March 17, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Fentanyl: The Next Wave of the Opioid Crisis"

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, March 21, 2017, at 10:15 a.m. in 2123 Rayburn House Office Building, entitled "Fentanyl: The Next Wave of the Opioid Crisis." The United States is experiencing an epidemic of opioid abuse and addiction, with drug overdose deaths increasing over the last two decades and becoming the leading cause of injury death in the U.S. In the early 21st century, overdose deaths primarily involved prescription opioids and then later, around 2005, heroin. Increasingly since 2013, opioid overdose deaths involve fentanyl, the apparent next wave of the opioid epidemic.

This hearing will examine the unique and emerging public health threat of fentanyl, a synthetic opioid. Since 2013, fentanyl and its analogues have contributed to at least 5,000 overdose deaths in the United States. As fentanyl is becoming the leading driver of drug overdose deaths in more states, this hearing will also examine the federal government's strategy to combat the fentanyl threat and how to strengthen the federal response to this crisis.

I. WITNESSES

- Kemp Chester, Acting Deputy Director, Office of National Drug Control Policy (ONDCP);
- Louis Milione, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA);
- William Brownfield, Assistant Secretary of State, International Narcotics and Law Enforcement Affairs, U.S. Department of State;
- Matthew Allen, Assistant Director, Homeland Security Investigative Programs, Homeland Security Investigations, U.S. Immigration and Customs Enforcement, Department of Homeland Security (DHS);
- Debra Houry, M.D., M.P.H., Director, National Center for Injury Prevention and Control, Center for Disease Control and Prevention (CDC); and

• Wilson Compton, M.D., M.P.E., Deputy Director, National Institute on Drug Abuse (NIDA).

II. BACKGROUND

a. Committee activity on the opioid epidemic

113th and 114th Congresses. The subcommittee held a series of hearings, beginning in April 2014 and continuing into early 2015 that examined the growing problem of prescription drugs and heroin abuse nationwide and evaluated solutions to address the crisis. In the course of these hearings, the subcommittee heard testimony from the federal, state, and local levels, and developed a record demonstrating not only the various factors contributing to the opioid abuse epidemic, but also a number of possible solutions. Solutions presented at these subcommittee hearings helped inform the committee's legislative efforts ultimately enacted into law as part of the Comprehensive Addiction and Recovery Act, followed by authorized funding included in the 21st Century Cures Act.

115th Congress. Earlier this year the committee began focusing on the synthetic opioid, fentanyl, which "has spawned a deadly drug crisis in the United States." On February 23, 2017, the bipartisan leaders of the full committee and the subcommittee sent a letter to the Acting Director of the Office of National Drug Control Policy (ONDCP) seeking details about the fentanyl problem, actions taken, and any strategic plan to address the fentanyl threat. As of the date of this memorandum, the committee has not yet received a response from ONDCP.

b. Scope of the fentanyl problem

What is fentanyl? Fentanyl is a synthetic (man-made) opioid.³ The drug resembles morphine, but is about 50 times more potent than heroin and 100 times more potent than morphine.⁴ Fentanyl was developed in 1959 and approved by the Food and Drug Administration (FDA) to treat severe pain, especially in patients with cancer and severe diseases. There are two types of fentanyl: 1) pharmaceutical fentanyl, which is primarily prescribed to manage acute and chronic pain associated with advanced cancer, and 2) non-pharmaceutical fentanyl, which is illicitly manufactured, and is often mixed with heroin and/or cocaine—with or without the user's knowledge—in order to increase the drug's effect.⁵ Available information from multiple

⁵ *Id*.

¹ Press Release, U.S. Drug Enforcement Admin., *DEA Warning to Police and Public: Fentanyl Exposure Kills*, June 10, 2016, https://www.dea.gov/divisions/hq/2016/hq061016.shtml.

² Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy & Commerce, Hon. Tim Murphy, Chairman, Subcommittee on Oversight and Investigations, & Hon. Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations, to Mr. Kemp Chester, Acting Director, ONDCP (Feb. 23, 2017).

³ Centers for Disease Control & Prevention, *Fentanyl: Incapacitating Agent, available at* https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750022.html (last accessed Mar. 15, 2017).

⁴ Centers for Disease Control & Prevention, *Injury Prevention & Control: Opioid Overdose, Synthetic Opioid Data, available at* https://www.cdc.gov/drugoverdose/data/fentanyl.html (last updated Dec. 16, 2016).

agencies and companies indicates that the current public health threat of fentanyl is not sourced significantly from the diversion of legitimate fentanyl.

Fentanyl analogues. Besides its high potency, another challenge with fentanyl is the number of analogues, or chemical variations, of the drug. A structural analogue, also known as a chemical analogue or simply an analogue, is a compound having a structure similar to that of another one, but differing slightly in composition. Because the drug is synthetic, and therefore man-made, the drug's chemical composition can be altered slightly to avoid scheduling regulations, yet still maintain its chemical and biological properties. This also makes it harder to detect in comparison to other drugs, such as heroin. As of June 2016, there were 30 known analogues of fentanyl. However, only 19 of these analogues are scheduled as controlled substances. While that number seems small, due to the simplistic nature of only needing to alter a small component of the drug's chemical makeup, there is potentially a far higher number of fentanyl analogues that have yet to be devised and manufactured.⁶

Carfentanil. The most notorious analogue is carfentanil, a drug that is typically used to sedate large animals, such as elephants. According to the Drug Enforcement Administration (DEA), carfentanil is 100 times stronger than fentanyl. This drug is so potent that less than a grain of table salt (0.02 milligrams) can be lethal. Carfentanil was responsible for an unprecedented 174 overdoses in six days—about seven times the usual rate —and at least eight overdose deaths in the Cincinnati, Ohio area in August 2016. More recently, an investigation conducted by committee staff found open source websites advertising carfentanil, in addition to other fentanyl products, under the guise of selling "research chemicals."

Fentanyl as a weapon. In addition to the obvious health concerns that this deadly drug poses, as well as the danger to first responders, concerns have been raised that this drug could be weaponized. ¹⁰ This is yet another reason for law enforcement and intelligence agencies to be engaged with the fentanyl issue.

Fentanyl is often hidden and very dangerous. Two milligrams of fentanyl is potentially lethal for a human being, therefore only minute amounts of fentanyl are necessary to produce effects similar to heroin. Since 2013, 11 fentanyl and its analogues have contributed to at least

⁶ R.S. Vardanyan and V.J. Hurby, *Fentanyl-related compounds and derivatives: current status and future prospects for pharmaceutical applications*, 6 Future Medicinal Chemistry (2014).

⁷ Max Kalinowicz, *10 million lethal doses of carfentanil seized at Mirabel Airport*, GLOBAL NEWS (Jan. 18, 2017), http://globalnews.ca/news/3190310/10-million-lethal-doses-of-carfentanil-seized-at-mirabel-airport/.

⁸ Katie Mettier, 'This is unprecedented': 174 heroin overdoses in 6 days in Cincinnati, WASH. POST (Aug. 29, 2016), https://www.washingtonpost.com/news/morning-mix/wp/2016/08/29/this-is-unprecedented-174-heroin-overdoses-in-6-days-in-cincinnati/?utm_term=.22f13b23ea6e. On average, Cincinnati has 4 overdose reports per day, and usually no more than 20 or 25 in a given week.

⁹ Remarks by U.S. Attorney Zachary T. Fardon at Northwestern University Pritzker School of Law (Oct. 20, 2016) *available at* https://www.justice.gov/usao-ndil/pr/remarks-us-attorney-zachary-t-fardon-northwestern-university-pritzker-school-law-oct-20.

¹⁰ Although the hearing and memorandum is focused on fentanyl use as an illicit drug, it should be noted that the National Institute on Occupational Safety and Health (NIOSH) has provided information and recommendations to address "a wide area release of fentanyl as a weapon of terrorism."

¹¹ Dear Colleague letter from H. Westley Clark, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA) (July 15, 2013) ("Many of you will remember the period

5,000 overdose deaths in the U.S.¹² The fentanyl crisis is significantly more dangerous than other opioids because of its high potency and the speed with which it reaches the brain. Fentanyl has taken on a silent but deadly characterization because it is most often laced with other drugs such as heroin, cocaine, and counterfeit pills that are advertised to be a more common opioid, such as generic Xanax.¹³ Often times, individuals did not specifically seek out fentanyl and do not know that they are taking something that has fentanyl in it. That danger, combined with the high potency of the drug, creates a high risk of overdose.

Emergency responders have found patients dead before the victim has finished injecting, needles still in hand. The lethality of fentanyl also undermines the effectiveness of evidence-based public health strategies. Fentanyl's rapid effect narrows the window for rescue with the overdose reversal drug, naloxone, and may require both higher doses and multiple administrations to reverse an overdose and stabilize a patient. Fentanyls also pose a "grave threat to law enforcement officials and first responders" since a lethal dose can be accidentally inhaled or absorbed through the skin. An open question is whether an individual's opioid dependency is increased when they take heroin laced with fentanyl versus taking pure heroin, and whether the combination with fentanyl makes opioid addiction even more difficult to treat.

Drug overdose trends. Drug-poisoning (overdose) is now the leading cause of death from injury in the U.S., surpassing motor vehicle accidents, suicide, firearms, and homicide. Deaths from fentanyl and other synthetic opioids are reaching epidemic proportions as well. Nationwide, "[t]he death rate of synthetic opioids other than methadone, which includes drugs such as tramadol and fentanyl, increased by 72.2% from 2014 to 2015, with a total of 9,580 deaths in 2015." As shown in the following table, synthetic opioid death rates (other than methadone) increased across all demographics, regions, and numerous states. ¹⁷

http://www.behavioral.net/article/rx-summit-fentanyl-overdoses-outpace-heroin

from 2005 through 2007 when illicit fentanyl-laced heroin caused a great number of overdose deaths. That was not the first time illicit fentanyl, also called fentanyl analogues, entered the drug market, and likely will not be the last. Recently, small clusters of overdoses and overdose fatalities in a variety of communities, mostly in the eastern United States, have raised alarm. Little is fully known about the situation but it appears fentanyl analogues are involved in at least some of the cases, and may be contaminating both heroin and cocaine.").

¹² R.A. Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States*, 2010-2015, 65 MMWR 1445 (Dec. 30, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

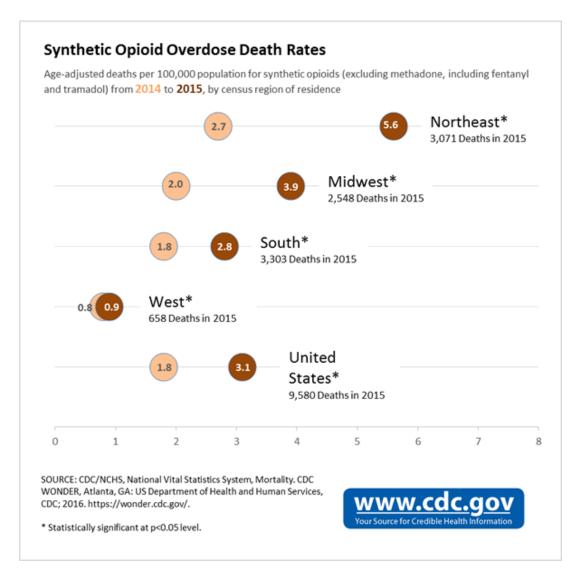
¹³ For example, between January and March 2016, nine people died from counterfeit Xanax pills, a benzodiazepine, containing fentanyl in Pinellas County, Florida. "This demonstrates that though traffickers are interested in expanding the fentanyl market to other counterfeit opioid medications, they are also willing to utilize fentanyls in other non-opiate drugs with exploitable user populations." Drug Enforcement Admin., DEA Intelligence Brief, Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, DEA-DCT-DIB-021016, 6 (July 2016).

¹⁴ In 40 percent of the fentanyl overdose deaths, naloxone was administered. However, when it was not used, it was often because the victim was already deceased by the time first responders arrived. The increased potency of fentanyl in most cases required at least two and sometimes up to six doses of naloxone for a rescue, according to John Halpin, M.D., M.P.H., medical officer with the Division of Unintentional Injury Prevention at CDC. Alison Knopf, *Rx Summit: Fentanyl overdoses outpace heroin*, Behavioral Healthcare Executive, (Mar. 30, 2016),

¹⁵ DEA Intelligence Brief, *supra* note 13, at 2.

¹⁶ Centers for Disease Control & Prevention, *Morbidity and Mortality Weekly Report*, *Increases in Drug and Opioid-Involved Overdose Deaths – United States*, 2010-2015, (Dec. 16, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

¹⁷ Centers for Disease Control & Prevention, *Injury Prevention & Control: Opioid Overdose*, *Synthetic Opioid Data*, (Dec. 16, 2016), *available at* https://www.cdc.gov/drugoverdose/data/fentanyl.html.



Limited data on fentanyl overdoses. Unfortunately, definitive national data on fentanyl overdoses is not available. The Centers for Disease Control and Prevention (CDC) is unable to report fentanyl-specific data because fentanyl-related overdose reports are not available in a significant number of states. In addition, there historically has been an 18 to 24 month time lag for CDC to report overdose data, although CDC recently was able to reduce the time lag to 12 months. That said, the CDC has reported to committee staff that there were 11 states with fentanyl-related overdose data from 2013-2015 and 13 states with fentanyl-related overdose data

¹⁸ Email from Staff, Centers for Disease Control & Prevention, to Staff, H. Comm. on Energy & Commerce (Mar. 15, 2017) ("In the past, the 18-24 month delay was due to the pace at which the states can collect, process and report back the data (based on their individual capacity). However, we [CDC] have been working to decrease the "lag" time by providing funding and technical assistance to the states. This year, we [CDC] reported out the 2015 data in December of 2016, so 12 months after the end of the collection period (i.e. the year)").

from 2015.¹⁹ Because the analysis is considered preliminary and there are key limitations with the state data, CDC advised that additional work is needed before the data can be released to the public.²⁰ Without citing specific statistics, committee staff can confirm that the CDC reported that the preliminary 2016 drug overdose data from a few states showed that fentanyl-related overdose deaths continued to increase.²¹

Due to a lag or lack of knowledge and technology with respect to testing and detection, many municipalities are just beginning to differentiate fentanyl-related deaths from other drug-related overdose deaths. As a result of the data gap, there may be a much higher rate of overdose-related deaths attributable to fentanyl that have not been detected or reported. As a DEA report noted, the deaths related to fentanyl in the U.S. are largely believed to be underestimated due to variations in state reporting techniques and deaths being attributed to heroin or other drugs. Test results of illicit drugs also suggest greater fentanyl contamination than assumed. For example, a recent analysis in Canada showed that fentanyl was present in 89 percent of seized counterfeit Oxycontin tablets. Likewise, a supervised injection facility in Vancouver, British Columbia, using a drug checking service over the summer of 2016, found 86 percent of the samples contained fentanyl, many of which were presumed to be methamphetamine, heroin, or cocaine. As a page of the samples contained fentanyl, many of which were presumed to be methamphetamine, heroin, or cocaine.

In addition to not having adequate data on the fentanyl threat, unless states and localities make the extra effort of identifying what kind of opioid was the cause of death, they may not get the levels of naloxone that they need.²⁵

The fentanyl threat is spreading. The title of an ABC News article from January 4, 2017, "Fentanyl Deaths Have Spiked Across the US, With No Sign of Slowing Down," summarizes the problem that our country currently faces. Fentanyl is more than an emerging regional problem; in the past 15 months, its presence and danger throughout the nation has greatly escalated. Current statistics from the CDC and other federal entities show data results as of 2015. Yet from January 2016 through March 2017, there has been a significant increase of fentanyl and fentanyl-related overdoses, overdose-related deaths, and arrests. While these incidents have been most prevalent in certain regions of the country, they are not limited to certain localities. For example, two of the largest arrests for fentanyl seized in pill form have occurred in San

¹⁹ Attachment to email from Staff, Centers for Disease Control & Prevention, to Staff, H. Comm. on Energy & Commerce (Feb, 22, 2017).

²⁰ *Id*.

²¹ *Id*.

²² DEA Intelligence Brief, *supra* note 13, at 2.

²³ R.G. Frank and H.A. Pollack, *Addressing the Fentanyl Threat to Public Health*, 376 NEJM 606 (Feb. 22, 2017). ²⁴Press Release, 86% of drugs checked at Insite contain fentanyl, Vancouver Coastal Health, Aug. 31, 2016, available at http://www.vch.ca/about-us/news/news-releases/86-of-drugs-checked-at-insite-contain-fentanyl%20.

²⁵Deanna Allbrittin, *Proposal to track drugs in Indiana overdose deaths*, Fox 59 (Jan. 11, 2017), http://fox59.com/2017/01/11/proposal-to-track-drugs-in-indiana-overdose-deaths/

http://fox59.com/2017/01/11/proposal-to-track-drugs-in-indiana-overdose-deaths/. $^{26}\,Id.$

Francisco in June 2016²⁷ and in Utah in November 2016.²⁸ Further, a man was extradited from Panama to Fargo, North Dakota, in January 2017, to face charges of leading a drug ring and arranging for fentanyl to be brought from China and Canada into Portland, Oregon and Fargo, North Dakota.²⁹

While there have been frightening spikes in overdoses and fentanyl-related overdose deaths throughout Ohio and New England in 2016, there have been significant increases in other areas across the country:

- Sacramento County, California with a reported 52 overdoses, 12 deaths in January 2017;³⁰
- The metropolitan Denver, Colorado area in November 2016 with a reported 31 overdose-related deaths in 4 counties;³¹
- Chicago's Cook County, Illinois with a reported 380 deaths as of early December 2016;³²
- Miami-Dade County, Florida where there have been a reported 228 deaths, triple the 2015 total, and 107 deaths from carfentanil alone as of November 2016;³³ and
- North Carolina, where fentanyl-related overdose deaths increased from 165 in 2014 to 226 in 2015 and to 321 in 2016.³⁴

Fentanyl much more lucrative than heroin. In comparison to heroin, fentanyl is a much more lucrative business for those selling the synthetic drug, including the cartels that are smuggling it into the U.S. For example, a kilogram of heroin purchased from Colombia for roughly \$6,000 can be sold wholesale for \$80,000, according to DEA data. However, a kilogram of pure fentanyl, purchased from China for less than \$5,000, is so potent that it can be stretched

20161209-story.html.

 $^{^{27}}$ 3 Arrested. Accused of Manufacturing Fentanyl-laced Pills Out of SF Sunset District, SAN FRANCISCO KTVU (June 13, 2016), http://www.ktvu.com/news/158680472-story.

²⁸ Courtney Tanner, *Thousands of Fentanyl Pills Confiscated in Utah Drug Raid*, SALT LAKE TRIB. (Nov. 22, 2016), http://www.sltrib.com/news/4623595-155/thousands-of-fentanyl-pills-confiscated-in-utah-drug-raid.

²⁹ April Baumgarten *Suspected Ringleader In Deadly Fentanyl Case Extradited to North Dakota*, BISMARCK TRIB. (Jan. 26. 2017), http://bismarcktribune.com/news/state-and-regional/suspected-ringleader-in-deadly-fentanyl-case-extradited-to-north-dakota/article_e082cad1-0bad-5974-8480-20c8b1bcf7a8.html.

³⁰ Sarah Heise, 12th Fentanyl Death Reported in Sacramento County; 52 Overdoses Reported in Sacramento County; 2 Deaths in Yolo County, KCRA (Jan. 26, 2017), http://www.kcra.com/article/12th-fentanyl-death-reported-in-sacramento-county/6428294.

³¹ Jennifer Brice *As Fentanyl Overdoses Increase, Officers Get Special Safety Training,* CBS DENVER (Nov. 14, 2016), http://denver.cbslocal.com/2016/11/14/as-fentanyl-overdoses-increase-officers-get-special-safety-training/. ³² John Keilman, *Lethal Synthetic 'Super Heroin' Triggers 1st Cook County Overdose Death,* CHICAGO TRIB. (Dec. 9, 2016), http://www.chicagotribune.com/news/local/breaking/ct-chicago-super-heroin-opioid-analog-deaths-met-

³³ Mike Clary, *South Florida's Opioid Overdose Crisis: At Least 800 Expected to Die by End of 2016*, SUN SENTINEL (Nov. 20, 2016), http://www.sun-sentinel.com/local/fl-heroin-overdose-epidemic-20161120-story.html. ³⁴ Pierre Thomas, et al., *Fentanyl Deaths Have Spiked Across the US, With No Sign of Slowing Down*, ABC NEWS (Jan. 4, 2017), http://abcnews.go.com/US/fentanyl-deaths-spiked-us-sign-slowing/story?id=44554601.

into 16 to 24 kilograms when using cutting agents like talcum powder or caffeine. Each kilogram of cut fentanyl can be sold wholesale for \$80,000—for a total profit in the neighborhood of \$1.6 million.³⁵ Because of this profitability, fentanyl is expected to become even more prevalent in the illicit drug market and spread further throughout the U.S. Although there is not comprehensive importation data related to fentanyl, data made available to committee staff substantiate a surge in illicit fentanyl.

c. Source of the Fentanyl Problem

China is a primary source country. According to the DEA, China is the main source of both illicit manufacturing of pure fentanyl as well as the ingredients, also known as precursors, that are being shipped to other countries for manufacturing of fentanyl. Fentanyl is illicitly manufactured in China and either shipped directly into the U.S. or processed at clandestine labs in Mexico and smuggled by drug cartels into the U.S. As noted by the DEA, "traffickers usually purchase powdered fentanyl and pill presses from China to create counterfeit pills to supply illicit U.S. drug markets." ³⁷

China has one of the world's largest chemical industries, with an estimated 160,000 chemical companies producing large quantities of precursor chemicals.³⁸ In response to this problem, the U.S. and Chinese governments have taken steps to address this issue. In October 2015, China added 116 synthetic chemicals, including six fentanyl products, to its list of controlled chemical substances. In February 2017, China agreed to schedule carfentanil and three other fentanyl analogues. At the request of the State Department, the U.N. Commission on Narcotic Drugs moved to control two key fentanyl precursors by adding them to the list of controlled chemicals under the 1988 U.N. Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. On March 16, 2017, the U.N. Commission on Narcotic Drugs accepted the recommendation of the International Narcotics Control Board and voted in favor of controlling these substances.³⁹ All U.N. member states now have 180 days to bring these precursors under their regulatory control system.⁴⁰

Routes of importation into the U.S. According to the DEA, synthetic opioids entering the U.S. travel through three major routes:

³⁵ Azam Ahmed *Drug That Killed Prince Is Making Mexican Cartels Richer, U.S. Says*, N.Y. TIMES (June 9, 2016), https://www.nytimes.com/2016/06/10/world/americas/drug-that-killed-prince-is-making-mexican-cartels-richer-us-says.html. A recent case illustrates the high profitability of fentanyl. On December 21, 2016, 55 pounds of fentanyl worth \$1.5 million was recovered in the cab of a tractor trailer truck on Route 34 in Derby, Connecticut. Staff Report, *Derby Police Recover \$1.5 Million Worth of Fentanyl in Route 34 Traffic Stop*, NEWS 8 WTNH (Dec. 22, 2016), http://wtnh.com/2016/12/21/derby-police-recover-1-5-million-worth-of-fentanyl-in-route-34-traffic-stop/. This is one of the five largest fentanyl busts in the U.S. to date.

³⁶ DEA Intelligence Brief, *supra* note 13, at 2.

 $^{^{37}}$ Id

³⁸ Letter from Julia Frifield, Assistant Sec'y, Legis. Affairs, U.S. Dep't of State, to the Hon. Edward J. Markey (May 25, 2016). *See also*, S. O'Connor, Fentanyl: China's Deadly Export to the United States, U.S.-China Economic and Security Review Commission Staff Research Report 7 (Feb. 1, 2017) (citing U.S. Dep't of State, 2014 International Narcotics Control Strategy Report (Mar. 2014)).

³⁹ Email from State Department Bureau of Legislative Affairs to committee staff, (Mar. 16, 2017). ⁴⁰ *Id*.

- Land/border crossing from Mexico;
- Land/border crossing from Canada; and
- Direct shipments from China (or via re-routed countries) to the U.S. from express consignment, or through international mail.

Illicit synthetic opioids are largely being manufactured in China and smuggled into the U.S. over the Southwest land border and via deliveries by the U.S. Postal Service, foreign mail, or air express consignment carriers. A simple internet search to order these drugs online from Chinese suppliers results in numerous open source e-commerce websites and dark web market options. Users of these sites can remain largely anonymous using currency such as bitcoin. Once the product is purchased, vendors often use discreet or disguised packaging to ship the drug, such as candles, printer accessories, toys, etc. In addition to China being the primary source country, Mexico is a source country for clandestine labs and drug cartels that are purchasing ingredients to manufacture the synthetic drugs themselves. Law enforcement authorities also believe that clandestine fentanyl labs exist in Guatemala and the Dominican Republic.

High-volume seizures on the southwest border. In June 2016, U.S. Customs and Border Protection (CBP) seized almost 200 pounds of fentanyl and other synthetic opioids like fentanyl, the majority of it along the southwest border. This is a 25-fold increase over the eight pounds seized in 2015. Last fall, federal agents in Mexico discovered 27 kilograms of fentanyl—the dosage equivalent of almost one ton of heroin—on a remote landing strip in the state of Sinaloa. The raid also uncovered about 19,000 tablets of fentanyl marked by traffickers to look like oxycodone. Two men detained in the raid were high-ranking members of the Sinaloa cartel, led by the drug kingpin Joaquín Guzmán Loera, also known as El Chapo.

Customs data on fentanyl-related seizures. CBP seizures of parcels containing fentanyl are increasing. In the fiscal year (FY) 2016 (October 2015–September 2016), CBP intercepted twelve parcels containing fentanyl at John F. Kennedy International Airport in New York. To date in FY 2017 (October 2016 – present), CBP has already intercepted nine parcels containing fentanyl. CBP data also indicates that the agency seized 73 pill press/tablet machines in FY 2014 and FY 2015.⁴³

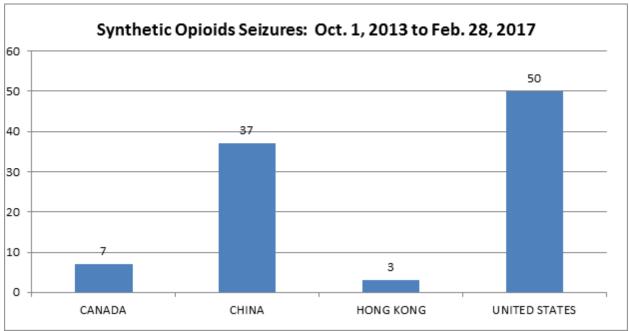
U.S. Postal Inspection Service seizures data. U.S. Postal Inspection Service (USPIS) data indicates that fentanyl shipments seized in the U.S. originate in a small number of nations, including the U.S. and China. In the period from October 1, 2013 through February 28, 2017 (41 months), the USPIS made 97 seizures of synthetic opioids. During the first five months of FY 2017 (October 1, 2016 – February 28, 2017), USPIS made 14 seizures of synthetic opioids,

⁴¹ For example, U.S. Border Patrol agents seized 52.69 pounds of fentanyl, along with 38.80 pounds of methamphetamine, and 116.29 pounds of cocaine near San Clemente, California during summer 2016.

⁴² Steven Melendez, *How America Gets Its Deadliest New Drug*, FAST COMPANY (Sept. 9, 2016), https://www.fastcompany.com/3063518/carfentanil-synthetic-opioids-heroin.

⁴³ U.S. Customs and Border Protection Response to Senator Wyden's May 20, 2016, Questions at 4 (Attachment to Letter from the Hon. R. Gil Kerlikowske, Commissioner, U.S. Customs & Border Protection, to Hon. Ron Wyden (Aug. 24, 2016)).

compared to five in the same period last year. Fifty of the seized packages (roughly 51 percent) originated in the U.S., 37 seized packages (roughly 38 percent) came from China, and three seized packages came from Hong Kong. The remainder of the seized packages originated in Canada (roughly seven percent).

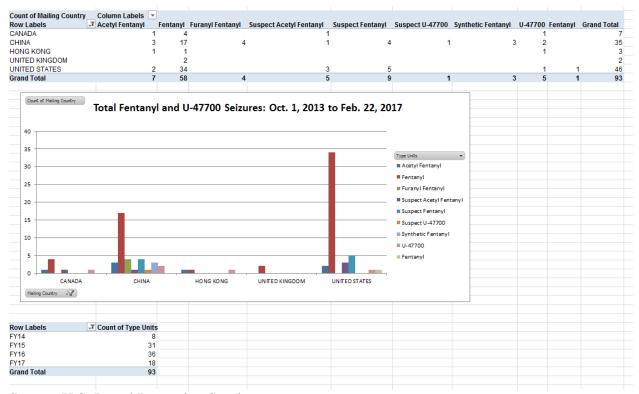


Source: U.S. Postal Inspection Service⁴⁴

Further, the USPIS data⁴⁵ showed that fentanyl and fentanyl-related products were involved in 86 out of the 93 seizures for the time period from October 2013 to February 2017 as shown in the below chart:

⁴⁴ Attachment to email from Staff, U.S. Postal Service to Staff, H. Comm. on Energy & Commerce (Mar. 8, 2017).

⁴⁵ Attachment to email from USPIS Inspector in Charge to Staff, H. Comm. on Energy & Commerce (February 28, 2017).



Source: U.S. Postal Inspection Service

At present, the U.S. Postal Inspection Service reports 29 active synthetic opioid investigations. Of these, 16 (roughly 55 percent) are either confirmed or believed to have a darkweb or an international online vendor nexus.

Regional data on fentanyl imports. State and regional data provide some insight into how fentanyl is imported into the U.S. For example, in July 2016, the local Baltimore/Washington High Intensity Drug Trafficking Area (B/W HIDTA) Office conducted a survey of over 100 health and public safety entities regarding the local fentanyl threat.⁴⁶ On average, respondents estimated that:

- Seventy-one percent of fentanyl is trafficked through traditional drug trafficking organization methods, e.g. personal vehicles, cargo contained within tractor-trailers, and domestic parcels (i.e. both consignment carriers and via U.S. mail);
- Twenty-eight percent of local fentanyl was transported through international packages via mail order from China; and
- One percent of fentanyl was synthesized in local laboratories.⁴⁷

⁴⁶ Briefing by Maryland Governor's Office of Crime Control & Prevention & Maryland Department of Health & Mental Hygiene for the H. Comm. on Energy & Commerce staff (Mar. 10, 2017).
⁴⁷ Id.

In addition, B/W HIDTA seizure data revealed that from 2015 to 2016, fentanyl seizures increased tenfold.⁴⁸

Blitz operations not finding fentanyl. Although data from CBP, USPIS, and B/W HIDTA indicate that seizures of fentanyl packages are occurring, targeted efforts to find fentanyl parcels have not been successful. Fentanyl was one of the targeted drugs of concern during federal law enforcement blitzes at international mail facilities at nine different U.S. airports from FY 2015 to current date FY 2017. However, not one package of fentanyl was detected out of 8,473 packages examined.⁴⁹

Fentanyl-related counterfeit drug investigations hampered. While the results from the blitz operations suggest more work is needed to develop better targeting intelligence on fentanyl packages, law enforcement faces other challenges with fentanyl-related investigations. Because fentanyl is classified as a controlled substance, law enforcement is further hampered in counterfeit drug cases because they cannot rely on test purchases or undercover buys from pharmaceutical security offices as they do in non-controlled counterfeit drug cases.

Pill presses used to make fentanyl. Illicit pill presses shipped to the U.S. from overseas have been linked to the fentanyl overdose epidemic. As reported by the Salt Lake Tribune, "[d]ealers can buy a pill press and brand-name die molds for little more than \$1,000 and order upward of \$10 million in street value of the drug for a few thousand dollars more. Branded and sold as 30 milligram oxycodone, a single counterfeit pill can fetch over \$30."⁵⁰

Illegally obtained pill presses allow small-scale milling operations in the U.S. to package between 3,000 and 5,000 pills per hour of illicit fentanyl.⁵¹ For example, in a drug bust of what is believed to be the second-largest distributor of fentanyl in the U.S. in November 2016 in Utah, agents discovered a pill press likely capable of manufacturing several thousand pills per hour.⁵²

The pill presses used to make fentanyl are shipped directly from China or indirectly through other countries such as Canada where pill presses are not regulated. Moreover, such

⁴⁹ Committee staff tabulation from data provided by U.S. Food & Drug Admin., List of IMF Blitz/Surge Operations (Safeguard and Pangea) from FY '15 (1/01/2014) thru Current Date FY' 17 (2/27/2017) attached to email from Staff, U.S. Food & Drug Admin., to Staff, H. Comm. on Energy & Commerce, (Mar. 9, 2017).

⁴⁸ *Id*.

⁵⁰ M. Piper, *Cottonwood Heights man accused of Utah's biggest-ever illicit opioid pill press makes first appearance in court*, SALT LAKE TRIB. (Nov. 23, 2016), http://www.sltrib.com/home/4625394-155/utah-man-accused-of-making-illicit.

⁵¹ S. O'Connor, Fentanyl: China's Deadly Export to the United States, U.S.-China Economic and Security Review Commission Staff Research Report 6 (Feb. 1, 2017) (citing Commission staff interview with DEA official (Sept. 13, 2016)).

⁵² K. Lockhart, *DEA busts 'catastrophic' pill distribution operation in Cottonwood Heights*, KSL.com (Nov. 22, 2016), https://www.ksl.com/?sid=42312087&nid=148&title=police-discover-major-drug-operation-in-cottonwood-heights. The video within this article states that the pill press could make up to 7,000 pills per hour. Another pill press found in Sandy City, Utah in June 2016 could also reportedly produce 7,000 pills per hour. Gephardt Daily Staff, *Update: Agents bust massive Cottonwood Heights drug operation; fake fentanyl, other opioids shipped by the millions nationwide*, GEPHARDT DAILY (Nov. 22, 2016), http://gephardtdaily.com/local/police-national-guard-on-scene-of-pill-making-operation-in-cottonwood-heights/.

equipment is only controlled by DEA for DEA registrants. Seizure data from CBP shows China or Hong Kong as the countries of origin in 94 percent of the seizures in FY 2014 and FY 2015.⁵³

ISSUES

The following issues may be examined at the hearing:

- Does the federal government accept that fentanyl presents a unique public health threat and law enforcement challenge that requires a systematic response from the whole-of-federal government?
- What is the structure of the federal response to the fentanyl epidemic?
- What is the current status of the federal response to the fentanyl epidemic?
- How can surveillance of the fentanyl epidemic be improved?
- What additional burdens is the fentanyl epidemic putting on society, the healthcare system, the criminal justice system, the emergency response system, and state budgets?

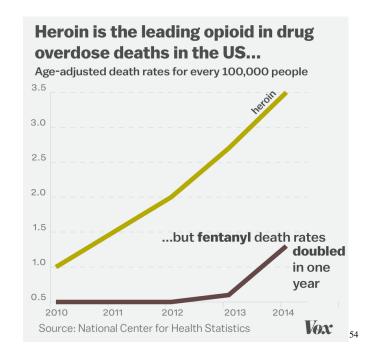
III. STAFF CONTACTS

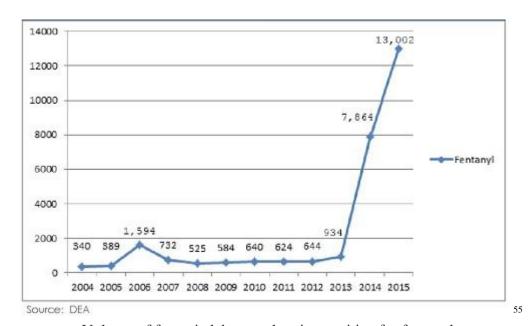
If you have any questions regarding the hearing, please contact Alan Slobodin, Brittany Havens, or David Schaub of the committee staff at (202) 225-2927.

⁵³ CBP response to Senator Wyden, *supra* note 42. For the years FY 2014 and 2015 (Oct. 1, 2013 through Sept. 30, 2015), CBP recorded 73 total seizures of illicit pill presses. China was identified as the country of origin for 26 of these seizures (36 percent of the total). By contrast, Hong Kong was the identified origin for 42 seizures (58 percent), while the U.K. (two seizures), India (two seizures) and Taiwan (one seizure) comprised the remainder.

V. APPENDICES

Although there is limited national data on the fentanyl crisis, the two following charts illustrate the surge in the fentanyl problem:





Volume of forensic lab tests showing positive for fentanyl

⁵⁴ Sarah Frostenson, *The Stunning Rise of Deaths from the Pain Drug Fentanyl, In One Chart,* VOX (Dec. 20, 2016), http://www.vox.com/science-and-health/2016/12/20/14005776/deaths-pain-drug-opioids-fentanyl-chart. ⁵⁵ *The Fentanyl-Opioid Crisis is a Counterfeiting Crisis,* PHARMACEUTICAL COMMERCE (Oct. 14, 2016), http://pharmaceuticalcommerce.com/brand-marketing-communications/fentanyl-opioid-crisis-counterfeiting-crisis/.