



Department of Justice

STATEMENT OF

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BEFORE THE

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

FOR A HEARING ENTITLED

**THE DRUG ENFORCEMENT ADMINISTRATION'S ROLE IN
COMBATING THE OPIOID EPIDEMIC**

PRESENTED

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Statement of Robert W. Patterson
Acting Administrator
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Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
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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 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.¹ 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.²

The misuse of CPDs and the growing use of heroin, 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 past month.³ 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.⁴ There are more current misusers of psychotherapeutic drugs than current users of cocaine, heroin, and hallucinogens combined.⁵

¹ Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.

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

³ 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/>.

⁴ 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/>.

⁵ 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/>.

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.⁶ More alarming is the proliferation of illicit fentanyl and its analogues. DEA investigations reveal that fentanyl and its analogues are increasingly being added to heroin and frequently pressed into counterfeit tablets resembling CPDs. Because of its high potency, the more illicit fentanyl and related analogues are introduced to the 11.5 million people that misused a pain reliever in the previous year, the more likely that drug overdoses will continue to climb.⁷

CONTROLLED PRESCRIPTION DRUGS

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.⁸ 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, this information provides valuable insight into the role that CPDs play in the opioid epidemic and underscores the need for a robust regulatory program that seeks to stop diversion of CPDs.

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)⁹ 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.¹⁰

HEROIN

The vast majority of heroin consumed in the United States is produced by powerful Mexico-based transnational criminal organizations (TCOs), such as the Sinaloa Cartel and New

⁶ 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

⁷ 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

⁸ 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/>.

⁹ 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.

¹⁰ 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/>.

Generation Jalisco Cartel, and transported to the United States across the Southwest Border. These TCOs are extremely dangerous, violent, 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.¹¹

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.¹² 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 opioid in the product they purchase on the street as heroin.¹³ Additionally, varying concentrations found in diverted or counterfeit prescription opioids purchased on the street have led to increased unintentional drug overdose deaths.

A report published by SAMHSA analyzing data through 2011 found that four out of five recent new heroin users had previously misused prescription pain relievers.¹⁴ 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 2010.¹⁵ 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.

¹¹ 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.

¹² U.S. Department of Justice, Drug Enforcement Administration, 2014 National Drug Threat Assessment Summary, November, 2014.

¹³ 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: 10.1016/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.

¹⁴ Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Department of Health and Human Services, August 2013, *available at*: <https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm>

¹⁵ 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>.

FENTANYL AND FENTANYL ANALOGUES

Fentanyl is a Schedule II controlled substance produced in the United States and widely used in medicine. It is an extremely potent analgesic used for anesthesia and pain control in people with serious pain problems and in such cases, it is 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. heroin supply domestically, 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 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.

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.¹⁶ During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,¹⁷ 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 analogs, and tramadol) doubled between 2015 and 2016, from 3.1 to 66.2 per 100,000).¹⁸

FLORIDA'S PILL MILLS – START OF THE PROLIFERATION OF CPDs

Between 2005 and 2009, Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into United States illicit markets. During this time, the diversion of millions of dosage units of hydrocodone products was facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing internet sites.¹⁹ *The Ryan Haight Online*

¹⁶ U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.

¹⁷ U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.

¹⁸ 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>.

¹⁹ The final rule rescheduling hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act was published in the Federal Register on August 22, 2014, and became effective on October 6, 2014. 79 FR 49661.

Pharmacy Consumer Protection Act (P.L. 110-425) took effect in April of 2009, combined with intensified law enforcement and regulatory actions, virtually eliminated the threat posed by domestic rogue internet pharmacies.

As the number of domestic internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics or “pill mills,” particularly in Florida.²⁰ In 2009, there was a high concentration of pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties). According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state, and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. After obtaining controlled prescription drugs, these individuals would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and Midwest.

WEST VIRGINIA

During this same timeframe, some DEA-registered practitioners in West Virginia turned their practices into pill mill operations, indiscriminately writing prescriptions for opioids. One pill mill operation in Kermit, West Virginia, was highlighted in a 2016 article published by the *Charleston Gazette-Mail* in which roughly nine million opioid pills were sent over the course of two years to a town with a population of 392 people.²¹ DEA, along with its Federal, State, local, and tribal partners, identified the individuals involved in violations of the Controlled Substances Act (CSA) and worked with the U.S. Attorney’s Office for the Southern District of West Virginia to arrest several individuals, all of whom were sent to jail for their crimes. Stemming from the same operation, DEA and its State and local counterparts took action taken against the Sav-Rite Pharmacy in Kermit, including the arrest of the owner and forfeiture of more than \$400,000.

Unfortunately, West Virginia continues to be the State with the highest rate of death due to drug overdoses with 52 overdose deaths per 100,000 population in 2016.²² Consequently, DEA has devoted additional resources to West Virginia by increasing its presence in the State. In 2016, DEA established an Assistant Special Agent in Charge position in Charleston, West Virginia. A senior level manager now oversees the entire State from the State’s capital, rather than Washington, DC. Additionally, in 2016 DEA added a second Tactical Diversion Squad (TDS) in Clarksburg and in 2017 DEA headquarters deployed one of its two “mobile” TDS groups to West Virginia. These groups pursue criminal investigations against those who traffic CPDs. In 2018, DEA is deploying six new heroin enforcement teams focused on

²⁰ In addition, the amount of heroin seized at the South West border increased over 300 percent from 2008 to 2013.

²¹ https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html, retrieved March 7, 2018.

²² Hedegaard H, Warner M, Minino AM. Drug overdose deaths in the United States, 1999 – 2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017/CDC.

combatting the flow of heroin and illicit fentanyl. The enforcement teams will be based in communities facing significant challenges with opioids, including Charleston, West Virginia, and five additional locations.

DEA has also established a new Field Division in Louisville. This office covers Kentucky, Tennessee, and West Virginia and will enhance DEA enforcement efforts within the Appalachian mountain region and unify drug trafficking investigations under a single Special Agent in Charge. DEA anticipates that this change will produce more effective investigations on heroin, fentanyl, and prescription opioid trafficking, all of which have a significant impact on the region. The division will also better align DEA with the U.S. Attorney's Office districts in those areas, similar to current Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Federal Bureau of Investigation (FBI) offices, and also with the Appalachia High Intensity Drug Trafficking Areas Program. Funded by the White House Office of National Drug Control Policy (ONDCP).

DEA LESSONS LEARNED AND RESPONSE TO THE PROLIFERATION OF CPDs

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 (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 A, and other groups to address diversion problems and educate the medical community on improving prescribing practices.²³ 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 May 2018, DEA will initiate 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 doctors nationwide alerting them of the CDC's recommendations for opioid prescribing for acute pain and alerted practitioners of 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

²³ In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

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 disorder.

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 50th, pursuant to the Governor's Executive Order in July 2017. 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.²⁴

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. CDC supports states to advance interventions for preventing prescription drug overdoses, through its *Prevention for States* program, which could include activities focused on improving interoperability between PDMPs and Electronic Health Record (EHR) technology and provide real-time provider access. The Indian Health Service (IHS) developed a policy that requires federal IHS facilities to report all controlled substance prescriptions to their respective State PDMPs and requires federal prescribers to check State PDMPs prior to prescribing opioids for a period longer than seven days. Forty-four states²⁵ are currently able to exchange prescription data between certain states. In some instances, data sharing may be limited to a single neighboring state. In other instances, data sharing may span states within a specific region. There are currently two interstate data sharing hubs in operation: RxCheck, BJA's open standards solution developed and operated in partnership by the IJIS Institute (IJIS) with funding from BJA; and PMP Interconnect (PMPi), a proprietary solution operated by NABP. As of August 2017, nine states are live or are implementing interstate data sharing using both hubs, 36

²⁴ PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf retrieved March 6, 2018.

²⁵ States with the capacity to participate in interstate data sharing include Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, New York, North Dakota, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Wisconsin, West Virginia.

states are live or are implementing interstate data sharing using the PMPi hub only, and 4 states are live or are implementing interstate data sharing using the RxCheck hub only.

Federal partners are working to address the interoperability. Brandeis University's PDMP Training and Technical Center, funded by BJA, has assisted the IHS to improve interoperability between IHS, its pharmacies and PDMPs. The BJA currently provides funding to 30 states through the *Harold Rogers PDMP program* for PDMP implementation or enhancements or enhanced data sharing, including interstate data sharing. CDC supports work 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 and Federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data.

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.²⁶ These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of March 2018, 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 October 25, 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 a total of 9.02 million pounds (4,508 tons) of medications from circulation. The DEA's next National Take Back Day is scheduled for April 28, 2018.

²⁶ 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/>.

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 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 within the drug supply chain. Finally, DEA is working collaboratively with a coalition of 41 States Attorneys General and a second coalition of 7 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 ensure that suspicious orders would 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 (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 Divisions 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). 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 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 present, 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.”²⁷ 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

²⁷ 21 CFR 1303.11(a)

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 years' (2016) level. In late 2017, 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 oxymorphone, 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, we are encouraged that more states have enacted and enforced laws mandating the use of PDMPs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

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 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 a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide deployment of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to “kick start” life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. This program will run for at least three consecutive school years (through spring 2019) and is free for all law enforcement, prevention, treatment, and community groups to use and distribute. As of February 2018, the program has reached more than 2.1 million students.

Since its implementation in 2016, the 360 Strategy has been implemented in eight cities—Louisville, Kentucky; St. Louis, Missouri; Pittsburgh, Pennsylvania; Milwaukee, Wisconsin; Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia; and Manchester, New Hampshire. DEA is expanding this program to additional locations including Salt Lake City, Utah and New Jersey in 2018. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

CONCLUSION

The United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of misuse of prescription opioids. 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 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 DOJ and our interagency partners, DEA will continue to engage our international counterparts, especially China. We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by controlled prescription drugs, heroin, fentanyl, and other synthetic opioids.