TACKLING FENTANYL: THE CHINA CONNECTION

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

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TACKLING FENTANYL: THE CHINA CONNECTION

THURSDAY, SEPTEMBER 6, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 o'clock p.m., in room 2200 Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. The committee will come to order. And I want to, first of all, thank all of our witnesses including our very distinguished witnesses from the administration, one, for your tremendous work that you are doing in this opioid crisis, and secondly, for taking the time out here to provide expert testimony. We do have a second panel of experts who will follow, so this, I think, will be a very enlightening and hopefully motivating hearing on what do we do next, and of course to go very deeply into the nature of the problem and how it has been exacerbated almost from month to month it is getting worse as we all know.

Chinese made fentanyl, a synthetic opioid, is killing Americans, more than 29,000 in 2017 alone. We must hold the Chinese Government accountable. Kirsten Madison, Assistant Secretary of State for International Narcotics and Law Enforcement Affairs will testify today that China is a "primary source of illicit synthetic drugs coming to the United States."

Paul Knierim, Deputy Chief of Operations at the Office of Global Enforcement for Drug Enforcement Administration, or DEA, stated in his testimony that China is one of the world's top producers of precursor chemicals used to manufacture fentanyl as well as chemicals used to process heroin and cocaine.

In our second panel we will hear from again some amazing experts. One is Ocean County, New Jersey prosecutor, Joseph Coronato, who has called the China-made fentanyl influx into the United States a synthetic storm that is "devastating." He will thankfully note that local law enforcement is doing something about it, like his program, the first in the State of New Jersey, to allow drug abusers who voluntarily turn themselves in at a police station, and thus far it has been over 800 since 2017, without being prosecuted. The idea of an engraved invitation that states, "Come we will help you." He is obviously very tough on crime but he also

has a great humanitarian heart and is saying we want to help and treatment is a way of intervening for a positive outcome.

And the program based on statistics has almost certainly reduced deaths. Still, Prosecutor Coronato will note that based on his medical examiner's toxicology analysis, in 2014, 10 percent of overdose deaths in the county had fentanyl in their systems. Shockingly, in 2018, fentanyl related deaths have jumped to over 80 percent or even more. He will tell the committee that synthetics will become the predominant type of illegal drugs abused within the next 5 years and that in many instances is being sold right over the internet.

I will ask both of our distinguished witnesses from State and DEA what the United States is doing to hold China accountable for fentanyl in the United States, what kind of cooperation are we receiving, are we using existing tools to hold bad actors in China accountable? We have tools such as the Global Magnitsky Act which targets corrupt officials and human rights abusers. Is that under consideration when it comes to this crisis that is slaughtering so many Americans?

Recently, the House passed bipartisan, comprehensive legislation to address the opioid crisis including the Synthetics and Overdose Prevention Act now pending in the Senate. The bill requires the U.S. Postal Service, as private carriers like UPS and FedEx are currently required to do, to obtain advanced electronic data, or AED provides detailed info on the shipper and the addressee and other data, empowering law enforcement, Customs and Border Protection and others, to target fentanyl and other illegal drug shipments.

Bryce Pardo of the RAND Corporation will testify today, and this is of high significance of course, that the potency of fentanyl has sharply increased the number of opioid overdoses and that the drug overdose crisis, in his words, now surpasses major public health epidemics of prior generations including the HIV AIDS epidemic.

As we all know, every single congressional district in America has felt the scourge of the epidemic. Two fathers, Don Holman and Eric Bolling, who are both in the audience today, both lost their sons to opioid overdoses last year. Don lost his son Garrett to an overdose to synthetic fentanyl, and as he will show in a written statement submitted to this committee for the record, the package came straight from China. His son ordered it online not knowing of the poisonous effects fentanyl has. His daughter Kristen testified before the House Judiciary Committee earlier this year and described how her loving brother fell into this trap. Eric's son had a similar ordeal in September 2017, losing his beloved son Eric Chase.

Last week, I spoke at a Mercer County International Overdose Awareness Day sponsored by Mercer County Prosecutor Onofri and Robinsville Mayor David Fried. Personal testimonies offered by survivors and recovering abusers were deeply moving. Trenton Police Chief Pedro Medina spoke of the loss of his son Petey. And I have known Pedro for decades, loves his son, he is a good guy. Not just him but his son, and yet he was overcome by this terrible, terrible opioid problem. In his comments he talked about how he has

relied on God to get him through this crisis and said God can help all of you who are surviving, the family members and the friends.

Advocate Mark Manning, who lost his son Christopher, made it very clear that his horrors of the addiction in losing his son Christopher, and the pain that just doesn't go away is ever-present.

And then we heard from Adrienne Petta who recounted the horrors of her addiction. She is one of the lucky ones who was able to get through it and she, herself, is now a recovery specialist. One of the moving parts of her testimony was she said, I have two children, and this was after she was off, she thought she was clean. And then she said, if you would have put a pack in front of me, a bag, my two kids would take second and the bag would come first. That is how strong, as you know so well from your good work, this terrible chemical is.

For the record, Monmouth County Prosecutor Christopher Gramiccioni's opioid diversion program steers certain low-income, nonviolent offenders to treatment rather than traditional criminal prosecution. And again Angelo Onofri from Mercer County is doing the same thing and announced that every municipality in Mercer County had agreed to sign up. And I think that is a very important step and a model for every municipality in this country to look at this as a disease. Go after those who do our hawking it and selling it, put them behind bars, but for the victims, treat it for what it is, a disease.

I would like to yield to my good friend and colleague, Karen Bass, for any comments you might have.

Ms. BASS. Thank you. Thank you, good afternoon, and thank our witnesses today and Chairman Smith for calling today's hearing and bringing attention to fentanyl and the horrific effects this drug has had on Americans of every stripe. Some foreign affairs issues seem remote and inconsequential to everyday Americans, but this issue has eviscerated individuals, families, and entire communities here at home.

Opioid addiction negatively impacts our healthcare system, our criminal justice system, our education system, and our child welfare system which is where the children go when the parents are unable to take care of them. And the primary reason that children are removed and put in foster care is substance abuse. Sourced mainly from China and Mexico, fentanyl have contributed to a dramatic uptick in opioid related overdoses and deaths in recent years.

I have also learned that fentanyl is being sprinkled into marijuana in States where marijuana is illegal. So it is not just in opioids. According to estimates, foreign-sourced fentanyl and its related compounds killed nearly 20,000 Americans in 2016, more than any other illicit drugs, even more than breast cancer. Between 2013 and 2016 these deaths increased over 600 percent.

Beyond death, we also know that fentanyl has insidious effects for pregnant mothers and children. The Washington Post reported on a recent study that found that learning disabilities and other special education needs are common in children born with opioid related symptoms from their mother's drug use while pregnant. I will say though that I do not believe that a child that is exposed to opioid at birth is necessarily condemned for side effects for their entire life. We actually thought that about the cocaine epidemic

and thought that children that were exposed to crack would be impacted their entire life.

So we have seen modest progress in international cooperation between the U.S. and China. Chinese authorities through pressure from the U.S. imposed domestic scheduling controls on 116 new psychoactive substances and 10 fentanyl analogues in recent years. I don't know if this is something that has continued, but we will certainly see through this hearing.

So, obviously much more needs to be done to move the needle on the opioid crisis and I look forward to hearing from today's panelists. I do want to make note though that one thing that has happened in our country over the years is when one drug presents itself all of our focus and efforts go on that one drug. And although opioid is a horrible scourge and thousands of people are dying from it, people are also continuing to die from crack, from meth and that might not be sourced from China, but when you look at Mexico, when you look at other countries where the crack and the meth is coming from, that is still impacting our communities terribly.

And as the chairman said, we need to look to how we prevent the drugs from coming into the country, but when they do come in the country we need to address it and one way we need to address it is through treatment. Twenty years ago when the crack cocaine epidemic was here we thought we could incarcerate the problem. And I am hoping that given this new epidemic we have learned better and when people are addicted it is a health problem, as you said, and the way you address a health problem is through substance abuse treatment.

So once again I thank you, Mr. Chairman, and yield back my time.

Mr. SMITH. Thank you very much, Ms. Bass. I would like to now yield to Dan Donovan who is a former prosecutor from Staten Island. He was very involved with combating drug abuse as a prosecutor and is a distinguished member of this committee.

Mr. DONOVAN. Thank you, Mr. Chairman. I think you and Ranking Member Bass described the problem very adequately.

As the chairman said, I was the elected DA for 12 years in Staten Island before I came to Congress. Before that for 8 years I was Deputy Chief of Narcotics at the Manhattan DA's Office. I am very well aware of in 1996 when the physicians who used to treat four vital signs—your heart rate, your respiratory rate, your blood pressure, and your temperature—were then tasked with dealing with the fifth vital sign, pain. Except that was subjective. They couldn't—they had to trust the patient to tell them. I remember in the hospitals the smiley faces going down to the frown and a physician or a physician's assistant would ask the patient show me where your pain is on this chart, because it couldn't be measured.

And that started the overprescribing of opioids for pain relief for people who legitimately had pain. When we did some things like InterConnect and formed a nationwide system database where people couldn't circumvent the restrictions on prescriptions, I on Staten Island had three crossings to New Jersey. We curtailed the availability of prescription drugs, but my residents just went over one of three bridges to New Jersey to get their prescriptions either

written or filled. But when I got to Congress we got New York included in that InterConnect.

So I understand the problem. I do also understand it took us awhile to get our hands around this fentanyl problem. I remember the medical examiners during an autopsy of an overdose never tested for fentanyl. They would see heroin in the system and they would deem it to be a heroin overdose. It took us awhile to then start to test for fentanyl and we found that so many of those overdoses were the results of this substance.

So I look forward to hearing from our experts on how we are going to deal with the importation of this deadly drug from China onto the streets of our nation. And, Mr. Chairman, with that I yield back.

Mr. SMITH. Mr. Donovan, thank you very much. I would like to now yield to Dr. Bera from California.

Mr. BERA. Thank you, Mr. Chairman. Thank you to the ranking member and to my colleague, Mr. Donovan. I remember that because I was practicing at that time and there was a push to more adequately assess pain and treat it. And now in this position, you know, having sat with parents who have lost their children, you know, who may have very legitimately injured themselves, you know, we were giving them a prescription of Vicodin and then, you know, became addicted and went down a dangerous path.

I am glad that this body and this country is taking this epidemic seriously. But as the ranking member mentioned, this is just a long chain of other illicit drugs that are out there, whether it was the crack epidemic of the '80s and we have been dealing with methamphetamines in California for awhile. But again I am glad that we are taking this seriously and using the language of the fact that this is a disease and thinking about it from the perspective of, you know, prevention, but then also treatment as opposed to, you know, just looking at it from the law enforcement perspective which is absolutely necessary as well.

You know, when I think about what is happening in California and even in our four-county Sacramento region, you know, we had over 250 deaths, many of them due to fentanyl and that is low compared to some of my colleagues. And I think, you know, we very much have to get ahead of this. I am glad that we are discussing this.

I am glad that we have through State Department and other means, exerted some pressure on China to stop producing some of the precursors to fentanyl. I am very much looking forward to the witnesses to, you know, get a sense of how effective that has been. But I also know that we have to do a lot more. I mean we have a lot of folks that currently are addicted and we have to use all of our measures to treat those individuals and help them rehab their lives and help them put their families back together. And in some cases, you know, help entire communities put their communities back together.

So again thank you for having this hearing and I will yield back.

Mr. SMITH. Thank you very much, Dr. Bera. I would like to yield now to Mr. Castro.

Mr. CASTRO. Well, thank you for your testimony today.

And, you know, for the last several years fentanyl and the opioid epidemic has ravaged many communities in many States in this country and I am glad that we are having this hearing. That we are talking about it for what it is, a health crisis. That addiction is a health crisis and hopefully together we can determine how best to help treat it. I am convinced that by and large the folks who suffer from this addiction want to get on with their lives, don't want to be addicted, want to get back to their families and back to their work. And so thank you for everything you all are doing in that regard.

Mr. SMITH. Thank you, Mr. Castro.

Mr. Suozzi, the gentleman from New York.

Mr. SUOZZI. Thank you, Mr. Chairman. Thank you, Ranking Member. Thank you to all the members here and for everyone testifying here today.

I don't think anyone has to be persuaded that this is a major crisis in our country right now, not only opioid addiction but the introduction of fentanyl, a synthetic drug that people really don't know that they are getting sometimes. I have personal experience with this where I have been called to the hospital, friends of mine, their son dead on the table because he took a pill that he didn't know had fentanyl in it and he overdosed immediately.

This is a very real problem for real families throughout America every single day. And I appreciate the chairman and ranking member for holding this hearing, for us to try and identify whether there is a link between Chinese production of fentanyl and whether or not it is being introduced to our country in large quantities in illicit ways and if there is anything we can do to try and combat the introduction of this manufactured substance into our country.

There are so many other drug problems in our country that have been going on and have been pointed out so eloquently by my colleagues for many years. It is important that we look at this as a health crisis, but we also have to look at where this drug is coming from and why it is being shipped here to the United States of America and what we can, if anything, do about it.

Mr. SMITH. Thank you. I would like to now introduce our distinguished panel beginning first with the Assistant Secretary for International Narcotics and Law Enforcement Affairs, Kirsten Madison, where she is responsible for the State Department programs combating illicit drugs and organized crime. Prior to her current post, Ms. Madison served in senior leadership positions in the executive branch including Deputy Secretary in the Bureau of Western Hemisphere Affairs; Director for Western Hemisphere Affairs on the National Security Council; the Foreign Policy Advisor to the Commandant of the Coast Guard.

She has also served as a senior professional staff member and deputy staff member of the U.S. Senate Committee on Foreign Relations, as well as legislative director and international affairs advisor for Chairman Porter Goss. Outside the government, Ms. Madison has held positions of senior advisor to the Secretary General of the Organization of American States and recently worked at the American Enterprise Institute as deputy director for foreign and defense policy studies. She holds a master of science from the London School of Economics and a B.A. from Goucher College.

Next, we will hear from the Deputy Chief of Operations, Office of Global Enforcement at the DEA, Paul Knierim. In this role he is responsible for overseeing operations to dismantle national and international drug trafficking organizations and supporting DEA investigative operations internationally. Mr. Knierim previously served in other positions in the DEA, starting his career in 1991 as a Special Agent in the Denver Field Division.

He has served in various posts internationally ranging from Ecuador, Costa Rica, and Mexico. Domestically, Mr. Knierim has worked in the DEA, Miami Field Division, served as Staff Coordinator in the DEA Headquarters Office of Congressional and Public Affairs, and as Special Agent in Charge of the Dallas Field Operation. He holds a degree from the University of Utah.

And again I thank both of them for your leadership and, without objection, your full statements will be made a part of the record, but please proceed as you would like.

STATEMENT OF THE HONORABLE KIRSTEN D. MADISON, ASSISTANT SECRETARY, BUREAU OF INTERNATIONAL NARCOTICS AND LAW ENFORCEMENT AFFAIRS, U.S. DEPARTMENT OF STATE

Ms. MADISON. Chairman Smith, Ranking Member Bass, distinguished members of the subcommittee, thank you for your efforts to highlight the tragic impact of synthetic opioids across this country. Across this administration, agencies are working to combat the illicit opioid threat and to blunt its impact on Americans.

My INL team understands that the work the State Department does to forge partnerships and consensus, to secure international cooperation, and to use foreign assistance to build the capacity of our partners to help disrupt the flow of opioids and other illicit narcotics is really just about one thing. It is about contributing to a larger effort to save American lives.

Traffickers have capitalized on the boom and global access to information and technology to facilitate their lethal trade. Illegal drug producers exploit the anonymity and convenience of the dark Web, encrypted peer-to-peer messaging applications, and other information platforms to market and sell aggressively to global clients including directly to American drug consumers. It is a new frontier in illicit trafficking and therefore a new frontier in our efforts to push back.

And I would just pick up on what some of the members of the panel have said, this I think is not displacing other parts of the drug market. We can't stop paying attention to methamphetamines, cocaine, or anything else. Those are all still real threats. This is additive not displacement.

With China, the Department is building upon the commitments made in President Trump's November 2017 meeting with President Xi to deepen bilateral counternarcotics cooperation. This effort has yielded concrete results including arrests, seizures, and take-downs of clandestine labs by Chinese law enforcement. Law enforcement information sharing has increased, including information used to combat the export of drugs that are controlled here but not in China.

Additionally, China has taken significant action to domestically control 175 substances with the 32 that were added to that list just last week including fentanyl analogues and key precursors to fentanyl production. We continue to press China to use every available tool to aggressively counter illegal production and the trafficking of synthetic opioids. Some synthetic opioids from China are flowing through Mexico where traffickers sometimes mix them, often mix them with cocaine and heroin before shipping them across our southwest border. Countering this flow is part of our partnership with the Mexican Government to disrupt drug production, dismantle drug distribution networks, prosecute drug traffickers, and deny transnational criminal organizations access to illicit revenue.

State also works multilaterally to address the proliferation of illicit synthetic drugs and uses foreign assistance working through international organizations to support real-time coordination and information sharing between law enforcement and forensic officials around the world. This increases the identification, detection, and tracking of synthetic drugs and precursor chemicals worldwide.

Working through multilateral organizations, we also deliver specialized training to strengthen the ability of key countries to intercept suspicious drugs and chemicals sold online and shipped through the mail and express consignments. The international tools that we use must actually be capable of addressing the 21st century challenge that we are facing. And I think this includes supporting an acceleration of the rate at which drugs are controlled at the international, regional, and national level. As is the case with China, international controls lay the groundwork for enhanced law enforcement cooperation with the U.S.

In March 2018, we mobilized countries at the U.N. Commission on Narcotic Drugs to control the deadly opioid carfentanil, for example, plus additional fentanyl analogues. The CND was also the venue in 2017 to assert controls on two primary fentanyl precursor chemicals, NPP and ANPP. And, at the U.S. instigation, the International Narcotics Control Board recently issued a call to all nations to voluntarily restrict 93 new substances that have no known medical use.

To have impact these controls have to be implemented. So in INL we are helping countries actually institute the treaty-mandated controls that they are supposed to at a national level. My team and I have been looking as well at additional ways that we can adapt INL's work to address the dynamic threat that is presented by illicit synthetics and to help our partners both in the U.S. Government and law enforcement and in the international community to tackle, really, all of the links in the illicit synthetic supply chain.

For example, we are developing new partnerships to expand global capacities to detect and interdict synthetic drugs shipped through the mail and express consignment shipping, including by expanding the global collection and sharing of advanced electronic data. INL also aims to broaden its cooperation with U.S. law enforcement partners to expand training and the use of technology to detect and interdict suspicious mail.

INL is also considering what additional practical steps it can take with international partners to prevent the diversion of legiti-

mate chemicals for illegal uses and to support partner governments' ability to seize and dispose of diverted chemicals and build law enforcement capacities to detect and safely dismantle clandestine labs. As part of this effort, we believe firmly that we will need to seek increased cooperation with industry to make licit modes of commerce more inhospitable to criminals without encumbering licit activity.

In addition to its other work, INL will be tapping into U.S. law enforcement expertise to provide foreign law enforcement counterparts with the skills to investigate, prosecute, and dismantle online drug vendors and to help our partners follow the digital money trail when vendors use crypto currencies to facilitate transactions.

I think, finally, we must respond to the global nature of this threat and prepare for the proliferation of synthetic drug production distribution and abuse well beyond China and the countries currently impacted. This problem requires a strategic and coordinated international response. In practical terms, this means that we are not alone and that our diplomacy needs to focus on ensuring that other countries share our commitment and dedication to tackling this issue.

Mr. Chairman, Ranking Member Bass, and members of the subcommittee, I can assure you that the Department is fully committed to the effort to address the threat posed by synthetic drugs and to address the impact that they are having on our citizens, on our communities, and on our families. Thank you for your time and I look forward to your questions.

[The prepared statement of Ms. Madison follows:]

Prepared Statement of:
Kirsten D. Madison
Assistant Secretary of State for
International Narcotics and Law Enforcement Affairs

Hearing before the:
House Foreign Affairs Subcommittee for Africa, Global Health, Global Human Rights and International Organizations

Tackling Fentanyl: The China Connection

September 6, 2018

Chairman Smith, Ranking Member Bass, distinguished members of the Subcommittee: Thank you for the opportunity to testify today and for the efforts of this committee to highlight the tragedy that is unfolding every day in families and communities across this country.

We have all heard and read the stories of promising young lives cut short, of families bankrupted emotionally and financially—often in failed attempts to save loved ones from addiction. Since I was nominated, I have found that people want to share tragic stories about the devastating impact of addiction and overdose on their families and their friends, even as they ask me -- as they should – what we are doing to help. The battle against opioids is being fought on many fronts. Doctors, nurses and other health care professionals are providing treatment and running prevention programs to help keep more Americans from joining the long line of Americans lost in this epidemic. Men and women in law enforcement are fighting drug dealers on our streets and leading interdiction efforts to prevent opioids from entering our country. This Administration has committed considerable resources and energy toward fighting this epidemic and toward the essential work that must be done on all fronts. My dedicated Bureau of International Narcotics and Law Enforcement Affairs (INL) team is a part of this larger effort. We understand that the work we do to forge partnerships and consensus, to secure international cooperation, and to use foreign assistance to build the capacity of our partners to help disrupt the flow of opioids and other illicit narcotics to our country is about one thing: contributing to a larger effort in our country to save America lives, American families, and American communities.

This opioid epidemic is the most severe drug crisis our country has ever faced, claiming tens of thousands of American lives annually. This crisis arose largely from over reliance on prescription opioids and increasing availability of heroin that led to rapid increases in opioid misuse. The emergence of dangerous new synthetic drugs, often mixed into supplies of heroin or other illicit drugs and trafficked through global illicit supply chains, has now morphed this crisis into an ever more deadly phenomenon with complex transnational linkages. The Centers for Disease Control and Prevention (CDC) estimates that more than 72,000 Americans died from drug overdoses in 2017. Over forty percent of these deaths involved synthetic opioids like fentanyl. Between 2012 and 2016, the number of overdose deaths involving synthetic opioids increased by nearly 640 percent, and provisional data from 2017 suggest that this trend is continuing upwards. A confluence of dangerous new trends in the transnational production, sales, and trafficking of illicit drugs has contributed to this tragic climb in American deaths.

Criminals are developing new substances at a rate faster than national and international frameworks can respond. Production costs are low, and drug traffickers, using low-level criminal chemists, can tailor the expected psychoactive effects of new psychoactive drug substances, or NPS, to meet consumer demand. The United Nations Office on Drugs and Crime (UNODC) reports that there are currently more than 800 new known synthetic drugs, with approximately one new substance created each week. At the same time, interrupting illicit drug production has become more challenging; unlike drugs derived from plant-based crops, synthetic drugs have lower overhead requirements – they are immune to weather conditions, and do not require large tracts of land or workers to cultivate them. Synthetic drugs can be produced wherever the necessary chemicals can be obtained.

Traffickers have exploited the boom in global access to information and technology to facilitate their lethal trade. Illegal drug producers exploit the perceived anonymity and convenience of the Internet, including the "Dark Web," encrypted peer-to-peer messaging applications, and other emerging information and communications technologies to market and sell aggressively to global clients, including directly to American drug users. Due to the extreme potency of synthetic opioids in particular, small quantities can readily be trafficked through international mail and express consignment shipments, in addition to traditional trafficking methods, yielding substantial illicit profits. Criminal misuse of these tools makes today's illicit drug trade highly profitable and difficult to monitor, investigate, and disrupt.

In October 2017, President Trump directed the Department of Health and Human Services to declare this epidemic a national public health emergency and has made combating this deadly drug crisis a cornerstone of his Administration. The vast majority of emerging synthetic drugs available in the United States will continue to be produced overseas, and the methods and locations of production and trafficking will continue to diversify. We cannot stem the flow of this crisis while ignoring its international components. Disrupting the illicit supply chains that are fueling thousands of American deaths is the Department of State's top drug control priority, and we are working tirelessly to facilitate the work of our partners to arrest the criminals and dismantle the criminal organizations facilitating this illicit trade. The Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL) is leading our response to these international challenges through our foreign assistance programs and diplomatic engagement.

With China, a primary source of illicit synthetic drugs coming to the United States, the Department of State is building upon the commitments made during President Trump's November 2017 meeting with President Xi to explore opportunities to deepen existing bilateral counternarcotics cooperation. This bilateral cooperation has yielded concrete results, including arrests, seizures, and takedowns of clandestine labs by Chinese law enforcement. Law enforcement information sharing has increased, including information used to combat the export of drugs that are controlled in the United States but not in China. Additionally, since 2015, China has taken significant action, primarily at the United States' request, to domestically control 143 substances, including 23 fentanyl analogues and the two key precursors to fentanyl production. And most recently on August 29, China's National Narcotics Control Commission announced controls on 32 additional NPS, which will bring the total to 175. We continue to encourage China to use every available tool to aggressively counter the threat from illegal production and trafficking of synthetic opioids. Further, the Department of State is engaging with China to promote effective drug demand reduction through prevention, treatment, and recovery support. In May, several members of China's government participated in a study visit to Washington, D.C. to observe best practices in the treatment and prevention of drug use, and further bilateral expert exchanges are being discussed.

Some of the synthetic opioids from China are flowing through Mexico, where traffickers sometimes mix them with cocaine and heroin before shipping them across our southwest border. Countering this flow is part of our partnership with the Mexican government to disrupt drug production, dismantle drug distribution networks, prosecute drug traffickers, and deny transnational criminal organizations' access to illicit revenue.

In addition to bilateral engagement with China and Mexico, the Department of State is using multilateral channels to address the proliferation of illicit synthetic drugs, including synthetic opioids. The Department uses foreign assistance to support real-time coordination and information sharing between law enforcement and forensic officials around the world. This international cooperation increases the identification, detection, and tracking of synthetic drugs and precursor chemicals in illicit markets worldwide. These programs illuminate emerging synthetic drug and precursor chemical trafficking trends and alert law enforcement and forensic practitioners to the presence of these substances in illicit markets. In turn, law enforcement officials worldwide use this information to solve drug trafficking cases. To reduce the presence of these drugs in illicit U.S. markets, we are also working through multilateral organizations to deliver specialized training that will strengthen the capacities of key countries, such as those in the western hemisphere, to intercept suspicious drugs and chemicals being sold online and shipped through the mail and express consignments.

An essential component of our efforts to address these threats is to adapt the international architecture to more effectively address these new 21st century challenges. For example, we must accelerate the rate at which these drugs are controlled at the international, regional, and national levels. Increased controls can drastically reduce the availability of these drugs for criminal purposes and will save American lives. As is the case in our cooperation with China, these international controls also can lay the groundwork for enhanced law enforcement cooperation with key nations. In March 2018, we continued mobilizing a response to the new synthetic drug threat through the international community at the UN Commission on Narcotics Drugs. With U.S. leadership, the world came together to control the deadly opioid carfentanil, plus five other fentanyl analogues. This was preceded by action, at the 2017 CND at our behest, to control the two primary fentanyl precursor chemicals NPP and ANPP. Recently, at U.S. instigation, the International Narcotics Control Board (INCB) issued a call to all nations to voluntarily restrict 93 new substances with no known medical use, including fentanyl analogs.

However, international controls are only the first step. It is also imperative to ensure that countries are able to institute these treaty-mandated controls at the national level. Key countries involved in the illicit trafficking of drugs, such as those in Central America, require significant capacity-building support to be able to establish the national regulatory frameworks to control drugs and precursor chemicals. For this reason, INL is training foreign law enforcement, regulatory, and forensic officials to establish the required domestic controls and to increase the identification and detection of these substances and chemicals in order to disrupt the illicit markets.

We are cognizant of the grave threat posed by synthetic drugs and the evolving nature of the illicit opioid trade, which is compounded by the rise of the internet and globalization. So, shortly after I arrived in INL, my team and I decided to take a hard look at what was missing in our strategy and to give some critical thought to how to realign our strategy to be more nimble, more adaptive, and more exhaustive in our approach to rise to the challenge of the dynamic threats we are combating. This process is still underway, but I can already tell you that we intend to use our diplomatic and foreign assistance tools – and our critical partnerships in law enforcement – to attack each link of the illicit synthetic drug manufacturing and supply chains, including production, sales, and transport. We will focus our detection and interdiction efforts across transit routes and at key borders and, working with overseas and U.S. government

partners, we will take on online sales and the use of cryptocurrencies. The private sector largely controls the tools of commerce upon which the traffickers operate, and therefore it is a vital part of the solution. So, we plan to seek increased cooperation with industry to explore how we can work together to make licit modes of commerce inhospitable to criminals without encumbering entrepreneurs and businesses with unnecessary regulation.

To counter the production of dangerous synthetic substances, INL is considering what additional steps it can take with international partners to prevent the diversion of legitimate chemicals for illegal uses, support partner governments' abilities to seize and dispose of diverted chemicals, and build law enforcement capacities to detect and safely dismantle clandestine labs. INL is looking at additional efforts, together with our allies, to strengthen international institutions to identify emerging threats so governments can mobilize their public health and law enforcement agencies to counter more rapidly these challenges as they arise.

INL will continue to support efforts to improve the ability of law enforcement to confront the threat posed by the online trafficking of illicit synthetic drugs and chemicals. In its training programs, INL will need to tap into U.S law enforcement expertise to provide foreign law enforcement counterparts with the skills to investigate, prosecute, and dismantle online drug vendors, including on the "Dark Web." This includes training and technical assistance on following the digital money trail when drug vendors use cryptocurrencies to facilitate transactions. The online marketplace allows direct interactions between illegal drug producers and users, subverting the hierarchical cartel organization and making it harder for law enforcement to investigate and detect them. We must continue to collaborate across the U.S. government to curb illicit online sales of synthetic drugs and precursor chemicals. To do this, INL plans to deepen relationships with our interagency colleagues to identify new opportunities for partnership and complementary interventions aimed at reducing online trafficking of drugs and chemicals.

We are exploring new partnerships to expand global capacities to detect and interdict synthetic drugs shipped through the mail and express consignment shipping, including by expanding the global collection and sharing of advanced electronic data (AED). This AED helps regulatory and law enforcement authorities prioritize screening to target suspicious shipments. INL also aims to broaden its cooperation with U.S. law enforcement partners to expand training and the use of technology to detect and interdict suspicious mail and shipping at international ports and other facilities, keeping them from U.S. shores.

In addition to working to reduce the availability of synthetic drugs entering the United States, INL will build upon its efforts with international partners to share research and promote best practices for prevention and treatment interventions. This includes supporting public health messaging on the risks of synthetics, assisting foreign governments in implementing evidence-based prevention, treatment, and recovery support services, and fostering the adoption evidence-based practices to reduce the likelihood of accidental exposure to dangerous synthetic drugs. INL is working with international partners to improve data collection on synthetics, including consumption trends, toxicological screening of synthetic drug profiles, and the prevalence of toxic adulterants in illicit drug supplies.

This is an enormous undertaking, and INL cannot do it alone. For an effective response, we will rely on close coordination with interagency partners, civil society, private industry,

international organizations, and partner governments. Any person in a nation with internet access and international shipping services can import this deadly opioid crisis, so we know this is not a uniquely American concern and we know that many countries are already experiencing significant impacts. This crisis is a global one touching many other countries, including those in Latin America, Europe, and Africa. According to UNODC's 2018 World Drug Report, opioid misuse remains high in Africa, the Middle East, and Oceania, and it has been expanding in Western Europe and North America. An estimated 168,000 deaths globally were directly attributed to drug use disorders in 2015, with more than 75 percent of cases involving opioids. This international problem requires a smart, strategic, and coordinated international response. In practical terms, this means that we are not alone and our diplomacy needs to focus on calling other impacted countries to ensure that they share our commitment and dedication to tackling this issue.

Mr. Chairman, Ranking Member Bass, and members of the Subcommittee, the Department of State is fully committed to fighting the new threat posed by the proliferation and new trafficking modalities of synthetic drugs. It is not an easy task, and the new initiatives and programs we think will be needed will take relentless effort, but we are driven by the goal of securing the health and safety of American citizens. I know this is an issue about which you and your constituents care deeply, and it is one that I care deeply about, because it affects so many American lives. I look forward to working with Congress as we seek to disrupt the flow of synthetic drugs, particularly deadly opioids, and thereby save American lives.

Mr. SMITH. Secretary Madison, thank you for your testimony and for leadership.

I would like to now recognize Mr. Knierim.

STATEMENT OF MR. PAUL E. KNIERIM, DEPUTY CHIEF OF OPERATIONS, OFFICE OF GLOBAL ENFORCEMENT, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Mr. KNIERIM. Good afternoon, Chairman Smith, Ranking Member Bass, and members of the subcommittee. It is an honor to be here today and speak with you about DEA's cooperation with China, Mexico, and our worldwide enforcement efforts to combat the opioid crisis. Heroin, fentanyl, and related analogues are the number one drug threat to our nation. Sadly, the use of these illicit drugs is destroying individuals, families, and American communities on a daily basis and in record numbers.

Over the last several years, we have witnessed a dangerous new trend, the convergence of synthetic drug threat and the epidemic opioid abuse. Recent preliminary CDC reporting for 2017 indicates that an estimated 49,000 Americans lost their lives to an opioid overdose. Similar to 2016, the increase in overdose deaths is being fueled by synthetics, primarily fentanyl and its analogues coming from China and Mexico.

Fentanyl and related analogues are often shipped directly to the U.S. via postal or express mail from China. These synthetic drugs are cheap to make, hard to detect, and dangerously potent. A kilogram of fentanyl from China can be purchased for less than $5,000 and potential profits from the sale of that kilogram yields roughly $1.5 million.

Further complicating the crisis are transnational criminal organizations. Let me be clear, the most significant criminal threat to the U.S. today are the Mexican drug cartels. The cartels continue to be the primary source of illicit drugs that are decimating our communities. Now Chinese and Mexican nationals are increasingly operating in concert resulting in an alignment responsible for the proliferation of heroin, fentanyl, and related synthetics coming across the southwest border.

This leads me to what DEA is doing to counter the threat. We recognize this will take persistent efforts across a broad spectrum to include interagency and global partnerships. For decades, we have maintained a worldwide presence to address the source of drugs and in this case we have a robust presence and critical partnerships in both China and Mexico.

Over the past decade, our relationship with China has steadily progressed. Many of the synthetic drugs encountered in the U.S. were not controlled in China. Through continued engagement by DEA and DOJ highlighting this serious issue, China passed legislation in 2015 that improved their ability to more effectively control newly identified destructive substances. China has now controlled 175 new psychoactive substances and precursor chemicals which have a direct and immediate impact and effect on the availability of these drugs in the United States. We are also encouraged by recent discussions with China drug control officials about the pros-

pect of scheduling fentanyl as a class. This would eliminate the need to control fentanyl and related substances one by one.

While we are appreciative of China's scheduling actions and enhanced cooperation on investigations, there is opportunity for more to be done. In 2019, DEA will be opening a new office in Guangzhou, China, where much of the shipping of fentanyl and other illicit drugs originate, to facilitate greater collaboration with our law enforcement counterparts and INL. We are also looking at opening an office in Shanghai as well.

In Mexico, DEA continues to synchronize and expand capabilities to combat the growing epidemic. We have developed the bilateral heroin strategy for intelligence sharing, coordinated investigations, training, increased sharing of forensic information, and the control of precursor chemicals. We participate in the North American Drug Dialogue along with Federal Government officials from Mexico, Canada, and the United States to include INL which focuses on building a strategy to attack the production, trafficking, consumption, and misuse of illicit narcotics in North America.

Domestically, DEA has moved aggressively to place temporary schedule controls on new and emerging synthetic drugs. Unfortunately, the temporary emergency scheduling process of a substance is reactive, requiring us to first observe deadly consequences and synthetic drug abuse before initiating control. Given the proliferation of synthetic substances including fentanyl across the nation, it is necessary to explore novel solutions to more expeditiously schedule these new substances. On February 6th, 2018, DEA proactively placed temporary emergency controls on the entire class of fentanyl related substances to curb fentanyl related overdose deaths. This is an unprecedented step to combat an unprecedented threat.

In closing, we are grateful for the tremendous support that Congress has provided to DEA to combat this national crisis. In addition to increased resources, the House passed H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues Act, which DEA believes is critical to combat the synthetic analogue threat and save lives.

We look forward to continuing our work with Congress to identify the resources and authorities necessary to address this devastating crisis and have a positive impact on our communities. Thank you for the opportunity to testify before your committee on this important issue today and I look forward to your questions.

[The prepared statement of Mr. Knierim follows:]

Department of Justice

STATEMENT OF

PAUL E. KNIERIM
DEPUTY CHIEF OF OPERATIONS
OFFICE OF GLOBAL ENFORCEMENT
DRUG ENFORCEMENT ADMINISTRATION
U.S. DEPARTMENT OF JUSTICE

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS AND INTERNATIONAL ORGANIZATIONS
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

"TACKLING FENTANYL: THE CHINA CONNECTION"

PRESENTED

SEPTEMBER 6, 2018

Statement of Paul E. Knierim
Deputy Chief of Operations, Office of Global Enforcement
Drug Enforcement Administration
Before the Subcommittee on Africa, Global Health, Global Human Rights and International Organizations
Committee on Foreign Affairs
U.S. House of Representatives
September 6, 2018

Chairman Smith, Ranking Member Bass, and Members of the Subcommittee: on behalf of the Department of Justice (the Department), and in particular the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss current cooperation between United States law enforcement agencies and China in the areas of drug enforcement.

Drug overdoses, suffered by family, friends, neighbors, and colleagues, are now the leading cause of injury-related deaths in the United States, eclipsing those from motor vehicle crashes or firearms.[1] An in-depth analysis of 2016 U.S. drug overdose data shows that America's overdose epidemic is spreading geographically, and is increasing across demographic groups. The sharp increase in drug overdose deaths between 2015 to 2016 was fueled by a surge in fentanyl and fentanyl analogue (synthetic opioids) involved overdoses.[2,3] Unfortunately, provisional drug overdose data from the Centers of Disease Control and Prevention (CDC) shows that fentanyl use drove drug overdose deaths to a record high in 2017. Annual deaths from all drug overdoses in 2017 rose to 72,287, with 49,060 of those deaths involving opioids. Overdose deaths in 2017 are expected to exceed 2016 figures with synthetic opioids being the prime driver of the increase.[4]

Under U.S. federal law, fentanyl is a Schedule II controlled substance, which is lawfully produced in the United States and widely used in medicine. It is an extremely potent analgesic used for anesthesia and pain control in people with serious pain problems, and, in such cases, it is generally indicated only for use in people who have a high opioid tolerance. Illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped primarily through express consignment carriers or international mail directly to the United States, or, alternatively, shipped directly to transnational criminal organizations (TCO) in Mexico, Canada, and the Caribbean. Once in the Western Hemisphere, fentanyl or its analogues are prepared for mixing into the heroin supply, other non-opioid drugs, or pressed into a tablet form, and then moved into the illicit U.S. market where demand for prescription opioids and heroin remains at epidemic proportions. In some instances, drug trafficking organizations have industrial pill presses shipped directly into the United States from China, which allows them to press fentanyl pills domestically. Mexican TCOs have seized upon

[1] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[2] https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html
[3] CDC WONDER data, retrieved from the National Institute of Health website; http://www.drugabuse.gov as reported on NIDA's website.
[4] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this market. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 - $5,000 can generate upwards of $1.5 million in revenue on the illicit market with the potential of being lethal for 500,000 people.[5]

According to the DEA National Forensic Laboratory Information System (NFLIS), from January 2013 through December 2016, over 58,000 fentanyl exhibits were identified by federal, state, and local forensic laboratories.[6] During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,[7] an exponential increase over the past four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a December 2017 CDC Data Brief, from 2015 to 2016, the death rate from synthetic opioids other than methadone, a category that includes fentanyl, doubled from 9,580 (age adjusted rate 3.1) to 19,413. The age-adjusted rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogues, and tramadol) doubled between 2015 and 2016, from 3.1 to 6.2 per 100,000.[8]

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 in Schedule I or Schedule II of the Controlled Substances Act (CSA), entrepreneurs procure new synthetic compounds with relative ease.[9] 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, these substances are often first discovered when DEA receives 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

[5] U.S. Department of Justice, Drug Enforcement Administration, 2017 National Drug Threat Assessment Summary, October, 2017.
[6] U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.
[7] U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.
[8] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew GladdenHedegaard, H., Margaret Warner, and Arialdi M. Miniño. Drug Overdose Deaths in the United States, 1999–2016Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly ReportNCHS Data Brief. 2016;64:1378-1382No. 294, Dec 2017. https://www.cdc.gov/nchs/data/databriefs/db294.pdf.
[9] 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.

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.

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, 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 often pressed into counterfeit pills made to look like controlled prescription drugs containing oxycodone or hydrocodone. They are then sold online from anonymous darknet markets and even overtly operated websites. It is extremely difficult for the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement (ICE), and Homeland Security Investigations (HSI), and the U.S. Postal Inspection Service (USPIS) to address the threat at ports of entry, due to the combination of: the questionable legal status of these substances, which are not specifically named in the CSA itself or by DEA through scheduling actions; 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 non-cartel-affiliated individuals to undertake fentanyl trafficking. DEA is working with CBP, HSI, and USPIS, to increase coordination on seized parcels.

Use of Freight Forwarders

Traffickers often use freight forwarders, companies that arrange importing and exporging 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

China is one of the world's top producers of the precursor chemicals used to manufacture methamphetamine and fentanyl, as well as the chemicals used to process heroin and cocaine. There are approximately 160,000 chemical companies in China.[10] Although the

10 U.S. Department of State, 2014 International Narcotics Control Strategy Report (INCSR), March 2014. http://www.state.gov/j/inl/rls/nrcrpt/2014/vol1/223172.htm; Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, American Enterprise Institute for Public Policy Research, 2012, 186. 67

majority of chemical production is intended for legitimate use, illicit drug manufacturers directly source or divert their chemicals from China for their drug production. The three major destinations for Chinese-sourced, illicit precursor chemicals are: Southwest Asia for opium and heroin production; Southeast Asia for opium, heroin, and methamphetamine production; and Latin America for cocaine, methamphetamine, and heroin production. Significant amounts of precursor chemicals are shipped from China to Central America for the production of methamphetamine, heroin, and fentanyl. Additionally, precursor chemicals transit through any number of Latin American countries on to Peru and Colombia for cocaine processing.

Combating illicit fentanyl is a top priority of this Administration. Recognizing that a significant amount of illicit fentanyl, fentanyl analogues, and their immediate precursors are manufactured in China, Attorney General Sessions and Deputy Attorney General Rosenstein both requested that China take action to stop the flow of these materials in meetings with then-State Councilor Guo Shengkun of the Chinese Ministry of Public Security. Deputy Attorney General Rosenstein met with Guo in Beijing, China on September 25, 2017, followed by a meeting with the Attorney General at the Law Enforcement and Cybersecurity Dialogue in Washington, D.C. on October 3-4, 2017.

The Attorney General and the Deputy Attorney General's efforts are built on long-standing working-level engagements with the Chinese on a number of levels. For example, DEA has maintained a liaison presence in the People's Republic of China, with an office in Beijing for the last three decades. DEA is currently working to staff offices in both Guangzhou and Shanghai. DEA's office in Beijing has direct engagement with drug control officials from China's Ministry of Public Security, Narcotics Control Bureau (NCB). DEA's well-established relationship with Chinese drug control authorities is a primary significant bilateral mechanism for addressing the threat from the shipment of illicit fentanyls, their precursors, and other synthetic drugs to the United States and elsewhere.

DEA and the NCB share drug-related intelligence and trends through the Bilateral Drug Intelligence Working Group (BDIWG), led by DEA's Intelligence Division. This annual engagement was established through a memorandum of agreement between DEA and the NCB in 2002.

At a higher policy level, the United States Government has also engaged China through two bilateral fora on law enforcement and counternarcotics matters: first, the Law Enforcement and Cybersecurity Dialogue (LECD), which is co-chaired by the Attorney General and the Secretary of Homeland Security and the Chinese Ministry of Public Security; and second, the U.S.-China Joint Liaison Group (JLG) on Law Enforcement (now re-cast as the LECD Senior Officials Meeting or "LECD-SOM"), a sub-ministerial group co-chaired by the Department, the Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL), and DHS. At the working level, DEA and the NCB participate in the Counter-Narcotics Working Group (CNWG) which has operated within the LECD-SOM framework, and that is chaired, respectively, by the Department and the Ministry of Public Security on the Chinese side.

These efforts have resulted in positive actions being taken by the Chinese Government over the last year. China, which has not yet suffered a domestic fentanyl misuse problem, has been increasingly cooperative with the United States in this area. Their actions are steps in the right direction, but more can be done.

Since 2014, the Department, DEA, and Chinese officials have met regularly to discuss bilateral efforts to counter the threat to the United States from fentanyl class substances. For the past four years, representatives from China's National Narcotics Laboratory have met with DEA experts to exchange information on emerging substances, trafficking trends, and drug sampling standards. This dialogue fosters an ongoing information exchange about new substances of misuse in the United States to be considered for control in China. In May 2017, and again in June 2018, China NCB and DEA hosted bilateral meetings of experts in Beijing to exchange information and perspectives at the technical level on the science and law pertaining to emerging NPS, including fentanyl class substances. These meetings answered China's request for more information about the misuse and pharmacology of the substances we were urging them to consider for scheduling. China's reform measures, effective in October 2015, allow their drug control authorities to consider public health harm in other countries, including the United States.

A key moment in enhanced cooperation on synthetic drugs came in October 2015, when, following similar discussions, China implemented domestic control on 116 New Psychoactive Substances (NPS), including a number of fentanyl analogues, and streamlined its procedures to control additional substances.

On December 28, 2017, China's Ministry of Public Security announced scheduling controls on two key fentanyl precursor chemicals, NPP and 4-ANPP. This action, taken with U.S. encouragment, also complied with the decision taken by the UN Commission on Narcotic Drugs (CND) in March 2017, to impose international controls on the precursors. The scheduling controls took effect on February 1, 2018. Chinese control of these substances, combined with the effects ofprior control efforts, on the availability of these substances in the United States is significant and reaffirms the need for the continued collaboration between DEA and the NCB.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls on four fentanyl-class substances: carfentanil; furanyl fentanyl; valeryl fentanyl; and, acryl fentanyl. This announcement was the culmination of the ongoing efforts of the United States and the Government of China, and reaffirms an expanding bilateral collaborative commitment to countering illicit fentanyl. On July 1, 2017, China controlled U-47700, also in compliance with the March 2017 CND decision. While not a fentanyl class substance, U-47700 is a powerful synthetic opioid that has been trafficked and misused in the United States. On August 29, 2018, the Government of China announced the control of an additional 32 NPS, bringing the total number of NPS and precursor chemicals controlled to 175 since 2015.

DEA will continue to engage the Chinese on the control of emerging fentanyl analogues and other NPS. We are further encouraged that the Chinese are willing to engage in discussions and technical exchanges with DEA regarding scheduling fentanyl as a class. In spite of the

complexity of this process, and the fact that Chinese authorities claim that domestic misuse of fentanyl and related substances is not a problem in China, they have continued to show an understanding of the problem and a willingness to listen and discuss class scheduling.

As the opioid epidemic continues, the Department and DEA are committed to working with Chinese officials through well-established bilateral efforts, including the high-level mechanisms noted above: liaison presence; the CNWG; the BDIWG; the scientific working group, as well as enhancing collaboration with DEA's interagency partners stationed abroad and in the United States.

Mexico

The Department and DEA continue to expand the robust relationship between Mexico and the United States, particularly with regards to countering the threat from heroin and synthetic opioids.

Mexico is the primary producer and supplier of heroin to the United States, and as poppy cultivation in Mexico has increased over the last three years, the Department and DEA have engaged with the Government of Mexico to address this issue. 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 Availbility Reduction Plan (HARP) implementation as a video teleconference, co-chaired by Mission Mexico and ONDCP and regularly attended by the National Security Council, DEA, the Department of Defense (DOD) U.S. Northern Command, and the Department of State Bureaus of Western Hemisphere Affairs and 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 between 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.

SIGNIFICANT ENFORCEMENT AND DOMESTIC EFFORTS

Heroin Fentanyl Task Force

The DEA Special Operations Division's (SOD) Heroin/Fentanyl Task Force (HFTF) working group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, ICE, HIS, and CBP, supplemented by the Federal Bureau of Investigation (FBI) and USPIS. The HFTF utilizes every resource available, including support from the Department's 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 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 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 shutting down of the largest criminal marketplace on the Internet, AlphaBay. As outlined by the Attorney General and DEA's then 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.

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 all "fentanyl related substances," which includes any substance structurally related to fentanyl based on specific chemical changes not otherwise controlled in any other schedule.

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 will be 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 will be based in specific cities, their investigations will not be geographically limited. DEA has always, and will continue, to pursue investigations wherever the evidence leads.

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. 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.

ADDITIONAL AUTHORITIES TO COMBAT SYNTHETIC DRUG THREAT

Illicit manufacturers and distributors have and will continue, if unabated, to stay one-step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new synthetic products that are not listed as such in any of the controlled substance schedules. Given the proliferation of synthetic analogues, including fentanyl, across the nation, it is necessary to explore novel solutions to more expeditiously schedule these new substances.

H.R. 2851, the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017 or SITSA, as passed by the House of Representatives, would provide critical tools to DEA to address the rapid proliferation, trafficking, and misuse of synthetic drugs. The proposed Schedule A would allow the Attorney General to more efficiently control synthetic analogue substances as they emerge, providing law enforcement with a much needed tool to enable us to keep up with this fast-moving threat. The bill also includes a provision that criminalizes exports of substances to a country where they are banned or controlled, regardless of their control status in the United States. This provision would enact a law in the United States parallel to the one we are asking China to consider. DEA believes that the enactment of SITSA and other scheduling-related legislation would show the United States' commitment to combating this scourge.

CONCLUSION

DEA will continue to engage the Government of China 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 the interagency and foreign partners in targeting, indicting, and arresting leadership of criminal networks, both foreign and domestic.

We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by fentanyl, its analogues, and other NPS.

Mr. SMITH. Thank you very, very much for your testimony. Let me just begin, if I could, with some questions and I will, since we have a large attendance today I will throw out a few questions right off the bat and then come back later if we don't get everything covered.

Chinese officials have repeatedly dodged the blame for contributing to the fentanyl crisis, as you know. Liu Yuejin, Deputy Chief of China's National Narcotics Control Commission, stated in June that and I quote Liu, the U.S. should adopt a comprehensive and balanced strategy to address fentanyl demand, remarking that when fewer and fewer Americans use fentanyl there will be no market for it.

As recently as last month, Yu Haibin, an official with China's National Narcotics Control Commission, stated, "The United States has no proof that most fentanyl in the country comes from China." And both of you have obviously testified otherwise. Despite the banning of multiple variations of fentanyl by the Chinese Government, the export of fentanyl from China to the U.S., as we know, persists.

I wonder if you could tell us law enforcement, all laws all that well, you can have the greatest law in the world, if it is not enforced what good is it. Those kinds of high level statements send a shiver down my spine about how you may on an operational level be working with some very dedicated Chinese colleagues, but if at the very top or at other places in the chain of command there is a dismissal that most of the fentanyl is not coming from China, it certainly raises questions.

I know that the President, mid-August, called for stronger action and I know he directed his Attorney General to do so. You might speak to what has been done in terms of mobilizing any additional resources or policies.

What other countries are known sources of fentanyl? Is India one of those countries, for example, you might want to speak to that. Because when we say majority coming, or most, where is the rest of it coming from? What holes in existing legislation need to be fixed? As I have said, and you said it just a moment ago, the idea of getting the Postal Service to finally adopt a system that at least gives another tool to border security and others to make sure that we know where it is coming from and where it is going, because they can ship it in small packages, unlike big hauls that they are taking through other routes.

And let me also ask if I could, the April announcement by DOJ of Chinese nationals' indictments, do we expect others to follow? What has been the progress on that indictment? I was encouraged when I saw it, I think most of us were, that DOJ is taking this very seriously, but obviously it is very hard when people are in China to apprehend them.

Is there any kind of ability for the Chinese Government to allow us to prosecute or at least to have them prosecute? How many arrests of Chinese narco traffickers has DEA made in cooperation with the Chinese authorities? It is cooperation with a capital C, or with a small C? Are they really working with us?

I think your statement moments ago about the opening in Shanghai and elsewhere of new efforts is an encouraging sign. But I have

been in Congress 38 years. I have worked on Chinese human rights since the day I got here and human rights all over the globe. The Chinese have been masters at purporting to be in compliance with international treaties including the U.N. treaty, the International Covenant on Civil and Political Rights, they milked that big time for years when high level officials would come and say we have signed it, but they wouldn't ratify it. And they would get this big upsurge that they are cooperating and yet at the level of human rights abuse, torture, and all the other abuses have gotten worse under Xi Jinping.

So I am wondering, what is your true assessment? Is that cooperation real, robust? I know that they could take offense at something any of us say here, but we have to be candid. Our American brothers and sisters are dying in every one of our districts. We have so many people who are dying from fentanyl and it is sneaking into so many other drugs as well, especially heroin. And so the idea would be to say there is a line here of real seriousness. And of course we combat all the other bad drugs as well, crack, everyone is on board with that. But this one kills so fast and so surreptitiously and it is so powerful that this calls for extraordinary efforts.

I did ask in my opening comment whether or not you think the Magnitsky Act would have applicability here. I think it does. I was the House sponsor of that legislation and believe that when you hold public officials especially accountable for egregious behavior, human rights violations, killing Americans, when you send fentanyl to the U.S. Americans will die, or anywhere else where you send it. So to me that is a gross violation of human rights which would fit the definition of the Magnitsky Act.

So if you could begin with that.

Ms. MADISON. Thank you for your questions, Mr. Chairman. I will start at the beginning which is this question of Chinese rhetoric and the pushback that you have seen with regard to treatment and demand reduction. It reminds me very much of back in the day, the kind of conversations we would have with Mexico and we have sort of evolved beyond that point.

And I think from my perspective, I think what is important with the Chinese is what they are actually doing. Personally, I know I have raised this issue with the Embassy of China, this issue of their rhetoric on demand reduction being the only answer, but I think what they are doing is what is important. They are working with us on controlling more substances. They are working with us in multilateral fora to advance controls. They are working through multilateral fora on real-time law enforcement cooperation. They are working with us on advanced electronic data for the mail.

And I think as disconcerting as the rhetoric might be, I think the results that we get out of them in terms of how they cooperate in practical terms is more meaningful. I think there is plenty of places where the rhetoric between our two governments is, you know, there are rub points. But I think as long as we are getting the cooperation we need out of them that is the most important thing.

I would imagine that Paul might have some things to say about that cooperation just as a——

Mr. SMITH. If I could on that point and maybe weave it further into your answer, I was the sponsor of the global online security act, held a series of hearings that began in '06 about the police state and how their surveillance is second to none in the world. The police state knows what people are doing, when they are doing it and in order, in my humble opinion, for such huge amounts. I know they can be done in small environs, but it doesn't take much for a police state like China if it is serious to crackdown. They certainly crackdown on dissent. They crackdown on labor unions. They crackdown if you want a labor union in China, good luck, you are going to jail. They know what people are saying when they go on Facebook or any of the other social media. You know, their abilities they are incredible.

So my question again further to your answer, cooperation with a capital C, are they employing those kinds of assets where they say we are serious about this, the way they are about even to some degree serious about surveilling their own people 24/7?

Ms. MADISON. I think that—and again Paul may have more to add on the law enforcement side. I think that we are actually seeing real cooperation with them on taking down labs, on helping us to get to end game on law enforcement and so I think that that is not to be taken lightly. I think even, you know, a year ago we were not where we are today with the Chinese. Is there much more to be done, without a doubt, but I do think that we are making progress.

Do you have anything?

Mr. KNIERIM. Thank you. I would just like to echo a few things that my friend and colleague Assistant Secretary Madison has mentioned. I can tell you that our cooperation and our coordination and collaboration with China, in my estimation, has expanded tremendously over the last several years. I firmly believe that they understand the nature of the threat. That they are working with us, I think, is evident by the fact that they have controlled 175 chemicals and new psychoactive substances, precursor chemicals and the like, fentanyl related substances as well.

I do believe that the relationships that have been established over three decades of presence in China are significant. I believe that those relationships are leading to a very robust dialogue and engagement. There is exchange of information both ways and it is very helpful to identify those substances and the individuals responsible which is our main focus to identify the persons and the organizations responsible for trafficking these substances to the United States.

I would also like to add that I think over the last few years it has also been evident that, you know, the impact of them controlling these substances through our high level engagements and our direct personal relationship and engagement with them does have an immediate impact on the substances that are analyzed in our laboratories. So we do see when they control and regulate those substances through the engagement with us and really working with us on a significant way does have an immediate impact at home.

And we are talking about the illicit fentanyl situation and the ability of these manufacturers to change the molecular structure in

order to circumvent the controls, so that is really a very challenging situation. And I think it is also important to highlight the subject matter exchanges and technical exchanges in order to identify for them the substances that we are finding so that they can work with us on a very significant way to take action and control those substances as well.

Mr. SMITH. Is fentanyl a problem in China itself?

Mr. KNIERIM. Fentanyl is not currently a problem in China.

Mr. SMITH. So it is an export?

Mr. KNIERIM. So it is, they are, these organizations and individuals are exporting it to the U.S., Mexico, and Canada and then it is brought in to the United States directly from China or through Mexico, but it is not a substance abuse issue in China.

Mr. SMITH. Now with crystal meth when they realized, they being the Chinese Government, that that was a serious problem for them, there has been a very significant crackdown on the mainland of China. A hundred and fifty tons, according to the Sydney morning news, was apprehended. And they are very serious because it is so horrifically affecting the Chinese people. Thousands of police are now engaged in the meth crisis that they are experiencing. Do we see any sign that there is any kind of mobilization like that vis-a-vis fentanyl? And if I could, is there any sign of complicity of high government officials or even operatives at midlevels with regards to fentanyl?

And I say that because, again, I have chaired 65-plus hearings on Chinese human rights abuses, and the complicity of the Chinese Government and human rights abuse is legendary. It is so awful. Even the U.N. has found that—Manfred Nowak when he did his piece on torture found it was everywhere in their laogai and prison system. If you are arrested you will be tortured. And if you are a political prisoner or a religious prisoner you are going to be tortured, horribly.

And so with all kinds of high government buy-ins to that again underscoring the need perhaps at least to have as a tool, utilization of the Magnitsky sanctions against individuals. Then I will go to Mr. Castro.

Do you want to speak to that?

Mr. KNIERIM. Regarding the Magnitsky Act, sir, honestly I am not familiar with that so I will have to take that back and work with you on getting a response for you at that later.

Ms. MADISON. So if——

Mr. SMITH. We need to be looking to see if high government officials are looking the other way or complicit, getting money. I mean this is, the money that can be gleaned from this is astronomical.

Ms. MADISON. And Global Magnitsky, it is a tool I am familiar with because we considered it on the Foreign Relations Committee when I was on the staff.

Mr. SMITH. Sure.

Ms. MADISON. I do not personally have any information to suggest the complicity of specific individuals but I understand the point, which is that Global Magnitsky is another tool that allows you to go after corruption and we are happy to sort of take that back and look at the question. But I understand the point which is it is another tool.

Mr. SMITH. Please go back and maybe get back to the subcommittee as soon as you can.

Mr. Castro?

Mr. CASTRO. Sure.

Let me ask you a practical question. Can you describe the tools and practices that you employ to detect fentanyl? For example, what tools do you use in regard to mail routed through the postal system?

Mr. KNIERIM. Go ahead.

Ms. MADISON. So INL's piece of this, we are not law enforcement on the front lines. CBP really owns the front line on this as stuff enters the country because they have the authorities to intercept and actually look at things as they enter. From an INL perspective, from a State Department perspective what we try to do, what we are working on is trying to get countries to provide more advanced electronic data that would allow our law enforcement folks to actually go after this. And we also work with countries like Mexico to provide fentanyl sniffing dogs and port inspection mechanisms and to work with them on controlling their port.

So our piece of it is the piece where we are trying to line up the tools that would actually help our law enforcement. And the advanced electronic data, CBP and the U.S. Postal Inspection Service have said that they need more data and it would be extraordinarily helpful to them as they try and control inbound packages.

So from a State Department perspective, we are working in the Universal Postal Union to try and continue to advance a requirement that all countries provide advanced electronic data. The second piece of that is, the challenge of that is there is a soft requirement for countries actually to do 100 percent advanced electronic data by 2020. Many countries are not capable of it.

So INL, one of the new partnerships that we are trying to build is a partnership with UPU. They have a training program that they have 13 countries in a pilot project trying to build their capability to provide advanced electronic data. So one of the things that the State Department is doing is we are negotiating with UPU to actually expand that program and to tap into their training. And really we would have to identify the priority countries that are the transport points for mail packages, but if we can help build the capacity of some of these countries to provide advanced electronic data that supports our law enforcement folks who are at the border.

I don't know if you have more to add, Paul.

Mr. KNIERIM. Well, I can't respond directly to what technical and tools are being used by CBP and the Postal Service. What I can tell you, however, is that we have a very robust interaction and collaboration with both CBP and the Postal Service to identify the organizations and have an impact on the availability.

One of the things that is very difficult and challenging and I will use this as a little demonstration, is if this were—this is about one gram. If this were a packet of fentanyl there is approximately 500 lethal doses in here. So we are looking for very small amounts at certain times. These aren't the tons that are coming in specific shipments through maritime efforts and things like that.

So it does represent challenges, but I do want you to understand and be aware that there is a very robust interaction amongst law enforcement to address this issue and work with our CBP and U.S. Postal Service partners. And also with our foreign partners, I think the Assistant Secretary made a very valuable point in recognizing that we are providing opportunities for training and capacity building so that our counterparts can also be prepared to handle and understand the significance of these threats from a safety and security perspective from their investigators as well.

Mr. CASTRO. Thank you. Just one more question from me which is of all the fentanyl in the United States how much of it comes from China versus Mexico versus somewhere else? Do you all have a sense for that?

Mr. KNIERIM. Sir, I don't know if we have a specific sense. One of the things that we do use as an identifier or origin is the purity. What we understand and find is that if it is coming directly from China it is over 90 percent pure. And if it is coming from Mexico it is generally less than 10 percent. We see it coming——

Mr. SMITH. Will the gentleman yield on that point?

Mr. CASTRO. Sure.

Mr. SMITH. Through Mexico, but what would be the origin?

Mr. KNIERIM. We see the origin coming from China as well. So when it gets to Mexico it is mixed in with heroin or other adulterants and also made and pressed into pills that would mimic or look like pharmaceuticals. So that is when we see it come, when it comes across the southwest border it is generally a little less than 10 percent.

Mr. CASTRO. And is any of it native to the United States?

Mr. KNIERIM. From the licit side or from the illicit sides? From the illicit side again coming in from China, and this does create a challenge as well because it is creating individuals who are capable of being non-cartel affiliated traffickers. There was an example of one in Utah where one individual was responsible for shipping over 400,000 packages throughout the United States. He was getting it on the Web and purchasing it and then putting it in and manufacturing it into fake pills in the basement of his mother's residence.

So it does create a challenge identifying those types of non-cartel affiliated individuals as well.

Mr. CASTRO. All right, thank you. I am going to have to leave you, Chairman. I have my other subcommittee at the same time.

Mr. SMITH. I am going to be there too.

I would like to now yield to Mr. Donovan.

Mr. DONOVAN. Thank you, Chairman. Most of my questions are already asked. I was going to ask the question about does China have a fentanyl problem as well and if they don't they really don't care what it is doing to our citizens. If it is so inexpensive why aren't we making it here? If it is made in labs, it is synthetic, why aren't our drug dealers making it, does anybody know?

Mr. KNIERIM. The precursor chemicals are controlled. So I think identifying and obtaining the precursor chemicals is——

Mr. DONOVAN. Is it difficult?

Mr. KNIERIM [continuing]. More challenging than obtaining the substance.

Mr. DONOVAN. It is just easier to buy. And I think you hit on it before that there is detection methods, you know, our dogs hit on cocaine packages or coffee beans or Ty-D-Bol cubes, whatever they are called. So are there methods that we are detecting fentanyl as it comes through the country that you are aware of?

Ms. MADISON. So from INL's work in Mexico it is the dog program that we have found to be the most effective. I don't know if there are other technical methods but that is certainly—and that is actually something that came out of the North American Drug Dialogue with the Canadians because the Canadians were the first to say hey, the dogs are actually the most effective way to detect this.

And the RCMP is, actually they started the training in Mexico, for example, which again it is a shared border so that is in our interest. And we in INL have supported the program in Mexico with dogs and additional training. So that is the primary one we work on in INL.

Mr. KNIERIM. And, sir, one thing I can highlight is the fact that there is technical equipment that does detect it, but we are still at least from my understanding within DEA looking at the technology to see what is the most effective. My understanding is that CBP does have some of this that they are using. I don't know specifically what it is, but I can take that back and find that out for you and get back to you.

Mr. DONOVAN. What are the sizes that we are seizing when they come across? I mean, you know, we used to do cocaine seizures of hundreds of kilos. We are not seeing that with fentanyl, right?

Mr. KNIERIM. We have seen some very significant seizures in Mexico in particular, upwards of 50 to 60 kilograms and then you are getting into the thousands of pills. So it is coming across in significant numbers and those are some seizures that have happened, some polydrug seizures recently by our Mexican counterpart.

Mr. DONOVAN. Do we see any other substances, narcotics being shipped, heroin from the Far East, cocaine from the south being shipped by mail, or is it fentanyl the predominant substance that we are seeing shipped by mail?

Mr. KNIERIM. In my experience, cocaine and meth is getting here in every way conceivable to include through the southwest border, being shipped through the mail, couriers, maritime; so they use all the available resources to get it across.

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

Mr. SMITH. Thank you very much, Mr. Donovan.

Mr. Suozzi?

Mr. SUOZZI. So, first, I have a preliminary question. Fentanyl is used for legal purposes as well, it is used for anesthesia and things like that; is that correct?

Ms. MADISON. It is correct. The synthetics are actually used for licit purposes as well.

Mr. SUOZZI. And when you talked about the precursor chemicals before and the lack of availability of the precursor chemicals here in America because it is regulated, but the unregulated nature of the precursor chemicals in China, for example, what are the precursor chemicals?

Mr. KNIERIM. That is a great question and I do want to just reiterate that precursor chemicals have been regulated by China and there are two specifically. One is NPP and one is 4ANPP, both have been controlled by China.

Mr. SUOZZI. Okay. I am not going to try and get you to tell me what NPP stands for, right?

Mr. KNIERIM. I couldn't do it, sir.

Mr. SUOZZI. Okay. All right, so just I want to try and get some clarity. So there are four parts that contribute to this problem. One is the lack of, we think, Chinese enforcement to go after these drugs being manufactured in China and then being shipped here. Two is detection of these drugs as they are entering our border, and I want you to talk about that just to clarify for me that you think mainly the way it is coming in is through the mail.

Three is the prosecution of the substances, the possession for these substances based upon the fact that they are these different analogues and they change the makeup and they are not all necessarily scheduled drugs that can be prosecuted for. And four of course is, you know, the demand for the drugs itself.

So are those the four big areas and can you just talk a little bit about each one like what is the biggest parts of the problem? Is it the lack of Chinese enforcement? Is it the failure or inability to detect the stuff coming across the border? Is it the inability to prosecute because of the different analogues or is it just simply because people are using this stuff too much? Or is there something I am leaving out?

Ms. MADISON. Paul will add after I do, but from my perspective I think all of these things are part of the challenge. I think you have a very agile part of the drug market, right. You have synthetics that are able to be produced and altered very rapidly. It is the reason we are asking China to control as a class, because basically if they tweak a formula and on a particular drug it is suddenly no longer controlled. I think it is very agile.

I think another big——

Mr. SUOZZI. So just China right now. You know, they are doing better now, they have gone after some precursor drugs. From 1 to 10, 10 doing the great job of enforcement and 1 they are not doing a great job of enforcement, how would you rank them from 1 to 10?

Mr. KNIERIM. What I would like to say is that they are working with us on a collaborative basis on our investigative efforts and so I think that over the last few years and what I have seen is that investigative cooperation and that exchange and those partnerships have significantly increased. So they have exchange information with us and us with them, they have taken action on the investigative information that is being passed. So I believe that those relationships are going to continue to strengthen. In particular, why we are opening an office in Guangzhou and looking at opening an office in Shanghai, because those partnerships and those relationships develop further investigative efforts and joint investigations.

I think on the detection piece, it is coming through the mail, right, so that does present challenges for us. I think we are looking at the cartels. And to your point about that with the prosecution and those types of things, I think again want to recognize and thank Congress for SITSA, because we do feel that that is a very

important legislative issue. As evidenced by our emergency scheduling, we also think any additional legislation that would permanently schedule these as a class would be very helpful as well.

Mr. SUOZZI. Anything you want to add, Ms. Madison?

Ms. MADISON. Just to say that I do think in addition to the——

Mr. SUOZZI. I am letting you off on the 1 to 10 thing because you obviously don't want to answer that.

Ms. MADISON. It is very merciful of you.

I would say, you know, that the issue of the scheduling as a class is so important because of the agility of the synthetic, illicit synthetic producers. I think the mail presents a really profound challenge because it is very diffuse. You know, this is not our old school interdiction approach. It is not what we have done with cocaine. It is not what we have done with——

Mr. SUOZZI. It is not some people taking a boat across the Caribbean and coming in some places, no border control and sneaking in that way.

Ms. MADISON. Right. And then there is the dark Web piece of it. It is very—this is not the word I want to use, but it is sort of democratized access, right. People can go online. They can go onto the dark Web. They can make these purchases. They can pay for them with crypto currencies and they can get them dumped in the mail and shipped to them. And then we are in a position where CBP is trying to stop it all at the border. So this is a very different kind of business model and it is a sort of new horizon in the challenge.

So, and I think that—and you can't ignore any piece of what you talk about. The demand piece of it is very important. It is not the work that the State Department does or DEA does, but it is a piece of this puzzle. But I think this is a very, very agile piece of the illicit drug market and it is requiring us to think differently and develop new techniques because it is not the old school way of trafficking or selling drugs.

Mr. SUOZZI. And how, is there a way that it could be detected in the mail if we changed the procedures or processes? I mean how we could we, I mean if it is coming in these small packages and that could be wrapped in something else and wrapped in something else, I mean how would we—it is not an x-ray thing. It is not a smell. How would you detect it in the mail?

Mr. KNIERIM. I think through the mail facilities is what CBP and U.S. Postal is trying to do through the express mail consignment. Shipping the volume is significant of the mail that is coming in from China. So I think from our perspective it is also continuing to focus our interagency efforts on identifying those individuals and organizations responsible and heading it off in that perspective and prosecuting them.

I think to piggyback on something that the Assistant Secretary said with regard to the internet and I previously mentioned it, this has created non-cartel affiliated trafficking opportunities for some individuals. So the robust efforts and our interagency efforts to address the internet and not just the dark Web but the open Web as well, and then to follow up with our, you know, money laundering investigations to identify the flow and to identify those assets for seizure is also something that we take very seriously.

You know, this is a top priority and so I think our interagency efforts and our international efforts collectively are going to continue to strengthen and improve as we identify these other areas of mutual interest.

Mr. SUOZZI. The last thing, so you are talking about, you know, we need to do a better job surveilling the dark Web, surveilling the open Web, and watching for where people get access to this stuff in the first place. And then there is a concern about surveilling the mails about where the origination point is for these drugs and then trying to track where they end up in the United States and look for patterns and processes of where the drugs are going related to where the overdoses are taking place or the use is taking place which will raise concerns of the libertarians and civil liberties folks that, you know, we are watching too much of what everybody is doing.

But you are saying that is the only way you can really track what is going on or am I putting words in your mouth?

Mr. KNIERIM. I think it is a combination of investigative efforts to include and incorporate the information and the investigations that we have that utilize the mail, utilize the internet, the cartel involvement, the non-cartel affiliated traffickers. So it is really a combined and faceted, multifaceted approach to address this significant problem.

Mr. SUOZZI. Thank you. Thank you, Mr. Chairman.

Mr. SMITH. I have some other additional questions, but we do have a vote series, five votes that are up, regrettably, in terms of time. I apologize for the inconvenience to our next panel, because we will have to take a short recess.

But I would, for the record you didn't say it when I asked it earlier, but maybe for the record you could provide it, how many arrests have Chinese narco traffickers had with the DEA? What kind of, I mean what are the numbers? Are they working with us? What is the outcome of the announced April indictments? Where is that if you could bring us to successful prosecution sometimes breeds more successful prosecution showing that it is doable and of course we learn lessons on cooperation when we actually do it and cooperate.

So I do have those questions. If you could provide that for the record I would appreciate that. And again getting back to enforcement, you have made the point that they have legal controls on the precursors. Again just my experience, I could be dead wrong, but by and large when the government gives an assurance of something that it has no willingness to execute, and nowhere is that more notorious than their utter failure to respect the human rights of their own people in a myriad of categories, they will have a piece of paper that says look, it is right here it is outlawed, and yet the proof has to be in how are you executing it.

So if you could get back to us with maybe some additional insight on how they are executing. Like I mentioned with the methamphetamine, they are serious about that one because Chinese citizens are dying from it and of course that is made in a lab too. So please get back to us on that one as well unless you wanted to comment right now.

Mr. KNIERIM. We will be happy to get back to you, sir.

Mr. SMITH. I appreciate that. Thank you.

I will do the introductions to our next panel and again I deeply apologize to the next panel.

And thank you again for your testimonies.

And then we will come back right after the vote to reconvene.

Maybe we will go in brief recess and then I will invite everybody to the witness table in a few moments. Thank you.

[Recess.]

Mr. SMITH. The subcommittee will resume its sitting and I do want to apologize for that hour delay or a little over because of votes. We did have five votes. So, but please accept that apology and I thank you for your patience most of all.

Let me begin, first of all, with our first witness on Panel 2, Joseph Coronato who has served as the prosecutor in Ocean County, New Jersey since 2013. Prior to his current position, Mr. Coronato established a private practice in Toms River, New Jersey, specializing in municipal prosecution, civil litigation, criminal matters, and personal injury, among other things.

He also served as assistant prosecutor at the Atlantic County Prosecutor's Office and was appointed deputy attorney general by the attorney general of New Jersey back in 1976, where he investigated and tried organized crime, narcotics, and white-collar crime as well, and worked in the Organized Crime Special Prosecutor Section of the Attorney General's Office.

Secondly, we will hear from Bryce Pardo who is an associate health policy researcher at the RAND Corporation where his work focuses on drug policy, specifically in the areas of cannabis regulation, opioid control, and new psychoactive substance markets. Prior to his current position, Mr. Pardo worked for 5 years as a legislative and policy analyst at the Inter-American Drug Abuse Control Commission within the OAS, the Organization of American States, and has independently consulted with multilateral institutions such as PAHO, the Pan American Health Organization and U.N. Office on Drugs and Crime.

In 2015, Mr. Pardo served as an analyst with BOTEC Analysis Corporation assisting the Government of Jamaica in drafting medical cannabis regulations. Mr. Pardo holds a doctorate of philosophy in public policy from the University of Maryland, an M.A. in Latin American studies, and a B.A. in political science from George Washington University.

And then finally we will hear from Dr. Dan Ciccarone who is a professor in the Department of Family and Community Medicine at the University of California San Francisco. He specializes in family medicine and addiction medicine, has been principal or co-investigator on numerous NIH-sponsored public health research projects.

He currently leads the Heroin in Transition Study which aims to examine the rise in heroin use, the expanding diversity of heroin source forms, and illicitly made synthetic opioids such as fentanyl and their relationship to the increase in illicitly opioid involved mortality as well as morbidity. He is the associate editor of the International Journal of Drug Policy and recently edited a special issue of the Journal on opioids, heroin, and fentanyl in the United States.

Three outstanding experts to inform the panel and, by extension, to inform the Congress, so I thank you for being here. And, Mr. Coronato, if you could begin.

STATEMENT OF MR. JOSEPH D. CORONATO, PROSECUTOR, PROSECUTOR'S OFFICE, OCEAN COUNTY, NEW JERSEY

Mr. CORONATO. My name is Joe Coronato and I am the prosecutor in Ocean County. Ocean County is the second largest landmass county in New Jersey. Our population is slightly over 600,000 which is the fifth largest, But during the summer months our population exceeds 1.2 million. That is due to our beaches along the Atlantic coast.

I was sworn in as prosecutor back in March 2013. As the prosecutor, I am the chief law enforcement officer for the county. As such, the police chiefs of 32 police departments and approximately 1,600 sworn officers report to my authority. My office itself consists of 200 employees: 50 assistant prosecutors, 95 detectives, and agents and support staff, just to show that we are an average county within not only the State of New Jersey but probably throughout the country.

Within 2 weeks of being sworn in as prosecutor there were eight overdose deaths in Ocean County. All the victims were under the age of 28. I had one young girl 18 years of age died in a motel room. This young woman was doing 50 packs of heroin a day, 25 in the morning and 25 at night. As a father of two children, I knew it was my responsibility to use every effort possible to address this epidemic.

Ocean County has become ground zero for the overdose deaths in New Jersey in the last several years. Back in 2012, before I was prosecutor, it was 53 overdose deaths due to opiates. In 2013 it went up to 112. In 2014 it went down to 106 and that is because of Narcan. In 2015 it went back up to 120. In 2016 it was the year where we had 217 people in my county died. I will note that in 2017 there was 174 people died. It was a 20 percent reduction and I will explain that later on.

The Ocean County Prosecutor's Office and its local and State and Federal partners have attacked the opiate epidemic and it appears that we are having some success in this regard. But that being said, the impact of what I call the synthetic storm, the addition of fentanyl to the mix has been devastating and continues to be a major concern.

Based on our medical examiner toxicology analysis, in 2014, 10 percent of my dead bodies had fentanyl in them. In 2015, 30 percent of my dead bodies had fentanyl in it. In 2016, 60 percent of my dead bodies had fentanyl in it. In 2017, 65 percent of my dead bodies had fentanyl in it. And now 2018, 80 percent of my dead bodies have fentanyl and I do say by the end of the year probably will rise to about 85 percent.

A brief summary from Ocean County Forensic Laboratory for 2017 and 2018 is also startling. The number of fentanyl-laced submissions rose from 37 percent, meaning of what we tested in 2017 to about 52 percent of our submissions now have fentanyl in it in 2018. Fentanyl-laced submissions now appear to be frequently combined with at least 14 other drugs such as cocaine, methamphet-

amine, and alprazolam. Our county labs are consistent with the New Jersey State Police Forensic Science Lab. So far the State lab is showing a 53 percent increase in fentanyl-laced submissions statewide in 2018.

Ocean County has been tracking the opioid death rate on a monthly basis since 2014. To further emphasize the impact of synthetic opioids, in February 2017 there were seven overdose deaths. In February 2018 there was a dramatic increase to 20 deaths. The increase can be attributed to a free heroin day that was promoted by the drug dealers in Camden, New Jersey. On that day there was no charge for heroin wax folds. Ocean County suffered eight deaths within a 3-day period. It should be noted that Camden and surrounding counties, Gloucester and Cumberland, had similarly high death rates for that same period. Essentially, a bad batch of synthetic-laced opioid was the cause.

To note, on June 25th, 2018, this year, the Customs and Border Protection seized 110 pounds of fentanyl in Philadelphia. The U.S. Customs and Protection agents in Philadelphia last week discovered 100 pounds inside barrels of iron oxide being shipped from China. The seizure occurred on June 25th and netted fentanyl with a street value of $1.7 million. An agency spokesman said the cargo was flown into Chicago then shipped by truck through Philadelphia, but the officials that are not going to specify exactly where the seizure occurred or identify the cargo's intended final destination.

That seizure further illustrates a significant impact that synthetic opioids have on the drug trade not only in New Jersey and Philadelphia area, but throughout the entire country. The drug traffickers are businessmen who are seizing the opportunity to maximize their profits simply through their distribution of same. Why grow a plant when you can synthetically produce and manufacture at a significantly lesser cost.

In recognition of that threat that heroin and opioids presents in my region, the DEA and HIDTA recently established a Monmouth County Post of Duty Task Force which will focus additional law enforcement resources to our problem. To that end, I really want to thank Chairman Smith, Senator Booker, and also Congressman Tom MacArthur who helped me get Ocean County to be part of that HIDTA task force.

As a result of that already strong working relationship between my office and federal, state, and local authorities, a drug investigation was recently conducted which involved six counties in New Jersey, New York, and the Dominican Republic. One of the target dealers, investigators from Jersey City—and basically what happened is that we were able to trace the drug dealer through Ocean County through Monmouth, up to Middlesex, up to Hudson County into Jersey City. That dealer then went over to the Bronx and then flew from the Bronx down to Miami, eventually going to the Dominican Republic.

We then were able to track that individual back into Miami, who then flew to California, and eventually was stopped crossing the United States. And when we did that stop was transporting 40 pounds of cocaine and 40 pounds of meth that was designated for the East Coast. And I use that to show how a county prosecutor

can show how it becomes an international source of drug dealing that actually leaves our shore, goes to another country, and comes clear across the State.

In my opinion, synthetics will become the predominant type of illegal drugs abused within the next 5 years. In fact, we now can see in Ocean County that synthetic drug transactions are being transacted at an alarming rate, in many instances right over the internet from sites located abroad. The subsequent delivery of the internet synthetic drugs is literally to the doorstep of our abusers and dealers by the U.S. Postal Service, Federal Express, and other delivery services as the case may be.

At least in Ocean County we have created a partnership between law enforcement and the healthcare community and additional services which has had a substantial impact on reducing our overdose rate by 20 percent of the synthetic storm. The death rate in Ocean County for 2018 matches our death rate of 2017 which means that we are holding our own.

While I am very proud of our anti-heroin/opiate programs we have implemented in Ocean County, I am most proud of our Blue HART Program. Blue HART allows an addict to voluntarily turn themselves into one of our eight police departments in our county and without fear of prosecution be referred to a long-term rehab center.

Since we rolled the program out and starting in January 2017, over 800 individuals have availed themselves of this program. Because of these synthetic opiates, our efforts to reduce overdose deaths here in Ocean County and elsewhere will be increasingly more difficult. I look forward to Congress to take the lead in this synthetic epidemic and to assist law enforcement and healthcare communities with adopting comprehensive legislation to address this epidemic.

I believe there are a couple recommendations this committee can consider in helping to stop the international illegal sale of fentanyl. First, I believe our Federal law enforcement needs to develop new partnership with law enforcement in China and other countries where we have traditionally not had a significant presence. It is extremely important to control the production and distribution of synthetic opioids worldwide, and I think we need to do that through the partnership of law enforcement agencies.

Secondly, I would also recommend to the committee to consider new investigative techniques needed to implement in this illegal drug trade. We have seen especially with fentanyl internet purchases with home delivery of this dangerous drug. Traditional drug enforcement needs to adapt to this change in distribution patterns and Federal resources need to be devoted to this issue. The internet ordering of illegal drugs including fentanyl and delivery of that drug to your doorstep is the next storm.

I would like to thank you for the opportunity to address this committee and express my thoughts and concerns. I would like to add one other thing, if I may. When I talk about the Blue HART Program, okay, that all kind of evolved out of Narcan. When it came in 2014, I could see that our death rate was climbing alarmingly. We turned to Narcan. We were the first county in the State of New Jersey to give out Narcan to the law enforcement officials. We gave

it to all the police departments and we used forfeiture funds to fund the Narcan within each of the departments.

But I soon learned even though our death rate started to go down as a result of giving out the Narcan that that was only a temporary fix. So the next program that we worked on in 2015 and 2016 was what we called the OORP program, which is the Opioid Overdose Response Program. And that meant that once an individual that was sprayed with Narcan and brought to the hospital, there would be a recovery coach that would approach him in that hospital, so we would have somebody available 7 days a week, 24 hours a day in the hospital that would be able to, as I would call them, catch that individual, tell them they were at death's doorstep, and get them into help. So we did that in 2015 and 2016.

But then it became upon me to say, wait a minute. The only way we are helping these people is that they almost have to die and almost have to be at death's doorstep to help them, and that is when the Blue HART Program came into being where you can walk into a police station without fear of being charged and that we would get help. I never thought in my wildest dreams that 800 people would be walking into my police stations to do that. But what that does show is why did they come into a police station and not present themselves to a hospital?

There is a gap there and obviously that is something that we needed to work with, with the hospitals to understand because this is a medical issue. It is a disease that needs to be worked upon. I really would believe that the next phase is a step-down unit within the hospital. I truly believe that we can't tie up the emergency room and have a throughput issue in the emergency room, but that we need to develop within the hospital a step-down unit where almost where we can hold them for 24 that may be up to 72 hours, that there be a clinical evaluation done and that we would then be able to process them through the system.

I think it also would give the State Health Department a better feel as to what the volume is going to be because we would have these step-down units located throughout the State. They would be able to better track and better assess the problems as they go forward. I think it is also a one-step, a one-flow issue because it would not only be limited to opiates, but it would also be for alcohol problems, mental health problems. I think that it would be broad-based as a result.

And then we would then, once we have these entries into this river as I call it to one, we should improve our river system and improve our recovery system as it goes through. So I think there is a lot of work. I think there is a bright future. I think you can see by the standard that we created that despite the fact that we have this storm and despite that we have fentanyl coming in that there is a possibility that we can work around this problem and actually reduce the death rate. Thank you.

[The prepared statement of Mr. Coronato follows:]

TESTIMONY

Presented by

Joseph D. Coronato

Ocean County Prosecutor

Before the

Subcommittee on Africa, Global Health,

Global Human Rights, and International Organizations

TACKLING FENTANYL

"The China Connection"

2 P.M. Thursday September 6, 2018

Addressing Illegal Fentanyl exports

U.S. House of Representatives

Room 2200

Rayburn House Office Building

Good afternoon, Chairman Smith, ranking member Bass and members of the committee. My name is Joseph D. Coronato, I am the Prosecutor in Ocean County, New Jersey. Ocean County is the second largest county (land wise) in New Jersey. Our population is slightly over 600,000 people, 5th largest in New Jersey, but during the summer months our population exceeds 1,200,000, due to our beaches along the Atlantic Ocean.

I was sworn in as Prosecutor of Ocean County on March 22, 2013. As Prosecutor, I am the Chief Law Enforcement officer for the county. As such, the police chiefs of 32 departments and their approximately 1,600 sworn officers report to my authority. My office itself consists of approximately 200 employees: 50 Assistant Prosecutors; 95 Detectives and Agents and Support Staff.

Within two weeks of being sworn in as Prosecutor, there were eight opiate overdose deaths in Ocean County. All the victims were under the age of 28. One young girl, 18 years of age, died in a motel room. This young woman was doing 50 packs of heroin a day, 25 in the morning and 25 at night.

As a father of 2 children, I knew it was my responsibility to use every effort possible to address this epidemic.

Ocean County has become ground zero for overdose deaths in New Jersey in the last several years:

2012 - 53 Deaths

2013 - 112 Deaths

2014 - 106 Deaths

2015 - 120 Deaths

2016 - 217 Deaths

2017 - 174 (20% Reduction)

The Ocean County Prosecutor's Office and its local, State and Federal partners have attacked the opiate epidemic and it appears that we are having some success in this regard. With that being said, the impact of the "synthetic storm", the addition of fentanyl to the mix, has been devastating and continues to be a major concern.

Based upon our medical examiner toxicology analysis:

2014 - 10% of the overdose deaths had the synthetic component of Fentanyl in their systems

2015 - 30% of the overdose deaths had the synthetic component of Fentanyl in their systems

2016- 60% of the overdose deaths had the synthetic component of Fentanyl in their systems

2017 - 65% of the overdose deaths had the synthetic component of Fentanyl in their systems

2018 - 80% of the overdose deaths had the synthetic component of Fentanyl in their systems

A brief summary from the Ocean County Forensic Laboratory for 2017 and 2018 is startling. The number of Fentanyl laced submissions rose from 35% in 2017 to 52% so far in 2018. In addition, Fentanyl laced submissions now appear to frequently be combined with at least 14 other drugs such as cocaine, methamphetamine and alprazolam. Our county lab results are consistent with the New Jersey State Police Forensic Science Laboratory results. So far the State lab is showing a 53% increase in Fentanyl laced submissions statewide for 2018.

Ocean County has been tracking the opioid death rate on a monthly basis since 2014. To further emphasize the impact of synthetic opioids, in February 2017 there were 7 overdose deaths. In February 2018, there was a dramatic increase to 20 deaths. The increase can be attributed to a free heroin day that was promoted by the drug dealers in Camden, New Jersey. On that day there was no charge for the heroin wax folds. Ocean County suffered 8 deaths within a 3 day period. It should be noted that Camden and the surrounding Counties, Gloucester and Cumberland had similarly high death rates for the same period. Essentially, a bad batch of synthetic laced opioids was the cause.

On June 25, 2018, the U. S. Customs & Border Protection seized 110 pounds of Fentanyl in Philadelphia. As reported in The (Philadelphia) Inquirer:

> U. S. Customs and Border Protection Agents in Philadelphia last week discovered 110 pounds of Fentanyl inside barrels of iron oxide shipped from China, authorities said.
>
> The seizure June 25th netted Fentanyl with a street value of about 1.7 million, according to the agency. Stephen Sapp, an agency spokesman, said the cargo was flown into Chicago and then shipped by "truck in bound" through Philadelphia, but the officials did not specify where the seizure occurred or identify the cargo's intended final destination.

This seizure further illustrates the significant impact that synthetic opioids have on the drug trade not only in the New Jersey/Philadelphia area, but throughout the entire country. The drug traffickers are businessmen who are seizing the opportunity to maximize their profits and simplify their distribution of same. Why grow a plant when you can synthetically produce/manufacture it at a significantly lesser cost.

In recognition of the threat that heroin and opioids presents to my region, the DEA/HIDTA recently established the Monmouth/Ocean County Post of Duty Task Force which will focus additional law enforcement resources to our problem. To that end, I want to again thank Senator Cory Booker, Representative Tom MacArthur, Representative Christopher Smith, NY/NJ HIDTA Executive Director Chauncey Parker and Monmouth County Prosecutor Chris Gramiccioni for their efforts.

As a result of an already strong working relationship between my Office and Federal, State and local authorities, a drug investigation was recently conducted which involved 6 counties in New Jersey , New York

and the Dominican Republic. One of the targeted drug dealers led investigators from Jersey City to the Bronx to Miami to the Dominican Republic. He then came back to Miami – went to California and was eventually apprehended in the Mid West. The individual was transporting 40 pounds of cocaine and 40 pounds of methamphetamine that was designated for our area (the East Coast). This is only one example of the national perspective and international aspect of the drug trade.

In my opinion, synthetics will become the predominate type of illegal drugs abused within the next 5 years. In fact we can now see in Ocean County that synthetic drug transactions are being transacted at an alarming rate, in many instances right over the internet from sites located abroad. The subsequent delivery of the internet synthetic drugs is literally to the door step of our abusers/dealers by the U. S. Postal Service, Federal Express or other delivery services as the case may be.

At least in Ocean County, we have created a partnership between law enforcement, the health care community and additional services which has had a substantial impact on reducing our overdose death rate by 20% despite the "synthetic storm". The death rate in Ocean County for 2018 matches our 2017 level to date, with no increase even as synthetic opiates continue to be more prevalent.

While I am very proud of a number of anti-heroin/opiate programs we have implemented in Ocean County, I am most proud of our Blue HART Program. Blue HART allows addicts to voluntarily turn

themselves into one of eight different police departments in our County, and, without fear of prosecution, be referred into a long term rehabilitation program. Since we rolled the program out 1-17-17, over 600 individuals have availed themselves of the program.

Because of these synthetic opiates our effort to reduce overdose deaths here in Ocean County and elsewhere will be increasingly more difficult. I look towards the Congress to take the lead in this synthetic epidemic and to assist the law enforcement and health care communities with adopting comprehensive legislation to address the epidemic.

I believe there are a couple recommendations this committee could consider in helping to stop the international illegal sale of fentanyl. First, I believe our federal law enforcement needs to develop new partnerships with law enforcement in China and other countries where we have traditionally not had a significant presence. It is extremely important to control the production and distribution of synthetic opioids worldwide.

Secondly, I would ask the committee to consider that new investigative techniques need to be implemented for this illegal drug trade. We have seen, especially with fentanyl, internet purchases with home delivery of this dangerous drug. Traditional drug enforcement needs to adapt to this change in distribution patterns and federal resources need to be devoted to this issue. The internet ordering of illegal drugs, including fentanyl, and the delivery of that drug to your doorstep is the next storm.

I would like to thank you for the opportunity to address this Committee and express my thoughts and concerns before you.

Mr. SMITH. Thank you very much, Mr. Coronato, a tough prosecutor with a great big heart for those who are suffering from drug abuse, so really appreciate it.

Dr. Pardo.

STATEMENT OF BRYCE PARDO, PH.D., ASSOCIATE POLICY RESEARCHER, RAND CORPORATION

Mr. PARDO. Chairman Smith, Ranking Member Bass, and other distinguished members of the subcommittee, thank you very much for the opportunity to testify before you today.

For almost 30 years, the RAND Drug Policy Research Center has worked to help decision makers in the United States and throughout the world understand and address issues involving alcohol and other drugs. I was asked to speak to you today about ongoing developments related to the opioid crisis in the United States and China's role in supplying synthetic opioids.

First, I briefly describe the emergence of these drugs. I then focus on elements related to the production and supply of substances coming from China. Finally, I conclude with some policy options aimed at the new challenges posed by synthetic opioids. The opioid crisis was originally fueled by oversupply of prescription painkillers, yet by 2017, synthetic opioids such as fentanyl were involved in approximately 60 percent of the almost 50,000 opioid overdose deaths that year. Similarly, in 2016, about 40 percent of fatal cocaine overdoses included synthetic opioids.

The upward trend in synthetic opioid overdoses is mirrored by supply-side indicators. Customs and Border Protection seized 675 kilograms of fentanyl in fiscal year 2017, up from just one kilogram in fiscal year 2013. Calculations in my written statement show that approximately 80 percent of the purity adjusted fentanyl seized by CBP in fiscal year 2017 occurred in the international postal and express consignment systems, almost all originating from China. This supports law enforcement's assessments that that country is a substantial source of synthetic opioids.

China is an important source of many legitimate chemicals and pharmaceutical ingredients. Today it is the world's largest exporter of active pharmaceutical ingredients and a leading exporter of chemicals for industrial and commercial use. However, economic growth in these sectors has outpaced the central government's ability to monitor producers.

As detailed in my written statement, there are several factors that allow for unscrupulous manufacturers to operate with impunity. First, regulatory design and enforcement is scattered across a handful of agencies creating gaps and oversight. Second, misaligned incentives between those who write the rules and those who enforce them allow for regulatory capture and corruption. And third, the central government's enforcement capacity is limited given the number of producers and distributors. Such conditions create a favorable environment for firms to operate in the legal margins allowing them to produce and export synthetic drugs to global markets.

This problem is not unique to pharmaceuticals or illicit drugs. Chinese manufacturers have been implicated in cutting corners at the expense of consumer safety. This includes manufacturing pet

food that contained melamine, toothpaste tainted with antifreeze, children's toys painted with lead, and contaminated blood thinners.

Considering the future, there are several things that Congress or Federal authorities could do. However, given the scope of this problem and the new challenges it presents, Congress must look beyond traditional and existing drug policy tools. First, given the lack of information on supply and demand Congress could ensure improved and streamlined data collection and analysis methods by Federal agencies. This includes directing law enforcement and public health authorities to improve measurement and analysis of seizures and other outcomes such as overdoses. Most of our drug policy collection and data analysis systems are inadequate to appropriately assess developments related to the arrival of these new and emerging drugs.

Second, Congress could encourage Federal authorities to utilize supply-side interventions strategically by working with Chinese counterparts to strengthen the country's regulatory and interdiction capabilities. Congress could consider appropriating additional resources to aid U.S. authorities that work with international partners as well as direct the FDA, the DEA, and the Department of State to improve interagency coordination and cooperation with the Chinese Government, encouraging it to close regulatory gaps, move more quickly with scheduling decisions, and increase enforcement capacity.

Third, Congress could encourage Department of State to engage diplomatically with China for the purposes of discussing an extradition agreement to prosecute and deter suppliers. Lack of such an agreement impedes U.S. law enforcement's ability to prosecute Chinese nationals that traffic synthetic opioids. And lastly and most importantly, Congress could increase demand reduction efforts at home. This includes encouraging the expansion of pharmacological treatments covered by private and public insurance, subsidizing the cost of medication therapies for those who cannot afford them, and reviewing and reducing regulatory barriers on their provision.

The arrival of illicitly manufactured synthetic opioids creates uncertainty in retail drug markets raising the risk of overdose. These substances are changing the drug policy landscape and stretching our ability to respond effectively. Decision makers will need to consider the new challenges presented by fentanyl and related substances to stem the rising trend in overdoses.

Thank you and I look forward to your questions.

[The prepared statement of Mr. Pardo follows:]

Testimony

Evolution of the U.S. Overdose Crisis

Understanding China's Role in the Production and Supply of Synthetic Opioids

Bryce Pardo

CT-497

Testimony presented before the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations on Tackling Fentanyl: The China Connection on September 6, 2018.

For more information on this publication, visit www.rand.org/pubs/testimonies/CT497.html

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Evolution of the U.S. Overdose Crisis: Understanding China's Role in the Production and Supply of Synthetic Opioids

Testimony of Bryce Pardo[1]
The RAND Corporation[2]

Before the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations on Tackling Fentanyl: The China Connection

September 6, 2018

Chairman Smith, Ranking Member Bass, and other distinguished members of the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations, thank you very much for the opportunity to testify before you today. I am a drug policy researcher at the RAND Corporation. For almost thirty years, the RAND Drug Policy Research Center has worked to help decisionmakers in the United States and throughout the world address issues involving alcohol and other drugs. In doing so, the center brings an objective and data-driven perspective to this often emotional and fractious policy arena. I was asked to speak to you today about ongoing developments related to the current opioid crisis in the United States and China's role in supplying potent synthetic opioids.

The introduction of illicitly manufactured synthetic opioids to U.S. drug markets presents new challenges for contemporary drug policy: The potency of many synthetic opioids increases risk to users and poses challenges for first responders, the development of novel opioids that fall outside existing drug controls complicates regulatory efforts, and their ability to be produced and shipped with ease disrupts traditional supply chains.

Today, I will briefly describe our country's ongoing opioid overdose crisis. Understanding recent developments and the shifting supply of opioids is critical to policy design. I will then describe the emergence of synthetic opioids, which have complicated many of our drug policy efforts. Given the topic of this hearing, I focus most of my testimony on China's role as a source of synthetic psychoactives and chemical precursors, describing what we know about the manufacture and export of potent opioids, such as fentanyl, to the United States. Although most of these substances appear to come from China, many dimensions of this problem remain

[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

[2] The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

unclear. That said, China's export-led economic strategy and lack of regulatory oversight have created favorable conditions for the production and exportation of synthetic opioids and related chemicals. I conclude with some policy options going forward, aimed at the new challenges posed by these substances.

Arrival of Synthetic Opioids to Illicit Markets

A decade and a half into the opioid crisis, the number of overdose deaths continues to accelerate, increasing by 6.6 percent from just 2016 to 2017.[3] The crisis was initially fueled by oversupply of prescription painkillers, such as oxycodone and hydrocodone. Yet, in 2017, synthetic opioids, such as fentanyl, were involved in approximately 60 percent of all opioid overdose deaths. Although diversion of prescription fentanyl (e.g., transdermal patches and transmucosal lozenges) has been documented,[4] today's problem largely comes from illicitly manufactured synthetic opioid powders. Unlike traditionally available street-sourced opioids, such as heroin or diverted prescription pills, synthetic opioids found in today's drug markets are often much more potent. Some of these chemicals are active in the tens of micrograms,[5] making precise dosing very difficult without sophisticated equipment. As the supply of fentanyl permeates U.S. markets, so does the risk of fatal overdose.

Provisional numbers from the Centers for Disease Control and Prevention (CDC) suggest that there were as many as 49,000 opioid-involved overdose deaths in 2017. Separating these by drug class shows that there were approximately 29,000 recorded overdoses involving synthetic opioids.[6] This is almost a tenfold increase since 2013. Today's drug overdose crisis now surpasses major public health epidemics of prior generations, including the HIV/AIDS epidemic.

Moreover, overdose figures and law enforcement reports suggest that synthetic opioids, initially sold as powdered heroin or prescription pills, are entering non-opioid drug markets.[7] Although about one-third of heroin-involved deaths in 2016 also involved synthetic opioids, approximately 40 percent of fatal cocaine overdoses included synthetic opioids. Figure 1 shows some trends regarding the presence of synthetic opioids among fatal overdoses with various other drugs. Early numbers for 2017 indicate that overdoses involving heroin and prescription opioids have remained steady since 2016, while overdoses from synthetic opioids increased by almost 50 percent, suggesting a continued diffusion across markets.

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[3] F. B. Ahmad, L. M. Rossen, M. R. Spencer, M. Warner, and P. Sutton, *Provisional Drug Overdose Death Counts*, Hyattsville, Md.: National Center for Health Statistics, 2018.

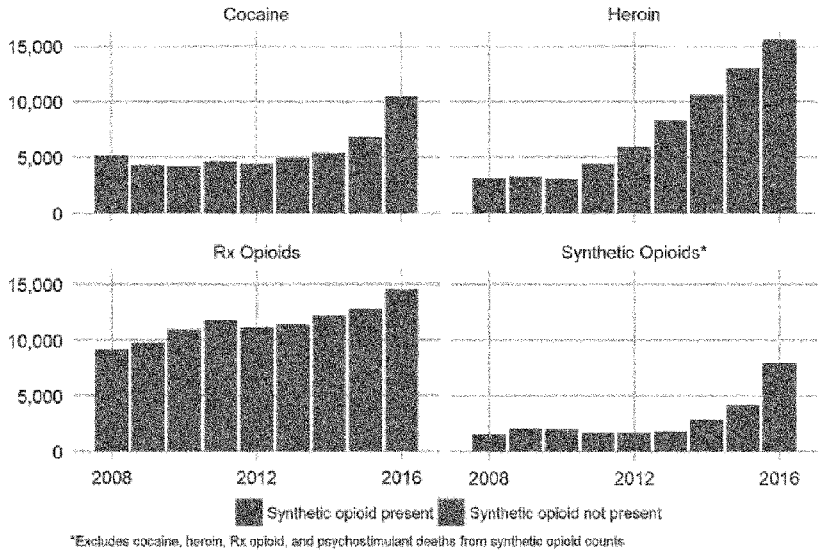
[4] J. Kuhlman, R. McCaulley, T. J. Valouch, and G. S. Behonick, "Fentanyl Use, Misuse, and Abuse: A Summary of 23 Postmortem Cases, *Journal of Analytical Toxicology*, Vol. 27, No. 7, 2003, pp. 499–504.

[5] According to the European Monitoring Centre for Drugs and Drug Addiction, the lethal dose of fentanyl for those without opioid tolerance is approximately two milligrams (2,000 micrograms), roughly the amount of two grains of salt. See http://www.emcdda.europa.eu/publications/drug-profiles/fentanyl#pharmacology. Transdermal patches containing fentanyl release 12.5 to 100 micrograms per hour, depending on the prescription.

[6] Ahmad et al., 2018.

[7] U.S. Drug Enforcement Administration, Special Testing and Research Laboratory, *Emerging Threat Report, Annual 2017*, Springfield, Va., 2018.

Figure 1. Number of Fatal Drug Overdoses in the United States



*Excludes cocaine, heroin, Rx opioid, and psychostimulant deaths from synthetic opioid counts

SOURCE: Data are deidentified public-use Multiple Cause of Death certificate files produced by the National Center for Health Statistics for 2008–2016.

The upward trend in overdoses is mirrored by supply-side indicators. U.S. Customs and Border Protection (CBP) seized approximately one kilogram of fentanyl in FY 2013; by FY 2017, CBP seized 675 kilograms.[8] Likewise, reports by the U.S. Drug Enforcement Administration's (DEA's) National Forensic Laboratory Information System (NFLIS) show a sharp increase in the number of seizures containing fentanyl submitted to state and local drug laboratories. Although this may be partially explained by changes in law enforcement procedures when handling unknown substances, reports of the number of incidents of fentanyl seizures submitted to NFLIS also jumped, from 978 in 2013 to more than 34,000 in 2016.[9] In addition to the rise in reports of seized fentanyl in domestic drug markets, DEA has noted increases in the number of novel synthetic opioids. According to DEA's *Emerging Threat Report* for 2017, ten synthetic opioids were seized and identified for the first time.[10] In other words, these chemicals

[8] U.S. Customs and Border Protection, *CBP Border Security Report: Fiscal Year 2017*, Washington, D.C., December 5, 2017.

[9] U.S. Drug Enforcement Administration, Diversion Control Division, *NFLIS Brief: Fentanyl, 2001–2015*, Springfield, Va., 2017; U.S. Drug Enforcement Administration, Diversion Control Division, *NFLIS Brief: Fentanyl and Fentanyl-Related Substances Reported in NFLIS, 2015–2016*, Springfield, Va., 2017.

[10] U.S. Drug Enforcement Administration, Special Testing and Research Laboratory, 2018.

were previously unknown in U.S. drug markets. Even though producers continue to innovate and create new substances, fentanyl remains the dominant synthetic opioid reported in laboratory seizure reports.

Although fentanyl and several of its analogues are controlled substances with recognized medical and veterinary applications in the United States, annual aggregate production quotas and prescriptions have remained relatively stable over time.[11] Today, the most likely source of these drugs is illicit manufacture. There was a brief period in the mid-2000s when illicitly manufactured fentanyl appeared in street markets in the Midwest, claiming about 1,000 lives.[12] The federal and local responses were swift, expanding access to naloxone and seizing product from markets. In May 2006, Mexican law enforcement and DEA identified and closed the illicit manufacturing operation in Toluca, Mexico.[13] Illicitly-manufactured synthetic opioids were not again a concern until late 2013.

Much has changed since the closure of the lab in Toluca. Members of law enforcement in the United States and Canada suggest that most synthetic opioids and precursors originate from manufacturers and vendors in China.[14] One route of supply comes via the international postal system and private express consignment carriers, such as FedEx and DHL.[15] According to DEA, Mexican drug traffickers are the other major source.[16] Given that drug trafficking organizations in Mexico have a history of importing methamphetamine precursors from China,[17] it is likely that they are doing the same with fentanyl precursors.

CBP reports seizing synthetic opioids, such as fentanyl, at land points of entry and checkpoints on the southwest border. Table 1 shows that for FY 2017, seizures of fentanyl near or at the border outweighed those at mail and express consignment carrier facilities. However, after adjusting for reported potency, almost 80 percent of purity-adjusted fentanyl seized by CBP in FY 2017 occurred at mail and express consignment carrier facilities. Law enforcement and

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[11] Production quotas for fentanyl trended upward starting in 2013, but they returned to their baseline levels by 2017. U.S. Drug Enforcement Administration, "Aggregate Production Quota History for Selected Substances," November 15, 2017; R. Gladden, *Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid–Involved Overdose Deaths — 27 States, 2013–2014*, Atlanta, Ga.: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, August 16, 2016.

[12] Centers for Disease Control and Prevention, *Nonpharmaceutical Fentanyl-Related Deaths—Multiple States, April 2005–March 2007*, Atlanta, Ga., Morbidity and Mortality Weekly Report, July 25, 2008.

[13] U.S. Drug Enforcement Administration, National Drug Intelligence Center, *Fentanyl: Situation Report*, Springfield, Va., SR-000001, June 5, 2006.

[14] C. Bairns, "Charges to Be Laid Involving Fentanyl Shipments from China: RCMP," *Globe and Mail*, September 18, 2017; U.S. Drug Enforcement Administration, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat*, Springfield, Va., 2016.

[15] U.S. Senate, Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations, *Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail*, Washington, D.C., staff report, 2018.

[16] U.S. Drug Enforcement Administration, 2016.

[17] S. O'Connor, *Meth Precursor Chemicals from China: Implications for the United States*, Washington, D.C.: U.S.-China Economic and Security Review Commission, 2016.

congressional investigations have suggested that these packages originated from China.[18] If we think that CBP seizures represent the true nature of trafficking patterns (i.e., that these are minimally biased samples), then these preliminary calculations support law enforcement's conclusion that the mail and express carrier consignment systems are a substantial supply channel of synthetic opioids coming from China.

Table 1. Breakdown of CBP Seizures Reported to Contain Fentanyl in FY 2017

Point of Interdiction	Amount Seized (kg)	Number of Seizures	Average Weight of Seizures (kg)	Reported Purity (%)	Purity-Adjusted Amount (kg)
Express consignment carrier facilities	110	118	0.932	90.0	99.0
International mail network	42	227	0.185	90.0	37.8
Land points of entry (southwest border)	388	65	5.970	7.5	29.1
Remainder* (presumably Border Patrol checkpoints)	135	—	—	7.5	10.1
Total	675				176.0

SOURCE: Owen, 2018.
NOTE: Purity at border is reportedly 5–10 percent; here, we use the midpoint.
* Remainder was calculated by taking the difference of reported fentanyl seizures from the FY 2017 total of 675 kg.

Nevertheless, smuggling trends may be evolving. In late June 2018, CBP at Philadelphia's port seized 50 kilograms of 4-flouroisobutyryl fentanyl hidden in barrels of iron oxide in a container ship from China.[19] CBP noted high purity, which would make this single seizure one of the largest to originate from China.

By most accounts, China remains an important source of synthetic opioids and fentanyl precursors entering North America, whether sent by mail or cargo or smuggled over the border by drug trafficking organizations.

China as a Source of New Drugs and Chemical Precursors

The manufacture of many of these new drugs and precursors, including synthetic opioids, is linked to China's large and underregulated chemical and pharmaceutical sectors. China is a leading exporter of active pharmaceutical ingredients and chemicals that can be used in the production of controlled substances. These include methamphetamine precursors and cocaine

[18] U.S. Senate, 2018: T. Owen, Executive Assistant Commissioner for Office of Field Operations, U.S. Customs and Border Protection, testimony before the U.S. Senate Committee on Homeland Security and Governmental Affairs, January 25, 2018.

[19] U.S. Customs and Border Protection, "Philadelphia CBP Seizes Nearly $1.7 Million in Fentanyl Shipped from China," June 28, 2018.

reagents, such as ephedrine, pseudoephedrine, and potassium permanganate.[20] To avoid detection at points of import, Chinese producers or distributors often employ technically legal workarounds and, when necessary, outright deception. It has been reported that Chinese traffickers and chemical exporters will mislabel shipments, modify chemicals, or ship pre-precursors that fall outside international controls.[21]

As this relates to synthetic opioids, lack of international scheduling has allowed Chinese manufacturers to export fentanyl precursors. Although they have been scheduled in the United States for a decade, N-Phenethyl-4-piperidinone (NPP) and anilino-N-phenethylpiperidine (ANPP) were not listed or subject to international controls until October 2017.[22] In late 2016, the U.S. Department of State identified nearly 260 producers of these precursors, more than half of which were in China.[23] These chemicals were finally scheduled in China this past February.[24] Prior to then, there was little scrutiny on their manufacture, and producers faced little, if any, reporting, production, or exporting restrictions.

Much like circumvention of precursor regulations, Chinese manufacturers have synthesized new substances that fall outside national and international laws, including drugs that mimic the effects of cannabis, stimulants, benzodiazepines, and opioids. In the case of synthetic opioids, such as fentanyl, individuals can order these substances online and have them shipped directly to destinations in the United States.[25] Chinese chemical and pharmaceutical firms openly advertise such drugs on English-language websites accessible by a simple internet search. Vendors will sometimes purposefully conceal shipments through freight forwarding systems, mislabel packages, or route them through a third country to conceal efforts to trace packages to their original source.[26]

To stem the growing production of uncontrolled psychoactives, the Chinese government has added new chemicals to national drug schedules. In late 2015, China added 116 new substances, including 38 synthetic cannabinoids, 26 synthetic cathinones (e.g., "bath salts"), 23 phenethylamines (e.g., MDMA analogues), as well as half a dozen synthetic opioids, to its drug control laws.[27] Since then, China has scheduled additional fentanyl analogues as they are brought to the attention of authorities by U.S. and Canadian law enforcement.[28] In January 2017, China's

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[20] O'Connor, 2016; U.S. Department of State, *International Narcotics Control Strategy Report*, Washington, D.C., 2017.

[21] O'Connor, 2016.

[22] International Narcotics Control Board, "INCB: Scheduling of Fentanyl Precursors Comes into Force," October 18, 2017.

[23] J. Whalen, "U.S. Seeks Curb on Chemicals Used to Make Fentanyl, a Powerful Opioid," *Wall Street Journal*, October 14, 2016.

[24] U.S. Drug Enforcement Administration, "China Announces Scheduling Controls on Two Fentanyl Precursor Chemicals," January 5, 2018.

[25] U.S. Senate, 2018.

[26] U.S. Senate, 2018.

[27] United Nations Office on Drugs and Crime, "China Announces Controls over 116 New Psychoactive Substances," October 2015.

[28] U.S. Drug Enforcement Administration, 2018; Royal Canadian Mounted Police, "RCMP and Chinese Ministry of Public Security Commit to Combat the Flow of Fentanyl into Canada," November 16, 2016.

Ministry of Public Security listed four additional synthetic opioids: acrylfentanyl, carfentanil, furanylfentanyl, and valerylfentanyl.[29] This was followed six months later with the control of four new substances, including two non-fentanyl synthetic opioids, U-47700 and MT-45.[30]

Industry Growth and Regulatory Deficiencies

Although the Chinese central government has taken steps to control new chemicals and precursors, the problem persists. There are two likely factors for this. First, as previously mentioned, many manufacturers adapt to controls by designing new drugs. But, more important, regulatory capacity in China appears to be inadequate to effectively police its expansive pharmaceutical and chemical industries. I now turn to this second factor.

Government-led market reforms in the past thirty years have helped China become a global manufacturing center driven by exports. The expansion of e-commerce and inexpensive shipping have made global trade cheaper and more convenient. Together, these phenomena helped make many of China's industries important links in international supply chains. The same is true for its expansive pharmaceutical and chemical industries. Initially, China prioritized the development of these sectors under strong central planning, but, over the years, it has slowly introduced privatization.[31]

As state-run producers privatized, the pharmaceutical and chemical industries experienced rapid economic development. During the 1980s, the pharmaceutical industry grew, on average, by 17 percent per year.[32] During the 1990s, the pharmaceutical industry was one of the fastest-growing sectors in China. By 1995, the number of pharmaceutical manufacturers had hit a peak of 5,300 firms.

Today, China's pharmaceutical industry counts some 5,000 manufacturers that produce more than 2,000 products, with an annual production capacity of more than 2 million tons, making the country the single largest exporter of active pharmaceutical ingredients (APIs) in the world.[33] According to the World Health Organization (WHO), most Chinese APIs are imported by the United States to produce legitimate pharmaceutical products. China's pharmaceutical industry is now the second-largest in the world, with recent annual sales revenues of more than $100 billion.[34]

In addition to China's pharmaceutical industry, the Department of State estimates that, in China, there are approximately 400,000 chemical manufacturers or distributors, some of which

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[29] Chinese Ministry of Public Security, "Notice on Inclusion of Four Fentanyl Substances, Such as Fentanyl, in the Supplement to the Catalog of Non-Medical Narcotic Drugs and Psychotropic Substances Control," March 1, 2017.

[30] U.S. Drug Enforcement Administration, "China Announces Scheduling Controls of New Psychoactive Substances/Fentanyl-Class Substances," June 19, 2017.

[31] World Health Organization, *China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health*, Geneva, 2017.

[32] H. Li. and H. Sun, "The Historical Evolution of China's Drug Regulatory System," *Value in Health*, Vol. 17, No. 3, 2014, pp. A30–A31.

[33] World Health Organization, 2017.

[34] World Health Organization, 2017.

are operating without legal approval.[35] These firms produce tons of chemicals each week intended for industrial and commercial use.[36] China is the world's leading chemical exporter by value.[37] One private-sector analysis estimates that China's chemical industry has grown by an annual average of 9 percent in recent years and made up 3 percent of the national economy in 2016, generating more than $100 billion in profits that year.[38]

Market-oriented reforms have generated rapid growth but also necessitated the creation of an independent regulatory system to police the industry and ensure product quality. Rapid commercial growth has outpaced the capacity and design of China's regulatory regime.[39] Regulatory gaps and bureaucratic fragmentation continue to hamper China's ability to oversee its pharmaceutical and chemical industries.

In 1998, the State Drug Administration (forerunner to today's China Food and Drug Administration [CFDA]) was created to regulate manufacturers of pharmaceutical and medical products. Henceforth, the regulatory authority was formally prohibited from joint ventures or profit-seeking activities in the pharmaceutical industry.[40] In the past decade, efforts have been made to adopt better enforcement and production guidelines, including good manufacturing practices (GMPs). The GMP standards cover most basic aspects of manufacturing, including environmental protections, sanitary working conditions, product testing and tracking, and record keeping.

However, the division of regulatory design and enforcement responsibilities among national governmental entities is a commonly noted problem. Given the confusing and competing overlap among agencies, efforts to regulate the chemical industry have been overlooked at times. By one account, API producers that were registered as non-pharmaceutical chemical manufacturers escaped the CFDA's regulatory oversight until 2014.[41]

Lack of coordination and competing regulatory oversight allow for such gaps to exist. This creates opportunities for some firms to hide unregulated activities in plain sight. According to one report written by staff of the U.S.-China Economic and Security Review Commission, there were eight governmental entities involved in promulgating and enforcing production and export requirements for pharmaceuticals or chemicals. These include the CFDA, the State Council Leading Group on Product Quality and Food Safety, the National Narcotics Control Commission, the Anti-Smuggling Bureau within the General Administration of Customs, the

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[35] U.S. Department of State, *International Narcotics Control Strategy Report*, Washington, D.C.: Bureau of International Narcotics and Law Enforcement Affairs, 2014; U.S. Department of State, *International Narcotics Control Strategy Report*, Washington, D.C.: Bureau of International Narcotics and Law Enforcement Affairs, 2015.

[36] O'Connor, 2016.

[37] International Trade Centre. "Trade Map," yearly trade data, 2018.

[38] Atradius, "Market Monitor: Focus on Chemicals Performance and Outlook," 2017.

[39] Li and Sun, 2014; World Health Organization, 2017.

[40] Li and Sun, 2014.

[41] S. O'Connor, *Fentanyl: China's Deadly Export to the United States*, Washington, D.C.: U.S.-China Economic and Security Review Commission, 2017.

Ministry of Chemical Industry, the Ministry of Agriculture, the Ministry of Commerce, and the General Administration of Quality Supervision, Inspection, and Quarantine.[42]

In addition to the patchwork of responsible agencies, competing incentives between levels of government may impede enforcement. Provincial authorities protect, promote, and sometimes manage local economies and industries.[43] Although the central government, through the CFDA, designs rules to govern GMP standards, it relies on provincial governments to enforce them. According to the WHO, the CFDA inspects manufacturers of products deemed sensitive by the central government (such as radioactive pharmaceuticals and biologics), whereas provincial governments are mainly tasked with inspecting and certifying companies for GMP approval.[44] This creates a principal-agent situation between the central and provincial governments. This division in regulatory design and enforcement generates opportunities for regulatory capture, non-enforcement, or outright corruption when the economic incentives of provincial governments misalign with those of good governance. In some cases, there is little or no independent regulatory oversight of firms.

Beyond gaps in regulatory design and misaligned incentives, the government's regulatory capacity is limited. The division in enforcement strategy, in which the CFDA inspects only a subset of manufacturers, leaving the rest up to provincial authorities, may reflect this limitation. The CFDA and other regulators are unable to effectively inspect and police the large number of pharmaceutical manufacturers. The WHO notes that, although the CFDA is attempting to hire more inspectors, its efforts are complicated by lack of time and resources; private industry salaries are highly competitive, complicating efforts to retain qualified staff.[45]

Data from the CFDA, produced in Table 2, show that regulators are increasing the number of inspections, yet gaps remain. Figures from annual reports show an increase in inspected firms and applicants from 698 in 2015 to 751 in 2017, although there was a dip in inspections in 2016.[46] The number of CFDA inspectors has remained around 2,000 over the same period; however, regulators have shifted focus to GMP certification inspections away from other forms of inspections, such as pre-approval and overseas inspections. These regulatory efforts, which have traditionally been assigned to provincial governments, more than doubled from just over 200 in 2015 and 2016 to 428 in 2017.[47] The number of unannounced inspections remained steady over this period, while those that included international inspectors (such as the U.S. Food and Drug Administration [FDA]) modestly increased in recent years.

Of the 428 GMP inspections carried out in 2017, 37 firms or applicants did not pass, and one-quarter were issued warning letters for violations. According to the most recent CFDA

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[42] O'Connor, 2017.

[43] T. Gong, "Corruption and Local Governance: The Double Identity of Chinese Local Governments in Market Reform," *The Pacific Review*, Vol. 19, No. 1, 2006, pp. 85–102.

[44] World Health Organization, 2017.

[45] World Health Organization, 2017.

[46] China Food and Drug Administration, Center for Food and Drug Inspection, *Annual Report of Drug Inspection 2015*, 2016; China Food and Drug Administration, Center for Food and Drug Inspection, *Annual Report of Drug Inspection 2016*, 2017; China Food and Drug Administration, Center for Food and Drug Inspection, *Annual Report of Drug Inspection 2017*, 2018.

[47] China Food and Drug Administration, Center for Food and Drug Inspection, 2016, 2017, 2018.

annual report, 15 firms that manufacture narcotic or psychotropic drugs, precursors, or pharmaceuticals were inspected that year; three did not pass inspection for failure to properly handle mailing and transportation certificates or failure to control samples.[48] These numbers suggest that regulators are inspecting a small share of companies and that a sizable portion of manufacturers of controlled substances assessed in 2017 failed inspection for improper handling and transport.

Table 2. China Food and Drug Inspections

	Number of Inspected Firms/Applicants			Number of Inspectors		
Inspection Type	**2015**	**2016**	**2017**	**2015**	**2016**	**2017**
GMP certification	221	204	428	784	47	1,234
Unannounced	59	39	57	170	155	183
Observation by international inspectors	74	81	84	76	85	92
Other	334	107	182	1,052	990	556
Total	698	431	751	2,082	1,277	2,065

SOURCES: China Food and Drug Administration, Center for Food and Drug Inspection, 2016, 2017, 2018.

The situation is similar for China's chemical regulators, who cannot adequately enforce regulations on all manufacturers and distributors.[49] Regulatory gaps have led to a large increase in the number of unlicensed or "semi-legitimate" chemical manufacturers or distributors.[50] There are reports that use of shell facilities and weak oversight lets some chemical and pharmaceutical manufacturers avoid scrutiny, allowing companies to produce and sell beyond their legal limits.[51] In 2007, industry insiders estimated that uncertified chemical manufacturers produced half of the APIs sold in China, with most exported to foreign markets.[52] It is unclear what proportion of uncertified manufacturers are supplying international API markets today or what amount of synthetic opioids is produced and exported via shell entities.

Gaps in regulatory design, the division of responsibility between provincial and central governments, and a lack of oversight and government and corporate accountability increase opportunities for corruption. The Regional Representative of the United Nations Office on Drugs and Crime, Jeremy Douglas, has asserted that corruption contributes to the ongoing illicit manufacturing and export of synthetic drugs and precursors. In 2015, after a major seizure of two and half tons of methamphetamine in Hong Kong—one of the biggest seizures in Asia at the time—Douglas stated, "To operate a lab like this, you need a lot of chemicals, which are legitimate, regulated chemicals from the pharmaceutical industry. There is some kind of

[48] China Food and Drug Administration, Center for Food and Drug Inspection, 2018.

[49] O'Connor, 2017.

[50] O'Connor, 2016.

[51] O'Connor, 2016.

[52] W. Bogdanich, "Chinese Chemicals Flow Unchecked onto World Drug Market," *New York Times*, October 31, 2007.

corruption in the chemical/pharmaceutical industry taking place allowing this to happen."[53] The Department of State also points to insufficient regulatory oversight and corruption of local government officials as explanations behind illicit drug and chemical production.[54]

Chinese authorities recognize these problems, and the government has made some efforts to expel corrupt officials. The high-profile conviction and execution of the former director of the forerunner to the CFDA in 2007 is one such example.[55] The central government has been tough on local officials and businesses, arresting nearly 2,000 people in a nationwide crackdown on counterfeit drug manufacturers in 2012.[56] In 2015, President Xi Jinping demanded that authorities increase penalties and stiffen drug regulation.[57] This past March, the central government proposed another reorganization of the CFDA, combining it with other regulatory entities.[58] Details are not final, but industry observers suggest that this reorganization is intended to extend the agency's regulatory reach and reduce gaps in oversight.[59]

Potential Policy Options

There are several options that Congress and federal authorities could consider. However, given the scope of this problem and the new challenges it presents, Congress must look beyond traditional drug policy tools.

First, given the lack of information about supply and demand, one option that Congress could take is to ensure improved and streamlined data collection and analysis methods. This includes directing law enforcement and public health authorities to improve measurement and analysis of seizures and outcome measures—such as overdoses, which are likely to be undercounted because of the novelty of analogues.[60] Most of our drug policy data collection and analysis systems are inadequate to appropriately assess developments related to the arrival of these new and emerging drugs. Congress could direct federal authorities to reintroduce expanded data collection systems, such as the Arrestee Drug Abuse Monitoring Program (ADAM) and the Drug Abuse Warning Network (DAWN) or other early warning systems. Given how fast new substances emerge in consumer markets, we need to improve measurement and reduce data lags.

Second, Congress could encourage federal authorities to use supply-side interventions strategically by working with Chinese counterparts to strengthen the country's regulatory and interdiction capabilities. Congress should consider appropriating additional resources to aid U.S. authorities that work with international partners and direct the FDA, DEA, and Department of

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[53] B. Harris, "Corrupt Mainland Drug Firms 'Fuelling Crystal Meth Scourge,' Says UN Official," *South China Morning Post*, February 22, 2015.

[54] U.S. Department of State, 2017.

[55] A. Olesen, "China Ex-Food and Drug Chief Executed," Associated Press, July 10, 2007.

[56] M. Lee and B. Hirschler, "Special Report: China's 'Wild East' Drug Store," Reuters, August 28, 2012.

[57] World Health Organization, 2017.

[58] Xinhua News Agency, "Explanation of the State Council's Institutional Reform Plan," March 14, 2018.

[59] A. Liu, "China Creates New Drug Regulator in Biggest Government Overhaul in Years," *FiercePharma*, March 13, 2018.

[60] C. J. Ruhm, "Corrected US Opioid-Involved Drug Poisoning Deaths and Mortality Rates, 1999–2015," *Addiction*, Vol. 113, No. 7, 2018.

State to improve interagency coordination and cooperation with Chinese counterparts. In some cases, source-country supply controls aimed at eradicating plant-based drugs have been limited in reducing total supply or have been seen as a source of political instability.[61] However, these factors may be less of a concern for synthetic opioids produced illegally by manufacturers. Congress could also encourage U.S. regulators to engage with Chinese counterparts to improve joint monitoring and evaluation efforts of regulation violations, as well as aid the CFDA in hiring, training, and retaining qualified personnel. Through these efforts and high-level diplomatic channels, China should be encouraged to modernize its regulatory regime to effectively address the corruption and oversight problems in its growing pharmaceutical and chemical industries. This includes efforts to improve China's scheduling system and, more importantly, its enforcement capacity.

Third, Congress could encourage the Department of State to engage diplomatically with China for the purposes of discussing an extradition agreement to prosecute and deter suppliers. The United States does not have an extradition agreement with China, but it does with several other major drug-producing and drug-trafficking countries that supply illicit drugs to the United States. The lack of an extradition agreement impedes U.S. law enforcement's ability to prosecute Chinese nationals who traffic synthetic opioids. Although the U.S. Department of Justice has indicted a handful of Chinese nationals since late last year,[62] it is unclear whether these individuals or others will be prosecuted.[63]

Lastly and most importantly, Congress could strengthen federal efforts aimed at reducing demand for illicit opioids. Demand reduction could help lessen economic incentives for drug dealers while saving the lives of those suffering from opioid-use disorder. Demand reduction includes improving access to existing and proven therapies, such as methadone and buprenorphine. Some steps that Congress could take are encouraging the expansion of pharmacological treatments covered by private and public insurance, subsidizing the cost of medication treatments to those who cannot afford them, and reviewing and reducing regulatory barriers on their provision. Congress could also direct federal health authorities, such as the FDA, to assess additional innovative and evidence-informed medication treatments. Similarly, increasing the availability of naloxone is one possible short-term, life-saving intervention. The advent of illicitly manufactured synthetic opioids coming from China creates uncertainty in the supply of drugs in markets. However, there is less uncertainty surrounding the impact of medication therapies when it comes to saving lives.[64]

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[61] P. Reuter, F. Trautmann, R. L. Pacula, B. Kilmer, A. Gageldonk, and D. van der Gouwe. *Assessing Changes in Global Drug Problems, 1998–2007*, Santa Monica, Calif.: RAND Corporation, TR-704-EC, 2009.

[62] U.S. Department of Justice, "Justice Department Announces First Ever Indictments Against Designated Chinese Manufacturers of Deadly Fentanyl and Other Opiate Substances," October 17, 2017; U.S. Department of Justice, "Two Chinese Nationals Charged with Operating Global Opioid and Drug Manufacturing Conspiracy Resulting in Deaths," August 22, 2018.

[63] S. L. Wee and J. Hernández, "Despite Trump's Pleas, China's Online Opioid Bazaar Is Booming," *New York Times*, November 8, 2017.

[64] R. Mattick, C. Breen, J. Kimber, and M. Davoli, "Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence," *Cochrane Database of Systematic Reviews*, February 6, 2014.

Mr. SMITH. Thank you very much, Dr. Pardo.
Dr. Ciccarone.

STATEMENT OF DANIEL CICCARONE, M.D., PROFESSOR OF FAMILY AND COMMUNITY MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Dr. CICCARONE. Chairman Smith, Ranking Member Bass, and other distinguished members of this subcommittee, thank you for the opportunity to testify before you today.

I have been a clinician for the past 30 years. I am also an academic researcher who has been focused on the public health consequences of heroin for the past 20 years. I have been asked to speak today on the public health dimensions of the fentanyl crisis in America. This is a drug crisis of historic proportions. For the first time in two generations, the U.S. death rate has gone up 2 years in a row. Driving this is drug poisoning deaths.

Since the beginning of the opioid epidemic, ½ million Americans have died from drug poisoning. Annual deaths due to drug overdoses now exceed deaths due to gun violence, motor vehicle accidents, and even HIV at the height of the 1990s epidemic. The leading cause of drug poisoning is due to opioids. We are witnessing a triple wave epidemic of overdoses from three classes of opioids: Prescription pills followed by heroin and now fentanyl. Each wave is crested on top of the one before, such that fentanyl deaths now exceed heroin deaths and heroin deaths exceed those from opioid pills.

For a drug epidemic to get to this size it requires both forces of supply and demand to create the enormous wave of consumption and consequences we are witnessing. Supply forces include an iatrogenic source with the tripling of opioid pill prescribing. In the second wave a new, unrecognized source of technologically advanced heroin from Mexico. And in the third wave, a new illicit opioid class, fentanyl, from a new source, China.

We also see demand in play. There are large-scale social and economic root causes driving pain pill demand and population dependency on opioid pills leading to spillover effects, driving heroin and subsequently fentanyl demand. Fentanyl is a synthetic opioid and is a well-regarded pharmaceutical. It is a highly potent drug, about 80 to 100 times as potent as morphine by weight.

The fentanyl we are discussing today is not a diverted pharmaceutical. It is illicitly manufactured and clandestinely distributed fentanyl. It is part of a chemical family that includes a number of analogues some of which are less potent than fentanyl, and some like carfentanil have much greater potency.

What is most telling in terms of supply is how regionally problematic the fentanyl epidemic is. Drug seizure data and overdose data are highest in the Midwest, down to Appalachia, over to the Mid-Atlantic, and up to New England. This strong regional distribution suggests that a large supply player or players are involved.

The demand side of the equation is complicated. Fentanyl is integrated into the illicit drug supply and sold as heroin in powder form or as counterfeit pills. Its intentional use is far outweighed by non-intentional use. That is, street users of illicit opioids are look-

ing for heroin or pills and the fentanyl comes along as an unexpected adulterant.

I have noted in my street-based research the lack of lingo or slang for fentanyl. Desired drugs have strong slang for them. This supports the notion that this fentanyl wave is supply not demand driven. However, there is still a demand element. Recall that demand for opioid pills feeds demand both directly and indirectly for heroin. Demand for heroin is indirectly feeding demand for synthetics as substitute.

Now onto addressing the fentanyl crisis. Fentanyl represents a strong supply shock in the U.S. illicit drug market. Thus, it is tempting to focus our efforts on controlling supply. The evidence shows that supply side interventions can work if part of a comprehensive program that includes demand reduction. Unipolar supply side interventions may actually cause paradoxical or unwanted results and we may have already seen some of this in play in the current crisis.

Considering source control we need to work, as has been mentioned a number of times today, diplomatically with the Chinese Government to curtail production and export of synthetic opioids. Considering interdiction, this is where it gets challenging given the size of the fentanyl flows. Fentanyl's potency allows it to be packaged in very small quantities. According to the congressional testimony given by Richard Baum, former Acting Director of ONDCP, an estimated 668 kilograms of illicit fentanyl was seized in 2016. This volume would fit into approximately three industrial drum barrels. A tiny volume that if divided up over the huge Pacific Rim is analogous to finding the proverbial needle in the haystack.

In constraining fentanyl supply we must be cognizant of potential balloon effects. There are dozens of known fentanyl analogues. It has been calculated that the number of potential analogues in this chemical family could exceed 600. We need to be careful not to foster the ingenuity and creativity of the illicit drug manufacturers to push in even more dangerous directions.

So I have heard today that one of the recommendations for that is to regulate the entire class and I would support that. One supply side intervention with potential wide impact is drug surveillance. There is an opportunity here with the rapidly evolving synthetic opioids to improve our surveillance techniques so that we can better detect the chemicals, their flows, and their mixtures.

Government officials have called for greater public safety and public health collaboration to address this crisis and the collection and sharing of this data is one key to that collaboration. Surveillance will help us in the low prevalence states. I am reminded that one of our subcommittee members is from California. In the low prevalence States we need to stay ahead of the curve. Drug surveillance will help us with that.

In addition, we also need to invest heavily in demand reduction which would include prevention, medical treatment, and harm reduction. Opioid use disorder has a number of effective treatment options including opiate agonist therapy. Low-barrier programs such as the Blue HART program in New Jersey are outstanding and need to be promoted. They also fit along with that public safety/public health collaboration.

We also must consider the benefits of harm reduction programs. The Surgeon General has called for greater distribution of naloxone, the antidote for opioid overdose. Harm reduction programs can aid in the prevention not just of overdose, but also in Hepatitis C and HIV transmission. We need a crisis-level response. The HIV epidemic of the 1990s provides an example of government intervention to curtail a crisis. The Ryan White Care Act led to a dramatic increase in funding for HIV prevention and treatment and for basic science. That fostered medical progress leading to a dramatic decrease in HIV incidence and mortality. The same can happen in this crisis.

Thank you for listening and I look forward to answering any questions you have.

[The prepared statement of Dr. Ciccarone follows:]

The Triple Wave Epidemic: Opioids, Heroin and Fentanyl: Supply Issues and Public Health Consequences

Testimony of Daniel Ciccarone, M.D., M.P.H.
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Before the Committee on Foreign Affairs,
Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations,
United Sates House of Representatives

Hearing: *Tackling Fentanyl: The China Connection*
September 6, 2018

Chairman Smith, ranking member Bass and other distinguished members of the subcommittee on Africa, Global Health, Global Human Rights and International Organizations, thank you very much for the opportunity to testify before you today. My name is Dan Ciccarone. I am a professor of family and community medicine at the University of California, San Francisco. I have been a clinician for over 30 years and an academic researcher in the area of substance use with a focus on heroin use and the medical and public health consequences of heroin use for the past 20 years. I have been asked to speak on the public health dimensions of the fentanyl and synthetic opioid crisis in America today.

My research and that of my team is multidisciplinary and multi-level. We use the tools of epidemiology, statistics, economics, clinical and basic sciences as well as ethnography and anthropological discipline. I am appreciative of my funder, which is the National Institutes of Health, National Institute on Drug Abuse, as well as my team, which includes Dr. Jay Unick, University of Maryland, Dr. Sarah G. Mars, UCSF, Dr. Dan Rosenblum, Dalhousie University, and Dr. Georgiy Bobashev from RTI, North Carolina.

In this testimony I will discuss the rapidly-evolving intertwined epidemic of overdose due to opioid pills, heroin, and fentanyl with a focus specifically on fentanyl and other synthetic opioids. I will discuss firstly the dimension of the public health crisis. Secondly, supply-side and demand-side issues that are feeding the triple wave epidemic. I will then focus specifically on fentanyl supply and demand. Finally, I discuss possible responses.

A Drug Crisis of Historic Proportions

For the first time in over two generations, the US death rate has gone up two years in a row from 2014 to 2015 and then again to 2016.[1] Correspondingly, life expectancy for an infant born

[1] NCHS Data Brief No. 293 December 2017. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Centers for Disease Control and Prevention. National Center for Health Statistics. Mortality in the United States, 2016

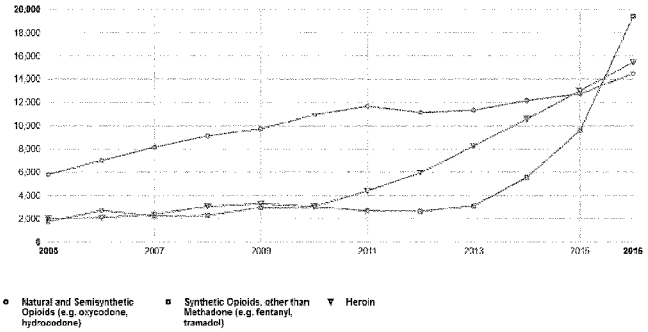
in 2015 and 2016 has also declined year over year. By examining the 10 leading causes of death, we see that heart disease and cancer, historically the top two causes of death, have maintained their positions but have gone, expectedly, down in rate. Most of the top 10 causes of death are expectedly declining year over year. However, the third leading cause of death in 2016, unintentional injuries, has been climbing the ranks following a dramatic increase in rate from 2014 to 2016.

Historically, the leading cause of unintentional injury death has been motor vehicle accidents but, as our cars have gotten safer, there's been another cause of unintentional injury that has constantly and steadily grown to surpass deaths due to motor vehicle accidents and that is deaths due to drug poisoning. Drug poisoning deaths exceeded motor vehicle deaths as of 2011 and continue to climb. According to the latest data from the US Centers for Disease Control and Prevention, deaths due to drug poisoning exceeded 72,000 in 2017.[2] Since the beginning of the opioid epidemic, a half a million Americans have died from drug poisoning. Annual deaths due to drug overdoses now exceed deaths due to car accidents, gun violence, and even HIV at the height of the 1990's HIV epidemic.

The Triple Wave Epidemic: Opioids, Heroin and Fentanyl

The current leading cause of drug poisoning is due to the family of chemicals called opioids. We are witnessing a triple wave epidemic of overdoses from three classes of opioids: prescription pills (semi-synthetic opioids), heroin and illicitly manufactured fentanyl (synthetic opioids). Figure 1 shows three waves of opioid use and consequences, each wave cresting on top of the one before it to produce even deadlier consequences.

Figure 1: Opioid Overdose Deaths by Type of Opioid



Source: Kaiser Family Foundation State Health Facts / Centers for Disease Control and Prevention.[3]

[2] NCHS, National Vital Statistics System. Estimates for 2017 are based on provisional data. Estimates for 2015 and 2016 are based on final data (available from: https://www.cdc.gov/nchs/nvss/mortality_public_use_data.htm). Accessed at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm on September 2, 2018.

[3] Kaiser Family Foundation analysis of Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Multiple Cause of Death 1999-2016 on CDC WONDER Online Database, released 2017. Data are from the Multiple Cause of Death Files, 1999-2016, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10.html on January 31, 2018.

The first wave, overdoses related to prescription pain medicines, started around the year 2000 and has steadily grown, according to the latest official data, through 2016. The second wave, building upon the first, are overdose deaths due to heroin, which started increasing around 2010 and continued to rise through 2016 passing the number of deaths due to opioid pills. The third wave, which is even deadlier, is that due to fentanyl, fentanyl analogues, and other synthetic opioids of illicit supply (i.e., not methadone). This wave began in 2014 and has climbed dramatically. Provisional 2017 drug overdose counts data from the National Center for Health Statistics, shows synthetic, e.g., fentanyl, opioid deaths continuing to rise, reaching a peak of almost 30,000, while semisynthetic and heroin overdose deaths level off, albeit at very high levels, approximately 15,000 per wave.[4]

Drug policy academics describe substance use upcycles as having two principle drivers, supply and demand; this comes out of economic theory and holds true for most consumable goods. For a drug epidemic to get to this size, it requires not just one, but both forces of supply and demand to create the enormous wave of consumption and consequences we are witnessing. First a bit of history and then I will briefly examine each of the aforementioned waves, one at a time, describing supply issues, demand issues, demographics of the population at risk, as well as some differences that exist between these three waves.

The opioid class of medications was developed to treat pain, to facilitate surgery and in general to reduce suffering at the extreme. These medications are both a miracle in their proper use, but also problematic in their misuse. Examining just this class of medications, we can consider the first epidemic of misuse and medical consequences due to morphine and heroin following their discoveries in the late 19th century.[5] They were novel drugs sourced through physicians and pharmacies and thus the subsequent misuse problem was iatrogenic, meaning medically caused. There was also a technological advance, the hypodermic syringe, which both advanced appropriate use, but also promoted problems related to misuse.

Heroin, diacetylmorphine, had a short life as a licit medication. We've seen a number of illicit heroin waves, beginning around the 1920's. The first of which may have been due to restriction on licit supplies driving drug use underground. We had heroin in the 1930-40's Jazz Era that had a social and cultural root to it. Moving on to the 1970's and the Vietnam Era, the heroin epidemic also had a sociocultural root to it as well as supply-driven factors including a new sources of heroin imported from Southeast and Southwest Asia. Then, in the 1990's, a new form of heroin produced by Colombian criminal trafficking organizations was brought into the United States. That new source of heroin caused a small epidemic of medical consequences.[6] In sum, the first century of opioids availability, including both licit, e.g. morphine and illicit e.g. heroin, opioids had a number of misuse and medical consequences waves caused by supply (iatrogenic, new illicit sources and forms) and demand forces (cultural and social, new technologies for use). Moving onto the current triple wave crisis, we see both forces at work again. Supply forces: iatrogenic source of opioid pills, a new source of technologically advanced heroin and a novel illicit opioid – fentanyl – also from a new source. Demand forces: social,

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[4] NCHS, National Vital Statistics System. Ibid.

[5] This history section is gleaned from multiple sources including: Courtwright, D.T., *Dark Paradise: A History of Opiate Addiction in America*, Cambridge: Harvard University Press, 2001. McCoy, A. W., *The Politics of Heroin*, 2nd Ed., Chicago: Lawrence Hill Books, 2003. Musto, D. F., *The American Disease: Origins of Narcotic Control*, 3rd ed., New York: Oxford University Press, 1999.

[6] Ciccarone D, Unick GJ, Kraus A. Impact of South American heroin on the US heroin market 1993-2004. The International journal on drug policy. 2009;20(5):392-401. Epub 2009/02/10. doi: 10.1016/j.drugpo.2008.12.001. PubMed PMID: 19201184; PubMed Central PMCID: PMC2719678.

cultural and economic root causes of opioid use; population dependency on opioid pills leading to spill-over effects driving heroin and subsequently, fentanyl demand.

The supply side drivers of the first wave of prescription opioid misuse and overdose have been extensively discussed in academic and policy circles. Wave one is often considered to have been driven by increased supply, i.e., a tripling of opioid prescriptions starting in the 90's and crescendoing around 2011.[7] This tripling of opioid prescriptions has been correlated to rising consequences, particularly overdose.[8] The introduction of extended release long-acting (ERLA) opioid formulations support both supply-side and demand-side pressure. ERLAs are a source of opioid in a novel form with a technological advance that allowed higher doses in a single capsule. Ease of misuse, e.g. crushing leading to insufflation (nasal 'snorting') or injection, led a wave of misuse.[9]

The conventional wisdom on the first wave places much the blame on the drugs involved and the sources of those drugs. A demand-side argument has been recently introduced examining the structural and social factors that might be driving the epidemic. The most compelling structural determinants include economic hardship and social and psychological malaise that may have led an at-risk population to seek opioids in the first place.[10]

Beginning in the late 2000's, especially by 2012, we began getting concerned about the rising number of heroin users and heroin-related overdose. Our team demonstrated a statistical relationship between the first two waves of the epidemic, opioid pills and heroin, describing them as "intertwined epidemics."[11] We also described how young and new heroin users at the time had transitioned to heroin from high dependency on opioid pills.[12] A new consciousness around the opioid pill epidemic led to a decline in physicians prescribing of opioids. Opioid pills became more difficult to get illicitly and as a consequence, a small proportion of patients found their way over to a new drug, heroin, which was more available, and at a lower price point, on the street. Thus, an unintended consequence of restrictions on opioid pill prescribing led to heroin use. There was a demand for powerful opioids that heroin fulfilled.

Data on users entering drug treatment showed that in successive cohorts from the 1960's through the 2000's, increasingly folks coming in with heroin use disorder reported starting their opioid dependency with opioid pills.[13] However, this has begun to change now as an increasing proportion of heroin dependent patients entering treatment report having started with heroin.[14] Another dramatic change occurred in late 2010, when OxyContin™, a brand name ERLA

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[7] Kolodny, A., Courtwright, D. T., Hwang, C. S., Kreiner, P., Eadie, J. L., Clark, T. W., & Alexander, G. C. (2015). The prescription opioid and heroin crisis: A public health approach to an epidemic of addiction. Annual Review of Public Health, 36, 559–574.

[8] CDC. Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR Morb Mortal Wkly Rep 2011;60:1487–92.

[9] Mars, S., Bourgois, P., Karandinos, G., Montero, F. and Ciccarone, D., Every 'Never' I Ever Said Came True: Pathways from pills to heroin injecting. International Journal of Drug Policy, 2014. 25(2): p. 257-266.

[10] Dasgupta, N., Beletsky, L., Ciccarone, D., Am J Public Health. 2018 Feb;108(2):182-186. doi: 10.2105/AJPH.2017.304187. Epub 2017 Dec 21.PMID:29267060

[11] Unick, G.J., et al., Intertwined epidemics: national demographic trends in hospitalizations for heroin- and opioid related overdoses, 1993-2009. PLoS One, 2013. 8(2): p. e54496.

[12] Mars et al. Ibid.

[13] Cicero TJ, Ellis MS. JAMA Psychiatry. 2015 May;72(5):424-30. doi: 10.1001/jamapsychiatry.2014.3043. PMID:25760692

[14] Cicero TJ, Ellis MS, Kasper ZA. Addict Behav. 2017 Nov;74:63-66. doi: 10.1016/j.addbeh.2017.05.030. Epub 2017 May 23. PMID:28582659

formulation of Oxycodone, was reformulated to be less abuse-able, ie less insufflatable or injectable. Because of this reformulation, that route of abuse was severely curtailed. This may be one of the triggers that increased interest in and use of illicit heroin. This reformulation of a popular drug, along with restrictions in prescribing and a new consciousness around more judicious prescribing of opioids, may in combination have had unintended consequences driving a small proportion of the at-risk population to heroin.

The first and second waves do have some contrasts in terms of demographics and regional distribution.[15] The age distribution of patients hospitalized for prescription opioid overdose, has its largest peaks in the 50 to 64 year old group and this has been stable for several years. In hospitalizations for heroin overdose, one sees a very different picture. The age group at highest risk are 20 to 34 year-olds with a rate of hospitalizations that is growing year by year. Another strong difference between prescription opioid overdose and heroin overdose is seen in their geographic distribution. Opioid pill overdose is relatively even across the four major US regions of the Northeast, Midwest, South and West, whereas heroin overdose is much higher, with rates of increase also higher, in the Northeast and Midwest. So, we see elements of demand-side drivers in wave two, with rising numbers of heroin users who are transitioning from prescription opioid dependency, as well as younger persons, naturally greater risk takers, initiating heroin use. In addition, there's also this notion that heroin is becoming more dangerous. Its supply is changing in quantity, source and quality and is being adulterated by synthetic opioids.

According to reports from the U.S. Drug Enforcement Administration (DEA), the U.S. heroin supply is changing dramatically, particularly during the wave two era from 2010 to 2015 in which we see an almost tripling of U.S. heroin seizures at the Southwest border.[16] Seizures are a proxy for supply, so as seizures go up, considering that the rate of seizure is not dramatically increasing, we assume that the supply has also expanded.

Another dramatic transformation in heroin supply, changes in sourcing, has occurred in the last 10 years. Historically imported heroin came from four source regions/countries in the world, including Southeast Asia, Southwest Asia, Mexico, and South America. In the 2000's we began an era in which most of our heroin came solely from to sources: Colombian and Mexican criminal trafficking organizations (CTOs).[17] Accelerating this trend towards fewer sources, since the mid 2000's to present, Mexican CTO's have increasingly dominated the U.S. heroin market; with 50% market share in 2005 and growing to 90% with the latest data.[18]

Mexican-sourced heroin is also becoming more refined. DEA documents reveal, that for a period of time in the late 2000's and early 2010's, that a substantial proportion of heroin samples were from an unknown source and of unknown quality.[19] This is now better understood as heroin sourced from Mexican CTOs, but is of a different, more refined, chemical composition than previous Mexican-sourced heroin. DEA reports highlight the evidence that the Mexico-based

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[15] Unick GJ, Ciccarone D. US regional and demographic differences in prescription opioid and heroin-related overdose hospitalizations. Int J Drug Policy. 2017 Aug;46:112-119. doi: 10.1016/j.drugpo.2017.06.003. Epub 2017 Jul 5. PMID:28688539

[16] National Seizure System. Reported in the *2016 National Heroin Threat Assessment Summary*; DOJ, DEA, 2016

[17] Update: Heroin Signature Program. Reported in the *2015 National Drug Threat Assessment Summary*; DOJ, DEA, 2015

[18] Drug Enforcement Administration, *2017 National Drug Threat Assessment*, DEA-DCTDIR-040-17, October 2017.

[19] Source: Domestic Monitoring Program. Reported in the *2015 National Drug Threat Assessment Summary*; DOJ, DEA, 2015

Sinaloa Cartel in particular has control of the U.S. heroin retail market, with particular domination in the Midwest, Mid-Atlantic and New England regions.[20]

In summary, there are significant supply-side forces behind rising heroin overdose – wave two – that we see in the Midwest, Mid-Atlantic, and New England areas. Mexican-sourced opium and heroin production has grown dramatically trading off with Colombian production. A more refined product coming from Mexico, so-called "Mexican White" heroin, which is a Colombian mimic, is going to areas where, traditionally, Colombia-sourced heroin has gone; this perhaps under the control of the Sinaloa CTO.

That brings us to the third wave, fentanyl and synthetic opioids in the heroin market.[21] Fentanyl is a synthetic opioid, i.e. a chemical manufactured in a pharmaceutical facility. This is different than, for example, morphine, which is a natural product derived from the opium poppy plant. It also distinguishes it from several other highly used pain medications like oxycodone and hydrocodone, which are semi-synthetic opioids derived from chemical constituents of the poppy plant, but then altered to make them more useful as pharmaceuticals. Heroin, which is diacetylmorphine, is also a semi-synthetic.

Fentanyl is a well-regarded pharmaceutical, used in surgery and to control severe pain. It's short-acting, so physicians and surgeons can dose it with a lot of control. On the other end of the spectrum, it can be used as a long-acting patch, in which the embedded fentanyl slowly enters the body; this is considered a boon to both chronic pain and hospice patients.

The fentanyl we are discussing today is not a diverged pharmaceutical product, it is an illicitly manufactured, clandestinely distributed fentanyl.[22] This fentanyl is integrated into the illicit drug supply and sold as "heroin" in powder form, or as counterfeit opioid or benzodiazepine pills. It is rarer, particularly on the street, that it is being sold as-is. Its intentional use is far outweighed by non-intentional use, that is, street users of illicit opioids are looking for heroin, or opioid pills, and the fentanyl comes along as an unexpected contaminant. Fentanyl is a highly potent drug, about 80-100 times as strong as morphine by weight, which makes it 30-40 times stronger than heroin by weight.

Heroin, particularly in the region with the greatest increases in wave two overdose, i.e. the Midwest, Mid-Atlantic and New England regions, exists as a *fentanyl-substituted and/or fentanyl-adulterated heroin.*[23] There is also increasing concerns of fentanyl contamination of the street market in methamphetamine and cocaine.

Fentanyl is the main chemical in a growing family of chemicals.[24] The central chemical – fentanyl – is also the main one of concern. However, there is also a growing family of analogues, which are like chemical cousins, to the fentanyl molecule. They would include such things as

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[20] Domestic Monitoring Program. Reported in the 2015 National Drug Threat Assessment Summary; DOJ, DEA, 2015

[21] Ciccarone D. Fentanyl in the US heroin supply: A rapidly changing risk environment. Int J Drug Policy. 2017 Aug;46:107-111. doi: 10.1016/j.drugpo.2017.06.010. Epub 2017 Jul 20. PMID:28735776

[22] Gladden RM, Martinez P, Seth P. Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths - 27 States, 2013-2014. MMWR Morb Mortal Wkly Rep. 2016 Aug 26;65(33):837-43. doi: 10.15585/mmwr.mm6533a2.

[23] Ciccarone D, Ondocsin J, Mars SG. Heroin uncertainties: Exploring users' perceptions of fentanyl-adulterated and -substituted 'heroin'. Int J Drug Policy. 2017 Aug;46:146-155. doi: 10.1016/j.drugpo.2017.06.004. Epub 2017 Jul 18. PMID:28735775

[24] Suzuki J, El-Haddad S. A review: Fentanyl and non-pharmaceutical fentanyls. Drug Alcohol Depend. 2017 Feb 1;171:107-116. doi: 10.1016/j.drugalcdep.2016.11.033. Epub 2016 Dec 16. Review. PMID:28068563

acetyl fentanyl and furanyl fentanyl, etc. The fentanyl analogues come in a range of morphine-equivalent potencies with some, e.g., acetyl-fentanyl being less potent than fentanyl by weight, while others have greater potency.

In addition to fentanyl and its analogues there are additional novel synthetics opioids that we are concerned about including U47700 and U48800, as well as others. The biggest concern is around a branch of the fentanyl family that includes some incredibly powerful medications including carfentanil, alfentanil, and sufentanil , which are exceedingly potent. It is unclear whether these super-high potency fentanyls will take off in the marketplace, or if they are just 'accidents' in the rapidly evolving illicit opioid supply.

According to the DEA, the main source of illicitly manufactured fentanyl is China.[25] Fentanyl sourced from China takes a number of routes on its way into the U.S. It is shipped directly into the United States in powdered form and sold as heroin, or pressed into counterfeit opioid pills and sold. It is also shipped into Canada, where it is sold domestically as heroin or pressed into pills and exported to the U.S. However, perhaps the largest part segment of this illicit market, is fentanyl that is shipped to Mexico, where it is then processed by the Mexican CTOs and either cut into heroin or transshipped with heroin for mixing in the regional markets of the U.S.

According to testimony given by Richard Baum, former Acting Director Office of National Drug Control to the Congressional Committee on Energy and Commerce, March 29, 2017, an estimated 668 kilograms of illicitly manufactured fentanyl, bound for the U.S. market was seized in 2016.[26] There is both CTO distribution of fentanyl in the United States, as well as individual and entrepreneurial distribution. The former is typically large scale with low purity product; the latter is small scale, often shipped through the postal system, albeit with high purity product. Fentanyl seizures stemming from screening of inbound international mail by Customs and Border Protection included 15 kilograms of inbound international mail and 21 kilograms from express mail carriers. In addition, Department of Homeland Security reported seizing 58 illicit pill pressing machines in 2016.

What is most telling, in terms of supply, about the third wave fentanyl epidemic is how regionally discrete it is in the United States. Comparing drug seizure data, from the DEA, with overdose death data, from the CDC, one finds remarkable geographical correlation between fentanyl seizures and fentanyl-related overdoses.[27] We see this overlap in the Midwest, e.g., Ohio, Pennsylvania, and down into Appalachia, e.g., Kentucky and West Virginia. We see it in the Mid-Atlantic region, e.g., New Jersey, and then up into England, e.g., New Hampshire and Massachusetts. Where the fentanyl is distributed is where the fentanyl-related deaths are. This strong regional distribution suggests, with support from DEA reports, that a large supply player or players are involved. If the epidemic of fentanyl overdose was more evenly spread around the country it would support the notion that the supply was entrepreneurially driven, e.g., people interested in fentanyl were finding it on the dark web and shipping it to their individual locations; that perhaps it is a culturally driven, or demand-driven event. The fact that it is so regional is evidence that illicitly manufactured fentanyl is predominately cartel CTO-driven; that this is a supply-side event. The DEA has in some of their documents agreed that the Sinaloa Cartel

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[25] Drug Enforcement Administration, *2016 National Drug Threat Assessment*, DEA-DCTDIR-001-17, November 2016.

[26] Baum, R J. 2017. Letter to Congress: Response to questions concerning fentanyl. Washington DC: Office of National Drug Control Policy.

[27] Gladden RM, et al. Ibid

seems to be heavily implicated.[28] We need to keep in mind that there are fentanyl and other synthetic opioid deaths elsewhere in the country, e.g., rising fentanyl-related overdose deaths in California are a growing concern, albeit of lower magnitude than in the most impacted regions.

I mentioned in the earliest part of my testimony that my team and I use ethnographic techniques in our research, which means we have the privilege of talking to people who are most impacted by this epidemic. We document their stories of how they are coping with changes in the drug supply, the decisions they are making, what they like and what they don't like about the drugs, and what kind of help they most want. They confirm that the changes in heroin due to its substitution by, or adulteration with fentanyl have been disturbing to them. That fentanyl was not a demand-driven phenomenon. There is currently a range of desirability for fentanyl, but this is only after several years of its constant presence in the heroin supply.[29]

One piece of evidence supporting the lack of demand for fentanyl is the lack of cultural idioms for fentanyl. Most desired illicit drugs have a slang for them. There is no slang developed yet for fentanyl despite four years of steady supply.

In addition to the dangerous potency of fentanyl, our ethnographic observations support the notion of a possibly greater danger: rapid changes in purity, as well as different mixtures of heroin and fentanyl and its analogues.[30] These vicissitudes, we may discover, may have profound effects on the overdose rate in a given location.

In summary of this description of the supply-side and demand-side drivers of the triple-wave epidemic, we have to consider whether this is one intertwined epidemic, or three separately evolving epidemics. The geographic, demographic, and supply disparities seen in the data confound any simple story. All three waves have impressive supply-side drivers including excessive medication prescribing, new forms of Mexican-sourced heroin and a new illicit source of opioid, Chinese-sourced synthetics adulterating heroin and counterfeit pills. Demand for opioid pills drove demand, both directly and indirectly, for heroin; demand for heroin indirectly feeds demand for synthetics-as-substitute. What is driving increases in opioid mortality now are deaths due to heroin and heroin adulterated by fentanyl. The second and third waves are regional, with the Midwest, Northeast, Mid-Atlantic and Appalachia regions affected the most.

There are other medical consequences, in addition to overdose, that are growing in concern. The change from pill misuse to heroin involved, for many, a change in route of administration. Pills tend to be swallowed although, as mentioned above, with ERLA oxycodone misuse some people were crushing them and insufflating or injecting the powder. Heroin, while it can be smoked or insufflated tends, in the U.S., to be injected. As the at-risk population shifts from oral misuse to injection we have to be cognizant of the infectious disease risk, including that due to blood-borne viruses such as hepatitis C and HIV. The U.S. has now had two documented injection-drug-related HIV epidemics, Scott County, Indiana,[31] and more recently in Massachusetts.[32] In addition to blood-borne viruses, we have to be concerned about injection-related bacterial infections such as endocarditis and skin and soft tissue infections.

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[28] DEA, 2017. Ibid.

[29] Ciccarone D., et al., 2017. Ibid

[30] Ciccarone D., 2017. Ibid

[31] P.J. Peters, P. Pontones, K.W. Hoover, M.R. Patel, R.R. Galang, J. Shields, *et al.* for the Indiana HIV Outbreak Investigation Team (2016). HIV infection linked to injection use of oxymorphone in Indiana, 2014–2015. The New England Journal of Medicine, 375 (2016), pp. 229-239

[32] CDC, Epi-Aid Number: 2018-027. *Undetermined Risk Factors and Mode of Transmission for HIV Infection Among Persons Who Inject Drugs — Massachusetts, 2018*. July 17, 2018

Addressing the Fentanyl Crisis

We can see this triple-wave epidemic as an intertwined, three drug epidemic, but to comprehend it fully we need to appreciate the drivers of each wave. We have noted how supply shocks can lead to drug epidemics both historically and in the current opioid crisis. Fentanyl in particular comes as a strong supply shock leading to disastrous consequences. Thus it is tempting to focus our efforts on controlling supply. We can examine supply control as one answer, but it must be one part of a more complex answer. The evidence shows that supply-side interventions can work if part of a comprehensive program that also includes demand reduction.[33] Unipolar supply-side interventions may actually cause paradoxical, unwanted results.[34] We may have already seen these phenomena within the current crisis. Downward pressure on opioid prescribing may be driving a portion of the at-risk population from opioid pill misuse to heroin, thus exposing them to the even more dangerous chemical family of fentanyls. Another driver of unintended consequences may have been the reformulation of ERLA opioids to abuse-deterrent formulations, examples of which include OxyContin™ and Opana™, another ERLA, misuse of which has been implicated in the Scott County Indiana HIV outbreak.[35] This is not to say that we should not pursue these goals of creating abuse-deterrent formulations or curtailing excessive prescribing practices. As we do these things we must also consider the consequences of our actions and respond accordingly.

Supply-Side Interventions

Considering the inadequate and paradoxical effects of current opioid supply interventions, we must broaden our supply-side policies to cover the range of illicit opioid flows and – *crucially* – combine these efforts with expansion of effective drug treatment and harm reduction.[36] Regarding fentanyl, supply-side interventions includes source control and interdiction in the drug supply chain. Considering source control, we need to work diplomatically and politically with representatives from the Chinese government and find incentives to have them curtail the production and export of fentanyl and other synthetic opioids. Interdiction will be challenging given the size of the fentanyl flows. In 2016 an estimated 668 kilograms of fentanyl was seized in the US.[37] This is but a fraction of the estimated 11 metric tons of cocaine seized, just at the U.S. Southwest Border, in 2016.[38] Fentanyl is a drug which has high potency in small volumes. Considering a seizure to importation ratio of 1:4, a total of 2.6 metric tons of fentanyl are distributed – per year – for the whole U.S. This would fit into approximately 10 industrial drum barrels. And that's a small volume that if divided up over the

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[33] Caulkins, J.P., Reuter, P., Iguchi, Y.P., Chiesa, J. *How Goes the "War on Drugs"? An Assessment of U.S. Drug Problems and Policy*. RAND Drug Policy Research Center, 2005.

[34] Ciccarone, et al. 2009. Ibid.

[35] Broz D, Zibbell J, Foote C, Roseberry JC, Patel MR, Conrad C, Chapman E, Peters PJ, Needle R, McAlister C, Duwve JM. Multiple injections per injection episode: High-risk injection practice among people who injected pills during the 2015 HIV outbreak in Indiana. Int J Drug Policy. 2018 Feb;52:97-101. doi:10.1016/j.drugpo.2017.12.003.

[36] Pacula RL and Powell D. A supply-side perspective on the opioid crisis. Journal of Policy Analysis and Management. 2018 DOI: 10.1002/pam

[37] Baum, 2017. Ibid.

[38] Drug Enforcement Administration, *Colombian Cocaine Production Expansion Contributes to Rise in Supply in the United States*, DEA Intelligence Brief, DEA-DCI-DIB-014-17, August 2017.

huge trade that occurs across the Pacific Rim constitutes a proverbial needle in a haystack of detection.

In drug policy theory there a famous notion of the balloon hypothesis, i.e., by squeezing drug supply too harshly in one direction it simply balloons out with a different source, or a different drug, routed to a different area. The concern is if we constrain fentanyl, i.e., the mother chemical, too robustly and too rapidly, it will foster the supply in fentanyl analogues. The number of known fentanyl analogues exceeds 60; the number of potential fentanyl analogues could exceed 600. We need to be careful not to foster the ingenuity and creativity of the illicit drug manufacturers to push in even more dangerous directions.

Surveillance of the Drug Supply

One supply-side intervention with potential wide impact is drug surveillance. Investments in drug monitoring, identification and data collection could assist in interdicting supply.[39] There is an opportunity here, with the rapidly evolving synthetic opioids, to improve our surveillance techniques so that we can better detect the chemicals, their flows and their mixtures. Of crucial import: how rapidly are those substances, flows, and mixtures changing? Surveillance is a crucial and underplayed card in our hand of options in addressing this crisis. Government officials have called for greater public safety and public health collaboration to address this crisis. One way for these two domains to work together is by increasing drug surveillance – *and sharing of the data*. Improved surveillance would benefit not just folks on the interdiction and public safety side, but also the public health side including first responders, emergency and hospital clinicians as well as those who work in community based programs serving the affected population.[40]

Demand Reduction

In summary, complex problems require complex solutions. We need combined approaches to reduce the unintended consequences of unipolar actions. In addition to putting our creativity and ingenuity into supply side detection, surveillance, interdiction and diplomatic supply control strategies, we also need to heavily invest in demand reduction, which would include prevention, medical substance use treatment and harm reduction. Opioid use disorder has a number of medical treatment options that have been shown to be effective as well as cost-effective.[41] Opiate agonist therapy with methadone and buprenorphine has been shown to be efficacious when coupled with high quality and low barrier treatment programs. We also must also consider the benefits of harm reduction programs. The Surgeon General has called for greater distribution of naloxone, the opioid antagonist used to treat an opioid, heroin or fentanyl overdose.[42] Getting wider distribution of naloxone into the community is an essential strategy in the current epidemic. Other harm reduction strategies include sterile syringe provision and supervised consumption spaces to aid in prevention of overdose and HIV and HCV transmission. These

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[39] Pacula and Powell, 2018. Ibid

[40] Ciccarone, IJDP, 2017. Ibid

[41] N.D. Volkow, T.R. Frieden, P.S. Hyde, and S.S. Cha, "Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic," *New England Journal of Medicine*, Vol. 370, No. 22, 2014.

[42] Surgeon General's Advisory on Naloxone and Opioid Overdose. U.S. Department of Health and Human Services. 2018. Accessed: https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html

services can provide a hub or magnet for persons at risk and provide them with the resources and referrals to services.

This is a crisis that requires crisis level response. We know that government intervention and funding can help. The HIV crisis of the 1990's provides a shining example of government intervention assisting to curtail a crisis. The Ryan White Care Act led to a dramatic increase in funding for HIV prevention and treatment. That coupled with scientific and medical progress on treatment and prevention led to a dramatic decrease in HIV incidence, prevalence, morbidity, and mortality. The costs of the current triple opioid crisis are enormous, some estimates approach 80 billion per year, and the costs to address it are ultimately likely to be very high. Estimates range from $60 billion for treatment over the next 5 years[43] to $100 billion for a multi-pronged approach to prevention, treatment and community resilience efforts.[44]

Thank you for inviting me and listening to my testimony. I welcome the opportunity to answer your questions.

[43] Simmons A. M. White House commission recommends president declare a national emergency over the deadly opioid epidemic. Los Angeles Times, Jul 31, 2017. http://www.latimes.com/nation/la-na-opioids-commission-report-20170731-story.html

[44] Katz, K. How a police chief, a governor and a sociologist would spend $100 billion to solve the opioid crisis. The Upshot, New York Times, Feb 14, 2018. https://www.nytimes.com/interactive/2018/02/14/upshot/opioid-crisis-solutions.html

Mr. SMITH. Thank you, Dr. Ciccarone, for your testimony and your leadership, all of you. I have a lot of questions but I will try to narrow it just because of the lateness of the hour because you have been so patient.

Is there any way, generally speaking, that someone who is intent on using heroin, for example, can detect the presence of fentanyl? Are many of these deaths inadvertent in the sense that they had no idea fentanyl was laced with the heroin that they are consuming?

Mr. CORONATO. I mean from my standpoint I will say this, I don't think that the user has any idea what they are consuming. They think it is heroin. They think it is good heroin. And certainly the answer would be I think they have no idea that they are taking fentanyl.

Mr. SMITH. Yes, Dr. Pardo?

Mr. PARDO. No, I definitely agree. The fact that 40 percent of cocaine overdose deaths in 2016 included mention of synthetic opioids is a shocking statistic. Users are just not aware.

Dr. CICCARONE. Most people are consuming it unknowingly. There is some ability to detect it. I have observed, I have listened to a lot of users as they consume. There is some sense they can detect, it is just clearly not good enough because people are still dying.

Mr. CORONATO. And I have one other comment if I can.

Mr. SMITH. Sure.

Mr. CORONATO. It used to be and I used to believe that you would go to get your marijuana dealer, you would go to your cocaine dealer, and you would go to your heroin dealer. I think now the dealers are all encompassing. I think that you go to your dealer and they will provide you with marijuana, they will provide you with cocaine, they will provide you with meth.

In that respect I think that you now can see that the fentanyl is in the heroin, it is in the meth, it is in the cocaine, and, you know, now starting to come into the marijuana. So I think the answer is nobody would know that they are consuming that and it is what they are looking to do is to kind of capture that individual so that, you know, it was a unique feeling that they got so this way they would come back. It is almost a marketing tool.

Mr. SMITH. We know that some people die from their first use of fentanyl. What is the common denominator there in terms of the number of times somebody might take it, say, with heroin and maybe on the fifth time that is when it takes their life? Or is it often the first?

Mr. CORONATO. I will try to answer that. I will tell you this. From my opinion, I think very few people take fentanyl the second or third time. I think that they aren't used to it. I think their body all of a sudden it is so strong it causes a reaction. The only difference that may happen is that if they take it and they are younger, and I know it sounds crazy but there happens to be somebody else present at the time there is a possibility that they can call 9-1-1, they can call the police, or they may have some Narcan and they may apply it.

But normally what happens is if they take it and they are by themselves, okay, it is not—if it is one, they are going to die.

Mr. SMITH. Let me just ask you—oh, did you, Dr. Pardo?

Mr. PARDO. I mean I would go again to the fact that if an individual, if these are entering non-opioid markets that is a serious concern. As individuals who are not tolerant of opioids coming into contact with fentanyl that presents a huge risk of overdose for those non-opioid markets, the methamphetamine and cocaine in particular.

As far as opioid users——

Dr. CICCARONE. I will agree with Dr. Pardo that if the fentanyl is contaminating a non-opiate such as methamphetamine or cocaine, the danger looms large for those folks because they do not have any tolerance. Among folks that are opioid tolerant, and that it would be a daily heroin user, there are a couple to several million daily heroin users in this country right now who are using fentanyl safely every day. It is a bit like Russian roulette because they don't know when the analogue is going to change or the purity is going to bump up or there is another powerful adulterant in there.

In our research what we found is that the drug supply, because of the mixtures of analogues and because of the unevenness of what is going on in the heroin market right now, is changing on a daily or weekly basis and those vicissitudes are quite likely causing the danger that we are seeing.

Mr. SMITH. As I think all of you know, on August 18th, the President at a Cabinet meeting admonished Jeff Sessions to really increase significantly the efforts regarding to fentanyl and to the opioid crisis. You heard two of our witnesses earlier today for the administration speak of things that they are doing and I wonder if you could give any insights as to if you think we are doing enough.

There is a bill, H.R. 6 that passed, a comprehensive bill pending in the Senate. It does include another bill that had passed independently that has stalled in the Senate with regards to the ability for the Postal Service to gather more information when packages are sent from there to here. But I am just wondering if you feel that we are doing enough.

Some of the answers that they will get back to leaves open, I think, some question as to whether or not this is an all-out effort. Added to that, I am the prime author of the Trafficking Victims Protection Act of 2000. It is our primary landmark law, government-wide, domestic and international to combat human trafficking. For years, administrations would not put China on what we call tier 3, egregious violator for labor and sex trafficking. This administration thankfully last year and again just a month ago or so did that, 2 months ago, made it very clear that they are horrible.

The Chinese reaction was predictable. It was filled with lie and deception because they are not doing anywhere near enough to mitigate this modern-day slavery. On international religious freedom they do the same thing. They had been designated a Country of Particular Concern and I wrote a law on that as well, the Frank Wolf International Religious Freedom Act. He did the original in 1998 and China gets on that list because of their attacks on all faiths from Falun Gong to Christians to the Tibetan Buddhists, Muslims, Uyghers to the Dalai Lama and Buddhists.

It is an all-out assault on religion and to hear the Chinese Government's response is as if religious freedom flourishes within the PRC. So you see time and again in human rights abuses there is no candor and which is why in my earlier questions to the administration we need to see concrete results, how many convictions, where are we really collaborating, you know, the DEA and their counterpart in the PRC? And added to that—and, Doctor, you might want to speak to this.

There are reports that they are cracking down on meth labs because it is taking a terrible toll on Chinese citizens and I am glad they are because all human life is absolutely valuable. But because fentanyl does not affect Chinese, per se, it is affecting Americans primarily, there seems to be a laissez-faire, if not an enabling response, on the part of the Chinese.

So the question is, is it time for some asymmetrical—do we need to be levying? You try to work with them, be disappointed as I am, you know, maybe they will do some things. Putting these precursor chemicals on a no-list or a controlled list, what does that really mean if there is no enforcement, or minimal enforcement that is PR oriented?

So if you could speak to that because I think, you know, if we don't get serious about this and, Mr. Coronato, you talked about the next 5 years. This is where the drugs are going, synthetic. We are in an epidemic and you had said three waves.

And, Dr. Pardo, you talked about it being worse than the HIV's pandemic and Congress did step up on that both domestically and with the President's Emergency Plan for AIDS Relief.

And I am the author—it hasn't passed yet—of a 5-year renewal of that tremendous program started by President Bush. You know, if don't really attack it and say real resources and, if necessary, real penalties levied on the Chinese. They rely on exports in all things. That is their economy. They are killing Americans. Your thoughts on that?

Dr. CICCARONE. Well, first, Chairman Smith, thank you for your leadership on human trafficking. It has been outstanding work and a big success. So, in short, to your first question is the Federal Government doing enough, I am sorry to say the answer is no. The death rate continues to increase year over year without end. We do not foresee how this turns around or how this ends.

We do need a crisis level response. I do believe that supply control—I am not an expert here. Supply control does have a role. I don't know how they are going to do it with such small volumes. But I agree with you that as much pressure diplomatic and otherwise on the Chinese Government is necessary. They do have responsibility here. They are the main source.

And then I will say the crisis level response has to include demand reduction. There are estimates from $60 billion to $100 billion are needed just on the demand side. We need to make our communities more resilient. As was mentioned earlier, I think it was by Representative Bass, we seem to have a decade over decade, continuous one drug morphing into another kind of problem. The way you address that is by addressing the root causes. The root causes are social, psychological and spiritual, and probably even economic. We need to kind of finally get serious.

Fentanyl might be the end game in terms of interdiction. We may not be able to stop the supply adequately. It is a 600-analogue family and processes to make these drugs are not that complicated. If we stop it in China how do we know it won't go to India or to somewhere else in Latin America? And so, multi-pronged, multilateral approaches and unfortunately the price tag will be big. The cost is estimated at $78 billion per year in loss of productivity for the current opioid crisis. Seventy-eight billion dollars. So to address it with $100 billion over 5, 10 years is not unreasonable.

Mr. PARDO. I would echo a lot of what Dr. Ciccarone said. To add specifically to the point about what the Federal Government is doing with regard to China, there were a lot of high level engagements with DEA and State with Chinese counterparts. Those haven't really happened as of recent so fostering high level cooperation would be encouraging.

Getting China to move more quickly with scheduling would also be encouraging. Adopting some sort of reciprocal scheduling system has been on the table, but that as far as I know has kind of stalled. So getting back to basics here and just trying to engage with them, trying to help them really improve their own capacity to enforce their own manufacturers and really clean house, I think, is key.

China has recently started to move in the area of restructuring its food and drug administration. It has taken efforts to increase inspector capacity to focus on this problem specifically in addition to all active pharmaceutical ingredient manufacturers. So working with our Chinese counterparts would be one way of trying to improve our ability to seize, detect, and regulate these substances coming out of China. I think I will stop with that.

Mr. CORONATO. Well, I would say I don't think that there is a magic bullet that is going to solve our problem. I would say Chairman Smith that we need to do it all. Look, this epidemic is killing our children. It is ripping apart our families and our family life. I think that you need to go back to the source and the source right now happens to be China.

And it doesn't necessarily have to come directly from China. It could be going through from China to either Mexico to China to India to China to Russia and then working its way back to the United States. We need to attack that and we need from the law enforcement standpoint to hold those people accountable for their actions because they are killing our children.

More importantly, I think that if we are going to look on the short term to save lives I think law enforcement has to communicate better and work with the healthcare community because this is a disease. And we need to treat it as a healthcare epidemic that is taking place and we need to treat it at the cause to help these people understand that we don't need, we need to defer them from the legal system not put them through the legal system.

And we need to be able to take these individuals—again that is why we use recovery coaches in New Jersey. We need to be able to communicate to get them the help that they need and then we need to have a better follow-up or a better tracking once they are in that system so we can make sure that they are going to complete the system and do it and not fall off the wagon after 30 days or

45 days, because quite honestly that is when they become more vulnerable.

To answer the question, they are going to go back and use again. They are going to use something that is really more powerful and actually what we are doing is killing them. So the bottom line for me is that we need to do it all.

Mr. SMITH. Let me ask you, Mr. Coronato, you were the first with your Blue HART program in the State of New Jersey to swing open the doors of our police departments and say you are welcome, we want to help you because this is a disease. I was just with Angelo Onofri. They have done that in Mercer County now, the prosecutor there, and they finally got the last municipality to join in that fight by being on the side of disease mitigation and intervention.

Any of you if you could, what are the other States and municipalities doing with regards to this? Is this a model that needs legislation and perhaps incentive grants coming out of the Federal Government? Is this perhaps a role for some new legislation to say let's take what you have done and perhaps what others have done, best practices, and get the police—I have found every police chief I talk to and every cop, because there were a lot of cops at last week's gathering in Robinsville, New Jersey with Mayor Fried, are gung-ho on this, you know, they want to help. They realize like you said it is a disease.

So I am just wondering, how do we roll this out to the country? Does it take legislation? Because we have to get ahead of this. Every municipality should have this.

Mr. CORONATO. I think an initiative, a financial initiative would make a difference, would make a difference with regard to it. I think in New Jersey, again the county prosecutor is the chief law enforcement so when I sat with my police chiefs they were all on board. Again we were the first county to use Narcan. And once the other police departments and the other county prosecutors saw how successful we were in using Narcan it spread throughout the entire State.

I think the same thing is happening with Blue HART. I think the problem with Blue HART though quite honestly is that you need a clinical evaluation that is going to take place. There is not enough beds. There is not enough availability. And that is why you kind of need to shift it into partnering up with the health care to be able to make a better assessment.

The bottom line is that we need to work cooperatively and also what we need to do is work more efficiently. Sometimes it is not that we need more money, it just needs—the money needs to be put in the right place. I think that really would make a difference.

Mr. SMITH. Well, Dr. Ciccarone had said about a crisis level response. Would this be part of that crisis level response?

Dr. CICCARONE. Oh yes. I have had the privilege of working in my research in a number of hotspot areas including Charleston, West Virginia, Baltimore, towns in Massachusetts and Chicago, as well as my hometown of San Francisco. There are a number of creative initiatives which would be under this umbrella of public safety/public health partnerships and I really applaud them. I mean I think this idea of diversion works, i.e., of recognizing that people

have a chronic disease that we can enable treatment capture and also work on, you know, treatment longevity. However, I don't know of any place that if you asked them, do you have enough resources to do what you want to do where the answer is yes. They will either say I have a labor shortage, I don't have enough docs, or they will say I have a financial resource problem where we liked this program, but we had to cap it at a certain number of people, and there are people knocking on the door but we had to cap it because we ran out of money.

We also need consistent flows of money, and maybe I will let Dr. Pardo jump in here because we were talking last night about this about how a lot of places are worried that, you know, the money is here this year, will it be here next year? Do I start a program, how big do I start a program because I don't know if I am going to have money in the next fiscal year? So, just like businesses in America, they want to know that there is some steady trajectory in the U.S. policy regarding fill in the blank.

Mr. PARDO. I mean, yes, to get to that we do know that drug addiction is a chronic relapsing disorder so we do need to have more sustained Federal funding or funding in general to treat and address this. But to get to both of these points, really what we need to, given this crisis what we need to be thinking about are kind of a broad branch approach to extracting individuals from these markets. So whether that is using the public safety system to get them into some sort of treatment facility or just reviewing regulations and limits on access and provision to medication therapies.

Talking with Dr. Ciccarone last night, the problem that some States still have moratoriums on opiate treatment provision, the fact that it is difficult for some people to access methadone and buprenorphine that puts a serious, it really hinders our ability to combat this problem at the domestic level.

Mr. SMITH. Now has the administration, DOJ, HHS, any others reached out for these kinds of insights that you are providing today? I mean they have good people I know around them, but you had said, Dr. Ciccarone, that we are not doing enough in response to that request for an answer and I appreciate your candor. Not doing enough means more dead people. Any thoughts that you have for what model legislation might look like we would appreciate it, even if it wasn't legislation, executive order, something that could be done overnight to further mobilize us.

Mr. CORONATO. I would want to add one thing. We have been talking about substance abuse the whole day today. But this is co-occurring. There is a mental health component of it. And I think that if you don't do both, if you don't attack both and go both at the mental health and also at the substance abuse and attack it at the same time—that is why the clinical evaluation is so important. And there is a benefit and there is a cost benefit because I will tell you this, the other benefit that we had in 2017, we were the only county in the State of New Jersey that had a reduced death rate and it was at 20 percent. It was significant. Not only did my death rate go down, but my spray rate went down. We sprayed 35 percent less people in Ocean County with Narcan in 2017, so it was a correlation.

Then I went back and took a look. My crime rate went down. My larceny rate went down. My shoplifting rate went down. The bottom line is, is that there are benefits if we do the job right. We are kind of defective in how we handle this and there is not a good, what I would call follow-through and not—it has to be outcome-based. I am really looking at outcomes. What I don't want to do is just recycle these individuals. I want to attack the problem and have good outcomes and that what we need to hold people accountable for. That is law enforcement.

Mr. SMITH. I did ask the previous panel a couple of times, they deferred, what other countries perhaps is this coming from, and I asked specifically whether or not India has become because they are a major producer of drugs that end up in our pharmacies. And I am just wondering if China were to get a handle on this does the labs just move and relocate?

Mr. PARDO. Yes. That is definitely a fear. That is a concern. They do have a robust pharmaceutical industry. There has been instances where they are producing controlled substances for export illicitly. So there are instances where I mean it definitely is a concern from a drug policy perspective. So thinking about this more holistically we do need to address, and getting back to Dr. Ciccarone's point, we need to really think about demand reduction as well as getting countries to focus on supply side initiatives.

Mr. SMITH. Is there anything else you would like to add?

Dr. CICCARONE. So just two comments, one is there is another major source of illicit fentanyl and that is Estonia with Russian connections. I don't think that will affect the U.S. market, it is more likely to affect the European market. The synthetic, you know, as Mr. Coronato said, the synthetic cat is out of the bag, right. The future of illicit drugs is going to be increasingly lab-based and less plant-based. We need to prepare for that future and understand what the chemicals are, what mixtures are coming in, what purities, what flows—back to the surveillance suggestion that is in my written testimony.

And then a comprehensive approach that allows not just a crisis response now, but a long response. We have been 15 years into this epidemic. It will quite likely last another 15 years. Drug epidemics do naturally cycle downward, but this is a long one. This is big one. This could go on for another almost generation if we don't act. If we do act, then we can see the curve that we saw with HIV in the 1990s with the Ryan White Care Act and technological and scientific medical progress: The death rate came plummeting down within a few years.

The same opportunity exists here. We have three medications that work. They need to be expanded. We need to work with SAMHSA and other regulatory agencies to allow greater access. Right now, docs are limited. They can prescribe. They have a certain number of patients that they can have put on buprenorphine. Why? I don't know of any other medication that limits a doctor's prescribing ability.

So I agree with you, Chairman Smith, that Congress can take leadership here, both in terms of dollars, but also in terms of working with the regulatory system, HHS and the subdivisions of HHS, to allow them the creative freedom, if you will, to explore new op-

tions given this crisis, even if they are temporary provisions. We don't want to, you know, liberalize the rules on buprenorphine forever, but what about a 5-year change, you know, so that we can get through this crisis? Buprenorphine is a high-benefit, low-risk drug. It has some risks. Not zero. No drug, no pharmaceutical we make has zero risks. A high-benefit, low-risk drug that is very useful in this current crisis.

Mr. SMITH. Would a White House—oh, I am sorry, Dr. Pardo.

Mr. PARDO. No, I would just to extend onto that we were talking last night and the fact that a doctor doesn't need a waiver to prescribe fentanyl transdermal patches to treat chronic pain but needs a waiver to prescribe buprenorphine to treat an individual's addiction problem is a notable problem here.

So thinking about this problem in terms of stock and flow, we have a massive stock of individuals who are potentially addicted to prescription painkillers. Trying to intervene before they enter the illicit market is probably the best way to save lives. So getting them to some sort of medication therapy before they enter the illicit markets, so expanding access to prescription buprenorphine or methadone is one thing that Congress should be looking into more aggressively.

Mr. CORONATO. I would agree with my esteemed colleagues, but the one thing I would say, and I believe in MAT treatment, is that we need best practices, true best practices that can be applied by the doctors. And I think that if we were going to go in that direction and I would advocate that we go in that direction, I really would want to see best practices both for methadone, suboxone, and also for Vivitrol as we go through and to make sure that the mental health component is being adequately addressed and not just a substance abuse.

Mr. SMITH. USAID does great work with infectious diseases, but health diplomacy is largely handled by HHS. What is your assessment as to how well or poorly how our efforts with WHO, PAHO—and I know you have worked with them in the past—other organizations like the African Union although this may not be an issue there, but it certainly is with PAHO and the OAS and of course the U.N. and WHO; are we doing enough there?

Mr. PARDO. So the State Department was very successful in working with international partners to get both major fentanyl precursors controlled in 2016. They worked with through the traditional channels, the Commission on Narcotic Drugs in Vienna. They worked with major pharmaceutical manufacturers in these countries to understand, you know, who is producing what.

So there was a very robust effort to get these precursors controlled. And we may be seeing, whether or not we see those benefits, it is going to take some time to kind of see whether or not those supply-side interventions are working. But it is true that the Canadians have controlled these substances. The Mexicans have controlled these precursor substances. The Chinese as well have started to control these precursor substances. So working with our international partners is one way to put some of the, you know, put some control measures on these firms that are producing these things in kind of these gray areas in underregulated industry so to speak.

Mr. CORONATO. And I will make one other comment if I could. In the State of New Jersey under Governor Christie and the legislature what they did is they limited the amount of prescription drugs that you can get right initially. I think you can get 5 days' worth of drugs initially. To me, I think if you set up a national standard with regard to that because it is clear that the pills is what really fueled this both in the '90s and the early 2000, I think that the government can come back and again regulate the distribution through the prescription plans that are being done, basically saying that you get 5 days' worth of prescriptions and then you have to go back to the doctor and you can monitor it.

Because the significance between the fifth day and the sixth day is tremendous, it is like a 60 or 70 percent addiction rate when you go from the fifth day to the sixth day. So, and you know that would also be another regulation I think that the Federal Government should look at.

Mr. SMITH. Let me just—is there any fear given that China has been expert at weaponizing so many things, even locally in my hometown of Hamilton Township when we got hit with the anthrax crisis that killed a couple of people here in Washington, and we had people sickened in Hamilton Township Post Office. Weaponized anything can be a very serious danger.

This is an outlier question, but is there any concern that somehow this could be weaponized since it is so highly concentrated and so lethal?

Dr. CICCARONE. The super high potency ones, yes. Carfentanil has made it into the news a lot about, you know, 1,000 next to morphine. There are even more potent by volume opioids than carfentanil. There are ones that make carfentanil look moderate. And so yes, and they could be aerosolized. Yes they could contaminate water supplies. So yes, we definitely have fears in that direction.

Mr. CORONATO. Yes, I will add this. We don't do, when we do our raids right now we don't do onsite any kind of testing because just the fact of either inhaling it possibly as it goes airborne, also if you touch or touch something that touched fentanyl it gets onto your skin and it actually will be absorbed right through your skin. And we have had police officers I know in Atlantic City and other parts of the State that overdosed on the fact of when they did a raid with regard going into.

So the answer is absolutely, depending on the analogue and depending on what you have in there. So, and that was a good reason why to be honest with you we weren't using dogs to sniff it because the dogs would die. So the bottom line is—that the K-9. So it is, it is a project. That it is something that we need to look at. It is something that has all kinds of ramifications and it is evolving as we speak.

Mr. PARDO. So two points I think that might—it is true that first responders are put at higher risk when engaging with this. As far as I am aware it is a concern when touching and then touching a mucous membrane, so getting in your eye or nose. Transdermally, powdered fentanyl from what I understand that risk is overstated. Nonetheless, for postal system workers, for police officers it can, it does increase the risk of overdose.

The second point is that there is, there was one event in Russia where Chechen terrorists were—yes, are you familiar with this? So the Russian Government did use two different forms of fentanyl to—they aerosolized it and pumped it into this theater to knock everybody out. In doing so they ended up killing over 120 people. So it could be, in theory, weaponized. Beyond that I have not seen any indication that it has been though.

Dr. CICCARONE. And just to add, DOJ has just come out with a letter supporting best practices in protecting law enforcement and other first responders with regards to fentanyl. A quick read of it, it looks very responsible and evidence-based.

Mr. CORONATO. We are pushing it out now because——

Mr. SMITH. Now the Department of Education, do you feel they are doing enough to warn our students about this dire risk?

Mr. CORONATO. I will just jump on the bandwagon on that. That is kind of similar to the tobacco industry, how long it took to get in schools. It took like what, 25, 30 years before we really addressed the tobacco industry in the schools. And I think it needs to be embedded in the curriculum. I think that it is something that needs—and it shouldn't be just in the fifth grade and just in the eighth grade and just in the twelfth grade. For me it needs to be repetitive every single year. It needs to understand. It needs to start in the first grade, because what we are looking at today with today's social media, everything is being driven down further and further into the grades at least that for me on the boots on the ground type thing.

So to me, if you ask my opinion we should be starting in the first grade and every single grade ever talking about drugs and how you don't want to put bad chemicals into your body. You need to put good nutriments into your body, not bad things into your body. And that is how I would start it off.

Dr. CICCARONE. So our former ONDCP director, Michael Botticelli, who is a recovering user himself, spoke very eloquently and has written eloquently about reducing stigma. If I was in charge of education of Americans, especially at the young level, I would tell them that addiction is just another problem that comes up with being human. And that we treat it medically, we treat it responsibly, we treat it sensitively and humanistically just like we treat diabetes or heart disease or cancer, which are the biggest killers of Americans.

Stigma gets in the way of everything that we do. It gets in the way of the patient entering the clinic. It gets in the way of them staying in treatment. It gets in the way of average Americans all the way up to the highest levels of government in doing our best in terms of this problem. It is a barrier. So reducing stigma, normalization of chemical dependency is what we need to do and then with open arms we get people into care, all levels of care.

The beauty of this notion is that people will come into care before they are the long-term, heavy, chronic user. They will come and they will say, "Whoa, what was I doing? I don't know, I was just messing around with that stuff for 3 months and I want off now." And they come and they can get help getting off sooner and more effectively. Like any disease, if I want to prevent cancer I want to screen for it before it is stage 3. Just like heart disease, get some-

one on a statin when the lipid levels are going up, but they haven't had a heart attack yet, that is prevention. Reducing stigma get us to lower stages of disease and makes prevention work better.

Mr. PARDO. I would agree with both statements. I can't speak specifically to what Department of Education is doing with regard to fentanyl, but I would state that drug prevention education programs do have their, they do have a place in the broader drug policy tool system. However, this crisis is an acute crisis. These individuals that are using fentanyl or coming into contact with fentanyl on the streets, they are already drug users in the system. They are already a high risk, so it might not do much to think about educating someone, you know, who may pick up a substance 10 years from now.

We need to figure out how to inform them about the risks in the illicit system. So trying to create some sort of transparency in those markets, letting them know that, for example, police seizures this week are showing high potency fentanyl in the markets, letting users know that the toxicity of those substances are in those markets might be one way of kind of reducing their harm or reducing their exposure to these substances in these markets today.

Mr. CORONATO. I am going to say something funny and I don't mean to criticize because these guys are great. But I tried that and it actually backfired. We used to come out and say, wait a minute, don't buy this type of bag of heroin that is stamped bud light or whatever it was stamped, and we drove the individuals to go and buy it. It was the most incredible sight that I have ever seen.

So we don't say that anymore because if we did we would actually market it for the drug dealers because then all of a sudden they are all going out looking out for this great stuff that is stamped bud light. It is the most—it is the exact opposite of what you would think it would be.

And I will just end up with this. I actually think that we all bear a certain amount of responsibility for where we are today. And what I mean by that is that when we raise our children we always seem to say this is a magic pill that is going to help you, that is going to solve your problem that is going to get you out of this cold, it is going to get you out of this infection.

And then before you know it, if a kid has a headache and they are 3 years old and but wait a minute they weigh 40 pounds and you now can take two tablets instead of three tablets depending on your weight, we teach our children to self-medicate and as a result everybody thinks they know their body. So they say, you know, this is what it is supposed to do, but I know my body, I can tolerate that. And by the time they are in their teens and their 20s, they say, you know, I know what I can tolerate, what I can't tolerate. I know what my body can handle.

And we all have a hand in this epidemic. That is what I am trying to say. So I think that the bottom line is that we need to educate our children. I think that we need to be woven into the school system because what it is, it is attack on our children. It is attack on our family, it is on an attack of way of living and unless we get a handle on this we are going to suffer the consequences.

Mr. SMITH. I want to thank you. If you have anything further you would like to add, your expertise is tremendous and I thank

you for that on behalf of the committee. We will follow up as a committee and me as chairman. You have given us so much to digest and convey to different parts of the government including the White House and I thank you for that.

And without any further comments, the hearing is adjourned. And I thank you.

[Whereupon, at 5:18 p.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Record

SUBCOMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Christopher H. Smith (R-NJ), Chairman

August 30, 2018

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs to be held by the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations in Room 2200 of the Rayburn House Office Building (and available live on the Committee website at http://www.ForeignAffairs.house.gov):

DATE: Thursday, September 6, 2018

TIME: 2:00 p.m.

SUBJECT: Tackling Fentanyl: Holding China Accountable

WITNESSES: Panel I
The Honorable Kirsten D. Madison
Assistant Secretary
Bureau of International Narcotics and Law Enforcement Affairs
U.S. Department of State

Mr. Paul E. Knierim
Deputy Chief of Operations
Office of Global Enforcement
Drug Enforcement Administration
U.S. Department of Justice

Panel II
Bryce Pardo, Ph.D.
Associate Policy Researcher
RAND Corporation

Daniel Ciccarone, M.D.
Professor of Family and Community Medicine
University of California, San Francisco

Mr. Joseph D. Coronato
Prosecutor
Prosecutor's Office
Ocean County, New Jersey

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON *Africa, Global Health, Global Human Rights, and International Organizations* HEARING

Day *Thursday* Date *September 6, 2018* Room *2200*

Starting Time *2:01pm* Ending Time *5:18pm*

Recesses *1* (*3:06pm* to *4:15pm*) (____ to ____) (____ to ____) (____ to ____) (____ to ____) (____ to ____)

Presiding Member(s)

Chairman Smith

Check all of the following that apply:

Open Session ☑
Executive (closed) Session ☐
Televised ☐

Electronically Recorded (taped) ☑
Stenographic Record ☑

TITLE OF HEARING:

Tackling Fentanyl: The China Connection

SUBCOMMITTEE MEMBERS PRESENT:

Ranking Member Bass, Rep. Donovan, Rep. Bera, Rep. Castro, Rep. Suozzi

NON-SUBCOMMITTEE MEMBERS PRESENT: *(Mark with an * if they are not members of full committee.)*

Rep. Chabot

HEARING WITNESSES: Same as meeting notice attached? Yes ☑ No ☐
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*

Chairman Smith: Statement by Don Holman
Chairman Smith: Statement by Christopher J. Gramiccioni, Prosecutor, Monmouth County, New Jersey
Chairman Smith: Information on the Blue HART Program

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED _____

Subcommittee Staff Associate

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTER*NATIONAL ORGANIZATIONS

Africa, Global Health, Global Human Rights, and International Organizations Sub Committee

Tackling Fentanyl: The China Connection – Hearing 9/6/2018

Thank you, Chairman Smith, Ranking Member Bass, and the Members of the Africa, Global Health, Global Human Rights, and International Organizations Sub Committee for the opportunity to share my son, Garrett's story.

Garrett's 21st birthday was on February 17, 2017, but he never saw it. He died on February 9th just 8 days prior from his third overdose to a Fentanyl Analog (U-47700) in 2 months. Garrett is a statistic of the current Opioid Crisis and makes up less than 1% of the victims that died that day from drug related Overdose or suicide in the US. Based on the current statistic, he was one of 720 people that made up just 1% of the Overdose deaths in 2017.

Garrett was born and grew up in Lynchburg, VA living in the same house most of his life with my wife, Bobbie and I and his sister Kristen. He established friendships in Grammar school that carried through High School and spent endless hours playing football, basketball, and lacrosse as well as wake boarding in the summer and snowboarding in the winter.

I would prefer to spend time talking about all the good qualities and the person Garrett really was but that would take a long time. Garrett was diagnosed at an early age with ADHD and took medication to help him concentrate in school. One of the side effects of ADHD medication is loss of appetite which presented an issue for someone athletic that enjoyed playing sports. As Garrett grew older he resisted taking the medication part because he didn't like the way it made him feel, and part because emotionally he felt it was what everyone else wanted not what he needed. I now know that Garrett started self-medicating early in High School after experimenting in Middle School and like so many he was introduced to Marijuana and convinced that it was a natural alternative to the ADHD Medication. As parents, we were not aware, and it wasn't until the 11th Grade that his behavior really started to concern us due to several incidents of him getting into trouble. However he had many more good days than bad and it seemed to be just a rebellious stage or at least we hoped.

Our focus was to make sure he kept his grades up so he could graduate High School and hoping he would mature so he could go to college. With constant pressure and push he was able to graduate and even get accepted to Liberty University for the Fall Semester.

Once he got out of High School, he struggled with the transition from child to young adult. He never adapted to College and ended up dropping his classes that semester. As parents we went through so many different scenarios, trying to set boundaries and rules to trying to get him treatment for Anxiety and Depression. He was very strong minded and as a result of defiance and bad decisions started to get into legal trouble. He quickly fell into a downward spiral and soon the focus was on keeping him from a felony conviction and going to jail.

Like so many parents, we would make excuses for Garrett's behavior to friends, family, and coworkers but never reveal the extent on which his illness had progressed. This is where the stigma plays a tough role in the person afflicted as well as the family that supports them. Mental Illness, Substance Abuse, and Addiction are not things that people want to talk about or other people want to hear. I never gave up hope and I was proud of my son. I did not want to imply that he was any more than a little wild and would settle down soon and be on track.

My wife and I were desperate, so I took a project in D.C. and brought Garrett with me to get him out of his current environment and hopefully give him a new start. Unfortunately, meeting legal obligations took precedence over any treatment for Mental Health or Substance Abuse. He was under a lot of pressure but the whole time still struggling with the need to escape reality. He needed medication for Anxiety but due to his legal issues and his tendency to abuse, he was never diagnosed or treated properly. Finally, someone told him about a Synthetic Opioid that would not show up on a drug test and that is all he heard.

Sometime in November 2016, he ordered a synthetic Opioid U-47700 online and it was delivered to the apartment by the mail carrier. So today, the mail carrier can inadvertently be the new drug dealer: (Garrett's story is sited in the WSJ Article, "When the Mailman Unwittingly Becomes the Drug Dealer" by Jon Kamp).

This was the beginning of the end.

Garrett overdosed the first time in early December 2016 and I had to perform CPR until the paramedics arrived to administer Naloxone and transport him to the Hospital. Once he awakened in ICU it was obvious that this was not the wakeup call we had hoped, so he was forced into a mental health evaluation by us. The system is weak and he was only required to stay 5 days. From there he reluctantly went into a 30 day in-house treatment program but a week after he got out he overdosed the second time and once again I called 911 and gave him CPR until Paramedics arrived and revived him. I forced him into a second evaluation but the judge decided he did not belong in a mental health facility and released him on Feb 6, 2017. His final overdose was three days later on Feb 9, 2017. His cause of death was determined accidental as a result of mixed drug use. He had taken the synthetic Opioid U-47700 and Xanax.

I am not sharing my story because I have the answer, I am sharing because I am sure I am not alone and I would like to do my part to make it easier to have the conversation. You may read a headline about the opioid epidemic and get information about Heroin, or fentanyl laced Heroin or maybe over prescribing of Pain medication. All of which are relevant and still carry the negative stigma and in many cases the opinion that a person addicted made a choice and deserves what they get. My son's Opioid exposure was less than 2 months. He did not have time to hit bottom. At 20 years old, I do not believe my son deserved to die for his initial bad choices.

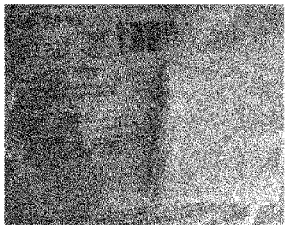
Today's hearing is to focus on the role China plays in combating (or not) the illegal Fentanyl being produced and distributed from China to the United States. There are many Political and legal concerns when dealing with this topic and China but, I believe together we can accomplish more than working against each other. I am in regular communication with individuals I have met at Customs and Border Protection (CBP) and Homeland Security Investigations (HIS). Over the last 18 months I have seen improvements in both Federal Agencies in their efforts to detect illegal Fentanyl shipments and to trace those back to the source in China. I am also told that China is cooperating with the U.S. in identifying and shutting down the Labs that produce these drugs and the websites used to sell them. I know firsthand how compassionate and motivated both Federal agencies are in fighting the Opioid crisis.

With that said, is it enough? Imagine someone standing on a roof with a bucket of 1000 marbles. They dump the bucket and scatter the marbles into the grass. Now a team of individuals with an arsenal of tools scour through the grass to locate the marbles. While they are looking another individual shows up on the roof and dumps a different bucket of 1000 marbles into the grass. Now the team on the ground is still hunting for the first 1000 marbles but if they find a marble from the second bucket they can't pick it up because they are waiting for approval on those, so they must only focus on the marbles from the first bucket.

In the meantime, individuals keep showing up on the roof dumping more marbles into the grass. This is an analogy of the illegal fentanyl being dumped from China into the U.S. As hard as we are working to locate and intercept the marbles, the only way to get this under control is to have someone on the roof to prevent anymore buckets of marbles from being dumped into the grass. Is China committed and focused 100% on preventing the manufacture and distribution of illegal Fentanyl to the United States? If not, why? I would have to ask if they are being complacent and if so this may be interpreted as acceptance by those in China involved in the business of killing Americans via the manufacture and distribution of illegal Fentanyl and Fentanyl analogs.

One of the Challenges of prosecuting for illegal Fentanyl and Fentanyl analogs is that as soon as one substance is classified as illegal, a similar substance is created that just misses that criteria and is considered legal. A non-scientific explanation of Fentanyl Analogs: Imagine the family secret bar-b-que sauce recipe. Everyone that has one basically has a list of ingredients and qty's of each that make up the secret blend. Now imagine that the recipe calls for 1 teaspoon of cyan pepper, but you decide to add a 1 ½ teaspoons to your recipe. In the world of illegal Fentanyl Analogs, the recipe with 1 teaspoon is classified as illegal but by adding an additional ½ teaspoon to your recipe you changed the documented criteria that makes it illegal therefore authorities are limited in the ability to prosecute. Once the Senate acts, they have several bills the House Judiciary Committee has recently passed to fight the Opioid Crisis including some that will help streamline the process to declare these slight variations of an illegal substance illegal.

Garrett was able to go online and using Bitcoins, make a purchase for a Fentanyl Analog known as U-47700 (Street name "Pinky") that was inexpensive and shipped directly to the apartment a few miles from Capital Hill. I challenge all of you to go online and simply search for U-4770. Your search will first return sponsored sites that will offer you the chance to purchase the drugs for around 50.00. If you continue to search you will see several links to articles that outline the dangers of this drug. Below is an image sent to me later by an ex-girlfriend of Garrett that shows the envelope he received in the mail and the white powder substance it contained inside.



Looking close at the return address on the envelope you can see plainly it originated from China. As Americans we must take responsibly for self-inflicting this Opioid Crisis on ourselves because of over prescribing and under acknowledging the addictive nature of Opioids. But if your house is on fire, would you expect your neighbor to help by pouring water on it or be enraged to find out they are dumping fuel? We need China to be our good neighbor and help us save lives.

Chairman Smith, Ranking Member Bass, and the Members of the Africa, Global Health, Global Human Rights, and International Organizations Sub Committee, when Americans go online to order illegal Fentanyl and Fentanyl Analogs from China, they are not required to disclose if they are Male or Female, Gay or Straight, Black or White or Hispanic, Asian, Indian or any other race, Christian, Jewish, Muslim, Hindu or any religion, and I am positive they do not have to disclose if they are Democrat or Republican. Today I encourage all of you to come together using your talents and strengths to focus holistically on this Bi Partisan issue that is a threat to our National Security.

Thank you for the opportunity to share my son's story.

Donald A. Holman
(Garrett's Dad)

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MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

FIGHTING THE OPIOIDS EPIDEMIC REQUIRES MORE THAN EFFORTS TO BREAK ADDICTION AND REDUCE DEMAND, BUT EQUAL EFFORTS TO CURB THE OPIOIDS SUPPLY AT ITS SOURCE

I have served as the Monmouth County Prosecutor since 2012. As the chief law enforcement officer in this county of 630,000, my primary responsibility is to ensure the safety and protection of our citizens. Upon taking the position, I quickly learned that the #1 killer of our citizens wasn't homicidal violence or fatal accidents on our roadways – it was the consumption of deadly heroin or opioids. At its peak, the opioids epidemic killed 164 Monmouth County residents in 2014. As such, addressing what was harming our citizens most became a priority of the Monmouth County Prosecutor's Office (MCPO).

It Boils Down to Supply & Demand

For the past 6 years, one of the cornerstones of my administration as Monmouth County Prosecutor has been a more forward-leaning, proactive strategy to reduce the *supply and demand* footprint across the county for these deadly substances. The illegal drug trafficking trade operates essentially like any legitimate business – it thrives from *demand* for a product, in this case heroin or opioids (Rx pills, Fentanyl or its derivatives). The MCPO's strategy was to reduce demand for opioids in our region, and *supply* would correspondingly decline as a result of less demand. This simple economic principle serves as the benchmark of our strategy to fight the opioids epidemic that plagues our region.

MCPO's Efforts to Reduce the Demand for Deadly Opioids in our Region

We have seen strong signs of success on the regional scale as a result of our efforts to affect demand for opioids. In 2012, we were the first county to launch the "*Heroin and Opioids Kill*" public awareness campaign at every public high school in Monmouth County. In schools, we began our "shock and awe" information campaign to soberly and candidly engage students, parents and public officials about the extent of the opioids epidemic. This campaign included the employment of PSA videos and materials to parents and students warning of the dangers of opioid-related abuse. School districts incorporated these materials into their mandatory curricula and e-backpack distributions to student households.

In 2014, Monmouth was the second county to arm all first-responding police officers with the lifesaving drug Narcan. Since most first responders to an overdose are law enforcement officers, this had the effect of saving hundreds of lives, bringing back overdose victims from sure death and giving them the chance at rehabilitation and a drug-free life. Recognizing that drug manufacturing companies angled to take advantage of the newfound demand for Narcan, we were the first county to create a *Narcan Replenishment Program.* This partnership with our three area network hospitals provided police officers with replacement Narcan kits free of charge from any hospital in the region. The program not only saved scarce funds for municipal police departments, but also ensured that police officers had Narcan kits on them at all times. We have also provided free Narcan kits to every public and private high school in the county.

In 2016, we implemented a county-wide *Opioids Diversion Program* that allowed defendants arrested for smaller possessory opioids charges to be diverted from traditional criminal prosecution, on the condition that he/she seek and continue drug rehabilitation treatment. Treatment sites and are typically arranged through our great relationships with recovery specialist companies (e.g., Lifeline Recovery Support Services/John Brogan). Upon successfully completing conditional terms, charges against the defendant may be downgraded or dismissed by the State. The key to all these programs is to *leverage the risk of criminal culpability, and steer those struggling from an addiction to an appropriate level of care with the end goal of breaking that all-too-common cycle of addiction*. Our Office, in addition to six municipal police departments have seen great success with this program, and more towns continue to agree to participate.

In this same year, we were the first of two counties to participate in the grant-funded, pilot *Opioids Overdose Recovery Program (OORP)*. Like the diversion program, the OORP similarly employs recovery specialists and patient navigators to help hospitalized individuals saved from an overdose obtain the necessary treatments and services towards rehabilitation. These programs and initiatives are but a few examples of our efforts to *reduce demand* for dangerous opioids, but this is only half the equation.

MCPO's Efforts to Reduce the Supply of Opioids Plaguing our Region

Equally important is a robust enforcement effort to eradicate illegal narcotics and narcotics distribution networks that thrive from this epidemic. To that end, the MCPO began concerted opioids interdiction efforts in 2013, focusing 85% of our Narcotics Strike Force investigations on opioids trafficking organizations where fatal overdose deaths were trending. In 2016, we were the first county to secure a co-located *High Intensity Drug Trafficking Organization (HIDTA) Task Force*, designed to disrupt and dismantle regional drug trafficking organizations without jurisdictional challenges or limitations.

As a result of the combination of the aforementioned efforts, we have seen a *10%* reduction of overdose deaths from 2016 to 2017 across the 53 municipalities in Monmouth County. Compared to this time last year in May 2017, we have seen a *15%* reduction in overdose deaths, and a *30%* reduction compared to May 2016. Moreover, Narcan deployments have increased by *15%* from 2016 to 2017, with the number of successful saves increasing by *14%*. This is welcome progress, but we certainly are not declaring victory by any means until we see such declines over a longer term.

The Rise of Even More Deadly Fentanyl

As a complement to these efforts, we continue to gather valuable intelligence on the scope of the overall opioids epidemic through our MCPO Intelligence Bureau, and strong federal, state and municipal law enforcement partnerships. Sadly, we continue to see more fatal overdoses with toxicology results indicating ingestion of fentanyl. What's more, our

enforcement efforts show increasing seizures of drugs containing fentanyl. Dozens of intelligence sources recognize that *more than 90% of the Fentanyl entering our region (and the U.S.) is produced in China.* Fentanyl is sent by Chinese manufacturers and other conspirators via mail from dark web purchases, or through traditional drug trafficking routes via the porous southern border. Fentanyl ultimately makes its way to a demand center. DEA and other law enforcement intelligence estimates that the illegal fentanyl market will completely usurp the illegal heroin market in the coming years. The reason is that fentanyl production and manufacture costs a fraction of what it takes to manufacture and process heroin, and is conservatively 50 times more powerful than heroin or morphine. Consumption of a quarter of a milligram can instantly kill you. A more powerful substance like this yields a quicker addiction, which leads to greater demand at a much cheaper production cost. With an increased profit margin realized by drug trafficking organizations, the outlook for a region already struggling from this epidemic is dangerous to say the least.

The Ask: Address the Fentanyl Problem at its Manufacturing Source – China

Prior to my appointment as the Prosecutor in Monmouth, I worked as a federal prosecutor at the United States Attorney's Office in both the Districts of New Jersey and Maryland for 10 years. Some of those years were spent investigating and prosecuting drug trafficking organizations that sent narcotics to the U.S. for American consumption, many of which operated outside of the U.S. and its territories. Examples included drug kingpins and conspirators operating in countries such as Colombia, the United Kingdom, Panama, Mexico, Japan, Belize, and dozens of other countries. American federal prosecutors are able to investigate and prosecute foreign nationals involved in illegal drug trafficking like this due to the existence of *Mutual Legal Assistance Treaties (MLATs)* that exist between our governments. MLATs are treaties that allow for the exchange of evidence and information in an effort to enforce criminal laws. The MLATs set forth mechanisms for doing things such as, arresting and extraditing foreign nationals who commit crimes under United States law; obtaining evidence and information for criminal investigations and prosecutions; and investigating criminal activity that may be occurring abroad.

Currently, there are no such MLATs that exist between the U.S. and China that allow for American federal law enforcement agencies to extradite Chinese nationals who manufacture and distribute fentanyl that ultimately arrives on U.S. shores. As stated earlier, more than 90% of illegal fentanyl coming to America is manufactured in China. What this means is that Chinese nationals and their conspirators, profiting off American citizens' addiction, operate with near immunity without fear of extradition to the U.S. to face federal criminal charges. My experience with prosecuting South American drug traffickers and money launderers dictates that, without such agreements in place in the *nation that serves as the source of fentanyl supply*, it will be extremely difficult to limit the flow of fatal fentanyl coming to the U.S. Any federal prosecutor would recognize that an MLAT with China to extradite narcotics manufacturers and traffickers would be a vital tool to help cut the fentanyl supply coming to America.

I presume that we retain a great deal of leverage with the tariffs recently imposed on Chinese exports, and generally considering how reliant China is on U.S. exports (an estimated 20% of their export sales are to the U.S.). My hope is that seeking the necessary MLAT with China to address the fentanyl source of supply will continue to be a strategic goal and priority in our negotiations with China. Successful extradition and prosecution of foreign nationals in American federal courts, coupled with appropriate criminal sentences, would create a great deterrence to others involved in manufacturing and distributing fentanyl.[1] Most importantly, it will go far in saving American lives by making creating penalties for illegal fentanyl traffickers operating with impunity in China.

Thank you for your consideration and review of this request, and please feel free to contact me with any questions or concerns.

Christopher J. Gramiccioni
Monmouth County Prosecutor
(908) 216-0582 (cell)

[1] In my experience, the point of deterrence cannot be overstated. Imagine the Chinese national profiting from sales of fatal fentanyl being arrested and extradited to the U.S. to face criminal charges in an American federal court. He or she is taken into custody, separated from family and forced to leave their home country to a foreign country thousands of miles from home. They remained detained pending trial and, if convicted, can serve decades or more in a foreign prison, isolated from their own family and culture. For example, Colombian drug traffickers feared nothing, except for extradition to the U.S. As American and Colombian diplomatic relationships improved, a great deal of the illegal narcotics trade dried up in Colombia, due in large part to concerns over arrest and extradition to face charges in United States courts.

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

PARTICIPATING POLICE DEPARTMENTS

Any person who voluntarily enters one of the following police departments on the scheduled day and time and requests help with their addiction to heroin, opiates or any substance will be immediately screened for potential participation in the Blue HART Program.

LACEY TOWNSHIP POLICE DEPARTMENT
808 West Lacey Road
Forked River, New Jersey 08731
609-693-5636
(MONDAY 9:00 A.M. to 5:00 P.M.)

OCEAN GATE POLICE DEPARTMENT
801 Ocean Gate Avenue
Ocean Gate, New Jersey 08740
732-269-6931
(MONDAY 9:00 A.M. to 5:00 P.M.)

LITTLE EGG HARBOR POLICE DEPARTMENT
665 Radio Road
Little Egg Harbor, New Jersey 08087
609-296-3666
(TUESDAY 9:00 A.M. to 5:00 P.M.)

STAFFORD TOWNSHIP POLICE DEPARTMENT
260 East Bay Avenue
Manahawkin, New Jersey 08050
609-597-8581
(TUESDAY 9:00 A.M. to 5:00 P.M.)

POINT PLEASANT BOROUGH POLICE DEPARTMENT
2233 Bridge Avenue
Point Pleasant, New Jersey 08742
732-892-0060
(TUESDAY 9:00 A.M. to 5:00 P.M.)

MANCHESTER TOWNSHIP POLICE DEPARTMENT
1 Colonial Drive
Manchester, New Jersey
732-657-2009
(WEDNESDAY 9:00 A.M. to 3:00 P.M.)

BRICK TOWNSHIP POLICE DEPARTMENT
401 Chambers Bridge Road
Brick, New Jersey 08723
732-262-1100
(THURSDAY 9:00 A.M. to 5:00 P.M.)

* In the future other Ocean County Police Departments will become participants in the Blue HART Program.

HEALTH CARE/TREATMENT PROVIDERS

SUNRISE DETOX
16 Whitesville Road
Suite A
Toms River, New Jersey 08753
732-797-2502

INTEGRITY HOUSE
310 Main Street
Suite B-2nd Floor
Toms River, New Jersey 08753
848-238-7000 x406

PREFERRED BEHAVIORAL HEALTH
700 Airport road
Lakewood, New Jersey 08701
732-367-4700

OCEAN MENTAL HEALTH SERVICES
687 Atlantic City Boulevard #1
Bayville, New Jersey 08721
732-269-4849

LIFE LINE RECOVERY SUPPORT SERVICE
108 Indian Head Road
Toms River, New Jersey 08753
888-520-0040

Question for the Record Submitted to
Assistant Secretary Kirsten D. Madison by
Representative Chris Smith
House Foreign Affairs Committee
September 6, 2018

Question:

Has the U.S. Government considered using the Global Magnitsky Act to target narco-traffickers and corrupt officials in China who facilitate the fentanyl trade? If not, why not?

Answer:

The Global Magnitsky sanctions program is intended to disrupt and deter serious human rights abuse and corruption abroad. Serious human rights abuse and corruption come in innumerable forms and while we cannot discuss potential or prospective actions related to sanctions, we remain deeply concerned about the fentanyl trade. We would also note that other sanctions authorities might address these topics. We recognize the importance of addressing this issue and its profound impact on so many Americans and will continue to consider which of our tools will be impactful in addressing it.

Question:

In 2002 there was an infamous hostage crisis at a Moscow theater (known as the "2002 Nord-Ost siege"). During the standoff, Russian special forces Spetsnaz opted to use a weaponized gas to snuff out the hostage takers. The identity of the gas was never disclosed, although it is considered by many experts to have been the fentanyl derivative carfentanil. In total, the special forces ended up killing not only 40 hostage takers but also between 100 and 200 of the hostages.

a. How easily can fentanyl be weaponized?

Answer:

Thank you for the question. The Department would need and be willing to address this issue in a classified setting.

Question:

In 2002 there was an infamous hostage crisis at a Moscow theater (known as the "2002 Nord-Ost siege"). During the standoff, Russian special forces Spetsnaz opted to use a weaponized gas to snuff out the hostage takers. The identity of the gas was never disclosed, although it is considered by many experts to have been the fentanyl derivative carfentanil. In total, the special forces ended up killing not only 40 hostage takers but also between 100 and 200 of the hostages.

b. What is you assessment of the threat posed by weaponized fentanyl in the hands of State and non-State actors?

Answer:
Thank you for the question. The Department would be willing to address this issue in a classified setting.

Question:

In 2002 there was an infamous hostage crisis at a Moscow theater (known as the "2002 Nord-Ost siege"). During the standoff, Russian special forces Spetsnaz opted to use a weaponized gas to snuff out the hostage takers. The identity of the gas was never disclosed, although it is considered by many experts to have been the fentanyl derivative carfentanil. In total, the special forces ended up killing not only 40 hostage takers but also between 100 and 200 of the hostages.

c. Do you know of any other country, or non-state actor that has weaponized fentanyl? Please be specific.

Answer:

Thank you for the question. The Department would be willing to address this issue in a classified setting.

Question:

In 2002 there was an infamous hostage crisis at a Moscow theater (known as the "2002 Nord-Ost siege"). During the standoff, Russian special forces Spetsnaz opted to use a weaponized gas to snuff out the hostage takers. The identity of the gas was never disclosed, although it is considered by many experts to have been the fentanyl derivative carfentanil. In total, the special forces ended up killing not only 40 hostage takers but also between 100 and 200 of the hostages.

d. If yes, what is the U.S. response to this threat?

Answer:

Thank you for the question. The Department would be willing to address this issue in a classified setting.

Question for the Record Submitted to
Deputy Chief of Operations Paul E. Knierim by
Representative Chris Smith
House Foreign Affairs Committee
September 6, 2018

Question:

Please provide a list of Chinese fentanyl traffickers that have been arrested through joint cooperation between the Drug Enforcement Agency and their Chinese counterparts.

a. Have any of them been extradited to the U.S.?
b. Assuming not, since China generally never extradites nationals, what is the punishment for these traffickers in China?

Question:

How does China really execute its law enforcement against drug trafficking?

a. With drugs like Methamphetamine (known in China as "Ice"), China has been known to mobilize its forces and crackdown as it affects Chinese people.
    i. Have launched the same type of crackdown with regards to the illicit fentanyl labs that export fentanyl globally?
    ii. If not, why do you think that is?

Question:

Have we created and disseminated best practices for responding to weaponized fentanyl among law enforcement, first responders, state and local officials, and medical personnel? (If necessary, answers may be provided in a classified annex or conveyed via classified briefing.)

[**Note:** No responses were received to the above questions prior to printing.]

QUESTION FOR THE RECORD

Representative F. James Sensenbrenner, Jr. formally submits the following question to the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organization's official record concerning its September 6, 2018 hearing titled: *Tackling Fentanyl: The China Connection*

To Mr. Paul Knierim:

"As the United States' law enforcement agencies combat the spread of fentanyl, there is a growing concern over the spread of opioid analogues that allow fentanyl traffickers to circumvent our laws and continue to profit over these dangerous drugs. In February of this year, I introduced the Stopping Overdoses of Fentanyl Analogues (SOFA) Act. The legislation would immediately add nineteen identified fentanyl analogues to the Schedule I drug list, and provide the DEA with the tools to quickly add additional analogues as they are discovered."

- **Has the DEA seen fentanyl analogues coming from China?**
- **How much (in quantity or value) of fentanyl analogues are imported to the United States each year?**
- **How many individuals have been able to avoid criminal prosecution because the trafficker was peddling an analogue rather than Schedule I fentanyl?**
  - Has the DEA ever caught someone trafficking analogues on multiple occasions, but unable to aggressively pursue because the analogues weren't Schedule I?
- **Given DEA's temporary emergency scheduling of the fentanyl class, can I assume that DEA supports my SOFA legislation that permanently places fentanyl analogues in Schedule I?**
  - Would passage of SOFA be helpful to the DEA?

[**Note:** No responses were received to the above questions prior to printing.]

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