



# Department of Justice

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**STATEMENT OF**

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**BEFORE THE**

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

**FOR A HEARING ENTITLED**

**“COMBATING THE OPIOID CRISIS: HELPING COMMUNITIES  
BALANCE ENFORCEMENT AND PATIENT SAFETY”**

**PRESENTED**

**FEBRUARY 28, 2018**

**Statement of  
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**Before the  
Subcommittee on Health  
Energy and Commerce Committee  
U.S. House of Representatives**

**For a Hearing Entitled  
“Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient  
Safety”**

**February 28, 2018**

## **INTRODUCTION**

Chairman Walden, Ranking Member Pallone, and Members of the Committee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss potential legislation intended to help combat the opioid epidemic.

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

Reports on the ongoing misuse of controlled prescription drugs (CPDs) and the growing use of heroin, fentanyl, and fentanyl analogues in the United States are at unprecedented levels. DEA has become increasingly alarmed over the proliferation of illicit fentanyl and its analogues, which have been added to heroin and other illicit substances and have also been encountered as counterfeit tablets resembling CPDs. Fentanyl and fentanyl analogues are potent synthetic opioids that present a serious risk of overdose and death by those who abuse these substances. The yearly market for illegal, non-medical prescription pain relievers is estimated to be over 11.5 million people, and if fentanyl and fentanyl analogues are introduced into even a small portion of the illicit opioids consumed, there is a likelihood overdoses will increase.<sup>3</sup> Fentanyl and fentanyl

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<sup>1</sup> 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.

<sup>2</sup> CDC WONDER data, retrieved from the National Institute of Health website; <http://www.drugabuse.gov> as reported on NIDA’s website.

<sup>3</sup> Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

analogues can be absorbed through the skin, inhaled, or introduced into the body via mucous membranes (e.g., mouth, nose, eyes, etc.), which makes them particularly dangerous for public safety personnel who encounter these substances during the course of their daily operations. Fentanyl and fentanyl analogues represent the deadly convergence of the synthetic drug threat and the current national opioid epidemic.

On a broader scale, synthetic designer drugs, also known as New Psychoactive Substances (NPS) refer to man-made substances designed to mimic the effects of known licit and illicit controlled substances; while fentanyl and fentanyl analogues are scheduled, emerging NPS are oftentimes unscheduled and unregulated.<sup>4</sup> There are a variety of synthetic designer drugs, which are categorized based on the types of controlled substances they are intended to mimic: opioids (including fentanyl and fentanyl analogues), cannabinoids, cathinones, and hallucinogens known as phenethylamines. Other than synthetic opioids, the two most commonly used categories of synthetic designer drugs in the United States are synthetic cannabinoids and synthetic cathinones. NPS, including synthetic opioids, continue to pose a nationwide threat to the United States and tragically, overdoses and deaths attributable to those substances continue to occur.

## **SYNTHETIC DESIGNER DRUGS OVERVIEW**

### *Fentanyl, Fentanyl Analogues, and Synthetic Opioids*

Fentanyl is a Schedule II controlled substance produced in the United States and used widely in medicine; its classification in Schedule II indicates its widely accepted medical use but high potential for abuse. It is an extremely potent analgesic indicated for use as an anesthetic or for use as a serious pain control option in opioid tolerant patients.<sup>5</sup>

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.<sup>6</sup> This makes prescription opioid misuse more common than use of any category of illicit drug in the United States except for marijuana. The illicit market for prescription drugs is of considerable size. Counterfeit versions of such drugs are easier and cheaper to produce, which significantly increases the risk that fentanyl or fentanyl analogue-laced counterfeit pills will be produced to meet the demand. Widespread use of these substances will cause more overdoses across the nation.

According to the DEA National Forensic Laboratory Information System (NFLIS), from January 2013 through December 2016, federal, state, and local forensic laboratories identified

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<sup>4</sup> On February 6, 2018, DEA published a final order in the Federal Register scheduling all fentanyl-related substances (i.e., fentanyl analogues) into Schedule I of the Controlled Substances Act on an emergency basis. The final order was made effective on the date of publication.

<sup>5</sup> Patients considered tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

<sup>6</sup> Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

fentanyl in over 58,000 toxicology reports.<sup>7</sup> During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,<sup>8</sup> an exponential increase over four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a November 2017 CDC Morbidity and Mortality Weekly Report on data from 10 states, fentanyl and fentanyl analogues were detected in 56.3 percent (5,152) of all drug overdose deaths in a 6-month period from July – December of 2016.<sup>9</sup>

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

#### *Synthetic Cannabinoids and Synthetic Cathinones*

Synthetic cannabinoids and their byproducts (sometimes sold under brand names such as K2 or Spice) continue to be a significant threat to public health and safety. These substances have a similar mechanism of action to that of delta-9-tetrahydrocannabinol (THC), the primary psychoactive constituent in marijuana, but they are much more powerful and significantly more toxic. Similar to fentanyl and its analogues, synthetic cannabinoids are sourced from chemical manufacturers and suppliers primarily in China. Products containing synthetic cannabinoids are typically prepared for packaging in the United States and marketed over the Internet or supplied to retail distributors before being sold to the public at retail stores (e.g., convenience stores, gas stations, and liquor stores). Laws governing the legality of the substances vary widely between states and the chemical components are frequently altered, making it an ongoing challenge for DEA to schedule these substances in a timely manner to protect the public.

Synthetic cathinones, often marketed to consumers as “bath salts” or “glass cleaner,” can produce pharmacological effects that are substantially similar to cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine. Whereas individuals consume stimulants for desired psychoactive effects such as euphoria, empathy, elevated mood, and

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<sup>7</sup> U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.

<sup>8</sup> U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.

<sup>9</sup> O'Donnell JK, Halpin J, Mattson CL, Goldberg BA, Gladden RM. Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 – 10 States, July-December 2016. MMWR Morb Mortal Wkly Rep 2017; 66:1197-1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>

improved mental function,<sup>10,11</sup> patients who present to first responders and emergency departments with sympathetic stimulation have profoundly altered mental status. Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity).<sup>12</sup> These substances are often labeled “not intended for human consumption” in an attempt to skirt the Government’s utilization of the federal Controlled Substance Analogue Enforcement Act (Analogue Act). While the Department of Justice (DOJ) has had successful prosecutions under the Analogue Act, hundreds, if not thousands of these substances are sold to unsuspecting consumers in the meantime. Synthetic cathinones are widely available and have been encountered as a replacement for MDMA, a Schedule I controlled substance that is often referred to as “Molly.”

Synthetic cathinones are usually snorted or swallowed in their powder or crystal forms. Many drugs in this class have been placed in Schedule I, either through legislative action or through DEA-initiated administrative action, to temporarily control the drug when the Administrator concludes that such action is necessary to avoid an imminent hazard to public safety. Unfortunately, when DEA initiates temporary control of a synthetic designer drug, those who produce and traffic the drug frequently alter the chemical composition of those drugs. These new substances, like the original substance, have serious adverse health effects including death and thus pose a severe public health threat.

Synthetic cannabinoids and synthetic cathinones are a significant area of concern for DEA. According to NFLIS, from January 2013 through December 2015, the 25 most frequently identified synthetic cannabinoids were identified in a total of 95,143 state and local forensic laboratory reports submitted to NFLIS. During the same period, state and local forensic laboratories reported finding the 20 most frequently identified synthetic cathinones a total of 51,824 times through the data submitted to NFLIS.<sup>13</sup> In 2016, synthetic cannabinoids were identified in 25,250 such reports.

## **CURRENT CHALLENGES WITH SYNTHETIC ANALOGUES**

### *Traffickers Adapting to the Law*

Even though fentanyl and fentanyl analogues, as well as NPS compounds have been controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA), entrepreneurs procure new synthetic compounds with relative ease.<sup>14</sup> Over the past several years, DEA has

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<sup>10</sup> L Karila and M Reynaud. GHB and synthetic cathinones: clinical effects and potential consequences. *Drug Testing and Analysis* 2010, 3: 552-559; JP Kelly. Cathinone Derivatives: A Review of their Chemistry, Pharmacology, and Toxicology. *Drug Testing Analysis* 2011, 3:439-453; JB Zawilska and J Wojcieszak. Designer cathinones – An emerging class of novel recreational drugs. *Forensic Science International* 2013, 231:42-53; JB Zawilska. Mephedrone and other cathinones. *Current Opinion in Psychiatry* 2014, 27: 256-262; CL German, AE Fleckenstein, and GR Hanson. Bath salts and synthetic cathinones: An emerging designer drug phenomenon. *Life Sciences* 2014, 97:2-8; PS Johnson, MW Johnson. Investigation of “bath salts” use patterns within an online sample of users in the United States. *Journal of Psychoactive Drugs* 2014, 46:369-378.

<sup>11</sup> M F Measham, K Moore, R Newcombe and Z Welch. Tweaking, bombing, dabbing and stockpiling: the emergence of mephedrone and the perversity of prohibition. *Drugs and Alcohol Today* 2010, 10:14-21; Psychonaut WebMapping Research Group. Ivory Wave report, Institute of Psychiatry 2010, King’s College London: London, UK. [Paolo Deluca et al.]; EMCDDA. European Monitoring Centre for Drugs and Drug Addiction. Report of the risk assessment of mephedrone in the framework of the Council Decision on new psychoactive substances. Luxembourg: Publications Office of the European Union, 2011, doi: 10.2810/40800.

<sup>12</sup> EA Ross, M Watson and B Goldberber. “Bath salts” intoxication. *New England Journal of Medicine* 2011, 967-968.

<sup>13</sup> U.S. Drug Enforcement Administration, Diversion Control Division. (2016). *Synthetic Cannabinoids and Synthetic Cathinones Reported in NFLIS, 2013–2015*. Springfield, VA: U.S. Drug Enforcement Administration, accessed on March 8, 2017 at <https://www.nflis.deadiversion.usdoj.gov/>

<sup>14</sup> On February 6, 2018, DEA published a final order in the Federal Register scheduling all fentanyl-related substances (i.e., fentanyl analogues) in Schedule I on an emergency basis. The final order was made effective on the date of publication.

identified numerous fentanyl class substances and hundreds of designer drugs from at least eight different drug classes, the vast majority of which are manufactured in China.

Regarding NPS more broadly, clandestine chemists can easily continue developing/synthesizing new synthetic opioid, cannabinoid, and cathinone products that do not appear on any schedule of controlled substances. Data from the patent and scientific literature for structures with psychoactive effects have provided clandestine laboratory operators with a blueprint to produce hundreds of NPS for the illicit market. When DEA has taken an action to temporarily schedule a substance, traffickers begin selling new versions of their products made from new, noncontrolled substances. In addition, manufacturers provide traffickers with spurious chemical analyses that purport to document that the new product does not contain a controlled substance. Manufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new synthetic products that are not listed as such in any of the controlled substance schedules.

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

Fentanyl, fentanyl analogues, synthetic cannabinoids, and synthetic cathinones are relatively inexpensive, available via the Internet and are often manufactured in China where they may be shipped (via U.S. mail or express consignment couriers) to the United States or alternatively 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 and pressed into counterfeit pills made to look like controlled prescription drugs containing oxycodone or hydrocodone and sold online from anonymous darknet markets and even overtly operated websites. Similarly, bulk powders containing synthetic cannabinoids produced in China are imported into the United States where they are sprayed or otherwise applied onto plant matter, packaged into individual saleable units, and distributed for sale at gas stations and convenience stores, or sold directly to individuals via the Internet. The combination of the questionable legal status of these substances that 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 technological and logistical challenges of detection and inspection, make it extremely difficult for the U.S. Customs and Border Protection (CBP) to effectively address the threat at ports of entry and pave the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. DEA is working with CBP to increase coordination on seized parcels.

#### *Use of Freight Forwarders*

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

### *Prosecutions Pursuant to the Analogue Act*

A compound, including a fentanyl analogue, may be a “controlled substance analogue” pursuant to the CSA if it is found to have a substantially similar chemical structure to and substantially similar or greater depressant, stimulant, or hallucinogenic effect on the central nervous system as a Schedule I or II controlled substance, or is represented to have such an effect. Even if a particular substance is widely regarded as a “controlled substance analogue” under the CSA, each criminal prosecution must establish that fact anew. The primary challenge to preventing the distribution and abuse of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is treated as a Schedule I controlled substance in a given case only once proven to meet the definition of a controlled substance analogue. In addition to proving a material is a controlled substance analogue, prosecutors must also prove that the substance was intended for human consumption. Accordingly, each prosecution requires expert testimony to obtain a conviction, even if the same substance was determined by a jury to meet the criteria of the analogue definition in a prior case. This holds true even if a prior conviction was in the same District Court or even in front of the same judge. This process is workable, but resource-intensive for DEA, federal prosecutors serving in United States Attorney’s Offices, the defense bar, and the court system.

The above considerations, along with the increasing volume and variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Analogue Act a cumbersome and resource-intensive tool to prevent manufacturing, trafficking, and abuse of designer drugs. Furthermore, clandestine manufacturers are continually introducing unique substances that have abuse liability but do not meet the legal definition of an analogue. That said, agents, chemists, pharmacologists, and prosecutors have worked together tirelessly to make the Analogue Act work, with many successful prosecutions to show for it. The Synthetic Drug Abuse Prevention Act of 2012 (SDAPA) approach to control specific, known, synthetic substances in some instances by a description of chemical characteristics, was a swift and effective contribution to the overall effort to combat the designer drug threat.<sup>15</sup> DEA will continue to identify ways to better combat the designer drug threat.

### *The Drug Control Process under the CSA is Reactive and Requires Evidence of Harm*

The CSA provides the Attorney General (delegated to the DEA Administrator) with a mechanism to bring new drugs of abuse under CSA control and subject them to a regulatory scheme to protect the public. Through an interagency process, determinations about placement in the CSA are dictated by the following eight enumerated scientific factors:<sup>16</sup> the state of current scientific knowledge about the substance; its pharmacological effect; its risk to the public health; its psychic or psychological dependence liability; whether the substance is an immediate precursor of a controlled substance; its actual or relative potential for abuse; its history or current pattern of abuse and its scope; and the scope, duration, and significance of use. In this process, the Secretary of Health and Human Services (HHS) is responsible for any

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<sup>15</sup> P.L. 112-144 – Food and Drug Administration Safety and Innovation Act, Subtitle D, Section 1151, titled “Synthetic Drug Abuse and Prevention Act of 2012.

<sup>16</sup> The eight factors are enumerated in 21 U.S.C. § 811(c).

scientific and medical considerations about a substance and the DEA Administrator considers a recommendation made by the HHS Secretary along with other relevant facts to determine whether there is substantial evidence to warrant control. These scheduling evaluations by both HHS and DEA require extensive collection and evaluation of scientific, medical, law enforcement, and other data. The acquisition of this data is often an arduous and time-consuming process which often relies heavily on actual evidence of harm to the public.

When the DEA Administrator concludes that control of a substance is necessary to avoid an “imminent hazard to public safety,” the DEA Administrator may initiate temporary control of that substance for a period of two years, subject to possible extension for up to one year,<sup>17</sup> during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.<sup>18</sup>

DEA believes a coordinated response by public health and law enforcement and other stakeholders remains the most effective response to this problem. Further, DEA will continue to share information and engage stakeholders to decrease the demand for NPS.

## **DEA RESPONSE TO THE THREAT OF FENTANYL, FENTANYL ANALOGUES AND OTHER SYNTHETIC DRUGS**

### *Scheduling by Administrative Rulemaking: Temporary Control*

DEA continues to utilize its regulatory authority to place many synthetic substances into the CSA pursuant to the aforementioned temporary scheduling authority. Once a substance is temporarily placed in Schedule I, DEA moves towards permanent control by requesting a scientific and medical evaluation and scheduling recommendation from HHS and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, medical examiners, treatment professionals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since March 2011, DEA has utilized this authority on nineteen occasions to place 56 synthetic designer 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. In addition, on February 6, 2018, DEA temporarily placed Schedule I controls on “fentanyl related substances” which includes any substance structurally related to fentanyl based on specific chemical changes not otherwise controlled in any other schedule.<sup>19</sup>

### *Significant Enforcement Efforts*

The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint “whole of government” approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from

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<sup>17</sup> The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).

<sup>18</sup> Temporary control of a substance may be extended for a period of 1 year if DEA receives the Secretary’s scientific and medical evaluation and scheduling recommendation within the 2-year temporary control period.

<sup>19</sup> 83 FR 5188 (Feb. 6, 2018).



DEA, U.S. Immigration and Custom Enforcement (ICE) Homeland Security Investigations (HSI) and CBP; supplemented by the Federal Bureau of Investigation (FBI), and the U.S. Postal Inspection Service. HFTF uses every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department of Justice's Criminal Division, the Department of Defense (DOD), Intelligence Community (IC), and other government entities, and provides field offices (all agencies) with valuable support in their respective investigations.

The HFTF mission aims to:

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

Close interagency cooperation via the HFTF has led to several large enforcement actions, including two separate OCDETF investigations centered in North Dakota and Southern Mississippi that resulted in the first-ever indictments in September 2017 of two Chinese nationals responsible for the manufacturing, importation, and distribution of illicit fentanyl and other NPS in the United States. On October 17, 2017, the Deputy Attorney General and the DEA Acting Administrator announced the indictments of the Chinese nationals, who were the first manufacturers and distributors of fentanyl and other opiate substances to be 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 seizing of assets and shutting down of the largest criminal marketplace on the Internet, AlphaBay. As outlined by the Attorney General and the DEA Acting Principal Deputy Administrator in July, 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 between 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 OCDEF investigations into AlphaBay revealed that numerous vendors, including many in China, sold illicit fentanyl and heroin on the site, and that there had been a substantial number of overdose deaths across the country attributed to such purchases.

#### *China: Government Action and Cooperation*

Recognizing that synthetic drugs are manufactured in China, Attorney General Sessions and Deputy Attorney General Rosenstein both requested that China take action during 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 in Washington, D.C. on October 3 and October 4, 2017.

The Attorney General and the Deputy Attorney General's efforts 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 a second office to be located in Guangzhou. 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 the primary bilateral conduit for addressing the threat resulting from the shipment of illicit fentanyls, their precursors, and other synthetic drugs from China to the United States and elsewhere.

At a higher policy level, the U.S. Government has also engaged China through an interagency working forum that operates under the U.S.-China Joint Liaison Group (JLG). The JLG is chaired by DOJ, the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, and the Department of Homeland Security. DEA and the NCB participate in the Counter Narcotics Working Group (CNWG) and the BDIWG within the JLG framework that are chaired, respectively, by DOJ and DEA on the U.S. side, and the Ministry of Public Security on the Chinese side. 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.

Engagement in the efforts mentioned above has resulted in positive actions by the Government of China taken over the last year. These actions are a step in the right direction, but much more needs to be done. Since 2014, the DOJ, DEA, and Chinese officials have met regularly to discuss bilateral efforts to counter the threat to the United States from synthetic drugs, including illicit fentanyl and its analogues. 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 information exchange about new substances of abuse in the United States to be considered for control in China. A larger and more formal bilateral exchange between legal and (especially) scientific experts took place in Beijing in May 2017. Plans are underway for DEA to welcome its scientific counterparts to Washington in early spring 2018.

A key moment in enhanced cooperation on synthetic drugs came in October 2015, when, following similar discussions, China implemented domestic control on 116 NPS, including a number of fentanyl analogues, and streamlined its procedures to control additional substances. In total, China has scheduled 138 different NPS.

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 followed ongoing collaboration between DOJ and the Government of China, and reaffirms an expanding collaborative commitment to countering illicit fentanyl. On July 1, 2017, China announced implementation of controls on U-47700. While not a fentanyl class substance, U-47700 is a powerful synthetic opioid that has been trafficked and abused in the United States and a substance that DEA placed in Schedule I on a temporary basis following significant evidence of abuse.

After requests by Administration officials, including the Attorney General and Deputy Attorney General, and in accordance with its obligations under the 1988 U.N. Convention, on December 28, 2017, China's Ministry of Public Security announced scheduling controls on two fentanyl precursor chemicals, NPP and 4ANPP. The scheduling controls took effect on February 1, 2018. Implementation of Chinese controls on all of these substances, and the effect that prior control efforts have had on the availability of these substances in the United States, is encouraging and affirms the need for the continued collaborative commitment between DEA and the NCB.

In 2018, 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. Officials from the NCB indicated that their scheduling process is long and complicated, that China has always scheduled one drug at a time, pursuant to its law, and that any change in that process would be groundbreaking for China. In spite of the complexity of this process, and the fact that domestic abuse of fentanyl and related substances has not been a problem in China, they have continued to show an understanding of the problem and a willingness to listen and at least discuss class scheduling.

#### *Recent Major Synthetic Cannabinoid and Cathinone Enforcement Operations*

Over the past six years, DEA has conducted two primary, national efforts (Operation Log Jam and Project Synergy) related to countering the threat from synthetic cannabinoid and cathinone operations, in addition to all other synthetic investigations executed by DEA field offices.

DEA's Operation Log Jam launched in 2011 and culminated in a nationwide takedown on July 25, 2012. This DEA SOD Operation resulted in multiple OCDETF Operations throughout the United States, including 25 federal districts. This operation was coordinated by DEA in cooperation with HSI, FBI, CBP, and the Internal Revenue Service (IRS). The goals of this operation included the targeting of manufacturers, wholesale distributors, and retail distributors of designer drug products, the development of information on foreign-based sources

of supply, raising public awareness of the dangers associated with the use of these drugs, and the development of leads for a Phase II initiative (Project Synergy).

Operation Log Jam resulted in 100 arrests, the execution of 300 search warrants and 80 consent searches, and the identification of 38 manufacturing sites. Law enforcement seized 196 kilograms of raw synthetic cathinones, 722 kilograms of raw synthetic cannabinoids, 167,187 packets of synthetic cathinones ready for distribution, 4,852,099 packets of synthetic cannabinoids ready for distribution, 4,766 kilograms of plant material treated with synthetic cannabinoids ready to be packaged, 21,933 kilograms of untreated plant material, over \$45,000,000 in U.S. currency and bank accounts, 88 vehicles, 77 firearms, additional assets valued at \$5,688,500, and 1,096 gallons of acetone.

Project Synergy, the second phase of a national cooperative effort in combating synthetic designer drug distribution, has resulted in multiple OCDETF operations in at least 13 federal districts. Project Synergy has resulted in nationwide take downs in 2013, 2014, and 2015 by DEA, HSI, FBI, CBP, IRS, and domestic law enforcement departments in 45 states, and international partners in Australia, New Zealand, Canada, and Barbados. Over 400 individuals were arrested and authorities seized assets valued at nearly \$75 million. In addition to curbing the flow of synthetic drugs into the country, Project Synergy III continued to reveal the flow of millions of dollars in U.S. synthetic drug proceeds to countries in the Middle East.

## **OTHER AREAS OF DEA FOCUS TO COMBAT THE OPIOID EPIDEMIC**

### *Medication Assisted Treatment (MAT)*

DEA plays an important part in the U.S. government's drug control strategy, which includes enforcement, treatment, and prevention. It is important to consider medication assisted treatment (MAT) as a part of any successful strategy to combat the opioid epidemic. It is imperative to determine how to best balance access to MAT against the potential for the diversion of the FDA-approved drugs to be used in the treatment of substance abuse disorder, such as buprenorphine.

As you are aware, the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) was enacted to address the opioid epidemic. One of CARA's important provisions expands access to MAT by authorizing certain mid-level practitioners (i.e., nurse practitioners and physicians assistants) to dispense or prescribe schedule III, IV, or V controlled substances that are FDA-approved for the treatment of opioid use disorder. This prescribing authority was previously limited to physicians only. In February 2017, the Substance Abuse and Mental Health Services Administration (SAMSHA) began providing waivers to qualifying practitioners and DEA published regulations in January 2018 to implement this provision.

### *Telemedicine and the Ryan Haight Act*

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was signed into law in October 2008 and authorized DEA-registered practitioners to prescribe controlled substances listed in Schedules II - V using telemedicine under seven distinct circumstances when

the prescriber is otherwise unable to fulfill the in-person medical evaluation required under the CSA.

DEA's implementing regulations (published in April 2009) lay out the following requirements that must be met in order for a practitioner to prescribe controlled substances using telemedicine: 1) the prescribing practitioner who is at a location remote from the patient must be acting in the usual course of his/her professional practice; 2) the practitioner's activity must be done in accordance with applicable federal and State laws; 3) the practitioner must be communicating with the patient (or health care professional who is treating the patient) using multimedia communications equipment referred to in section 1834(m) of the Social Security Act; and; 4) the patient must be physically located at a DEA-registered hospital or clinic or must be in the physical presence of a DEA-registered practitioner.

There is confusion over whether a doctor authorized to treat opioid use disorder utilizing MAT can perform these services utilizing telemedicine. Some have sought the assistance of the Secretary of the Department of Health and Human Services (HHS) to use his authority to authorize telemedicine for MAT pursuant to a public health emergency declaration. We are working closely with HHS, the Department of Veterans Affairs and other federal partners to identify opportunities to improve access to MAT as DEA continues the drafting process to implement regulations regarding special registration for telemedicine.

### *Proper Medication Disposal*

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs, and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the misuse of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free.<sup>20</sup> These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of February 12, 2018, 3,450 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired, and/or unwanted prescription drugs. DEA's most recent NTBI was held on October 28, 2017. As a result of all fourteen National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed over 9 million pounds (4,508 tons) of medications from circulation. DEA is conducting its fifteenth National Drug Take Back Day on April 28, 2018.

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<sup>20</sup> Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

## *Tableting and Encapsulating Machines*

In December 2016, DEA concluded several years of regulatory work to implement a 2014 Executive Order (E.O. 13659) which aimed to streamline federal import and export processes by utilizing a government-wide system called the International Trade Data System (ITDS). As part of that effort, DEA amended its regulations pertaining to domestic transactions and import/export transactions involving tableting and encapsulating machines (21 C.F.R. 1310.05(a)(4)). The rule became effective on January 30, 2017 and regulated persons were required to comply no later than July 30, 2017. The information below outlines the CSA's regulatory requirements pertaining to the trade of pill presses.

**Domestic Transactions:** Previously in 21 C.F.R 1310.05(a)(4) and (b), regulated persons who engaged in a domestic regulated transaction in a tableting or encapsulating machine were required, whenever possible, to make an oral report to the DEA Divisional Office in advance of the transaction, followed by a written report. The new rule makes the oral reporting mandatory and mandates the electronic filing of a written report (DEA Form 452). In addition, the amended regulations require regulated persons to orally report domestic regulated transactions in a tableting machine or an encapsulating machine when an order is placed rather than at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. The written report (DEA Form 452) is required to be filed within 15 calendar days after the order has been shipped by the seller.

**Import/Export Transactions:** An electronic report filing (DEA Form 452) is required to be submitted to DEA 15 calendar days before the anticipated date of arrival at the port of entry or port of export. In addition, the importer or exporter may not initiate an import or export transaction involving a tableting machine or encapsulating machine until the regulated person has been issued a transaction identification number from DEA. The importer or exporter may proceed with the import or export of the machine(s) as soon as the transaction identification number has been issued. In addition, these new regulations require electronic filing of return information, specifying the particulars of the transaction, for tableting and encapsulating machines imported or exported within 30 calendar days after actual receipt of a tableting or encapsulating machine, or within 10 calendar days after receipt of a written request by DEA to the importer.

## **CONCLUSION**

Synthetic opioids, cannabinoids, cathinones, and phenethylamines will continue to pose a nationwide threat. Synthetic drug producers modify and experiment with chemical formulas in search of new psychoactive substances. Once a new drug is formulated, the Internet and social media are used to market its arrival on the scene, allowing for its fast adoption and use. Due to the changing nature of the chemical formulas for synthetic designer drugs, distributors are able to reap significant profits before legislative and regulatory controls of these specific psychoactive substances are implemented. Sadly, it is likely the United States will continue to see overdoses and deaths as a result of synthetic drug use.

Additionally, the United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of nonmedical prescription opioid use and the large

number of people with active SUDs who are not currently in treatment. It is likely that this demand will continue to be met in part by counterfeit prescription opioids which are being laced with fentanyl, fentanyl analogues, and other synthetic opioids (e.g., U-47700), and that Mexican-based TCOs will push to expand their profits. DEA will continue to address this threat by pursuing the Mexican-based TCOs which have brought tremendous harm to our communities. Additionally, DEA's Diversion Control Division will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. Finally, DEA is committed to looking at all available options to combat the opioid epidemic and will continue to work with the Committee to provide legislative assistance on bills aiming to attack this public health emergency.