Mexico, and throughout Southeast Asia including Vietnam, Thailand, and Singapore. By targeting these drug trafficker networks with these sanctions, we are ending their access to U.S.-based financial assets that help them flood communities with fentanyl.

Today, permanently controlling fentanyl as a class of drugs in the United States, as we have asked China to do, is imperative to addressing the dynamic and ever-changing threat of synthetic opioids. Fentanyl analogues have additions or substitutions to the core fentanyl molecule, as described under DEA's temporary scheduling of fentanyl-related substances.<sup>23</sup> Those fentanyl analogues not used for human or veterinary purposes have been placed under control as Schedule I substances, on either a permanent or emergency basis, because of the current lack of evidence for their medical utility and their potential ability to lead to abuse and

death. Additions or substitutions to the fentanyl molecule are not technically difficult, and given the possible number of variations to the fentanyl molecule observed to date, there is the potential for 3,024 analogues<sup>24</sup> that may be created from the fentanyl molecule. These resulting analogues have a wide variance in potency. Some fentanyl analogues, like acetylfentanyl, are less potent than fentanyl. Others, like carfentanil, are many times more potent.

On February 6, 2018, DEA placed all fentanyl-related substances under Schedule I on a temporary basis for a two-year period. Initial indications are that the scheduling had some positive effect; however, our experience has shown that when substances are scheduled under the Controlled Substances Act, illicit drug producers expand their inventory to include compounds that fall outside of the scheduling regime to circumvent detection and avoid law enforcement actions. Over the past several years, as regulatory action was taken against a particular fentanyl analogue, we saw traffickers simply switch their production and trafficking efforts to a different fentanyl analogue or non-fentanyl synthetic opioid, such as the U-series drugs that are now causing fatalities in the United States. These non-fentanyl opioids may have the same qualitative effect on the human body as fentanyl or a fentanyl analogue, but they are not fentanyl-related in their chemical structure and are therefore not controlled under DEA's temporary scheduling order.

ONDCP is working with the interagency to broaden the universe of synthetic drugs that can be brought under regulatory control while maintaining our research community's access to these compounds. This is crucial because the global illicit drug industry is able to synthesize thousands of these chemicals in drug libraries each year to determine new substances that they can then market to people with substance use disorders based on each drug's desired effects. It is a consumer-driven enterprise combining basic market demands with 21<sup>st</sup> century science. At the

same time, legitimate research on any of these compounds could lead to improved treatments for pain and addiction or a potential cure for some other disease, so we need to ensure scientists have the access they need to conduct such research.

It would not be an exaggeration to say that given what we know about the dynamism and rapid pace of illicit drug production we see today, the synthetic opioid that will be killing Americans in 2021 or 2022 has not yet been invented. Therefore, while we must act to make permanent the temporary scheduling of the class of fentanyl analogues, it is important to also provide a framework to more comprehensively address the rapid and emerging changes in the dynamic illicit drug market, seizing the initiative from illicit drug producers and traffickers, while ensuring that scientists have appropriate access to controlled substances in their exploration of beneficial uses of these drugs.

As stated in the Administration's 2019 *National Drug Control Strategy*, "While confronting today's drug crisis to arrest its growth and reduce its effects, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century."<sup>25</sup> Director Carroll and the men and women of ONDCP are wholly committed to doing just that.

I would like to thank this Subcommittee and your Congressional colleagues for your foresight and leadership in addressing this critical national security, law enforcement, and public health challenge. On behalf of the Administration, ONDCP looks forward to working with you on legislative solutions to address this extremely complex environment.

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<sup>1</sup> H Hedegaard, AM Miniño, and M Warner. Drug Overdose Deaths in the United States, 1999-2017. NCHS Data Brief No. 329. National Center for Health Statistics, Centers for Disease Control and Prevention. November 2018. Available at: <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>.

<sup>2</sup> "Synthetic Opioid" refers to opioids that are not plant-derived (fentanyl, fentanyl analogues, and other novel

opioids). Heroin, which is plant-derived, is not a synthetic opioid.

<sup>3</sup> U.S. Department of Justice, Drug Enforcement Administration. National Forensic Information Laboratory System (NFLIS). Extracted by ONDCP in April 2019.

<sup>4</sup> *Ibid.*

<sup>5</sup> El Paso Intelligence Center (EPIC), National Seizure System (NSS). Extracted by ONDCP on August 28, 2018.

<sup>6</sup> U.S. Department of Justice, Drug Enforcement Administration. STARLiMS forensic drug chemistry database. Analysis by ONDCP on export through April 15, 2019

<sup>7</sup> U.S. Department of Homeland Security, Customs and Borders Protection. Analysis of FTIR data on drugs encountered at points of entry in May 2019.

<sup>8</sup> Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. *MMWR Morb Mortal Wkly Rep* 2019;67:1419–1427. DOI:<http://dx.doi.org/10.15585/mmwr.mm675152e1>external icon

<sup>9</sup> University of Florida College of Medicine. Florida Drug-Related Outcomes Surveillance and Tracking System (FROST). Deaths with Fentanyl Analogs in 2017. Queried by ONDCP in May 2019

<sup>10</sup> Sorg, Marcella. University of Maine. Margaret Chase Smith Policy Center. Maine 2<sup>nd</sup> Quarter Drug Death Report: January – June 2018.

<sup>11</sup> Daniulaityte, R., Juhascik, M., Strayer, K., Sizemore, I., Harshbarger, JD, Antonides, H., Carlson, R. Overdose deaths related to fentanyl and its analogs: Ohio, January-February 2017. *Morbidity and Mortality Weekly Report*. 2017;66(34):904-908.

<sup>12</sup> U.S. Department of Justice Drug Enforcement Administration: 2017 National Drug Threat Assessment, October 2017, DEA-DCT-DIR-040-17. [https://www.dea.gov/docs/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/docs/DIR-040-17_2017-NDTA.pdf)

<sup>13</sup> 2019 National Drug Control Strategy, <https://www.whitehouse.gov/briefings-statements/white-house-releases-national-drug-control-strategy/>

<sup>14</sup> During the Obama Administration NSC meetings to coordinate interagency activities and assign tasks were referred to as Interagency Policy Committees (IPCs) or Sub-Interagency Policy Committees (Sub-IPCs). After the Presidential transition, they became known as Policy Coordination Committees (PCCs) or Sub-Policy Coordination Committees (Sub-PCCs).

<sup>15</sup> The NHC will be referenced as the NOSC from this point forward in document.

<sup>16</sup> This forum has met more than 28 times and has consistent participation from the NSC, FBI, DEA, DOJ Criminal Division, the Executive Office for United States Attorneys (EOUSA), CBP, DHS Policy, Immigration and Customs Enforcement (ICE), HSI, Department of Treasury Office of Foreign Asset Control (OFAC) and Financial Crimes Enforcement Network (FinCEN), US Marshal Service, USPIIS, and the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF).

<sup>17</sup> <https://www.whitehouse.gov/briefings-statements/statement-chinas-class-scheduling-fentanyl/>

<sup>18</sup> The newest outstations include The Interdiction Committee (TIC); Department of Health and Human Services (HHS) Office of Security and Strategic Information; Department of Homeland Security (DHS) Office of Intelligence and Analysis; Department of Defense National Targeting Center (DOD/NTC); and Joint Inter-Agency Task Force-West (JIATF-W).

<sup>19</sup> <https://www.whitehouse.gov/briefings-statements/multi-agency-partnership-launches-1-55m-challenge-new-solutions-detect-opioids/>

<sup>20</sup> <https://www.whitehouse.gov/briefings-statements/8-finalists-announced-1-55m-challenge-new-solutions-detect-opioids-international-mail/>

<sup>21</sup> *Fentanyl Handling Guidelines for First Responders*. <https://www.whitehouse.gov/ondcp/key-issues/fentanyl/>

<sup>22</sup> President's Commission on Combating Drug Addiction and the Opioid Crisis, [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

<sup>23</sup> Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018), <https://www.federalregister.gov/documents/2018/02/06/2018-02319/schedules-of-controlled-substances-temporary-placement-of-fentanyl-related-substances-in-schedule-i>.

<sup>24</sup> U.S. Department of Homeland Security, Customs and Borders Protection Analysis

<sup>25</sup> Executive Office of the President, Office of National Drug Control Policy. (January 2019). National Drug Control Strategy. Available at, <https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf>.



Ms. DEGETTE. Thank you, Mr. Chester.  
Mr. Donahue, you're now recognized for five minutes.

#### STATEMENT OF MATTHEW DONAHUE

Mr. DONAHUE. Good morning, Chairman DeGette, Ranking Member Guthrie, and members of the subcommittee. It is my honor to appear before you today to discuss the critically important issue of illicit fentanyl and fentanyl like substances that have had a tremendous impact on the health and safety of our communities.

Illicit fentanyl and other fentanyl like substances are especially dangerous drugs are often far more potent and deadly than other drugs like heroin and cocaine.

I have had the privilege of being a DEA special agent for almost 30 years, having worked in South America, the Caribbean, and now North and Central American region.

When I reflect on my time with DEA, the challenge we face with the ongoing opioid crisis, along with the sophistication, capacity, and global reach of Mexican poly-drug cartels is what worries me and deeply concerns me the most.

As the regional director of North and Central America region, I see firsthand everyday the extreme lawlessness and other atrocities committed by Mexican cartels to maintain their dominant market share to provide illegal substances to individuals in the United States.

The ruthlessness of these cartels, combined with their callous greed, is devastating families and communities, resulting in an increase of violent crime in the United States.

Dangerous and highly sophisticated cartels operating in both Mexico and the United States have been and will continue to be the most significant source of illicit narcotics trafficked into and throughout the United States.

When it comes to illicit fentanyl, China is the primary manufacturing source as well as the source of precursor chemicals needed to manufacture fentanyl outside of China.

However, I would be remiss if I didn't say that China has taken important action to stem this manufacturing by the extraordinary step of controlling the entire class of fentanyl-based drugs.

History has shown that when China and the United States have jointly controlled the drug it has drastically decreased its importation into the United States.

However, Mexican cartels now have increasingly an important role in the fentanyl trafficking. We have witnessed a transition from importation of precursor chemicals for the production of fentanyl to the manufacturing of precursor chemicals and fentanyl within Mexico itself. This is a very alarming development.

Fentanyl comes into the United States in three ways. It is shipped directly to the United States through the U.S. mail services, it is trafficked in through our northern border, and most importantly, it is trafficked over our southern border via Mexican cartels by various means and methods.

In many cases, fentanyl comes in the form of counterfeit prescription pills. Oftentimes, people believe they may be ordering Hydrocodone or Oxycodone on the internet but they're receiving a

fentanyl or a fentanyl analog, which could lead to deadly consequences.

As a leader of DEA in Mexico, I can say confidently that we have not been a spectator in this battle. DEA has the largest footprint of the United States Government in Mexico. We are addressing this threat by focussing on efforts of identifying the supply chain and disrupting it. We are working bilaterally and judiciously targeting and dismantling the cartels.

Through our more than 300 domestic and international field offices, our special operations division, which works with our inter-agency and international partners, we are conducting large-scale investigations and prosecuting those who seek to profit and are responsible for the production, transportation, distribution, and sale of these deadly substances.

Perhaps one of the most notable examples of these efforts is the 2016 arrest of Sinaloa cartel leader Joaquin Guzman Loera, commonly known as El Chapo, who coincidentally is being sentenced tomorrow in New York City.

The DEA will continue to investigate the biggest and most egregious organizations that are poisoning our communities. We will continue to focus on targeting drug cartels and significant organizations operating in and outside the United States whose only motive is to make tremendous profits on unsuspecting and vulnerable populations.

But there is more work to be done. On February 6, 2018, the DEA used its authority under the Controlled Substances Act to temporarily place all nonscheduled fentanyl like substances in Schedule I and it has had a significant impact.

Let me reiterate that point. The temporary control of all non-scheduled fentanyl substances has had a significant positive impact in this fight. The class control action has substantially slowed the rate at which new substances are introduced to and encountered on the illicit market.

However, this temporary action expires February 2020, which is only 206 days away. Additionally, if lawful access is not addressed, criminals will continue to use our own laws to evade detection and exploit members of our communities as technology advances and law enforcement is prevented from judicial interception and collection.

Make no mistake—no matter the challenge, DEA will never stop aggressively pursuing the most dangerous and prolific criminals trafficking in illicit drugs in our communities.

Thank you for the opportunity to testify before your subcommittee on this important issue and I look forward to your questions.

[The prepared statement of Mr. Donahue follows:]



# **Department of Justice**

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**STATEMENT OF**

**MATTHEW DONAHUE  
REGIONAL DIRECTOR, NORTH AND CENTRAL AMERICAS DIVISION  
DRUG ENFORCEMENT ADMINISTRATION**

**BEFORE THE**

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

**FOR A HEARING ENTITLED**

**“OVERSIGHT OF FEDERAL EFFORTS TO COMBAT THE SPREAD OF  
ILLICIT FENTANYL”**

**PRESENTED**

**JULY 16, 2019**

**Statement of Matthew Donahue  
Regional Director, North and Central Americas Division  
Drug Enforcement Administration  
Before the House Energy and Commerce Committee  
Subcommittee on Oversight and Investigations  
For a Hearing Entitled  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

Chairman DeGette, Ranking Member Guthrie, and Members of the Subcommittee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the ongoing illicit fentanyl crisis.

It is well known that overdose deaths in the United States are on the rise and have already reached record levels. While the most recent provisional overdose death data published by the Centers for Disease Control and Prevention (CDC) indicate that deaths involving all drugs have begun to stabilize in the past year; however deaths from synthetic opioids continue to rise. Of note, in 2017, over half of the death certificates for cocaine- or heroin-involved overdose deaths also involved a synthetic opioid such as fentanyl. While a number of factors appear to be contributing to this public health crisis, one of the chief causes is the proliferation of illicitly produced fentanyl and potent substances structurally related to fentanyl, commonly called “fentanyl analogues” or “fentanyl-like substances.” Fentanyl’s analgesic potency is approximately 100 times higher than morphine, and the substances structurally related to fentanyl tend to be even more potent. Because of fentanyl’s 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.

The lethality of fentanyl and fentanyl-like substances is virtually unmatched. Law enforcement is increasingly encountering fentanyl and fentanyl-like substances laced with other illicit drugs such as methamphetamine, cocaine, and heroin. These deadly combinations only enhance the urgency of this public health crisis and increase the risks for those who may be unknowingly using these fentanyl laced drugs.

However, licit fentanyl is an important treatment agent in the practice of medicine and is utilized for its potent analgesic effects. Because of its potency, careful dosing and titration are essential. Some forms of the drug are indicated for use in people who have high opioid tolerance. Due to their high potential for abuse, fentanyl and various fentanyl-like substances have been placed in Schedule I or Schedule II control under the Controlled Substances Act (CSA) on a substance-by-substance basis. Yet, with relative ease, clandestine chemists have been able to create new potent and potentially deadly synthetic compounds by merely altering the chemical composition of the substances, resulting in new, non-controlled synthetics. *These fentanyl-related substances are specifically engineered to skirt U.S. law.*

Whether via mail, express consignment, or through Mexico, China has been the principal source country of fentanyl-like substances and other synthetic opioids, producing most illicit

fentanyl and fentanyl like-substances that reach U.S. users. DEA works closely with China to bring attention to and help combat the rise of illicit fentanyl and fentanyl analogues. Because of robust engagement by multiple U.S. Government agencies, China has made progress in this space, and announced on April 1, 2019 the class-wide control of fentanyl-like substances effective May 1, 2019.

This is a promising development; however, if increased regulatory controls taking effect in China, Mexican Transnational Criminal Organizations (TCOs) may fill the void. DEA is continuing to see a shift from importation of precursor chemicals for the production of fentanyl and fentanyl like substances to the manufacturing of precursor chemicals within Mexico itself. This is an alarming development.

### **CURRENT CHALLENGES WITH FENTANYL AND RELATED ANALOGUES**

#### *Traffickers Adapting to the Law*

Even though fentanyl and fentanyl analogues, as well as other New Psychoactive Substances (NPS), have been controlled under Schedule I or Schedule II of the CSA, entrepreneurs procure/create new synthetic compounds with relative ease, by merely altering the chemical composition of the substances.<sup>1</sup> Over the past several years, DEA has identified numerous illicit fentanyl-class substances and hundreds of synthetic drugs from at least eight different drug classes, the vast majority of which are manufactured in China.

Using published data from the patent and scientific literature as their guide, clandestine chemists have continued to develop and synthesize new synthetic opioids, cannabinoids, and cathinones for the illicit market. Clandestine chemists can easily continue developing and synthesizing new synthetic opioids that do not appear on any schedule of controlled substances. Sadly, DEA often learns of these substances for the first time from reports from local hospitals and coroners in connection with a spate of overdoses. Temporary scheduling alone is not enough to address this epidemic. When DEA takes action to temporarily schedule a substance, traffickers begin selling new versions of their products made from new, non-controlled substances in as little as several weeks. Unfortunately, the existing process to temporarily schedule a substance is reactionary, and not agile enough to keep up with bad actors engineering illicit substances for the express purpose of skirting our laws. Similarly, while we have had considerable success in pursuing prosecutions under the Analogue Act, such cases are resource-intensive and complex, and the results are uncertain and non-transferable from one case to another.

#### *Importation vs. Domestic Production and Use of the Internet*

Illicit fentanyl, fentanyl analogues, and other NPS are relatively inexpensive, available via the Internet, and are often manufactured in China where they may be shipped (via the international postal system or express consignment couriers) to the United States; alternatively,

<sup>1</sup>On February 6, 2018, DEA published a final order in the Federal Register scheduling all fentanyl-related substances (i.e., fentanyl analogues) in Schedule I on an emergency basis. The final order was made effective on the date of publication and is in effect for a period of two years.

they may be shipped directly to transnational criminal organizations in Mexico, Canada, and the Caribbean. Once in the Western Hemisphere, fentanyl and fentanyl analogues in particular are combined with heroin, cocaine, and other substances, and/or pressed into counterfeit pills made to look like controlled prescription drugs containing oxycodone or hydrocodone. They are then sold online on anonymous darknet markets, and even on overtly-operated websites or on the street. It is extremely difficult for the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement's (ICE) Homeland Security Investigations (HSI), and the U.S. Postal Inspection Service (USPIS) to address the threat of illicit importation at ports of entry, due to the combination of: the questionable legal status of these substances;; the enormous volume of international parcel traffic by mail and express consignment couriers; and the technological and logistical challenges of detection and inspection. These challenges have paved the way for both cartel and non-cartel-affiliated individuals to undertake fentanyl trafficking.

#### Use of Freight Forwarders

Traffickers often use freight forwarding companies that arrange importing and exporting of goods to ship fentanyl, fentanyl analogues, and other NPS from China to TCOs in the United States, Mexico, and Canada. 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 challenging for law enforcement to track these packages. Often, the package will intentionally have missing, incomplete, and/or inaccurate information.

### **DEPARTMENT OF JUSTICE INTERACTIONS WITH CHINESE COUNTERPARTS**

#### China: Government Action and Cooperation

As part of a whole of government approach of the Administration, the Department of Justice, and DEA, which has an active Beijing-based country office, have engaged Chinese counterparts on the control of emerging fentanyl-like substances and other NPS. When China takes action in controlling a specific drug or precursor chemical, we typically see a significant drop in that substance being used for illicit purposes in the United States, although it has always been accompanied by a rise in use of a similar unregulated substance. Nonetheless, it's through these bilateral communications and bridge building efforts that we can work to reduce the supply of illegal substances around the world.

On April 1, 2019, China announced that it would schedule fentanyl-like substances as a class, effective May 1, 2019, and DEA understands that the action is now in place. This will prevent chemical work-arounds to be exploited by clandestine synthetic opioid producers in China by allowing the United States and China to cooperate on a broader range of cases. Similar to DEA's emergency temporary scheduling order of fentanyl-like substances, this novel approach taken by the Government of China is responsive to our Nation's unprecedented opioid threat. Indeed, officials from the Ministry of Public Security Narcotics Control Board in China

had indicated that their scheduling process is long and complicated, that China has always scheduled one drug at a time, pursuant to its law, and that any change in that process would be groundbreaking for China.

As the opioid threat continues, DEA is committed to working with Chinese officials through well-established bilateral efforts: liaison presence; the Counter-Narcotics Working Group, Bilateral Drug Intelligence Working Group, regular meetings of scientists; and enhancing collaboration with DEA's interagency partners stationed abroad and in the United States. DEA is encouraged by China's recent class-wide controls of fentanyl-like substances.

#### **UNITED STATES – MEXICO LAW ENFORCEMENT ENGAGEMENT**

Mexico is the primary producer and supplier of heroin to the United States, additionally, Mexico is an increasing source of fentanyl and fentanyl-like substances. DEA investigative reporting indicates that the Sinaloa Cartel and the Cartel Jalisco Nueva Generacion (CJNG) are likely the primary groups trafficking fentanyl and fentanyl-like substances into the United States via the Southwest Border. The presence of fentanyl comingled with other poly-drug loads typical of Sinaloa and CJNG suggests strong links between these TCOs and fentanyl trafficking into the United States. This is not surprising considering Sinaloa maintains the most expansive footprint in the United States, while CJNG's domestic presence has significantly expanded in the past few years.

These developments drive DEA's continued efforts to expand the robust relationship between Mexico and the United States, particularly with regards to countering the threat from heroin and increasingly fentanyl and fentanyl-like substances. DEA has developed a U.S.-Mexico bilateral heroin strategy to increase intelligence sharing, coordination of investigations, training, sharing of forensic information, and the control of precursor chemicals. DEA's Mexico City Country Office has engaged the interagency within the U.S. Embassy through creation of a Heroin Fentanyl Working Group (HFWG). The HFWG, first convened in April 2015, meets on a monthly basis and synchronizes interagency efforts and capabilities. In early 2016, this forum became part of the Office of National Drug Control Policy's (ONDCP) Heroin Availability Reduction Plan (HARP) implementation, which continues as a monthly video teleconference, co-chaired by Mission Mexico and ONDCP and regularly attended by the National Security Council, DEA, the Department of Defense (DOD), and the Department of State Bureaus of Western Hemisphere Affairs and the Department of State's Bureaus of International Narcotics and Law Enforcement Affairs (INL). This one-hour monthly forum has become the most effective tool for synchronizing policy formulation and implementation between Mission Mexico and ONDCP. The HFWG has allowed the Federal government to speak with one voice and maintain critical security relationships with our Mexican partners. The HFWG has enabled close coordination on efforts to develop accurate Mexican heroin yield estimates, improve the Government of Mexico's poppy eradication efforts, support investigations of fentanyl seizures, track ongoing clandestine lab training, and reinforce interdiction efforts.

DEA also participates in the North American Drug Dialogue (NADD), a trilateral Assistant Secretary-level forum among the United States, Mexico, and Canada. Chaired by

ONDCP and INL, the NADD provides a framework for expanding cooperation on the heroin and fentanyl problem-set across the entire continent. For example, as a result of the NADD, and with funding from INL, the Royal Canadian Mounted Police (RCMP) has provided fentanyl detection training to Mexican Federal Police (PF) and canine units affiliated with Mexico's Tax Administration Service (SAT), which performs a customs function.

The DEA's presence in Mexico represents our largest international footprint. The ability to have DEA Special Agents assigned to 11 different offices throughout Mexico is a reflection of the level of cooperation that we continue to enjoy with our Mexican counterparts. DEA supports bi-lateral investigations with the Government of Mexico by providing information and intelligence to develop investigations that target TCO networks, leadership command, and control elements throughout Mexico.

#### **DEA RESPONSE TO THE FENTANYL THREAT**

DEA is combating the threat both domestically and internationally. DEA prioritizes its resources by targeting Consolidated Priority Organization Targets (CPOTs) and Priority Target Organizations (PTOs), which are the most significant international and domestic drug trafficking and money laundering organizations. We partner with federal, state, local, tribal, and international entities to target these identified threats utilizing a range of programs.

##### *Special Operations Division*

Established in 1994, the Special Operations Division (SOD) is a DEA-led multi-agency operations coordination center with participation from Federal law enforcement agencies, the Department of Defense (DOD), the Intelligence Community, and international law enforcement partners. SOD's mission is to establish strategies and operations to dismantle national and international trafficking organizations by attacking their command and control communications. Special emphasis is placed on those major drug trafficking organizations that operate across jurisdictional boundaries on a regional, national, and international level.

##### *Heroin Fentanyl Task Force*

The DEA Special Operations Division's (SOD) Heroin/Fentanyl Task Force (HFTF) working group consists of several agencies using a "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, ICE, and CBP, supplemented by the Federal Bureau of Investigation (FBI) and USPIA. The HFTF utilizes every resource available, including support from the Organized Crime Drug Enforcement Task Forces (OCDETF), OCDETF Fusion Center (OFC) and the Criminal Division, DOD, the Intelligence Community (IC), and other government entities, and provides field offices (of 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 heroin, 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 sources 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 heroin, fentanyl, and other NPS related cases.

Close interagency cooperation via the HFTF has led to several key enforcement actions, including the announcement on October 17, 2017, of the first-ever indictments, in two separate OCDETF cases, of two Chinese nationals responsible for the manufacturing and distribution of illicit fentanyl in the United States. The indictments represented the first of manufacturers and distributors of fentanyl and other opioid substances designated as Consolidated Priority Organization Targets (CPOTs). CPOT designations are of those who have “command and control” elements of the most prolific international drug trafficking and money laundering organizations operating in the world.

In addition, SOD’s HFTF played an integral role in the July 2017 seizure and closure of the largest criminal marketplace on the Internet, AlphaBay. As outlined by then Attorney General and the DEA Acting Principal Deputy Administrator, AlphaBay operated for over two years on the dark web, and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay’s infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. Multiple interagency OCDETF investigations into AlphaBay revealed that numerous vendors, including many in China, sold illicit fentanyl and heroin on the site, and that there have been a substantial number of overdose deaths across the country attributed to such purchases.

Operation Synthetic Opioid Surge (SOS)

In July of 2018, then-Attorney General Sessions announced the creation of Operation Synthetic Opioid Surge (SOS), a new initiative that aims to reduce the supply of deadly synthetic opioids in high impact areas and to identify wholesale distribution networks as well as international and domestic suppliers. Operation SOS focuses its activities in ten specific districts throughout the United States. Specifically, the Attorney General directed each of the identified districts to prosecute every readily provable investigation involving the distribution of synthetic opioids, primarily fentanyl and its analogues, occurring in their identified counties, regardless of drug quantity. SOS seeks to reduce the supply of synthetic opioids in “hot spot” counties, thereby reducing drug overdoses and drug overdose deaths, and identify wholesale distribution networks and sources of supply operating nationally and internationally. SOS also involves a coordinated OFC and SOD effort to ensure that leads from these street-level cases are used to identify and prosecute larger-scale distributors.

As part of SOS, SOD harnesses participating interagency databases, tools, and programs to exploit traditional and cyber communications, travel, trade, finance, open source, and social media, to illuminate and target unknown TCO networks by pursuing a top down analytical focus. SOD assists in coordinating overlapping investigations, ensuring tactical and strategic intelligence occurs between law enforcement agencies and providing financial support to those investigations that meet investigative priorities across the interagency. SOS districts have reported significant increases in the number of pending fentanyl investigations and prosecutions and at least 10 pending ODETF investigations.

Heroin-Fentanyl Enforcement Teams

Utilizing the appropriations under the Consolidated Appropriations Act of 2017 (P.L. 115-31), DEA has created six new heroin-fentanyl enforcement teams to combat trafficking in heroin, fentanyl, and fentanyl analogues. The establishment of the teams began in January 2018, and they are located in some of the regions hardest hit by the opioid epidemic: New Bedford, Massachusetts; Charleston, West Virginia; Cincinnati, Ohio; Cleveland, Ohio; Raleigh, North Carolina; and Long Island, New York. Thanks to the robust Consolidated Appropriations Act of 2018 (P.L. 115-141) appropriation, DEA will be creating three additional heroin-fentanyl teams. In determining the locations for these teams, DEA will consider multiple factors, including rates of opioid mortality, level of heroin and fentanyl seizures, and where additional resources would make the greatest impact in addressing the ongoing threat. While the teams are based in specific cities, their investigations are not geographically limited. DEA has always, and will continue, to pursue investigations wherever the evidence leads.

International Enforcement: Sensitive Investigative Units

A significant component of DEA’s International Drug Enforcement Priorities is to support and expand a key element of DEA’s international efforts: the Sensitive Investigative Unit (SIU) program. DEA’s SIU program, nine of which are in the Western Hemisphere,

including Mexico, helps build effective and vetted host nation units capable of conducting complex investigations targeting major TCOs.

*International Enforcement: Bilateral Investigations Units*

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

*Fentanyl Signature Profiling Program*

The overarching goal of the Fentanyl Signature Profiling Program (FSPP) is to provide new insights in support of ongoing DEA investigations. The FSPP does this by providing both real-time data from the in-depth analyses of seized samples and unique science-based forensic investigative leads on seizures where linkages were unknown or only suspected. These linkages are imperative to discover relationships between these investigative leads. For instance, examples from qualified seizures throughout DEA (e.g., exhibits containing a sufficient amount of fentanyl necessary for in-depth testing) are automatically submitted to DEA laboratories for FSPP testing; each profiled sample is then compared to all other such fentanyl submissions. If linkages between samples are identified, this information is communicated to the appropriate DEA Field Division to advance the investigation. Since the program's implementation, over 500 illicit fentanyl samples have been examined, resulting in the establishment of several sets of seizure linkages tying separate cases and seizures together.

*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 a scheduling recommendation, from the Department of Health and Human Services (HHS). DEA also gathers and analyzes 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 19 occasions to place 56 synthetic drugs temporarily (emergency control) into Schedule I, including 17 fentanyl analogues. 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. The process is workable but often lags behind the dynamic pace of illicit drug producers and distributors. In a significant step, on February 6, 2018, DEA temporarily placed Schedule I controls on "fentanyl related substances," which includes the class of substances structurally related to fentanyl based on specific chemical changes but not otherwise controlled in any other schedule.

DEA's temporary actions are the catalyst for communication with a number of international counterparts, not just China, who are interested in following our example and implementing a similar class-based control for fentanyl related substances. The Department of Justice, DEA, and ultimately the United States is leading from the front with our efforts to emergency control fentanyl-like substances as a class, but that regulatory authority soon expires. If no action is taken to permanently class-wide schedule these dangerous, lethal substances, **in just 206 days from today**, they will again fall out of our controls. Should the temporary order expire, it will result in significant negative outcomes for our communities and users. We are working with our interagency colleagues on a means to comprehensively address the scheduling of opioid analogues.

## CONCLUSION

Mexican TCOs remain the greatest criminal drug threat to the United States. These Mexican poly-drug organizations traffic heroin, methamphetamine, cocaine, marijuana, and now more than ever illicit fentanyl and synthetic opioid analogues, which are responsible for so many deaths over the last several years throughout the United States using established transportation routes and distribution networks. They control drug trafficking across the Southwest Border and are moving to expand their share of U.S. illicit drug markets. Their influence up and down the supply chain, their ability to enter into new markets, and their associations with domestic gangs are of particular concern for the DEA. DEA will continue to address this threat domestically and abroad by attacking the crime and violence perpetrated by the Mexican-based TCOs, which have brought tremendous harm to our communities. Targeting the world's most prolific and dangerous drug traffickers is a dynamic and evolving mission, and with it comes myriad challenges. But throughout our history, DEA has met those challenges and produced impressive results.

The fight against drug abuse is a generations-long struggle; it will not be completed overnight. DEA plays a critically important role in our country's holistic strategy of prevention, treatment and recovery support, and in reducing the availability of illicit drugs in the United States. DEA remains committed to bringing the "Most Wanted" drug traffickers and their entire networks to justice in cooperation with our law enforcement partners. With that, DEA continues to engage the Governments of China, Mexico, and others in our efforts to stem the flow of fentanyl and fentanyl precursors, which are fueling the national opioid epidemic. DEA is further committed to working with our interagency and international partners in targeting, indicting, and arresting leadership of criminal networks, both foreign and domestic. By taking harmful drugs off of the street, dismantling major drug organizations, and seizing the profits associated with this trade, we are making our nation a safer place to live and do business.

Thank you for the opportunity to testify today and we look forward to continuing to work with Congress to find solutions necessary to address the threats posed by TCOs and the harmful substances and illegal activity they are involved in, no matter where they may operate.

Ms. DEGETTE. Thank you so much, Mr. Donahue.  
Mr. Overacker, you are now recognized for five minutes.

**STATEMENT OF THOMAS F. OVERACKER**

Mr. OVERACKER. Chairwoman DeGette, Ranking Member Guthrie, members of the subcommittee, thank you for the opportunity to testify before you today.

I am proud to represent the men and women of the U.S. Customs and Border Protection, our nation's unified border agency with a vital counter narcotics mission.

On a typical day, CBP seizes more than 5,800 pounds of narcotics that would otherwise make their way into American communities. While today's hearing focusses on the opioid crisis and its devastating effects, CBP is committed to stopping all illicit drugs from crossing our borders.

For example, last month, with our partners at Homeland Security investigations and the United States Coast Guard, CBP seized more than 19 tons of cocaine on a container ship in Philadelphia.

The cocaine had an estimated street value in excess of \$1.3 billion and was the largest cocaine seizure in the combined 230-year history of the U.S. Customs Service and CBP.

Compared to cocaine or methamphetamine, CBP seizures of fentanyl are relatively low. However, these seizures have increased dramatically in recent years and that is cause for concern.

In fiscal year 2013, CBP seized approximately two pounds of fentanyl. Last year, we seized over 2,100 pounds. Through June of this year, we have already seized as much as we did last year. Most of the fentanyl coming into our country does so at ports of entry along the Southwest border. It's brought in by privately owned vehicles, commercial vehicles, even pedestrians.

Less frequent is fentanyl entering through international mail packages and express consignment environments. In those cases, most of the shipments originate from China.

However, the fentanyl in the international mail and express environments is far more potent and pure than the fentanyl crossing the Southwest border. Stopping fentanyl and other narcotics takes a collaborative effort.

Through CBP's national targeting center we work with our partners to identify and disrupt fentanyl smuggling at ports of entry, international mail facilities, and express consignment carrier facilities.

Our partners include Homeland Security investigations, the United States Postal Inspection Service, the Drug Enforcement Administration, Health and Human Services, Food and Drug Administration, the Office of National Drug Control Policy, the Organized Crime Drug Enforcement Task Force, and numerous other domestic and international partners.

Based on our encounters, CBP produces intelligence products to help identify the tactics, techniques, and flow of drug trafficking. This enhances targeting efforts and supports investigations.

It also provides policymakers, agency leadership, and the intelligence community with information that can lead to drug interdiction.

Information sharing, advanced electronic data, the targeting of precursors and pill presses are among the many elements that inform our actionable intelligence and allow us to combat narcotics trafficking in a dynamic threat environment.

In addition, CBP uses a variety of technologies and techniques to detect and identify illicit drugs. With the support of Congress, we are making significant investments and improvements in these capabilities, including additional narcotics detection K9 teams, enhanced field testing and new nonintrusive inspection, or NII, equipment.

NII contributes to more than 98 percent of the number and total weight of seizures. Currently, CBP scans approximately two percent of privately-owned vehicles and 16 percent of commercial vehicles arriving at the Southwest border ports of entry.

To enhance our capabilities, CBP has developed a new model port concept that prioritizes the use of drive through scanning equipment to streamline the inspection process and increase scanning rates, thereby increasing the probability of interdiction.

To protect CBP personnel, who may be exposed to dangerous substances during the course of their duties, we have deployed more than 1,100 2-dose boxes of counter narcotic Naloxone to train personnel in the field.

CBP was the first federal law enforcement agency to implement such a program and we have already administered nine lifesaving doses to members of the public.

Together, CBP and its partners are focused on enhancing collaboration and information sharing to reduce the amounts of illicit opioids that cross our land, air, and sea borders.

Thank you for allowing me the opportunity to tell our story. I look forward to your questions.

[The prepared statement of Mr. Overacker follows:]



TESTIMONY OF

Thomas F. Overacker  
Executive Director  
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Office of Field Operations  
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U.S. Department of Homeland Security

For a Hearing

BEFORE

U.S. House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

ON

“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”

July 16, 2019  
Washington, DC

### Introduction

Chairwoman DeGette, Ranking Member Guthrie, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to discuss the role of U.S. Customs and Border Protection (CBP) in combating the flow of illicit opioids, including synthetic opioids such as fentanyl, into the United States.

In 2017, among 70,237 drug overdose deaths, 47,600 (67.8%) involved opioids, with increases across age groups, racial/ethnic groups, county urbanization levels, and in multiple states.<sup>1</sup> Opioid misuse, addiction, and overdose put a significant strain on law enforcement, healthcare, and social service providers. The opioid crisis is one of the most important, complex, and difficult challenges our nation faces today, and was declared a National Public Health Emergency by President Donald Trump in October 2017.<sup>2</sup>

As America's unified border agency, CBP plays a critical role in preventing illicit narcotics, including opioids, from reaching the American public. CBP leverages targeting and intelligence-driven strategies, and works in close coordination with our partners as part of our multi-layered, risk-based approach to enhance the security of our borders and our country. This layered approach reduces our reliance on any single point or program, and extends our zone of security outward, ensuring our physical border is not the first or last line of defense, but one of many.

### Opioid Trends, Interdictions, and Challenges

From October 1, 2018 through May 31, 2019, U.S. Customs and Border Protection has seized more than 447,500 lbs. of narcotics nationwide, including more than 47,600 lbs. of methamphetamine, more than 47,800 lbs. of cocaine, and more than 3,500 lbs. of heroin.

CBP seizures of illicit fentanyl have also significantly increased from approximately two lbs. seized in FY 2013 to approximately 2,170 lbs. seized in FY 2018. Fentanyl is the most frequently seized illicit synthetic opioid, but CBP has observed fentanyl and 25 of its analogues, as well as 14 unique synthetic opioids that are not from the fentanyl class.<sup>3</sup>

Illicit drug interdictions in the border environment is both challenging and complex. Drug Trafficking Organizations (DTOs) and Transnational Criminal Organizations (TCOs) continually adjust their operations to circumvent detection and interdiction by law enforcement, quickly taking advantage of technological and scientific advancements and improving fabrication and concealment techniques.

<sup>1</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm>

<sup>2</sup> <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>

<sup>3</sup> These include: acetylfentanyl, butyrylfentanyl,  $\beta$ -hydroxythiofentanyl,  $\alpha$ -methylacetylfentanyl, p-fluorobutyrylfentanyl, p-fluorofentanyl, pentanoylfentanyl (a.k.a. valerylfentanyl), 2-furanylfentanyl, p-fluoroisobutyrylfentanyl, n-hexanoylfentanyl, carfentanil, benzodioxolefentanyl, acrylfentanyl, 2,2'-difluorofentanyl, methoxyacetylfentanyl, benzoylfentanyl, cyclopropylylfentanyl, and hydrocinnamoylfentanyl.



### *International Airports*

The most pure and potent fentanyl enters the United States at international airports within international mail facilities (IMF) and express consignment courier (ECC) environments. Most of these shipments originate from China, with some also coming from Canada and Mexico.

Illicit fentanyl can be purchased from sellers through online transactions and then shipped via international mail packages or ECCs. DTOs and suppliers move fentanyl in small quantities, making detection a significant challenge.

### *Along the Southern Border*

Although far less pure, most of the illicit fentanyl entering our country by weight does so at ports of entry (POEs) along our southwest border by private vehicles, pedestrian, and commercial vehicles. The reach and influence of Mexican cartels stretch across and beyond the Southwest border, operating through business ties with smaller organizations in communities across the United States. The threat of these cartels is dynamic; rival organizations are constantly vying for control, and as U.S. and Mexican anti-drug efforts disrupt criminal networks, new groups arise and form new alliances.

### *Along the Northern Border*

Illicit fentanyl entering from the Northern border does so by international mail packages and express consignment courier.

### **CBP Strategy to Combat Opioids**

In September of 2018, CBP released the *CBP Strategy to Combat Opioids*. The strategy provides a blueprint to mobilize and prioritize resources in the fight against illicit opioids while allowing for adjustments to be made as the environment evolves. Based on the deadly threat posed by fentanyl and its analogues, CBP is committed to dedicating its resources to thwart the illicit opioid supply chain and the networks promoting it.

The strategy has four strategic goals:

1. Enhance collaboration and information-sharing to combat illicit opioids;
2. Produce actionable intelligence on illicit opioids;
3. Target the illicit opioid supply chain; and
4. Protect CBP personnel from exposure to opioids.

### ***Enhance Collaboration and Information-Sharing***

Substantive and timely horizontal and vertical information-sharing is critical to targeting and interdicting illicit drugs. CBP works extensively with our federal, state, local, tribal, and international partners and provides critical capabilities toward the whole-of-government approach to address drug trafficking and other transnational threats at POEs, in our IMFs and ECCs, and along the southwest border, northern border, and coastal approaches. Our targeting, detection and interdiction efforts are enhanced through joint operations and task forces conducted under the auspices of multi-agency enforcement teams. These teams are composed of representatives from international and federal law enforcement agencies who work together with state, local, and tribal

agencies to target drug and transnational criminal activity, including investigations involving national security and organized crime.

The DHS S&T, U.S. Immigration and Customs Enforcement (ICE), the Drug Enforcement Administration (DEA), the United States Postal Inspection Service (USPIS), other law enforcement partners, and international partners collaborate with CBP to identify and disrupt fentanyl smuggling through the National Targeting Center (NTC) and POEs, IMFs, and ECC facilities. These efforts involve advanced targeting and counter network activities and utilization of Non-Intrusive Inspection (NII) technology, canine enforcement teams, new detection technology, and collaboration efforts at local POEs with other law enforcement partner resources.

We also host briefings with federal, state and local partners regarding the current state of the border to monitor emerging trends and threats and provide a cross-component, multi-agency venue for discussing trends and threats. The engagements focus on interdictions and arrests at the border and the interior areas within United States. These briefings also include participants from the Government of Canada and the Government of Mexico.

CBP is a key partner in the implementation of the Office of National Drug Control Policy's Heroin Availability Reduction Plan and utilizes the U.S. Department of Justice's Nationwide Deconfliction System for interagency coordination.

#### ***Produce Actionable Intelligence***

Actionable intelligence and intelligence products provide policy makers, agency leadership, and the intelligence community with information that can lead to interdiction operations through the identification of tactics, techniques, and flow of drug trafficking. These resources, along with enhanced information sharing and partnerships, are critical components of CBP's ability to identify and deter the entry of dangerous illicit drugs in all operational environments.

#### ***Advance Information and Targeting***

An important element of CBP's layered security strategy is obtaining advance information to help identify shipments that are potentially at a higher risk of containing contraband. Under section 343 of the *Trade Act of 2002* (Pub. L. No. 107-210), as amended, and under the *Security and Accountability for Every Port Act* or *SAFE Port Act of 2006*, (Pub. L. No. 109-347), CBP has the legal authority to collect key cargo data elements provided by air, sea, and land commercial transport companies (carriers), including ECCs and importers.<sup>4</sup> This information is automatically fed into the Automated Targeting System (ATS), a secure intranet-based enforcement and decision

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<sup>4</sup> Under TSA regulations, international mail destined for the United States is subject to security controls. These security controls, which include screening for unauthorized explosive, incendiary, and other destructive substances or items in accordance with TSA regulations and security program requirements, are applied to international mail prior to transporting on aircraft at Last Point of Departure locations to the United States. 49 U.S.C. 44901(a) states: "The Under Secretary of Transportation for Security shall provide for the screening of all passengers and property, including United States mail, cargo, carry-on and checked baggage, and other articles, that will be carried aboard a passenger aircraft." Under 49 C.F.R. 1540.5, "Cargo means property tendered for air transportation accounted for on an air waybill. All accompanied commercial courier consignments whether or not accounted for on an air waybill, are classified as cargo. Aircraft operator security programs further define the term 'cargo.' These requirements are not dependent on advance electronic manifest data, as provided by ECC operators and other participants in the Air Cargo Advance Screening (ACAS) pilot program.

support system that compares cargo and conveyance information against intelligence and other enforcement data.

#### *National Targeting Center*

At CBP's NTC, advance data and access to law enforcement and intelligence records converge to facilitate the targeting of travelers and items of cargo that pose the highest risk to our security in all modes of inbound transportation. The NTC takes in large amounts of data and uses sophisticated targeting tools and subject matter expertise to analyze, assess, and segment risk at every stage in the cargo/shipment and travel life cycles. As the focal point of that strategy, the NTC leverages classified, law enforcement, commercial, and open-source information in unique, proactive ways to identify high-risk travelers and shipments at the earliest possible point prior to arrival in the United States.

To bolster its targeting mission, the dedicated men and women of the NTC collaborate with critical partners on a daily basis. Investigative case data is fused with CBP targeting information to bolster investigations targeting fentanyl smuggling and trafficking organizations. NTC works in close coordination with several pertinent task forces including the Organized Crime Drug Enforcement Task Forces, the High Intensity Drug Trafficking Areas, and the Joint Interagency Task Force-South and West, as well as the DHS Joint Task Forces.

#### *Advance Electronic Data*

In the postal environment, recent bilateral agreements regarding advance electronic data (AED) between USPS and foreign postal operators have increased CBP's ability to target high-risk shipments. Additionally, the *Synthetics Trafficking and Overdose Prevention (STOP) Act* requires that DHS prescribe regulations requiring U.S. Postal Service to transmit advance electronic information for international to CBP consistent with the statute. Currently, USPS provides AED from more than 50 foreign postal services, and CBP utilizes the AED to actively target international mail shipments at seven IMFs.

#### *Targeting Precursors*

Many of the precursor chemicals that can be used to synthesize synthetic illicit opioids such as fentanyl are currently non-regulated and many have legitimate uses. CBP has sufficient authority to seize precursors if they can be identified as having illicit end-use intentions, including the production of illicit drugs. We target precursor chemicals transiting the United States with destinations to Mexico and other countries. When these shipments are identified through interagency collaboration as having illicit end-use intentions, the shipments are offloaded for further inspection and enforcement actions.

In addition to targeting illicit substances directly, CBP also targets related equipment such as pill presses and tableting machines. DEA regulates pill press/tableting machines and there is an ICE Diversion Coordinator assigned to the DEA, who oversees the investigations of pill press/tablet machine imports being diverted for illicit uses. The Diversion Coordinator works closely with the NTC to identify and target individuals importing and diverting pill press/tablet machines to produce illicit fentanyl and other synthetic drugs.

#### *Pollen Analysis*

One capability CBP is using to close intelligence gaps related to the illicit opioid supply chain is palynology, more commonly referred to as pollen analysis. Pollen analysis is conducted by CBP's Laboratories and Scientific Services (LSS) scientists on illicit narcotic shipments that have been seized at the border. The pollen testing has been used to geolocate illicit opioid shipments, which may be used to identify transit routes of illicit opioids. CBP has developed intelligence products based on the pollen analysis and shared it with relevant partners.

#### ***Target the Illicit Opioid Supply Chain***

CBP, with the support of Congress, has made significant investments and improvements in our drug detection and interdiction technology and targeting capabilities. Our officers utilize a variety of technologies and narcotics detection canines to detect and presumptively identify illicit drugs, including illicit opioids, at international mail and express consignment carrier facilities.

#### *Non-Intrusive Inspection Equipment*

CBP utilizes over 326 large-scale and 4,500 small-scale NII x-ray and gamma ray imaging systems to detect the illegal transit of narcotics, including synthetic drugs, hidden within passenger belongings, cargo containers, and in other conveyances entering the United States. Currently, the systems are primarily deployed in secondary inspection operations to examine targeted cargo conveyances, such as sea containers, commercial trucks rail cars, privately owned vehicles, as well as ECC and international mail parcels for the presence of illicit contraband.

As indicated earlier, TCOs commonly exploit the southwest land POEs to smuggle illicit goods into the United States, specifically within vehicles. Greater than 98 percent of the nationwide total of NII seizures and total weight of narcotics seized occur by scanning approximately one percent of privately owned vehicles and 16 percent of commercially owned vehicles arriving at southwest land POEs. We continue to focus on further closing the limited vehicle scanning capacity gap, and have prioritized the need for drive-through NII operational concepts that will help streamline the vehicle inspection process and increase scanning rates, thereby increasing the probability of interdiction.

The Fiscal Year 2019 enacted appropriations allows CBP to advance acquisition planning for new and drive-through NII technology, further refine and inform requirements via the results of the ongoing pre-primary drive through NII operational assessments, and incrementally increase scanning rates. The key operational change involves placing the new drive-through NII systems in pre-primary inspection versus secondary, and transmitting the image to an officer remotely located in a command center. This work builds upon prior automation and transformation initiatives, and also leverages advancements made to scanning and imagery analysis capabilities. Overall, this approach will increase security and facilitation across our nation's borders.

#### *Canines*

Canine operations are an invaluable component of counternarcotic operations. The CBP Canine Training Program maintains the largest and most diverse law enforcement canine training program in the country. CBP officers utilize specially trained canines for the interdiction of narcotics, firearms, and undeclared currency, as well as in support of specialized programs aimed at combating terrorism and countering human trafficking. Concealed Human and Narcotic Detection

Canines are trained to detect concealed humans and the odors of marijuana, cocaine, heroin, methamphetamine, hashish, ecstasy, fentanyl and fentanyl analogues. An increase of 15 narcotic detection canine teams was funded this year with \$2.5 million to combat the opioid epidemic.

The use of canines in the detection of narcotics is a team effort. CBP's Laboratories and Scientific Services Directorate (LSSD) produces canine training aids and provides analytical support to the CBP Canine Training Program, including controlled substance purity determinations, training aid quality analyses, and research on delivery mechanisms that maximize safe vapor delivery during training exercises. Recently, the feasibility of safely and effectively adding fentanyl as a trained odor to deployed narcotic detection canine teams was assessed. As of October 1, 2018, all new canine handler teams have successfully completed a comprehensive CBP Canine Detection Team Certification to include the odor of fentanyl and fentanyl analogs. Today, all Concealed Human and Narcotic Detection canine teams have completed fentanyl training.

#### *Laboratory Testing*

As the narcotics seized through the international mail and at ECC facilities usually have a very high purity, CBP officers at IMFs and ECC facilities use various field testing devices to rapidly screen suspected controlled substances and obtain presumptive results. CBP officers can transmit sample data for scientific interpretation and identification by the LSSD. When any synthetic opioids are detected by the reachback program, the NTC and our liaisons at the DEA are notified. CBP is working to expand the field testing program, along with the scientific assets and personnel who are able to provide real-time chemical composition determinations.

#### *Protect CBP Personnel*

The potential for contact with dangerous substances—especially illicit synthetic opioids—is a very real health and safety risk to law enforcement personnel and canines. For example, in its pure powder form, fentanyl is approximately 50-100 times more potent of an analgesic than morphine, and, at first glance, it is often mistaken for other drugs, which appear as white powders such as cocaine or heroin. Due to the risk of unintentional exposure and subsequent hazardous drug absorption and/or inhalation, the confirmatory testing for the presence of synthetic opioids such as fentanyl and its analogues is best executed in a laboratory by trained scientists and technicians.

To date, 1,119 two-dose boxes of naloxone have been deployed to trained CBP officers in the field. Additional naloxone is being deployed to field offices upon request, as additional personnel are trained in its administration. The naloxone program has also expanded to help protect LSSD scientists in laboratories. CBP was the first federal law enforcement agency to implement such a program. As of June 2019, OFO has administered nine life-saving doses of Naloxone to members of the public.

In addition, CBP has deployed the presumptive testing glove box to the field to aid in the safe testing and identification of opioids. The sampling glove box is designed for use in the field as the first level of protection when inspecting, probing, and conducting presumptive testing of high risk or unknown substances.

**Conclusion**

As the opioid epidemic devastates communities and families across the nation, we are dedicating its resources to thwart illicit opioid supply chains and networks. Together, CBP and its partners are focused on enhancing collaboration and information-sharing to reduce the amounts of illicit opioids that cross our land, sea, and air borders. Thank you for allowing us this opportunity to tell our story. I look forward to your questions.

Ms. DEGETTE. Thank you so much.

Mr. Barksdale, you are now recognized for five minutes.

#### STATEMENT OF GARY R. BARKSDALE

Mr. BARKSDALE. Good morning, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee.

I appreciate this opportunity to be here today to discuss efforts to combat opioids, including fentanyl.

My name is Gary Barksdale. I am the chief postal inspector for the United States Postal Inspection Service, the law enforcement arm—

Ms. DEGETTE. Mr. Barksdale, can you move the microphone just a little closer? Thank you.

Mr. BARKSDALE. Winning the battle against illicit drugs in the mail stream is one of our top priorities. Postal inspectors work not only to remove drugs from the mail but to investigate and arrest individuals and disrupt drug trafficking networks across the U.S.

Internationally, the inspection service is working aggressively to stem the flow of illegal drugs entering the country.

Due to the opioid crisis, nearly two years ago we created an internal team of cross-functional subject matter experts specifically focussed on narcotics trafficking through the mail.

The Contraband Interdiction and Investigations team, or CII, uses enhanced investigative methods, deploys resources as needed, and strengthens strategic partnerships to achieve significant improvements in our ability to seize fentanyl and synthetic opioids from the mail.

The inspection service works closely with other law enforcement agencies to share intelligence, coordinate cases, and conduct joint enforcement operations to maximize our resources and impact.

Relationships with partners such as DEA, HSI, CBP, and FDA allow us to better advance our mission to enforce the laws that defend the nation's mail.

Inspection Service personnel are assigned full time at ONDCP, the DEA's Special Operations Division, the National Fusion Center, and CBP's national targeting center. Internationally, the Postal Inspector is now detailed at Europol and the Hague.

We also work with state and local law enforcement to share intelligence and conduct joint operations including several Inspection Service sponsored task forces. These relationships facilitate communication and data sharing that enable the identification of drug trafficking organizations which would not be possible without inter-agency cooperation.

The Inspection Service launched cyber and analytics unit to enhance investigative techniques to better utilize data to target parcels. Due to many illicit dark web vendors aligned with physical delivery networks for their products, the Inspection Service is involved with investigations into vendors and the take down of their illicit marketplaces.

The Inspection Service has also joined DHS, CBP, and ONDCP as a sponsor for the opioid detection challenge, which is a global prize competition for rapid nonintrusive detection tools that will help find illicit opioids in international mail.

Postal inspectors interdict and seize thousands of illegal drug shipments in the mail. From fiscal year 2016 through 2018, we achieved a thousand percent increase in international synthetic opioid seizures and a 750 percent increase in domestic synthetic opioid seizures.

Thus far in fiscal year 2019 we have seized 185 synthetic opioid parcels, 153 of which were in the domestic mail stream. Our current stats represent a decrease in international seizures while our domestic seizures are trending up.

This shift may suggest synthetic opioids are increasingly entering the country through means other than international mail.

In 2018, Congress enacted the STOP Act, which requires the Postal Service to receive advanced electronic data, or AED, on at least 70 percent of inbound package shipments including 100 percent of shipments from the People's Republic of China by December 2018 and 100 percent of all inbound international shipments by December 2020.

The volume of inbound packages with AED has improved from 26 percent in October of 2017 to approximately 60 percent in May of 2019, while the volume of packages with AED from China has increased from 32 percent to approximately 85 percent in May of 2019. This represents a significant improvement within a relatively limited period of time.

The Postal Service continues to collaborate with foreign postal operators and organizations that support international postal operations to work towards obtaining AED on 100 percent of inbound packages and shipments.

We have significantly improved coordination with CBP and developed processes to ensure we take action on requests to hold packages for inspection.

The Postal Service currently has a 93 percent success rate in the capture of CBP hold requests and they will continue to focus on employing technology to improve interception capability and reach 100 percent.

The Postal Service takes seriously its mission to protect the security and sanctity of the mail and is committed to taking all necessary actions to combat illicit drugs in the mail.

Thank you for this opportunity to testify and I look forward to your questions.

[The prepared statement of Mr. Barksdale follows:]





**Statement of Gary R. Barksdale  
Chief Postal Inspector  
United States Postal Inspection Service  
Before the Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations  
United States House of Representatives  
July 16, 2019**

Good morning, Chair DeGette, Ranking Member Guthrie, and members of the Subcommittee. I appreciate this opportunity to testify on the United States Postal Service's efforts to combat opioids, including fentanyl, in both international and domestic mail.

My name is Gary Barksdale and I am Chief Postal Inspector for the U.S. Postal Inspection Service (Inspection Service), the law enforcement, crime prevention, and security arm of the United States Postal Service (Postal Service). In this role, I oversee all operations of the Inspection Service, including national headquarters, 17 field divisions, two service centers and a national forensic laboratory. These installations are staffed by over 1,200 postal inspectors, more than 550 postal police officers and nearly 600 support personnel. I am also the chairman of the Universal Postal Union's (UPU) Postal Security Group, which provides training, support materials and assistance to foreign posts; and spearheaded the development of standardized security guidelines.

Prior to my appointment to Chief in March of this year, I served three years as Deputy Chief Inspector at national headquarters and was responsible for several of the Inspection Service's functional areas: Criminal Investigations; Communications, Governance and Strategy; Security; and Contraband Interdiction and Investigations. I began my law enforcement career as a police officer in Chesapeake, Virginia, and was appointed as a Postal Inspector in 1999. I have served in our Los Angeles, Houston, and Phoenix Divisions, and throughout my law enforcement career, have conducted numerous criminal investigations of narcotics, identity theft, mail theft, robbery and assaults.

As detailed throughout my testimony, winning the battle against illicit drugs in the mail stream is a top priority for the Postal Service and the Inspection Service. Postal Inspectors work not only to remove drugs from the mail, but to investigate and arrest individuals and disrupt drug trafficking networks across the U.S. Internationally, the Inspection Service is working aggressively to stem the flow of illegal drugs entering the United States, as well as improving detection through advancements in the collection and receipt of customs advance electronic data (AED) as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. These efforts include working aggressively with other law enforcement agencies and key trade partners to stem the flow of illegal drugs entering the United States.

The Inspection Service works in collaboration with federal agencies and state and local law enforcement to implement improved investigative techniques that significantly increase our ability to intercept dangerous opioids. From fiscal year (FY) 2016 through 2018, we achieved a 1,000 percent increase in international synthetic opioid parcel seizures and a 750 percent increase in

domestic parcel seizures related to opioids. These efforts and partnerships will be detailed throughout my testimony.

#### **Contraband Interdiction & Investigations**

Battling synthetic opioids in the U.S. Mail is one of our highest priorities. To that end, nearly two years ago, we created an internal team of cross-functional subject matter experts specifically focused on narcotics trafficking through the mail, both international and domestic. We did so in recognition that the opioid crisis demanded a law enforcement response separate from our traditional criminal investigations group. The Contraband Interdiction and Investigations (CI2) team uses enhanced investigative methods, deploys resources as needed, and strengthens strategic partnerships to achieve significant improvements in our ability to seize fentanyl and synthetic opioids from the U.S. Mail. In addition to other actions, the Inspection Service, through our CI2 team, has developed and nurtured strategic partnerships, conducted investigations using cyber and analytic capabilities and invested in advanced technology.

#### ***Strategic Partnerships***

The Inspection Service investigates mail-related crime and works closely with other law enforcement agencies to share intelligence, coordinate cases and conduct joint enforcement operations to maximize our resources and impact. Relationships with partners such as the Drug Enforcement Administration (DEA), Homeland Security Investigations (HSI), U.S. Customs and Border Protection (CBP), the Federal Bureau of Investigation (FBI), the Department of Justice (DOJ), and the U.S. Food and Drug Administration (FDA) allow the Inspection Service to better advance its mission to enforce the laws that defend the nation's mail.

Inspection Service personnel are assigned full-time at the White House's Office of National Drug Control Policy (ONDCP), the DEA's Special Operations Division (SOD), the Organized Crime Drug Enforcement Task Force (OCDETF) Fusion Center, and CBP's National Targeting Center (NTC). Internationally, a Postal Inspector is now detailed at Europol in The Hague. The Inspection Service is also part of the Joint Criminal Opioid Darknet Enforcement (J-CODE) team, a DOJ sponsored initiative that seeks to combat online opioid trafficking. On a monthly basis, the Inspection Service and other federal agencies meet to share intelligence and strategies through the Heroin Availability Reduction Plan (HARP), which includes fentanyl.

The NTC and Inspection Service work to target incoming international parcels containing drugs based on intelligence and analytics. The Inspection Service identifies the International Service Center (ISC) where the parcel will be processed, and this and other relevant information is shared with CBP to locate the parcel. Once located, Postal Inspectors coordinate with their federal and state partners for investigative attention as appropriate. This program is now in place at all five ISCs (New York, Miami, Chicago, San Francisco, and Los Angeles).

We also work with state and local law enforcement to share intelligence and conduct joint operations, including several Inspection Service sponsored task forces. The Inspection Service partners with High Intensity Drug Trafficking Areas (HIDTA) and other state and local task forces across the country to coordinate investigations. These relationships facilitate communication and data sharing that enable the identification of drug trafficking organizations, which would not be possible without interagency cooperation.

### ***Analytics and the Dark Web***

The Inspection Service launched a Cyber and Analytics Unit to enhance investigative techniques and analytics to better utilize data to target both international and domestic parcels. Due to many illicit dark web vendors relying on physical delivery networks for their products, the Inspection Service is involved with dark web investigations into vendors and the takedown of their illicit marketplaces. The goal of the cybercrime program is to remove contraband, including narcotics, from the U.S. Mail and to disrupt and dismantle the underground marketplaces.

Our Cyber and Analytics Unit uses past and current data from a variety of sources, including CBP seizure data, to improve our investigative efforts and develop leads. The Cyber and Analytics Unit uses a variety of sources to detect synthetic opioids within the U.S. Mail through the use of statistics, data modeling, analysis, investigation and intelligence.

### ***Technology***

#### **Tru-Narc®**

Quickly and safely identifying unknown and potentially dangerous substances such as fentanyl is a top priority for the Inspection Service. To protect our field inspectors and deliver reliable results, we have invested in TruNarc® handheld narcotic analyzers. TruNarc® devices enable our inspectors to scan more than 450 suspected controlled substances in a single, definitive test. This technology reduces the risk of accidental exposure by our inspectors, Postal Service employees and laboratory personnel.

#### **Opioid Detection Challenge**

As part of the comprehensive government effort to address the opioid crisis, the Inspection Service has joined the Department of Homeland Security (DHS) Science and Technology Directorate (S&T), CBP, and the ONDCP in seeking new tools and technologies to detect opioids in parcels without disrupting processing at the ISCs and express consignment facilities. The Opioid Detection Challenge is a \$1.55 million global prize competition for rapid, nonintrusive detection tools that will help find illicit opioids in international mail. Eight finalists have been chosen from among 83 submissions from U.S. and international innovators to develop prototypes during the next phase of the challenge, which is expected to conclude with live testing of the technology this summer. A winner is expected to be selected in the fall.

### **Seizures**

Postal Inspectors interdict and seize thousands of illegal drug shipments in the mail. Thus far in FY 2019, we have seized 185 synthetic opioid parcels, 153 of which were in the domestic mail stream. We have also seized 363 parcels containing heroin, 961 containing cocaine and 1,237 containing methamphetamines. Our current synthetic opioid and fentanyl seizure statistics represent a decrease in international seizures related to synthetic opioids and fentanyl, while domestic seizures are trending up. This shift may suggest synthetic opioids are increasingly entering the country through means other than international mail before being distributed through the domestic Postal Service network, the express consignment carriers, or traditional drug distribution networks. The Inspection Service will continue to work to interdict and seize any illicit

substance in the mail stream and to arrest those who abuse the U.S. mail system, whether originating internationally or domestically.

#### **Improvements in AED Performance and CBP Capture Rates**

In 2018, Congress enacted the *Synthetics Trafficking and Overdose Prevention (STOP) Act* as part of the comprehensive *SUPPORT Act*. That legislation required the Postal Service to receive AED on at least 70 percent of aggregate inbound package shipments, including 100 percent of shipments from the People's Republic of China, by December 31, 2018, and on 100 percent of all inbound international shipments by December 31, 2020. AED includes the sender's full name and address (including full business name), the recipient's full name and address, the stated content description, unit of measure, and the quantity, weight, value, and date of the mailing.

In addition to its efforts to reach these AED thresholds, the Postal Service has prioritized capturing 100 percent of CBP hold requests as part of its strategy to combat illicit drugs in the mail.

#### **Secure AED on 100 Percent of Inbound Shipments**

The volume of inbound packages with AED has improved from 26 percent in October 2017 to approximately 60 percent in May 2019. The Postal Service has specifically targeted efforts to increase AED on inbound shipments from the People's Republic of China, where the volume of packages with AED has increased from 32 percent in October 2017 to approximately 85 percent in May 2019. This represents a significant improvement within a relatively limited period of time.

To work towards obtaining AED on 100 percent of inbound package shipments, the Postal Service continues to collaborate with foreign postal operators (FPOs) through the use of data-sharing arrangements and capacity-building efforts both bilaterally and as part of existing UPU technical development outreach efforts. The Postal Service requires AED as a condition of providing bilaterally negotiated package rates and has prioritized obtaining AED from the largest volume FPOs, which collectively account for more than 90 percent of all inbound volume. The Postmaster General sends monthly letters to top volume FPOs that reflect their recent AED performance and requests an update regarding their current efforts and timelines. The most significant hurdle to obtaining AED is that the Postal Service does not control the provision of AED from FPOs. Ultimately, it is necessary for the FPOs to provide the data.

The Postal Service also continues to emphasize the importance of AED in its multilateral relationships by working closely with organizations that support international postal operations, such as the UPU, the International Postal Corporation, and the Kahala Posts Group, to improve international data quality and to facilitate the transmission of the data.

With the support of the United States, new binding UPU Convention Regulations were approved at the April 2019 session of the Postal Operations Council, the UPU body responsible for technical and operational matters. These regulations will require, rather than recommend, transmittal of AED on parcels and small packages exchanged among FPOs. The regulations become effective on January 1, 2021, consistent with the statutory requirement for 100 percent AED on all inbound international shipments received after December 31, 2020.

### ***Capture 100 Percent of CBP Hold Requests***

Over the past several years, the Postal Service and Inspection Service have significantly improved coordination with CBP and developed processes to ensure we take action on CBP requests to hold packages for inspection. The Postal Service has made significant strides in the capture of CBP hold requests, reaching a 93 percent success rate. The Postal Service will continue to focus on this initiative until 100 percent of hold requests are captured. The Postal Service developed and deployed technologies to improve interception capabilities at its ISCs, in processing facilities that typically handle international volume, and, most recently, at more than 30,000 delivery units. This allows the Postal Service to act on hold requests at different points throughout its network. As the Postal Service continues to advance mail sorting technology, these successes will grow.

### **Employee Prevention and Safety Programs**

Employee safety has always been a top priority for the Postal Service. The organization is continuing that focus by reinforcing employee safety programs, engaging in comprehensive awareness campaigns that include training and safety protocols and deploying communications to all Postal Service employees.

In addition to training and awareness campaigns, the Postal Service has also taken extra steps to protect employees from accidental exposure to opioids in the mail by deploying naloxone (brand name Narcan®) nasal spray as an emergency first response measure at key facilities across the nation, including mail processing plants, national distribution centers, ISCs, Post Offices and specific customer service locations.

To complement the Postal Service's efforts, the Inspection Service has developed formal guidelines for Inspection Service employees handling fentanyl that are consistent with the policies and practices of the DEA, ONDCP and the Center for Disease Control and Prevention (CDC). The Inspection Service also developed and distributed a reference aid entitled "Fentanyl and Fentanyl Compounds: Special Considerations and Best Practices for Safely Handling Controlled Substances."

### **Conclusion**

The Postal Service takes seriously its mission to protect the security and sanctity of the U.S. Mail. Throughout every level of the organization, winning the battle against illicit drugs in the mail stream is a top priority. As the Postal Service carries out its mandate to bind the nation together through its universal service obligation, it will continue to work aggressively to address this crisis.

As it has done throughout its history, the Postal Service is committed to taking all necessary actions to combat criminal use of the mail as it continues to provide reliable and efficient service to the American public.

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Ms. DEGETTE. Thank you, Mr. Barksdale.  
Mr. Prince, you're now recognized for five minutes.

#### STATEMENT OF DAVID A. PRINCE

Mr. PRINCE. Chairwoman DeGette, Ranking Member Guthrie, and distinguished members of the subcommittee, thank you for the opportunity to appear before you to discuss my agency's efforts in attacking the national opioid crisis impacting our communities.

Homeland Security investigations is the department's primary criminal investigative agency and is focussed on disrupting and dismantling transnational criminal organizations.

As the sole investigative agency with combined customs and immigration authorities, HSI investigates and enforces more than 400 federal criminal statutes that protect our nation's trade, travel, financial, and immigration systems.

Today, I would like to speak about our successful efforts in combatting the flow of illicit fentanyl into the United States. In fiscal year 2018, HSI initiated 1,393 opioid related criminal investigations, executed 5,262 opioid related criminal arrests, and seized a total of 9,928 opioid—pounds of opioids, which consisted of 2,737 pounds of fentanyl and 7,103 pounds of heroin.

Our 2019 fiscal year statistics are set to exceed 2018 statistics in these areas. HSI has collaborated with Chinese authorities to address the China-sourced fentanyl threat through investigative information sharing. As of May 1st, 2019, Chinese authorities passed legislation making all fentanyl illegal.

However, it is still—it still remains a threat. We are now urging general administration of China customs and China postal services to secure its mail and express consignment industry.

Through our transnational criminal investigative units in Mexico, HSI works to disrupt Mexico-based opioid TCOs. TCIUs are multi-discipline units comprised of foreign law enforcement officials who ensure that shared information and operational activities are collaborated upon without compromise.

HSI's customs authorities extend to the virtual border of the open internet and the dark net. HSI's Cyber Crime Center, known as C3, provides support and assistance to global cyber investigations targeting illicit marketplaces where fentanyl and opioid sales proliferate.

Today, HSI has more than 700 open cyber crime investigations and more than 200 investigations specifically targeting criminal dark net organizations.

Many of these investigations focus on illicit opioid suppliers. HSI is at the forefront of cyber investigations and has been successful in developing methods to track and trace digital crypto currency, often used as a payment system for online opioid transactions.

In fiscal year 2018, HSI delivered its online international opioid smuggling training course to more than 4,000 local, state, federal, and international law enforcement partners.

This course provides law enforcement with the technical knowledge and in-depth case briefings to assist criminal investigations involving the dark net and crypto currency-related crimes.

The Border Enforcement Security Task Force, known as BEST, utilizes local, state, and federal agencies at land border sea port, international airport, and mail facility locations to target TCOs.

There are currently 65 BEST teams across the United States and we have increased our presence at international mail facilities and express consignment carrier to include JFK, LAX, Memphis, and Louisville.

We have also established BEST teams in areas hardest hit by the opioid epidemic such as Ohio and West Virginia. In fiscal year 2018, BEST Memphis initiated 204 narcotic control deliveries, executed 46 criminal arrests. It effected 149 seizures.

BEST Cleveland has initiated Operation Darkness Falls to target top dark net vendors. Darkness Falls has led to the disruption and dismantlement of large-scale opioid vendors to include the largest identified fentanyl vendor with the most verified transactions.

The National Targeting Center Investigations—NTCI—partners with CBP and Postal Inspection Service to interdict illicit opioids entering the United States.

Recently, NTCI assisted in an investigation where 171 pounds of fentanyl was seized from a New Jersey-based TCO involved in the importation of opioids.

To date, this investigation is one of the largest domestic seizures of fentanyl from China. HSI seeks to identify, disrupt, and dismantle criminal financial networks and leverages a multitude of investigative techniques to target money service businesses, all cash smuggling, and crypto currency.

In fiscal year 2019 thus far, HSI seized nearly \$1.9 million in fentanyl-related digital currency and has over 268 open investigations involving the illicit use of crypto currency.

I am grateful for the opportunity to appear before you to share HSI's efforts to combat the opioid epidemic. We will continue our commitment to maximize our full complement of authorities.

I thank you for the support that you provide to HSI as we execute our mission and I look forward to any questions you have.

[The prepared statement of Mr. Prince follows:]



# U.S. Immigration and Customs Enforcement

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STATEMENT

OF

DAVID A. PRINCE

DEPUTY ASSISTANT DIRECTOR  
TRANSNATIONAL ORGANIZED CRIME – I  
HOMELAND SECURITY INVESTIGATIONS

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

REGARDING A HEARING ON

*“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”*

BEFORE THE

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

Tuesday, July 16, 2019  
10:00 a.m.  
2123 Rayburn House Office Building



### Introduction

Chairwoman DeGette, Ranking Member Guthrie, and distinguished members of the Subcommittee:

Thank you for the opportunity to appear before you today to discuss the opioid epidemic, the proliferation of illicit fentanyl in the United States, and U.S. Immigration and Customs Enforcement's (ICE) Homeland Security Investigations' (HSI) strategy to combat this public safety issue through investigative and enforcement methods. HSI is the U.S. Department of Homeland Security's (DHS) primary criminal investigative agency, focused on disrupting and dismantling Transnational Criminal Organizations (TCOs) that exploit the nation's trade, travel, financial, and immigration systems. As the sole investigative agency with combined customs and immigration authorities, HSI investigates violations of and enforces more than 400 federal criminal statutes, including 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).

Today, I would like to speak on our successful efforts to combat the flow of illicit fentanyl into the United States. During our 2018 fiscal year, HSI initiated 1,393 opioid-related criminal investigations, executed 5,262 opioid-related criminal arrests, and seized a total of 9,928 pounds of opioids, which consisted of 2,737 pounds of fentanyl and 7,103 pounds of heroin. In the current fiscal year, HSI has nearly doubled the number of arrests and will significantly exceed the number of pounds of fentanyl seized from 2018.

In an effort to effect maximum impact on the Chinese fentanyl threat to the United States, HSI has implemented a proactive approach with Chinese authorities to align the priorities of the Government of China with those of the United States. This collaborative effort is shaped by information sharing, such as of certified lab reports and shipping labels that surround illicit fentanyl and opioids parcels and exports. These successful efforts led China to add 32 new substances to its controlled substances list, effective September 1, 2018. In addition, on May 1, 2019, Chinese authorities passed legislation making all fentanyl and fentanyl analogues illegal. Since that time, HSI has increased its focus on urging China to secure its mail and express consignment industry, and has found fewer Chinese vendors willing to sell/export fentanyl products. HSI, alongside Department of Justice components, Customs and Border Protection (CBP), and US Postal Inspection Service (USPIS), are working with the General Administration of China Customs and China Postal Service to strengthen cooperation in addressing the shipment of illicit fentanyl and fentanyl analogues via mail.

HSI also holds a key position in the U.S. Embassy heroin and fentanyl working group in Mexico. This group consists of numerous members of the U.S. Embassy country team, and meets bi-weekly to discuss key smuggling trends and coordinate investigative efforts. Mexican TCOs are a major supplier of illicit fentanyl and fentanyl-related substances to the United States, using established smuggling routes and network systems along the Southwest Border and throughout the country. Fentanyl seized along the border can be attributed to cartels in Mexico and has been seized in pill and powder form. Mexico-sourced powdered fentanyl is often diluted before bundled in kilogram quantities, with 10 percent purity rates; and, when discovered in the

interior of the United States, is often being poly-smuggled with other narcotics, such as heroin and cocaine.

Through its Transnational Criminal Investigative Unit (TCIU), HSI works to identify and disrupt Mexico-based TCOs that manufacture and smuggle fentanyl through information sharing. TCIUs are multi-discipline units comprised of foreign law enforcement and prosecutors, customs, immigration, and intelligence officials who are vetted to ensure that shared information and operational activities are not compromised. The purpose of the TCIU is to enhance cooperation between HSI and partner nations in international investigations. HSI currently has 16 TCIUs throughout the world and is working to identify other fentanyl-source-countries through its international partnerships. In Mexico, the TCIU is located within the investigative arm of Mexico's Prosectuor General's Office, Fiscalia General de la Republica (FGR), and is further expanding to incorporate state police agencies.

The HSI Cyber Crimes Center (C3) provides support and assistance to worldwide cyber investigations targeting DarkNet illicit marketplaces, where fentanyl and opioids sales proliferate. Today, HSI has more than 700 open cybercrime investigations, and more than 200 investigations specifically targeting DarkNet illicit organizations. During the 2018 fiscal year, HSI delivered cyber training in over 25 locations worldwide to more than 5,000 state, local, federal, and international law enforcement personnel in online opioid smuggling tactics.

The Border Enforcement Security Task Force (BEST) Program is the investigative platform to carry out HSI's comprehensive, multi-layered strategy to combat TCOs involved in smuggling activity through their long-established networks and smuggling routes. BEST utilizes the "whole of government" approach as its foundation and BEST teams are strategically positioned in key land border locations, seaports, international airports and mail facilities. As of June 2019, there are 65 sanctioned BEST teams across the United States which are comprised of 2,479 task force officers.

HSI has increased its presence at international mail facilities (IMFs) and express consignment carriers (ECCs) by establishing BEST teams at IMFs within JFK and LAX, at ECCs in Memphis, Northern Kentucky, and Louisville; and, in areas hardest hit by the opioid epidemic, including Ohio, Kentucky, and West Virginia. The aforementioned expansion was in direct response to the opioid crisis and modeled after the successful BEST Memphis that was established at an ECC to specifically target daily opioid shipments. With the support of the Organized Crime Drug Enforcement Task Forces (OCDETF), BEST Memphis is maximizing fentanyl interdictions and opportunities for investigative follow-up. During the 2018 fiscal year, BEST Memphis, in collaboration with foreign and domestic law enforcement partners, initiated 204 controlled deliveries resulting in 46 criminal arrests and an additional 149 narcotics-related seizures.

Following cyber training and BEST designation, HSI Cleveland, in partnership with CBP and USPIS, initiated Operation Darkness Falls, which targets the top DarkNet Vendors (DNVs) on the Darknet Market Places. Operation Darkness Falls has led to the disruption and dismantlement of large scale DNVs, including the largest identified DNV fentanyl vendor with the most verified Darknet fentanyl transactions, MH4Life.

HSI special agents assigned to the National Targeting Center-Investigations (NTC-I) work collaboratively with partners from CBP and USPIS utilizing a myriad of intelligence, interdiction, and investigative resources to identify and interdict illicit fentanyl and opioids entering and transiting the United States. Recently, these efforts have pivoted to also include the targeting of precursor and analogue shipments between the Asian markets and Mexico. Requests for assistance from HSI offices and law enforcement partners to NTC-I have doubled over the last year.

Recently, NTC-I assisted in an investigation in which a combined total of 77.6 kilograms of fentanyl was seized during enforcement actions targeting a New Jersey-based organization involved in the importation of fentanyl from China. To date, this investigation accounts for one of the largest domestic seizures of fentanyl from China. NTC-I, in partnership with HSI Mexico City and the U.S. Drug Enforcement Administration (DEA), has also developed a precursor targeting initiative that leverages all interagency partners' equities in the targeting of fentanyl precursor shipments to Mexico.

HSI adheres to a philosophy that there is a financial component to every criminal investigation, and that illicit finance encompasses so much more than traditional fiat currency transactions. Through a value-transfer approach, HSI maintains a robust and multi-faceted financial investigative portfolio which seeks to identify, deny, disrupt and dismantle financial networks associated with criminal acts. HSI utilizes traditional investigative methods such as surveillance, undercover operations, and confidential informants, coupled with advanced forensic analysis of financial records, the block-chain, and seized electronics such as computers and phones.

HSI's financial investigative efforts generally focus on the two key payment systems which support illicit procurement of opioids: money services businesses (MSBs) and cryptocurrencies. Generally, illicit opioids that are purchased on the "indexed" or "clear net" internet are paid for through licensed mainstream MSBs. In this current fiscal year, HSI has seized nearly \$1.9 million in fentanyl-related digital currency and has over 268 open investigations involving the illicit use of cryptocurrency.

### **Conclusion**

I wish to express my gratitude for the opportunity to appear before you and to share our agency's complex strategy to combat the opioid epidemic. I thank you for the support you provide to HSI and its vast law enforcement mission. HSI will continue its steadfast commitment to maximize its full complement of authorities to battle the U.S. opioid epidemic with the cooperation of law enforcement stakeholders, and experts in the scientific, medical, and public health communities.

Ms. DEGETTE. Thank you so much, Mr. Prince.  
And Ms. Cave, you are now recognized for five minutes.

#### STATEMENT OF CAROL CAVE

Ms. CAVE. Good morning, Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee.

Thank you for the opportunity to be here today to discuss the Food and Drug Administration's role in combatting our nation's ongoing crisis of opioid addiction, specifically regarding fentanyl.

I am Carol Cave, the director of the Office of Enforcement and Import Operations within FDA's Office of Regulatory Affairs.

FDA, along with our partner government agencies, continue to work together to consider more active and creative steps to make inroads against this crisis.

I am pleased to be here today to discuss the work we are doing at our nation's borders and at the international mail facilities, or IMFs.

FDA plays an important role related to the interdiction work that takes place in IMFs and has acted to enhance our operations there. In the international mail environment, Customs and Border Protection is the leading interdicting authority for controlled substances including fentanyl and other opioids.

As such, they examine before FDA and generally will act against these types of shipments without forwarding for FDA for review. FDA is focusing on inspecting and sometimes testing products that may be counterfeit or unapproved drug products.

Last year, Congress gave FDA more tools to intercept illicit drugs coming through our nation's IMFs by enacting the SUPPORT Act. On behalf of FDA, I would like to thank the members of this committee for your work on these important authorities.

The SUPPORT Act, specifically Section 3022(d), gives the FDA new authority to treat imported articles as drugs when they meet certain requirements, even in the absence of certain evidence of intended use.

This allows FDA to apply its existing authorities to appropriately detain, refuse, and administratively destroy these subject articles.

The implementation of this section, which began in March of this year, has been an unquestioned success. For articles determined to be under the 801(u) product specifically our destruction rate is, roughly, 99 percent, thus eliminating distribution of these products into the hands of consumers.

Additionally, on April 4th of 2019, FDA and CBP leaders signed a letter of intent that addresses the areas of cooperation outlined in Section 3014 of the SUPPORT Act, including information sharing, operational coordination for better targeting of high-risk parcels, and collaborative strategies. FDA and CBP have actively been exploring ways to enhance collaboration and increased efficiency of operations by sharing existing but limited space.

As FDA is able to increase the amount of space allocated to its activities in the IMS, FDA can further add staff, enabling the agency to expand its admissibility review of drugs shipped into the U.S. international mail parcels.

The letter of intent also addresses FDA's and CBP's commitment to establish, expand its scientific presence at the IMS considered

most of risk of receiving opioids and other illegal or dangerous drugs entering the United States.

FDA and CBP are looking at ways to develop and refine laboratory-based methods to identify unapproved, counterfeit, and other unlawful controlled substances.

The division of import operations managers have met several times with their counterparts at CBP and U.S. Postal Service to assess how our respective systems can be utilized to share data and information on actions taken by the agencies on individual parcels and commodities.

All three agencies are considering the most appropriate and efficient means of using existing data streams to share IMS specific data and investigational outcomes.

We remain committed to using our regulatory authority to the fullest extent to address the opioid crisis including new authorities granted by FDA—granted to FDA by the SUPPORT Act.

Thank you for the opportunity to testify today and I look forward to answering your questions.

[The prepared statement of Ms. Cave follows:]



**TESTIMONY**  
**OF**  
**CAROL CAVE**  
**DIRECTOR, OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS**  
**OFFICE OF REGULATORY AFFAIRS**  
**FOOD AND DRUG ADMINISTRATION**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
  
**BEFORE THE**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**  
**UNITED STATES HOUSE OF REPRESENTATIVES**

**“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

**July 16, 2019**

**RELEASE ONLY UPON DELIVERY**

## Introduction

Good morning, Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) role in combating our Nation's ongoing crisis of opioid addiction, specifically regarding fentanyl. I am Carol Cave, Director of the Office of Enforcement and Import Operations (OEIO) within FDA's Office of Regulatory Affairs (ORA). OEIO provides direction, assistance, management and oversight of field import operations, including investigational and compliance activities; and serves as the Agency focal point for headquarters/field relationships on all import programs, operations, and problems. OEIO staff monitor more than 43 million import lines<sup>1</sup> in a given year, including medical devices, drugs and biologics, human and animal foods, cosmetics and tobacco products. OEIO coordinates agency import activities with U.S. Customs and Border Protection (CBP), including the development and institution of joint regulations, procedures, policies, and operations; and coordinates activities with other Federal agencies and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships.

As FDA has stated, and I am sure we all agree, this is one of the most profound public health challenges facing our country. FDA along with our partner government agencies continue to work together, to consider more active and creative steps to make inroads against this crisis. We must continue to be vigilant in our efforts to identify and stop unlawful drugs like illicit fentanyl from entering the United States, and as such, I am pleased to be here today to discuss the work we are doing at our Nation's borders and at the International Mail Facilities (IMF).

## How controlled substances are managed at the border

In the commercial environment, CBP is the initial regulatory authority over all imported products and shipments are accompanied by formal entry declarations. For pharmaceutical products, including controlled substances like fentanyl, CBP evaluates these entry declarations and routes entries to the appropriate partner government agency for review. Controlled substances falling directly within the purview of the U.S. Drug Enforcement Administration (DEA) will be processed accordingly by CBP. Controlled substances that are also FDA-regulated drugs (i.e. approved pharmaceuticals or investigational use drugs) will be routed to FDA to determine admissibility: 1) FDA-regulated drugs must come from firms registered with FDA, 2) those firms must include the drugs they intend to market in the U.S. in a list provided to FDA, 3) new drugs must be approved by FDA, and 4) the entry declarations must reflect a supply chain identified in that approval (i.e. the product must be coming from and destined to firms indicated as part of the

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<sup>1</sup> An import line is a distinct product within a shipment. A single shipment may include multiple lines.

drug's manufacturing process). If any of these requirements are not met, the drug will be refused admission into the U.S.

In the international mail environment, CBP is the lead interdicting authority for controlled substances, including fentanyl and other opioids. As such, they examine before FDA and generally will act against these types of shipments without forwarding for FDA review. These types of shipments do not fit the business-to-business supply chain pattern that the Agency typically notes for legitimate shipments of drug components.

It is our experience that legitimate commercial shipments of drug products enter the country via conventional means; air, rail, ship, and express consignment can all be part of a legitimate supply chain. However, FDA does not consider informal entry through international mail to be a method that sponsors of legitimate pharmaceutical products commonly use. So far in FY 2019, we have found 99.1% of the drug products entered the U.S. through international mail to be non-compliant.

FDA plays an important role related to the interdiction work that takes place in IMFs and has acted to enhance our operations there. When an illegal controlled substance is identified at an IMF, our partners at CBP will immediately seize it, and it will therefore not come to FDA investigators in these facilities. Instead, FDA is focused on inspecting, and sometimes testing, products that may be FDA-regulated drug products that violate the Food, Drug, and Cosmetic Act; for example, if they appear to be counterfeit or unapproved drug products.

While we examine what initially are believed to be non-opioid drug products, we still identify a large amount of controlled substances, in some cases because they are disguised as other types of drug products. From October 2018 through May 2019, FDA staff at the IMFs processed nearly 17,204 suspicious packages containing 28,356 products that FDA was tasked with inspecting because they were suspected of containing illegal prescription or counterfeit drugs or dietary supplements.

#### **SUPPORT Act and FDA/CBP Letter of Intent**

Last year, Congress gave FDA more tools to intercept illicit drugs coming through our Nation's IMFs by enacting the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). On behalf of FDA, I would like to thank the members of this Committee for your work on these important authorities. It calls for strengthening coordination and capacity between FDA and CBP on activities designed to improve detection and response to illegal controlled substances and drug imports, particularly those imported through the nine IMFs throughout the country. Section 3014 provides that these collaborative activities may be set forth in a memorandum of understanding between FDA and CBP and should include infrastructure and resource enhancements to increase inspection capacity at IMF locations while ensuring employee safety.



On April 4, 2019, FDA and CBP leaders signed a Letter of Intent that addresses the areas of cooperation outlined in Section 3014, including information sharing, operational coordination for better targeting of higher risk parcels, and collaborative strategies more specific to each agency's respective regulatory enforcement requirements. FDA and CBP have been actively working to expand the scientific presence at IMFs where most appropriate and to explore ways to enhance collaboration and increase efficiency of operations by sharing existing, limited space.

Section 3022(d) of the SUPPORT Act gives FDA new authority to treat imported articles as drugs when they meet certain requirements, even in the absence of certain evidence of intended use. This authority, codified as section 801(u) of the Federal Food, Drug, and Cosmetic Act, applies to articles that are "ingredients that present significant public health concern," and that are, or contain, either 1) active pharmaceutical ingredients (APIs) in a drug or biologic approved or licensed for marketing or for investigational use; or 2) an analog of that API. Furthermore, the article must not be accompanied by an electronic import entry submitted using an authorized electronic data interchange system and not be designated in such system as an article that is FDA-regulated (in other words, the import entry is not a commercial entry that is filed in the Automated Commercial Environment (ACE)). This means any imported product entering the U.S. via international mail that meets the requirements of section 801(u) is considered a drug under FDA jurisdiction. This allows FDA to apply its existing authorities to appropriately detain, refuse, and/or administratively destroy these subject articles.

Between March 4, 2019, when 801(u) implementation began, and the end of May 2019, FDA staff in the IMFs processed 7,011 parcels containing 11,295 products. Of those 11,295 products, we have applied our new 801(u) authority to 4,017 drug products (35.6% of the overall products encountered; and 39.8% of the drug products encountered). Of the 4,017 drug products on which we have used our 801(u) authority, 2,639 have been refused admission into the U.S. and will be destroyed; another 1,176 have been detained and identified for destruction, if refused. As of the end of June, an additional 185 drug products are still going through our admissibility process. For those drug products without a final admissibility decision, a final decision will be made based on additional review and follow-up.

The implementation of 801(u) is an unquestioned success: in FY2018 we destroyed approximately 5% of refused drug products; in FY2019 pre-801(u) implementation that number was about 16%. Since 801(u) implementation (through May 2019), we have raised our overall destruction rate to 35%; for 801(u) products specifically, our destruction rate is roughly 99%. FDA continues to identify additional APIs amenable to 801(u).

#### **Office of Criminal Investigations**

My office works closely with ORA's Office of Criminal Investigations (OCI). OCI's Special Agents work with other federal law enforcement agencies in a combined effort to disrupt and dismantle criminal organizations that threaten public health through the manufacture and sale of unlawful FDA-regulated products, including drug products containing illicit fentanyl. OCI

focuses their investigative efforts involving imported fentanyl specifically to drug counterfeiting operations to ensure case work is not duplicated and resources are properly managed. Many of OCI's investigations concerning fentanyl involve raw materials or tooling originally manufactured in other countries, such as China, and shipped to the United States via internet sales.

FDA's intelligence obtained through criminal investigations, data from import and regulatory inspections, and open source information shows that many Chinese-based manufacturing operations not only lack sufficient controls for drug products, but also produce and export a variety of synthetic opioids. Some of these manufacturers also synthesize new substances that produce effects similar to opioids with pre-market analytical reference names, such as Am-2201, Jwh-018, and U-47700. In addition, many counterfeit drugs sold online that appear to be FDA-approved medications, such as Oxycontin (oxycodone), Xanax (alprazolam), Vicodin (hydrocodone), or Percocet (oxycodone), may contain fentanyl or fentanyl analogs. OCI has investigated several such cases.

FDA continues to work with foreign authorities to combat the illicit manufacture of drugs. When actionable criminal information or intelligence is obtained, OCI works jointly with foreign and domestic law enforcement partners to identify and dismantle the source of supply. OCI has developed relationships with our law enforcement partners in India and the United Kingdom, for example, to work joint operations targeting illicit FDA-regulated products, including those that have been adulterated to contain fentanyl, intended for distribution in the United States.

OCI's Import Operations Program Special Agents are assigned to IMFs and directly coordinate investigative leads generated by the inspectional activities of FDA. These agents work closely with other Federal partners such as DEA, CBP, U.S. Immigration and Customs Enforcement, and the U.S. Postal Inspection Service to investigate the source and destination of parcels found to contain illegal FDA-regulated products as well as share valuable intelligence with our domestic and foreign law enforcement partners.

#### **Facility, equipment and information technology improvements**

Improvements and upgrades to facilities and resource enhancements to strengthen coordination and increase inspection capacity at IMFs are ongoing and have been accomplished to varying degrees across the nine IMFs throughout the country. As set forth in the Letter of Intent, FDA and CBP will be working through FY 2019 to improve the effectiveness and efficiency of their operations in the IMFs by continuing to share existing space and have submitted to the General Services Administration (GSA) space requests cooperatively, looking for co-location opportunities that meet each agencies' requirements.

FDA has assigned additional dedicated staff to coordinate space requirements and formal GSA space requests and has submitted these requests for seven of the nine IMFs. In many cases, onsite space is very limited and difficult to secure, and alternatives, such as the use of nearby sites and placement of office trailers and mobile laboratories on a temporary basis are being considered. Facility “build out” plans to improve capacity and efficiency of existing facilities are being developed while FDA and CBP await a final national GSA/U.S. Postal Service (USPS) common lease agreement. FDA is working collaboratively with GSA and USPS leadership towards reaching an agreement. The common lease agreement will dictate terms of GSA leases with USPS at the IMFs.

As FDA is able to increase the amount of space allocated to its activities in the IMFs, FDA can further add staff, enabling the Agency to expand its admissibility review of drugs shipped into the U.S. in international mail parcels.

FDA is committed to adding dedicated personnel to support increasing IMF workloads, particularly to help stop illegal opioids and other controlled substances from coming into the U.S., and to increase overall inspection capacity. As of July 1, 2019, ORA has hired more than half of the 125 full-time equivalents (FTEs) allocated to this purpose. This includes import review Consumer Safety Officers, OCI Special Agents, laboratory personnel, and support staff. ORA has developed a strategic hiring plan to maximize the ability to recruit and hire additional FTEs, and expects to have the remaining FTEs hired by December 2019.

The Letter of Intent also addresses FDA’s and CBP’s commitment to establish an expanded scientific presence at IMFs considered most at risk of receiving opioids and other illegal or dangerous drugs entering the United States. FDA and CBP are looking at ways to develop and refine laboratory-based methods to identify unapproved, counterfeit, and other unlawful controlled substances.

ORA’s Forensic Chemistry Center (FCC) is a rapid-response laboratory that performs laboratory research and analyses on a day-to-day basis, regularly providing expert technical support for OCI. The laboratory also provides forensic analyses for high profile samples collected within the rest of ORA and other Federal and State agencies. The FCC has evaluated field-deployable instruments in the IMFs, resulting in recommendations regarding toolkits for screening of counterfeit or unknown substances. The FCC continues to evaluate new field-deployable devices to assess applicability for use to detect additional substances. Efforts to develop laboratory-based methods to identify and quantify fentanyl, fentanyl analogs, and other natural, semi-synthetic, and synthetic opioids continues at the FCC. In addition, FDA/ORA Medical Products Laboratories are also standing up capabilities to identify and quantify selected opioids as well as other illegal/unapproved drugs in preparation for confirmation of field-based findings in pharmaceutical products.

FDA is currently expanding its use of field-deployable instruments to detect illegal drugs in mail parcels. Laboratory personnel hired in support of this work are expected to provide permanent scientific and technical coverage at selected IMFs, but finding space that would allow laboratory

analysts to work alongside FDA import review staff and OCI's Special Agents remains a challenge. Plans are underway that will provide permanent space for analytical equipment and laboratory analysts to conduct testing.

While plans for larger and more permanent space to detect and test for illegal drugs by FDA laboratory personnel are being developed, discussions with CBP to identify space at selected IMFs to place temporary or mobile laboratories are ongoing. Provided space agreements between GSA and USPS can be reached, the intention is to have these temporary labs in place and operational by the end of FY19. In addition, we are developing plans for the FCC building renovation to include expansion within its current facility. Additional FCC laboratory space is needed to house personnel and analytical tools required to support FDA's commitments at the IMFs and Ports of Entry.

ORA import managers have met several times with their counterparts at CBP and USPS to discuss each agency's operational processes and look at their respective data systems to assess how they can be utilized to share data and information on actions taken by the agencies on individual parcels and commodities. All three agencies are considering the most appropriate and efficient means of using existing data streams to share IMF-specific data and investigational outcomes. For years, agencies have been working to align with ACE, as this may be the most efficient way to provide access to agencies that need it.

FDA is also improving IT infrastructure within the IMFs to increase overall connectivity and speed. Historically, connectivity to FDA systems from within the IMFs has been limited; we are currently assessing several approaches to determine effectiveness in enhancing connectivity within the IMFs.

ORA's Office of Regulatory Science continues to work with the CBP Director of Laboratory and Scientific Services to plan for laboratory personnel from both agencies to have a greater presence and complementary tools to share real time data at IMFs. The agencies will share historical data to improve consistency in their decision making. This will include sharing analytical reference library information developed by each organization related to this work.

### **Conclusion**

We remain committed to using our regulatory authority to the fullest extent to address the opioid crisis, including using new authorities granted to FDA by the SUPPORT Act, and building on the important work I have outlined to change the trajectory of this crisis. As the committee continues to address this crisis, FDA looks to support where we can. Thank you for the opportunity to testify today, and I look forward to answering your questions.

Ms. DEGETTE. Thank you so much, Ms. Cave.

It's now time for Members to ask you questions and the Chair will recognize herself for five minutes.

Mr. Donahue, combatting fentanyl is challenging because, as we all know, it is cheap and easy to make. It has huge profits. It is hard to detect in shipments and it is deadly even in small amounts.

It's also increasingly mixed into other drugs, often without the user's knowledge, and so that leads to more overdoses.

Would you agree with me with that assessment of the challenge that we are facing?

Mr. DONAHUE. Yes, Congresswoman. I appreciate the question and it's not an easy one because with all the drugs and the fentanyl and the different types of drugs coming in from other countries we are required to have their cooperation and we actually investigate these cartels specifically here with the fentanyl coming in. We are concerned with China, sometimes India, sometimes Holland where the drugs are coming in—

Ms. DEGETTE. Right.

Mr. DONAHUE [continuing]. Directly to United States and/or to Mexico to produce it and send it up.

Ms. DEGETTE. But it's—because of all the things I said it's harder to make those identifications and so working with the other countries is even more important. Wouldn't that be fair?

Mr. DONAHUE. Extremely important, and with our panel members here as well working collectively on attacking the people who are actually producing the drugs and shipping the drugs and actually really the key is prosecutions.

Ms. DEGETTE. Right.

Mr. DONAHUE. We got to do something with the seizures that we make in the United States and bring it back to the source countries and gain their cooperation to attack the source of the drugs.

Ms. DEGETTE. To do it there.

Mr. Chester, your agency has been trying to coordinate drug control efforts for a long time. What are we doing to think outside the box in addressing the fentanyl threat that's different from what we've been doing with some of the previous illicit drug control strategies?

Mr. CHESTER. Thank you for the question, ma'am. I think we've done a couple of things. The first 1 is we have, through our inter-agency coordination and our work with the intelligence community and with partner nations, we are a generation ahead of where we were before in understanding the problem first, which I don't believe we had a good grasp on what the nature of the problem was and we didn't have an ability—

Ms. DEGETTE. When was that? When was that?

Mr. CHESTER. This was really about the 2014–2015 time frame, and so what this does is with this greater understanding we can—we can look beyond the immediate actions that we take and are better able to anticipate trafficker actions in switching to other synthetic opioids. I think that's the first thing.

And then I think the second thing is we look outside of the bounds of one particular class of drugs to things like nonsynthetic opioids and things of that nature, and our understanding has al-

lowed us to be able to be more—much more anticipatory than we have been in the past.

Ms. DEGETTE. Do you think that the agency cooperation has been different than it was before and if so, how?

Mr. CHESTER. Absolutely. I think the level of information sharing—the first one is in the mechanisms that we have put in place, and when I say ten times every single month all of the members of this—of this panel and the agencies and departments that they represent, we have mechanisms to share cooperations at all levels of classification.

The ability to coordinate and the ability not only to shape our own actions domestically but our approach with other countries as well much, much better than it has been in the past.

Ms. DEGETTE. Mr. Overacker, I would like to ask you, do you agree that the agencies are doing a better job of sharing data and working together than in the past?

Mr. OVERACKER. Yes, I believe so. My experience tells me that when we can link up, you know, investigators with operators we can do a better job of basically identifying targets and supporting, you know, investigations in the field.

This is something we've done at our national targeting center. It's been successful, and now with this fentanyl crisis we've really amped up our capabilities for that purpose.

Ms. DEGETTE. What is it that you're doing differently now? Obviously, we can all agree that coordination is great. But what is it that you're doing differently?

Mr. OVERACKER. Well, I wouldn't necessarily say it's different, just to say that I think what we've learned over the years is we have to be working on this daily.

It has to—you know, it's a collaboration and it really is something you have to work on every day and I think it's just—the level of collaboration we have for the fentanyl crisis is more than what we've seen for other issues in the past.

Ms. DEGETTE. And what can we do to help you do your job better? Is there something—is there a better way to share data across the agencies? Is there something that we can do to help?

Mr. OVERACKER. Well, you know, we certainly appreciate your support—your continued support for CBP. As far as data sharing, we do have, you know, data sharing arrangements with all of these agencies, and because we work collectively at our national targeting center we are able to share information in a sort of rapid real-time format.

Ms. DEGETTE. OK. Thank you.

I yield back and recognize Mr. Guthrie for five minutes.

Mr. GUTHRIE. Thank you very much, and I want to go down the panel with this question, and so be mindful I got to do that in five minutes and ask a couple of other questions, too. So, I am going to be brief.

So, I just want each of you to say your agencies in fentanyl, what is your biggest accomplishment the past two years—your agencies.

I know you have done a lot, but your biggest—and then what your biggest challenge is.

Mr. CHESTER. I would say that our biggest accomplishment is the publishing of the National Drug Control Strategy, which

contextualized everything the departments and agencies are doing in this particular regard for all drug issues, but in this 1 specifically.

I would say that our biggest challenge is the rapidity with which new substances appear in the United States either have crossed our borders or are detected in post-mortem toxicology testing.

That is—that is something that requires an enormous amount of effort.

Mr. GUTHRIE. Thank you.

Mr. Donahue?

Mr. DONAHUE. I would say one of our biggest accomplishment is actually scheduling—emergency scheduling all analogs of the fentanyl, which has really greatly helped DEA in our investigations. One of our biggest challenges is actually obtaining the evidence required to enter to the Grand Jury in the United States to target these cartels that are producing and trafficking in fentanyl in the court of law in the United States.

We recently established our Sensitive Investigative Units specifically for that reason to work with our counterparts to obtain evidence in the foreign countries to utilize back in the Grand Jury in the United States. But that's a very big accomplishment for us that we are going to use, going forward.

Mr. GUTHRIE. Thank you.

Mr. Overacker?

Mr. OVERACKER. From a CBP perspective, I would say one is our detection capabilities. We now have a fully staffed 24/7 laboratory in Springfield, Virginia, dedicated exclusively to fentanyl and we've also deployed detection equipment throughout CBP so we can identify fentanyl in a safe way.

I would also say that our collaboration with the U.S. Postal Inspection Service is another big success story for us as we increased our level of effort with them. And also just through our national targeting center the partners that we work with there and the coordination efforts, the sort of community of effort that we've established through the national targeting center is important.

Mr. GUTHRIE. Thank you.

Mr. Barksdale?

Mr. BARKSDALE. Thank you. I would say our biggest accomplishment, as Mr. Overacker has said, is our collaboration and data sharing, our embedded inspectors at the national targeting center and DEA's SOD. I've seen a difference in the type of cases we are making.

As far as challenges, I think our biggest challenge is also one of our biggest successes is although we've improved in our capability to attack the problem, internet sales is still a challenge, going forward.

As good as we are taking down one site, they will quickly stand up another site or a different marketplace so that will be a challenge, going forward.

Mr. GUTHRIE. Thank you.

Mr. Prince?

Mr. PRINCE. I would say some of our things that we can—we can definitely say we've accomplished is our development of the innovation lab, which is something we bring problem sets to to help us

expand our capability to deal with stuff like opioids and our expansion of the BEST initiative as well, particularly with our recent expansions, which we think are going to bear fruit.

You know, our block chain analysis as well in the crypto currency space is something that we are very proud of. We continue to make inroads in that and it helps us develop much more robust target packages on our complex conspiracy investigations.

Obviously, China is recalcitrant when it comes to a lot of these issues that we are dealing with that was part of our oral testimony, and I would say that's a challenge that we continue to deal with.

Mr. GUTHRIE. Thank you.

Ms. Cave?

Ms. CAVE. Good morning. I would say the number-one thing for the FDA is, clearly, the 801(u) authority that was given to us by the SUPPORT Act, which actually allows us to destroy product when it's coming in as opposed to refusing admission and exporting.

So thank you very much for that. In terms of challenge, I would say it's just in the international mail facilities in terms of the volume and the sheer volume that we are dealing with and the advanced—you know, lack of advanced data that comes in, for example, on addressing those issues.

Mr. GUTHRIE. A colleague of mine, a couple of them, have seen different targeting centers the thing you're talking about and just amazed at the effort that you guys are doing in working, and then second of all, and just also amazed at the volume you're dealing with.

So, we are mindful of that. I hope to see one of those as well.

Mr. Donahue, I just have less than a minute left. But the Wilson Center Mexico Institute reported that fentanyl is entering Mexico via the Ports of Manzanilla and Lazaro Cárdenas,—we say Cárdenas,, who's our colleague here—but Cárdenas,.

Do you agree with that finding and, if so, what level of cooperation is DEA getting from Mexico law enforcement authorities at these ports in taking and seizing fentanyl?

And when are their—I will go ahead and ask the second question—you may answer them together. In an interview with the Wilson Center Mexico Institute, Mexico federal forces said that they did not believe that fentanyl was a significant part of the Mexican drug traffickers' criminal portfolios.

In your opinion, what do you comment on that?

Mr. DONAHUE. They are both two big ports where we see enormous amount of precursor chemicals coming in, not just for fentanyl but for methamphetamine and for production of heroin as well.

We are seeing chemicals coming in through the airports as well from China in various forms. We are working with OFAC as well to take those addresses that we are getting in China, working with our offices in China to follow up to see what laboratories they're coming from.

So you see large numbers coming in through the ports. But we also see them coming in through the airports and other small airports as well in Mexico.



In our assessment and active investigations and intelligence they are synthesizing fentanyl inside of Mexico and we've seen pill mills with industrial size pill presses making fentanyl pills inside of Mexico, specifically on the border, and we've had seizures in the airports of pills—

Mr. GUTHRIE. I didn't leave you much time to answer. My time has expired. So, I appreciate your answer.

Ms. DEGETTE. Thank you so much.

The Chair now recognizes Ms. Schakowsky for five minutes.

Ms. SCHAKOWSKY. I thank the Chair and ranking member and I thank you all for coming today to testify.

I am really glad that you all gather together to discuss this critical issue and I believe it will require a broad government approach to tackle the spread of illicit fentanyl across the public health, law enforcement, and international relations sector.

In particular, I am glad that in recent years both the legislative and executive branches appear to have realized the devastating failure of the previous war on drugs and have turned to a system of helping rather than locking up drug users, which has led to mass incarceration of hundreds of thousands of Americans, mostly brown and black.

Recently, Secretary of Health and Human Services Alex Azar indicated that he would be fully in support, for example, of needle exchange programs as part of his agency's plan to combat HIV—the HIV epidemic. But needle exchanges are also critical responses to the opioid epidemic.

In Illinois, Lindsay Hartman of Kane County runs a van every Saturday that provides clean needles, clean straws, Naloxone, and everything else a drug user needs to stay alive, and thankfully the Illinois state legislature passed a bill last month to ensure public health vans like Lindsay's can continue to run without fear of legal repercussions.

One important item that's on that van is—are test strips that can detect the presence of fentanyl in drugs. A recent study from RTI International found that, quote, "People who use illicitly made street opioids and tests them for fentanyl by using fentanyl test strips are 5 times more likely to engage in safer drug use behavior than when the test comes back positive," end quote.

So you can imagine I was disappointed to learn that Assistant Secretary of Mental Health and Substance Use Dr. Elinore McCance-Katz has publicly come out against the use of these test strips, and she wrote, quote, "Is it our goal simply to stop people from dying so they can continue a life of 'safe' heroin use or should our goal be different?" End quote.

So Mr. Chester and Ms. Cave, and then anybody else who would like to respond, do you believe that fentanyl testing strips and other similar innovative measures are essential to—for preventing death and shouldn't that be an objective in light of the current fentanyl epidemic?

Mr. CHESTER. Thank you, Congresswoman. I can't speak on behalf of anyone else. I can just—

Ms. SCHAKOWSKY. No, I am asking you.

Mr. CHESTER. Yes, I understand. So the approaches as we laid out in the drug control strategy is three pillars, and two of those

three pillars are public health. One of them is to prevent drug use before it starts and then the second one is to provide treatment leading to long-term recovery. Those are our main efforts, and any public health interventions, and when I mentioned in my testimony innovative public health interventions there are a wide range of things that we discuss and that we consider. We look for their efficacy in the public health space, all designed to save lives and to get people on their path to recovery.

That is our principle concern and that is the bulk of our efforts in the public health space specifically when it comes to opioids.

Ms. SCHAKOWSKY. So saving lives is a goal?

Mr. CHESTER. Absolutely. That is the single and, as it states in the strategy, the single criterion of success is to save American lives and stop Americans from losing their lives to these deadly drugs. Yes, ma'am.

Ms. SCHAKOWSKY. Thank you.

Ms. CAVE?

Ms. CAVE. So to echo that, I would say I am not a scientist or a physician either, and so I would—honestly, I would take this back to our department and have them answer as an HHS response in terms of what their opinion would be on this issue.

Ms. SCHAKOWSKY. OK. But it doesn't take a scientist, it seems to me, if test strips would actually show that fentanyl is present and prevent people—five times more people—lives saved because of it, that that's really a values question.

Ms. CAVE. Right. I would say safety, obviously, is number one.

Ms. SCHAKOWSKY. Thank you. I yield back.

Ms. DEGETTE. Thank you.

The Chair now recognizes Mr. McKinley for five minutes.

Mr. MCKINLEY. Thank you, Madam Chair, and I want to thank you for holding this hearing. I got to tell you, I am really disappointed that it's taken us seven months to have another hearing on this topic. Seven months.

It looks like we are going to get started again because we had a hiatus from last—the last Congress. Think about it. During the last Congress we had H.R. 6.

We had CARA, 21st Century CURES. We were having multiple hearings on this, and then it all went silent. And I thank you for bringing it back up again.

I think everyone has to understand during that hiatus, during that period of time—seven months—215 people died yesterday from substance abuse. Two hundred and fifteen people died today. Two hundred and fifteen people are going to die tomorrow.

In my state of West Virginia, the epicenter of this problem, we have one person dying every eight hours from a drug problem. I think we need to be faster with this.

So let me question, though. The theme or the concept that I am still struggling with is that why, and I've had a conversation with NIH.

We've had conversations with other folks. Why are—why are Americans turning to drugs to deal with their problems? Why is it that we have such a problem?

I've got the report here that has been filed that talks about why America is leading the globe in the use of drugs. As an example,

in France about 350 people died two years ago from drug overdose out of 66 million.

That's a half of a person per 100,000. In Ohio, it's 35. Nearly 40 persons per 100,000 is dying from drugs. Why is France not using drugs? What are they doing right in France?

Or take England, for example. England's ratio of death overdose by drugs is 4 per 100,000. In West Virginia, it's 52. What are we doing about—what are we actually doing?

Some of you, like Mr. Barksdale—it's not your issue with the Postal—but I want to understand why are Americans turning to drugs so rapidly and quickly instead of finding another way to deal with drugs.

Because what we are dealing in this hearing right now is the results. We want to chase the drug after it's come here. I want to understand why our kids, adults, others, are turning to drugs in the first place when the rest of the world isn't. They're finding other ways to deal with this problem.

So I would like maybe each of you to tell me why is it that you think America is using drugs at such a greater rate than anyplace else in the world.

Start with you, Mr. Chester.

Mr. CHESTER. Thank you for the question, Congressman. I am not—I am not prepared to answer why that is. I don't know just as you don't. I think that there are a lot of—a lot of variables as to why individuals choose to use drugs.

However, I will say that we no longer speak in terms of supply and demand. We speak in terms of availability and use, because we do know and our experience has shown that the greater availability of drugs in a community the greater chance that an individual will be able to use them for the first time and that first use leads to chronic use very, very quickly, particularly with opioids.

Mr. MCKINLEY. Reclaiming my time.

Last year we had Zuckerberg in here from Facebook. We had Dorsey in here from Twitter. And both of them were saying how—thumping their chest they don't use—they don't sell—they don't allow that to be sold on their platforms.

But yet, we demonstrated on both occasions that you can get drugs without prescriptions with Facebook, Twitter, Google, all these other accounts, and within hours each of them pulled it back down again.

And I am here to say I am told they're back up again. So regardless of—we took them to task. They're back out there again.

So we talk about availability. Are our social media platforms—are they being used and how can we structure that? How can we in Congress do a better job to prevent Facebook, Twitter, and others from selling drugs over the internet?

Mr. Donahue?

Mr. DONAHUE. Well, two things. I will get with our demand reduction unit in our DEA headquarters because it's an important question that you asked and I will get you our answer and our opinion that we got with DEA why people are using drugs.

I know one of the things we are always pushing for is the ability to be able to judiciously intercept devices—Facebook, other things—that we currently can't do with a judicial order which

causes a huge problem for law enforcement to infiltrate certain organizations, not having the ability to get into certain encrypted devices.

Mr. MCKINLEY. Thank you. My time has expired. I yield back.

Ms. DEGETTE. The gentleman's time has expired.

The Chair recognizes the gentle lady from New Hampshire, Ms. Kuster.

Ms. KUSTER. Thank you, Madam Chair, and thank you again for holding this hearing.

As we know, the opioid epidemic continues to impact communities across this country. This is a crisis that knows no demographic and impacts urban and rural communities like mine alike.

My home state of New Hampshire has been one of the hardest hit by the country's fentanyl crisis. This is a crisis that knows no border, no ocean deep enough, no continent broad enough to stop the flow of deadlier and deadlier fentanyl analogs.

As the epidemic evolves, we must evolve our approach to combat it and if one thing having all of these agencies before us today has shown it's that there's a greater need for an even more coordinated approach across international, national, and local agencies.

I want to start with you, Mr. Chester. As you have relayed, fentanyl is the biggest driver of overdose deaths, providing the best business model to drug traffickers, and being the hardest to detect.

You told committee staff that enforcement has historically been focused on interdicting 20th century drug trafficking and that it has taken us awhile to develop the architecture and means to combat 21st century drug trafficking.

What do you mean that fentanyl trafficking is following a 21st century architecture and what challenges do we face in adapting our strategy to meet this new threat?

Mr. CHESTER. Thank you for the question, ma'am, and I do want to be clear about one thing. We still have a 20th century drug trafficking problem in the United States and that's principally heroin, and New Hampshire is one of our state partners that we hear from every single month, and we've seen how heroin has tapered off in New Hampshire while synthetic opioids like fentanyl and fentanyl analogs have continued—have continued to rise.

Twentieth century drug trafficking, plant-based drugs that are packaged, moved across the borders through a hierarchical drug-trafficking organization, and that ends in a face-to-face cash transaction somewhere—that's what we refer to as 20th century drug trafficking.

Twenty-first century drug trafficking is an individual who does not need to interface with a drug trafficker or a drug-trafficking organization. They can get on their own laptop.

They can get on the dark web. They can go to—go to a vendor that will sell them the drugs. They can pay for it with bitcoin. It will be delivered directly to their house through the mail service or through express consignment. That's what we refer to as 21st century drug trafficking.

Unfortunately, we have both of those models that we are dealing with right now and I will tell you that our law enforcement community and our State Department and our other partners have done a remarkable job in being able to take on the 21st century drug

trafficking at the same time we are still dealing with the traditional model that we've dealt with for 30-plus years of drug policy.

Ms. KUSTER. Thank you.

Mr. Prince, fentanyl poses unique challenges compared to other drugs. Cheap to make, clandestinely produced in labs, easily transportable and, as we know, hard to detect.

Traffickers are increasingly mixing the drug into other narcotics as well as counterfeit prescription drugs. I ask you what is HSI doing to tackle the fentanyl epidemic that is uniquely different from its efforts to combatting heroin, cocaine, and other narcotics?

Mr. PRINCE. Thank you for the question, ma'am.

As my colleague had illustrated the 20th century versus 21st century drug problem, I call it analog versus digital. Our analog methodologies haven't changed in 35 years.

Surveillance, informant management, cultivation development, cooperating defendants, execution of search and arrest warrants, those are all our analog tools that we use that are always going to be relevant.

They will be relevant a hundred years from now.

As far as how we deal with the digital aspect of it, we have our innovation lab that I mentioned earlier. We have NTC and NTCI. NTCI is placed very squarely in NTC where there's information sharing.

Many of the people here on the panel are part of NTCI or NTC, collaborate with us on a daily basis. We have the OCDTF program that shepherds large-scale federal investigations in a collaborative team effort, and the two meet.

At some point the digital crypto currency space and the dark net activity is going to turn into something at the corner of what I say walk and don't walk where a drug deal is done, and that's where our ability to deal with the digital space while at the same time dealing with the analog space is going to bear fruit.

In my oral testimony, I mentioned just a few cases that developed into some significant opioid and fentanyl seizures. That's a collaboration of the digital space mingling with the analog space and providing arrests, seizures, and significant results.

Many of those investigations are ongoing. Some of those investigations are over. But we are moving with the digital transformations of the criminal enterprises. We are keeping up with what is going on.

Ms. KUSTER. Thank you. I yield back.

Ms. DEGETTE. I thank the gentle lady.

The Chair now recognizes the ranking member, Mr. Walden, for five minutes.

Mr. WALDEN. Thank you, Madam Chair, and again, thanks to the panel. We have two hearings going on simultaneously. So, I am kind of bouncing between all of that.

Mr. Overacker, I was down at the Southwest border touring some CBP facilities in Yuma, Arizona on Sunday, and I asked CBP whether they had seen an uptick in fentanyl coming in from Mexico in the Yuma sector.

The answer was no, they had not seen an uptick and, in fact, drug interdictions on the whole are down across the Yuma sector as the CBP checkpoints were shut down for months because of the

humanitarian crisis on the border, and that meant CBP agents could not staff those checkpoints during the border emergency, given the huge influx of people.

So, my question is the data show interdictions are down, but with those checkpoints closed I am not sure we can rely on those data this year.

And are there other CBP sectors being similarly impacted by this humanitarian crisis at the border and is there anything you can tell us about the way the cartels are using and profiting from the humanitarian crisis to overwhelm your agents—our agents—and then get the drugs in along the way?

What can you tell us about that?

Mr. OVERACKER. Thank you for the question, sir. The first thing I would say is that what we are tracking right now is overall our interdictions on the Southwest border are as much as we had last year.

That includes not just what the Border Patrol does at checkpoints. That includes our ports of entry and, roughly, 90 percent of what we seize is at a port of entry as opposed to in—between the ports by the Border Patrol.

I understand the humanitarian crisis has impacted their operations. They've also impacted the operations at our ports of entry as we've redirected CBP officers to support the Border Patrol sector.

Mr. WALDEN. So we were hearing.

Mr. OVERACKER. As a result, we've had to close lanes at ports of entries, which has slowed the amount of traffic.

But given that 90 percent of what we seize is at a port of entry, we are seizing just as much as we did last year overall as an agency.

But with respect to the other Border Patrol sectors, I would gladly take that back and get you more information on what they are seeing as well.

Mr. WALDEN. You might take another look at it because some data we were seeing over the weekend showed that it was down considerably in some categories.

Mr. OVERACKER. Some categories.

Mr. WALDEN. And so, I just want to make sure that—you know, we know your folks are getting overwhelmed when you go thousands of people coming in in a given night or hundreds where you had 10 or 20 or 30 in the past, and I know we've got colleagues that want to get rid of CBP or get rid of ICE and don't respect the tough conditions and what you and your folks are doing on things like this.

But we keep hearing they're being pulled aside to do the processing of the asylum claims. I mean, there's a lot of this work being done. They're not out in the field doing the interdictions.

And so, to what extent do you think this humanitarian crisis at the border is affecting the ability to interdict these drugs?

Mr. OVERACKER. Well, like I say, it has impacted not only Border Patrol resources between the ports of entry. It is also impacting field operations at the ports of entry in terms of just by—just the manpower that we have to dedicate to those traditional interceptions.

Mr. WALDEN. Right.

Mr. OVERACKER. But I think at the port of entry we've seen things stabilize and, of course, with the apprehension numbers declining now between the ports of entry, we think that the situation is improving.

Mr. WALDEN. All right. Mr. Prince, do you have any comment on this from your agency's view—DHS?

Mr. PRINCE. Most of the agents that are responding to the border crisis are responding to human smuggling or human trafficking events. The border crisis at some point could create a tipping point for us in the investigative space.

At this time we are not seeing that. We are deploying bodies, agents, to the border. Most of the agents that are responding are already at those special agent in charge offices along the Southwest border.

I will say that it has created some opportunities for us to open up new portfolios in the investigative tool space, 1 of those being DNA testing. The DNA testing is allowing us to actually separate children who are being used in a human trafficking scheme or a smuggling scheme.

Mr. WALDEN. We met with some investigators who had just gotten that tool and said they can turn a DNA test in 90 minutes I think they told us.

Mr. PRINCE. Right, and the DNA testing is actually identifying children that don't—that aren't of these individuals that are crossing the border with them. And so we are rescuing kids in this effort.

Mr. WALDEN. Yes. All right.

Madam Chair, my time has expired. Thank you all.

Ms. DEGETTE. I thank the gentleman.

The Chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for five minutes.

Mr. SARBANES. Thank you, Madam Chair. Thanks to the panel for being here.

Obviously, we all know well the threat that fentanyl is posing to the health and safety of our communities. We've been hearing a lot of very strong testimony on that and the experience in our districts clearly bears that out as well, and it has to be a very coordinated role, which you're trying to project here today. I appreciate that.

I did, Mr. Chester, want to focus a little bit more on the role of ONDCP because it asserts this coordinating function among all the various agencies that we need leaning in to address this crisis and this threat in terms of how our federal agencies are responding.

So tell me a little bit, to try to illustrate the coordinating role, what would be happening if your agency did not exist in terms of being able to pull the resources together across these agencies.

Mr. CHESTER. Well, the first thing, Congressman, I think there would be a lack of focus and a lack of direction in advancing the administration's drug control priorities, and that's one of the more important functions that ONDCP does is to—is to document our priorities and lay out the lines of effort that we are going to—that we are going to operate on. I think that's the first thing.

I think the second thing is that the day-to-day activity of ensuring that when departments and the agencies are doing things in

the drug control space they're doing it for a higher purpose and they're doing it in—to get complementary effects from other departments and agencies that are working in the same space.

This happens all the time in government, right. You have got three or four departments and agencies that are redundant. They are doing the same thing.

They don't—they don't know that the other ones are operating and that they are doing that. The third thing is when it comes to the interface between what we are doing on the national security and law enforcement side of the house and what we are doing in the public health space, and we've said from the very beginning that we can be as productive on the front end of the supply chain of drugs coming in the country as we want to.

But our true effectiveness has to be measured in the public health space, and you can—you can increase seizures and increase arrests and increase removals in the transit zone and do all of that.

But if Americans continue to die from these drugs then you're not being truly effective.

And ONDCP, by being an organization not only in the executive office of the president but one that has national security, law enforcement, and public health responsibilities, we are the organization that can bring both of those things together in a complementary fashion, unlike—

Mr. SARBANES. So let me—let me follow up on that, because that last observation in terms of the health dimension of this—the public health dimension may be a rationale for why some of the grant programs that you have previously administered are being proposed to be placed in other agencies—the High Intensity Drug Trafficking Areas program.

Maybe I think it would go to DOJ and the drug-free community support programs at HHS.

So maybe you could explain why that decision is being made, and then in terms of your emphasizing the role that the—the importance, the priority, that the administration gives to this fight and the coordinating, sort of traffic cop role that your agency can play in that.

I don't, frankly, understand how the administration has come I think three years running in its proposed budget with a proposal to cut your budget by 90 percent.

Now, we have restored in our appropriations—we recognize the value that your agency plays and I think we even plussed it up over prior years because we want you to play that role.

But you need to help me reconcile what you just said, which I agree with, that this should be a priority and it should reflect the administration's emphasis here on coordinating the efforts of all these agencies—on the one hand, reconcile that with the fact that the president's budget keeps coming with a 90 percent proposed cut; on the other hand, which doesn't send, I wouldn't think, the right message in terms of the role you want to play with respect to all of these agencies in terms of coordination.

So I won't ask any more questions because I am out of time. But if you could answer that I would appreciate it.

Mr. CHESTER. Thank you, Congressman.



The discussion about those 2 particular grant programs has been going on for many, many years, and the Congress has decided where those programs would be originally placed at their inception and the Congress will decide where they go.

I will tell you that both the HIDTA and the DFC program are critical to not only the coordination that we do across the federal government, and we'll talk about the HIDTA program for a second, but the integration of federal, state, local, and tribal together is incredibly important, and to ensure that that function is rolled into the broader efforts that ONDCP does is working very, very well.

When we talk about preventing drug use before it starts. I would struggle to find a program more successful than the drug-free communities program doing just that.

And so the placement of the HIDTA program and the DFCs together is a great example of what I talked about in bringing our national security, law enforcement, and our public health programs together in one place and ONDCP is glad to have those programs.

Ms. DEGETTE. Thank you, Mr. Chester.

The Chair now recognizes Mr.—the gentleman from Virginia, Mr. Griffith, for five minutes.

Mr. GRIFFITH. Thank you very much, Madam Chair, and appreciate you calling this hearing. I know how important this subject and other drug issues are to you, and I do appreciate it.

Let me quickly say in response to the previous questioning that I fully support the High Intensity Drug Trafficking Area program and it's been very helpful in my district.

Mr. Chester, in May of 2017, the Drug Enforcement Administration recovered 50 kilos of NPP. Now, I am going to botch this up, but that's N-Phenethyl-4-piperidinone—if I got close. But NPP is what we'll call it, a fentanyl precursor chemical that could yield about 19 million fentanyl tablets with a street value of more than \$570 million.

The NPP was found in a storage locker in Northborough, Massachusetts. This recovery of NPP was one of the DEA's largest seizures of a fentanyl precursor chemical in U.S. history.

It had been believed prior to that that fentanyl synthesis using precursor chemicals is conducted at clandestine labs in China or in Mexico. But this appears to call that into question.

Prior to May 2017, do you recall any previous fentanyl precursor seizures of this size indicating possible synthesis occurring here in the U.S.? Yes or no.

Mr. CHESTER. I do not recall a seizure of that size prior to that event. No, sir.

Mr. GRIFFITH. And given the size of the seizure that it was a fentanyl precursor chemical and would presumably support a nearby fentanyl synthesis lab in the United States, would this case be important enough to the Office of National Drug Control Policy—ONDCP—on fentanyl issues to be notified about it and briefed about it? Yes or no.

Mr. CHESTER. Yes, it would be. But when I get the chance I would like to talk about its—NPP's relationship with fentanyl synthesis. But please finish your questions.

Mr. GRIFFITH. All right. Let me get—let me keep moving.

Did the DEA report or brief you—did they either report to you or brief you or someone else at the Office of ONDCP about this situation?

Mr. CHESTER. I don't remember a specific briefing. But we get continual reports from the DEA on drug events.

Mr. GRIFFITH. But you don't remember getting one on this one?

Mr. CHESTER. This one is not particularly memorable to me. No, sir.

Mr. GRIFFITH. Even though it would have been a very large size. I mean, this is—this is what it looks like and it's just one of the precursors, and that's a picture of what they seized. That's a fairly significant amount of precursor when you realize it could be—back to my notes—19 million fentanyl tablets with a street value of \$570 million. I would have thought you might remember that if you had been informed of it. I understand you don't. That's fine.

In cases like this, do you believe sharing information would be helpful to law enforcement?

Mr. CHESTER. Yes, and I will tell you that we have many, many, many mechanisms to be able to share information and intelligence information. In this particular case as a precursor chemical we do know a couple of things.

The first 1 is the presence of a precursor chemical in the United States does not necessarily mean that there's synthesis going on nearby because precursor chemicals are shipped from the United States to other countries.

And the second thing is about 2 months before that particular seizure, under United States leadership the international community placed controls on the two chemicals related to fentanyl synthesis—NPP, which was the one that was seized, and ANPP. So—

Mr. GRIFFITH. OK. In this case—let's see that picture again, if we could—on many of those boxes there are Chinese characters. It would indicate it did not come from the United States. It came in—the precursor came in from China to the United States.

Mr. CHESTER. Absolutely, and it could be—although I don't know this, it could be that the individual was warehousing it for use, not turning it into someplace close by. We don't know.

Mr. GRIFFITH. OK. And here's my problem, and Mr. Donahue, I am going to ask you a question about whether or not your agency notified them. Here's my problem.

If we found that precursor, it would seem to me you would want to at least check, see who the storage locker belonged to, do an investigation, and it would seem like to me there needed to be a lot of coordination.

And as far as I know, that didn't happen.

Mr. Donahue, do you know if your agency briefed other agencies and Mr. Chester's agency on this particular seizure of a large amount of precursor?

Mr. DONAHUE. I appreciate the opportunity to respond to that. The case is currently under investigation. It's coming up to trial, which is a lot of times why stuff is not put out in the open due to the protections of the people testifying.

We daily notify other agencies on seizures that are made. That specific seizure was work with state and locals as well. It's ongoing.

It was built up, and it's still ongoing, and we do these daily—these types of investigations—at our international scale.

So you mentioned the markings that are in Chinese. They go to our offices over in Beijing, which follow up on those companies, whether we can task a foreign country to do certain intel gathering for us to bring it back, to identify the source all the way back to where the seizure is made.

So we do the follow up on those investigations. So sometimes they take a year, sometimes six months, sometimes two years because you're dealing with foreign countries.

Mr. GRIFFITH. We are already on two years and it doesn't look like we followed up.

And, look, I think we need to just do a lot better job. Mr. Barksdale might have been liked to have known about that so he could check those addresses out.

I think we do a better job if we are all working together and as President Reagan said, there's no limit to the amount of good you can do if you don't care who gets the credit.

And I yield back.

Ms. DEGETTE. The gentleman yields back.

The Chair now recognizes the gentleman from New York, Mr. Tonko, for five minutes.

Mr. TONKO. Thank you, Madam Chair.

As others have stated today, the fentanyl threat is unlike any drug problem we have seen before and it is going to take the totality of the Federal Government's capabilities to fight it.

Each of these agencies has unique skill sets. But they each only see a piece of this picture. We need them to actually come together and pool their resources, information, and expertise.

Unfortunately, it does not appear that that's happening as much as it could. For example, committee staff visited CBP's National Target Center and saw how CBP is able to use algorithms to target shipments and packages likely to contain contraband.

But that is only as good as the data that is fed into the system, and CBP does not receive all of the data it could from other agencies.

So how do we get past this burden, Mr. Overacker? Why is this—why are we not getting the most that we can here? What is holding back the progress that we need to realize?

Mr. OVERACKER. Well, I would say that, first of all, we do have good levels of collaboration. We do receive data that is required by regulation and then we fuse that data with other information to try to identify high risk.

Mr. TONKO. But if I might, though—see, when we look at the National Target Center visit, they're saying it's not happening as well as it could.

What is holding that back?

Mr. OVERACKER. Well, there is room for improvement and I would just say that this is an example within the law enforcement community of where I believe that we need to have investigators get to a comfort level where they can share their case information with CBP, knowing that as law enforcement officers, ourselves, that we can protect those cases.

But we can also use that information to advance those cases by basically giving them greater feedback and greater information.

So I just think it's a question of education of the investigators in the field of what our capabilities are and what value we can add to their cases.

Mr. TONKO. And what additional data would CBP like to receive from other agencies involved in this fight to feed into your targeting system?

Mr. OVERACKER. Well, like I said, I think the case-specific information, that will allow us to pinpoint target and also provide meaningful interdictions for those agents in the field.

Mr. TONKO. And, Mr. Donahue, I understand DEA frequently shares data with CBP on specific cases when DEA deems it appropriate. But what is stopping DEA from providing CBP with more data on an automatic ongoing routine basis?

Mr. DONAHUE. We work with CBP daily down in Mexico City and various other countries. We are mandated by DOJ policy to provide all of our data into the Special Operations Division where there's over 38 foreign and domestic agencies, both state, local, and federal, that seize that data that can share it and CBP actually has officers stationed in the Special Operations Division, and we work a lot along the border with them passing information on seizures that we need them to make for our investigative purposes that we can use in a court of law in United States.

So there's daily engagement.

Mr. TONKO. Why then is CBP stating that they're not receiving all of the data that they need to?

Mr. DONAHUE. You know, I don't—they're not tied in directly to SOD but they can see all of our data there because they have representatives stationed in the Special Operations Division that coordinate with all the other agencies there to include people out in the field and in foreign offices.

Mr. TONKO. Well, let me give a specific example. If DEA executes a search warrant related to fentanyl and discovers packages containing fentanyl that include names and addresses, can that information automatically be sent to CBP for it to interdict all related shipments coming in?

Mr. DONAHUE. If they're working that investigation in conjunction with DEA, they would have it right then and there. We provide all that to our targeting over in SOD and they would, in turn, share it with the CBP officer there when they could give value add to that investigation to help identifying the people responsible for that seizure.

Mr. TONKO. Well, Mr. Chester, this is one of ONDCP's essential missions, to make sure that these agencies are working together and sharing all of the information that they can. But, clearly, there is more that can be done in terms of ongoing information sharing and for there to be this proclamation by some of the groups saying we are not doing as well as we should. What are the roadblocks here?

Mr. CHESTER. Clearly, there are roadblocks. There is always room for improvement in the ability—

Mr. TONKO. But what are the roadblocks?

Mr. CHESTER. I think some of them may be procedural. Some of them may be technical in nature, the ability for databases to speak with—to one another on a routine basis, and as those issues arise we absolutely are more than happy to work with the interagency to try and reduce them, as you pointed out.

Mr. TONKO. But why can't we link up more of these data systems so that the agencies can help one another?

Mr. CHESTER. Yes, sir. We would have to take a good close look at the reason why it's not happening and fix that problem. We absolutely will.

Mr. TONKO. We have a crisis on our hands. Why are we not taking that closer look?

Mr. CHESTER. Yes, sir.

Mr. TONKO. We could look at it. Why aren't we?

Mr. CHESTER. We absolutely will look at it. This particular case that you raise we absolutely will take a look at why the information is not routinely shared and we will reduce that barrier and make sure that that happens.

Mr. TONKO. Madam Chair, I yield back.

Ms. DEGETTE. The Chair now recognizes the gentle lady from Indiana, Mrs. Brooks, for five minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman, for holding this incredibly important hearing. I am really pleased that we are focusing in large part on law enforcement issues.

I am a former U.S. attorney from '01 to '07, and so worked with all of your agencies. Was there when Homeland Security was stood up, and so just want to thank you all very, very much for your work.

I think what the frustration is is we are trying to determine if there are any legal barriers, legal authorities, or anything that is keeping the agencies from sharing at the level that we all think you should be sharing at.

And so my question is to any of you, and your counsels who might be here, are there any legal barriers that exist in law that are keeping you from sharing information?

Discovery issues—is there anything? Mr. Donahue, anything you know of?

Mr. DONAHUE. I think that depends on what the seizure is, if it's actually in judicial processes—is it actually protected information from other countries.

But there is no legal, you know, policy or anything preventing us from sharing information. I could tell you what we've done in Mexico City in our offices. We have HSI agents and FBI agents sitting right in the office with DEA for that deconfliction purpose and for the immediate sharing of information.

Mrs. BROOKS. OK. And do any of the other agencies know of any legal reasons why our law enforcement agencies aren't sharing or can't share anything? Or is it just operational?

Mr. OVERACKER. I am not aware of any legal restriction—

Mrs. BROOKS. OK.

Mr. OVERACKER [continuing]. And I think our default position always should be we have an obligation to share.

Mrs. BROOKS. OK. And I assume—is that anything different?

Mr. PRINCE. Again, yes, I am not aware of any legal prohibitions but I think that, you know, the size of some of these agencies—these are large enterprises that we are talking about.

But a lot of these gaps are closed through deconfliction houses, case coordination such as OCDTF, HIDTA. A lot of these things I am sure you're very much aware of, and I think it's not—these aren't insurmountable issues. These are issues that we collaborate on daily—

Mrs. BROOKS. Right.

Mr. PRINCE [continuing]. With respect to the international space—

Mrs. BROOKS. OK. Just wanted to make sure there were no legal impediments because actually Mr. Donahue talked about a legal impediment, which I've been very concerned about for a long time, and that's the encrypted phones, which we have not resolved, have we, Mr. Donahue?

Mr. DONAHUE. No, we've been pending that issue for years now.

Mrs. BROOKS. OK. And could you very succinctly remind us all what that is?

Mr. DONAHUE. So it's a law that's going to enable us to judicially intercept a device that's signed by a judge on a target that we can demonstrate is violating U.S. law.

Mrs. BROOKS. But then the encryption is what's keeping you from getting to the information in the phone. Is that correct?

Mr. DONAHUE. Correct. Certain companies don't cooperate—aren't obligated to cooperate to give us the technology to intercept the encryption.

Mrs. BROOKS. OK. I want to talk about some of the technology challenges, and Mr. Prince, you talked about the dark web, and can you please share with us what—how it is that it's more of a law enforcement challenge than, you know, other issues that we've seen and whether the issues with cryptic currency, and I just read that Facebook is now contemplating a currency. Can you please talk with us about any successes or challenges you're having on the dark web?

Mr. PRINCE. The successes are I mentioned in my oral testimony. The challenges are, obviously, with respect to crypto currency and that when we are looking at transactions that are occurring in the dark net and the dark net is largely where nefarious activities are occurring and transactions are happening.

We don't necessarily know what these purchases and sales are unless or until we arrest an individual who is engaged in this criminal activity and perhaps commandeer their account, in which case we can see their entire wallet and what those transactions translate to.

If we are looking at it from the outside in what we see is transactions that are occurring we can presume that those transactions are in fact criminal in nature because we are in the dark net space. But we don't know what they're selling, what they're buying.

So those are some challenges. But we overcome those challenges through a variety of different techniques that I can't really get into here.

Mrs. BROOKS. Right.

Mr. PRINCE. But, certainly, we do make an impact and we are making inroads in that space.

Mrs. BROOKS. And I would like to follow up on that further. But one thing that I know CBP mentioned but I would also like to ask you, Mr. Barksdale. Can we talk a little bit in my time that I have left about the Narcan availability for—I know it's at key facilities.

Obviously, when we are dealing with fentanyl all the law enforcement—everyone who touches it it's of significant concern because it could kill.

What percentage of postal and—I am curious, and I think we'll have to do this in written form to all the agencies—what percentage of your officers have access to Narcan?

Mr. BARKSDALE. Well, first, as far as postal inspectors, every postal inspector has access to Narcan.

Mrs. BROOKS. OK. Good.

Mr. BARKSDALE. Those on our drug teams has access to Narcan.

On the operational side, all of our key facilities does have Narcan distributed to them, and that would include all of our process and in distribution centers and other large facilities.

As far as the percentage of employees that covers, I will have to get back to you with an exact number.

Mrs. BROOKS. OK. And I will be submitting for—written questions about the availability of Narcan, the percentage of your employees that are all covered or have access to that because I think this is a serious issue for law enforcement.

Thank you. I yield back.

Ms. DEGETTE. The Chair now recognizes the gentleman from Massachusetts, Mr. Kennedy, for five minutes.

Mr. KENNEDY. Thank you, Madame Chair. Thank you for hosting this incredibly important hearing. Thank you for the witnesses to be here today and for your service to our country.

A number of complexities that—and hot issues that been brought up over the course of the testimony today, and I appreciate your focus on that.

I want to try to drill down on some of that, given that Congress has the opportunity to make some changes here and some investments here that I think are necessary, although we need to do that right.

So, Mr. Overacker, you told us earlier that, quote, “Most of the illicit fentanyl entering our country by weight does so at ports of entry along the Southwest border by private vehicles, pedestrian, and commercial vehicles,” and that, quote, “Fentanyl entering from the northern border does so by international mail packages and express consignment courier,” end quote.

So in your opinion, sir, would a border wall at a cost of up to \$25 billion be the most effective way to stop fentanyl from arriving in our country through mail and ports of entry?

Mr. OVERACKER. Let me just say that I think when we talk about border management you have to have a comprehensive approach. You know, most of what we encounter is at a port of entry and—but we are working with—working to change our concept of operations at these ports so we can increase the scanning rates, and when we increase those scanning rates I think it will have an impact on the patterns of crossing and if we deter these drugs—

Mr. KENNEDY. Understood.

Mr. OVERACKER [continuing]. Deter them from coming to the ports they're going to go someplace else.

Mr. KENNEDY. Right. So I am going to interpret that based upon the phrasing in which you answered that question as a no, not the most effective way to spend the initial first \$25 billion.

So if Congress was to appropriate \$25 billion to the CBP to combat fentanyl trafficking, would you choose to spend that money on a border wall or, as you said, increase technology focused on screening cars and pedestrians at ports of entry and packages that are arriving through the mail?

Mr. OVERACKER. Well, in the 2019 appropriation we received \$570 million to improve our scanning capabilities at ports of entry—

Mr. KENNEDY. And given what you just said, we are not there yet in terms of trying to—

Mr. OVERACKER. No, that's going to be a multi-year investment. But that's our first priority right there.

Mr. KENNEDY. Appreciate that, sir.

Mr. Donahue, if given \$25 billion by Congress, do you believe the most effective way to stop any arrival of illicit drugs to the United States is a border wall?

Mr. DONAHUE. Again, collectively, with all different tools, can't say, you know, it won't help. I mean, I can't say it's the solution. But it would help. It's just another tool in our toolbox that we can actually filter certain threats to certain areas and we can focus on in personnel—

Mr. KENNEDY. So but the most—if you had \$25 billion is the intervention that you would go with first a border wall?

Mr. DONAHUE. It would just be part of our comprehensive plan on how we approach the issue.

Mr. KENNEDY. Sir, you touched on the importance of treatment and recovery options here in the United States as a way to reduce demand.

Do you think that a \$25 billion border wall would help us increase access to care in places like Massachusetts that would lead to reduced demand?

Mr. DONAHUE. I mean, again, that's part of our—we believe in the rehabilitation. We believe in the demand reduction and the enforcement, and the international focus on the sources of supply. So we—

Mr. KENNEDY. And so would that—

Mr. DONAHUE [continuing]. We'd spread that money out, look at it collectively on the entire problem.

Mr. KENNEDY. And so that \$25 billion could be spent on something like Medicaid, which is the largest payer of mental behavior health services in the country that accounts for more than 40 percent or nearly 40 percent of all adults with opioid addiction in the country?

Mr. DONAHUE. It would help that too, and our concern is to have less drugs and less flow into the United States, have less drugs addicts and less people dependent on those programs.

Mr. KENNEDY. And so if I am understanding your answer that that would help—expanding access to Medicaid would be a criti-



cally important part to ensuring that people get access to the treatment that's necessary.

Mr. DONAHUE. The DEA doesn't run anything on—in Medicaid. We are targeting the cartels that are responsible for bringing the drugs into the country.

Mr. KENNEDY. Right. But as you said, if you're trying to reduce demand, getting people treated that are affected with addiction is probably part of that, no?

Mr. DONAHUE. Yes, it is.

Mr. KENNEDY. OK.

Mr. Chester, on multiple occasions the administration has opposed—has proposed gutting ONDCP by 95 percent. Do you believe that our response to this epidemic would be improved without a centralized agency tasked with leading that response?

Mr. CHESTER. As the central EOP office for advancing the administration's drug control policy, ONDCP has been very effective in doing that role.

Mr. KENNEDY. Do you think cutting your budget by 95 percent would make you more effective or less effective?

Mr. CHESTER. Well, clearly, cutting our budget by 95 percent would make us less effective.

But I will also tell you that the administration's support for ONDCP has been very strong and they've allowed us to do our jobs very, very well in this particular crisis over the last—

Mr. KENNEDY. Would you characterized the proposed cut by 95 percent as being very strong support, sir?

Mr. CHESTER. The proposed cut by 95 percent was the inclusion of the other two programs that were very pricey. So it wasn't a—it wasn't 100 people from ONDCP became five people.

But what I will tell you that the relationship that we have with the administration they have allowed us to be able to do our jobs at advancing the drug policy across the federal government.

Mr. KENNEDY. So why do you think they'd propose cutting your office by 95 percent?

Mr. CHESTER. I think that these were all parts of budget discussions in the past but we are all very glad that ONDCP exists and continues to do its good work to this day.

Mr. KENNEDY. Me, too. Thank you.

I yield back.

Ms. DEGETTE. The Chair now recognizes the gentleman from Oklahoma, Mr. Mullin.

Mr. MULLIN. Thank you, Madam Chair.

My questions are going to be for Mr. Donahue and Mr. Overacker, if you could both kind of answer when you can.

How much fentanyl is coming directly from China?

Mr. OVERACKER. So the fentanyl that comes directly from China typically we see that in mail or express, and I can tell you that—

Mr. MULLIN. How much? I mean, give me—like, how much have we—have we stopped? How much do we estimate is entering the country from China directly?

Mr. OVERACKER. Well, the numbers have dropped precipitously this year.

Mr. MULLIN. OK.

Mr. OVERACKER. So we are talking about only pounds of fentanyl—

Mr. MULLIN. Pounds?

Mr. OVERACKER [continuing]. That we have encountered so far this year.

Mr. MULLIN. Mr. Donahue?

Mr. DONAHUE. We couldn't give you the exact number coming in because we only know what we know. We can give you our seizures numbers that—

Mr. MULLIN. Right. That's what I am looking for. How much have you seized?

Mr. DONAHUE. So I will get those exact seizure numbers for you.

Mr. MULLIN. Thank you.

Mr. DONAHUE. One thing we are looking for in China is actually the precursor chemicals coming from China actually utilized to produce more fentanyl.

Mr. MULLIN. How much is coming over our southern border that we are apprehending?

Mr. OVERACKER. On the southern border, that's where, basically, most of what we are seeing—

Mr. MULLIN. Right.

Mr. OVERACKER [continuing]. And I think this year we are tracking at over 1,800 pounds or—

Mr. MULLIN. Eighteen hundred pounds.

Mr. OVERACKER [continuing]. Close to 2,000 so far. But this is not pure fentanyl. This is fentanyl that would be either—

Mr. MULLIN. It's laced. Right. I get it. Right.

Mr. OVERACKER [continuing]. Yes, laced or cut or however you want to—

Mr. MULLIN. I get it. Mr. Donahue, would you agree with those numbers?

Mr. DONAHUE. They seem accurate, and we see a lot going up through the corridor for Tijuana and Mexico.

Mr. MULLIN. Are we grabbing most of that at the port of entry?

Mr. OVERACKER. Absolutely. Ninety percent of our seizures occur at a port of entry.

Mr. MULLIN. And if I am—if I am not mistaken we are only inspecting, roughly, 20 percent of the—of the vehicles. We are only able to inspect 20 percent of the vehicles coming across the port of entry. Is that correct?

Mr. OVERACKER. Well, currently, our scanning rates for privately-owned vehicles coming across the southern border are around two percent and it's, roughly, 16 percent for commercial vehicles, and that's really a function of the volume of what's crossing. We have—

Mr. MULLIN. Well, the point I am trying to get to is my colleague that was before me was bringing up the \$25 billion for the southern border for building the wall, and underneath the president's proposal he also designated a significant amount of money for the port of entry to scan 100 percent of the vehicles as they were driving through because right now we are only inspecting, roughly, 20 percent and we are already catching the largest amount but through the port of entry.

To get back to what my colleague was referring to, would the wall work. Well, what the wall would do is draw more people to that port of entry. Is that not correct? If the wall is there, then they would have to look for a more—a different avenue to be able to enter the country through, which would be the legal point of entries.

Mr. Donahue, would you like to respond to that?

Mr. DONAHUE. We do a lot of great work with CBP and passing information when we can drive people or operations that we do at the port of entry where we can focus on cars and trucks.

Mr. MULLIN. It's to funnel them there to a certain point.

Mr. DONAHUE. Yes.

Mr. MULLIN. So would the wall help funnel that?

Mr. DONAHUE. Absolutely would.

Mr. MULLIN. Mr. Overacker, would you agree with that?

Mr. OVERACKER. I would say that the port of entry is a controlled place.

Mr. MULLIN. Sure. Where the—where the open border isn't, correct?

Mr. OVERACKER. And so because it's a controlled place and we have better opportunities to interdict.

Mr. MULLIN. OK. So my point that I am trying to drive home here is there's not just one thing that's going to solve this problem.

But the amount that we can keep from flowing over our southern border, which is where the majority of the drugs are coming from—if we can get a better control on that and designate dollars specifically for those and make our southern border a harder target rather than right now being an easy target because, as we all know, the easy target is an opportunity for success and a harder target most criminals aren't going to attack.

If we are able to make it a hard target, would that help us with combatting the overdoses that are taking place and the addiction issues that are taking place here inside the United States?

Mr. DONAHUE. We look at all tools because, you know, we are speaking about fentanyl today and we are concerned with the enormous amount of methamphetamine that's being produced that's coming up—

Mr. MULLIN. Right.

Mr. DONAHUE [continuing]. The enormous amount of cocaine and the heroin as well, which are bulky to bring in that they need big trucks to do it.

So we are looking at every tool possible to identify and disrupt and seize those drugs that are coming in.

Mr. MULLIN. With the amount of human trafficking that's going on in our southern border right now—the overflow that's taking place—is it distracting your mission from being able to—being able to look directly to drug trafficking or you have to spend resources to the human trafficking side of it, too?

Mr. Overacker, you want to—

Mr. OVERACKER. Well, there's no question that the current conditions on the Southwest border have caused us to have to shift, you know, our personnel. So it does have some impact. There's no question about that.

Mr. MULLIN. See, what I am thinking is that the cartels are purposely flooding our southern border so that the drug routes can be easily accessed because they know that we having to put resources to the human trafficking crisis that's taking place and the humanitarian that's taking place.

So the wall, to which my colleague brought up, is to help all the above picture, not just one single issue.

With that, I will yield back.

Ms. DEGETTE. The gentleman yields back.

The Chair now recognizes Mr. Duncan for five minutes.

Mr. DUNCAN. Thank you, Madam Chairwoman, and thanks for holding this hearing.

I sat here a long time listening because I am concerned about the 28,000 deaths in the United States from synthetic opioids like fentanyl.

And my colleague made a great point just now that cartels are going to exploit weaknesses or crises to get their product across. I think they are. I think walls do work and I think they create corridors that our law enforcement can better utilize the resources we give them within those corridors to stop the bad guys from wanting to bring these horrendous drugs into our cities and killing our fellow Americans.

I've been sitting here and for—sat here for several hours listening to all the other questions. One of the benefits or challenges being last is all the groovy questions have been asked.

You all have been great to answer those questions. I want to give you a chance to tell us what more we can do in Congress. We passed the SUPPORT Act last year, the SUPPORT for Patients and Communities Act. I want to see the implementation of that.

But what I would like to do is just ask Mr. Overacker first what can we do in Congress to help keep our law enforcement officers best positioned to continue infiltrating the supply chain. What more can we do?

Mr. OVERACKER. Thank you for that, Congressman.

First of all, I would just like to say that we are very fortunate that Congress has supported us most generously over the last two budgets with respect to our detection capabilities, and so we are grateful for that, and we know we have a multi-year effort to improve our scanning capabilities on the Southwest border but also throughout CBP.

We are also grateful for the continued support we've received with respect to improving our laboratory capabilities and also appropriations for improving our facilities.

That's an important part, particularly what we are doing now to improve the international mail facilities where we process mail with the U.S. Postal Service.

So that continued support is most helpful for us. So that's what I would say, just thank you for the support we've received so far.

Mr. DUNCAN. Let me ask Mr. Donahue from the DEA standpoint. What can we do to help you disrupt the distribution process of opioids and what more can we do?

Mr. DONAHUE. I think having hearings and meetings like this and keeping it to the forefront is really important, and inviting DEA to these meetings. We bring something specific to the table.

We have extraordinary amount of resources in our overseas offices which is where the drugs come from—the cocaine, the methamphetamine, the heroin, the fentanyl. It all comes from international and other countries.

So bringing this to the forefront I think is really important for the DEA and letting our message get out there, and I think having the youth and other people seeing the damage of the drugs that are coming in from a foreign country, just the damage to our cultures and our communities. It's really important not to do it every six months but to do it daily.

Mr. DUNCAN. I've got a—my best friend from college is a doctor and we talked about fentanyl just this week, and we were talking about the smuggling efforts.

And as you guys become more and more effective, my concern is the very potent fentanyl could be put into food supplies as part of the smuggling effort in containers and contaminate food supply that ultimately gets in.

Not talking about drug users that are looking for that stronger high. I am talking about fentanyl get into an area where it contaminates food or liquids that ultimately end up on the digestives systems of just average Americans, and then we have a lot of other innocent deaths.

I want to ask Mr. Prince with HSI—you know, as containers are being brought in, I know HSI is doing a great job overseas. Is that a reality that we should think about is fentanyl contaminating any other sort of food supply or liquids that are coming into this country?

Mr. PRINCE. I think it's an abstract thought that I have that I will share but, you know, lack of imagination is something that we shouldn't have when it comes to fentanyl in the same sense that when you think about 9/11 and how that happened.

So we should have an imagination about the various ways that fentanyl can be introduced into the United States as we put pressure on organizations. We should be creative. We should continue to leverage tools that we have. We should continue to create new tools and expand our aperture within the cyber space.

And don't forget about our, as I mentioned earlier, our analog tool sets that allow us to also be effective.

Mr. DUNCAN. Madam Chairwoman, before I came to this committee I was on the Homeland Security, and I was on the Border and Customs Border Patrol—Border and Maritime Subcommittee.

We went to the ports and we looked at container security, and we looked at the screen for radioactive devices. We looked at what drug smugglers have done.

But fentanyl being put on containers it's going to be very difficult for these guys to detect. That's something we ought to consider in future hearings.

And with that, I yield back.

Ms. DEGETTE. The gentleman is right. Fentanyl is really difficult to detect and that's 1 of the real dangers.

I want to thank all of the witnesses for coming today. Your participation has been very informative and helpful.

I do have a document that Ms. Schakowsky asked me to enter into the record. It's an article from the International Journal of Drug Policy and I would ask unanimous consent. So ordered.

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

Ms. DEGETTE. I can assure all of you, and everyone in the audience, this committee does intend to stay on this issue. This has been a multi-year process, a bipartisan process, and we intend to continue to look quite closely at it, because it is really a national crisis.

And I want to thank all of our witnesses for recognizing it as such and for increasing your cooperation between your agencies.

I also want to remind Members that pursuant to committee rules they have 10 business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee.

I would just ask if all of our witnesses would agree to respond promptly to any such questions if you receive any. I think you will be getting some from Mrs. Brooks, for example.

And with that, the subcommittee is adjourned.

[Whereupon, at 12:06 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

#### PREPARED STATEMENT OF HON. ANNIE KUSTER

We have seen the opioid crisis evolve and take many different forms. No community in this country has been spared, but New England and New Hampshire in particular have been devastated by this crisis.

That is why it is imperative that we anticipate how the fentanyl crisis will continue to evolve. We need to get ahead of this ever-changing threat, so we are not caught flat-footed.

As I look at the witness panel, I am struck by their diverse missions. It is not every day that we have a hearing with the U.S. Postal Service and the DEA on the same witness panel.

We need a national strategy on our fentanyl response. And I don't just mean a white paper document or a task force report. I mean we need a coherent, practical plan for how we are going to beat this problem.

For example, the Office of National Drug Control Policy (ONDCP) is supposed to formulate a strategy, bring all the agencies together, and see to it that the strategy is implemented effectively.

DEA, you are on the front lines and often develop important leads for targeting drugs. And FDA is suddenly in the middle of this fight because fentanyl is increasingly being mixed with other drugs, including counterfeit prescription drugs.

These are just a few of the issues we will explore today. If we are going to solve this problem, we need better cooperation across agencies, and we need to think differently than we have on past drug epidemics.

Finally, this hearing is just one piece of our oversight. This Subcommittee will stay on this issue and ensure progress is being made so that we are not back here again next year talking about the same problems.

I thank the witnesses for their service on this critical issue, and for being here today.

I yield back.



Amanda's Way

July 16, 2018

Chairwoman DeGette, and all distinguished members:

We represent The Actus Foundation, which was founded after the death of our beloved daughter Amanda to Fentanyl Toxicity on January 11, 2018. While our Foundation sees substantial reason for hope regarding our nation's present Opioid Crisis ("The Crisis") within the present Administration and Congress, we also see the warning signs of conditions ahead which may encourage a politically based response on the part of some Lawmakers. We would like to detail some of these hopeful signs, as well as our concerns, for your consideration.

A. Some Background Facts:

- 1) In 2013, a deadly group of chemicals entered the US illicit drug supply stream and began to ravage numerous user groups within The Crisis. These chemicals, properly named "Synthetic opioids", are generically referred to by their summary moniker, Fentanyl. Fentanyl is indeed a "synthetic opioid", but there are many sub-chemicals related to Fentanyl ("analogues") in the market, as well as numerous other compounds, such as the "U" series and various analogues of the drug *Bucinnazine*.

All these synthetic opioids are of grave concern. We are wary of the tendency to lump all under the term "Fentanyl", as it may tend to simplify the issue in people's minds. Fentanyl is the lion's share of what arrives on our shores, but it is by no means the only one.

2) Synthetic Opioids are a grave threat for several reasons:

- a. As synthetic chemicals, they can be made without the tedium of growing plants and extracting their natural chemicals. Synthetics can be made clandestinely from very simple "precursor" chemicals in a laboratory. It should be noted that a synthetic chemical can be made from any number of recipes, rendering authorities incapable of consistently tracking the necessary precursors as a means of restricting manufacturing.

Controlling heroin is aided by the need of acres of poppy fields which are visible by any number of means. Synthetic opioid manufacturing is relatively undetectable as there are no natural plants involved, and recipes can be updated frequently to avoid detection by tracking of precursors.

- b. As synthetic chemicals, endless versions of the chemical can be spun-out with insignificant differences in what they do, but significant differences in their chemical structure, rendering them outside the reach of DEA Scheduling (why passage of SITSA is urgently important). At present, there are >1,900 analogues calculated just for Fentanyl, of which we have only documented 18. This means that each time DEA works through the process of scheduling the 19<sup>th</sup>, 20<sup>th</sup>, etc., the manufacturers can introduce yet another analogue. Without SITSA, they can play that game as long as it takes DEA to schedule 1,882 more analogues, one at a time.

- c. The key danger is that these synthetics, especially Fentanyl, which is the dominant synthetic in the market now, **are significantly more potent** than their natural, plant-based cousins. The relative potency is not controllable under the present scheme of distribution. The dealers do the mixing and their ability to make a 100:1 ratio mix with any degree of consistency (what we call in pharma “homogeneity”) is non-existent. Therefore, we can roughly say that every time a pure Fentanyl batch is mixed – without any natural heroin – approximately 20% of the retail-level doses will produce fatalities.

The only thing preventing 20% of **all** street-opioid from producing fatal results, is that most of the drugs being seized at this time are a mixture of natural and synthetic because the mix makes for the “best product” from the **user’s** perspective. However, the “best product” from the **dealer’s** perspective is pure Fentanyl. Our Foundation uses historical business modelling to predict that it is the dealer’s perspective which really matters, and that this means Fentanyl will indeed displace heroin – **completely** – at some future point. The 20% deadliness of that drug means that we will see death rates of >300,000/annum once that displacement is fully executed. The displacement of heroin by Fentanyl, et al, is a certainty which is well under way.

- d. They are Narcan resistant. Narcan has been saving thousands of lives in this crisis, but Fentanyl’s strength and unique interaction with the body demands more doses, delivered intermittently. In fact, one of the analogues appearing in 2017 (acryl fentanyl) was the subject of a myth that it was “Narcan-proof” and was later the subject of a clarification memo by DHS (11 July 2017). In that memo, DHS claims there “are no fentanyl analogues resistant to Naloxone”. This is a matter of semantics. From the perspective of first-responder or medical personnel, **all** fentanyl analogues are *resistant* to Naloxone (Narcan).
- e. Unlike all illicit drugs which have fed this waxing Crisis throughout the decades, none of them has had the terror implications of Synthetic Opioid. From their appearance on the scene during the Moscow Theater Incident (Remifentanyl), to the devastation they have wrought in this country since their sudden appearance in 2013, these chemicals have certainly caught the attention of terror groups. Most security people we talk to say the question is not one of “if”, but one of “when”.

We have asked the question of many of these experts why it has yet to happen. There is no clear answer, but the best we’ve heard is that they are waiting for an analogue which is so Narcan-resistant as to be, de facto, Narcan-*proof*. Reminder: We have at least 1,882 more analogues for them to choose from.

- 3) Synthetic Opioid Death is dramatically under-reported. While CDC publishes 72,000 as the number who died in 2017 from OD, there are numerous jurisdictions where Medical Examiners forego the cost, tedium and delay of toxicology, which is required to call a manner of death “drug poisoning”. In such cases, an OD is declared “natural causes”. It is estimated that this is a 30-50% occurrence. This puts the true death number at 100,000. This is close to 2 Vietnams each year.



#### B. Our Position

Our Foundation raises these facts, and the displacement dynamic, to the level of a true *paradigm change* in the world of illicit drug distribution and use in America. Paradigm is an overused word in our sensationalized culture, but we use the phrase *paradigm shift* in the scientifically disciplined spirit intended by the term's key developer, Thomas Kuhn. A paradigm shift, what Immanuel Kant described as a "revolution of the way of thinking", demands revolutionary methods.

We need to act differently at the federal, international level to defer the displacement date as far in the future as possible, and then develop revolutionary thinking at all levels to help reduce the dreadful effects of The Crisis.

What do we need to do?

- 1) While dealing and using drugs are a very *difficult* problem to solve, the sudden and massive introduction of Fentanyl and other synthetics has created a problem which is as *simple* as it is *difficult*. All Fentanyl comes from China, for many very good reasons. These reasons are detailed by our Foundation and need not be detailed here. Suffice it to say, China will remain the dominant, virtually sole, manufacturer of America's illicit Fentanyl for the foreseeable future. The simplicity of that fact presents a window of opportunity.
- 2) We need to get Law Enforcement (LE) re-engaged. Numerous District Attorneys throughout the country have demanded Law Enforcement cede drug scene responses to HazMat due to the potential of synthetic opioid at any drug scene. While this reaction was prudent at one time, there are tools available now which give us the ability to protect officer safety. Only by re-engaging Law Enforcement will we be able to mount the control processes we need to handle this crisis.

For those legislators who immediately associate re-engagement of Law Enforcement as a restart of the "war-on-drugs" we can assure you that nothing could be farther from the truth. In our years of traveling the country and training narcotics-based Law Enforcement groups of all levels, one thing is immediately clear: We have yet to meet a single narcotics officer, at any level, who thinks locking up users and low-level dealers provides any value. "We cannot arrest our way out of this problem" has been fully accepted and endorsed by all Law Enforcement resources our Foundation has worked with.

#### C. Hopeful Signs

- 1) President Trump repeatedly discusses the issue and has raised it with GS Xi Jinping directly. This is encouraging, although we believe the discussions and actions thus far fall short of any tangible benefit (the May 1 law in China is valueless); but at least the discussion has opened.
- 2) Law Enforcement sees the need to deal with this Crisis at the distribution level, and universally sees addicts/users as the true victims they are.

- 3) Narcan as social responsibility. There are several unintended negative consequences of our nation's quick response of making Narcan readily available, but each use saves a life! The Surgeon General compares Narcan to the Heimlich maneuver or CPR. This is tremendously encouraging.
- 4) Passage of the INTERDICT and STOP Acts in the last Congress.
- 5) Introduction of SITSA and POWER acts in the last Congress.
- 6) The empaneling of *victims* of The Crisis by E&C Committee Chairman during the 115<sup>th</sup> Congress in anticipation of legislative activities. We recommend the 116<sup>th</sup> E&C Chairman do the same.
- 7) Myth/stigma-free discussions of the benefits of Medically Assisted Treatment (MAT)
- 8) Myth/stigma-free discussion of controversial harm-reduction concepts such as safe-shooting sites
  - a. The Actus Foundation is not here endorsing any specific harm-reduction method, but merely applauding the willingness to discuss any and all potential solutions.

#### D. Risks of politicizing

We turn to risks we see on the horizon. While response to The Crisis has mostly been non-partisan, there have been moments where certain lawmakers have behaved as political animals to the detriment of the dying children of The Crisis, which includes our daughter, Amanda Beatrice Rose (†2018):

- 1) Many lawmakers have been applauding the passage of a law (in China) making Fentanyl manufacturing a felony. As any businessman knows, the law in China is only worth the Party's willingness to enforce. Applauding this law as productive without GS Xi's personal commitment to do something productive with that law, will not move the needle one iota. We believe lawmakers know this, and their exuberance about the law is for show.
- 2) The same applies to the Southern Border. It is encouraging that we passed laws dealing with the USPS's place in The Crisis last year, and we are likewise encouraged that Mr. Barksdale is testifying today on what has developed within that context. We believe we should all recognize that the USPS, and other delivery services, are used to bring in kilotons of this poison, and that a myopic focus on the place of the Southern Border in The Crisis is a statement for political populism, for which there is no place when 100,000 young Americans are dying each year.
- 3) When SITSA was presented to the 115<sup>th</sup> Congress, it passed the house overwhelmingly – and generally without partisanship. However, two nights before the vote in the Senate, there was a criminally irresponsible article published in the Washington Post, which was devoid of facts, and only contained comment by one-sided extremists. Yet, that article and its use of the term “war-on-drugs” was enough to cause Senators on both sides of the aisle to abandon the provision, and STOP Act was sent to the President without the most important provision it contained. We wish we could figure a way to calculate how many young people died due to that disgraceful turn of events. If we could, it might serve as a sobering warning to avoid politics and just do the right thing.

## E. Summary

The reason for concern is that this is perhaps the greatest threat to our country since the cold war. Moreover, the combination of The Opioid Crisis and the rising of anti-American hate around the world are converging at a nexus where Fentanyl/Synthetic Opioid is waiting like a spark for a tinder box.

For instance, if we play partisan politics with the “war-on-drugs”, and dismiss out of hand any significant penalty increases intended to treat these chemicals as the WMDs that they are, we will allow the terrorists, who are surely watching what we do, to work out plans to exploit the greatest weapon they’ve ever known. Our Foundation has facts and figures to justify “Fentanyl Specific Legislation” as means to distinguish dealing in these chemicals from dealing in all other illicit drugs, because it is far more than a drug. Our position on this is easily dismissed as a redo of the “war-on-drugs” by people who want to politicize. However, how would they explain our position that penalties for all other “drugs” should be *reduced* since we believe that the war-on-drugs has clearly been ineffective. Yet, we seem to be much more effective at fighting terrorism, and Fentanyl will be a terrorist tool soon.

Perhaps more terrifying than anything else we see in The Crisis at this moment is an article in the WSJ (June 26, 2018) that provisional data shows that the US may see our first reduction in drug death in 20 years for the Y-O-Y period of 2017-2018. This is very clearly a false reduction in The Crisis caused by the masking characteristic of Narcan (one of the unintended negative consequences referred to above). While this is indeed a reduction in death and, as such, is indescribably valuable to the families spared of the death of their loved ones, it is a false reduction in the extent of The Crisis.

We explain: The only metric for deciding whether The Crisis is increasing, or decreasing is OD rates – fatal and non-fatal. How many kids are dying may be nothing more than an indication of how much Narcan is out there. How many are *overdosing*, whether they survive or not, tells us how bad the problem is in real terms. Therefore, we support an aggressive deployment of OD MAP Software.

If death data showing a nominal reduction is used by politicians to declare victory, we run the risks of taking our foot off the accelerator. That would indeed be tragic, since we have barely gotten geared up to take this problem on, and we have yet to find our footing with solutions for the new paradigm.

The Actus Foundation

The Founders of The Actus Foundation are Michael and Nancy Gray. The Grays are the parents of Declan Gray, 24, and Amanda Rose Gray, who was killed by a poisoning of straight Fentanyl on January 11, 2018 at the age of 24. The Gray family battled with acute mental illness throughout Amanda's life, and intermittent substance abuse in the last year before her passing.

Michael and Nancy founded The Actus Foundation, a 501(c)(3) charitable organization, in 2018. Our Foundation's purpose is to advocate for solutions for the forgotten mentally ill in the United States. While our country boasts a medical science infrastructure which is the envy of all the world, our treatment of the mentally ill, nascent as it was in the late 20<sup>th</sup> century, has since reverted a true state of antiquation. America's medical science is the fair-haired child we proudly show-off to the world, while behavioral science is something we sheepishly hide in the closet.

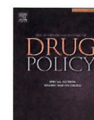
At present, one of the greatest threats to the mentally ill in America is the surge of dangerous synthetic opioids into our country's illicit drug market. The Actus Foundation advocates for solutions to treating the entirety of the overdose epidemic problem in America, including the largely forgotten constituency of *intermittent* users. Most notable among them are acutely mentally ill, who abuse opioids or other drugs (prescription and non-prescription) to the point of addiction and death in their search for symptom relief from tragically under-treated, and often undiagnosed, diseases.

The introduction of Fentanyl into the supply stream means all aspects of illicit drug use must be considered to save lives, since any single instance of illicit opioid use may lead to death. The time to see the threat as related only to addicts is long past. Michael Gray is a popular speaker, offering unique analyses and suggestions for creative solutions to a new problem, i.e., an old problem with a recently altered paradigm. Michael walks participants through the murky world of the drug problem clarifying the threat and dispelling myths.



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Research Paper

## Fentanyl test strips as an opioid overdose prevention strategy: Findings from a syringe services program in the Southeastern United States

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## ABSTRACT

**Background:** In 2016, the number of overdose deaths involving illicitly-manufactured fentanyl (IMF) surpassed heroin and prescription opioid deaths in the United States for the first time, with IMF-involved overdose deaths increasing more than 500% across 10 states from 2013 to 2016. IMF is an extremely potent synthetic opioid that is regularly mixed with heroin and often sold to unwitting consumers. Community-based organizations have started to distribute fentanyl test strips (FTS) as a strategy to identify IMF in street purchased products. We investigated the association between FTS use and changes in drug use behavior and perceived overdose safety among a community-based sample of people who inject drugs (PWID) in the United States.

**Methods:** Between September–October 2017, a total of 125 PWID completed an online survey about their most recent FTS use in Greensboro, North Carolina. Our first outcome of interest included whether PWID engaged in any of the following changes in drug use behavior after using FTS: used less than usual, administered tester shot, pushed syringe plunger slower than usual, and snorted instead of injected. Our second outcome of interest was whether PWID felt that FTS use made them feel better able to protect themselves from overdose. We conducted bivariate and multivariate analyses to determine the association between FTS use and these two outcomes.

**Results:** Overall, 63% of the sample reported a positive FTS test result and 81% reported using FTS prior to consuming their drugs. For the outcomes, 43% reported a change in drug use behavior and 77% indicated increased perceived overdose safety by using FTS. In multivariable models adjusting for demographic and FTS correlates, PWID with a positive FTS test result had five times the odds of reporting changes in drug use behavior compared to those with a negative result. PWID who used the FTS after drug consumption were 70% less likely to report behavioral changes at subsequent drug consumption compared to those who used it before consumption. PWID who were not existing clients of the syringe services program had four times higher odds than existing clients to report increased overdose safety from using FTS.

**Conclusions:** We found that using FTS and receiving a positive test result was associated with changes in drug use behavior and perceptions of overdose safety. FTS may represent an effective addition to current overdose prevention efforts when included with other evidence-based strategies to prevent opioid overdose and related harm.

## Introduction

The opioid overdose crisis in the United States continues to generate unprecedented levels of mortality. Over 63,000 people died from a drug overdose in 2016, with more than 60% of deaths involving an opioid (Hedegaard et al., 2017). In 2016, the number of overdose deaths involving illicitly-manufactured fentanyl (IMF) surpassed the number of heroin-involved deaths and prescription opioid-involved deaths for the first time, with IMF-involved overdose deaths increasing more than

500% across 10 states from 2013 to 2016 (O'Donnell, Halpin, Mattson, Goldberger, & Gladden, 2017). A recent report published by the Centers for Disease Control and Prevention (CDC) detected IMF in 56% of opioid overdose deaths (O'Donnell, Halpin, et al., 2017), with the highest burden in the Northeast and Midwest regions of the country and rising trends identified in the South and West (Peterson et al., 2016; Tomassoni et al., 2017). Postmortem toxicological reports from opioid overdose decedents have identified new polydrug combinations (e.g., alprazolam + gabapentin + IMF) that suggest the emergence of high-

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risk consumption patterns and complex clinical presentations (Dragovic et al., 2016; Marinetti & Ehlers, 2014).

Fentanyl is a synthetic opioid 50 times more potent by weight than heroin, with a rapid onset of action and relatively short duration of effect. The vast majority of fentanyl overdose deaths since 2013 involve IMF, not diverted prescription fentanyl. Manufactured in clandestine labs outside of the U.S., IMF typically enters the country alongside heroin and other illicit drugs through illicit channels before being sold by itself or used to adulterate heroin (Drug Enforcement Administration, 2017a). IMF includes fentanyl analogs (e.g., carfentanyl) that may be purchased on the internet and shipped through international postal services before being distributed throughout regional drug markets in the U.S. (Frank & Pollack, 2017). IMF has also been pressed into counterfeit prescription drugs, with fake versions of Oxy-Contin, Percodan, and Xanax linked to overdose outbreaks in several states (Green & Gilbert, 2016). In addition, IMF has been found on illustrated blotter paper commonly associated with paper tablets of lysergic acid diethylamide (LSD; Drug Enforcement Administration, 2015).

National estimates from the Drug Enforcement Administration show law enforcement seizures of IMF have increased substantially, from 4,697 reports in 2014 to 14,400 in 2015 (O'Donnell, Gladden, & Seth, 2017). This rapid growth in supply has led to increased saturation of IMF in existing and emerging heroin markets while exacerbating the opioid overdose risk environment by introducing a new level of difficulty for consumers as they try to parse out different “heroin” types and discern IMF from heroin (Somerville et al., 2017; Marshall et al., 2017). Due to a heightened risk environment and the urgent need to prevent and treat opioid overdose, several public health strategies established by harm reduction organizations have been implemented in high-burden communities throughout the U.S., including overdose education and naloxone distribution (OEND) programs and Good Samaritan Laws (Lambdin et al., 2018; McClellan et al., 2018; Strang et al., 2012; Walley et al., 2013).

Most recently, fentanyl test strip (FTS) technology has emerged as a drug checking strategy to address the fentanyl crisis. FTS was originally developed as a field immunoassay to screen for the presence of fentanyl in urine, but harm reduction organizations discovered that FTS can also detect fentanyl in illicit drug solutions. This realization has led many harm reduction organizations to distribute FTS to people who consume street opioids as an off-label approach to test street drugs for fentanyl (Harm Reduction Coalition, 2018). One type of FTS technology commonly distributed by harm reductions organizations is manufactured by BTNX, Inc., a Canadian biotechnology company that specializes in drug testing research and development.

A recent report compared BTNX's FTS technology with both Raman Spectroscopy (TruNarc machine) and Fourier-transform infrared spectroscopy (Bruker Alpha machine) to determine FTS's effectiveness for detecting fentanyl's presence (sensitivity) and absence (specificity) in street drug products (Johns Hopkins University, 2018). Among the three technologies, BTNX's FTS performed the best with the lowest detection limit (0.13 mcg/ml) and highest sensitivity (96% and 100%) and specificity (90% and 98%) for fentanyl, in addition to detecting 4-out-of-4 fentanyl analogs (two cases involving acetyl fentanyl and two cases involving furanyl fentanyl). These findings suggest that BTNX's FTS technology is effective and can be used off-label to detect the presence of fentanyl and several fentanyl analogs in street drug products.

Numerous international studies have demonstrated the utility of drug checking services for consumers of illicit drugs (Butterfield et al., 2016; Decorte, 2001; Giné et al., 2017; Harper et al., 2017; Hungerbuehler et al., 2011), especially MDMA testing among club and rave culture (Barratt et al., 2018; Mountney et al., 2016; Saleemi et al., 2017). A recent study in Rhode Island among young (aged 18–35 years) people who use drugs showed high levels (> 90%) of willingness to use FTS (Krieger et al., 2018). Comparably less is known about whether FTS

use can help facilitate safer drug use behavior and protect against overdose for this population (Prekupec et al., 2017).

The current study investigated behavioral outcomes associated with the off-label use of FTS among a community-based sample of people who inject drugs (PWID). The study was conducted at a harm reduction organization in the southeastern United States that recently started distributing FTS as part of their overdose prevention efforts. Our primary objective was to determine the influence of FTS results on drug use behavior and perceptions of overdose safety. Based on existing literature and our collective fieldwork experience, we hypothesized that PWID who received a positive FTS result would be more likely to change their drug use behavior than those who received a negative result.

## Methods

### Study sample

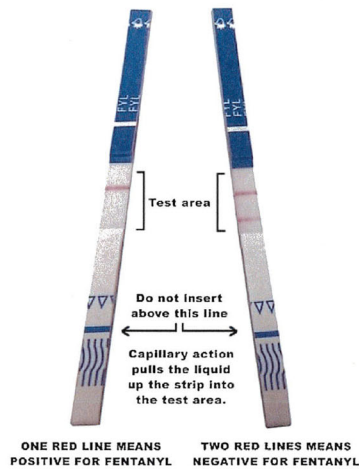
We administered anonymous online surveys to PWID in Greensboro, North Carolina to examine the association among self-reported FTS results and behaviors and attitudes. The study was conducted in September and October 2017 in collaboration with the Urban Survivors Union (USU), a community-based organization that provides syringe services and OEND programs to PWID. Study recruitment began on International Overdose Awareness Day (August 31, 2017) to publicize the study and maximize enrollment. Initial recruitment involved direct intercept with people receiving services at USU. Informational flyers were also posted at USU and made available for people to disseminate amongst their social networks. PWID interested in study participation visited USU's fixed site where they were referred to study staff for instructions on determining eligibility for the study. Eligibility criteria included being aged 18 years or older, having injected illicit opioids within the past 24 hours, and reporting having ever used FTS to test street drugs.

In the Spring of 2017, USU began distributing BTNX Inc.'s Rapid Response Fentanyl Test Strips as part of their overdose prevention strategy. BTNX FTS is a lateral flow chromatographic immunoassay that qualitatively detects the presence or absence of fentanyl and fentanyl analogs in urine but does not assess concentration levels. Positive and negative results are signified by single and double red lines, respectively (Fig. 1). USU offered FTS to program participants in combination with naloxone and overdose education literature, which included directions for how to use the FTS and a directive to use the strips prior to drug consumption (Asher, 2018; Harm Reduction Coalition, 2018).

Data collection occurred on computers made available at USU's SSP in Greensboro using a secured online data collection platform (SurveyGizmo, Boulder, Colorado). To ensure both anonymity and prevent duplicate responses, we implemented a quality control mechanism that used existing program participants' anonymous program identifiers as their study identification (ID). Study participants who were not already enrolled at USU were assigned a randomly-generated, unique identifier as their study ID. After respondents confirmed their eligibility and provided informed consent, they proceeded to a 20-minute online survey that asked about their most recent FTS use. Upon survey completion and verification by study staff, respondents were provided a \$20 Visa gift card as remuneration. The study protocol was approved through a full review by the institutional review board at RTI International.

### Survey measures

Data were collected using an online survey instrument pertaining to social and demographic characteristics, including age, gender, race/ethnicity, education, marital status, living situation, health insurance status, employment status, and quality of life. In addition, access to transportation was added based upon its identification as one of six key



variables for rural program access in a recent vulnerability assessment published by the CDC (Van Handel et al., 2016). FTS correlates included ever experiencing an opioid overdose, previous experience with naloxone (e.g., ever administered naloxone during overdose, received naloxone training), SSP utilization, purposively seeking fentanyl, FTS usage before or after drug consumption, and the FTS result from last test.

Participants were instructed to report on their behavior and perception as it related to the most recent FTS use. Several a priori measures of safer drug use behavior were identified by extensive community-based field work with PWID and further confirmed by discussions with key harm reduction stakeholders. Four safer drug use behaviors were combined to make a generalized drug use behavior variable (any behavior vs none): used less drug than usual; pushed syringe plunger slower than usual; administered tester shot; and snorted instead of injected. Of note, two other safer drug use behaviors—threw away the drugs ( $n = 0, 0\%$ ) and staggered drug use with injection partner ( $n = 1, 1.6\%$ )—were included on the survey, but due to sparseness, were not included in the generalized drug use behavior variable. Perceived overdose safety was assessed by asking participants, “Does using FTS make you feel better able to protect yourself from overdose?” (yes/no).

#### Statistical analysis

Descriptive statistics were calculated for demographics, FTS correlates, and the study outcomes. We employed a stepwise process to arrive at a parsimonious set of covariates for the final multivariable models (Hosmer & Lemeshow, 2000). First, we conducted bivariate analyses to determine significant associations between demographics and FTS correlates with changes in drug use behavior and perceived overdose safety using the  $\chi^2$  statistic, or Fisher's exact test in instances of small cell sizes. Variables that were significant at the  $P < 0.20$  level in the bivariate analyses were then included in multivariable logistic regression models. We used a backward selection process to retain covariates that were significantly associated with drug use behavior and perceived overdose safety at the  $P < 0.05$  level. Firth's penalized

**Table 1**  
Characteristics of Survey Respondents: Greensboro, NC, United States, September–October 2017.

Characteristics		Overall (N = 125)	
		n (%)	
Gender	Female	55	(44.0)
	Male	70	(56.0)
Age	20–29	28	(22.4)
	30–39	59	(47.2)
	40 +	38	(30.4)
Race	NH White	97	(77.6)
	NH Black	15	(12.0)
	Other <sup>a</sup>	13	(10.4)
Marital Status	Single	41	(32.8)
	Married/Partnership	45	(36.0)
	Separated/Divorced	39	(31.2)
Education	< College	55	(44.0)
	Some College	40	(32.0)
	Tech/College Graduate	30	(24.0)
Living Situation	Home/Apartment	87	(69.6)
	Shelter/Halfway House	13	(10.4)
	Park/Public Place	10	(8.0)
	Friends/Family	15	(12.0)
Employment Status	FT/PT	52	(41.6)
	Unemployed	61	(48.8)
	Retired/Disabled	12	(9.6)
Health Insurance Status	No	71	(56.8)
	Yes	54	(43.2)
Car Available to Drive	No	52	(41.6)
	Yes	73	(58.4)
Quality of Life	Poor/Fair	39	(31.2)
	Good/Excellent	86	(68.8)
Lifetime Overdose	No	65	(52.0)
	Yes	60	(48.0)
Naloxone Experience <sup>b</sup>	No	22	(30.2)
	Yes	103	(82.4)
SSP Client	No	68	(54.4)
	Yes	57	(45.6)
Wanted Fentanyl	No	86	(68.8)
	Yes	39	(31.2)
FTS Usage	Before	101	(80.8)
	After	24	(19.2)
FTS Result	Negative	46	(36.8)
	Positive	79	(63.2)

Abbreviations: NH, non-Hispanic; HS/GED, high school/general equivalency degree; Tech, technical school; FT/PT, full-time/part-time; SSP, syringe services program.

<sup>a</sup> Other races include Hispanic, Asian American, Pacific Islander, Native American, Alaska Native, and Multiracial.

<sup>b</sup> Naloxone experience includes “ever having administered naloxone to another person” or “ever having received training to administer naloxone”.

likelihood method was used to estimate the final models to address issues of separation and bias of the parameter estimates due to small sample sizes (Greenland & Mansournia, 2015). This computed adjusted odds ratios (aOR) and 95% confidence intervals (CI) for the demographics and FTS correlates associated with the outcomes. To test the robustness of our findings, we conducted a sensitivity analysis that



modeled associations between demographics and FTS correlates with changes in drug use behavior and perceived overdose safety only among those PWID who reported using FTS prior to drug consumption ( $n = 101$ ). Stata version 15.1 was used to execute all analyses.

## Results

A total of 129 PWID completed the online survey. Respondents who reported an uncertain FTS result ( $n = 4$ ) were excluded from analyses. Of the remaining 125 respondents, 56% were male, 70% were 20–39 years old, 78% were white, 24% were college or technical school graduates, 70% lived in a home/house, and 49% were unemployed (Table 1). Nearly half of the sample (48%) reported having experienced an overdose in their lifetime, while 82% reported previous experience with naloxone. More than three quarters of the sample (81%) reported using FTS before drug consumption and nearly one-third (31%) reported seeking fentanyl when performing the FTS test. Approximately two-thirds (63%) of the FTS results at last use were positive.

For the study outcomes overall, 43% of the sample reported changes in drug use behavior and 77% indicated that FTS increased their perceived overdose safety. Using less drug than usual was the most commonly reported change in drug use behavior (32%) followed by performing a tester shot (17%), snorting instead of injecting (10%), and pushing the plunger more slowly (9%). Based on the bivariate analyses, marital status, education, employment status, health insurance, naloxone experience, FTS usage, and FTS result were retained for further analysis with changes in drug use behavior, while age, race, employment status, and SSP client status were retained for perceived overdose safety.

In the final multivariable models (Table 2), unemployed PWID had lower odds of reporting changes in drug use behavior compared to employed PWID ( $aOR = 0.29$ , 95%  $CI = 0.13$ – $0.66$ ) and PWID who used FTS after drug consumption also had lower odds of changing drug use behavior compared to PWID who used FTS before consumption ( $aOR = 0.33$ , 95%  $CI = 0.11$ – $0.95$ ). PWID reporting a positive FTS result had higher odds than those with a negative result to report changes in drug use behavior ( $aOR = 5.08$ , 95%  $CI = 2.12$ – $12.17$ ). PWID aged 40 years and older had higher odds than people aged 20–29 years to report perceived overdose safety ( $aOR = 3.98$ , 95%  $CI = 1.18$ – $13.40$ ). Non-SSP clients had higher odds than existing clients to report increased perceived overdose safety ( $aOR = 4.06$ , 95%  $CI = 1.63$ – $10.13$ ).

The sensitivity analysis of PWID who used FTS before drug consumption ( $N = 101$ ) yielded highly comparable results to the analysis of the full sample ( $N = 125$ ). Among the subsample of 101 PWID, respondents who reported a positive FTS result had increased odds of changing their drug use behavior compared to respondents with negative FTS results ( $aOR = 4.88$ , 95%  $CI = 1.91$ – $12.46$ ); unemployed PWID had lower odds of reporting changes in drug use behavior compared to employed PWID ( $aOR = 0.21$ , 95%  $CI = 0.09$ – $0.55$ ); PWID aged > 40 years had higher odds than those aged 20–29 years reporting increased overdose safety ( $aOR = 4.03$ , 95%  $CI = 1.08$ – $15.02$ ); and non-SSP clients had higher odds than existing clients to report increased overdose safety ( $aOR = 4.51$ , 95%  $CI = 1.58$ – $12.88$ ).

## Discussion

This study examined the off-label use of FTS technology by PWID and its effect on changes in drug use behavior and perceptions of overdose risk. Of 125 PWID, nearly two-thirds (63%) reported a positive FTS result from their most recent use. PWID who reported positive FTS results had five times higher odds of changing their drug use behavior compared to those with negative results. Although we found no statistically significant association between FTS results and perceptions of overdose risk, a high percentage of respondents (77%) indicated that FTS made them feel more able to protect themselves from overdose.

In contrast to reports claiming that “opioid addicts” lack impulse

control and are unable to make healthy decisions (Grant et al., 2000; Jones et al., 2012; Volkow & Fowler, 2000), PWID’s capacity to make safer drug use decisions when confronted with test results has been well documented (Bandura, 1990; Celentano et al., 2002; Weinstein, 1989). One example consistent with our findings comes from the hepatitis C (HCV) literature and involves injection equipment serosorting: a disease prevention strategy whereby PWID choose injection partners based on disease status (e.g., HCV+) to reduce infectious disease transmission (Smith et al., 2013; van den Boom et al., 2014). In a national study of 9,690 PWID, Smith et al. (2013) found that PWID who received HCV antibody test results and knew their anti-HCV status were more likely than those with an unknown HCV status to engage in safer injection behaviors (e.g., sharing injection equipment only with partners of concordant disease status).

Our study employs the logic of serosorting to situate “drug checking” with FTS as a test that can influence PWID’s decision to practice safer drug use behaviors based on the result. In the current analysis, PWID who reported a positive test result at last use were significantly more likely to change drug use behavior compared to those with a negative test result ( $aOR = 5.1$ , 95%  $CI = 2.1$ – $12.2$ ). Like serosorting, this finding provides additional evidence that PWID, when receiving test results indicating potential harm, can change how they inject drugs to prevent adverse health outcomes.

Another notable finding is that over three-quarters of our sample (81%) reported using FTS to test their drugs prior to consuming them. This contrasts with a recent Canadian study that found only 38% of PWID used FTS before consumption (Lysyshyn et al., 2017). As our study found that respondents who used FTS after consumption had lower odds of reporting changes in drug use behavior, it is possible that discrepancies between studies emerged due to the Canadian study recruiting PWID from a supervised consumption site (SCS). SCSs are staffed by health professionals and PWID may be less motivated to use FTS before consuming street-purchased opioids because they are using them in a safe environment (Kennedy et al., 2018; Kerr et al., 2017; Kral & Davidson, 2017). In the absence of SCSs, the high percentage of FTS use before consumption in the current study suggests that PWID are willing to use FTS as an added strategy to protect against fentanyl overdose and preempt the need for emergency interventions (e.g., naloxone, EMS, acute hospitalization).

The impact of FTS distribution on service utilization is also noteworthy. Slightly over half of our sample (54%) were non-SSP participants, and this group had four times higher odds than existing SSP clients to report FTS increased overdose safety. Studies in the U.S. show that SSPs provide direct harm reduction services to only a small proportion of PWID in a given community or locality (Lorvick et al., 2006; Riley et al., 2010). Results from this study provide evidence that FTS distribution may represent a cost-effective strategy to increase program participation among PWID not currently utilizing harm reduction services in their community.

Nearly one-third (31%) of our study sample reported wanting fentanyl when testing their most recently purchased street drugs. This finding is consistent with another study that found 26% of respondents ( $N = 256$ ) reported their preference for fentanyl (Johns Hopkins University, 2018). Ethnographic research suggests that recent shifts in illicit opioid preferences may be a function of the specific psychoactive effects associated with fentanyl (Ciccarone et al., 2017), such as a stronger “rush” compared to heroin (Armenian et al., 2018). Increased preference for fentanyl may also reflect IMF’s growing saturation in illicit drug markets and associated increases in (witting and unwitting) fentanyl exposure that can result in exacerbated physical dependence and greater tolerance among PWID (Cicero, Ellis, & Kasper, 2017; Helander, Backberg, Signell, & Beck, 2017; Marshall et al., 2017; Somerville et al., 2017). Together, these findings may represent a growing proportion of PWID who prefer IMF and IMF-adulterated heroin over heroin alone.

Further complicating fatal overdose risk are recent reviews



**Table 2**  
Multivariable Logistic Regression Models of Associations with Changed Drug Use Behavior and Perceived Overdose Safety.

Correlates	Changed Drug Use Behavior			Perceived Overdose Safety		
	Prevalence		Adjusted <sup>a</sup> aOR (95% CI)	Prevalence		Adjusted <sup>a</sup> aOR (95% CI)
	n (%)			n (%)		
Gender						
Female	27 (49.1)	—		42 (76.4)	—	
Male	27 (38.6)	—		54 (77.1)	—	
Age						
20–29	12 (42.9)	—		18 (64.3)	1.00	
30–39	23 (39.0)	—		46 (78.0)	2.42	(0.86–6.83)
40+	19 (50.0)	—		32 (84.2)	3.98	(1.18–13.40)
Race <sup>b</sup>						
NH White	41 (42.3)	—		75 (77.3)	—	
NH Black	8 (53.3)	—		14 (93.3)	—	
Other	5 (38.5)	—		7 (53.8)	—	
Marital Status						
Single	12 (29.3)	—		30 (73.2)	—	
Married/Partnership	22 (48.9)	—		38 (84.4)	—	
Separated/Divorced	20 (51.3)	—		28 (71.8)	—	
Education						
< College	22 (40.0)	—		43 (78.2)	—	
Some College	14 (35.0)	—		31 (77.5)	—	
Tech./College Graduate	18 (60.0)	—		22 (73.3)	—	
Living Situation						
Home/Apartment	40 (46.0)	—		64 (73.6)	—	
Shelter/Halfway House	5 (38.5)	—		11 (84.6)	—	
Park/Public Place	2 (20.0)	—		9 (90.0)	—	
Friends/Family	7 (46.7)	—		12 (80.0)	—	
Employment Status						
FT/PT	31 (59.6)	1.00		36 (69.2)	—	
Unemployed	18 (29.5)	0.29	(0.13–0.66)	48 (78.7)	—	
Retired/Disabled	5 (41.7)	0.63	(0.15–2.58)	12 (100.0)	—	
Health Insurance Status						
No	27 (38.0)	—		57 (80.3)	—	
Yes	27 (50.0)	—		39 (72.2)	—	
Car Available to Drive						
No	21 (40.4)	—		39 (75.0)	—	
Yes	33 (45.2)	—		57 (78.1)	—	
Quality of Life						
Poor/Fair	17 (43.6)	—		28 (71.8)	—	
Good/Excellent	37 (43.0)	—		68 (79.1)	—	
Lifetime Overdose						
No	31 (47.7)	—		47 (72.3)	—	
Yes	23 (38.3)	—		49 (81.7)	—	
Naloxone Experience <sup>c</sup>						
No	5 (22.7)	—		18 (81.8)	—	
Yes	49 (47.6)	—		78 (75.7)	—	
SSP Client						
No	27 (39.7)	—		59 (86.8)	4.06	(1.63–10.13)
Yes	27 (47.4)	—		37 (64.9)	1.00	
Wanted Fentanyl						
No	35 (40.7)	—		67 (77.9)	—	
Yes	19 (48.7)	—		29 (74.4)	—	
FTS Usage						
Before Drug Consumption	48 (47.5)	1.00		76 (75.2)	—	
After Drug Consumption	6 (25.0)	0.33	(0.11–0.95)	20 (83.3)	—	
FTS Result						
Negative	10 (21.7)	1.00		36 (78.3)	—	
Positive	44 (55.7)	5.08	(2.12–12.17)	60 (76.0)	—	

Abbreviations: NH, non-Hispanic; HS/GED, high school/general equivalency degree; Tech, technical school; FT/PT, full-time/part-time; SSP, syringe services program.

<sup>a</sup> The adjusted models retained covariates that achieved significance at the  $P < 0.05$  level using a backward stepwise procedure.

<sup>b</sup> Other races included Hispanic, Asian American, Pacific Islander, Native American, Alaska Native, and Multiracial.

<sup>c</sup> Naloxone experience includes “ever having administered naloxone to another person” or “ever having received training on how to administer naloxone.”.

identifying strong links between economic instability and “deaths of despair” (i.e., deaths from drug overdose, alcohol-related disease, and suicide) in states hard hit by the opioid epidemic (Case & Deaton, 2017; Diez Roux, 2017; Rudd et al., 2016; Zibbell et al., 2017). Our study found that unemployed PWID had lower odds of reporting changes in drug use behavior compared with employed PWID. This finding highlights the impact economic instability exerts on drug use behavior and

overdose risk, especially among PWID who experience homelessness, unemployment, incarceration, eviction, and residential transience (Galea & Vlahov, 2002). These “root” causes of the ongoing opioid crisis need further exploration (Dasgupta et al., 2018). Targeted outreach efforts, tailored interventions, and referral to specialty services are necessary to provide supplemental support for economically disadvantaged PWID.

The use of FTS as a primary overdose prevention strategy is gaining traction and rapidly becoming a component of harm reduction programs in the U.S. At present, however, there is a paucity of evidence on their safety and efficacy, and numerous questions remain as to whether their use can indeed reduce overdose risk. Qualitative research (Marshall et al., 2017; Somerville et al., 2017), including rapid assessment ethnography (Ciccarone, 2017), can serve as key supports of implementation science when examining drug checking technologies (Barratt et al., 2018). Further studies that investigate attitudes and risk-reduction behaviors associated with FTS use, including barriers to behavioral change, would also benefit from direct observation in real world settings. For example, field research can aid in studying the correlation between consumer perceptions and discernment of fentanyl with FTS detection alongside gold standard gas/liquid chromatography coupled with mass spectrometry. With reports of fentanyl increasingly being detected in non-opioid drugs like cocaine and methamphetamine (Marinetti & Ehlers, 2014; Seth et al., 2018), clinical and toxicological studies are needed to address the issue of fentanyl testing in different drug classes or different source-forms of heroin (e.g., black tar).

#### Limitations

These results should be considered in light of several potential limitations. The generalizability of this study is limited, given that data were from just one community in the southeastern U.S. According to the Drug Enforcement Administration, IMF is more prevalent in Greensboro, NC and other states east of the Mississippi River, regions where heroin powder is dominant and can be more easily mixed with IMF (also a powder), compared to western states like California, New Mexico and Texas where black tar heroin is dominant and more difficult to adulterate with IMF (Drug Enforcement Administration, 2017b). The small sample size limited our ability to derive more precise estimates in the multivariable analyses, although stepwise and sample size penalization procedures improved model parsimony. Limited sample size also precluded a more thorough examination of FTS use with the four changes in drug use behaviors. Because the survey was taken anonymously, it is possible that some respondents could have participated twice and double counted in the sample, particularly persons not already enrolled at USU and unfamiliar to SSP staff. We suspect subject duplication was minimal, however, given the short time frame of the study (two months) and its rigorous, in-person enrollment procedures. In addition, a small proportion of the total sample (3%) reported an uncertain FTS result, a finding comparable to other recent FTS studies (Harm Reduction Coalition, 2018; Health Canada, 2017; Johns Hopkins University, 2018). Our study suggests, however, that the effects of FTS use on drug use behavior outweigh the very small likelihood of an uncertain result. As the general population is still encouraged to use other common types of health protections (e.g., condoms, over-the-counter pregnancy tests) despite being subject to diagnostic error or improper use, the public health message that PWID not use FTS and assume that all street drugs are tainted with IMF may be counterproductive regarding informed decision-making and maintaining an internal locus of control (Celentano et al., 2002; Mitchell et al., 2017). Larger prospective studies are now needed to further evaluate patterns of FTS use and the types of changes in drug use behavior that can lead to reductions in opioid overdose, including the need to develop strategies in situations of product uncertainty.

The current study suggests that FTS use has the potential to facilitate changes in drug use behavior among PWID, but the question as to whether FTS can lead to reductions in overdose was beyond the study's scope and requires further investigation. Nevertheless, the need for more evidence should not prevent community-based organizations and public health agencies from distributing FTS as part of a comprehensive overdose prevention strategy. When seen in this light, FTS can follow the path of syringe exchange and lay naloxone distribution, interventions initially developed by harm reduction activists and organizations

before adequate evidence was available and prior to being endorsed by state and federal public health agencies. A recent commentary recommends a similar approach for FTS, echoing the importance of additional research and the need to provide FTS within a package of evidence-based harm reduction services (McGowan, Harris, Platt, Hope, & Rhodes, 2018). In addition to FTS, there remains a need to evaluate other types of drug checking technologies, including portable chromatography and spectroscopy devices that can be utilized onsite at SSPs and SCSs, or through community-based drop-off laboratories and mail order tests that provide more comprehensive drug panels. Given an increasingly lethal fentanyl risk environment, FTS technology represents a low-cost and timely strategy that can inform evidence-based overdose prevention and provide the foundation for developing safer drug use practices for PWID.

#### Contributors

Jon. E. Zibbell, Nicholas C. Peiper, Dan Ciccarone, and Louise B. Vincent originated the idea and design for this article. Nicholas C. Peiper, Sarah Duhart Clarke, and Alex H. Kral analyzed the data. Nicholas C. Peiper and Sarah Duhart Clarke created the figures and tables. Nicholas C. Peiper, Jon E. Zibbell, Sarah Duhart Clarke, and Dan Ciccarone conducted literature searches and wrote the article. This manuscript has been approved by all authors and is not being reviewed or considered for publication at another journal.

#### Conflict of interest

The authors declare no conflicts of interest.

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**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Hearing on  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

**July 16, 2019**

**Mr. Kemp Chester, Assistant Director of the National Opioids and Synthetics Coordination Group, Office of National Drug Control Policy, Executive Office of the President**

**The Honorable Frank Pallone, Jr. (D-NJ)**

1. A key role of the Office of National Drug Control Policy (ONDCP) is to coordinate the federal agencies that have responsibility for the prevention, treatment, and enforcement of drug control activities in the United States. In your testimony, you cite ONDCP efforts to coordinate these agencies in addressing the fentanyl crisis, including through meetings, video teleconferences, and webinars.
  - a. What has been the effect of this coordination? What tangible results have occurred because of these coordination efforts?

**ANSWER:** The Office of National Drug Control Policy (ONDCP) leads the interagency effort to implement the *National Drug Control Strategy* (NDCS), which clearly establishes the strategic framework that guides the Federal Government’s efforts to reduce both the supply and the demand for illicit fentanyl and its analogues in the United States, and indeed all drugs that are harming individuals and negatively impacting the safety of America’s communities.

The three fundamental elements that form the heart of the NDCS -- prevention, treatment and recovery, and reducing availability -- are complementary and mutually supporting. Implementation includes preventing initiates to illicit drug use through education and evidence-based prevention programs. It also involves providing treatment services leading to long-term recovery for those suffering from substance use disorder. By reducing the number of individuals who use illicit drugs, we diminish the market forces pulling illicit drugs across our borders and into our communities.

To reduce the availability of illicit drugs, ONDCP works with our international partners to combat illicit internet drug sales and educate them and others with respect to mail and express consignment delivery services. Domestically, ONDCP works with Customs and Border Protection (CBP) to prevent illicit drugs from entering the United States at the borders and ports of entry and with the Treasury Department to identify and forfeit drug proceeds.

ONDCP’s monthly coordination engagements are outlined in the response to question 2b below. The most tangible result has been the increase in interagency liaisons detailed to the Federal fusion centers and task forces outlined in the response to question 2a below. More recently, the



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addition of 13 counties across 12 states to ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program (<https://www.whitehouse.gov/briefings-statements/ondcp-designates-13-new-counties-curb-drug-trafficking/> and <https://www.whitehouse.gov/wp-content/uploads/2017/12/HIDTA-Map.pdf>) speaks to the continued successful coordination of Federal, State, local, and tribal law enforcement agencies combating drug activities in the United States. In August 2019, ONDCP coordinated the interagency release of four advisories addressing the manufacturing, marketing, movement, and money associated with illicit fentanyl trafficking (<https://www.whitehouse.gov/wp-content/uploads/2019/08/White-House-Fentanyl-Advisories-Summary.pdf>).

b. How does ONDCP measure success as it relates to addressing the fentanyl crisis?

**ANSWER:** The number one measure of ONDCP's success is reducing the number of Americans dying from drug overdose. Additional measures of success can be found in ONDCP's National Drug Control Strategy Performance Reporting System ([https://www.whitehouse.gov/wp-content/uploads/2019/05/ONDCP\\_PRS.pdf](https://www.whitehouse.gov/wp-content/uploads/2019/05/ONDCP_PRS.pdf)).

2. Some agencies have told the Committee they have experienced difficulties receiving information or data from other agencies that could be helpful in identifying leads or developing cases related to illicit fentanyl.

a. What issues has ONDCP identified in information sharing between agencies working to counter the threat of fentanyl?

**ANSWER:** Efforts such as ONDCP's HIDTA program, DOJ's Organized Crime and Drug Enforcement Task Forces, and CBP's National Targeting Center leverage state, local, tribal, and Federal partners to ensure that all agencies are working to counter the threat of fentanyl. They share information, are properly resourced, and are able to maximize unique capabilities and capacity. ONDCP fully supports these fusion cells and centers of excellence.

b. What steps has ONDCP taken to resolve those issues, and what have been the results?

**ANSWER:** In an effort to increase connectivity and facilitate interagency collaboration, ONDCP hosts monthly engagements across Federal, state, local, and tribal professionals.

- Weekly classified secure video teleconferences (SVTCs) focus the intelligence community, to include five eye partners, on the collection, analysis, and production needed to answer policymaker questions and share intelligence.
- Monthly video teleconference (VTC) with U.S. Embassy Mexico emphasizes U.S. priorities in Mexico such as eradication, lab identification, and capacity building in Mexico.
- Monthly VTC with U.S. Embassy Beijing coordinates policy on the U.S. approach with China to address fentanyl and synthetic opioids.

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- Monthly Federal law enforcement SVTCs facilitate information sharing on major active cases between Federal law enforcement agencies to ensure coordination of all Federal capabilities.
- Monthly nationwide webinars provide a platform for partner states (five per U.S. census region) to collaborate and share public health and public safety trends, best practices, and lessons learned.

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**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Hearing on  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

**July 16, 2019**

**Mr. Kemp Chester, Assistant Director of the National Opioids and Synthetics Coordination  
Group, Office of National Drug Control Policy, Executive Office of the President**

**The Honorable Brett Guthrie (R-KY)**

1. In October 2017, the U.S. Department of Justice announced the first indictments against Chinese nationals who were manufacturers and distributors of fentanyl. Even though there is little prospect that the Chinese nationals will ever be in an American courtroom, what is the purpose and impact of indicting Chinese nationals for illicit fentanyl trafficking?

**ANSWER:** The formal indictment and designation of these individuals as Consolidated Priority Organization Targets, or CPOTs, is crucial. These procedures create additional opportunities for law enforcement agencies, domestic and international, to disrupt and dismantle the criminal apparatus supporting these individuals and their international drug trafficking actions. Without these indictments or designations, future law enforcement actions may be limited.

In addition, Federal indictment of Chinese drug traffickers can result in official designation by the Treasury Department’s Office of Foreign Asset Control (OFAC) for sanctions of these targets under the Foreign Narcotics Kingpin Designation Act (Kingpin Act). These sanctions have an immediate and visceral effect on drug traffickers. Upon a sanctions designation, all property and interests in property of these individuals and entities that are in the United States or in the possession or control of U.S. persons must be blocked and reported to OFAC. OFAC’s regulations generally prohibit all dealings by U.S. persons or within (or transiting) the United States that involve any property or interests in property of blocked or designated persons. The sanctions therefore cut off Chinese drug traffickers from their existing assets and generally prevent them from engaging in any commerce that involves the United States or any interests that touch the U.S. economy.

2. How many different fentanyl analogs have been identified as coming from China?

**ANSWER:** Between 2010 and July 2019, fentanyl plus at least 39 unique fentanyl analogues have been seen in Federal, state, local, and international forensics laboratories, many if not all are believed to be of Chinese origin.

3. What are some of the common ways in which fentanyl is trafficked from China to the United States?

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**ANSWER:** The most common method is transshipment through Mexican drug trafficking organizations (DTOs). This has generally occurred at our Southwest border. According to the United States Postal Inspection Service (USPIS), synthetic opioid and fentanyl seizure statistics for Fiscal Year 2019 illustrated a sharp decrease in international seizures, while domestic seizures have correspondingly increased. A majority of these domestic mailings originated from states close to the Southwest border, such as California and Arizona. USPIS has also seen an increase in smaller mailings originating from Canada. Other methods of for fentanyl to be trafficked from China to the United States include bulk shipments, 100 to 1,000 grams, through express consignment carriers (e.g., FedEx, UPS, DHL) and smaller quantity shipments, under 100 grams, through the United States Postal Service.

4. Diplomacy and law enforcement each have a vital role in the fight against fentanyl. However, like the efforts against rogue internet pharmacies a few years ago, I understand a strategy for disrupting operations and creating risk is also a part of the overall approach. To the extent appropriate, please describe the United States strategy for the disruption of illicit fentanyl trafficking.

**ANSWER:** The Office of National Drug Control Policy (ONDCP) leads the interagency effort to implement the *National Drug Control Strategy* (NDCS), which clearly establishes the strategic framework that guides the Federal Government's efforts to reduce both the supply and the demand for illicit fentanyl and its analogues in the United States, and indeed all drugs that are harming individuals and negatively impacting the safety of America's communities.

The three fundamental elements that form the heart of the NDCS -- prevention, treatment and recovery, and reducing availability -- are complementary and mutually supporting. Implementation includes preventing initiates to illicit drug use through education and evidence-based prevention programs. It also involves providing treatment services leading to long-term recovery for those suffering from substance use disorder. By reducing the number of individuals who use illicit drugs, we diminish the market forces pulling illicit drugs across our borders and into our communities.

To reduce the availability of illicit drugs, ONDCP works with our international partners to combat illicit internet drug sales and educate them and others with respect to mail and express consignment delivery services. Domestically, ONDCP works with Customs and Border Protection to prevent illicit drugs from entering the United States at the borders and ports of entry and with the Treasury Department to identify and forfeit drug proceeds.

5. What are some of the ballooning effects we could see if the scheduling of fentanyl in China is effective in reducing the supply coming from China?

**ANSWER:** The Chinese class scheduling action may lead drug manufacturers and traffickers to shift their manufacturing and trafficking efforts to fentanyl analogues outside of the class scheduling or to non-fentanyl synthetic opioids to circumvent law enforcement. Criminals may also shift Chinese production to ingredients, or precursors, needed to make fentanyl, and produce fentanyl closer to the U.S. market.



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- a. If so, do we expect there to be a shift of fentanyl production to other countries, like India?

**ANSWER:** We may indeed see drug traffickers in other countries begin to supply, or amplify their current trafficking of illicit fentanyl, fentanyl-related substances, non-fentanyl synthetic opioids, and their precursors. Currently, these are primarily produced overseas in countries with large chemical or pharmaceutical industries, particularly China. Manufacturers in other countries, such as India, the Netherlands, and Bangladesh, have the potential to become increasingly involved in supplying illicit synthetic opioids and their precursors if substantial law enforcement action is conducted by China to dramatically disrupt the flow of these illicit drugs into the United States. We may also begin to see drug traffickers in Mexico become more independent in synthesizing precursors and illicit drugs for their U.S.-bound illicit fentanyl, fentanyl-related substances, and non-fentanyl synthetic opioids. Finally, we may see domestic manufacturing develop within our own borders.

Within the annual Heroin Availability Reduction Plan (HARP), ONDCP works with our interagency partners to identify future trends and conduct a gap analysis to reshuffle priorities. Through our U.S. Embassy Mexico engagements we have seen Mexico take steps to disrupt domestic fentanyl production. Similarly, we have engaged our interagency partners and the intelligence community to identify any changes to the illicit drug market to include significant changes in global flows, geographic transitions from plant-based to synthetic-based markets, and diversion or production within the United States.

6. Is there reason to believe that pharmaceutical or chemical companies produce fentanyl as a third-shift operation at Chinese pharmaceutical factories?

**ANSWER:** At present there is insufficient information to make a determination on this question. Whether fentanyl or its analogues are manufactured during normal business operations with the witting complicity of the business owners and operators, or as a so-called “third-shift operation” by clandestine actors at the same facility, is difficult to determine. Further, it is also difficult to determine why certain chemicals that have legitimate and licit uses are manufactured, whether they be expressly for the purpose of supplying the illicit drug trade, or for legitimate uses but are later diverted away from the intended legitimate market.

- a. If so, is such intelligence shared with the U.S. Food and Drug Administration (FDA) to see if any of the factories are associated with drug manufacturers registered with the FDA?

**ANSWER:** To the maximum extent possible, ONDCP makes every effort to share intelligence among Federal Departments and Agencies and, when possible, with our international partners. ONDCP routinely hosts classified community of interest meetings to share both policy and intelligence on a weekly and monthly basis. It is ONDCP’s and the United States intelligence community’s routine practice to share actionable intelligence in a timely fashion across the United States Government to include the Food and Drug Administration. This effort is enhanced by the concerted effort of the intelligence community to establish intelligence liaisons across many Federal Departments and Agencies.

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7. Do we expect a shift to other drugs such as methamphetamine and cocaine?

**ANSWER:** Multiple shifts may occur in this dynamic environment. It is possible shifts could occur across drug classes (e.g., from fentanyl to methamphetamine or cocaine) or within drug classes (e.g., from fentanyl to U-series non-fentanyl synthetic opioids) and be user or manufacturer driven. Through the annual HARP update and the various HARP webinars, ONDCP is uniquely suited to identify these shifts and posture the Federal response accordingly.

8. What are some of the challenges that still exist when it comes to combating the fentanyl problem in the United States?

**ANSWER:** The greatest challenge is the expiring temporary class-wide scheduling of fentanyl-related substances (expires February 2020) and the lack of permanent class scheduling of fentanyl analogues. Expiration of the temporary order will leave a gap in U.S. law regarding fentanyl analogues. We fully expect drug traffickers to exploit that void. We will likely see a surge in smuggling of fentanyl analogues into the United States by all means possible. An increased amount of fentanyl and its analogues in the United States would be disastrous, given our ongoing efforts save lives from drug use. Prosecutions under the Analogues Act of substances previously emergency controlled would be affected, as a drug's lapse in control status could affect prosecution outcomes. This would be an enormous setback in our efforts to stem the opioid crisis in the United States. Similarly, if the United States fails to make class scheduling of fentanyl analogues permanent, we will lose substantial credibility with other international partners. If we fail to permanently schedule illicit fentanyl analogues and non-fentanyl synthetic opioids, we risk serious damage to our domestic effort to save lives and our ability to lead on this and similar issues internationally. At the same time, we must also ensure access to these substances for legitimate scientific research that may lead to the development of new treatments or other scientific advances that could help mitigate the opioid crisis.

9. How do we anticipate the threat changing over the next few months if the scheduling of fentanyl in China is effective?

**ANSWER:** The Chinese class scheduling action may lead drug manufacturers and traffickers to shift their manufacturing and trafficking efforts to fentanyl analogues outside of the class scheduling or to non-fentanyl synthetic opioids to circumvent law enforcement. Similarly, we may see drug traffickers in other countries begin to supply, or amplify their current trafficking of illicit fentanyl, fentanyl-related substances, non-fentanyl synthetic opioids, and their precursors. These are currently primarily produced overseas in countries with large chemical or pharmaceutical industries, particularly China. Manufacturers in other countries, such as India, the Netherlands, and Bangladesh, have the potential to become increasingly involved in supplying illicit synthetic opioids and their precursors if substantial law enforcement action is conducted by China to dramatically disrupt the flow of these illicit drugs into the United States. We may also begin to see drug traffickers in Mexico become more independent in synthesizing precursors and illicit drugs for their U.S.-bound illicit fentanyl, fentanyl-related substances, and non-fentanyl synthetic opioids. Finally, we may see domestic manufacturing develop within our own borders.

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10. What synthetic opioids could emerge as alternatives to fentanyl if Chinese fentanyl restrictions are effective?

**ANSWER:** Any suspected non-fentanyl synthetic opioid, or analogue thereof, could emerge if Chinese fentanyl and fentanyl-class restrictions are effective. This includes, for example, U-series drugs like U-47700 and analogues of tramadol.

11. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?

**ANSWER:** The latest increases in funding for the National Intelligence Program and the Military Intelligence Program should prove helpful across the intelligence community in improving interdiction efforts. Equally important is the recent elevation in priority of Counter Drug (CD) and Counter Transnational Organized Crime (CTOC) among the National Intelligence Priority Framework (NIPF) and the President's Intelligence Priorities.

**Questions for the Record  
Matthew Donahue  
Regional Director North and Central Americas  
Operation Division  
Drug Enforcement Administration  
U.S. Department of Justice**

**U.S. House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations  
Hearing Entitled  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”  
July 16, 2019**

**Questions from Rep. Pallone, Jr.**

- 1. Please explain how the United States Drug Enforcement Administration (DEA) is addressing the use of the Dark Net to facilitate fentanyl purchases, including by responding to the following:**

**Response:**

The DEA has established or contributes to several initiatives that address the dark net; specifically fentanyl distribution. These initiatives include the Cyber Support Section (CSS), the Virtual Currency Initiative (VCI), National Cyber Investigative Joint Task Force (NCIJTF) and the Joint Criminal Opioid and Dark Net Enforcement Team (JCODE). The CSS provides processes that enable investigators to thoroughly investigate vendors on the dark net selling narcotics to include fentanyl. These processes include: training on establishing an operational plan to investigate vendors; ability to purchase evidence, such as controlled substances, paraphernalia, and merchandise used in the manufacturing of controlled substances like pill presses, utilizing virtual currency; support in utilizing appropriate methods in identifying vendors; and search warrant and seizure support. The VCI provides the ability to leverage money laundering schemes utilized by the vendors in order to fully disrupt this nefarious activity. Since dark net vendors utilize virtual currency, schemes are deployed to launder the illicit funds. DEA is also a participating member of JCODE, a program designed to disrupt and dismantle dark net illicit marketplaces facilitating the distribution of fentanyl and other opioids. JCODE is led by the FBI and coordinated through the DEA-led Special Operations Division (SOD) with participation from several federal law enforcement partner agencies to launch a coordinated government effort to attack dark net marketplaces.

- a. Whether DEA routinely shares information regarding Dark Net purchases with other agencies, including whether and in what circumstances DEA shares information with U.S. Customs and Border Protection (CBP) so that**

**CBP can use this information to target and interdict fentanyl shipments through its automated targeting tool; and**

**Response:**

CBP is a participating member of JCODE. DEA routinely provides CBP with information regarding trafficker identities, shipping methodologies, and locations through the JCODE process. Furthermore, the deconfliction, coordination, and sharing of information among the interagency partners continues throughout the investigative process through JCODE and SOD. Additionally, a CBP representative from the CBP-National Targeting Center is also assigned to DEA SOD to facilitate the exchange of intelligence and investigative collaboration between CBP and interagency that are represented at SOD. DEA participates on the National Cyber Investigative Joint Task Force (NCIJTF) which also has a representative from CBP. Many of the dark net market monikers and virtual currency addresses are exploited and shared in and by the NCIJTF. DEA also shares physical addresses, shipment methods, and routes with its interagency partners.

- b. Whether DEA conducts controlled buys on the Dark Net mainly for individual prosecutions, or whether it systemically uses this data to disrupt the marketplace, such as by using credit card information or shipping information to identify and eliminate the means and incentives to traffic fentanyl.**

**Response:**

DEA conducts controlled buys for individual investigations and prosecutions. It also exploits cash out methods utilized by vendors to support the overarching goal of disrupting and dismantling dark net marketplaces. Evidence obtained from individual buys will be used by the prosecution to prove the totality and depth of culpability against marketplace administrator(s). DEA takes a holistic approach to targeting the entire chain of bad actors utilizing the dark net to purchase and distribute controlled substances, including fentanyl. DEA targets the administrators, moderators, and individual buyers and sellers. Targeting just one part of this chain will only result in the criminal activity moving to another dark net marketplace. Gathering evidence and intelligence regarding means and methodology is just as important as securing specific seizures, arrests, and prosecutions.

National Targeting Center-Cargo Division currently has a representative that reports to JCODE on a routine basis to facilitate the exchange of information. A DEA representative assigned to the Office of Diversion Control is imbedded with the CBP-NTC facilitate the exchange of intelligence and investigative collaboration between CBP and interagency that are represented at SOD.

**Questions from Rep. Guthrie****2. What has been the impact of the temporary emergency scheduling of all fentanyl-related substances as Schedule I drugs since February 2018?****Response:**

In recognition of the heretofore unseen escalation in opioid-related overdoses, on February 6, 2018, DEA used its authority under Section 201 of the Controlled Substances Act (CSA) to place all non-scheduled fentanyl-related substances into Schedule I *temporarily*, on an emergency basis, for two years to combat the practice of unscrupulous chemists altering fentanyl-related substances to circumnavigate existing law. The positive effects in the two years since implementation are significant. The class control has substantially slowed the rate at which new fentanyl-related substances are introduced to, and are encountered in, the illicit market. Prior to this action, DEA observed a rapid and continuous emergence of new fentanyl-related substances each time it scheduled a specific fentanyl-related substance. Under the temporary emergency scheduling order, there is little incentive for drug trafficking organizations to invent new substances in the fentanyl family for the purpose of evading DEA's control. Specifically, DEA laboratories have not encountered any new fentanyl analogue substances through fiscal year (FY) 2019. Additionally, in the two years since temporary scheduling, DEA has permanently scheduled seven fentanyl-related substances and is currently working with our colleagues at the Department of Health and Human Services (HHS) to schedule 12 more.

Congress has extended this temporary order by an additional 15 months so the temporary order controlling fentanyl-related substances in the United States will now expire on May 6, 2021, without any further action. At that time, any substance that meets the definition of a fentanyl-related substance will no longer be expressly identified as subject to regulatory control under the CSA, except for substances that DEA has identified and for which DEA has requested HHS to prepare a scientific and medical evaluation and to make a scheduling recommendation. At that point, DEA expects the renewed emergence of new fentanyl-related substances on the illicit market consistent with previous attempts to circumvent largely reactive, substance-specific control measures. DEA looks forward to continuing its work with Congress and its interagency partners to find a permanent solution to this fentanyl crisis.

The Department of Justice and DEA have worked closely with the Government of China and Chinese law enforcement to bring attention to and help combat the rise of illicit fentanyl and fentanyl-related substances. Engagement between the President and his Chinese counterpart led China to control fentanyl-related substances as a class effective May 1, 2019.

**3. What are the justifications for making the temporary emergency scheduling permanent?**

**Response:**

As stated above, the temporary class control has substantially slowed the rate at which new fentanyl-related substances are introduced to, and are encountered in, the illicit market. However, it will expire on May 6, 2021, and at that time, any substance that meets the definition of a fentanyl-related substance will no longer be expressly identified as subject to regulatory control under the CSA, except for substances that DEA has identified and for which DEA has requested HHS to prepare a scientific and medical evaluation and to make a scheduling recommendation. At that point, should the temporary ban on non-scheduled fentanyl-related substances expire, DEA expects the renewed emergence of new fentanyl-related substances on the illicit market consistent with previous attempts to circumvent largely reactive, substance-specific control measures. Prosecution and enforcement with respect to conduct involving these substances, when possible, would rely on the Controlled Substance Analogue Enforcement Act of 1986. The applicable law and required elements of proof, coupled with the frequent “battle of experts,” make Analogue Act prosecutions time-consuming and resource-intensive for investigators, drug testing laboratories, prosecutors, and the entire judicial system.

**4. The United States-China Economic and Security Review Commission stated in a November 2018 report that “China remains the largest source of illicit fentanyl and fentanyl-like substances in the United States.” However, numerous federal officials and drug agents have said Mexican groups are behind the bulk of the fentanyl arriving in the United States. What is your professional judgment as to which country is the largest source of illicit fentanyl coming into the United States?**

**Response:**

Illicit fentanyl, fentanyl-related substances, and their immediate precursors historically were often produced in China. Current reporting indicates production of illicit fentanyl substances has now shifted to Mexico and other countries. From China, these substances were shipped primarily through express consignment carriers or international mail directly to the United States. These substances were moved via the mail system in small quantities yet are highly potent. Alternatively, fentanyl and fentanyl-related substances, and their precursors, are also shipped directly to transnational criminal organizations (TCO) in Mexico, Canada, and the Caribbean. Once in the Western Hemisphere, fentanyl and fentanyl-like substances are prepared to be mixed into the heroin supply, or pressed into a pill form, and then smuggled into the U.S. market by TCOs. These shipments of fentanyl and fentanyl-related substances seized by law enforcement primarily on the southwest border are larger in volume than those smuggled directly from China; however, they typically range from five percent to 10 percent fentanyl purity.

DEA has worked closely with China to bring attention to and help combat the rise of illicit fentanyl and fentanyl-related substances being smuggled out of China. After the President engaged directly with his counterpart on this topic, on April 1, 2019, China announced the class-wide control of fentanyl-related substances effective May 1, 2019.

- 5. In October 2017, the U.S. Department of Justice announced the first indictments against Chinese nationals who were manufacturers and distributors of fentanyl. Even though there is little prospect that the Chinese nationals will ever be in an American courtroom, what is the purpose and impact of indicting Chinese nationals for illicit fentanyl trafficking?**

**Response:**

There is no extradition treaty between the United States and China; however, DEA has engaged with its Chinese counterparts for over thirty years by providing investigative and intelligence information on a near daily basis. Since the onset of the opioid epidemic in the U.S., DEA and the Department of Justice have engaged with the Chinese Ministry of Public Security and the Narcotics Control Board regarding the manufacturing and distribution of fentanyl and fentanyl-related substances, as well as other new psychoactive substances (NPS) inside China. Chinese law regarding the chemical composition of fentanyl-related substances and other NPS varies and, at times, some of these substances fall outside the control of Chinese law. When a substance falls within the control of Chinese law, the Ministry of Public Security and the Narcotics Control Bureau have demonstrated the ability to identify, investigate and enforce their own laws. Once an investigation is concluded, the likelihood of conviction and sentencing is very high. Although the U.S. may not be able to extradite Chinese fugitives for prosecution in the U.S., the indictment of Chinese nationals serves to highlight the public health concerns associated with the flow of illicit opioids from China into the United States. Moreover, we are able to effectively seize and forfeit assets associated with narcotics trafficking by pursuing administrative or civil forfeiture against the property, when criminal prosecutions of fugitives are not possible. The loss of funds and real property often have a significant negative impact on drug trafficking organizations.

- 6. How many different fentanyl analogues have been identified as coming from China?**

**Response:**

Fentanyl analogues cannot be expressly sourced as coming from China. What can be said is that whether via mail or through Mexico, China is the principal source country of fentanyl-related substances, their precursors, and other synthetic opioids, producing most illicit fentanyl and fentanyl analogues reaching U.S. users. DEA works closely with China to bring attention to and help combat the rise of illicit fentanyl, fentanyl analogues, and their precursors. Because of the President's direct engagement with his Chinese counterpart, on April 1, 2019, China announced the class-wide control of fentanyl-related substances effective May 1, 2019.

This is a promising development; however, as increased regulatory controls are effective in China, Mexican TCOs are filling the void. As a result, DEA is continuing to see a shift from the shipment from China into Mexico of precursor chemicals for the production of fentanyl and fentanyl-related substances to the manufacturing of precursor chemicals within Mexico itself. However, the uncontrolled pre-precursors used to make fentanyl precursors are predominantly originating in China. This is an alarming development.



**7. What are some of the common ways in which fentanyl is trafficked from China to the United States?**

**Response:**

According to CBP data, the number of direct fentanyl seizures coming from China has dropped dramatically since the May 1, 2019 Chinese class scheduling. While it is true that fentanyl is shipped into Mexico from China, in the last 12 months we have also seen numerous fentanyl synthesis production labs and processing facilities seized in Mexico. The intelligence indicates a shift in production to Mexico, for the U.S. illicit market.

**8. Do you agree with the Wilson Center Mexico Institute report that the key fentanyl trafficking route in Mexico is through the Baja-California border area? Do you agree with the Wilson Center Mexico Institute report that fentanyl is not a priority for Mexican law enforcement?**

**Response:**

Mexican TCOs continue to control lucrative smuggling corridors, primarily across the Southwest Border including the Baja-California border area, and maintain the greatest drug trafficking influence in the United States, with continued signs of growth. They continue to manage the effective use of compartmentalizing information in furtherance of expanding their criminal influence by engaging in business alliances with other TCOs, including working with independent TCOs, and work in conjunction with Mexican transportation groups, transnational gangs, U.S.-based street gangs, prison gangs, and Asian money laundering organizations.

Based on DEA investigative reporting and available seizure data, the Baja-California corridor continues to be a major trafficking route for fentanyl entering the United States; however, there have been seizures of fentanyl and fentanyl-laced counterfeit pills in the Arizona-New Mexico corridor, and to a lesser extent in western and eastern Texas border corridors.

Since publication of the Wilson Center report, recent high-level bilateral exchanges between DEA and the government of Mexico (GOM) have occurred, and senior Mexican law enforcement officials now acknowledge the threat fentanyl manufacturing and distribution poses in both countries. These Mexican officials have stated that addressing the growing fentanyl threat in Mexico is a priority for their agencies. In 2019, parallel criminal investigations between the DEA and Mexican law enforcement agencies have led to the seizure or dismantling of at least three laboratories in Mexico that were either actively synthesizing fentanyl or were capable of producing fentanyl. During the same time frame, there have been multiple seizures of counterfeit pill operations in Mexico. Current DEA investigative reporting has identified at least five additional suspected fentanyl laboratories in Mexico, which are being investigated with Mexican law enforcement counterparts for future enforcement operations. DEA and Mexican law enforcement capabilities include gathering evidence, seizing drugs, sharing information and intelligence, as well as extraditing individuals to face prosecution in United States courts. Combatting TCOs is a priority for DEA. The DEA has been supported by Mexican law

enforcement for well over three decades. In Mexico, DEA currently has 11 offices, staffed by one hundred seven (107) positions including Special Agents, Intelligence Analysts, Diversion Investigators and administrative staff. In Mexico, DEA continues to synchronize and expand capabilities to combat the growing epidemic. DEA has developed a bilateral opioid (heroin/fentanyl) strategy for intelligence sharing, coordination of investigations, training, increased sharing of forensic information, and the control of precursor chemicals. DEA participates in the North American Drug Dialogue, which focusses on addressing strategic-level drug policies of interest to the U.S., Mexico, and Canada to attack the production, trafficking, consumption and misuse of illicit narcotics in North America. DEA will continue to aggressively pursue criminals trafficking in illicit drugs. Targeting the world's most dangerous drug traffickers and their criminal organizations is a dynamic and evolving mission, and with it comes myriad challenges, including understanding the geopolitical influences in countries such as Mexico.

**9. Could Mexico increase its capacity to detect and test for fentanyl and its analogues at its laboratories?**

**Response:**

DEA has worked closely with Mexico's federal laboratories and believes they are currently equipped with instrumentation found in most forensic laboratories that would allow for the identification of controlled substances to include fentanyl and any fentanyl-related compounds. DEA has had very limited interaction with other laboratories in Mexico and cannot comment regarding their analytical capabilities or instrumentation.

**10. Is there a problem with Mexican law enforcement providing the U.S. Drug Enforcement Administration (DEA) with access to inspections of seized laboratories and chemicals? If so, what can be done to address this problem?**

**Response:**

DEA continually works with the GOM to expand its intelligence-sharing network tied to parallel investigations through various programs. The GOM currently has over a 100-person vetted Sensitive Investigative Unit team working with the Federal Police, which has given the GOM and DEA valuable insights into TCOs operating in Mexico. Additionally, DEA has been proactive in sharing information and improving awareness regarding the dangers posed by fentanyl. This proactive stance has further strengthened DEA's relationship with the GOM and has increased interest in additional opportunities for cooperation, including access to seized labs and chemicals.

**11. How many fentanyl synthesis labs are believed to exist in Mexico?**

**Response:**

It is impossible to know how many fentanyl synthesis laboratories are active in Mexico given the clandestine nature of this activity and the fact that fentanyl production facilities are

easily concealed in urban or rural settings. In 2019, parallel criminal investigations between the DEA and Mexican law enforcement agencies have led to the seizure or dismantling of at least three laboratories in Mexico that were either actively synthesizing fentanyl or were capable of producing fentanyl. During the same time frame, there have been multiple seizures of counterfeit pill operations in Mexico. Current DEA investigative reporting has identified at least five additional suspected fentanyl laboratories in Mexico, which are being investigated with Mexican law enforcement counterparts for future enforcement operations. As DEA and Mexican law enforcement information-sharing and investigative coordination continues to expand, it is expected the number of fentanyl synthesis laboratories identified in Mexico will increase substantially.

**12. What are some of the common ways in which fentanyl is trafficked from Mexico into the United States?**

**Response:**

The most common way fentanyl is smuggled into the U.S. from Mexico is via Mexican TCOs over the Southwest land border. Chinese-origin fentanyl and fentanyl precursor chemicals are smuggled into Mexico, where Mexican TCOs will synthesize the precursor chemicals and manufacture fentanyl. TCOs will often press fentanyl into pill form to make it appear as a medication. These counterfeit medications can take the form of popular brand name opioids like OxyContin and Vicodin. While unsuspecting users may think they are ingesting these legitimate medications they are, in fact, consuming fentanyl.

**13. How much of a threat does illicit fentanyl trafficking from Canada pose to the United States? What is being done to monitor and respond to this threat?**

**Response:**

Illicit fentanyl trafficking from Canada continues to pose a serious threat to the United States. In response to this threat, the Drug Enforcement Administration works closely with its Canadian law enforcement partners, identifying and targeting individuals and organizations involved in the illicit importation or exportation of fentanyl and other synthetic opioids. The DEA has identified several Canada-based dark web drug trafficking organizations (DTOs), to include DTOs responsible for the distribution of fentanyl and other synthetic opioids to customers and consumers in the United States. Despite the recent efforts by some dark web administrators to ban the sale of fentanyl, vendors continue to sell the drug, often marketing it under different names in order to circumvent marketplace restrictions. Similarly, within Canada, authorities have identified an increased use of fentanyl and fentanyl analogues as adulterants or ingredients in a number of different street-level drugs and counterfeit controlled prescription drugs (CPDs). For this reason, the cross-border trafficking of fentanyl-laced drugs poses a significant threat to users in the United States.

Although restrictions have been put in place to curb production, China remains the primary source country for the fentanyl and fentanyl analogues smuggled into Canada. The DEA works closely with its Canadian partners to identify large-scale and wholesale fentanyl

suppliers from China and other countries around the world. Facing enhanced scrutiny from law enforcement and postal authorities, there are indications that large-scale fentanyl suppliers are increasingly illicitly trans-shipping their drugs through “low risk” countries, oftentimes in Europe, where the drugs are then forwarded to Canada or the United States with fake country-of-origin designations. Similarly, traffickers in Canada are increasingly using traditional letter mail to ship powder fentanyl to customers in Canada and the United States. To this point, seizures of powder fentanyl in letter mail increased significantly over the first half of 2019, with authorities assessing that dark web vendors are increasingly using the method to ship fentanyl to their customers. Because letter mail provides law enforcement authorities with limited tracking options, combined with the sheer volume of letter mail moving through the system, traffickers may increasingly opt to send powder fentanyl via letter mail, believing the method poses a lower risk of apprehension or detection. This shift raises additional concerns regarding the safety of postal employees and others, given the potential for contamination of other letter mail. Such trends also highlight the importance of bilateral cooperation and information sharing between DEA and Canadian law enforcement partners, in order to combat the current fentanyl threat.

**14. If the Chinese scheduling of fentanyl is effective, is there a concern that there will be more fentanyl analogues and fentanyl precursors manufactured and illicitly sourced in the United States?**

**Response:**

DEA has not seen any indication that widespread manufacturing of illicit fentanyl or fentanyl precursors is occurring in the United States. DEA is concerned that as China becomes more effective in restricting fentanyl and fentanyl-related substances, the United States will start to see other countries, such as India, Mexico, Singapore and some European countries, producing illicit fentanyl-related substances to fill the international demand for these substances.

**15. What role do gangs from the Dominican Republic play in fentanyl trafficking?**

**Response:**

The Dominican Republic is a major transit point for illicit narcotics in the Caribbean region. Although Dominican TCOs have historically worked with Venezuelan and Colombian TCOs, there has been a significant increase in coordination with Mexican TCOs. These Dominican TCOs are working with Mexican TCOs to smuggle heroin and fentanyl into the United States via the Southwest Border. Once inside the United States, Dominican TCOs coordinate the transportation and distribution of these drugs throughout the eastern United States, particularly in the northeast.

**16. Is there reason to believe that there is illicit fentanyl trafficking in Russia and the Ukraine?**

**Response:**

TCOs operate around the world and will always work to exploit the most vulnerable of communities. Russia and Ukraine like all nations are not immune from the fentanyl crisis and from the activities of TCOs.

**17. It is my understanding that there are two primary methods to synthesize fentanyl: the Janssen method and the Siegfried method. The DEA has stated that the Janssen method is difficult to perform and is beyond the rudimentary skills of most clandestine laboratory operators. In the 2018 Drug Threat Assessment, DEA stated that clandestinely produced fentanyl is synthesized using the Siegfried method, as it is simpler for drug trafficking organizations to follow the steps involved. However, the DEA's January 2019 Fentanyl Signature Profiling Program using new techniques was able to analyze many more fentanyl samples and found that the Janssen method was the predominant synthetic route. What are the possible implications of this finding?**

**Response:**

Historically, it has been accepted that the Siegfried method was the most predominant route of clandestinely producing fentanyl, since it is generally easier to acquire the necessary precursors and equipment; hence, the generality made in the 2018 National Drug Threat Assessment. However, a newly implemented methodology developed by DEA researchers in about November 2018 has allowed the identification of the fentanyl synthesis route over 65 percent of the time; whereas the older method could only determine the route one percent of the time. The results, therefore, were not considered a surprise; since DEA had been unable to determine definitively the synthetic route for the majority of samples prior to the development of this new methodology. Given that DEA has only been acquiring this enhanced data for the past year, we are cautious to draw conclusions from this data regarding the skill of the operator or the availability of precursor chemicals. The prevalence of the Janssen method does not necessarily mean that skilled clandestine operators are producing the fentanyl. While this is a possible conclusion, it is also possible that skilled processors have provided training to less-skilled clandestine laboratory operators who routinely perform the necessary tasks. DEA will continue to evaluate the profiling data from the analysis of seized fentanyl to discern any changes in the synthetic route or precursors employed.

**18. Drug traffickers often use freight forwarders to ship fentanyl and fentanyl analogues from China. Such multiple transfers of custody make it difficult for law enforcement to track these packages. Are changes in the law needed to combat the problem of freight forwarding of fentanyl in the mail? If so, what are some suggestions to do so?**

**Response:**

DTOs and TCOs attempt to conceal the origin and contents of packages containing illicit narcotics in a variety of ways. These DTOs and TCOs have often used freight forwarders to ship fentanyl and fentanyl related substances from China. 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, combined with intentionally missing, incomplete, or inaccurate information, make detection and tracking extremely difficult. DEA does not believe there is a single nor simple domestic solution to this problem, because in many cases the freight forward system utilized is based out of China and presents jurisdictional difficulties for the U.S. Government. Furthermore, validation of information entered in the system by a foreign entity, including language translation, abbreviations, and other relevant consignor/consignee information, contribute to the difficulty. DEA would defer to USPS on suggested legislative ideas to assist in tracking packages.

**19. What are the Organized Crime Drug Enforcement Task Forces (OCDETF)?**

**Response:**

The OCDETF program was established in 1982 to conduct comprehensive, multilevel attacks on major drug trafficking and money laundering organizations. OCDETF is a partnership that brings together the combined expertise and unique abilities of federal, state, and local enforcement agencies. The principal mission of the OCDETF program is to identify, disrupt, dismantle and prosecute high-level members of drug trafficking, weapons trafficking, and money laundering organizations and enterprises.

**20. How is OCDETF important in the effort combat illicit fentanyl trafficking?**

**Response:**

The OCDETF program helps to dismantle major drug trafficking organizations and operations. This program has achieved many successes over the years, and has helped to disrupt the flow of drugs into the U.S. The greater the success of the OCDETF program the greater the positive impact in disrupting the supply of fentanyl into the U.S.

- 21. Many of the fentanyl sources operate on the dark web and use bitcoin for financing. Are DEA or Homeland Security Investigations (HSI) seeing any evidence that credit card companies, consignment carriers, or domain registrars are accepting bitcoin as payment?**

**Response:**

Yes, DEA has seen this; however, it should be noted that if credit card companies, consignment carriers, or domain registrars are accepting bitcoin as payment, it is not necessarily indicative of being involved in illicit activity.

- 22. Are credit card companies, consignment carriers, and internet service providers (ISP) helping law enforcement to combat fentanyl trafficking on the dark web?**

**Response:**

Domestic credit card companies, consignment carriers, and ISPs respond to legal process by law enforcement.

- 23. How have the dark web and crypto currency complicated attempts to target and shut down these supply chains? What is being done to overcome these difficulties?**

**Response:**

In some cases, crypto-currency offers individuals pseudo-anonymity. Agents have experienced success in identifying the users behind the cryptocurrency addresses through serving legal process to cryptocurrency exchangers, and using analytical tools and previously seized dark net market data maintained by law enforcement.

- 24. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?**

**Response:**

DEA uses a variety of tools to collect data and intelligence to further criminal investigations. One such tool that is crucial for DEA's success is court-ordered lawful interception of electronic communications. DTOs and TCOs are increasingly utilizing encrypted applications to communicate. End-to-end encryption utilized on popular applications such as WhatsApp and Signal does not provide for lawful access to the content of communications, despite lawful authority such as a wiretap order to obtain that evidence. The majority of DEA investigations encounter DTO members utilizing end-to-end encrypted applications. DEA investigations reveal that utilization of end-to-end encrypted applications is occurring in both domestic and foreign DTOs and at all levels of the DTO hierarchy from cartel heads to local United States-based distributors. It is now extremely difficult for DEA to obtain lawful access to electronic evidence and intelligence necessary to investigate threats to public safety. In order for

DEA's data and intelligence collection to improve, DEA needs the capability to intercept communications over applications that employ end-to-end encryption.

**25. Are labs at DEA, U.S. Customs and Border Protection (CBP), and FDA coordinating on fentanyl research and sharing fentanyl samples for each agency's specialized testing?**

**Response:**

DEA conducts fentanyl-related research with other federal agencies that are focused on increasing the government's ability to detect illicit fentanyl shipments. DEA also routinely analyzes CBP seizures from the Southwest Border. These samples provide intelligence regarding the major sources of fentanyl to the United States and these conclusions are often compared and contrasted with similar information generated by CBP. DEA and CBP coordinate with FDA as relevant.

CBP strengthened its partnership with other federal agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Postal Inspection Service (USPIS), as well as worked closely with our counterparts in source countries such as China and Mexico to thwart the opioid supply chain. The deployment of CBP scientists to ports of entry allowed for real time analysis and scientific support, and an increase in the sharing of actionable intelligence, particularly as it relates to source countries, has helped inform targeting efforts.

**26. CBP's written testimony mentions pollen testing and analysis is being conducted by CBP's Laboratories and Scientific Services scientists to geolocate illicit opioid shipments. Are labs at other agencies working on testing techniques that could help geolocate illicit fentanyl shipments?**

**Response:**

DEA has attempted to identify analytical techniques for geo-sourcing fentanyl; however, since fentanyl is a synthetic drug, it does not contain markers that can aid in determining the origin or trafficking patterns of a seizure. Consequently, DEA has provided other material to CBP to perform pollen analysis on select drug seizures.

One capability CBP is using to close intelligence gaps related to the opioid supply chain is palynology, more commonly referred to as pollen analysis. Pollen analysis is conducted by CBP's Laboratories and Scientific Services (LSS) scientists on illicit narcotic shipments that have been seized by CBP Officers and Border Patrol Agents at the border. The pollen testing has been used to determine the origin of illicit opioid shipments which has been used to help identify transit routes of illicit opioids. CBP has developed intelligence products based on the pollen analysis and shared it with relevant partners.



**27. Could federal labs work to complement each other's effort to enhance geolocation of illicit fentanyl shipments?**

**Response:**

Yes, and they do. To date, DEA has provided CBP a few seizure samples for pollen analysis.

Law enforcement collaboration and information-sharing is an essential tool to effectively produce actionable intelligence that can assist CBP and our partners identify targets and interdict illicit opioids from entering the country. Critical data points include accurate seizure data from all operational components and confirmed laboratory test results, particularly as it relates to fentanyl and its analogues. Part of the challenge is insuring there are consistent data reporting processes across the board, and that confirmed laboratory test results are captured in databases.

**Questions from Rep. Burgess, M.D. (R-TX)**

**28. I have reviewed a document published by the Drug Enforcement Administration's Diversion Control Division listing the DEA "cases against doctors". I was surprised to see that this list, despite going back to the early 2000s, is only 174 pages long. There are a few years that peaked, but it seems like the numbers have generally been low. Can you explain the trends of investigations of physician registrants that resulted in the arrest and prosecution of the registrant?**

<b><u>Year</u></b>	<b><u># Cases Against Doctors<sup>1</sup></u></b>
2000	25
2001	23
2002	66
2003	35
2004	74
2005	40
2006	32
2007	42
2008	24
2009	26
2010	25
2011	70
2012	44
2013	31
2014	21
2015	37

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<sup>1</sup> United States, Drug Enforcement Agency, Diversion Control Division. Cases Against Doctors, available at <https://apps2.deadiversion.usdoj.gov/CasesAgainstDoctors/spring/main?execution=c1s1>.

<b>2016</b>	<b>28</b>
<b>2017</b>	<b>47</b>
<b>2018</b>	<b>40</b>
<b>2019 (as of June 13)</b>	<b>14</b>

**Response:**

The DEA uses its very limited resources to target the most egregious offenders. Some years doctors may be among the most serious offenders more than other years. The DEA must focus its limited resources to have the greatest impact to help preserve the public health and safety. It should also be noted that State prosecutions and DEA administrative actions result in the removal of numerous physicians' and other registrants' authority to dispense controlled substances.

**Questions from Rep. Brooks (R-IN)**

**29. What is the availability of Narcan for all your law enforcement employees?**

**Response:**

Narcan is available for all DEA employees.

<b>Question#:</b>	1
<b>Topic:</b>	Detecting Fentanyl
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Frank Pallone Jr.
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Thomas Overacker**

**Question:** In your testimony, you note that “Drug Trafficking Organizations and Transnational Criminal Organizations continually adjust their operations to circumvent detection and interdiction by law enforcement.” We would like further information on the current capabilities of U.S. Customs and Border Protection (CBP) to address the fentanyl crisis and the evolving threat it poses. Please provide further information on the following:

Is CBP's ability to detect fentanyl limited by the current array of tools available to CBP?

**Response:** U.S. Customs and Border Protection (CBP) utilizes an array of tools to aid in the identification of illicit substances such as fentanyl. As Transnational Criminal Organizations rapidly evolve their smuggling methods, CBP must rapidly evolve its capabilities to detect, identify, and interdict this ever-changing threat to protect the American public.

As there is no single tool that works for all situations, CBP utilizes a layered identification field testing strategy that includes Raman and Fourier-Transform Infrared spectroscopy, Immunoassay strips, Narcotic Identification tests, CBP's Laboratory and Scientific Services personnel, and equipment to aid in presumptive identification of unknown substances and that chemicals CBP encounters daily. Raman Spectroscopy is an inelastic scattering phenomenon that probes molecular vibrations to provide a molecular fingerprint of materials. Fourier-Transform Infrared Spectroscopy is a form of vibrational spectroscopy that relies on the absorbance, transmittance, or reflectance of infrared light. CBP is constantly trying to identify new and innovative technology to aid in these layered enforcement and identification strategy efforts.

**Question:** If so, what additional tools would be helpful to assist CBP in detecting fentanyl?

**Response:** With continued support from Congress, CBP, in coordination with our internal and external partners, will continue to refine and further enhance the effectiveness of our detection, interdiction, and identification capabilities to combat transnational threats and the entry of illegal drugs into the United States. The continued support of CBP's current efforts to identify new and innovative technology to aid in the layered enforcement and identification strategy efforts, to include safety measures for frontline personnel and procurement of additional chemical screening, detection, and identification tools, is instrumental in the fight against this ever-evolving threat.

<b>Question#:</b>	2
<b>Topic:</b>	Fentanyl Intelligence
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Frank Pallone Jr.
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** Is the extent of CBP's intelligence on the scope of the fentanyl crisis limited to what CBP has been able to seize?

**Response:** CBP's intelligence related to the scope of the fentanyl crisis goes beyond CBP seizures to include collection emphasis messages and analysis of global supply chains. CBP has well-established relationships with foreign partners, which includes the FIVE EYES countries (United States, Canada, Australia, United Kingdom, New Zealand) and works extensively with them on determining foreign flows and production activity. Additionally, CBP coordinates and communicates with state and local partners to maintain a consistent understanding of the fentanyl threat picture nationally, not just at the borders, which includes CBP collaborating with the Office of National Drug Control Policy High Intensity Drug Trafficking Area program. CBP shares drug-related intelligence and trends with various members of the Intelligence Community. CBP also monitors user forums to see the latest discussions among users to see what the latest trends are, including new analogues for sale and who is selling them.

**Question:** Other than seizures, what else is CBP doing to understand the quantity, methods, and sources of illicit fentanyl entering the country?

**Response:** Beyond seizure data, CBP reviews other available intelligence and law enforcement reporting to understand the overall fentanyl threat, which includes the quantity, methods, and sources of illicit fentanyl and fentanyl precursors entering the country. CBP Laboratories and Scientific Services is able to perform pollen analysis to attempt to geolocate the origin and smuggling routes of certain seizures to assist investigators and intelligence personnel in solving criminal or civil legal issues. CBP also leverages collaboration with other federal, state, and local agencies. This includes working closely with the Office of National Drug Control Policy High Intensity Drug Trafficking Area program and continuous work with other laboratories and the medical community, including coroners and medical examiners, to identify emerging drug threats.

<b>Question#:</b>	3
<b>Topic:</b>	Interdictions
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Greg Walden
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** I recently visited the Southwest border to tour border facilities, including a U.S. Customs and Border Protection (CBP) facility in Yuma, Arizona. I learned drug interdictions on the whole are down across the Yuma Sector as the CBP checkpoints were shut down for months because CBP agents could not man the checkpoints during the border emergency given the huge influx of people crossing the border. How many interdictions of illicit fentanyl and other narcotics were interdicted at the Yuma Sector during the first six months of 2018 and how many interdictions of illicit fentanyl and other narcotics were interdicted during the first six months of 2019? Please distinguish between interdictions of illicit fentanyl and other narcotics at ports of entry and interdictions either between ports of entry or at interior checkpoints in the Yuma Sector.

**Response:** Below represents the illicit fentanyl and other narcotics (heroin, morphine, and oxycodone) seizures within the first 6 months of both calendar year (CY) 2018 and CY 2019 both at and between ports of entry within the Yuma Sector area.

Narcotics	At POEs				Between POEs			
	Drug Seizures		Incident Count		Drug Seizures		Incident Count	
	CY18	CY19	CY18	CY19	CY18	CY19	CY18	CY19
FENTANYL	34.39	28.78	6	24	6.88	37.35	2	6
OTHER NARCOTICS	28.82	42.49	9	10	33.65	4.69	15	4
<b>TOTAL</b>	<b>63.21</b>	<b>71.27</b>	<b>15</b>	<b>34</b>	<b>40.53</b>	<b>42.04</b>	<b>17</b>	<b>10</b>

Note(s): Other Narcotics = Heroin, Morphine, Oxycodone. Data represents first 6 months of each CY. San Luis is the only Port of Entry within the Yuma Sector.

**Question:** How many interdictions of illicit fentanyl and other narcotics occurred at the Southwest border during the first six months of 2018 and how many interdictions of illicit fentanyl and other narcotics occurred during the first six months of 2019? Please distinguish between interdictions of illicit fentanyl and other narcotics at ports of entry and interdictions either between ports of entry or at interior checkpoints along the Southwest border.

**Response:**

OFO Southwest Land Border Drug Seizures				
Drug Type	1/1/2018 to 6/30/2018		1/1/2019 to 6/30/2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)

<b>Question#:</b>	3
<b>Topic:</b>	Interdictions
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Greg Walden
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

<b>FENTANYL</b>	<b>73</b>	<b>612.22</b>	<b>164</b>	<b>1,512.23</b>
<b>ALL OTHER DRUGS TOTAL</b>	<b>3,028</b>	<b>177,623.29</b>	<b>3,253</b>	<b>198,713.81</b>
COCAINE	370	9,070.05	348	8,503.87
CRYSTAL METHAMPHETAMINES	188	5,635.71	538	24,565.12
ECSTASY	2	0.00	6	0.07
GAMMA HYDROXY BUTYRATE	1	1.46		
HASH, LIQUID (HASH OIL)	7	3.82	43	93.58
HASHISH	2	4.50	3	5.04
HEROIN	270	2,167.21	292	2,332.40
KETAMINE	4	29.66	4	9.22
LSD			4	0.01
MARIJUANA	1,044	132,090.29	983	127,671.47
MARIJUANA PLANTS	1	0.15		
METHAMPHETAMINE	788	28,256.30	674	35,136.07
METHYLPHENIDATE (RITALIN)	2	0.14	10	0.89
MORPHINE	2	0.07	3	1.28
OPIUM	1	6.97	1	0.01
OTHER DRUGS, PRESCRIPTIONS, CHEMICALS	305	252.01	294	315.31
OXYCODONE(OXYCONTIN)	10	1.63	20	10.93
PEYOTE	4	1.35	3	1.63
PRECURSOR CHEMICALS EXCEPT EPHEDRINE	8	88.66	3	40.26
PSILOCYN OR PSILOCYBIN				
MUSHROOMS	1	0.68	3	0.04
STERIODS	16	5.56	21	26.62
SYNTHETIC CANNABINOIDS - ALL TYPES	2	7.09		
<b>TOTAL</b>	<b>3,101</b>	<b>178,235.50</b>	<b>3,417</b>	<b>200,226.04</b>

**USBP Southwest Border Drug Seizures**

<b>1/1/2018 to 6/30/2018</b>	<b>1/1/2019 to 6/30/2019</b>
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<b>Question#:</b>	3
<b>Topic:</b>	Interdictions
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Greg Walden
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

Drug Type	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
FENTANYL	19	185.94	23	148.39
ALL OTHER DRUGS TOTAL	4,737	253,728.58	3,003	143,525.36
CAPSULES	7	0.62	3	0.07
COCAINE	231	2,725.64	175	2,771.91
ECSTASY	29	0.43	16	0.83
HASHISH	66	15.59	34	6.24
HASHISH OIL	38	283.10	43	5.00
HEROIN	93	301.11	94	350.90
LSD	13	0.12	4	0.01
MARIJUANA	3,663	244,636.70	2,139	133,042.20
METHAMPHETAMINE	445	5,726.53	384	7,114.87
MORPHINE	1	0.19	1	0.01
OPIUM	1	6.80	2	0.27
OTHER DRUGS OR BARBITURATES	44	20.91	59	224.74
PILLS	103	10.70	48	8.20
SMALL PILLS	3	0.13	1	0.12
<b>SBO Total</b>	<b>4,756</b>	<b>253,914.52</b>	<b>3,026</b>	<b>143,673.76</b>

**Question:** How many methamphetamine and fentanyl seizures occurred in the United States during the first six months of 2018 and in the first six months of 2019?

**Response:**

OFO Nationwide FEN & METH Drug Seizures				
Drug Type	1/1/2018 to 6/30/2018		1/1/2019 to 6/30/2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
METHAMPHETAMINES	2,372	35,995.24	1,796	65,863.55

<b>Question#:</b>	3
<b>Topic:</b>	Interdictions
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Greg Walden
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

CRYSTAL METHAMPHETAMINES	256	5,798.63	670	29,568.03
METHAMPHETAMINE	2,116	30,196.60	1,126	36,295.53
FENTANYL	346	852.81	278	1,628.67
<b>TOTAL</b>	<b>2,718</b>	<b>36,848.05</b>	<b>2,074</b>	<b>67,492.22</b>

	1/1/2018 to 6/30/2018		1/1/2019 to 6/30/2019	
Drug Type	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
FENTANYL	19	185.94	23	148.39
METHAMPHETAMINE	445	5,726.53	384	7,114.87
<b>Total</b>	<b>464</b>	<b>5,912.46</b>	<b>407</b>	<b>7,263.26</b>



<b>Question#:</b>	4
<b>Topic:</b>	Checkpoints Closed
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Greg Walden
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** According to a July 17, 2019 article in the Washington Examiner, "Drugs pour in from Mexico as Border Patrol forced to focus on migrants," seven Border Patrol checkpoints in southern New Mexico have been shut down since late March 2019. If this information is correct, why were these checkpoints closed?

**Response:** U.S. Border Patrol (USBP) leadership made the tough decision to close immigration checkpoints in El Paso Sector based on an operational need to address high numbers of apprehensions associated with the migrant crisis. Resources were reallocated from checkpoint operations to processing and transportation.

**Question:** How many border checkpoints have been closed to move personnel to the border to assist with apprehend, process, and care for the high number of migrants and migrant families arriving?

**Response:** Effects stemming from the migrant crisis resulted in the closures of 10 permanent checkpoints (7 in El Paso and 3 in Yuma) to include periodic closures of Tucson Sector checkpoints in support of processing and transportation overflow.

<b>Question#:</b>	5
<b>Topic:</b>	Fentanyl Sources
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** How much of the illicit fentanyl is coming in directly from China?

**Response:**

OFO Fentanyl Seizures from China FY18, FY19TD-8/31/2019*				
From Country*	FY 2018		FY 2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
CHINA	314	278.34	12	11.58
* From country data is not a mandatory field and should only be used as an estimate of total seizures				

**Question:** How much of the illicit fentanyl is coming from Mexico?

**Response:**

OFO Fentanyl Seizures from Mexico FY18, FY19TD-8/31/2019*				
From Country*	FY 2018		FY 2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
MEXICO	171	1,514.45	255	1,808.88
* From country data is not a mandatory field and should only be used as an estimate of total seizures				

**Question:** How much illicit fentanyl is coming from Canada?

**Response:**

OFO Fentanyl Seizures from Canada FY18, FY19TD-8/31/2019*				
From Country*	FY 2018		FY 2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
CANADA	72	14.86	197	5.24
* From country data is not a mandatory field and should only be used as an estimate of total seizures				

<b>Question#:</b>	6
<b>Topic:</b>	Fentanyl Shipments
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** With regard to parcel shipments of illicit fentanyl, how many of these shipments are through United States mail?

**Response:** The Office of Field Operations (OFO) does not measure U.S. Postal Service (USPS) mail seizures. OFO does not have visibility on USPS seizures within domestic mail as this is the equivalent of United States mail. OFO enforcement actions are limited to international mail and OFO does not inspect domestic mail.

**Question:** How many illicit fentanyl shipments through foreign mail?

**Response:**

OFO Fentanyl Mail Seizures FY18, FY19TD-8/31/2019				
Conveyance	FY 2018		FY 2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
MAIL(S)	442	150.17	238	19.96

**Question:** How many illicit fentanyl shipments through air express carriers?

**Response:**

OFO Fentanyl Express Consignment Seizures FY18, FY19TD-8/31/2019				
Conveyance	FY 2018		FY 2019	
	Incident Count	Seizure Weight (lbs)	Incident Count	Seizure Weight (lbs)
EXPRESS CONSIGNMENT(Z)	73	116.01	33	111.46

<b>Question#:</b>	7
<b>Topic:</b>	AED
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** How is advanced electronic data (AED) going to help target and intercept packages containing fentanyl?

**Response:** Advance electronic data is analyzed by the Automated Targeting System, the National Targeting Center, and local Advanced Targeting Units to identify shipments for secondary examination.

**Question:** On average, how many packages are coming into our international mail facilities (IMF) on any given day?

**Response:** The average volume of mail processed on any given day through the international mail facilities is approximately 1.25 million pieces.

**Question:** How many of those packages currently come with advanced electronic data (AED)?

**Response:** CBP is currently receiving advance electronic data (AED) on approximately 70 percent, or 875,000 pieces of international mail per day.

**Question:** How reliable and useful is the advanced electronic data when it comes to helping mail entities and law enforcement interdict packages containing narcotics?

**Response:** AED is a critical element in the layered enforcement strategy CBP utilizes to identify cargo for examination. Accurate and reliable AED is critical to our targeting efforts to ascertain legitimate shipments transactions from those involved in illegal and illicit business transaction utilizing the US Postal Services.

<b>Question#:</b>	8
<b>Topic:</b>	Fentanyl Through the Mail
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** What unique challenges does fentanyl pose as opposed to other narcotics when it comes to detecting and interdicting fentanyl coming in through the mail?

**Response:** Fentanyl is often shipped in very small quantities, due to its potency. These minute amounts make detection and interdiction challenging.

**Question:** What more would law enforcement need in order to be best positioned to interdict more packages containing narcotics, like fentanyl?

**Response:** CBP is working to re-engineer and modernize the International Mail Facilities operations to increase the volume and speed of mail inspected. Future investments in infrastructure and technology will provide parcel sorting, singulation, and processing equipment, which is fully integrated with Non-Intrusive Inspection (NII) equipment. The new NII equipment will incorporate Automated Threat Recognition and targeting algorithms. This technology will independently identify and route high-risk packages for examination. These investments will dramatically improve CBP's ability to inspect, detect, and interdict threats within international mail.

<b>Question#:</b>	9
<b>Topic:</b>	SUPPORT Act
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** What is the status of implementation of SUPPORT Act provisions related to advanced electronic data or debarment authorities related to illegal imports of drugs?

**Response:** CBP's Office of Trade (OT), Regulation and Rulings (RR), has developed a draft regulations package pursuant to Title VIII, Subtitle A – Synthetics Trafficking and Overdose Prevention, Section 8003 - Mandatory Advance Electronic Information for Postal shipments. The document is currently under review by Office of Field Operations (OFO) executive management. Upon completion of the review, the document will be submitted to CBP's Acting Commissioner for final approval. The document will then be submitted to the Department of Homeland Security for signature. Finally, the document will be submitted to the Office of Management and Budget for review and approval.

Pursuant to Title VIII, Subpart A – Synthetics Trafficking and Overdose Prevention, Section 8002 – Customs Fees, OT, RR, is currently developing draft regulations related to the new fee for Inbound Express Mail items. CBP anticipates the document will then go to OFO review and then for signature by CBP's Acting Commissioner. The OFO executive management review and approval process can take several weeks to complete. Once the OFO process is completed, the document must then be submitted to the Department of Treasury for approval/signature and an OMB review.

**Question:** How has the SUPPORT Act changed the way in which you all operate on a day-to-day basis?

**Response:** Although CBP's regulations related to Sections 8002 and 8003 of the Act will not be implemented until after December 31, 2020, a number of administrative improvements have already been developed and operationalized that allows a more efficient process. CBP has developed a technical solution in an effort to analyze the quality of information received from foreign postal operators. CBP has also automated the process of reviewing monthly sample shipments of international mail to regularly assess data quality and identify areas targeted for improvements.

Currently over 45 fleet post offices provide some advance electronic data on international mail shipments to the United States Postal Service, advance electronic data for inbound mail shipments has increased from approximately 1 percent in FY 2015 to more than 70 percent today.

<b>Question#:</b>	10
<b>Topic:</b>	FDA and CBP Agreement
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** In April 2019, the FDA and CBP signed an agreement to maximize inspection and detection capabilities in order to prevent illegal and harmful products such as fentanyl from the United States through the international mail facilities. What are some of the results from this agreement so far?

**Response:** As directed by the SUPPORT Act, CBP continues to collaborate with the U.S. Food and Drug Administration (FDA) to implement the Letter of Intent, which was agreed to by the agencies in April 2019. Due to legal and privacy requirements, the agencies are currently working to draft the individual system Memoranda of Agreement that will facilitate the required information sharing by granting access to the appropriate CBP systems for FDA personnel. The agencies are also working to identify and resolve any legal or operational issues. Finally, the agencies are working to develop a joint approach to facility usage that also takes into account the impacts to General Services Administration and the U.S. Postal System.

<b>Question#:</b>	11
<b>Topic:</b>	Data Collection
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?

**Response:** Machine learning and advanced data analytic solutions could potentially enhance CBP strategic capabilities to increase package seizure rates.



<b>Question#:</b>	12
<b>Topic:</b>	Information on Potency
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** According to law enforcement officials, CBP data measures the fentanyl seizures in pounds without reflecting the differences in potency such as the 90 percent pure fentanyl from China to only seven percent pure fentanyl from Mexico. Should CBP seizure data also include information on fentanyl potency?

**Response:** Current sentencing guidelines for fentanyl are not based on purity, therefore, CBP Laboratories and Scientific Services does not conduct quantitative analysis on fentanyl seizures.

**Question:** How can information on potency be expressed in seizure statistics?

**Response:** CBP does not currently collect or report on potency and would be unable to include potency as a statistic, when reporting seizure data. Current sentencing guidelines are not based upon purity levels; therefore, front-line personnel do not test for potency as part of the seizure process, and the system of record does not capture such information.

<b>Question#:</b>	13
<b>Topic:</b>	Coordination Research
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** Are labs at DEA, CBP, and FDA coordinating on fentanyl research and sharing fentanyl samples for each agency's specialized testing?

**Response:** CBP Labs does not conduct fentanyl research, but does provide its federal partners detailed information of laboratory findings in regards to fentanyl, fentanyl analogues and other opioids. In regards to sample sharing, CBP laboratories does not transfer seized samples to other agencies. Sample transfers to federal partner laboratories are initiated through requests to CBP's Fines, Penalties, and Forfeitures Division.

<b>Question#:</b>	14
<b>Topic:</b>	Geolocation
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** CBP's written testimony mentions pollen testing and analysis is being conducted by CBP's Laboratories and Scientific Services scientists to geolocate illicit opioid shipments. Are labs at other agencies working on testing techniques that could help geolocate illicit fentanyl shipments?

**Response:** Unlike plant-based drugs, there are no sub-molecular markers contained within synthetic drugs to indicate geographic origin. An alternative means to determine geolocation comes from environmental contamination of the samples, through substances such as pollen. CBP Laboratories and Scientific Services is not aware of any other federal government lab looking at other means to geolocate synthetic drugs at this time.

**Question:** Could federal labs work to complement each other's effort to enhance geolocation of illicit fentanyl shipments?

**Response:** Potentially yes; however, at this time, CBP Laboratories and Scientific Services is not aware of any other federal government lab looking at other means to geolocate synthetic drugs.

<b>Question#:</b>	15
<b>Topic:</b>	Naloxone Training
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Susan Brooks
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** In your [prepared] testimony, you highlighted how trained officers are receiving naloxone and that 9 life-saving doses had been administered. So, I applaud those efforts, but wanted to ask a few follow up questions:

Are the officers receiving a community-use naloxone product?

**Response:** OFO issues Narcan™ Nasal Spray, 4 milligrams (mg) dosing, which has been approved by CBP physician oversight and Department of Homeland Security (DHS) Protocol.

**Question:** And what sort of training are the officers receiving? If they are not receiving a community use product: it seems to me that more officers would be able to carry and deploy naloxone if the agency was prioritizing community-use naloxone products like Narcan nasal spray.

**Response:** Required Computer-Based Training has been created and posted in the DHS Performance and Learning Management System (PALMS). The video course is designed and intended to educate and prepare CBP employees for safe-handling procedures when you encounter fentanyl or other unknown substances.

Training for non-medical personnel use of naloxone was developed by OFO, and the Office of Health Affairs, within the DHS Countering Weapons of Mass Destruction (CWMD) Office. This training includes Cardiopulmonary Resuscitation, Automated External Defibrillator, and naloxone administration, and is approved by the DHS Chief Medical Officer.

OFO and USBP each have naloxone training programs. USBP continues to train its personnel on naloxone use and recently updated its naloxone training presentation. As of August 22, 2019, CBP requires all current and new employees (sworn/non-sworn) to view the award-winning training video entitled “Fentanyl: The Real Deal.” The video is a result of a partnership between the Office of National Drug Control Policy, CBP, 10 federal agencies, and 24 non-governmental partners. The video was designed for public safety responders and was released last year to promote officer safety; and specifically, the safe handling of fentanyl, fentanyl analogues, and other synthetic opioids. The video complements the White House Fact Sheet entitled “Fentanyl: Safety Recommendations for First Responders.” The video is available on YouTube for all to access and view and the fact sheet is available on the White House website.

<b>Question#:</b>	15
<b>Topic:</b>	Naloxone Training
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Susan Brooks
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

USBP has observed recent increases in narcotic seizures involving known or suspected fentanyl and has responded by establishing uniform training guidelines for safe handling, selection and use of personal protective equipment, and testing procedures to ensure uniformity and operational consistency.

In addition to standardized training procedures involving the recognition, general safe handling, transportation, and storage of narcotics, in October 2018, USBP implemented a voluntary nationwide Non-Healthcare Provider Nasal Naloxone program and training protocols to assist personnel with learning the dangers, symptoms, and treatment options to mitigate the potential risk of exposure to fentanyl. Through this program, USBP established a training curriculum and protocols to protect employees, and others, from exposure to opioids by governing the storage, control, accountability, and administration of intranasal naloxone. In addition to this program, the administration of naloxone is also available via trained and certified USBP Emergency Medical Services providers such as Emergency Medical Technicians and Paramedics.

<b>Question#:</b>	16
<b>Topic:</b>	Access to Naloxone
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Susan Brooks
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** Do you know the percentage of trained CBP officers who have access to naloxone?

**Response:** Naloxone has been deployed to all OFO field offices for placement where contraband is handled. As of August 13, 2019, approximately 24 percent (5,054) of the OFO workforce has been trained in naloxone administration. Considering not all OFO personnel are assigned to areas where contraband is handled (e.g. office, targeting, training, etc.), it would be accurate to say that OFO has deployed naloxone to all areas identified by the field as having risk factors for exposure to opioids. Additionally, OFO stands ready to deploy additional naloxone, as requested by the field.

**Question:** How about the percentage out of all CBP officers?

**Response:** Naloxone has been deployed to all OFO field offices for placement where contraband is handled. As of August 13, 2019, approximately 24 percent (5,054) of the OFO workforce has been trained in naloxone administration. Although not all OFO personnel are assigned to areas where contraband is handled (e.g. office, targeting, training environments, etc.), OFO has deployed naloxone to all areas identified by the field as having risk factors for exposure to opioids. Additionally, OFO stands ready to deploy additional naloxone, as needed by the field.

<b>Question#:</b>	17
<b>Topic:</b>	Deployment of Naloxone
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Susan Brooks
<b>Committee:</b>	ENERGY & COMMERCE (HOUSE)

**Question:** You highlighted the role of naloxone in protecting your employees and the public. There was legislation that passed last Congress focused on ensuring that CBP has tools to screen for fentanyl, and a similar bill introduced to allow local law enforcement agencies to screen - but it seems like that is only part of the solution, and that Congress could work on similar legislation to ensure there is access to adequate supplies of naloxone to protect your employees and the public.

So, I wanted to ask both you if you would support Congress providing funding to increase the deployment of naloxone to your employees?

**Response:** Yes, OFO would support funding to increase the deployment of naloxone to employees. However, in addition to the funds needed to purchase more naloxone (which expires every 1.5-2 years), additional funding would be needed to train end-users, instructors, and Emergency Medical Services providers, and for acquisition and maintenance of training equipment and supplies. All of which contribute to the chain of survival for anyone exposed to a hazardous substance.

Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”

July 16, 2019

Mr. Gary Barksdale, Chief Postal Inspector, United States Postal Service

The Honorable Brett Guthrie (R-KY)

1. Drug traffickers often use freight forwarders to ship fentanyl and fentanyl analogs from China. Such multiple transfers of custody make it difficult for law enforcement to track these packages. Are changes in the law needed to combat the problem of freight forwarding of fentanyl in the mail? If so, what are USPS’ suggestions?

**Response:**

**I respectfully defer to CBP, which is the agency that is responsible for targeting suspicious parcels coming into the United States.**

2. How is advanced electronic data (AED) going to help target and intercept packages containing fentanyl?

**Response:**

**I respectfully defer to CBP, which is the agency that utilizes AED to target suspicious parcels coming into the United States. As the federal agency charged with securing and controlling the nation’s borders, CBP has longstanding statutory and constitutional border search authority. CBP agents are permitted to open inbound international mail without a warrant, including mail otherwise sealed against inspection.**

**The U.S. Postal Service is responsible for supplying the AED received from foreign posts to CBP. Over the past two years, the Postal Service has provided hundreds of thousands of records per day to CBP, and expanded the number of countries and types of packages available for targeting. The Postal Service has also implemented an automated process to identify targeted pieces requested by CBP.**



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3. On average, how many packages are coming into our international mail facilities (IMF) on any given day?

**Response:**

**The average daily package volume, which includes Express, parcels, tracked packets and untracked packets, was 1.03M packages per day in August 2019.**

4. How many of those packages currently come with AED?

**Response:**

**Of the 34.6M inbound packages received in August 2019, 64.9% were accompanied by AED.**

5. How reliable and useful is the AED when it comes to helping mail entities and law enforcement interdict packages containing narcotics?

**Response:**

**I respectfully defer to CBP as to usefulness of AED due to its role in utilizing AED to target suspicious parcels coming into the United States. The USPIS will continue to collaboratively work with CBP and Homeland Security Investigations (HSI) in seizing any illicit substance in the mail stream and to arrest those who abuse the U.S. mail system.**

6. What unique challenges does fentanyl pose as opposed to other narcotics when it comes to detecting and interdicting fentanyl coming in through the mail?

**Response:**

**Unlike larger, bulkier narcotics, fentanyl and its analogues pose a unique challenge due to their ability to be contained in a parcel of any size. Fentanyl can then be secreted inside otherwise innocuous items, further concealing it from law enforcement. Fentanyl can also take many forms, including powder or pressed into pills, which may be counterfeits of otherwise legitimate drugs. Additionally, the high profit margin of fentanyl creates an inviting opportunity for illicit drug dealers.**

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7. What more would law enforcement need in order to be best positioned to interdict more packages containing narcotics, like fentanyl?

**Response:**

The USPIS is not currently authorized to issue administrative subpoenas for the investigation of narcotics-related offenses. A change in the USPIS's current limited administrative subpoena authority to include narcotics offenses would place U.S. Postal Inspectors on par with federal law enforcement peers such as the DEA and DHS, among many others. This authority would greatly expedite the ability of postal inspectors to learn relevant information that can expand or dispel suspicion about a parcel suspected of containing narcotics.

Under current law, the USPIS is only authorized to issue administrative subpoenas related to false representations and lotteries under 39 U.S.C. §3016(a)(1)(A). Section 3016(a)(1)(A) establishes this authority in stating, *"In any investigation conducted under section §3005(a), the Postmaster General may require the production of any records... which the Postmaster General considers relevant or material to such investigation."* 39 U.S.C. §3005(a) establishes USPIS's administrative power regarding false representations and lotteries.

The USPIS proposes a provision amending 39 U.S.C. §3016 to remove "3005(a)" and to replace it with "3001." This amendment to §3016(a) would have the effect of granting USPIS the authority to issue administrative subpoenas for investigations into nonmailable matter, which includes narcotics investigations. Because of the nonmailability of false representations and lotteries, this change will not limit the ability of the USPIS to investigate these important fraud cases.

Due to the expected increase in issuances of administrative subpoenas based on the above change, USPIS also proposes extending the ability of the Postmaster General to delegate this authority to the Chief Postal Inspector or his designees, which can be limited to certain Senior Executive Service positions. This administrative change will not otherwise expand the conditions necessary to issue an administrative subpoena as enumerated in §3016(a)(1)(B)(i) and (ii).

This change will not affect the current requirement of a federal search warrant to open mail sealed against inspection.

8. Your written testimony states that current seizure statistics show a decrease in international seizures related to fentanyl, while domestic seizures are trending up. Your testimony suggests that synthetic opioids are increasingly entering the country through means other than international mail before distributed through mail, consignment carriers,

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or traditional drug distribution networks. Outside of these international channels, what are the other potential means for fentanyl and synthetic opioids to enter the United States?

**Response:**

To update my testimony, as of September 8, 2019, the Postal Inspection Service has seized 269 synthetic opioid parcels, of which 225 were in the domestic mail stream. These seizure statistics represent a decrease in international seizures related to synthetic opioids and fentanyl, while domestic seizures are trending up. I respectfully defer to my colleagues at ONDCP, CBP, ICE, and the DEA as to the other means fentanyl and synthetic opioids are entering the country. The Inspection Service will continue to work to interdict and seize any illicit substance in the mail stream and to arrest those who abuse the U.S. mail system, whether originating internationally or domestically.

9. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?

**Response:**

The Postal Service is committed to harnessing the technology required to support the critical data exchange involved with AED on inbound shipments. This is a complex big data exchange that is relied upon by all of the key partners — Postal Service Business Units, Inspection Service, CBP and OIG — that work jointly to stem the flow of illicit drugs from international sources. Monthly cross-functional meetings chaired by Postal Service senior leadership are held to track progress and discuss initiatives regarding AED across the organization.

The Postal Service receives and acts upon CBP holds associated with AED by leveraging its Package Remote Encoding System (PRES) and more than 400 parcel sorting machines to facilitate intercepts. The Postal Service has automated intercept capabilities for CBP holds in the mail processing environment at five International Service Centers and 19 mail processing facilities. It has also enabled CBP holds in 30,000 Delivery Units and on more than 75,000 scanning devices. The Postal Service leverages high volume transaction processing capabilities to handle these requests in real time, and continues to deploy technology to improve interception capability to meet the goal of 100 percent capture of CBP hold requests.

Through coordination with USPIS, CBP and internal stakeholders, the Postal Service integrates these technologies by developing efficient work methods for capture and handoff of packages. The Postal Service developed and deployed a Delivery Unit Intercept dashboard to track intercept success rates and to follow up on missed requests.

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**The Postal Service is committed to reach 100 percent interception through technology enhancements. By leveraging scan data, the Postal Service and CBP continue to improve the efficiency and effectiveness of their efforts. The Postal Service will continue to enhance and scale technological solutions to support the interdiction mission.**

**The Honorable Susan Brooks (R-IN)**

1. One thing I am concerned about is that many opioids in the mail are fentanyl and its derivatives, which are potent enough that a dose smaller than the size of a penny can cause a fatal overdose. In your [prepared] testimony, you highlighted the importance of employee safety and the extra steps taken by the Postal Service to protect employees from accidental exposure to opioids with Narcan nasal spray.

Could you provide more specific information about how many postal facilities and the percent of them that have access to Narcan nasal spray?

**Response:**

**In July of 2018, the Postal Service initially deployed naloxone response kits to all mail processing facilities and large Post Offices, about 758 facilities. The kits were deployed to these facilities because employees in these facilities have the highest potential to be exposed to products containing fentanyl in mail packages, as the packages are processed in these facilities and transported to Post Offices for delivery to customers. These facilities comprise approximately 51% of our workforce. We will be deploying to an additional 3,702 medium-sized Post Offices in late October 2019. Following this second phase of deployment, a total of 75% of our workforce will have access to the naloxone nasal spray.**

2. Your testimony only mentions key facilities, which suggests many of our nations postal workers are unprotected. Can you provide some more information about efforts to better protect postal workers and our constituents?

**Response:**

**In addition to the deployment of naloxone response kits, the Postal Service has a long-standing program to communicate and train employees to identify and take appropriate actions when suspicious mail or packages are identified in the mail stream. The suspicious package program requires that the Postal Inspection Service is immediately notified. In addition, local emergency responders are notified as appropriate. A variety of employee training materials are used, including videos, publications, checklists, and stand-up talks. Stand-up talks are specific communications**

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developed for our managers and supervisors to share information face to face with our employees. Postal employees receive initial and annual refresher training twice per year, with additional presentations delivered as circumstances require. Management is required to document that the training and stand-up talks are completed. While all employees receive training on how to recognize and respond to hazardous materials, the Postal Inspection Service has Dangerous Mail Investigation (DMI) specialists trained to respond to incidents including unidentified or potentially illegal substances that are found in the mail stream or in postal facilities.

Specific to the opioid epidemic, the Postal Service provided a series of mandatory stand-up talks to employees to provide education regarding the dangers of using opioids and treatment options. The Postal Service plans to continue to provide education to our employees in the coming fiscal year, as well as an opioid awareness training for supervisors on identifying and managing risks related to prescription opioids.

The Postal Service is further coordinating policy changes with the U.S. Department of Labor to shorten the prescription length for opioids given to Postal employees in connection with job-related injuries and illnesses before they are required to provide documentation from a physician. The Department of Labor recently announced that for injured on-duty workers, it plans to impose additional limitations and reduce the time period that employees can receive opioid prescriptions with prior approval. The Postal Service plans to continue to collaborate with the Department of Labor on this important issue, and we have begun to monitor the opioid trends for our employees as part of the workers' compensation program.

3. You highlighted the role of naloxone in protecting your employees and the public. There was legislation that passed last Congress focused on ensuring that CBP has tools to screen for fentanyl, and a similar bill introduced to allow local law enforcement agencies to screen – but it seems like that is only part of the solution, and that Congress could work on similar legislation to ensure there is access to adequate supplies of naloxone to protect your employees and the public.

So, I wanted to ask both you if you would support Congress providing funding to increase the deployment of naloxone to your employees?

**Response:**

As we indicated in a previous answer, the Postal Service has prioritized its funding of naloxone response kits to those employees that have the highest potential exposure to products in the mail containing fentanyl. After our Phase II deployment of the naloxone kits, approximately 75% percent of our workforce will have access to the naloxone nasal spray. That said, given our current fiscal challenges and our ongoing efforts to return us to a financially sustainable path, the Postal Service would support a

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**decision by Congress to provide funding to increase the deployment of naloxone to our employees.**

<b>Question#:</b>	1
<b>Topic:</b>	Freight Forwarding
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**David A. Prince**

**Question:** Freight forwarding of drug shipments may involve bundling or consolidating several kinds of items into one shipment. Is Homeland Security Investigations (HSI) using manifest data from consignment carriers about patterns of freight forwarding?

If so, what changes would you suggest?

**Response:** Yes, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), in collaboration with U.S. Customs and Border Protection (CBP), uses manifest data from consignment carriers to target and interdict shipments containing contraband and narcotics based on post seizure analysis. A suggested change would be mandatory disclosure of individual manifest data to CBP for each individual parcel within consolidated shipments.

In Fiscal Year (FY) 2017, the ICE HSI Memphis Border Enforcement Security Task Force (BEST) initiated approximately 282 controlled deliveries to ICE HSI offices throughout the world. One example of these cases occurred in August 2017 when ICE HSI Memphis BEST seized 4.7 grams of highly potent carfentanil destined for Brockton, Massachusetts. ICE HSI Memphis BEST collaborated with ICE HSI Boston who accepted the package and substituted sham product for controlled delivery purposes. Subsequent to the sham delivery, special agents executed a search warrant resulting in the seizure of multiple firearms, cocaine, and heroin. One of the seized firearms was matched to an unsolved shooting in the Brockton, Massachusetts, area. In FY 2018, ICE HSI BEST Memphis initiated 204 controlled deliveries throughout the world that resulted in 46 criminal arrests, 24 indictments, 10 convictions, 149 additional seizures, 29 search warrants, and 1 administrative arrest.

ICE HSI BEST JFK has further capitalized on its participation in the Organized Crime Drug Enforcement Task Force Program by leading a Heroin Initiative, which targets parcels suspected of containing illicit narcotics smuggled through voluminous e-commerce shipping routes. In FY 2018, ICE HSI BEST JFK seized 243 fentanyl-laden parcels weighing 85 pounds that resulted in 219 referrals for controlled deliveries.

ICE HSI Houston, National Targeting Center-Investigations, and the U.S. Postal Inspection Service developed an initial target list of parcels suspected of containing illicit substances destined for U.S.-based recipients. The initial target list was shared with other cooperating agencies for potential interception and execution of controlled deliveries. These operations resulted in the seizure of 72 parcels containing some form of illicit

<b>Question#:</b>	1
<b>Topic:</b>	Freight Forwarding
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

substances, including illicit fentanyl. Based on the contents of the 72 parcels seized, a common link in the flow of these illicit drugs to the United States was identified.



<b>Question#:</b>	2
<b>Topic:</b>	Dark Web Challenges
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** How is the dark web more of a law enforcement challenge than rogue internet pharmacies on the open web?

**Response:** ICE HSI has observed a continuously accelerating increase in the level of criminal activity facilitated via the dark web, which is an underground online safe haven for a myriad of illicit activity including illegal drugs.

Since the infiltration of Silk Road, the number of dark web illicit market users has increased rapidly. With crypto currencies serving as mediums of exchange to operate entirely within a digital economy, these underground markets offer access to a vast amount of illicit goods and services without the risk of being easily uncovered and arrested.

In contrast, rogue internet pharmacies do not typically use the same anonymization and security measures as dark web markets, as such rogue internet pharmacies generally attempt to portray an image of legitimacy. As internet pharmacies are on the open web, they are easily detectable and more accessible to the public and law enforcement. Additionally, crypto currencies are not as commonly utilized by rogue internet pharmacies, making the tracing of financial transactions easier for law enforcement. Customers of such rogue internet pharmacies are also more likely to cooperate with law enforcement as they are often victims of criminal activity.

<b>Question#:</b>	3
<b>Topic:</b>	Dark Web Use
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** How has the use of the dark web changed the way in which our intelligence and law enforcement communities have had to approach combatting narcotics, such as fentanyl?

**Response:** ICE HSI is the principal investigative component of the Department of Homeland Security. ICE HSI Special Agents are utilizing their unique combination of customs and immigration authorities in their investigations to identify, infiltrate, interdict, and dismantle the organizations that utilize the dark web for criminal activity. The dark web's technical composition has posed challenges for law enforcement in combating illicit fentanyl and other illegal narcotics as it has added layers of anonymity to criminals. Law enforcement has had to adapt investigative techniques and utilize new technologies to counter these added layers of anonymity.

ICE HSI works with private industry, academia, and international partners in an effort to expand and enhance emerging computer technology and proactively uses these new technologies to investigate criminal activity in dark net markets. ICE HSI has been very successful in developing methods to track and trace digital cryptocurrency, which is often used as the payment system for illicit online opioid transactions, through several means such as exploiting choke points like bitcoin exchanges and blockchain analysis.

The ICE HSI Cyber Crimes Unit (CCU) within the ICE Cyber Crimes Center has a variety of investigative resources and tools to facilitate and support casework and investigators in the field. Some of these resources include:

- Blockchain and cryptocurrency analytical tools utilized to detect criminal activities and suspicious financial connections in cryptocurrencies;
- Website and social media scraping tools to assist in the search, collection, and archiving of information used to facilitate a wide variety of investigations;
- Undercover website development and backstopping; and
- Technical guidance, programs, and networks associated with high-tech investigations.

The Joint Criminal Opioid and Darknet Enforcement Team (J-CODE) is a Department of Justice sponsored initiative that was established in January 2018 to combat the proliferation and distribution of fentanyl and other opioids via illicit dark net marketplaces. As an active J-CODE member agency, ICE HSI leverages its investigative authorities with those of other law enforcement agencies to combat illicit fentanyl and

<b>Question#:</b>	3
<b>Topic:</b>	Dark Web Use
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

other illegal opioids utilizing a collaborative approach. The ICE HSI CCU has actively participated in coordination meetings with J-CODE team members to receive and distribute target packages to ICE HSI field offices to initiate joint opioid investigations with other J-CODE member agencies.

Additionally, and in response to the President's initiative in reduction of opioid demand in the United States, ICE HSI developed a cyber-training curriculum with a focus on dark net investigations and illicit payment networks, associated with fentanyl smuggling and distribution. This training has been successful in improving collective law enforcement capabilities against online marketplaces and tools for illicit trafficking. This course provides law enforcement with technical knowledge and in-depth case briefings to assist criminal investigations involving the dark net and cryptocurrency related crimes, which facilitate the international distribution channels related to opioid smuggling.

In FY 2018, ICE HSI delivered its Online International Opioid Smuggling training course in over 25 locations worldwide to more than 4,500 federal, state, local, and international law enforcement personnel.

<b>Question#:</b>	4
<b>Topic:</b>	Combatting Dark Web
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** What successes has HSI had in combatting the use of the dark web for the sale and purchase of fentanyl?

**Response:** Silk Road, Alpha Bay, and Dream Market were all dark net marketplaces that were successfully taken down through the collaborative efforts of multi-federal law enforcement agencies leveraging their intelligence and resources to combat dark net marketplaces where fentanyl was being sold.

Most recently, ICE HSI, through Operation Dark Gold, took down the largest unlicensed cryptocurrency exchanger and money launder on the dark net and led to the deanonymization and subsequent take down of some of the largest dark net market fentanyl vendors. Operation Dark Gold resulted in the seizure of approximately \$20,000,000 US Dollars in cryptocurrency.

<b>Question#:</b>	5
<b>Topic:</b>	Bitcoin Financing
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** Many of the fentanyl sources operate on the dark web and use bitcoin for financing. Is the U.S. Drug Enforcement Administration DEA or HSI seeing any evidence that credit card companies, consignment carriers, or domain registrars are accepting bitcoin as payment?

**Response:** Although Bitcoin and other cryptocurrencies are now used worldwide to carry out day-to-day financial transactions, ICE HSI does not have any evidence that credit card companies or consignment carriers are accepting Bitcoin or other cryptocurrencies for payment.

<b>Question#:</b>	6
<b>Topic:</b>	Combat Trafficking
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** Are credit card companies, consignment carriers, and internet service providers (ISP) helping law enforcement to combat fentanyl trafficking on the dark web?

**Response:** Yes, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), in collaboration with U.S. Customs and Border Protection (CBP), uses manifest data from consignment carriers to target and interdict shipments containing contraband and narcotics based on post seizure analysis. A suggested change would be mandatory disclosure of individual manifest data to CBP for each individual parcel within consolidated shipments.

Credit card companies and internet service providers have both been cooperative with ICE HSI and have complied with requests to produce records and data upon being served with the appropriate legal process.

<b>Question#:</b>	7
<b>Topic:</b>	Shut Down Supply Chains
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** How have the dark web and crypto currency complicated attempts to target and shut down these supply chains? What is being done to overcome these difficulties?

**Response:** Cryptocurrency by design is pseudo-anonymous. By applying traditional investigative techniques as well as using advanced blockchain tracing tools, law enforcement can de-anonymize some cryptocurrency wallets and identify the purchaser of fentanyl or contraband on dark net markets.

Anonymity-enhanced cryptocurrencies such as Monero, Dash, and ZCash, among others, are designed specifically to protect privacy and currently pose the greatest challenge for law enforcement. To overcome these difficulties, Homeland Security Investigations has partnered with blockchain tracing companies, as well as cryptocurrency exchangers and financial institutions, to bolster our knowledge in these evolving technologies and work collaboratively in countering the fentanyl crisis.

<b>Question#:</b>	8
<b>Topic:</b>	Data Collection
<b>Hearing:</b>	Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl
<b>Primary:</b>	The Honorable Brett Guthrie
<b>Committee:</b>	ENERGY AND COMMERCE (HOUSE)

**Question:** How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?

**Response:** Intelligence data collection and consolidation into Department of Homeland Security holdings can improve U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigation's (HSI) ability to target, interdict, and investigate suspect packages. ICE HSI works closely with the Drug Enforcement Administration (DEA), the Federal Bureau of Investigation, U.S. Customs and Border Protection, United States Postal Inspection Service, the Food and Drug Administration, and other federal partners to deconflict intelligence and investigative efforts combating transnational criminal organizations, which are not only focused on the interdiction, but also on dismantling the supply chain of illicit narcotics. Much of this information sharing is currently being done at the National Targeting Center, the Organized Crime Drug Enforcement Task Forces fusion center, and through the DEA Special Operations Division, focusing on a one law enforcement approach.

Data collection can be improved and bolstered through greater collaboration and information sharing with private sector entities. This can be done at both the agency headquarters and field levels through targeted outreach efforts specifically focused on industries that have data and product holdings that can be used for the production of illicit fentanyl and other "hard" narcotics. An example of this are companies that manufacture and ship legal precursor chemicals that could be used by Drug Trafficking Organizations to produce illegal narcotics. Collection and manipulation of this information could lead to more specific targeting efforts to interdict the chemicals and/or allow investigative agencies to follow them to their foreign source (clandestine laboratory, etc.).





**FDA U.S. FOOD & DRUG**  
ADMINISTRATION

JAN 23 2020

The Honorable Frank Pallone, Jr.  
Chairman  
Committee on Energy and Commerce  
Washington, D.C. 20515-6115

Dear Chairman Pallone:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the July 16, 2019, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

Karas Gross  
Associate Commissioner for  
Legislative Affairs

cc: The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce  
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations  
The Honorable Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations

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**The Honorable Frank Pallone, Jr. (D-NJ)**

1. **The inability of individuals to detect the presence of illicit fentanyl in counterfeit pills can result in the individuals unknowingly exposing themselves to fentanyl. As the agency tasked with addressing counterfeit drugs, how is the Food and Drug Administration preventing these pills from entering the marketplace, other than by prosecuting through DOJ?**

FDA refers any drug product that is determined to contain fentanyl to CBP as the lead interdicting authority for controlled substances generally. FDA currently uses a rapid screening tool to screen products of interest to identify suspected counterfeit pills coming through the International Mail Facilities (IMF) that have been referred to the FDA by CBP. These articles are then evaluated by FDA's Forensic Chemistry Center to confirm authenticity against the established library of drugs. Finally, if the article is determined to be a non-controlled drug and is counterfeit, FDA will destroy the drug using our administrative destruction authority.

**The Honorable Brett Guthrie (R-KY)**

1. **Is the U.S. Food and Drug Administration (FDA) receiving intelligence from any other federal agencies on Chinese drug companies potentially involved with illicit fentanyl?**

FDA's Office of Criminal Investigation routinely shares intelligence with DEA, CBP and ICE related to illicit fentanyl trafficking through agents assigned to work at International Mail Facilities, CBP's National Targeting Center and DEA's Special Operations Division as well as through routine criminal investigations such as Operation CyberPharma which targets online sellers of counterfeit opioids.

2. **Is FDA sending and receiving intelligence among federal agencies related to combating illicit fentanyl trafficking?**

See previous answer.

3. **Does FDA have a mechanism to receive or share intelligence related to illicit fentanyl trafficking?**

FDA's Office of Criminal Investigations has access to information-sharing databases as part of our work at International Mail Facilities, CBP's National Targeting Center and DEA's Special Operations Division. In addition, FDA continues to work with United States Postal Service (USPS) and CBP on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening.

4. **What is the status of implementation of SUPPORT Act provisions related to advanced electronic data or debarment authorities related to illegal imports of drugs?**

FDA continues to work with United States Postal Service (USPS) and U.S. Customs and Border Protection (CBP) on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening. Meetings have begun between CBP, USPS and the partner government agencies (PGAs) regarding the ability to receive advanced electronic data through the Automated Commercial Environment (ACE) and/or other electronic data systems. In addition, FDA is actively implementing the new debarment authority added by section 3022 of the SUPPORT Act and is currently seeking the debarment of several individuals related to the illegal importation of drugs or controlled substances. In one of the cases, an individual was served with an FDA Notice of Debarment in July 2019 and we are currently processing that debarment order.

**5. How has the SUPPORT Act changed the way in which you all operate on a day-to-day basis?**

The SUPPORT Act allows investigators in the IMFs to more efficiently and effectively determine that a product is an illicit drug and focus their resources on documenting the violation and refusing the product. This allows FDA staff to review more parcels and process more violative drugs for destruction, thereby preventing the entry of illicit articles containing identified active pharmaceutical ingredients (APIs) into U.S. commerce. Largely as a result of the implementation of section 801(u) of the Federal Food, Drug, and Cosmetic (FD&C) Act, as added by the SUPPORT Act, the destruction rate for illicit drugs entering the U.S. through the IMFs has increased eightfold compared to the same time period in FY2018 (through August 2018, our destruction rate was 5.42%, for the same time period through August 2019, it is 44.27%). FDA continues to identify additional APIs amenable to this new authority.

**6. In April 2019, the FDA and U.S. Customs and Border Protection (CBP) signed an agreement to maximize inspection and detection capabilities in order to prevent illegal and harmful products such as fentanyl from the United States through the international mail facilities. What are some of the results from this agreement so far?**

FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in Jamaica, Secaucus, Miami, Long Beach and Chicago. These facilities will be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants. FDA and CBP laid the foundation to pilot this effort at the Chicago IMF using a mobile laboratory unit, which has been prepared by the US Army Futures Command, and delivered to the IMF in November. That unit will be staffed by scientists trained by FDA's Forensic Chemistry Center specialists, along with CBP's Laboratories and Scientific Services scientists.

In support of the Letter of Intent, FDA and CBP have held multiple discussions regarding operational areas for agreement, and a draft MOU based on those discussions, shared with both CBP and USPIS, is currently being vetted within those agencies.

**7. Over the last two years, how has FDA improved targeting of fentanyl entering the United States?**

CBP is generally the lead interdicting authority for controlled substances, including fentanyl and other opioids. Operationally, CBP is the agency with first review of products and will handle fentanyl and other opioids following their processes. If FDA encounters products containing fentanyl, FDA will refer these products back to CBP for processing.

**8. What is the role of the FDA's Office of Criminal Investigations (OCI) in combating the illicit fentanyl threat?**

OCI continues to leverage FDA's enforcement authorities to combat a wide range of criminal conduct involving opioids, including combatting illicit fentanyl. Online, OCI's Cybercrime Investigation Unit is targeting darknet marketplaces and vendors manufacturing and selling counterfeit opioids, including fentanyl-tainted counterfeits, through arrest and the seizure of assets. Thus far, Operation CyberPharma has led to the arrest of 7 darknet vendors and aided in the takedown of a major darknet marketplace as well as the seizure of drug counterfeiting tools and tens of thousands of dollars in virtual currencies and other assets. Additional arrests and seizures are anticipated with this on-going operation.

OCI's Import Operations Program also plays an important role combating the illicit fentanyl threat at our International Mail Facilities. While CBP handles the majority of opioid-related interdictions, FDA also encounters these products. OCI agents work to identify the source and destination of these drugs and collaborate with other federal agencies such as ICE, DEA and the Postal Inspection Service.

**9. Over the last two years, how much has FDA increased staffing of OCI special agents working at points of entry?**

In FY 19 the number of criminal investigators assigned to the OCI Import Operations Program (IOP) increased from 17 in fiscal year 2018 to 21 agents currently.

**10. What is the role of FDA's Forensic Chemistry Center in supporting FDA's efforts to combat illicit fentanyl?**

FDA's Forensic Chemistry Center (FCC) developed proposals to assist in increasing the number of packages screened at the IMFs, putting advanced tools in the hands of FDA investigators and agents and providing training. FCC also developed a toolkit for use by scientists at the IMFs including associated training courses and materials, as well as, developed safety protocols for handling fentanyl and fentanyl analogs.

**11. Has FDA received additional resources to combat illicit fentanyl? If so, how much, and how are these additional resources being deployed?**

The Office of Regulatory Affairs (ORA) was allocated 125 FTEs and approximately \$86M to support the increased workload associated with combating the Opioid crisis. As of Sept

2019, 75 of 125 positions are onboarded and approximately \$76M has been obligated to support field work, laboratory sciences, and criminal investigations. Some highlights of expenditures are \$41.7M for Forensic Chemistry Center (FCC) expansion, approximately \$8M in payroll, \$1.2M IMF build out, \$15M for IT enhancements, and \$5M for equipment for Office of Regulatory Science (ORS) and Office of Criminal Investigations (OCI).

**12. FDA's testimony stated that it had applied its new section 801(u) authority to 4,017 drug products. Did any of these products contain fentanyl?**

**a. If so, about how many of the drug products contained fentanyl?**

To use our FD&C Act section 801(u) authority, FDA must identify specific active pharmaceutical ingredients (API) which meet the criteria indicated in this provision. When FDA implemented this new authority, we targeted the highest volume APIs we see entering the U.S. via international mail. Fentanyl citrate is not among the APIs with the highest volume, thus we have not applied the new authority to drug products containing this API at this time.

**13. FDA's testimony stated that FDA and CBP have been actively working to expand the scientific presence at international mail facilities (IMF). What are some of the ideas being examined to expand the scientific presence?**

FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in Jamaica, Secaucus, Miami, Long Beach and Chicago. These facilities will be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants. FDA and CBP laid the foundation to pilot this effort at the Chicago IMF using a mobile laboratory unit, which has been prepared by the US Army Futures Command, and was delivered to the IMF in November. That unit will be staffed by scientists trained by FDA's Forensic Chemistry Center specialists, along with CBP's Laboratories and Scientific Services Scientists in the use of the toolkit.

In addition, FDA plans to deploy additional rapid screening tools to the IMF facilities to help identify counterfeit products and products containing undeclared and/or non-permitted drug ingredients.

**14. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?**

With access to automated postal data, FDA would be able to automate targeting of incoming mail parcels based on historical results from parcel and product reviews, which benefits FDA through better parcel screening for FDA-regulated product issues. Using our experience with our PREDICT screening tool for screening and targeting non-IMF import entries, we would envision creating similar risk-based targeting for IMF parcels.

FDA would also gain operational benefits from having advanced electronic data for international mail parcels. First, it would streamline the main time expenditure in FDA's processing of international mail parcels – data entry. Currently all mail parcel information is manually entered by FDA staff into FDA's entry processing system. With access to advanced electronic data, FDA can automate data collection, greatly reducing processing time, further expanding our coverage, and getting more quickly to the process of determining admissibility of the parcel contents.

Second, we envision an operational benefit not only for FDA but also for USPS and CBP from automated data and processing by removing steps from the current process, which require routing of parcels by USPS to CBP, for CBP to then screen and determine which should be forwarded on to FDA. FDA can take greater ownership of this part of the process, freeing up the other two agencies to focus on areas more germane to their day-to-day operations.

**15. Are labs at DEA, CBP, and FDA coordinating on fentanyl research and sharing fentanyl samples for each agency's specialized testing?**

FDA and CBP have been communicating and sharing information on the opioid problem, focusing on improving screening at the IMFs in keeping with an agreement in the form of a Letter of Intent between the two agencies. We do not maintain the same level of communications and information sharing with DEA, as CBP is generally the lead interdicting authority for fentanyl and other controlled substances. FDA has participated in meetings with the Joint Project Manager for Nuclear, Biological, and Chemical Contamination Avoidance (JPM NBC CA) and the TICO (Technology Innovation to Combat the Opioid epidemic) Workgroup, where information on opioid testing capabilities is exchanged.

**16. CBP's written testimony mentions pollen testing and analysis is being conducted by CBP's Laboratories and Scientific Services scientists to geolocate illicit opioid shipments. Are labs at other agencies working on testing techniques that could help geolocate illicit fentanyl shipments?**

FDA's FCC is exchanging information with CBP's LSS, has the ability to detect the presence of pollen in submissions, and can leverage CBP's expertise. FCC also has the ability to establish chemical profiles or a chemical fingerprint of materials used in the production of opioid containing products. This information assists in connecting products with raw materials and material suppliers.

**17. Could federal labs work to complement each other's effort to enhance geolocation of illicit fentanyl shipments?**

Yes. See response to 15 and 16 above.

**The Honorable Michael C. Burgess, M.D. (R-TX)**

- 1. In April, FDA and CBP signed an agreement regarding International Mail Facilities to prevent illegal fentanyl and other substances from entering our country through the mail. I toured the International Mail Facility at JFK International Airport last year with former Commissioner Gottlieb. What specific actions has FDA taken to combat fentanyl in International Mail Facilities since the signing of this agreement?**

The FDA and CBP signed a Letter of Intent on April 4, 2019, to establish an outline of strategies for advanced collaboration between the agencies that will be carried out through a series of separate written agreements. These agreements are expected to include procedures to enhance information sharing and operations, including the establishment of a list of controlled substances that are imported via international mail and which agency will retain primary interdiction responsibility. Three FDA/CBP work groups to implement the Letter of Intent have been established in the following areas: (1) Collaboration at Ports of Entry; (2) On-Site Laboratory and Scientific Services; and (3) Shared Facilities and Space at the IMFs.

In support of the Letter of Intent, FDA and CBP have held multiple discussions regarding operational areas for agreement, and a draft MOU based on those discussions was shared with both CBP and USPIS and is currently being vetted within those agencies.

Additionally, FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in NY, Secaucus, Miami, Long Beach and Chicago. These facilities would be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants.

- 2. How has CBP's work informed FDA's decision making and recent actions to combat fentanyl?**

CBP has provided information identifying International Mail Facilities as points of entry, among others, for counterfeit and unapproved drugs including fentanyl and fentanyl analogs.

FDA continues to collaborate with CBP on the implementation of section 3022 of the SUPPORT Act. FDA and CBP leaders have met to discuss the development of a list of controlled substances that, under section 3022(a)(1) of the SUPPORT Act, FDA will transfer to CBP when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.) (CSA), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Letter

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of Intent and the pursuant MOU will enhance the coordination activities between agencies at the mail facilities.

**3. The SUPPORT for Patients and Communities Act included a provision to require advanced electronic data submission for all international mail shipments. How has the use of technology and data shaped FDA's response to the influx of fentanyl?**

FDA continues to work with United States Postal Service (USPS) and U.S. Customs and Border Protection (CBP) on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening. Meetings have begun between CBP, USPS and the partner government agencies (PGAs) regarding the ability to receive advanced electronic data through the Automated Commercial Environment (ACE) and/or other electronic data systems. Receiving accurate and complete electronic data in advance of shipment arrival would allow for better targeting and resource allocation within the international mail facilities (IMFs).

