



# Department of Justice

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**STATEMENT OF**

**ROBERT W. PATTERSON  
ACTING ADMINISTRATOR  
DRUG ENFORCEMENT ADMINISTRATION**

**BEFORE THE**

**HOUSE JUDICIARY COMMITTEE  
U.S. HOUSE OF REPRESENTATIVES**

**FOR A HEARING ENTITLED**

**“CHALLENGES AND SOLUTIONS IN THE OPIOID ABUSE CRISIS”**

**PRESENTED**

**MAY 08, 2018**

**Statement of  
Robert W. Patterson  
Acting Administrator  
Drug Enforcement Administration**

**Before the House Judiciary Committee  
U.S. House of Representatives**

**For a Hearing Entitled:  
“Challenges and Solutions in the Opioid Abuse Crisis”**

**Presented on  
May 08, 2018**

Chairman Goodlatte, Ranking Member Nadler, 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 the threat posed by the opioid epidemic. The misuse of controlled prescription drugs (CPDs) is inextricably linked with the threat the United States faces from the trafficking of heroin, illicit fentanyl, and fentanyl analogues.

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 the Centers for Disease Control and Prevention (CDC), there were nearly 64,000 overdose deaths in 2016, or approximately 174 per day. Over 42,249 (66 percent) of these deaths involved opioids. 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.<sup>2</sup> According to a March 6, 2018, report from the CDC, the U.S. opioid overdose epidemic is still worsening: emergency department visits for suspected opioid overdoses increased 30% in 45 states between July 2016 and September 2017, and all five U.S. regions experienced rate increases: 70% in the Midwest, 40% in the West, 21 % in the Northeast, 20% in the Southwest, and 14% in the Southeast.<sup>3</sup>

The misuse of CPDs and the growing use of heroin, illicit fentanyl, and fentanyl analogues are being reported in the United States in unprecedented numbers. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) 2016 National Survey on Drug Use and Health (NSDUH), 6.2 million people over the age of 12 misused psychotherapeutic drugs (e.g., pain relievers, tranquilizers, stimulants, and sedatives) during the

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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> Drug Overdose Deaths in the United States, 1999–2016, NCHS Data Brief No. 294, December 2017, *Centers for Disease Control and Prevention*, <https://www.cdc.gov/nchs/products/databriefs/db294.htm>.

<sup>3</sup> Centers for Disease Control and Prevention, EMERGENCY DEPARTMENT DATA SHOW RAPID INCREASES IN OPIOID OVERDOSES, Mar. 6, 2018, <https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html>.

past month.<sup>4</sup> This represents 22 percent of the 28.6 million current illicit drug users and is second only to marijuana (24 million users) in terms of usage.<sup>5</sup> There are more current misusers of psychotherapeutic drugs than current users of cocaine, heroin, and hallucinogens combined.<sup>6</sup>

The increase in the number of people using heroin in recent years – from 373,000 past year users in 2007 to 948,000 in 2016 – is troubling.<sup>7</sup> More alarming is the proliferation of illicit fentanyl and its analogues. DEA investigations reveal that illicit fentanyl and its analogues are increasingly being added to heroin and frequently pressed into counterfeit tablets resembling CPDs. In 2016, 11.5 million Americans reported past-year misuse of opioid prescription medications.<sup>8</sup> In many instances, they may have actually misused a counterfeit prescription pain medication. As illicit fentanyl and related analogues are introduced at increasing rates into counterfeit CPDs, heroin, cocaine and other drugs, the more likely that drug overdoses will continue to climb. Data show that heroin, fentanyl, and fentanyl analogues have surpassed prescription opioids as the leading cause of opioid overdose. In 2016, prescription opioids accounted for over 40 percent of opioid overdose deaths.<sup>9</sup>

## **CONTROLLED PRESCRIPTION DRUGS**

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.<sup>10</sup> This makes prescription opioid misuse more common than use of any category of illicit drug in the United States except for marijuana. Whereas the vast majority of individuals misusing opioid CPDs do not go on to use heroin, roughly 75 percent reported nonmedical use of prescription opioids before initiating heroin use.<sup>11</sup> This illustrates the role that CPDs have played in the opioid epidemic and underscores the continued need for robust regulatory and enforcement measures to stop diversion of CPDs.

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<sup>4</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/>.

<sup>5</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/>.

<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/>.

<sup>7</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

<sup>8</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

<sup>9</sup> Seth P, Rudd RA, Noonan RK, Haegerich. (2018). Quantifying the Epidemic of Prescription Opioid Overdose Deaths. *American Journal of Public Health* 108, no. 4 pp. 500-502.

<sup>10</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/>.

<sup>11</sup> Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. (2014). The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*.71(7):821-826.

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the “street” cost of prescription opioids steadily increases with the relative strength of the drug. For example, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)<sup>12</sup> can generally be purchased for \$5 to \$7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for \$7 to \$10 per tablet on the street. Even stronger prescription drugs are sold for as much as \$1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost \$30 to \$40 per tablet on the street. The costs that ensue with greater tolerance make it difficult to purchase these drugs in order to support a developing substance use disorder, particularly when many first obtain these drugs for free from the family medicine cabinet or from friends.<sup>13</sup>

## HEROIN

The vast majority of heroin consumed in the United States is produced in Mexico, and distributed by powerful Mexico-based transnational criminal organizations (TCOs), such as the Sinaloa Cartel and Jalisco New Generation Cartel, and transported to the United States across the Southwest Border. These TCOs are extremely dangerous, violent, and sophisticated, and will continue to leverage established transportation and distribution networks within the United States.

Not surprisingly, some people who misuse prescription opioids turn to heroin. Heroin traffickers produce high purity white powder heroin that costs approximately \$10 per bag, and usually contains approximately 0.30 grams per bag. This makes heroin significantly less expensive than CPDs. Heroin produces a “high” similar to CPDs and can keep some individuals who are dependent on opioids from experiencing painful withdrawal symptoms. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began misusing prescription opioids.<sup>14</sup>

According to reporting by treatment providers, many individuals with serious opioid use disorders will use whichever drug is cheaper and/or available to them at the time.<sup>15</sup> Heroin purity and dosage amounts vary, and heroin is often adulterated with other substances (e.g., fentanyl and fentanyl analogues). This means that heroin users are at higher risk of unintentional overdose because they cannot predict the dosage of synthetic opioid in the product they purchase

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<sup>12</sup> On October 6, 2014, DEA published a final rule in the *Federal Register* to move hydrocodone combination products from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services.

<sup>13</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/>.

<sup>14</sup> U.S. Department of Justice, Drug Enforcement Administration, 2016 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2016, available at: [https://www.dea.gov/divisions/hq/2016/hq062716\\_attach.pdf](https://www.dea.gov/divisions/hq/2016/hq062716_attach.pdf).

<sup>15</sup> U.S. Department of Justice, Drug Enforcement Administration, 2017 National Drug Threat Assessment Summary, October, 2017.

on the street as heroin.<sup>16</sup> Additionally, varying concentrations found in diverted or counterfeit prescription opioids purchased on the street have led to increased unintentional drug overdose deaths.

Roughly 75 percent reported nonmedical use of prescription opioids before initiating heroin use.<sup>17</sup> The reasons an individual may shift from one opioid to another vary, but today's heroin is high in purity, less expensive and often easier to obtain than illegal CPDs.

Overdose deaths involving heroin are increasing at an alarming rate, having increased more than five-fold since 2010.<sup>18</sup> Today's heroin at the retail level costs less and is more potent than the heroin that DEA encountered two decades ago. It is also not uncommon for heroin users to seek out heroin that dealers claim is "hot," meaning that it is likely cut with fentanyl or its analogues. Users seeking "hot" heroin is an indicator that as higher opioid tolerance levels develop among users, they will continue to seek out more potent forms of opioids.

## FENTANYL AND FENTANYL ANALOGUES

Fentanyl is a Schedule II controlled substance produced in the United States and many other countries 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 indicated only for use in individuals who have high opioid tolerance.

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 directly to TCOs in Mexico, Canada, or the Caribbean. Once in the Western Hemisphere, fentanyl or its analogues are prepared to be mixed into the U.S. domestic heroin supply, or pressed into a pill form, and then moved to the illicit U.S. market where demand for prescription opioids and heroin remain at epidemic proportions. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this illicit 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.<sup>19</sup>

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<sup>16</sup> Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, *Int J Drug Policy*, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: *Int J Drug Policy*, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi:

1016/j.drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D., "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, *Int J Drug Policy*, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

<sup>17</sup> Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. (2014). The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*.71(7):821-826.

<sup>18</sup> CDC WONDER data accessed on 10/15/17, as reported at NIDA's website: 3,036 heroin overdoses in 2010; 15,446 overdoses in 2016. <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

<sup>19</sup> U.S. Department of Justice, Drug Enforcement Administration, 2017 National Drug Threat Assessment Summary, October, 2017.

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.<sup>20</sup> During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,<sup>21</sup> 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.<sup>22</sup>

## **DEA LESSONS LEARNED AND RESPONSE TO THE PROLIFERATION OF CPDs**

The opioid epidemic began with the proliferation of pill mills and CPDs and DEA has worked tirelessly to combat these threats, develop lessons learned, and implement effective strategies to turn the tide against the opioid epidemic:

### *Effective Registrant Outreach*

Due to the complexity of DEA's regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its more than 1.7 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by: (1) hosting Pharmacy Diversion Awareness Conferences and Practitioner Diversion Awareness Conferences (PDACs) throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy (NABP), American Medical Association (AMA), Federation of State Medical Boards, and other groups to address diversion problems and educate the medical community on improving prescribing practices.<sup>23</sup> By the end of 2017, DEA had hosted 100 PDACs in 50 states (as well as the District of Columbia and Puerto Rico) training more than 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In early May 2018, DEA initiated a nationwide program to offer similar training to individual practitioners.

In addition to the training opportunities offered to registrants, DEA has also begun a program to proactively send targeted email messages to various segments of its registrant population on matters of mutual interest. For example, in February 2018, DEA sent correspondence to 1.3 million prescribers nationwide alerting them of the CDC's recommendation (part of CDC's Prescribing Guideline for Chronic Pain) for opioid prescribing

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<sup>20</sup> U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.

<sup>21</sup> U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.

<sup>22</sup> 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>.

<sup>23</sup> In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

for acute pain and alerted practitioners to a free training webinar available from CDC. DEA is working on similar correspondence alerting these same practitioners about resources available from SAMHSA on locating a substance abuse treatment provider in their state. We have also sent targeted messages to DEA's Schedule I researcher population on enhancements made to streamline the registration process for them, as well as to the manufacturer and distributor populations on new enhancements aimed at assisting them with fulfilling their regulatory responsibilities to identify and report suspicious orders. In the coming months, DEA will send targeted messages on certain practitioners on how they may utilize telemedicine to treat opioid use disorders.

### Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly champions robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50<sup>th</sup>, pursuant to the Governor's July 2017 Executive Order. As of January 2018, 40 of these states require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance, in certain circumstances, as mandated by each state's legislation.<sup>24</sup>

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to pain clinics and physicians that are operating unscrupulously and outside of the law, making interconnectivity between PDMPs vital. As a result, ONDCP and the Bureau of Justice Assistance (BJA) currently offer assistance for interstate and state-tribal PDMP linkages. Federal partners are working to address the interoperability of PDMPs. Examples range from Brandeis University's PDMP Training and Technical Assistance Center, funded by BJA, assisting the Indian Health Service (IHS) to improve interoperability between IHS, its pharmacies and PDMPs to CDC working in states to enhance and maximize PDMPs as a public health and clinical tool.

Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information is vital. Access to information in support of active State, Federal and Tribal investigations varies widely from state to state, with some states requiring a court order for law enforcement to obtain data.

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<sup>24</sup> PDMP Center of Excellence, Brandeis University. [http://www.pdmpassist.org/pdf/Mandatory\\_Query\\_Conditions\\_20180102.pdf](http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf) retrieved March 6, 2018.

## 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 (P.L. 111-273) 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 issue of the misuse of prescription drugs and related substance use disorders, and promotes awareness that one source of these drugs is often the household 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>25</sup> These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of March 2018, approximately 3,812 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 April 28, 2018. As a result of all 15 National Take Back Days, DEA, in conjunction with its State, local, and tribal law enforcement partners, has removed a total of 9.02 million pounds (4,508 tons) of medications from circulation. DEA also hosted another successful Capitol Hill Take-Back Day on April 25, 2018.

## Automated Reporting and Consolidated Orders System (ARCOS) Data

ARCOS reporting is required by 21 U.S.C. §827(d)(1) and applicable DEA regulations. Manufacturers and distributors of Schedule I, II, or III narcotic controlled substances (and Gamm-Hydroxybutyric acid, known as “GHB”) must report the manufacture, sale, purchase, loss, or other disposition of these controlled substances (e.g., a manufacturer’s sales to distributors; a distributor’s sales to pharmacies, hospitals/clinics, and doctors). DEA’s Diversion Control Division has taken numerous steps to examine sales and monitoring processes in ARCOS. For example, Diversion Control utilizes various reports and records to monitor trends or determine anomalous transactions, which can then be developed into investigative leads. A unit within the Diversion Control’s Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit prepares regular threat assessment reports for each of DEA’s 22 Field Divisions to prioritize DEA resources in furtherance of criminal, civil, and regulatory investigations. Additionally, DEA is working on enhancements to the ARCOS system, which will require those entities submitting data to ARCOS to fix any transaction errors in order for the report to be accepted. This will help the ARCOS system to capture more accurate data and provide a more “real-time” snapshot of the flow of controlled substances

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<sup>25</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/>.

within the drug supply chain. Finally, as highlighted by the signed memorandums of understanding announced April 17, 2018, DEA is working collaboratively with a coalition of States Attorneys General to provide non-public, law enforcement sensitive ARCOS data to support their active investigations against certain manufacturers and distributors.

### Suspicious Order Reports (SORs)

Since the enactment of the CSA in 1970, all DEA registrants who distribute controlled substances have a statutory duty to “maintain effective controls against diversion” of controlled substances into other than legitimate medical, scientific, and industrial channels. The first regulations implementing the CSA in 1971 contained a provision regarding “suspicious orders of controlled substances.” This provision, which has remained essentially unchanged since 1971, currently appears in 21 CFR § 1301.74(b) and reads as follows: “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

These reports are currently fielded and verified by DEA personnel and can be used as a tool to identify and pinpoint vulnerabilities throughout the closed system of drug distribution. Since 2010, DEA has found that certain distributors were not adequately following their internal controls or not reporting suspicious orders. Through negotiated settlements involving civil penalties and compliance agreements and other means, DEA has worked with DEA-registered manufacturers and distributors to strengthen suspicious order monitoring and reporting. DEA is also exploring ways to require suspicious orders to be submitted to a central database. Centralized reporting would provide for a more efficient review, dissemination, and investigation of suspicious activity.

In addition, we have launched a new tool within the ARCOS system to assist drug manufacturers and distributors with their regulatory obligations under the CSA. The tool will allow a distributor (or manufacturer) to enter the DEA registration number of a prospective purchaser (e.g., pharmacy, hospital, doctor, etc.) as well as a drug code for the controlled substance the buyer wishes to purchase and the ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last 6 months. This new query application will help distributors identify red flags indicative of suspicious orders.

Finally, DEA Diversion Control urges DEA registrants and the public at large to “submit a tip” regarding possible CSA violations, including: illicit drug distribution or trafficking; suspicious online pharmacies selling controlled substances over the internet; and the illegal sale and distribution of a prescription drug by individuals, including doctors and pharmacists. These tips are submitted to a DEA Field Division for prompt action by either a DEA Special Agent or a professional staff member. These tips are submitted through DEA’s Diversion Control website ([https://www.deadiversion.usdoj.gov/tips\\_online.htm](https://www.deadiversion.usdoj.gov/tips_online.htm)). DEA also maintains a telephone hotline

(877-RxABUSE) for the community to submit tips which may establish leads relating to the potential diversion of controlled substances.

### Tactical Diversion Squads

DEA Tactical Diversion Squads (TDS) investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., “doctor shoppers,” prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and May 2018, DEA increased the number of operational TDSs from 37 to 77. In addition, DEA established two mobile TDS that can deploy quickly to “hot spots” around the country in furtherance of the Diversion Control Division’s mission.

### Production Quotas for Schedule II Opioids

The Diversion Control Division is responsible for setting Aggregate Production Quotas (APQs) every year. These APQs are the “total quantity of each basic class of controlled substance listed in Schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.”<sup>26</sup> Since 2014, DEA has observed a decline in prescriptions written for certain Schedule II opioids. These declines have led to overall reductions in licit demand which in turn, have directly impacted the factors DEA considers when establishing the APQs for Schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous year’s (2016) level. Last year, DEA announced a nearly 20 percent reduction in the 2018 APQs (from the 2017 levels) for controlled substances, and these reductions included the aforementioned opioids as well as oxycodone, codeine, and meperidine. These decreases can be attributed to combined local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the CDC *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. In addition, DEA is encouraged that more states have enacted and are enforcing laws mandating the use of PDMPs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

On March 1, 2018, the Department of Justice (the Department) announced that Attorney General Sessions issued a memo directing DEA to evaluate and consider amending its regulations governing the APQ. The Diversion Control Division worked to identify potential areas to amend DEA’s regulations in order to make improvements in the quota setting process. On April 19, 2018, DEA published in the Federal Register a Notice of Proposed Rulemaking

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<sup>26</sup> 21 CFR 1303.11(a)

(NPRM) that would affect its limits on annual opioid production. Under this NPRM, DEA's quota setting process would consider the extent that a drug is diverted for abuse when it sets its annual APQ. DEA would also consider information other than its own ARCOS data, including information from the Department of Health and Human Services, the Food and Drug Administration, CDC, Medicare and Medicaid, and the states. The public comment period concluded on May 4, 2018. DEA is evaluating all comments as it proceeds in the regulation drafting process.

### DEA's 360 Strategy

To counter the opioid crisis, DEA initiated and continues to expand upon its 360 Strategy. The strategy leverages existing Federal, State, local, and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and demand reduction. Our domestic enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding the heroin and prescription drug epidemic in our communities. We are also enhancing our diversion control efforts and working with community partners for them to implement evidence-based programs and efforts designed to reduce demand and to prevent the same problems from resurfacing.

As part of the 360 Strategy, DEA recently partnered with Discovery Education, a division of Discovery Communications, to develop and distribute, Operation Prevention, a prescription opioid and heroin education curriculum, to middle and high school students, their teachers, and parents. Since its implementation in 2016, the 360 Strategy has been implemented in eight cities across the nation and DEA is expanding this program to additional locations in 2018, including Salt Lake City, Utah; North and South New Jersey; and Philadelphia, Pennsylvania. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

## **NEW THREATS – 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>27</sup> Over the past several years, DEA has identified numerous illicit 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. 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. Sadly, these

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<sup>27</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.

substances are often first discovered when DEA receives reports from local hospitals and coroners in connection with a spate of overdoses. For example, before scheduling the synthetic cannabinoid MAB-CHMINACA, DEA received reports of overdose clusters attributed to this substance in Shreveport, Louisiana; Bryan, Texas; Beaumont, Texas; Hampton, Virginia; Hagerstown, Maryland; and multiple cities in the State of Mississippi, totaling over 2000 overdoses and at least 33 deaths.<sup>28</sup> 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 as little as several weeks. Unfortunately, the existing process to temporarily schedule a substance is reactionary and not agile enough to keep up with bad actors engineering illicit substances for the express purpose of skirting our laws. Illicit manufacturers and distributors have and 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. 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.

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

Illicit 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 both 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 the technological and logistical challenges of detection and inspection, makes it extremely challenging for U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement, Homeland Security Investigations (HSI), and the U.S. Postal Inspection Service (USPIS) 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, HSI, and USPIS, 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

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<sup>28</sup> See DEA, SCHEDULES OF CONTROLLED SUBSTANCES: TEMPORARY PLACEMENT OF THE SYNTHETIC CANNABINOID MAB-CHMINACA INTO SCHEDULE I, [https://www.dea.gov/divisions/office-of-regulatory-affairs/rules-and-regulations/2016/fr0205\\_2.htm](https://www.dea.gov/divisions/office-of-regulatory-affairs/rules-and-regulations/2016/fr0205_2.htm)

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. 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. 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>29</sup> during which time the interagency conducts the below mentioned scientific review for permanent placement under the CSA.<sup>30</sup> The acquisition of data to underpin temporary emergency scheduling is in many cases a reactionary, time-consuming process which often relies heavily on actual evidence of harm to the public.

The an interagency process for permanently scheduling a substance under the CSA requires analysis based on the following eight enumerated scientific factors:<sup>31</sup> (1) the state of current scientific knowledge about the substance; (2) its pharmacological effect; (3) its risk to the public health; (4) its psychic or psychological dependence liability; (5) whether the substance is an immediate precursor of a controlled substance; (6) its actual or relative potential for abuse; (7) its history or current pattern of abuse and its scope; and (8) the scope, duration, and significance of use. In this process, the Secretary of Health and Human Services (HHS) is responsible for any scientific and medical considerations about a substance and the DEA Administrator considers a recommendation made by the HHS Secretary 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.

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 New Psychoactive Substances (NPS).

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

### *China: Government Action and Cooperation*

Combatting 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 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 in Washington, D.C. on October 3 and October 4, 2017.

The Attorney General and the Deputy Attorney General's efforts are built on long-standing bilateral 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

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<sup>29</sup> The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).

<sup>30</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>31</sup> The eight factors are enumerated in 21 U.S.C. § 811(c).

well-established relationship with Chinese drug control authorities is a significant bi-lateral mechanism to address the threat resulting 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 their counterpart at the Chinese Ministry of Public Security, and second, the U.S.-China Joint Liaison Group (JLG) on Law Enforcement a sub-ministerial group co-chaired by the Department, the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, and the Department of Homeland Security. At the working level, DEA and the NCB participate in the Counter Narcotics Working Group (CNWG) within the JLG framework that are chaired, respectively, by the Department and DEA on the U.S. side and the Ministry of Public Security on the Chinese side.

Engagement in the efforts mentioned above has resulted in positive actions by the Government of China over the last year. These actions are a step in the right direction, but we can do more collectively.

Since 2014, the Department, DEA, and Chinese officials have met regularly to discuss bilateral efforts to counter the threat posed 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 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 the next meeting to take place in Beijing in June 2018.

A key moment which demonstrates enhanced collaboration 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.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls against four fentanyl-class substances: carfentanil; furanyl fentanyl; valeryl fentanyl; and, acryl fentanyl. This announcement was the culmination of ongoing collaboration between the Department and the Government of China, and reaffirms an expanding bi-lateral collaborative commitment to countering illicit fentanyl. On July 1, 2017, China controlled 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. In total, China has scheduled 143 different NPS.

On December 28, 2017, China’s Ministry of Public Security announced scheduling controls on two fentanyl precursor chemicals, NPP and 4-ANPP, to comply with the UN Convention on Narcotic Drugs decision in March 2017—at the behest of the United States—to impose international controls on the precursors. The scheduling controls took effect on February 1, 2018. Chinese control of these substances, and the effect that prior control efforts have had 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.

In 2018 and moving forward, 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 abuse 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.

Additionally, two Chinese nationals were indicted and designated as Consolidated Priority Organization Targets (CPOTs) in September of 2017, for their conspiracy to distribute fentanyl and fentanyl analogues in the United States and their role in an international money laundering conspiracy. In Late April 2018, these two CPOTs were given an Office of Foreign Assets Control (OFAC) designation. The OFAC of the U.S. Department of the Treasury administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, and other threats to the national security, foreign policy or economy of the United States.<sup>32</sup> It is anticipated that these designations will deter and disrupt the financial activities and money laundering actions utilized by Chinese TCOs. As the opioid threat continues, the Department and DEA are committed to working with Chinese officials through its well-established bilateral efforts, including: liaison presence; the JLG/CNWG; the BDIWG; and enhancing collaboration with DEA’s interagency partners stationed abroad and in the United States.

## **SIGNIFICANT ENFORCEMENT EFFORTS**

### *Heroin Fentanyl Task Force*

The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) working group consists of several agencies using a joint “whole of government” approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, HSI and CBP; supplemented by the Federal Bureau of Investigation (FBI) and USPIS. 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, the U.S. Department of Defense (DOD), the Intelligence Community (IC) and

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<sup>32</sup> U.S. Department of the Treasury Office: The Office of Foreign Assets Control <https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> retrieved April 26, 2018.

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 the first-ever indictment, in two separate OCDETF cases, of two Chinese nationals responsible for the manufacturing and distribution of illicit fentanyl in the United States in October 2017. On October 17, 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 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 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 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 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.

### Heroin-Fentanyl Enforcement Teams

As part of the Consolidated Appropriations Act of 2017 (P.L. 115-31) enacted appropriation, DEA has created six new heroin-fentanyl enforcement teams to combat trafficking in heroin, fentanyl, and fentanyl analogues. The establishment of the teams began this past January and they will be located in some of the regions that have been 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 several sets of seizure linkages tying separate cases and seizures together.

## **CONCLUSION**

The United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of opioid prescribing and misuse. DEA can and must do better and will continue to use all criminal, civil, 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. DEA expects that demand for illicit opioids will continue to be met in part by Mexican-based TCOs that produce high purity heroin, which is being laced with fentanyl, fentanyl analogues, and other synthetic opioids, and then pressed into counterfeit pills. DEA will continue to address this threat by pursuing these TCOs, which have brought tremendous harm to our communities. Working with the Department and our interagency partners, DEA will continue to engage our international counterparts, especially China and Mexico. We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by controlled prescription drugs, heroin, illicit fentanyl, and other synthetic opioids.