



# Department of Justice

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**STATEMENT OF**  
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**ACTING ASSISTANT ADMINISTRATOR**  
**DIVERSION CONTROL DIVISION**  
**DRUG ENFORCEMENT ADMINISTRATION**

**BEFORE THE**  
**JUDICIARY COMMITTEE**  
**UNITED STATES SENATE**

**FOR A HEARING ENTITLED**  
**OVERSIGHT OF THE ENSURING PATIENT ACCESS AND EFFECTIVE**  
**DRUG ENFORCEMENT ACT**

**PRESENTED**  
**DECEMBER 12, 2017**

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**Statement of  
Demetra Ashley  
Acting Assistant Administrator  
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**Before the  
Judiciary Committee  
U.S. Senate**

**For a Hearing Entitled  
“Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act”**

**December 12, 2017**

Chairman Grassley, Ranking Member Feinstein, 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 Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDA) and its relationship to the current opioid epidemic. The over-prescribing and abuse 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 initial estimates provided by the Centers for Disease Control and Prevention (CDC), there were more than 64,000 overdose deaths in 2016 or approximately 175 per day. Over 34,500 (54 percent) of these deaths were caused by prescription opioids, fentanyl or fentanyl analogues.<sup>2</sup> The sharpest increase in drug overdose deaths from 2015 to 2016 was fueled by a surge in fentanyl and fentanyl analogue (synthetic opioids) overdoses.<sup>3</sup>

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.<sup>4</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, a report published by SAMHSA found that four out of five recent new heroin users had previously misused prescription pain relievers.<sup>5</sup> This information provides valuable insight into the role that CPDs play in the opioid

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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> <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>

<sup>3</sup> CDC WONDER data, retrieved from the National Institute of Health website; <http://www.drugabuse.gov> as reported on NIDA’s website.

<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, *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> . Also see Compton WM, Jones CM, Baldwin GT. “Relationship between Nonmedical Prescription-Opioid Use and Heroin Use”. *New England Journal of Medicine*, 2016 Jan 14, available at: <http://www.nejm.org/doi/full/10.1056/NEJMra1508490?rss=mostEmailed&#t=articl>

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)<sup>6</sup> can be purchased for \$5 to \$7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen 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. As addiction and tolerance increase, the costs of these drugs make it difficult to support a growing substance use disorder, and unfortunately, these constraints may drive individuals to cheaper heroin and/or fentanyl.

## DEA RESPONSE TO THE OPIOID EPIDEMIC

With four out of five new heroin initiates reporting that they previously misused prescription pain relievers,<sup>7</sup> the efforts of DEA’s Diversion Control Division have never been more critical. The DEA has a wide array of tools to ensure its more than 1.7 million registrants are in compliance with the Controlled Substances Act. These include outreach to industry, medication disposal, regulatory oversight, administrative actions, civil penalties, and criminal charges, among others. DEA has and will continue to use all available tools to combat the opioid epidemic.

### Outreach to Industry

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), and other groups to address diversion problems and educate the medical community on improving prescribing practices.<sup>8</sup> As of November 2017, DEA has hosted 100 PDACs in all 50 states (and the District of Columbia and Puerto Rico) resulting in the training of more than 13,300 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In 2018, DEA will initiate a nationwide program to offer similar training to individual practitioners.

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<sup>6</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>7</sup> 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> . Also see Compton WM, Jones CM, Baldwin GT. “Relationship between Nonmedical Prescription-Opioid Use and Heroin Use”. *New England Journal of Medicine*, 2016 Jan 14, available at: <http://www.nejm.org/doi/full/10.1056/NEJMr1508490?rss=mostEmailed&#t=articl>

<sup>8</sup> In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

## Medication Disposal

On September 9, 2014, DEA issued a final rule, titled “Disposal of Controlled Substances.” These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail-back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free.<sup>9</sup> These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of November 30, 2017, 2,948 DEA registrants have become “authorized collectors.”

Since 2010, DEA has held its National Drug “Take Back” Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA’s most recent NTBI was held on October 28, 2017, which collected a record-setting 912,305 pounds—456 tons—of potentially dangerous expired, unused, and unwanted prescription drugs for disposal at more than 5,300 collection sites. As a result of all 14 National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed over 9 million pounds (4,508 tons) of medications from circulation. The fifteenth National Drug Take Back Day is scheduled for April 28, 2018.

## 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 their organization and operation varies according to state law, including who can access information contained in the PDMP database. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly supports 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, and the Governor of Missouri signed an Executive Order in July 2017 directing work to begin creating a PDMP in that state. As of August 2017, 24 of the 49 states with operational PDMPs 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>10</sup> The DEA encourages all practitioners and pharmacists to use their state PDMPs.

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<sup>9</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>10</sup> PDMP Center of Excellence, Brandeis University. [http://www.pdmassist.org/pdf/Mandatory\\_Query\\_Conditions\\_20170824.pdf](http://www.pdmassist.org/pdf/Mandatory_Query_Conditions_20170824.pdf) retrieved October 19, 2017.

### Production Quotas for Schedule II Opioids

The Diversion 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>11</sup> The APQs are determined after consideration of certain statutory factors, described in 21 C.F.R. § 1303.11 (b), which includes:

1. Total net disposal (e.g., domestic sales, exports, waste) of the substance by all manufacturers during the current and two preceding years;
2. Trends in the national rate of net disposal of the substance; Total actual (or estimated) inventories of the substance and of all substances manufactured from that substance, and trends in inventory accumulation;
3. Projected demand as indicated by procurement quotas requested in accordance with DEA regulations; and
4. Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

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 years’ (2016) level. In August 2017, DEA proposed a nearly 20 percent reduction in the 2018 APQs (from the 2017 levels) for controlled substances and these reductions include 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 Centers for Disease Control and Preventions *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. Also, we are encouraged that more states have enacted and enforced laws mandating the use of prescription drug monitoring programs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

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<sup>11</sup> 21 CFR 1303.11(a)

### DEA'S 360 Strategy and Operation Prevention

To counter the opioid crisis, DEA continues to expand its 360 Strategy, a comprehensive three-pronged approach tackling the cycle of violence and addiction generated by the link between drug cartels, violent gangs, and the rising problem of prescription opioid misuse and heroin use in U.S. cities. The 360 Strategy features: coordinated law enforcement actions against drug cartels and heroin traffickers in specific communities; diversion actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners; and community outreach through local partnerships that empower communities to take back affected neighborhoods after enforcement actions and prevent the same problems from cropping up again. In 2016, DEA implemented its 360 strategy in Louisville, Kentucky, Milwaukee, Wisconsin, St. Louis, Missouri, and Pittsburgh, Pennsylvania. In 2017, DEA implemented its strategy in Dayton, Ohio, Albuquerque, New Mexico, Charleston, West Virginia, and Manchester, New Hampshire. In 2018, we are implementing this program in Salt Lake City, Utah, as well as other cities yet to be announced.

As part of the 360 Strategy, DEA has partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to elementary, middle and high school students, their teachers, and parents. This program named *Operation Prevention*<sup>12</sup> was deployed in 2016 with the goal of educating 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 and is also available in Spanish. *Operation Prevention* has reached more than 1.6 million students in all 50 States and seven foreign countries. It will run for at least three consecutive school years (through spring 2019) and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

### Significant Enforcement Efforts

In addition to the actions of the Diversion Division, DEA continues to aggressively combat the opioid epidemic through a variety of enforcement and partnership efforts. The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint “whole of government” approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Customs Enforcement Homeland Security Investigations (HSI) and Customs and Border Protection (CBP); supplemented by the Federal Bureau of Investigation (FBI) and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the Department of Justice’s Organized Crime Drug Enforcement Task Forces (OCDETF) Fusion Center (OFC) and Criminal Division, the Department of Defense (DOD), Intelligence Community (IC) and other government entities, and provides field offices (all agencies) with valuable support in their respective investigations.

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<sup>12</sup> [www.operationprevention.com](http://www.operationprevention.com)

These relationships have led to several large enforcement actions including the first-ever indictment of two Chinese nationals responsible for the manufacturing and distribution of illicit fentanyl in the United States in October 2017. In addition, SOD played an integral role in the July 2017 seizure of the largest criminal marketplace on the Internet, AlphaBay, which 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. The interagency investigation into AlphaBay revealed that numerous vendors sold illicit fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

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

DEA's Diversion Control Division has also taken numerous steps to examine sales and monitoring processes. 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 is now proactively preparing quarterly threat assessment reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil and regulatory investigations. DEA is working collaboratively with a coalition of 41 States Attorneys General to provide non-public, law enforcement sensitive ARCOS data to support their active investigations against certain manufacturers and distributors.

#### Diversion Enforcement Actions

DEA uses a wide array of diversion enforcement tools to ensure its more than 1.7 million registrants are in compliance with the Controlled Substances Act. These include administrative actions, civil penalties, and criminal charges. Within DEA's administrative authorities, there are multiple actions which may lead to an individual or entity having a registration revoked, which include orders to show cause (OTSC), immediate suspension orders (ISO), and voluntary surrenders. Upon a registrant surrendering a registration for cause, or DEA obtaining a suspension/revocation of the registration, the registrant can no longer dispense, prescribe or administer controlled substances. Since FY 2011, these combined actions result in an average of roughly 980 registration revocations per year. Of the total registration revocations, ISOs have historically made up a small portion, averaging less than three percent annually. Additionally, combined ISO and OTSC actions in 2017 have more than doubled since 2014.

Since 2010, DEA has re-prioritized its criminal investigators and embedded them with diversion investigators into enforcement groups called tactical diversion squads (TDS). TDSs investigate suspected violations of the Controlled Substances Act (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 groups that can deploy quickly to “hot spots” in furtherance of the Diversion Control Program’s mission. For example, one mobile TDS team recently deployed to Charleston and Clarksburg, West Virginia. Each of these groups focuses primarily on criminal enforcement and the results of their work often lead DEA registrants to surrender their DEA registration for cause. Over the last seven years, these TDS groups have initiated an average of more than 1,500 cases per year and made an average of more than 2,000 arrests per year.

## **ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT**

The United States is currently facing a opioid epidemic. One of the DEA’s most critical missions in the fight to address this crisis is to prevent and combat the diversion of controlled substances. Congress designed the Controlled Substances Act to give DEA the ability to issue ISOs to suspend a registration in those instances when DEA concludes that the continued registration represents an imminent danger to public health or safety or the registrant fails to comply with statutory control standards. The “Ensuring Patient Access and Effective Drug Enforcement Act of 2016” (EPAEDA or the Act), by defining “imminent danger,” conditioned the issuance of an ISO on a determination that there is a “substantial likelihood of an immediate threat of death, serious bodily harm, or abuse of a controlled substance” due to the failure of the registrant to maintain effective diversion controls.

DEA issued 104 ISOs between FY2011 and FY2012, with all but four being issued against practitioners (doctors, nurse practitioners, physicians assistants, etc.) and pharmacies. Those actions were largely attributed to significant efforts to combat pill mills in Florida through a major operation dubbed *Operation Pill Nation*. The number of ISOs issued in FY2011 and FY2012 were seen as atypical by historical DEA data. For example, in FY2014, DEA issued eight ISOs and issued five in FY2015. ISOs are an important tool for DEA. However, the number of ISOs alone should not be deemed the sole metric for the success (or failure) of the DEA’s Diversion Control Division. There are many criminal, civil, and administrative tools by which DEA takes action against registrants that are not in compliance with the CSA.

EPAEDA did not have the effect of eliminating DEA’s authority. However, it has altered the manner in which DEA pursues ISOs. Pursuant to the law, DEA will pursue an ISO in those circumstances when it can make a finding that demonstrates that “[d]ue to the failure of the registrant to . . . comply with the obligations of a registrant under this title . . . there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the Registration.” Utilizing this statutory definition, DEA has issued nine ISOs against certain practitioners and pharmacies since the bill’s passage into law.

In addition, the EPAEDA altered the process by which DEA seeks to revoke a registration through an OTSC. Based on statutory changes to the CSA resulting from the EPAEDA, when DEA advises the registrant of the legal basis for issuing the OTSC, the registrant is now afforded the

opportunity under EPAEDA to submit a corrective action plan (CAP). Upon review of the CAP, the DEA<sup>13</sup> shall determine whether denial, revocation or suspension proceeding should be discontinued or deferred. A registrant has always had the opportunity to present mitigating factors and evidence of corrective action as part of any proceeding prior to any DEA action and, as a consequence, the CAP results an additional layer to an existing process. In the 100 OTSCs that DEA has issued since passage of the EPAEDA, 11 registrants have submitted a CAP and DEA has not discontinued or deferred its action against any of those registrants.

Ultimately, DEA's role is to enforce the law, and DEA will continue to use the totality of its administrative, civil, and criminal enforcement actions to prevent diversion and ensure compliance with the Controlled Substances Act. We would be happy to work with the Committee in its activities to enhance these efforts.

The DEA needs every tool it can get to combat the opioid crisis. DEA supports changing the Ensuring Patient Access and Effective Drug Enforcement Act, to allow DEA to more effectively stop bad actors from engaging in opioid diversion. We are dealing with very dangerous drugs that can result in addiction and even death. That being said, it is necessary that we accurately inform manufacturers, distributors, and sellers of what they are expected to do to be in compliance with their regulatory responsibilities.

As we move forward, we recognize the importance of working with registrants – not just at workshops and conferences – but in writing that they can count on – to provide them all the information and, especially, the certainty that they need to be in full compliance, as they want to be and as we expect them to be. We look forward to working with members of this committee as we move forward.

## **CONCLUSION**

The United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of abuse of prescription opioids. DEA's Diversion Control Division will continue to use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by controlled prescription drugs, heroin, and fentanyl.

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<sup>13</sup> Delegated to the DEA.