



**Office of the Inspector General**  
U.S. Department of Justice

**OVERSIGHT ★ INTEGRITY ★ GUIDANCE**



**Review of the Drug Enforcement  
Administration's Regulatory and  
Enforcement Efforts to Control the  
Diversion of Opioids**

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# Executive Summary

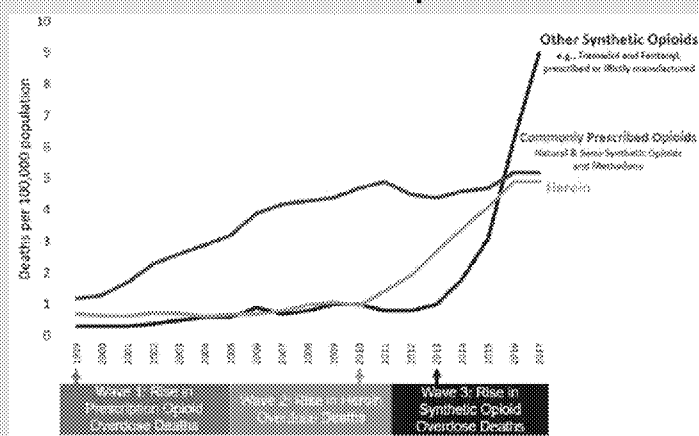
## Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids

### Introduction

In this review, the Office of the Inspector General (OIG) examined the regulatory activities and enforcement efforts of the Drug Enforcement Administration (DEA) from fiscal year (FY) 2010 through FY 2017 to combat the diversion of opioids to unauthorized users. According to the Centers for Disease Control and Prevention (CDC), as of 2017 in the United States more than 130 people die every day from opioid overdose. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose. The misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl, has led to a national crisis that affects not only public health, but also the social and economic welfare of the country. As a result, in October 2017 the White House declared the opioid epidemic a public health emergency.

Figure 1

### The Three Waves in the Rise of Opioid Overdose Deaths



Source: CDC National Vital Statistics System Mortality File

DEA enforces Titles II and III of the Controlled Substances Act of 1970 (CSA), which require importers, exporters, manufacturers, distributors, dispensers, and healthcare practitioners that handle controlled substances, collectively known as registrants, to register with DEA. DEA's Office of Diversion Control is responsible for ensuring that all controlled substance transactions take place within the closed system of distribution established by Congress. When controlled substance transactions fall outside the closed system of distribution, the activity constitutes diversion. Registrants that violate the CSA or its implementing regulations may be subject to DEA administrative enforcement actions or may face civil penalties or criminal prosecution by the U.S. Department of Justice (Department).

### Results in Brief

We found that DEA was slow to respond to the significant increase in the use and diversion of opioids since 2000. We also found that DEA did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively. Further, we found that DEA policies and regulations did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids. Lastly, we found that while the Department and DEA have recently taken steps to address the crisis, more work is needed.

#### *DEA Was Slow to Respond to the Dramatic Increase in Opioid Abuse and Needs to More Fully Utilize Its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances*

We found that the rate of opioid overdose deaths in the United States grew, on average, by 8 percent per year from 1999 through 2013 and by 71 percent per year from 2013 through 2017. Yet, from 2003 through 2013 DEA was authorizing manufacturers to produce substantially larger amounts of opioids. For example, the 2013 Aggregate Production Quota (APQ) of oxycodone in the United States, which DEA establishes annually, was over 400 percent of the 2002 APQ.\* It was not until 2017 that DEA significantly reduced the APQ for oxycodone, by 25 percent. In 2018, DEA further reduced the APQ for oxycodone by 6 percent.

We identified other areas in which DEA's regulatory and enforcement efforts could have been more effective in combating opioid diversion. First, DEA's preregistration process did not adequately vet all new applicants before DEA registration was granted. Second, we found that DEA has regulations that fail to assess the suitability of potential new registrants, which may prevent DEA from identifying registrants whose applications merit heightened scrutiny. Third, while electronic prescriptions can prevent prescription fraud in many instances, DEA has not taken steps to revise its regulations and require all prescribers to submit prescriptions electronically. Fourth, stringent DEA headquarters requirements for field divisions to complete their headquarters-assigned Diversion Control work plans left little room for targeting registrants suspected of diversion. Finally, beginning in 2013, DEA rarely used its strongest enforcement tool, the Immediate Suspension Order, to stop registrants from diverting prescription drugs and DEA continues to experience challenges in rendering timely final decisions in administrative actions against registrants for diversion and other alleged violations.

\* We revised this report to clarify the APQ increase from 2002 to 2013. See page 13 for more information.





# Executive Summary

## *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids*

### *Improved Data Systems Would Facilitate Better Detection of the Diversion of Pharmaceutical Opioids and New Opioid Analogues*

We found that DEA does not capture sufficient data to detect the diversion of opioids or emerging drug trends in a timely manner. DEA investigators rely on a number of databases, including the Automated Reports and Consolidated Orders System (ARCOS) and the Suspicious Order Reporting System (SORS), to identify emerging trends in diversion and drug abuse.

We found multiple deficiencies in ARCOS data. Specifically, because some registrants report ordering information to ARCOS on a monthly or quarterly basis, DEA often must wait a full year before ARCOS contains all of the ordering information DEA needs to fully analyze the data and develop leads and trends. In addition, ARCOS does not track the diversion of all pharmaceuticals, including some Schedule III and all Schedule IV and V opioids and other controlled substances. As a result, DEA cannot create ARCOS targeting packages for those drugs and is not tracking drugs, such as benzodiazepines, which are Schedule IV controlled substances often used in conjunction with opioids. Due to these deficiencies, we believe that DEA is ill-equipped to effectively monitor ordering patterns for all pharmaceutical opioids, which could enable the diversion of these prescription drugs and compromise public safety.

We also found that the SORS database, developed in 2008 to house suspicious order reports that federal regulations require manufacturers and distributors of controlled substances to send to DEA, is incomplete and therefore cannot be used effectively to detect diversion. We determined that this was due to the fact that most suspicious order reports are sent to DEA field divisions and that those reports are never uploaded into the SORS database. As a result, of the approximately 1,400 manufacturers and distributors required to report suspicious orders to DEA, the SORS database included reports from only the 8 manufacturers and distributors that had agreements with DEA to send such reports to DEA headquarters. When we asked DEA for records of suspicious orders reports sent to field divisions rather than headquarters, DEA was unable to locate them.

We did, however, find that DEA is currently working more closely with its federal partners, including the U.S. Department of Health and Human Services (HHS) and the HHS Office of Inspector General, to obtain the data it needs to identify diversion through Medicare billing records. Collaboration with federal partners also enhances DEA's data sharing capabilities, which facilitates data-driven oversight and improves

regulatory oversight. However, we also learned that DEA faces challenges accessing states' Prescription Drug Monitoring Programs (PDMP), which contain physician and patient prescription histories. The level of DEA access to PDMP data varies across states; however, if DEA had greater access to this information, while also ensuring protection of sensitive patient medical data, DEA could improve its ability to investigate registrants that may be diverting pharmaceutical opioids. Further, we found that DEA must continue to improve its information sharing with state and local medical and pharmacy boards to ensure that all parties are aware of enforcement actions against registrants that may have violated conditions of their state licenses or registrations.

### *The Department and DEA Have Taken Steps to Address the Opioid Epidemic as a National Crisis*

We found that the Department and DEA have recently taken steps to address the opioid epidemic, but more work remains. For example, in November 2015 DEA implemented its 360 Strategy, which focuses on law enforcement coordination, diversion control and regulatory enforcement efforts, and community outreach. However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine whether the program's diversion-related activities have improved its field offices' diversion control enforcement capabilities.

We also found that DEA has taken steps to increase enforcement staffing and enforcement actions. In response to a national decline in enforcement staffing, DEA is making an effort to increase both Diversion Investigator and Special Agent staffing levels in the field divisions hardest hit by the opioid epidemic. DEA also conducted a 45-day enforcement surge that resulted in 273 enforcement actions, although we found that some of these actions were scheduled investigations that were routinely conducted as part of DEA's annual Diversion Control work plan. Additionally, the Department's Opioid Fraud and Abuse Detection Unit started providing targeting packages to 12 U.S. Attorney's Offices (USAO). As a result, we were told that USAOs have been able to generate leads and supplement ongoing DEA investigations.

## **Recommendations**

In this report, we make 9 recommendations to improve the Department's and DEA's ability to combat the diversion of pharmaceutical opioids and effectively target and regulate registrants that engage in diversion.

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## INTRODUCTION

The Office of the Inspector General (OIG) undertook this review to assess the Drug Enforcement Administration's (DEA) regulatory activities and enforcement efforts involving opioid manufacturers, distributors, doctors, and pharmacies. We examined whether DEA's efforts effectively prevented registrants from diverting controlled substances, particularly opioids, from fiscal year (FY) 2010 through FY 2017.<sup>1</sup>

### Background

DEA's Diversion Control Program seeks to prevent, detect, and investigate the redirection of controlled pharmaceuticals and listed chemicals from illegitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

According to DEA, controlled pharmaceuticals can be diverted from legitimate channels through theft or fraud during the manufacturing and distribution process by anyone involved in the process, including medical and pharmacy staff and individuals involved in selling or using pharmaceuticals.<sup>2</sup> Registrants that violate the CSA or its implementing regulations may be subject to DEA administrative enforcement actions or, depending on the seriousness of the violations, face civil penalties or criminal prosecution by the U.S. Department of Justice (Department, DOJ).<sup>3</sup>

In recent years, the United States has confronted one of the worst drug epidemics in its history. According to the Centers for Disease Control and Prevention (CDC), in 2017 the United States experienced more than 70,237 overdose deaths, of which 47,600 (67.8 percent) involved an opioid, averaging 130 opioid overdose deaths each day.<sup>4</sup> National Institute on Drug Abuse data also shows that nearly 80 percent of people who began abusing illicit opioids

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<sup>1</sup> While OIG did assess DEA's enforcement efforts with respect to pharmaceutical opioids, we did not assess these efforts with regard to illicit opioids such as heroin nor did we examine DEA's transnational trafficking and money laundering operations involving synthetic opioids such as fentanyl and fentanyl analogues. For more information about these topics, see U.S. Government Accountability Office (GAO), *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts*, GAO-18-205 (March 2018), [www.gao.gov/assets/700/690972.pdf](http://www.gao.gov/assets/700/690972.pdf) (accessed September 25, 2019).

<sup>2</sup> DEA defines "diversion" as any activity whereby legitimately made controlled substances that are intended to be used for lawful purposes are sold or exchanged in the illegitimate drug market as illicit substances. Controlled substances are contained in Drug Schedules I-V and are regulated by DEA.

<sup>3</sup> 21 U.S.C. § 801 et seq. and 21 C.F.R. § 1300 et seq.

<sup>4</sup> CDC, "Drug Overdose Deaths in the United States, 1999–2017," [www.cdc.gov/nchs/products/databriefs/db329.htm](http://www.cdc.gov/nchs/products/databriefs/db329.htm), and "Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017," [www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s\\_cid=mm675152e1\\_w](http://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w) (both accessed September 25, 2019).

during the 2000s started by abusing a prescription opioid.<sup>5</sup> Further, misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl, has led to a serious national crisis that affects not only public health but also the social and economic welfare of the country. For example, according to the National Institute on Drug Abuse, the economic burden of the opioid epidemic is an estimated \$78.5 billion every year, with state and local governments funding 25 percent of that burden.<sup>6</sup> In addition, increased healthcare and substance abuse treatment costs contributed \$28.9 billion to this economic burden, with over 14 percent of the aggregate costs of the opioid epidemic being funded by public health insurance programs such as Medicare, Medicaid, and Veterans Administration benefits.<sup>7</sup>

Below, we provide a historical perspective on the opioid epidemic. We also describe DEA's management of its Diversion Control Program through a closed system of distribution within the regulatory population, its reporting databases, registrant enforcement actions, and overall efforts to combat the opioid epidemic.

## **Historical Perspective on the Opioid Epidemic**

In October 2017, with pharmaceutical prescription drugs and illicit opioids such as heroin contributing to more than 300,000 overdose deaths in the United States since 2000, the White House declared the opioid epidemic a public health emergency.<sup>8</sup> CDC has reported that from 2000 through 2014 drug overdose deaths increased by 137 percent, including a 200 percent rise in overdose deaths involving opioids due to the abuse of pain relieving prescription drugs and heroin.<sup>9</sup> In fact, the rate of drug overdose deaths involving prescription opioids other than methadone increased by 45 percent from 2016 through 2017.<sup>10</sup>

### *Origin of the Opioid Epidemic: The OxyContin® Crisis of the Late 1990s and Early 2000s*

During the late 1990s and early 2000s, the abuse of prescription drugs was a growing problem. In 1998, 2.5 million Americans admitted to abusing prescription

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<sup>5</sup> National Institutes of Health (NIH) National Institute on Drug Abuse, "Prescription Opioids and Heroin," [www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use](http://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use) (accessed September 25, 2019).

<sup>6</sup> NIH National Institute on Drug Abuse, "Opioid Overdose Crisis," [www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis](http://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis) (accessed September 25, 2019).

<sup>7</sup> NIH National Institute on Drug Abuse, "Opioid Overdose Crisis."

<sup>8</sup> White House, "Ending America's Opioid Crisis," [www.whitehouse.gov/opioids](http://www.whitehouse.gov/opioids) (accessed September 25, 2019).

<sup>9</sup> CDC, "Increase in Drug and Opioid Overdose Deaths—United States, 2000–2014," [www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm) (accessed September 10, 2019).

<sup>10</sup> CDC, "Drug Overdose Deaths in the United States, 1999–2017."



drugs, and by 2001 that number had nearly doubled to 4.8 million.<sup>11</sup> DEA estimated that by 2003 the number of people who were abusing prescription drugs roughly equaled the number who abused cocaine, which was about 2–4 percent of the U.S. population.<sup>12</sup>

For example, according to DEA, OxyContin was one of the most abused prescription drugs of the late 1990s and early 2000s. In 1996, pharmaceutical manufacturer Purdue Pharma introduced OxyContin as a time-released form of oxycodone to treat people with chronic pain. DEA told us that OxyContin was being diverted through fraudulent prescriptions; over-prescribing; theft and illegal sales; and “doctor shopping,” the practice of going to different doctors until one prescribes the narcotic the patient seeks. According to DEA, OxyContin became a target for diverters and abusers due to its large amount of oxycodone and the ability of abusers to easily compromise its controlled release mechanism.<sup>13</sup> Simply crushing a tablet negates the timed effect of the drug, enabling abusers to swallow, inhale, or inject the drug for a powerful, morphine-like high. In 2009, the U.S. Department of Health and Human Services’ (HHS) Drug Abuse Warning Network Live (DAWN Live) reported that emergency room visits for oxycodone overdoses were more than 100 percent higher in 2000 than in 1998.<sup>14</sup>

The President’s Commission on Combating Drug Addiction and the Opioid Crisis noted in its June 2018 report to the President that the large-scale manufacture and distribution of opioids during the 1990s was one factor that led to overprescription of painkillers.<sup>15</sup> Further contributing to the opioid epidemic at that time were “black tar” heroin networks and the proliferation of pill mill medical

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<sup>11</sup> DEA, “History, 1999–2003,” 91, [www.dea.gov/sites/default/files/2018-07/1999-2003%20p%2091-118.pdf](http://www.dea.gov/sites/default/files/2018-07/1999-2003%20p%2091-118.pdf) (accessed September 25, 2019).

<sup>12</sup> DEA, “History, 1999–2003,” 113.

<sup>13</sup> A controlled release mechanism (in contrast to immediate-release dosage) delivers a drug delayed, over a prolonged period of time or to a specific part of the body (targeted-release dosage). Controlled release was put in place for OxyContin to prevent the user from achieving a “high,” or feeling of euphoria, upon its immediate release into the bloodstream.

<sup>14</sup> DAWN gathered information from hospitals, emergency rooms, and medical examiners to monitor trends in the types of drugs being abused and patterns of abuse in certain areas. HHS discontinued DAWN in 2011.

<sup>15</sup> White House, *The President’s Commission on Combating Drug Addiction and the Opioid Crisis* (November 2017), 20, [www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](http://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf) (accessed September 25, 2019). According to this report:

Aggressive promotion of an oxycodone brand from 1997–2002 led to a 10-fold rise in prescriptions to treat moderate to severe noncancer pain, and increases in prescribing of other opioids. Subsequently, the highest strengths permissible was increased for opioid-tolerant patients, likely contributing to its misuse.... It has been hypothesized that the marked rise in heroin and other illicit synthetic opioids is, in part, associated with unintended consequences of reformulation of OxyContin, and a reduced supply and greater expense of prescription opioids.

clinics (sometimes called pain management clinics).<sup>16</sup> (See the text box for a timeline of the opioid epidemic).

### *DEA's Response to the OxyContin Crisis*

To combat the growing OxyContin crisis, in the spring of 2001 DEA initiated an OxyContin National Action Plan.<sup>17</sup> According to DEA, this was the first time in DEA's history that it developed a plan to target a brand-specific controlled substance with a focus on enforcement and regulatory investigations that targeted key points of diversion. The plan directed DEA field divisions and DEA's Office of Diversion Control (OD) to conduct in-depth investigations of OxyContin's

manufacturer and distributors to determine their compliance with regulatory requirements designed to prevent diversion.<sup>18</sup> The plan also sought to coordinate enforcement and intelligence sharing with federal, state, and local agencies; take regulatory and administrative action to limit abusers' access to OxyContin; and

### **Timeline of the Opioid Epidemic**

**1984:** Purdue Pharma releases MS Contin, a time-released morphine painkiller marketed to cancer patients.

**1995:** The U.S. Food and Drug Administration (FDA) approves OxyContin for use in the United States.

**1996:** Purdue Pharma releases OxyContin, time-released oxycodone, which is marketed largely for chronic pain.

**1998:** FDA approves Actiq (fentanyl), the first pain medicine approved to treat cancer breakthrough pain.

**1997–2002:** OxyContin prescriptions for non-cancer related pain increase from about 670,000 in 1997 to about 6.2 million in 2002.

**2000:** Xalisco black tar heroin networks emerge; during the scope of our review, they still existed in at least 17 states.

**Mid-2000s:** Operation Tar Pit, the largest joint DEA/Federal Bureau of Investigation operation and first drug conspiracy case to stretch from coast to coast, targets Xalisco heroin networks.

**2006:** DEA launches Operation Black Gold Rush, a second operation targeting Xalisco heroin networks across the country.

**2007:** Purdue Pharma and three of its executives plead guilty to misdemeanor charges of false branding of OxyContin and are fined \$634 million.

**2008:** Drug overdoses, mostly from opiates, surpass auto fatalities as a leading cause of accidental death in the United States.

**2014:** FDA approves Zohydro, a time-released hydrocodone painkiller with no abuse deterrent. It also approves Purdue Pharma's Targiniq ER, the opiate abuse antidote that combines time-released oxycodone with naloxone.

Sources: Quinones, *Dreamland*, and FDA

<sup>16</sup> "Black tar" heroin is a generally less expensive form of heroin that is dark in color and sticky like tar. Pill mills are clinics that distribute—without a legitimate medical purpose—large amounts of controlled substances such as painkillers or antianxiety medications. Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* (New York: Bloomsbury Press, 2015).

<sup>17</sup> DEA Office of Diversion Control (OD), "OxyContin®: Diversion and Abuse," October 2003, [www.media.washingtonpost.com/wp-srv/politics/documents/giuliani\\_dea\\_action\\_plan\\_oct2003.pdf](http://www.media.washingtonpost.com/wp-srv/politics/documents/giuliani_dea_action_plan_oct2003.pdf) (accessed September 25, 2019).

<sup>18</sup> In September 2016, the OD was restructured and became known as the Diversion Control Division. For purposes of consistency in this report, we refer to this division as OD because that was the name of the division during the majority of our review period.

conduct outreach, awareness, and education initiatives to educate the public on the dangers of abusing OxyContin.

According to a 2003 U.S. Government Accountability (GAO) report, part of DEA's National Action Plan set the Procurement Quota for oxycodone at levels lower than requested by Purdue Pharma, OxyContin's manufacturer.<sup>19</sup> Specifically, when OxyContin was first introduced to the market in 1996, DEA granted Purdue Pharma's initial Procurement Quota request but began to notice dramatic increases in sales. As a result, DEA required Purdue Pharma to provide additional information to support its requests to increase the quota and DEA set the Procurement and Aggregate Production Quotas for oxycodone at lower levels in 2002. However, in the years following the OxyContin crisis, DEA increased the Aggregate Production Quota (APQ) for oxycodone, which we discuss later in this report. DEA told GAO about the difficulty it had faced in determining an appropriate Production Quota level that ensured that adequate quantities were available for legitimate medical use while also seeking to limit abuse and diversion.<sup>20</sup>

GAO reported that other federal agencies, including the U.S. Food and Drug Administration (FDA), also took action in response to the OxyContin crisis. In April 2001, FDA and Purdue Pharma developed a risk management plan to help detect and prevent the abuse and diversion of OxyContin.<sup>21</sup> The plan ultimately strengthened the safety, or "black box," warnings on OxyContin's label for professionals and patients; required training for Purdue's sales force on the revised label; directed that Purdue conduct comprehensive education programs for healthcare professionals; and directed Purdue to develop a database for identifying and monitoring abuse and diversion of OxyContin. Purdue also reiterated to its sales representatives that failure to promote products according to the approved label, promotional materials, and applicable FDA standards would result in disciplinary action by the company.<sup>22</sup>

Despite these responses by DEA and other federal agencies to the OxyContin crisis, since the early 2000s there has been a steady increase in the rate of opioid overdose deaths caused by natural and semisynthetic opioids, such as oxycodone and hydrocodone, which coincided with an increase in the production quotas for these controlled substances. We specifically discuss the increase in the APQ for oxycodone later in this report. Since approximately 2010, the rate of overdose

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<sup>19</sup> The Procurement Quota is issued to registered manufacturers that desire to obtain any Schedule I and/or II basic class of controlled substances in order to further manufacture that substance by packaging, repackaging, labeling, relabeling, or using it to produce dosage forms or other substances. See 21 C.F.R. § 1303.13.

<sup>20</sup> GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (December 2003), [www.govinfo.gov/app/details/GAOREPORTS-GAO-04-110](http://www.govinfo.gov/app/details/GAOREPORTS-GAO-04-110) (accessed September 25, 2019).

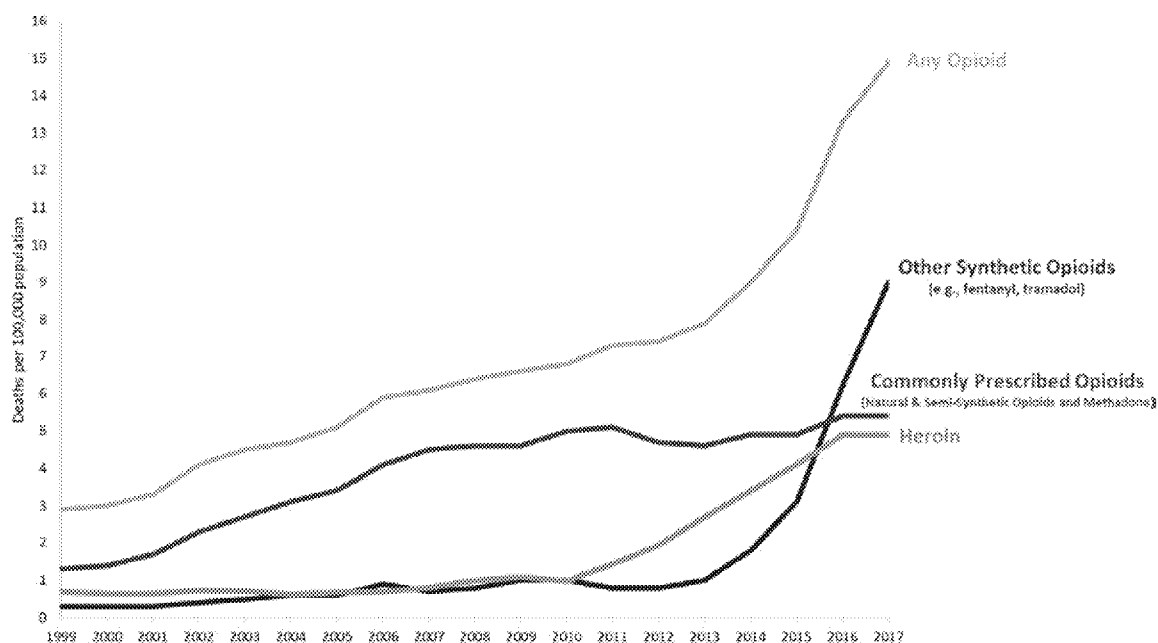
<sup>21</sup> GAO, *OxyContin Abuse and Diversion*.

<sup>22</sup> GAO reported that, according to Purdue Pharma, from April 2001 through May 2003 at least 10 Purdue employees were disciplined for using unapproved materials in promoting OxyContin. Disciplinary actions included warning letters, suspension without pay, and termination.



deaths from heroin has also risen sharply. As a result, while nearly 3 opioid overdose deaths occurred per 100,000 people in the year 2000, by 2017 that number had more than quadrupled to 15 opioid overdose deaths per 100,000 people.<sup>23</sup> Figure 2 outlines the rate of overdose deaths for various types of opioids from 2000 through 2017.

**Figure 2**  
**Overdose Deaths Involving Opioids, by Type of Opioid, United States 2000–2017**



Source: CDC National Center for Health Statistics, National Vital Statistics System, "Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000–2017"

### **The Closed System of Distribution, Regulating Registrants, and Investigating the Diversion of Controlled Substances**

Under the CSA, DEA is responsible for ensuring that all controlled substance transactions take place within a congressionally mandated closed system of distribution. The closed system of distribution regulates the flow of controlled substances from the different types of registrants, which include importers, manufacturers, distributors, practitioners, and dispensers. When controlled substance transactions fall outside the closed system of distribution, the activity constitutes diversion.

DEA's OD manages the Diversion Control Program to regulate the registrant population and investigate diversion matters. The Diversion Control Program has two major objectives with respect to practitioner-level diversion: (1) identify,

<sup>23</sup> CDC National Center for Health Statistics, National Vital Statistics System, "Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000–2017," [www.cdc.gov/drugoverdose/images/data/OpioidDeathsByTypeUS.PNG](http://www.cdc.gov/drugoverdose/images/data/OpioidDeathsByTypeUS.PNG) (accessed September 25, 2019).

investigate, and prosecute violators that are operating in a manner that requires federal action and (2) assist the states with their regulatory responsibilities through active investigations and information sharing. Although these objectives address diversion at the practitioner level, OD initiates investigations resulting from complaints against registrants at every level, including manufacturers and distributors.<sup>24</sup>

#### *DEA Oversight and Management of the National Diversion Control Program*

DEA's United Nations Reporting and Quota Section, also referred to as the "Quota Section," sets the domestic quotas and international estimates for the manufacture, import, and export of controlled substances on Schedules I–IV and some List I chemicals.<sup>25</sup> Each calendar year, the Quota Section determines three types of pharmaceutical quotas for the basic classes of controlled substances and ensures that DEA is compliant with its diversion control responsibilities pursuant to United Nations treaties:

1. The APQ, or the national quota, in part comprises the total amount of the Individual Manufacturing Quotas issued to registered bulk manufacturers. The APQ is the maximum amount of each basic class of Schedule I and II controlled substances the DEA Administrator deems necessary for manufacture in a calendar year, by all pharmaceutical manufacturers combined, for the estimated medical, scientific, research, and industrial needs of the United States or for lawful export. DEA receives estimates from FDA for the amount of controlled substances that FDA believes should be manufactured during a calendar year. Once DEA considers FDA's viewpoint, the DEA Administrator sets the APQ.
2. The Individual Manufacturing Quota is the amount of a basic class of controlled substances the DEA Administrator allocates, in consultation with the Quota Section, to specific registered bulk manufacturers in order to manufacture the substance by producing, preparing, propagating, compounding, or processing it from another substance.
3. The DEA Administrator, in consultation with the Quota Section, sets the Procurement Quota to registered manufacturers that desire to obtain any Schedule I and/or II basic class of controlled substance in order to continue manufacturing that substance by packaging, repackaging, labeling, relabeling, or producing dosage forms or other substances.

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<sup>24</sup> DEA Diversion Control Manual, October 2017, Section 5245.1, Introduction, 16.

<sup>25</sup> DEA, "Quotas," [www.dea.gov/diversion.usdoj.gov/mtgs/man\\_imp\\_exp/conf\\_2013/dang\\_1.pdf#search=Quota](http://www.dea.gov/diversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/dang_1.pdf#search=Quota) (accessed June 28, 2018). See also DEA, "Drug Scheduling," [www.dea.gov/drug-scheduling](http://www.dea.gov/drug-scheduling) and "List I and List II Chemicals," [www.dea.gov/diversion.usdoj.gov/chem\\_prog/34chemicals.htm](http://www.dea.gov/diversion.usdoj.gov/chem_prog/34chemicals.htm) (both accessed September 25, 2019).

Later in this report, we discuss how DEA set these quotas during the scope of our review.<sup>26</sup>

DEA also has Tactical Diversion Squads (TDS) to investigate registrants, particularly doctors and pharmacists, that divert controlled substances outside the scope of their professional medical practice.<sup>27</sup> These squads investigate criminal diversion cases with a nexus to prescription drugs that are diverted for profit.<sup>28</sup> A typical TDS consists of Diversion Investigators; Special Agents; Intelligence Analysts and, at times, other federal law enforcement professionals, who work alongside state and local Task Force Officers to investigate the diversion of controlled pharmaceuticals.

In addition, DEA Diversion Investigators enforce the CSA, the Chemical Diversion and Trafficking Act of 1987, and DEA regulations to ensure compliance by all current and prospective registrants.<sup>29</sup> Although some Diversion Investigators are assigned to a TDS exclusively, others focus primarily on conducting scheduled regulatory investigations based on a work plan established by DEA headquarters, which sets the cycle of regulatory inspections as well as investigations of registrants that are based upon complaints, discovery of noncompliance, or as part of criminal investigations brought to their attention. When the diversion unit of a DEA field division receives a tip, Diversion Investigators, whether or not they are assigned to a TDS group, may also conduct criminal investigations of registrants suspected of diverting pharmaceutical drugs for illicit use.

DEA's Office of Chief Counsel (CCD), Diversion & Regulatory Litigation Section, represents the government in all administrative hearings held by DEA's Office of Administrative Law Judges. In regulatory cases, CCD Attorneys litigate administrative actions against registrants (doctors, pharmacies, distributors, manufacturers, or anyone that holds a DEA registration to handle controlled

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<sup>26</sup> See 21 C.F.R. § 1303.11 (Aggregate Production Quota) and § 1303.13 (Procurement Quota) and 21 C.F.R. §§ 1303.21–1303.27 (Individual Manufacturing Quota).

<sup>27</sup> DEA, Press Release, "Announcement of New Tools to Address Opioid Crisis," November 29, 2017, [www.dea.gov/pr/speeches-testimony/2017t/112917t.pdf](http://www.dea.gov/pr/speeches-testimony/2017t/112917t.pdf) (accessed September 25, 2019).

As of August 2017, DEA had established 77 TDS groups in 44 states.

<sup>28</sup> TDS members are authorized to work only on investigations that have a connection to prescription pills, such as OxyContin and hydrocodone. A TDS is not authorized to work on investigations that involve only non-pill related drugs, including heroin, or synthetic opioids, such as fentanyl, that were manufactured in other countries and smuggled into the United States. The proscription on TDS members' work is due to funding regulations that aim to preserve diversion funds exclusively for diversion activities.

<sup>29</sup> The Chemical Diversion and Trafficking Act of 1987 amended the CSA to establish recordkeeping and reporting requirements for the manufacture, distribution, importation, and exportation of listed precursor and essential chemicals. The Chemical Diversion and Trafficking Act prohibits the distribution of such chemicals unless the recipient provides a certification of lawful use and proper identification. See P.L. 100-690 and 21 U.S.C. §§ 801–971.



substances) that are potentially in violation of the CSA and DEA regulations.<sup>30</sup> Regulatory violations that warrant an administrative enforcement action, such as an Order to Show Cause (OTSC) or an Immediate Suspension Order (ISO), described in more detail below, are referred by Diversion Investigators to CCD for litigation. DEA uses OTSCs and ISOs to hold registrants accountable for violations, such as poor recordkeeping; inadequate security; practicing without a state medical license; and unlawfully prescribing any federally controlled substance, including a prescription opioid, outside the usual course of professional practice.<sup>31</sup>

In accordance with the Administrative Procedure Act of 1946, 5 U.S.C. § 551, DEA Administrative Law Judges (ALJ) conduct formal hearings in regulatory cases and provide a recommended decision in cases referred by Diversion Investigators to CCD as a result of a registrant's violations.<sup>32</sup> ALJs track the number of cases filed by CCD and report statistical information and significant trends to the DEA Administrator. In all regulatory cases in which an OTSC or an ISO is issued, the DEA Administrator makes the final agency decision.

### *DEA Registrant Databases and Reporting Systems*

Following the enactment of the CSA in 1971, DEA began to systematically collect and maintain registrant records regarding production and ordering information, theft and loss, and suspicious orders.<sup>33</sup> Beginning in the late 1970s, pursuant to 21 C.F.R. § 1304.33, all manufacturers and distributors of select controlled substances were required to report their controlled substance activity to DEA using the Automated Reports and Consolidated Orders System (ARCOS). DEA developed ARCOS to monitor ordering information from manufacturers and distributors for Schedule I, Schedule II, and some Schedule III controlled substances.<sup>34</sup> Also, federal regulations require registrants to report drug theft or

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<sup>30</sup> CCD exercises DEA's authority under 21 C.F.R. §§ 1301.31–46 and 1316.41–68, which establish procedures for DEA to revoke, deny, or suspend registrations and set a standard of imminent danger to the public health for issuing an Immediate Suspension Order (ISO). However, CCD does not decide whether administrative cases are viable. Rather, senior leadership of the Office of Chief Counsel makes decisions on whether and how to proceed in any administrative DEA case.

<sup>31</sup> When DEA issues an OTSC, the registrant is permitted to continue operations unless the registrant voluntarily surrenders its registration prior to an administrative hearing. If DEA issues an ISO, a registrant must immediately suspend operations until the case is resolved by an administrative hearing and a final decision is issued. A registrant subject to an ISO may also voluntarily surrender its registration.

<sup>32</sup> The Administrative Procedure Act of 1946 applies to all Executive Branch agencies, including some independent government agencies, and prescribes procedures for agency actions such as rulemaking, as well as standards for judicial review of agency actions.

<sup>33</sup> Effective May 1, 1971, the CSA, § 827 of the *U.S. Code*, required DEA to report controlled substance activity to the U.S. Attorney General.

<sup>34</sup> DEA, "ARCOS Reporting," [www.deadiversion.usdoj.gov/arcos/index.html](http://www.deadiversion.usdoj.gov/arcos/index.html) (accessed June 28, 2018). Most manufacturers and distributors must use ARCOS to report inventories, acquisitions, and dispositions of all controlled substances on Schedules I and II, as well as gamma-hydroxybutyric acid controlled substances on Schedule III.

loss to their local DEA field division in writing within 1 business day of discovering the loss.<sup>35</sup> The DEA Theft or Loss Reports System database houses these reports.<sup>36</sup>

Additionally, the Registrant Information Consolidated System (RICS), also known as "CSA II," is a database that consolidates several of DEA's internal systems, each with its own uniquely different functions, including Quota information, ARCOS, and providing access to registrant actions and other information. DEA uses RICS to manage all registrant records.<sup>37</sup>

Finally, in 2008 DEA developed the Suspicious Order Reporting System (SORS) to house reports that manufacturers and distributors of controlled substances are required by federal regulation to provide DEA when they detect suspicious orders, including those of unusual quantities or deviations from normal ordering practices. However, during the scope of our review, we found that the SORS database included reports from only 8 of the approximately 1,400 manufacturers and distributors of controlled substances. Each of those 8 manufacturers and distributors had provided their reports directly to DEA headquarters, while the remaining registrants reported suspicious orders to DEA field divisions.<sup>38</sup> We discuss these systems later in this report and in greater detail in Appendix 2.

#### Collaboration with State Partners and the Prescription Drug Monitoring Program

As indicated above, one of the objectives of DEA's Diversion Control Program is to assist the states, through active investigations and information sharing, with monitoring the prescribing and dispensing practices of practitioners to prevent diversion and prescription drug abuse.<sup>39</sup> According to DEA, its field divisions and headquarters communicate with state medical and pharmacy boards to share information about DEA regulations and registrant reporting requirements. DEA told OIG that it is through information sharing that it keeps state partners apprised of administrative enforcement actions, such as suspensions or revocations of DEA registrations.

While databases such as ARCOS capture ordering information reported to DEA from manufacturers and distributors of controlled substances, DEA does not have the ability to capture prescription information on doctors, dentists, pharmacies, and patients. Instead, Prescription Drug Monitoring Programs (PDMP) are state-run databases that capture this information through electronic monitoring.

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<sup>35</sup> 21 C.F.R. § 1301.76(b).

<sup>36</sup> DEA, "Report Theft or Loss of Controlled Substances," [www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html) (accessed September 25, 2019).

<sup>37</sup> DEA, "Privacy Impact Assessment for the Registrant Information Consolidated System," [www.dea.gov/sites/default/files/2018-06/rics\\_%20pia\\_060414.pdf](http://www.dea.gov/sites/default/files/2018-06/rics_%20pia_060414.pdf) (accessed September 25, 2019).

<sup>38</sup> According to 21 C.F.R. § 1301.74(b), registrants "shall notify the local DEA field division when suspicious orders are discovered."

<sup>39</sup> DEA Diversion Manual, 5245.12, Objectives, 16.

According to DEA's 2017 National Drug Threat Assessment, as of April 2017 all 50 states and Guam have active PDMPs tracking in-state prescriptions and the District of Columbia has been given authorization to create a PDMP. The goal of the PDMP is to assist medical professionals in the identification and prevention of prescription drug abuse. Some Diversion Investigators and Special Agents work with their state partners to access data from the PDMP on an ad hoc basis because some states limit or prohibit federal law enforcement's access to this information.

### Federal Interagency Coordination

According to DEA, DEA collaborates with HHS on some cases to obtain information related to doctors and pharmacies that participate in healthcare fraud. DEA told us that these types of investigations increasingly have ties to the diversion of controlled pharmaceuticals, including opioids. When registrants lose their eligibility to participate in federal programs such as the Medicare and Medicaid program due to involvement in healthcare fraud, DEA has the authority to revoke a registrant's DEA registration. (We further discuss DEA's collaboration with HHS later in the report.) DEA also works with the U.S. Postal Service to combat the illegal importation of controlled substances, including pharmaceutical opioids, through the mail and with the U.S. Department of Homeland Security to combat the smuggling of controlled substances through U.S. ports of entry, particularly along the Southwest border.<sup>40</sup> Finally, DEA works with the Office of National Drug Control Policy to draft guidance, in collaboration with all of the Executive Branch agencies, on a National Drug Control Strategy for illicit and pharmaceutical controlled substances.<sup>41</sup>

### **DEA Registrant Enforcement Process and Actions**

In accordance with 21 U.S.C. §§ 824(c)(2)(A) and 824(d)(1), DEA uses administrative enforcement actions to suspend, revoke, or deny a DEA registration. DEA may issue a registrant an OTSC to explain the basis for DEA's initiation of administrative proceedings that may lead to revoking the registration.<sup>42</sup> Registrant violations that are more egregious in nature may require immediate action. In these cases, DEA will encourage the registrant to voluntarily surrender its registration. If the registrant does not, DEA will also issue an ISO against the registrant to immediately suspend the registration if there is evidence of "imminent danger to public health or safety."<sup>43</sup> If the violations do not warrant immediate

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<sup>40</sup> OIG also reviewed cooperation between the Departments of Justice and Homeland Security in Southwest border criminal investigations. See DOJ OIG, *A Joint Review of Law Enforcement Cooperation on the Southwest Border between the Federal Bureau of Investigation and Homeland Security Investigations*, Evaluation and Inspections Report 19-03 (July 2019), [www.oig.justice.gov/reports/2019/e1903.pdf](http://www.oig.justice.gov/reports/2019/e1903.pdf) (accessed September 10, 2019).

<sup>41</sup> Despite the ongoing national impact of the opioid epidemic, the Office of National Drug Control Policy did not publish the current National Drug Control Strategy until late January 2019.

<sup>42</sup> 21 U.S.C. § 824(c)(2)(A).

<sup>43</sup> 21 U.S.C. § 824(d)(1).



action, DEA will encourage the registrant to voluntarily surrender its registration or it may use an OTSC to initiate the revocation process.

In April 2016, Congress enacted the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, or the “Marino Bill,” which created a new standard of proof necessary for DEA to issue an ISO. Pursuant to 21 U.S.C. § 824(d)(2), in order to issue an ISO against a registrant, DEA must prove that the registrant’s conduct was an “imminent danger to the public health or safety” because the registrant failed to maintain effective controls against diversion, or to otherwise comply with the obligations of DEA registration, and there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance would occur unless there is an immediate suspension of the registration.<sup>44</sup>

A Letter of Admonition is an administrative enforcement action that DEA uses to bring a registrant into compliance for minor infractions, such as recordkeeping violations. In addition, DEA may use a Memorandum of Agreement (MOA) to establish a written contract between DEA and a registrant to resolve more severe violations, such as failing to report all suspicious orders. An MOA, typically issued in a case that has nationwide impact, establishes the basis for more severe administrative enforcement actions when violations persist.

### **Scope and Methodology of the OIG Review**

This review examined DEA’s regulatory activities and enforcement efforts to combat the diversion of opioids to unauthorized users. Specifically, we evaluated (1) DEA’s enforcement regulations, policies, and procedures; (2) DEA’s use of enforcement actions involving manufacturers, distributors, physicians, and pharmacists that violate these regulations, policies, and procedures; and (3) DEA’s coordination with state and local partners to combat the opioid epidemic. Our fieldwork occurred from August 2017 through June 2018 and consisted of document review, data analysis, and interviews. We assessed DEA’s enforcement efforts involving registrants that occurred from FY 2010 through FY 2017.

We conducted interviews with officials at DEA, U.S. Attorney’s Offices, and the Office of the Deputy Attorney General. We also reviewed DEA policies and procedures and charging documents and conducted extensive analysis of DEA data. Additionally, we reviewed data related to all of DEA’s opioid anti-diversion activities, including investigations opened and closed by OD; civil and criminal case filings against distributors, manufacturers, pharmacies, and doctors; Letters of Admonition, MOAs, ISOs, and OTSCs concerning registrants; voluntary registrant surrenders of DEA registration, including the number of such surrenders related to DEA enforcement actions; and actions brought against distributors and manufacturers. We also reviewed all fines that DEA levied against registrants, including the amount, date, and recipient of each fine. For more details about our scope and methodology, see [Appendix 1](#).

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<sup>44</sup> 21 U.S.C. §§ 823 and 824(d)(2).

## RESULTS OF THE REVIEW

### **DEA Was Slow to Respond to the Dramatic Increase in Opioid Abuse and Needs to More Fully Utilize Its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances**

We found that DEA did not fully utilize its available regulatory authorities as part of its effort to combat the diversion of pharmaceutical opioids, even as the rate of opioid use and abuse in the United States increased dramatically from 1999 to 2017. Due mostly to opioid abuse, the rate of opioid overdose deaths in the United States grew, on average, by 8 percent per year from 1999 through 2013 and by 71 percent per year from 2013 through 2017.<sup>45</sup> Yet, from 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids.<sup>46</sup> For example, by 2013, the Aggregate Production Quota (APQ) of oxycodone in the United States was over 400 percent of the 2002 APQ, having increased to 153,750 kilograms in 2013 from 34,482 kilograms in 2002.\* From 2014 to 2016, DEA slightly reduced the APQ for oxycodone, from the high of 153,750 kilograms in 2013 to 139,150 kilograms in 2016.<sup>47</sup>

However, it was not until 2017 that then acting DEA Administrator Chuck Rosenberg reduced the APQ for most controlled substances, including oxycodone, by 25 percent. Rosenberg approved a reduction in the APQ of oxycodone from 139,150 kilograms in 2016 to 101,500 kilograms in 2017. In 2018, DEA further reduced the APQ for oxycodone by 6 percent, to 95,692 kilograms. See Figure 3 below for the historical trends in APQs for oxycodone.

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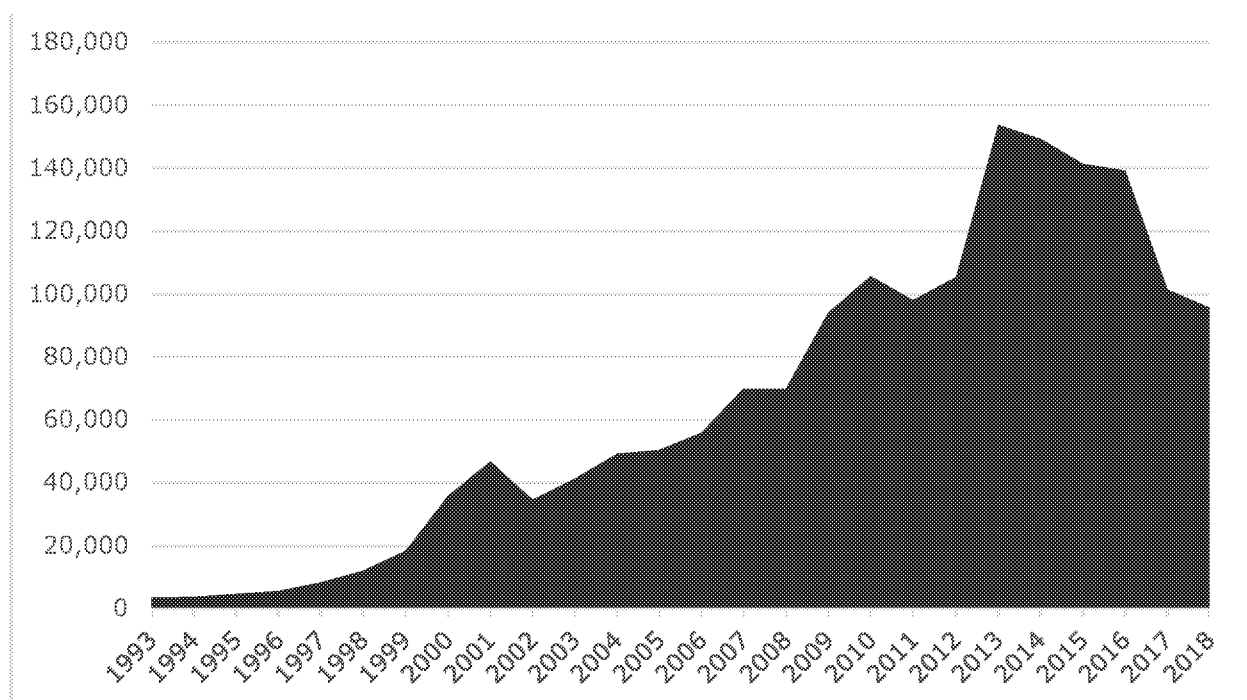
\* Stated otherwise, this represents an increase in the APQ of 346 percent from 2002 to 2013.

<sup>45</sup> Centers for Disease Control and Prevention, "Drug Overdose Deaths in the United States, 1999–2017," [www.cdc.gov/nchs/products/databriefs/db329.htm](http://www.cdc.gov/nchs/products/databriefs/db329.htm) (accessed September 25, 2019).

<sup>46</sup> As discussed in the Introduction, DEA approves the amount of the basic class of controlled substances that individual pharmaceutical manufacturers can produce each year, which is known as the Individual Manufacturing Quota. The Aggregate Production Quota (APQ) is the total combined amount of quotas set by the DEA for all manufacturers producing basic classes of controlled substances. The Controlled Substances Act of 1970 requires DEA to establish aggregate production quotas by July 1 of the year preceding the year to which the quota applies. For example, for quota year 2015 the proposed notice was published on July 2, 2014. See 21 C.F.R. § 1303.21.

<sup>47</sup> The APQ for oxycodone was 149,375 kilograms in 2014; 141,375 kilograms in 2015; and 139,150 kilograms in 2016.

**Figure 3**  
**Aggregate Quota Production for Oxycodone (in Kilograms of Anhydrous Base)**



Source: OIG analysis of DEA data

In March 2018, then Attorney General Jeff Sessions directed DEA “to evaluate and consider whether or not to amend its regulations governing the aggregate production quota.”<sup>48</sup> At the time, DEA’s regulations already contained a catch-all provision that enabled the DEA Administrator to consider “any relevant factor” in making quota decisions. Pursuant to those existing regulations, then acting Administrator Rosenberg ordered a substantial reduction in the 2017 APQ for opioids and other controlled substances, as noted above. In response to Sessions’ direction, DEA proposed a regulation that explicitly detailed the additional factors, including the diversion of pharmaceutical opioids and the opioid epidemic, that DEA can consider in setting quotas.<sup>49</sup>

<sup>48</sup> DOJ, Press Release No. 18-255, “Attorney General Sessions Takes Further Action to Combat Opioid Crisis—Directs the DEA to Evaluate Aggregate Production Quotas,” March 1, 2018, [www.justice.gov/opa/pr/attorney-general-sessions-takes-further-action-combat-opioid-crisis-directs-dea-evaluate](http://www.justice.gov/opa/pr/attorney-general-sessions-takes-further-action-combat-opioid-crisis-directs-dea-evaluate) (accessed September 25, 2019).

<sup>49</sup> Proposed Rules, 21 C.F.R. Part 1303, Docket No. DEA-480, RIN 1117-AB48, Controlled Substance Quotas, 83 Fed. Reg. 76,17329 (Apr. 19, 2018), [www.deadiversion.usdoj.gov/fed\\_regs/rules/2018/fr0419.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0419.htm) (accessed June 28, 2018). On July 16, 2018, the proposed rule became final, and it became effective on August 15, 2018. See Final Rule, 21 C.F.R. Part 1303, Docket No. DEA-480, RIN 1117-AB48, Controlled Substance Quotas, 83 Fed. Reg. 136,32784 (Jul. 16, 2018).

## *DEA's Administrative Enforcement Actions Have Not Been Fully Effective in Detecting and Combating the Diversion of Opioids and Other Controlled Substances*

We identified other areas in which DEA's regulatory and enforcement efforts could have been more effective in combating opioid diversion. First, DEA's preregistration process did not adequately vet all new applicants before granting DEA registration.<sup>50</sup> Second, DEA policy allowed, and still allows, registrants that have had their registration revoked, or that have surrendered it, to reapply for registration the day after a revocation is enforced or a surrender occurs.<sup>51</sup> Third, in 2010, DEA gave practitioners the option to use electronic prescriptions instead of paper prescriptions to keep pace with technology and combat prescription fraud. However, despite the rampant use of paper prescriptions to divert pharmaceutical opioids, DEA took no additional steps to further revise its regulations to require that all prescriptions be electronic, considering the opioid crisis.<sup>52</sup> Fourth, DEA headquarters had stringent requirements for field divisions to complete their annual Diversion Control work plans, which left little room for targeting registrants suspected of diversion.<sup>53</sup> Finally, beginning in 2013, DEA rarely used its strongest enforcement tool, the Immediate Suspension Order (ISO), to stop registrants from diverting prescription drugs, and DEA continues to experience challenges in rendering final decisions on administrative actions in a timely manner.

### Preregistration Investigations Did Not Adequately Vet Applicants

The Controlled Substances Act of 1970 (CSA) requires that each person or firm that proposes to handle controlled substances or List I chemicals obtain a DEA registration unless exempted.<sup>54</sup> The purpose of a preregistration investigation is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested and to ensure that the applicant is familiar with its responsibilities to prevent diversion. However, we found that DEA's preregistration process did not appropriately safeguard against the diversion of pharmaceutical opioids, or any other drug, because DEA did not conduct background checks on all new applicants and relied instead on the good faith of applicants to disclose relevant information, even in cases in which the applicant had previously engaged in criminal activity.

According to the Associate Section Chief of DEA's Regulatory Section, DEA conducts preregistration inspections only on "Type B" registrants, which includes manufacturers, distributors, exporters, importers, narcotic treatment programs, and applicants whose registration previously had been suspended or revoked. Therefore, "Type A" registrants, which include physicians, dentists, and

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<sup>50</sup> DEA Diversion Control Manual, October 2017, Sections 5221.1, 5221.3, and 5222.1.

<sup>51</sup> 21 C.F.R. § 1301.13.

<sup>52</sup> 21 C.F.R. § 1304.04(h)(4).

<sup>53</sup> DEA Diversion Control Manual, Sections 5231.11 and 5231.12.

<sup>54</sup> According to DEA's Diversion Control Manual, applicants can receive exemption from DEA registration under 21 U.S.C. § 822(c) or 21 C.F.R. §§ 1301.23–1301.27, 1309.25, or 1309.26.

pharmacists, are rarely required to undergo a preregistration investigation. We also found that only two DEA field divisions routinely conducted preregistration investigations on pharmacy applicants. All other field divisions issued a registration if a pharmacy applicant had a valid state license.

During interviews, some field division staff expressed concerns about the lack of vetting of physicians and pharmacies during the preregistration process. One Diversion Program Manager (DPM) told us that if a pharmacy owned by a corporation is sold to another corporation, the new corporation could circumvent the preregistration process and DEA would have no knowledge of any conduct inconsistent with holding a DEA registration. The new corporation could assume the previous corporation's registration and order as much oxycodone or any other controlled substance as desired without obtaining a new DEA registration.<sup>55</sup> Another DPM told us that, due to local issues with some pharmacy applicants, routine preregistration checks would be helpful. However, the DPM also told us that in general practice such checks are discouraged because DPMs are directed to do their work only within the annual Diversion Control work plan.

Further, we found that if a potential registrant does not disclose past criminal history, suspensions, revocations, or other unbecoming conduct, DEA does not inquire further. During interviews, several Diversion Investigators told us that, if an applicant with a valid state license does not answer "yes" to the registrant application's liability questions (as to whether the applicant has had issues with previous state licenses or allegations of misconduct), DEA approves the application without further verification from the state medical and pharmacy boards. As a result, an applicant that falsifies answers on the application could fraudulently obtain a DEA registration. The Associate Section Chief of the Regulatory Section told us that with 1.7 million registrants there is no way for DEA to know whether applicants are being untruthful unless DEA is already aware of disqualifying information. Indeed, one Diversion Investigator told us that, even if an applicant answered answers "yes" to one or more of the liability questions, some of her colleagues do not follow up to determine whether the applicant should be denied a DEA registration.

In response to a working draft of this report, DEA provided a copy of its policy prohibiting DEA Diversion Control staff from using the Federal Bureau of Investigation's National Crime Information Center (NCIC) database to perform criminal background checks on registrants' employees, as well as DEA's own Narcotics and Dangerous Drugs Information System (NADDIS), which captures

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<sup>55</sup> See 21 C.F.R. § 1301.52. According to DEA's Registration Section, if a registrant is incorporated or is a limited liability company it is considered a legal entity. If someone buys the legal entity in its entirety and the legal entity has not ceased to exist, in effect nothing has changed and DEA does not need to be notified.

information collected during DEA investigations generally.<sup>56</sup> According to DEA, Diversion Control staff rely on information obtained from a privately run proprietary database to conduct background checks on registrants' employees, which limits the staff's ability to conduct criminal background checks during the preregistration process.

DEA's preregistration investigations are an important tool for vetting applicants to ensure that they are suitable candidates for handling controlled substances. While we are not questioning the validity of state medical and pharmacy board investigations, we believe that DEA's failure to conduct preregistration investigations on all applicants, including pharmacies, creates the risk that DEA would be unaware that some of these registrants may have engaged in conduct or criminal activity that would render them unfit to obtain a DEA registration.

#### The Impact of Revoking a Registration Is Limited because Registrants Can Reapply for Registration Immediately Following Revocation

We found that registrants that have had their registration revoked, or that have surrendered it, can reapply for registration the day after the enforcement action or surrender occurs.<sup>57</sup> As a result, registrants that potentially pose a significant risk of diverting pharmaceutical opioids may be given the opportunity to do so once again. Moreover, as one DEA Chief Counsel Attorney told us, when a registrant reapplies the Diversion Investigator is required to reinvestigate the applicant because the burden is on DEA to prove that the former registrant should not receive a new DEA registration. In addition, under the CSA, a registrant must be issued an Order to Show Cause (OTSC) and provided the opportunity to be heard by a DEA Administrative Law Judge (ALJ) before DEA can deny the registrant's application.<sup>58</sup>

Several Diversion Control staff also told us that, typically, if a revoked registrant immediately reapplies for a registration, staff will request an OTSC to prevent the registrant from receiving a new registration. However, a DEA Chief

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<sup>56</sup> Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, Policy Regarding the Use of NADDIS and NCIC for Criminal History Checks for DEA Registrants, DFN: 060-01, April 25, 2011.

NCIC is a computerized index of criminal justice information (i.e., criminal record history information, fugitives, stolen properties, missing persons) that is available to federal, state, and local law enforcement and other criminal justice agencies to provide ready access to information from other criminal justice agencies. The information is used in apprehending fugitives, locating missing persons, locating and returning stolen property, as well as in the protection of the law enforcement officers encountering the individuals described in the system.

NADDIS is a computerized database containing information regarding DEA narcotics investigations that is used across DEA field divisions.

<sup>57</sup> 21 C.F.R. § 1301.13.

<sup>58</sup> 21 U.S.C. §§ 824(c)(1) and (2). The statute and its implementing regulations, 21 C.F.R. §§ 1300, et seq., are silent with respect to circumstances wherein a registration is previously revoked or surrendered for cause and the registrant immediately reapplies for DEA registration.



Counsel Attorney told us that there are cases in which an OTSC was not issued and a new DEA registration was granted even though the registrant had prior violations. He said that in one case the field division was simply “worn out” because it had spent years putting together the original revocation case. Once the registrant reapplied, the field division considered pursuing a Memorandum of Agreement (MOA), which is a less stringent enforcement tool than an OTSC. He explained that these cases were the hardest for him because the field division and DEA’s Office of Chief Counsel (CCD), Diversion & Regulatory Litigation Section, was aware of the registrant’s history of diversion yet the regulations permitted the registrant to obtain a new registration.

In another example, also provided by a Chief Counsel Attorney, a doctor, who had engaged in serious misconduct and had his registration revoked, moved to another state under the authority of a different DEA field division and immediately reapplied for and was granted a new DEA registration, even though the field division that revoked the previous registration expressed concerns. The same attorney stated that renewing the doctor’s registration was “a terrible mistake” and that such cases really “defang” diversion control. (See the text box for an example of a registration that was reinstated under similar circumstances.)

We believe that registrants who reapply for registration immediately after revocation or surrender may pose a heightened risk to public safety and that, therefore, it is in the public’s interest for DEA to ensure that those registrants’ reapplications receive heightened scrutiny.<sup>59</sup> In view of our finding that DEA has granted applications for registration after the applicants’ DEA registration had been recently revoked or surrendered, DEA should take steps to (1) ensure that DEA Diversion Control staff responsible for adjudicating registrant reapplications are fully informed of the applicants’ prior history and (2) improve information provided to staff about the standards to apply in making decisions on such applications. These steps should be designed to

**Reinstatement of Registrant Dentist  
with a History of Substance Abuse and  
a Criminal Record**

We learned that DEA reinstated the registration of a dentist who had voluntarily surrendered his medical license and DEA registration on two separate occasions. The dentist had a 25-year history of substance abuse and had had interactions with federal and state law enforcement. The dentist allegedly bought a firearm from an undercover police officer after having been convicted of a felony and allegedly purchased cocaine and heroin during the course of an unrelated investigation. The dentist also failed an initial drug test, having tested positive for marijuana.

In light of this information, the DEA Diversion Investigator requested that an OTSC be issued to prevent the approval of the dentist’s reapplication. However, according to the Diversion Investigator, DEA’s CCD declined to issue an OTSC because the dentist’s transgressions were over 5 years old. Instead, DEA entered into an MOA with the dentist, which enabled him to obtain another DEA registration.

Source: OIG analysis

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<sup>59</sup> 21 U.S.C. §§ 824(a)(1–5) of the CSA outline the factors considered when determining whether a DEA registration should be suspended or revoked. Specifically, 21 U.S.C. § 824(a)(4) states that DEA considers acts committed by a registrant that are “inconsistent with the public interest” as grounds for suspension or revocation of a DEA registration.

provide DEA Diversion Control staff a sufficient basis, consistent with law, to deny registration to such applicants absent changed circumstances and could include:

- enhancing existing guidance and training and developing guidance for DEA Diversion Control staff on the factors that should be considered in determining whether to grant such applications, including changed circumstances and passage of time;
- ensuring that all Diversion Control staff have access to information through a national database relating to registrants that have been subject to prior revocations, surrenders, or loss of state medical licenses;
- requiring that Diversion Control staff provide a written explanation describing the change of circumstances if their decision is to grant a registration to an applicant whose registration had previously been revoked or surrendered or whose state medical license had been revoked; and
- considering revisions to DEA's registration form to gather additional information relevant to the decision from applicants.

#### DEA Does Not Mandate Electronic Prescriptions for Controlled Substances

Various DEA staff told us that paper prescriptions are far less secure and are more susceptible to prescription fraud, a pervasive issue throughout the country that has led to opioid diversion. We found that in 2010 DEA revised its regulations to allow practitioners to issue electronic prescriptions to combat prescription fraud.<sup>60</sup> However, DEA did not mandate electronic prescriptions for all DEA registrants. Former acting DEA Administrator Robert Patterson told us that DEA has not mandated that all registrants issue electronic prescriptions because some smaller pharmacies could not meet the computer requirements for electronic prescriptions.

Diversion Control staff described to us "prescription rings" that involve street-level dealers working alongside medical professionals and "runners" fraudulently obtaining paper prescriptions and filling them at local pharmacies. We learned that, in an effort to prevent prescription fraud, several states, such as Connecticut, New York, Massachusetts, Minnesota, and Maine, have passed legislation mandating electronic prescribing and that California, Missouri, Vermont, Texas, and Ohio are considering similar legislation. In light of the pervasive nature of prescription fraud, and given that several states already mandate electronic prescriptions, DEA should consider changing its regulations to assist in preventing prescription fraud and to enable DEA to focus on other forms of diversion.

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<sup>60</sup> Interim Rule, 21 C.F.R. Parts 1300, 1304, 1306, and 1311, Docket No. DEA-218, RIN 1117-AA61, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236 (Mar. 31, 2010), as codified in 21 C.F.R. § 1306.08, Electronic Prescriptions, and 21 C.F.R. § 1304.06, Records and reports for electronic prescriptions.

## DEA's Work Plan Requirements Hinder Diversion Investigators' Ability to Inspect Registrants That Are Most Likely Involved in Diversion

We found that DEA headquarters has stringent requirements for Diversion Control work plans. The work plans detail the type of registrants that field divisions must investigate each year, and Diversion Investigators must complete the investigations within specific timeframes. We also found that field divisions are evaluated based on whether they complete their work plans, which leaves little room for quickly responding to new information targeting local registrants suspected of prescribing or dispensing opioids outside the scope of legitimate medical practice.

According to DEA's Diversion Control Manual, the Office of Diversion Control (OD) develops Diversion Control work plans for the field divisions. The work plans provide a schedule for conducting on-site investigations of non-practitioners to ensure their compliance with the CSA and continued eligibility for DEA registration. Diversion Control work plans require Diversion Investigators to conduct three levels of scheduled investigations: (1) primary/full investigations every 3 to 5 years, (2) secondary/follow-up investigations within 1 year of an administrative action, and (3) new registrant investigations no later than 1 year from a registrant's initial registration. The manual further states that the priority for the Scheduled Investigations Program is considered obligatory.

Diversion Control staff in DEA field divisions voiced concerns regarding the obligations of their work plan. For example, a DPM told us that her field division implemented an operation from 2013 through 2016 to eradicate pharmacies that were dispensing a large amounts of pills in that region. Through this initiative, her office's Diversion Control group secured 134 voluntary registration surrenders and issued 24 OTSCs to pharmacies. However, the operation was not in the field division's work plan and the DPM told us that, despite the impact of the group's actions, she felt that her field division leadership did not "appreciate" the group's targeted approach and just wanted the work plan completed. A Diversion Investigator told us of his frustration that following the work plan requires Diversion Investigators to inspect the same registrants over and over since there were no requirements for how often a registrant must be inspected.<sup>61</sup>

Former acting DEA Administrator Patterson acknowledged the constraints of Diversion Control work plans, which limit the field divisions' input on prioritizing investigations based on local issues. He understood that some Diversion Control staff in the field were frustrated over their lack of input. He told us that, from a

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<sup>61</sup> To ensure compliance with the CSA and a registrant's eligibility for continued registration with DEA, the Diversion Control Manual requires DEA to conduct periodic on-site investigations of all controlled substance manufacturers; distributors; reverse distributors; importers; exporters; narcotic treatment programs; and Drug Abuse Treatment Act of 2000 waived physicians, also known as DATA waived physicians. DATA waived physicians are permitted to treat narcotic dependence with Schedule III-V narcotic controlled substances. The manual requires these registrants to be reinvestigated at least once every 3 years, with the exception of DATA waived physicians, who are reinvestigated once every 5 years.

Special Agent in Charge's perspective, working solely on the items in the work plan is too rigid and "not the way it needs to be," especially given the opioid epidemic. Patterson said that a working group was attempting to create more flexibilities in the work plans.<sup>62</sup> Further, an Assistant Special Agent in Charge expressed concerns about how the work plan affects employees' work ethic. He stated that, because the division's work plan sets inspection requirements at the beginning of the year, some Diversion Investigators end up investigating only what is required of them. OIG believes that, if true, this may result in missed opportunities to identify and detect serious diversion.

We believe that it is important for DEA to allow for flexibilities in Diversion Control work plans so that Diversion Investigators can balance the need to target noncompliant registrants that may be diverting pharmaceutical opioids and other dangerous drugs with the need to conduct routine investigations.<sup>63</sup>

#### DEA Rarely Used Its Strongest Enforcement Tool, the ISO, to Stop Registrants That Were Diverting Opioids and Other Prescription Drugs

We found that DEA's use of the ISO, its strongest enforcement tool, significantly decreased from FY 2011 through FY 2015, and again in FY 2017, as compared to prior years. Under the CSA, if a registrant's violation poses an "imminent threat" to public health or safety, DEA may issue an ISO, which immediately deprives the registrant of the right to manufacture, distribute, prescribe, or dispense controlled substances.<sup>64</sup> If a registrant or applicant violates the law but the threat is not imminent, DEA may issue an OTSC to the registrant, which must then prove why its registration should not be revoked, suspended, or denied.

We found that DEA reduced its use of ISOs by over 80 percent (38 to 6) between FYs 2010 and 2017, including by nearly 70 percent (45 to 14) in FY 2013 alone. Even prior to our review period, there was a 42 percent decrease (24 to 14) in ISOs issued between FYs 2008 and 2013. In fact, DEA issued more ISOs in

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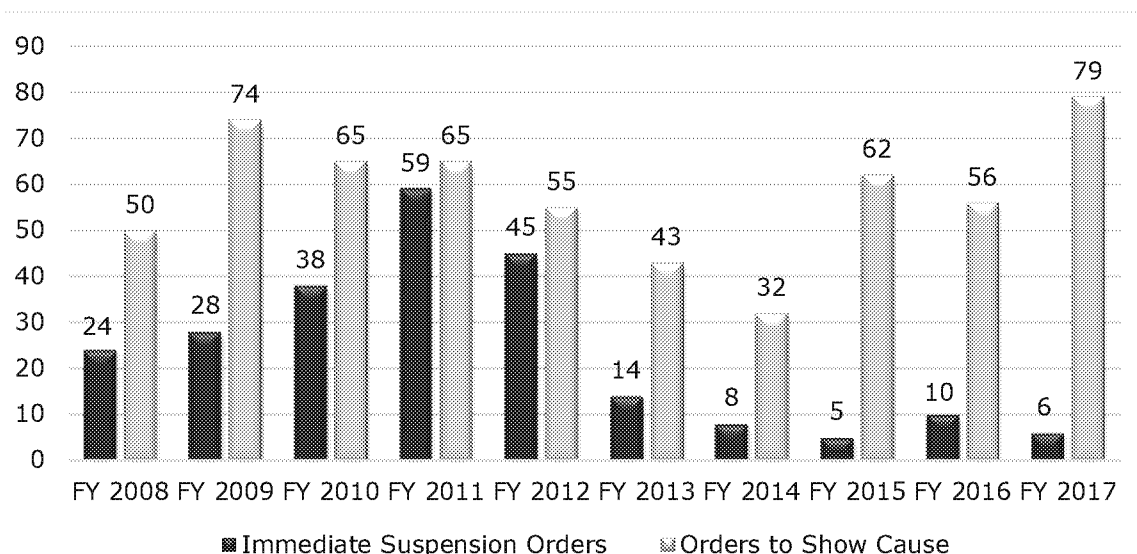
<sup>62</sup> In November 2015, the DEA Diversion Control Division formed a Field Advisory Committee, composed of five DPMs and four Assistant Special Agents in Charge, to facilitate communication between DEA field divisions and headquarters by providing a platform for input, discussion, and prioritization regarding issues facing the Diversion Control Program. In the spring of 2017, a working group began reviewing DEA's Diversion Control investigation work plans for the various field divisions and provided recommendations to the OD to modify them for FY 2019.

<sup>63</sup> In response to a working draft of this report, DEA provided the OIG with DEA's September 2018 policy, which modifies and provides greater flexibilities in the FY 2019 field division scheduled work plans to allow Diversion Control staff to better respond to the opioid epidemic. John Martin, Assistant Administrator, Diversion Control Division, DEA, Modification of the Controlled Substance and Chemical Regulatory Work Plan, DFN: 630-15, September 7, 2018.

<sup>64</sup> 21 U.S.C. §§ 823 and 824. In April 2016, Congress passed legislation that included a definition of "imminent danger" that raised the standard of proof necessary for DEA to issue an ISO. We discuss this change in greater detail below.

FY 2012 than FYs 2013–2017 combined.<sup>65</sup> By comparison, since FY 2014 the number of OTSCs issued by DEA has generally increased. See Figure 4.

**Figure 4**  
**ISOs and OTSCs Issued by DEA, FYs 2008–2017**



Source: OIG analysis of DEA documents

We sought to determine the basis for the significant decrease between FY 2011 and FY 2017 in DEA’s use of the one administrative tool that can immediately stop a registrant from diverting controlled substances. We were told about several factors that may have affected DEA’s use of ISOs during this time period.<sup>66</sup> For example, the CCD Section Chief for the Diversion & Regulatory Litigation Section referenced a temporary restraining order issued by a U.S. District Court Judge in Washington, D.C., on February 3, 2012, that initially prevented DEA from enforcing an ISO against Cardinal Health, Inc.<sup>67</sup> The U.S. District Court Judge

<sup>65</sup> The data we used to determine the number of ISOs and OTSCs that were issued in FYs 2008–2009 was derived from our previous report, *Review of the Drug Enforcement Administration’s Adjudication of Registrant Actions, Evaluation and Inspections (E&I) Report I-2014-003* (May 2014), [www.oig.justice.gov/reports/2014/e1403.pdf](http://www.oig.justice.gov/reports/2014/e1403.pdf) (accessed September 25, 2019). See Appendix 3 for information on prior work related to DEA diversion control efforts.

<sup>66</sup> In response to a working draft of this report, DEA acknowledged additional factors that it believed had contributed to the decrease in ISOs during our scope. Specifically, DEA noted that prescriptions declined nationwide, in many cases administrative enforcement actions were taken that did not result in ISOs, DEA did not pursue ISOs against registrants when it conflicted with an ongoing U.S. Attorney’s Office (USAO) criminal investigation, Diversion Control staff had been insufficiently trained regarding administrative diversion remedies, and registration surrenders increased during the first few years of our scope.

<sup>67</sup> At the time of the Cardinal Health case, the CCD Section Chief for the Diversion & Regulatory Litigation Section worked as a DOJ Civil Division attorney and was defending the case on behalf of the U.S. government. According to Department protocol, if a registrant appeals an ISO in federal court, the government’s case is defended by either the Department’s Narcotics and Dangerous Drug Section or its Civil Division. Later in 2012, this official joined DEA as the CCD Section Chief for the Diversion & Regulatory Litigation Section.

granted the temporary restraining order because he could not determine how Cardinal Health posed an imminent threat to the community based on the evidence presented by the government. On February 29, the court held a preliminary injunction hearing and the government presented additional evidence demonstrating why an ISO against Cardinal Health was warranted. After learning the full extent of the government's evidence, some of which was not presented initially, the court ruled in the government's favor and allowed DEA to enforce the ISO against Cardinal Health.

However, in doing so, the CCD Section Chief told us that the U.S. District Court Judge was critical of DEA's evidentiary presentations in a number of cases. Specifically, according to the CCD Section Chief, the judge stated that, if DEA had presented all of its evidence against Cardinal Health initially, he never would have granted the temporary restraining order in Cardinal Health's favor. Further, in talking with colleagues regarding DEA cases, the court believed that "DEA is cutting corners" and "is not doing a good enough job with its evidentiary presentations and [DEA] needs to do better." The DPM with direct involvement in this case also told us that she recalled the judge advising DEA to include more evidence in its ISOs because DEA cannot shut down a business without telling the registrant why. After this case, the DPM said that DEA's use of ISOs started to "slow down." The CCD Section Chief told us that he keeps the court's feedback in mind moving forward as he wants every case to be able to stand up in court.<sup>68</sup>

Additionally, a former DEA Assistant Administrator, who led the OD from August 2015 to June 2017, advised us that an unusually high volume of ISOs from FY 2010 through FY 2012 resulted from DEA's Operation Pill Nation I (2011) and Operation Pill Nation II (2012) investigations in Florida. Collectively, Operations Pill Nation I and II resulted in ISOs against 63 DEA registrations. Thus, according to the former Assistant Administrator, the reduction in ISOs appears more pronounced from FY 2013 onward because those operations ended in FY 2012.<sup>69</sup> See the text box below for information regarding the effect of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (the "Marino Bill") on DEA's use of ISOs.

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<sup>68</sup> The CCD Section Chief also stated that, based on his discussions with DEA leadership, between 2011 and 2012 DEA made a strategic decision "to go after" pharmaceutical suppliers such as distributors and pharmacies. In doing so, he acknowledged that these cases were more resource intensive and complicated and that the number of cases made against physicians would decline.

<sup>69</sup> Based on our analysis of DEA charging documents, we found that 46 percent (65 out of 142) of all ISOs between FY 2010 and FY 2012 were issued throughout the state of Florida. We believe that these ISOs were largely the result of DEA's Operations Pill Nation I and II, which combined led to 118 arrests, the surrender of more than 80 DEA registrations, the seizure of more than \$19 million in assets, and the closure of at least 40 pain clinics. While we recognize that the high volume of ISOs in Florida may partly explain the sharp decrease we found since FY 2012, DEA issued only one ISO in Florida between FY 2013 and FY 2017. The CCD Section Chief for the Diversion & Regulatory Litigation Section acknowledged that this seemed low but said that the field did not refer cases to CCD that warranted more ISOs in Florida.



Finally, we found that the Diversion Control and CCD staffs had a poor working relationship, which sometimes hindered diversion investigations and the issuance of ISOs. Former acting DEA Administrator Patterson characterized the relationship between field division Diversion Control staff, OD, and CCD as historically “toxic.” As one example of the issues between CCD and Diversion Control staff in the field, a DEA Special Agent told us about, and CCD acknowledged, problems during the investigation of an oxycodone and hydrocodone “pill mill” case in September 2016 that delayed the resolution of this case for over a year. The delay was particularly of concern because the doctor was allegedly linked to multiple individuals who fatally overdosed from the drugs he prescribed. After the Special Agent requested information from the initial CCD attorney, the attorney described his interaction with the Special Agent in an email exchange with the CCD Section Chief for the Diversion & Regulatory Litigation Section:

[Special Agent] called me. He was really pissed, telling me not to talk to the [Assistant U.S. Attorney (AUSA)], demanding my work product on the case, etc. I basically lost it with him, explained (to the extent I was able) why it is problematic to proceed administratively, told him [not] to ask you for my work product (as I don’t [think] that is appropriate under these circumstances). I also told him to lose the attitude, and to act more professionally.

In interviews, the Special Agent told us that CCD repeatedly had asked him to submit and resubmit investigative materials because CCD had misplaced them, which caused delays. It was not until a new CCD attorney was assigned months later that the case moved forward and DEA issued an OTSC against the doctor. Although the CCD Section Chief acknowledged the communication issues between the initial attorney and the Special Agent, he told us that a parallel U.S. Attorney’s

#### **Effect of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 on DEA’s Use of ISOs**

During the course of our review, we also considered the passage of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (Act) and its effect on DEA’s use of ISOs. The Act’s definition of imminent danger to the public health or safety required DEA to meet a higher standard of proof before issuing an ISO. While we were told that the new proof standard could negatively affect DEA’s future ability to use ISOs effectively, we found, as shown in Figure 4, that DEA’s use of ISOs had already decreased sharply in the years prior to the bill’s passage. Given that the bill did not become law until April 2016, there was not yet sufficient data available during our fieldwork to assess the legislation’s actual impact on DEA’s ability to use ISOs.

Former acting DEA Administrator Patterson told us that he believed the only challenge the Act presented to DEA was that it required Diversion Investigators to be diligent about providing evidence to CCD attorneys as soon as they received it in order to satisfy the bill’s imminent threat standard. Patterson stated that, if an alleged harm occurred a year before the investigator presented the case to the Chief Counsel, the imminent threat standard could not be met and the investigator would have to pursue another course of action, such as an OTSC.

Sources: OIG analysis and interviews

Office (USAO) investigation and expert witness issues also may have caused delays.<sup>70</sup>

In another example, Diversion Control staff expressed concerns to us that CCD did not take swift and aggressive action to issue an ISO in a particularly egregious case involving criminal conduct. Staff told us about a March 2015 request to CCD by a Tactical Diversion Squad (TDS) for an ISO against a California doctor. The TDS had obtained pictures and text messages showing that in exchange for opioid pharmaceuticals the then 62-year-old doctor was having sex with three patients, all of whom were addicts between the ages of 20 and 25. Diversion Control staff told us that CCD did not authorize the ISO. When we asked CCD about the case, CCD stated that in May 2015 it emailed TDS investigators a case file analysis describing the concerns it had and providing guidance about the evidence it would need to prove improper prescribing practices. Specifically, CCD told us:

Although the allegations of improper prescribing were deeply troubling, the case file lacked essential evidence needed to proceed forward with an administrative case. Among other concerns, the case file lacked any of the prescriptions that DEA maintained that [the doctor] issued improperly, as well as the patient files corresponding to those prescriptions.

CCD responded to the TDS that once all the identified issues were addressed CCD would pursue an administrative enforcement action.<sup>71</sup> After receiving CCD's assessment, which the TDS Group Supervisor said he perceived as CCD "slamm[ing] the case," he instead referred the case to the USAO, which later indicted the doctor. The doctor pled guilty and is serving a 30-month prison sentence.

These examples illustrate a poor working relationship between the Diversion Control and CCD staffs. As a result of the difficulties that Diversion Control and CCD staffs had working together, CCD attorneys and numerous headquarters and field division Diversion Control staff told us that there was a reluctance on the part of the field to bring cases, particularly ISO referrals, to CCD.

We note that DEA has recently implemented a number of reforms to improve the working relationship between the Diversion Control and CCD staffs. In 2016 DEA implemented a new enforcement action intake process, which includes a conference call with CCD, the DEA Pharmaceutical Investigations Section, and field

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<sup>70</sup> The CCD Section Chief for the Diversion & Regulatory Litigation Section said that DEA was not allowed to use the USAO's medical expert, who concluded that the doctor had issued prescriptions outside the course of legitimate medical practice. The CCD Section Chief also told us that another medical expert whom DEA was allowed to use did not reach the same conclusion.

<sup>71</sup> According to CCD, while the Diversion Control Unit Chief responded that he would consult with investigators about how to proceed, CCD officials stated that CCD "heard nothing further from either Diversion Control or San Diego [Field Division] on this matter for approximately 14 months." CCD told us that an OTSC against the doctor was issued on September 27, 2016. In November 2016, the doctor waived his right to a hearing on the OTSC and surrendered his DEA registration.

division Diversion Control staff, so that all parties can offer input and feedback on new cases.<sup>72</sup> DEA also co-located the Pharmaceutical Investigations Section and CCD to facilitate a more collaborative working relationship. Finally, CCD assigned attorneys to work with specific field divisions to improve relationships with field division Diversion Control staff.

*Timeliness on the Part of the DEA Administrator Plays a Crucial Role in DEA Administrative Enforcement Actions*

DEA's regulatory process provides that the DEA Administrator is the final decision maker in an administrative enforcement action. We found that in prior years a lack of timeliness significantly delayed revocations.<sup>73</sup> Based on our review of OTSCs, we determined that from FY 2010 through FY 2017, on average, the former acting DEA Administrator took nearly 10 months (302 days), and in a few cases approximately 2 years, to render a final decision after an ALJ issued a recommendation. However, we also observed that the DEA Administrator's timeliness in issuing final decisions showed signs of improvement during the scope of our review, decreasing from an average of 440 days in FY 2011 to an average of 103 days in FY 2017.<sup>74</sup> Nonetheless, this

**DEA Did Not Consistently Meet Its Timeliness Guidelines**

In 2014, DEA established timeliness guidelines for adjudicating OTSCs. The new guidelines generally provided the Office of the Administrator 180 days to issue a final decision after receiving the ALJ's recommendation. In addition, DEA's guidelines altered the timeline for the entire administrative process for OTSCs to 360 days. Despite the establishment of these guidelines, we found that, following their implementation, 25 percent (27 out of 110 cases) of all OTSCs that culminated in a final decision from the DEA Administrator did not meet the timeliness guidelines. We also found that on average five of these cases took the Administrator 13 months (390 days) to issue a final decision after the ALJ's recommendation.

Although we found indications that DEA has improved its timeliness in adjudicating OTSCs, we believe that additional improvement is necessary, given that registrants subject to an OTSC may continue to divert pharmaceutical opioids and endanger the community until the Administrator renders a final decision.

Source: OIG analysis of DEA documents

<sup>72</sup> Under the previous process, the OD and CCD evaluated administrative referrals from the field.

The administrative referral process begins when DEA issues an OTSC or an ISO to suspend or revoke a registration. According to 21 C.F.R. § 1301.43(a), a hearing with an ALJ takes place only if the registrant files a formal request within 30 days of being issued the OTSC or ISO. After pre-hearing statements and conferences are held with both DEA and the registrant, an administrative hearing occurs. Following the deadline for filing post-hearing briefs, the ALJ issues a recommended decision, which is forwarded to DEA's Office of the Administrator for final review. The DEA Administrator issues a final decision by adopting, modifying, or rejecting the ALJ's recommended decision.

<sup>73</sup> Although we reviewed DEA Administrator decisions for every ISO and OTSC that DEA issued during the scope of our review, our analysis includes only those 70 cases in which the date of the ALJ's recommendation was provided for an OTSC.

<sup>74</sup> Our analysis excluded cases that had not received a final decision from the DEA Administrator as of the end of FY 2017. Although our analysis appears to indicate that DEA improved its timeliness, we recognize that the results for the later years of our scope may be skewed because pending cases, which may linger for years, were not included in our analysis. For example, the sample size for our analysis for FY 2017 was limited to 4 cases, compared to 20 cases for FY 2011.

continuing failure to render a timely final decision is particularly concerning as registrants may continue to do business and potentially divert pharmaceutical opioids until DEA revokes their registrations.

DEA's inability to adjudicate enforcement actions in a timely manner is a challenge that has persisted for several years. OIG first identified this issue in our May 2014 report on DEA's adjudication of registrant actions, in which we found that, with the exception of ISOs, DEA generally did not have timeliness standards in place for the adjudication of registrant actions. In response to recommendations made in our 2014 report, DEA established timeliness guidelines for its administrative actions, including for OTSCs.<sup>75</sup> While our review of DEA records appears to indicate that DEA has improved its timeliness in adjudicating OTSCs since the implementation of timeliness guidelines, it also appears that additional improvement is needed. See the text box above.

### **Improved Data Systems Would Facilitate Better Detection of the Diversion of Pharmaceutical Opioids and New Opioid Analogues**

While DEA is responsible for setting the annual quotas for opioid production by manufacturers, and therefore was aware of the substantial growth in the demand for opioids over the past 20 years, we found that DEA did not capture (and still does not capture) sufficient data at the manufacturer, distributor, practitioner, and prescriber levels to enable it to detect the diversion of opioids and identify emerging drug abuse trends.

As described below, DEA uses the Automated Reports and Consolidated Orders System (ARCOS) to monitor manufacturer and distributor inventories, acquisitions, and dispositions of controlled substances. However, the system does not contain current, up-to-date information and does not capture information about all pharmaceutical opioids. Additionally, while DEA's consolidated Suspicious Order Reporting System (SORS), established in 2008, is a potentially useful regulatory tool, we found during our review that it captured suspicious orders from very few registrants. Because SORS does not have data and information on all 1.7 million registrants, we believe that DEA is hampered in its ability to identify and combat the diversion of controlled substances. Further, we found that DEA's ability to use data to respond to emerging drug threats is limited since DEA discontinued the Medical Examiners Database in 2007 and the U.S. Department of Health and Human Services (HHS) discontinued the Drug Abuse Warning Network Live (DAWN

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<sup>75</sup> In the 2014 report, OIG made three recommendations to improve DEA's timeliness in adjudicating registrant actions: (1) establishing timeliness standards for adjudicating all OTSCs, (2) establishing policy and procedures for forwarding a case to the Office of the Administrator for final decision when a hearing is waived or terminated, and (3) instituting a formal process for tracking the timeliness of each adjudication. We note that DEA also established several exceptions to its timeliness guidelines, including delays due to other pending cases, record size, case complexity, and the quality of the ALJ's recommendation. DOJ OIG, *DEA's Adjudication of Registrant Actions*. See [Appendix 3](#) for more information.

Live) in 2011.<sup>76</sup> Although DEA is now working with federal and state partners to share data and information, additional improvements, including gaining more access to information from some state-run Prescription Drug Monitoring Programs (PDMP), are necessary. Finally, we found that DEA must continue to strengthen its external partnerships and improve information sharing with state medical and pharmacy boards.

### *DEA Does Not Capture Sufficient Data to Promptly Detect the Diversion of Opioids and Identify Emerging Drug Trends*

We learned that, in order to detect the diversion of controlled substances, DEA investigators use a number of databases, including ARCOS; SORS; and, at one time, DAWN, to detect emerging drug abuse trends. While DEA's diversion detection efforts are critically important in combating the opioid epidemic, we found significant deficiencies that could prevent DEA from promptly detecting potential diversion.

#### Automated Reports and Consolidated Orders System

According to DEA, ARCOS contains ordering information from about 1,100 manufacturers and distributors for all Schedule I and II controlled substances and certain Schedule III and IV controlled substances.<sup>77</sup> Although DEA officials and staff told us that ARCOS was the primary data tool used to detect the diversion of controlled substances, we found that some manufacturers and distributors report ordering information for Schedule I and II controlled substances to ARCOS on a monthly basis while others report this information on a quarterly basis. This dichotomy of reporting schedules forces DEA to wait a full year before ARCOS contains all of the ordering information needed to fully analyze the data and develop leads and trends. The Associate Section Chief of DEA's Pharmaceutical

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<sup>76</sup> In 2019, HHS announced that it would reestablish the DAWN Live database. For more information on DAWN, see HHS Substance Abuse and Mental Health Services Administration, "Drug Abuse Warning Network," [www.datafiles.samhsa.gov/study-series/drug-abuse-warning-network-dawn-nid13516](http://www.datafiles.samhsa.gov/study-series/drug-abuse-warning-network-dawn-nid13516) (accessed September 25, 2019).

In response to a working draft of this report, DEA provided the OIG with documentation regarding the expansion of its collaboration with the National Forensics Laboratory Information System (NFLIS), which is as a centralized data collection effort of drug chemistry analysis results from federal, state, and local forensic laboratories (now called NFLIS-Drug). According to DEA, since 1997 NFLIS-Drug has become an operational information system that includes data from 98 percent of the nation's forensic laboratories, reporting approximately 1.5 million drug cases annually. These laboratories analyze substances secured in law enforcement operations across the country, and reporting serves as a valuable resource for monitoring drug trafficking and abuse trends. DEA recently conducted a feasibility study and initiated the expansion of NFLIS to include toxicology and medical examiner and coroner reporting.

<sup>77</sup> More specifically, ARCOS contains ordering information about bulk and/or dosage form controlled substances from manufacturers and distributors that must report inventories, acquisitions, and dispositions of all substances on Schedules I and II, as well as narcotic and gamma-hydroxybutyric acid substances on Schedule III (see 21 C.F.R. § 1308). In addition, manufacturers must report synthesizing activities involving all substances on Schedules I and II, narcotic and gamma-hydroxybutyric acid substances on Schedule III, and selected psychotropic controlled substances on Schedules III and IV (see 21 C.F.R. § 1304.33).

Investigations Section told us that, for example, he would not be able to create the 2017 ARCOS data targeting packages until he received all of the data for 2017, sometime in 2018. Thus, the 2017 ARCOS targeting packages reflected ordering information from 2017 but DEA would not be able to identify issues emerging in 2018 until sometime in 2019. Moreover, DEA cannot create targeting packages for some Schedule III, and all of Schedule IV and V controlled substances, including some opioids, because the registrants for these substances are not required to report ordering information to DEA.

We also found that ARCOS does not contain all of the information necessary to detect the diversion of all pharmaceutical opioids. Some manufacturers and distributors of certain pharmaceutical opioids on Schedules III, IV, and V are not required to report ordering information to DEA. A DEA official told us that DEA did not consider requiring all manufacturers and distributors to report all ordering information when it standardized ARCOS reporting in the late 1970s because DEA thought it was more important to require this of registrants manufacturing and distributing the most dangerous categories of pharmaceuticals, those on Schedules I and II. In fact, as many as 9 opioid compounds found in over 20 pharmaceutical brands were not reported in ARCOS, making it much more difficult to detect the diversion of these prescription drugs.<sup>78</sup>

We are concerned that the nine opioid compounds not reported in ARCOS are just as dangerous to public safety as those on Schedules I and II. For example, a 2016 Florida Medical Examiners Commission report found that tramadol, a Schedule IV controlled substance used to treat moderate to severe pain, was detected in 949 overdose fatalities in Florida since 2015.<sup>79</sup> In addition, ARCOS does not contain ordering information for certain codeine products (such as cough syrup containing codeine, a Schedule V controlled substance) that are particularly susceptible to abuse.<sup>80</sup> DEA officials told us that cough syrups containing codeine are commonly abused throughout the country, particularly along the Southwest border of the United States; however, DEA does not have sufficient data to monitor codeine ordering patterns.

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<sup>78</sup> Pharmaceutical opioids not captured by ARCOS include dextropropoxyphene, difenoxin, tramadol, codeine preparations, difenoxin preparations, dihydrocodeine preparations, diphenoxylate preparations, ethyl morphine preparations, and opium preparations.

<sup>79</sup> Florida Department of Law Enforcement Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2016 Annual Report* (November 2017), [www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx](http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx) (accessed September 25, 2019).

<sup>80</sup> In 2012, DEA reported that more than 1 out of 10 teenagers were abusing cough syrups. Commonly, cough syrups may be abused through drink concoctions such as “lean,” a mixture of prescription-strength cough medicine in a soft drink with fruit-flavored candy. Some prescription-strength cough syrups used to make lean also include promethazine, an antihistamine that causes sedative effects and can impair motor function. DEA, *Prescription for Disaster: How Teens Abuse Medicine*, 2nd edition (August 2012), [www.getsmartaboutdrugs.gov/sites/getsmartaboutdrugs.com/files/publications/DEA\\_Prescription-For-Disaster\\_508ver.pdf](http://www.getsmartaboutdrugs.gov/sites/getsmartaboutdrugs.com/files/publications/DEA_Prescription-For-Disaster_508ver.pdf) (accessed September 25, 2019).



We believe that increasing the reporting requirement in ARCOS to include all controlled substances will allow for a more complete picture of the transactional data of controlled substances. A number of DEA officials we spoke with said that they also believe that the reporting requirement should be expanded, and DEA continues to work with legislators to achieve this.

Further, we learned that ARCOS does not contain ordering information for benzodiazepines, which are Schedule IV controlled substances.<sup>81</sup> DEA officials and staff told us that benzodiazepines, while not opioids, are often used in conjunction with opioids and can produce a particularly lethal drug cocktail often referred to as the “holy trinity.”<sup>82</sup> The National Institute on Drug Abuse reported that more than 30 percent of overdoses involving opioids also involve benzodiazepines.<sup>83</sup> The Associate Section Chief of the DEA Pharmaceutical Investigations Section acknowledged ARCOS’s shortcomings related to benzodiazepines and other potentially diverted pharmaceuticals. He told us that DEA was “missing the cocktails,” i.e., lacking data on the Schedule III, IV, or V controlled substances that are often taken with a Schedule I or II substance. He told us that he wished that ARCOS collected ordering information for all controlled substances. We believe that, due to these deficiencies in ARCOS data, DEA is ill-equipped to effectively monitor ordering patterns for all pharmaceutical opioids, which could enable the diversion of these prescription drugs and compromise public safety.

#### Suspicious Order Reporting System

Federal regulations require DEA registrants that manufacture and distribute controlled substances to identify and report suspicious orders to DEA and to maintain a system to disclose suspicious order reports to DEA. The *Code of Federal Regulations* defines suspicious orders as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency,” each of which is a red flag for diversion.<sup>84</sup> In 2008, DEA developed the SORS database, which is maintained and overseen by DEA headquarters to consolidate and house these suspicious order reports.

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<sup>81</sup> According to the National Institute on Drug Abuse, benzodiazepines are pharmaceutical sedatives, including alprazolam, diazepam, and clonazepam, which are commonly prescribed for anxiety or to help with insomnia. National Institutes of Health (NIH) National Institute on Drug Abuse, “Benzodiazepines and Opioids,” March 2018, [www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids](http://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids) (accessed September 25, 2019).

<sup>82</sup> An AUSA from the USAO for the Eastern District of New York told OIG that the “holy trinity” consists of an opioid used in conjunction with a benzodiazepine and a muscle relaxant such as carisoprodol.

<sup>83</sup> The National Institute on Drug Abuse warns that combining opioids and benzodiazepines can be unsafe because both sedate users, suppress breathing, and impair cognitive functioning and can cause overdose fatalities. NIH National Institute on Drug Abuse, “Benzodiazepines and Opioids.”

<sup>84</sup> In addition to reporting a suspicious order to DEA, a registrant that determines that an order is suspicious must not fill it. See also 21 U.S.C. § 823, which codifies 21 C.F.R. § 1301.74.

We found that the SORS database did not include all suspicious reports provided to DEA, thereby significantly impacting its usefulness. This was due largely to the fact that most DEA registrants are not required to report suspicious orders to DEA headquarters. Instead, consistent with federal regulation, nearly all such information is sent to DEA field division offices and DEA has not created a mechanism whereby reports sent to its field divisions are uploaded into the SORS database.<sup>85</sup> As of August 2017, approximately 1,400 DEA registrants were manufacturers and distributors of controlled substances and ARCOS contained ordering information from about 1,100 of these registrants. Yet, we found that the SORS database contained suspicious order reports from only eight registrants. All eight of those registrants were currently, or had been, subject to a Memorandum of Agreement (MOA) with DEA (due to prior violations of DEA regulations) that required them to submit suspicious order reports directly to DEA headquarters.<sup>86</sup>

During interviews, we asked DEA headquarters officials where the remaining suspicious order reports were located for the roughly 1,400 registered manufacturers and distributors of controlled substances; we were informed that DEA requires field divisions to maintain custody of the suspicious order reports. However, when we asked DEA field division staff to locate these reports at multiple sites throughout the country, staff were unaware of the requirement to maintain the reports and could not locate them. One Diversion Program Manager (DPM) described the SORS database as a “joke,” noting that DEA field division staff did not receive access to the SORS database until 2017, nearly 10 years after it was created. We believe that the lack of consistent procedures for reporting suspicious orders, and uploading those reports into the SORS database, hampers DEA’s ability to detect and target the diversion of controlled substances, including pharmaceutical opioids.

We further found that the current language of 21 C.F.R. § 1301.74(b) does not require manufacturers and distributors reporting suspicious orders to state why they believe an order is suspicious. This results in inconsistencies in reporting because registrants seemingly are applying varying standards and thresholds regarding unusual ordering behavior. This apparent lack of consistent standards creates a risk that suspicious orders may be underreported. The Associate Section Chief of the Pharmaceutical Investigations Section told us that it would help enforcement efforts to have some information on the record regarding why the reporting registrant considered a specific transaction suspicious.

To address these shortcomings, two DEA officials told us that DEA is revising its regulations to mandate that all manufacturers and distributors report suspicious

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<sup>85</sup> Pursuant to 21 C.F.R. § 1301.74(b), registrants “shall notify the local DEA field division when suspicious orders are discovered.”

<sup>86</sup> The Associate Section Chief of the Pharmaceutical Investigations Section stated that SORS generally captures suspicious orders only from registrants that have an existing MOA that mandates they report suspicious orders to DEA headquarters. Moreover, because MOAs do not exceed 5 years, the number of manufacturers and distributors that are submitting reports to the SORS database fluctuates over time. At the time of our interview with the Associate Section Chief, only one registrant was still required to report suspicious orders to DEA headquarters.

orders to headquarters, not to the field divisions, so that SORS has complete information that can be monitored and analyzed for all registrants. The Associate Section Chief of the Pharmaceutical Investigations Section told us that the revised regulation would help ensure that the data is reported to DEA headquarters consistently from all registrants and that it is appropriately vetted. We agree that the regulations, policies, and procedures should clearly instruct registrants where they should send suspicious order reports and that DEA should ensure that all reports are included in its SORS database. We also believe that DEA should establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report.<sup>87</sup> This is important because most of the major enforcement actions taken against manufacturers and distributors of controlled substances heavily relied on suspicious order reports, or a lack thereof, as evidence that led to administrative actions and settlements that prevented future diversion.

#### Discontinuation of the Medical Examiners Database in 2007

In 2005, DEA began working with medical examiners to develop a drug abuse warning network called the Medical Examiners Database. We were told that, because medical examiners are often the first to observe the impact of new drugs or analogues, the database allowed them to share their information with DEA, which assisted DEA in more quickly identifying new opioid analogues and assessing emerging overdose trends.<sup>88</sup> Specifically, once a medical examiner determined that a new opioid analogue had caused an overdose death, DEA could receive this “real-time” data and use it to justify formally scheduling the analogue by showing how it had caused harm to the public. In addition, the database improved information sharing among medical examiners, as they could use the data to run toxicology screens and find new drug compounds.

Despite the early success of the Medical Examiners Database, in 2007 then DEA Administrator Michele Leonhart discontinued it after HHS argued that the database contained the same information as HHS’s DAWN Live. The current DEA Principal Deputy Administrator, Preston Grubbs, acknowledged that a drug abuse warning network would be beneficial in helping DEA combat the opioid epidemic.

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<sup>87</sup> The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, became effective in October 2018. To address the issues discussed above, Sections 3291–3292 on preventing drug diversion codify new standards and definitions with respect to what constitutes a suspicious order. We discuss this change in the law in greater detail at the end of this report.

<sup>88</sup> A controlled substance analogue is a substance that is intended for human consumption, is structurally or pharmacologically similar to or is represented as being similar to a Schedule I or Schedule II substance, and is not an approved medication in the United States. See 21 U.S.C. § 802(32)(A).

## *DEA Is Working with Federal and State Partners to Share Data, but Additional Improvements Are Necessary*

We found that DEA is working with its federal partners, such as HHS and the USAOs, to enhance its data sharing capabilities to facilitate data-driven oversight and improve its regulatory oversight. However, we also found that DEA faces challenges in some field divisions when seeking information from some state-run PDMPs. Such information is vital to DEA's work, given that DEA does not collect information on the prescribing and dispensing behavior of practitioners and pharmacists.

### HHS Medicare Data

We found that DEA is working with HHS to facilitate data-driven oversight and improve its regulatory oversight. For instance, the Associate Section Chief of the DEA Pharmaceutical Investigations Section informed us that DEA recently entered into a data-sharing agreement with the HHS Office of Inspector General and that DEA now receives Medicare data, which among other things identifies physicians that are excluded from Medicare billing.<sup>89</sup> The Associate Section Chief told us that if a physician is unable to bill Medicare he or she generally can sustain a practice only through cash payments, which is a red flag for diversion. He also said that if the data shows that a physician was excluded from Medicare due to fraudulent activity DEA can issue an OTSC against the registration.

We note that in October 2018 Congress passed the Substance Use–Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which contains multiple provisions requiring consultation between HHS and DEA.<sup>90</sup> For example, the SUPPORT Act requires HHS, in consultation with DEA, to develop national milestones to measure their success in curbing the opioid epidemic, to report on the impact of federal and state laws and regulations on opioid prescriptions, and to recommend additional steps to limit the over-prescribing of opioids by medical practitioners. The SUPPORT Act also requires DEA to work with HHS to develop special registration procedures for telemedicine. Later in this report, we discuss additional requirements that the SUPPORT Act directed at the Department of Justice and DEA.

In addition, DEA is coordinating with the USAO for the Eastern District of Michigan, which has a program in place to evaluate a series of HHS Medicare data metrics in order to identify physicians throughout the country that may be at high risk for diverting drugs. According to the Associate Section Chief of DEA's Pharmaceutical Investigations Section, the USAO provides DEA headquarters with information packages identifying registrants suspected of diverting controlled substances based on its analysis, which includes HHS Medicare data. DEA headquarters subsequently forwards the information packages to the appropriate

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<sup>89</sup> According to DEA, the data sharing agreement with HHS requires the sharing of data/documentation every 6 months. HHS is sharing with DEA mandatory exclusionary documentation on registrants that have controlled substance or Title 18 convictions. DEA is sharing with HHS final disposition arrest data on registrants and non-registrants, as its exclusion authority is extensive.

<sup>90</sup> The SUPPORT Act, Pub. L. No. 115-271, Title VII, Subtitle C, Public Health Provisions, §§ 7021–7024.

field divisions. Later in this report, we discuss how these information packages generate leads and result in diversion investigations.

### Prescription Drug Monitoring Programs

As described in the Introduction, PDMPs are state-run databases that include prescription information on doctors, dentists, pharmacies, and patients and that electronically monitor and house records regarding dispensed pharmaceutical drugs that contain controlled substances. The goal of the PDMP is to assist medical professionals and state regulators in the identification and prevention of prescription drug abuse. However, numerous DEA Diversion Investigators and Special Agents told us that they experience challenges in accessing PDMP information, which hinders their ability to investigate registrants that are suspected of diverting prescription drugs.

DEA staff told us that state-run PDMPs contain important and useful prescription information that helps investigators identify anomalies in physicians' prescribing practices. States, however, have significantly varying requirements regarding how DEA can obtain access to this information. Some states permit DEA to access their PDMP data provided there is an open law-enforcement investigation, while other states require DEA to have an administrative subpoena or a search warrant.<sup>91</sup> One state, Vermont, prohibits law enforcement from obtaining PDMP information under any circumstance, which we were told creates significant challenges for DEA Diversion Investigators in a state with one of the highest opioid overdose rates in the country.<sup>92</sup>

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<sup>91</sup> Under federal law, law enforcement must demonstrate probable cause that a crime has occurred in order to meet the threshold for a search warrant (see Rule 41 of the *Federal Rules of Criminal Procedure*). For an administrative subpoena, law enforcement must demonstrate only reasonable suspicion that a crime has occurred, a much lower threshold (see 21 U.S.C. § 876).

We note that in FY 2003 the Department's Bureau of Justice Assistance developed the Harold Rogers Prescription Drug Monitoring Grant Program to assist in the implementation and enhancement of state-run PDMPs, including by developing data-driven strategies to address prescription drug abuse, misuse, and diversion within local communities. The grant announcement envisions that states will collaborate and share data and information regarding unsolicited prescriber and patient prescription histories with law enforcement investigators, regulatory agencies, and licensing boards to target prescription drug abuse and diversion. The announcement also states that the Bureau of Justice Assistance administers the program in coordination with several federal agencies, including DEA. While we did not evaluate this program as part of this review, it is puzzling to OIG that DEA Diversion Investigators and Special Agents, who should be able to receive PDMP data and information from this DOJ-funded program, still face challenges to their ability to access the PDMP in some states, especially given that the Department has funded this program since FY 2003.

See DOJ Office of Justice Programs Bureau of Justice Assistance, "Harold Rogers Prescription Drug Monitoring Program, FY 2016 Competitive Grant Announcement," April 16, 2016, OMB No. 1121-0329, [www.bja.gov/funding/PDMP16.pdf](http://www.bja.gov/funding/PDMP16.pdf) (accessed September 25, 2019).

<sup>92</sup> According to the National Institute on Drug Abuse, Vermont had 101 opioid-related overdose deaths in 2016, a rate of 18.4 deaths per 100,000 persons, which exceeds the national rate of 13.3 opioid-related overdose deaths per 100,000 persons. NIH National Institute on Drug Abuse, "Vermont Opioid Summary," March 2019, [www.drugabuse.gov/opioid-summaries-by-state/vermont-opioid-summary](http://www.drugabuse.gov/opioid-summaries-by-state/vermont-opioid-summary) (accessed September 25, 2019).

In response to these issues, the Department and DEA have taken steps to enhance DEA's access to PDMP data. In 2017, a Ninth Circuit decision held that an administrative subpoena was sufficient to obtain PDMP information and that access did not violate privacy interests.<sup>93</sup> In turn, several states within the Ninth Circuit, including Utah and California, began allowing DEA to use an administrative subpoena to gain PDMP access, rather than requiring a search warrant. An Attorney Advisor with the Department's Office of Legislative Affairs stated that DEA has engaged with and will continue to work with congressional offices on solutions that will furnish law enforcement with access to state PDMP data while protecting individual patient privacy.

The Associate Section Chief of the Pharmaceutical Investigations Section also told us that in December 2017 DEA started negotiating a data sharing agreement with states that were seeking ARCOS data from DEA, which in turn may afford DEA improved access to these states' PDMP data. Finally, the Bureau of Justice Assistance funded a PDMP data hub, called RxCheck, which offers states the opportunity to securely and efficiently share PDMP data with other states. As of June 2018, RxCheck could facilitate prescription data sharing with only 5 states (Florida, Oklahoma, Alabama, Maine, and Kentucky) and 10 more states were in the process of joining the program.<sup>94</sup>

For DEA to better perform its regulatory responsibilities and to cooperate with states to prevent any future epidemics, we believe that the Department and DEA should continue to work with states to reach agreements that will enable DEA to have timely access to PDMP prescription data as needed to effectively perform its regulatory and law enforcement responsibilities while also ensuring adequate protections for the important healthcare privacy interests of patients.

#### State Pharmacy and Medical Boards

Another area in which DEA needs to improve its information sharing is with state medical and pharmacy boards. For example, we learned that DEA is not always notified in a timely manner of actions that state pharmacy and medical boards take against physicians, pharmacists, and pharmacies. We were told that, as a result, physicians were able to continue to prescribe opioids and other controlled substances even after their medical licenses were revoked because DEA was not aware of the license revocations.

In addition, a former Tactical Diversion Squad (TDS) Group Supervisor told us that DEA needs to foster better working relationships with its external stakeholders, including state boards. According to this former DEA official, the

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<sup>93</sup> See *Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Admin.*, 860 F.3d 1228 (9th Cir. 2017).

<sup>94</sup> According to the Bureau of Justice Assistance, an additional 9 states (West Virginia, Tennessee, Rhode Island, Arizona, North Dakota, Nebraska, Wisconsin, Georgia, and Vermont) have expressed interest in joining RxCheck. Their participation, added to that of the states mentioned above, would expand the initiative to as many as 24 states.



state Board of Pharmacy he was working for when we interviewed him had 50 inspectors, all of which were licensed pharmacists. He stated that given their subject matter expertise these inspectors would be a great resource for DEA to use during pharmacy inspections, which DEA recently added to the Diversion Control work plan. However, at the time of our interview such coordination had not occurred.<sup>95</sup>

We believe that DEA must continue to work to foster relationships with state medical and pharmacy boards in order to keep these state entities informed about DEA regulations and registrant reporting requirements, as well as any administrative enforcement actions that DEA takes against registrants. This would also help to ensure that DEA is kept apprised of any administrative actions that state boards take against registrants.

### **The Department and DEA Have Taken Steps to Address the Opioid Epidemic as a National Crisis**

We found that the Department and DEA have taken steps to address the opioid epidemic as a national crisis. For example, in November 2015 DEA announced the piloting of its 360 Strategy to combat the opioid epidemic.<sup>96</sup> The strategy involves coordinated law enforcement efforts with federal, state, and local partners; diversion control enforcement actions; and community outreach through local partnerships to provide support in outreach, education, and prevention. In 2018 DEA conducted a 45-day enforcement surge, which resulted in 273 enforcement actions; however, we found that some of these actions were scheduled investigations routinely conducted as part of DEA's annual Diversion Control work plan. Additionally, DEA is making an effort to increase both Diversion Investigator and Special Agent staffing levels in the field divisions located in areas hardest hit by the opioid epidemic. Further, the Department's Opioid Fraud and Abuse Detection Unit began providing targeting packages to the USAOs, which have generated leads and resulted in ongoing DEA investigations. Finally, as discussed

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<sup>95</sup> At the time of our review, DEA had several opioid-related initiatives with state and federal partners, including the National Healthcare Fraud Takedown, National Takeback Initiative, Memoranda of Understanding with state Attorneys General for Data Sharing, and National Opioid Strike Forces with the Department and other federal partners. In addition, the DEA Special Operations Division and Diversion Control Division are in discussions with the U.S. Food and Drug Administration to collaborate on a joint "Warning Letter" campaign to officially notify purported internet pharmacy website owners to discontinue their alleged illegal activity.

In addition to this review, OIG is conducting an audit of DEA's prescription drug take back activities.

<sup>96</sup> At the time of our review, DEA had deployed its 360 Strategy in 12 pilot cities for 1 year in each city. DEA, "DEA 360 Strategy: Overview," [www.dea.gov/prevention/360-strategy/360-strategy.shtml](http://www.dea.gov/prevention/360-strategy/360-strategy.shtml) (accessed September 25, 2018).

above, the SUPPORT Act, enacted in October 2018 to combat the opioid epidemic, includes several provisions that may help DEA increase its enforcement efforts.

*DEA's 360 Strategy Has Improved Its Community Outreach Efforts, but DEA Needs to Assess the Effect on Diversion Control Enforcement Actions*

In November 2015, DEA began implementing its 360 Strategy in cities across the country to respond to the heroin and prescription opioid pill crisis. According to DEA, its 360 Strategy combats opioid abuse using a three-pronged approach: (1) coordinating law enforcement actions against drug cartels and heroin traffickers in specific communities, (2) leveraging diversion control enforcement actions against DEA registrants operating outside the law, and (3) pursuing community outreach through local partnerships that empower communities to take back affected neighborhoods and prevent problems from recurring.<sup>97</sup> Based on interviews with DEA officials, including those responsible for implementing the 360 Strategy in West Virginia and Ohio, two states hit hard by the opioid epidemic, we found that the program has improved DEA's community outreach efforts to raise awareness of the dangers of opioids and increased intelligence sharing with law enforcement in the community.<sup>98</sup>

However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine how the program's diversion-related activities impact the field divisions' diversion control enforcement capabilities.<sup>99</sup> According to the DEA headquarters official responsible for the 360 Strategy, in 2017 DEA hired an independent, third-party consultant to

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<sup>97</sup> Diversion control enforcement actions consist of ISOs, OTSCs, MOAs, and Letters of Admonition. Depending on the severity of a registrant's conduct, DEA may suspend, revoke, or deny a DEA registration by issuing an ISO or OTSC; enter into a written contract, known as an MOA, with the registrant, which could place greater restrictions or conditions on the registrant; or issue a Letter of Admonition, which officially warns the registrant to resolve minor infractions. Based on our review of DEA's administrative enforcement data, we found that the 360 Strategy did not have a material effect on DEA's administrative enforcement actions in 360-designated locations. For instance, while DEA launched the 360 Strategy in Manchester, New Hampshire; Charleston, West Virginia; and Dayton, Ohio, in FY 2017, DEA issued only one OTSC and no ISOs against registrants operating in these three states during FY 2017.

OIG is conducting an audit of DEA's community-based efforts to combat the opioid crisis. See DOJ OIG, "Ongoing Work," [www.oig.justice.gov/ongoing/dea.htm](http://www.oig.justice.gov/ongoing/dea.htm) (accessed September 25, 2019).

<sup>98</sup> The Assistant Special Agent in Charge in the West Virginia field office at the time of our review told us that the 360 Strategy facilitated greater coordination with law enforcement in the community. However, he also said that intelligence sharing and deconfliction among DEA, local law enforcement, and the USAO was an ongoing issue that needed to be resolved. Consequently, he believes that law enforcement is "missing a lot of the boat on exploiting [the] case beyond the borders."

<sup>99</sup> According to DEA, the goals of the 360 Strategy include: (1) stopping the deadly cycle of heroin and opioid pill abuse by eliminating drug trafficking organizations and gangs fueling violence on the streets and cycles of addiction in our communities, (2) partnering with the medical community and others to raise awareness of the dangers of prescription opioid misuse and the link to heroin, and (3) strengthening community organizations best positioned to provide long-term help and support for building drug-free communities.

assess DEA's implementation efforts for two 360 Strategy pilot cities with a goal to evaluate additional pilot cities to measure the effectiveness of the program. We reviewed two independent consultant reports completed during our review and found that they do not address or evaluate DEA's diversion control enforcement efforts. Also, according to three DPMs that oversee DEA's Diversion Control Program in 360 Strategy pilot cities, the program has not enhanced their field divisions' diversion control enforcement efforts.<sup>100</sup>

In addition, a 2018 U.S. Government Accountability Office (GAO) report found that the 360 Strategy did not include goals or performance measures for two parts of the strategy: "enforcement operations and diversion control initiatives."<sup>101</sup> GAO recommended that the DEA Administrator establish goals and outcome-oriented performance measures for enforcement and diversion control activities and establish outcome-oriented performance measures for community engagement activities within the 360 Strategy.<sup>102</sup> According to GAO, DEA was considering applying its Threat Enforcement Planning Process to the 360 Strategy to develop outcome-oriented metrics, which includes an impact report that assesses the strategy's effect of DEA's enforcement and diversion control activities.<sup>103</sup> However, GAO noted that these efforts are yet to be fully implemented and it is too soon to assess whether these efforts fully address GAO's recommendation.

While DEA's community outreach efforts are notable, DEA cannot demonstrate that the implementation of its 360 Strategy has changed its diversion control enforcement efforts in response to the opioid crisis. We believe that DEA must assess whether the program is meeting all of its objectives and that DEA must establish measureable performance metrics that show how the 360 Strategy enhances DEA's ability to bring diversion control enforcement actions against registrants that may be diverting pharmaceutical opioids.

#### DEA Has Taken Steps to Pursue Administrative Cases

Unlike DEA's response to the OxyContin crisis, which targeted all registrants, including opioid distributors and manufacturers, in February 2018 DEA surged its enforcement and administrative resources to identify and investigate prescribers and pharmacies that dispensed disproportionately large amounts of controlled substances. During the surge, DEA suspended its scheduled regulatory

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<sup>100</sup> Additionally, in June 2018 the Section Chief for the DEA Planning and Resource Section stated that, while DEA provides additional funding to 360 Strategy pilot city offices, these funds are largely allocated for public outreach efforts as opposed to bolstering offices' diversion control enforcement efforts against registrants that may be diverting controlled substances.

<sup>101</sup> See GAO, *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts*, GAO-18-205 (March 2018), [www.gao.gov/assets/700/690972.pdf](http://www.gao.gov/assets/700/690972.pdf) (accessed September 25, 2019).

<sup>102</sup> GAO, *Illicit Opioids*, 65.

<sup>103</sup> According to DEA's FY 2019 budget request, the Threat Enforcement Planning Process uses data analysis to maximize the allocation of resources and personnel against DEA-wide national level threats.

investigations so that the DEA Diversion Control staff could focus on specific leads and targets.<sup>104</sup> The goal of the surge was to remediate or remove prescriber and pharmacy registrants whose actions “perpetuate the controlled prescription drug crisis in America, particularly opioid drugs.”<sup>105</sup>

According to DEA, the 45-day enforcement surge resulted in 273 enforcement actions. However, we found that these actions included scheduled regulatory investigations that DEA would have conducted as part of its annual Diversion Control work plan and that these scheduled investigations did not specifically target the diversion of pharmaceutical opioids. The inclusion of these scheduled investigations increased DEA’s reported enforcement data by almost 15 percent. Additionally, we found that only 15 (5 percent) of the 273 enforcement actions that DEA issued were OTSCs (10) or ISOs (5).<sup>106</sup>

*While DEA’s Diversion Control Staffing Had Declined Nationally During the Opioid Epidemic, DEA Is Now Making Efforts to Increase Staff in Locations Hardest Hit by the Opioid Epidemic*

Although the DEA registrant population has increased on average by about 40,000 registrants each year, we found that DEA’s enforcement staffing has not grown at the same rate during the opioid epidemic. Over the last decade, the registrant population grew from about 1.29 million registrants in FY 2007 to over 1.7 million registrants by the end of FY 2017. As a result, the ratio of registrants to Diversion Investigators increased by over 30 percent in the past decade, from about 2,500 to 1 in FY 2007 (a total of 509 Diversion Investigators) to about 3,300 to 1 by FY 2017 (a total of 511 Diversion Investigators).

Based on our review of DEA data, we found that Diversion Investigator staffing increased by about 20 percent during our scope (from 422 in FY 2010 to 511 in FY 2017) but has slightly decreased since FY 2015. Meanwhile, Special Agent staffing decreased by about 10 percent from FY 2010 to FY 2017 (from 5,006 in FY 2010 to 4,506 in FY 2017). See Figure 5 below.

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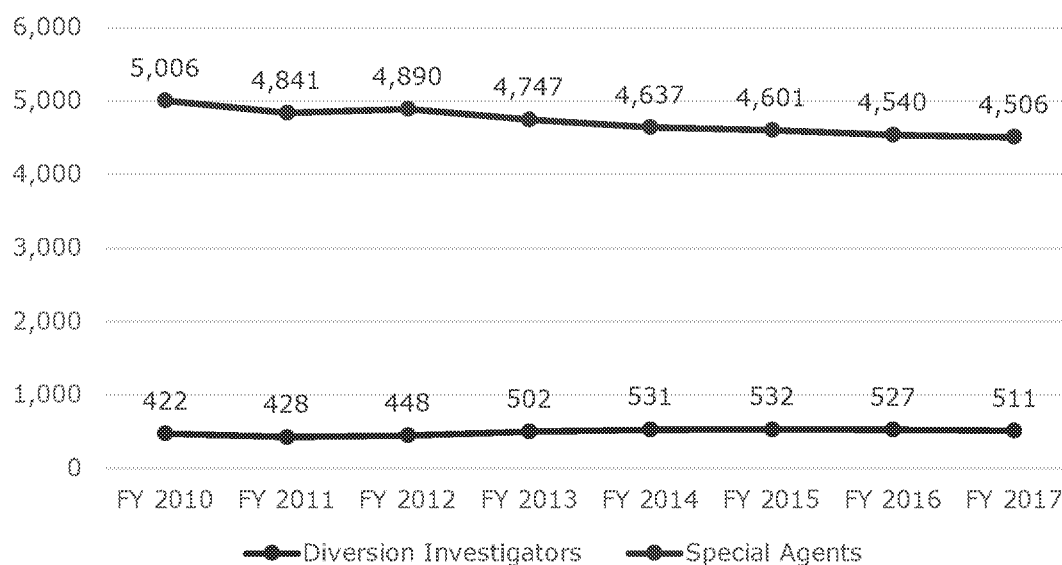
<sup>104</sup> DOJ, Press Release No. 18-290, “DEA Surge in Drug Diversion Investigations Leads to 28 Arrests and 147 Revoked Registrations,” April 2, 2018, [www.justice.gov/opa/pr/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked-registrations](http://www.justice.gov/opa/pr/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked-registrations) (accessed September 25, 2019).

In response to a working draft of this report, DEA provided to the OIG a January 2018 email from the Deputy Assistant Administrator, Office of Diversion Control Operations, to Special Agents in Charge, Assistant Special Agents in Charge, and DPMs in all DEA field divisions regarding the suspension of regulatory scheduled investigations during the 45-day enforcement surge. The 45–60 day suspension of scheduled investigations was imposed so that DEA diversion staff could focus on specific leads and targets.

<sup>105</sup> DOJ, Press Release No. 18-290.

<sup>106</sup> Former acting DEA Administrator Patterson told us that he did not know why the results from scheduled investigations were included in the reported numbers because these activities were already part of the field division work plans that were approved at the beginning of FY 2017. He further stated that although these scheduled investigations did not specifically target pharmaceutical opioid diversion, they coincidentally produced results during the 45-day surge.

**Figure 5**  
**Diversion Investigator and Special Agent Staffing, FYs 2010–2017**



Source: OIG analysis of DEA data

Throughout the course of our review, many DEA officials and staff told us that DEA did not have adequate staffing to combat the opioid epidemic in their local areas. For instance, by 2016 West Virginia had the highest rate of opioid-related overdose deaths (43.4 deaths per 100,000 people) in the United States, with the majority of deaths attributed to synthetic opioids, such as oxycodone, hydrocodone, and heroin.<sup>107</sup> However, we found that until 2016 DEA had established only one TDS to cover the entire state of West Virginia.<sup>108</sup> As of August 2017, DEA's two West Virginia offices had 13 Special Agents and 6 Diversion Investigators that were responsible for regulating over 10,000 registrants throughout the entire state.<sup>109</sup> In addition, a DPM told us that DEA did not have adequate staffing in Florida, a state that has historically faced challenges with combating the diversion of opioids.<sup>110</sup>

<sup>107</sup> See NIH National Institute on Drug Abuse, "West Virginia Opioid Summary," March 2019, [www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/west-virginia-opioid-summary](http://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/west-virginia-opioid-summary) (accessed September 25, 2019).

<sup>108</sup> In 2016, DEA established a second TDS located in Clarksburg, West Virginia.

<sup>109</sup> In January 2018, DEA established the Louisville Field Division to manage its diversion control efforts in West Virginia, Tennessee, and Kentucky. According to DEA, the new division was established to unify DEA's drug trafficking investigations throughout the Appalachian mountain region, which has been "impacted by an increasing amount of activity related to heroin, fentanyl, and prescription opioid trafficking." In addition, the new division provides better alignment between DEA and corresponding USAO districts.

<sup>110</sup> As we discussed above, there was a high volume of diversion in Florida during the early part of our scope. In fact, it was in Florida that DEA launched both Operation Pill Nation (2011) and Operation Pill Nation II (2012), which together led to 118 arrests, the surrender of more than 80 DEA registrations, the seizure of more than \$19 million in assets, and the closure of at least 40 pain clinics.

The official told us that DEA had only about 20 Diversion Investigators that were responsible for regulating over 88,000 Florida registrants in the “pill mill capital of the world.”

During our interview with then acting DEA Administrator Patterson, he acknowledged DEA’s staffing shortfalls but noted that DEA could bring on only so many new staff at one time due to physical limitations at its training academy.<sup>111</sup> He told us that DEA anticipates hosting 2 new Diversion Investigator classes and 7 new Special Agent classes through FY 2019, which together will add 100 new Diversion Investigators and 350 new Special Agents to DEA’s roster of employees. In addition, the Section Chief for the Planning and Resources Section told us that DEA plans to more than double its Diversion Investigator staffing, to about 1,100 positions nationwide over the next decade. The Section Chief added that if Congress provided DEA with direct hiring authority for diversion staff, as it has for Special Agent positions, DEA could hire candidates more quickly.<sup>112</sup> However, as of June 2019, DEA had not made a formal request to obtain direct hiring authority to staff Diversion Investigator positions.

*To Supplement DEA’s Diversion Control Efforts, the Department Created the Opioid Fraud and Abuse Detection Unit*

The Department is responsible for prosecuting opioid-related cases primarily through the U.S. Attorney’s Offices (USAO), with Assistant U.S. Attorneys (AUSA) exercising their discretion in determining whether and how to move forward with a case once a DEA Diversion Investigator or Special Agent presents evidence of violations.<sup>113</sup> However, we found that DEA’s ability to bring federal criminal charges against registrants is challenging, due in part to a lack of resources within some USAOs to prosecute pharmaceutical opioid cases.

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<sup>111</sup> In contrast to most DEA positions, Diversion Control staff, including TDS Special Agents, are funded by the Diversion Control Fee Account, which collects registration fees from manufacturers, distributors, dispensers, importers, and exporters of controlled substances and certain regulated chemicals. Although Congress must still approve proposed increases to DEA’s staffing levels, DEA’s Diversion Control funding is not limited to the traditional resource constraints of most government agencies. For instance, DEA reported that the Diversion Control Fee Account had generated over \$416 million through registrant fees and maintained a balance of \$175 million in FY 2017. Meanwhile, DEA reported that the National Diversion Control Program cost \$420 million in FY 2017.

<sup>112</sup> According to our review on gender equity throughout the Department’s law enforcement components, the Bureau of Alcohol, Tobacco, Firearms and Explosives; Federal Bureau of Investigation; and DEA may all use excepted service hiring authority for certain positions and issue position announcements in specific locations or cities based on need. The use of excepted service hiring authority increases an agency’s applicant pool and offers targeted recruitment opportunities. See DOJ OIG, *Review of Gender Equity in the Department’s Law Enforcement Components*, E&I Report 18-03 (June 2018), [www.oig.justice.gov/reports/2018/e1803.pdf](http://www.oig.justice.gov/reports/2018/e1803.pdf) (accessed September 25, 2019). Although DEA may use excepted service hiring authority for Special Agents, Intelligence Research Specialists, and Task Force positions, DEA does not have this authority for diversion-specific positions.

<sup>113</sup> DEA Diversion Control Manual, Section 5263.2, 37.

To address this issue, in the fall of 2017 the Department established the Opioid Fraud and Abuse Detection Unit, a pilot program that uses data to focus on opioid-related healthcare fraud cases.<sup>114</sup> The Opioid Fraud and Abuse Detection Unit provides targeting packages, which identify registrants suspected of diverting controlled substances, to AUSAs selected from USAO districts across the country to assist in identifying and prosecuting individuals that are contributing to the opioid epidemic.<sup>115</sup> During our interviews with AUSAs assigned to the Opioid Fraud and Abuse Detection Unit, we learned that these packages have supplemented some of DEA's diversion efforts, generated leads, and resulted in ongoing investigations of overprescribing medical professionals and pharmacy thefts. We also learned that requests for targeting packages have expanded beyond the initial 12 USAO districts. We believe that these packages have the potential to benefit more USAOs across the country.<sup>116</sup>

### *Legislation Intended to Combat the Opioid Epidemic May Help DEA Increase Its Enforcement Efforts*

In October 2018, the SUPPORT Act was signed into law to combat the opioid crisis. The SUPPORT Act includes provisions to reduce the number of illegal opioids and excess prescription opioids that are available, to share data to address over-prescribing, and to authorize new support for community efforts to reduce the

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<sup>114</sup> DOJ, Press Release No. 17-861, "Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit," August 2, 2017, [www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit](http://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit) (accessed September 25, 2019).

<sup>115</sup> At the time the program started, the Department initially selected 12 USAOs including the (1) Middle District of Florida, (2) Eastern District of Michigan, (3) Northern District of Alabama, (4) Eastern District of Tennessee, (5) District of Nevada, (6) Eastern District of Kentucky, (7) District of Maryland, (8) Western District of Pennsylvania, (9) Southern District of Ohio, (10) Eastern District of California, (11) Middle District of North Carolina, and (12) Southern District of West Virginia. In response to a working draft of this report, the Executive Office for U.S. Attorneys told us that the Eastern District of California was no longer participating in the program.

<sup>116</sup> In response to a working draft of this report, the Executive Office for U.S. Attorneys told us that dissemination is not limited to particular USAOs and that any USAO that requests a package can get one. Additionally, the DOJ Criminal Division and DEA noted additional steps taken by the Department, DEA, and state and federal partners to address the opioid epidemic as a national crisis. These steps include the creation of the Appalachian Regional Prescription Opioid Strike Force in October 2018, as well as some actions taken outside the scope of this review, such as two National Health Care Fraud Takedowns in July 2017 and June 2018.

DOJ, Press Release, "Appalachian Regional Prescription Opioid Strike Force Takedown," April 17, 2019, [www.justice.gov/usao-sdov/pr/appalachian-regional-prescription-opioid-strike-force-takedown-0](http://www.justice.gov/usao-sdov/pr/appalachian-regional-prescription-opioid-strike-force-takedown-0) (accessed September 25, 2019).

DOJ, Press Release No. 18-1388, "Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions," October 25, 2018, [www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid](http://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid) (accessed September 25, 2019).

DOJ, Press Release No. 18-866, "National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses," June 28, 2018, [www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over](http://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over) (accessed September 25, 2019).



availability of illicit opioids. According to DEA officials, the SUPPORT Act also increases some of DEA's authorities to combat the opioid epidemic. Based on our review of the SUPPORT Act, as well as DEA documents summarizing its provisions, we found that it amends several provisions of the Controlled Substances Act of 1970 (CSA), codifies DEA regulations, and creates new reporting requirements for DEA to Congress and the states, which could address some of the concerns we identified throughout this report.<sup>117</sup>

For example, the SUPPORT Act codifies the new quota regulation regarding the factors that the DEA Administrator can consider when determining the Aggregate Production Quota (APQ).<sup>118</sup> We also found that the SUPPORT Act requires DEA to establish a centralized database for collecting reports of suspicious orders from all registrants. In addition, it requires DEA to make a standardized report regarding suspicious orders available to state regulatory and licensing agencies, Attorneys General, and law enforcement agencies. The SUPPORT Act explicitly defines the term "suspicious order" to ensure consistency and aid registrants in making reports.<sup>119</sup>

Further, the SUPPORT Act includes several provisions regarding the Automated Reports and Consolidated Orders System (ARCOS), which we found cannot detect the diversion of all pharmaceuticals, including some Schedule III and all Schedule IV and V opioids and other controlled substances. Below, we list the SUPPORT Act requirements that are relevant to our review:

- On a quarterly basis, DEA will provide drug manufacturers and distributors with access to anonymized information from ARCOS to assist them in identifying, reporting, and stopping suspicious orders of opioids. All registered manufacturers and distributors must review the information provided by DEA.<sup>120</sup> The SUPPORT Act also amends the CSA to establish civil and criminal penalties for registered manufacturers and distributors for failing

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<sup>117</sup> The CSA requires that each person or firm that proposes to handle controlled substances or List I chemicals obtain a DEA registration unless exempted.

<sup>118</sup> Proposed Rules, 21 C.F.R. Part 1303, Docket No. DEA-480, RIN 1117-AB48, Controlled Substance Quotas, 83 Fed. Reg. 76,17329 (Apr. 19, 2018), [www.deadiversion.usdoj.gov/fed\\_regs/rules/2018/fr0419.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0419.htm) (accessed June 28, 2018). On July 16, 2018, the proposed rule became final, and it became effective on August 15, 2018. See Final Rule, 21 C.F.R. Part 1303, Docket No. DEA-480, RIN 1117-AB48, Controlled Substance Quotas, 83 Fed. Reg. 136,32784 (Jul. 16, 2018).

As discussed in the Introduction, the APQ is the maximum amount of each basic class of Schedule I and II controlled substances that the DEA Administrator deems necessary for manufacture in a calendar year, by all pharmaceutical manufacturers combined, for the estimated medical, scientific, research, and industrial needs of the United States or for lawful export.

See also the SUPPORT Act, Pub. L. No. 115-271, Title VII, Subtitle C, Quota Reform, §§ 3281-3282.

<sup>119</sup> The SUPPORT Act, Title III, Subtitle B, Chapter 9, §§ 3291-3292.

<sup>120</sup> Title III, Subtitle B, §§ 3272 and 3273 of the SUPPORT Act establish that if the Department initiates proceedings against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or for violations of the CSA, the Department may take into account that anonymized ARCOS data was made available to the registrant.

to review quarterly ARCOS data, failing to report suspicious orders of opioids, or failing to maintain effective controls.<sup>121</sup>

- The Department will prepare a standardized report and make it available to state regulatory and licensing agencies, Attorneys General, and law enforcement agencies in those states that the Department determines have the highest rate of opioid abuse. The report will contain descriptive and analytic information on the actual distribution patterns gathered from ARCOS, which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants in such states for Schedule II controlled substances.<sup>122</sup> The report must be provided to the entities every 6 months.
- The Department will report to Congress on how the Department is using ARCOS to identify and stop suspicious activity, including whether the Department is looking at aggregate orders from individual pharmacies to multiple distributors that in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributor.<sup>123</sup>

Finally, the SUPPORT Act includes provisions requiring DEA to promulgate certain regulations. For example, while the legislation does not mandate electronic prescribing, it does instruct DEA to update its regulations that require multifactor authentication to access e-prescribing tools so that they include biometric components, such as fingerprint, thumbprint, and voice, as an approved means of authentication.<sup>124</sup>

Given that the SUPPORT Act was passed in October 2018, we are unable to measure or even predict its effect on the opioid crisis or DEA's opioid enforcement efforts. However, we believe that the legislation contains several provisions that could help DEA address some of the issues that we identified in this report.

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<sup>121</sup> The SUPPORT Act, Title III, Subtitle B, § 3273(c), Using Data to Prevent Opioid Diversion, amends 21 U.S.C. § 842 and § 402 of the CSA.

<sup>122</sup> The SUPPORT Act, Title III, Subtitle B, § 3273(b), amends 21 U.S.C. § 873 and § 503 of the CSA.

<sup>123</sup> The SUPPORT Act, Title III, Subtitle B, § 3274.

<sup>124</sup> The SUPPORT Act, Title II, § 2003, Every Prescription Conveyed Securely.

## CONCLUSION AND RECOMMENDATIONS

### Conclusion

As the United States is confronted with one of the worst drug epidemics in its history, with opioid-related overdoses accounting for more than 47,600 deaths in 2017, an estimated 35 percent of which involved a prescription opioid, we found that DEA was slow to respond to this crisis in a number of ways. First, unlike past drug crises, in combating the current opioid epidemic DEA failed to develop a comprehensive national strategy that could have focused and directed its regulatory and enforcement efforts. For example, as the rate of opioid use and abuse in the United States continued to increase from 1999 to 2016, the amount of opioid manufacturing authorized by DEA also increased dramatically during that same time. We found that DEA did not reduce the Aggregate Production Quota for most controlled substances until 2016, the year during which opioid production fell by 25 percent.

Second, in November 2015 DEA initiated its 360 Strategy, which was publicly touted as a program with a focus on law enforcement efforts, diversion control, and community outreach. However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine how the program's diversion-related activities impact its field divisions' diversion control enforcement capabilities. While DEA's community outreach efforts are notable, we believe that DEA must assess how the 360 Strategy impacts DEA's ability to bring diversion control enforcement actions against registrants that may be diverting pharmaceutical opioids.

Third, DEA does not capture sufficient data to detect the diversion of opioids or identify emerging drug abuse trends. Specifically, we found that DEA's system that monitors registrants' ordering patterns and behavior cannot detect the diversion of all pharmaceuticals, including some Schedule III, IV, and V opioids and other controlled substances. As a result, possible prescription abuse and diversion of these controlled substances are likely undetected. We also found that DEA's database to track registrant suspicious order reports is not used by the majority of its registrants, with only 8 registrants reporting suspicious orders to DEA in this manner. While we were told that the remaining registrants continue to report suspicious orders to local field division offices, DEA field division staff at multiple sites could not locate suspicious order reports when we asked them.

Fourth, we believe that DEA needs to bolster its recent efforts to work more closely with other federal and state partners to improve data sharing. For example, we found that DEA Special Agents and Diversion Investigators continue to face challenges accessing pharmacy and patient-level information from state-run Prescription Drug Monitoring Programs. The level of access to this data varies across states, and we believe that timely and consistent access to this information could improve DEA's ability to investigate registrants that may be diverting pharmaceutical opioids.

Fifth, DEA did not fully utilize its regulatory authorities and enforcement resources to detect diversion. We found that DEA regulations fail to assess the suitability of potential new registrants, which may prevent DEA from identifying registrants whose applications merit heightened scrutiny. These regulations hinder DEA's ability to prevent the diversion of all controlled substances, including pharmaceutical opioids. We also found that DEA did not maximize its resources to investigate diversion. Specifically, in the majority of cases DEA did not use its strongest enforcement tool, the Immediate Suspension Order (ISO), to combat diversion. Despite reports that pointed to the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, or the "Marino Bill," as impeding DEA's ability to issue ISOs, we found that there was a reduction in the number of ISOs issued by DEA 3 years before the passage of this legislation. Also, we believe that the decline in ISOs was related to two key factors: the end of DEA's successful efforts to take down "pill mills" and the poor working relationship between DEA's Office of Chief Counsel and Diversion Control staff.

Further, we found that the Department and DEA have taken some recent steps to address the opioid epidemic, but that significant work remains. While DEA's enforcement staffing declined nationally during the opioid epidemic, at the time of our review DEA was making efforts to increase Diversion Investigator and Special Agent staffing levels. The Department's Opioid Fraud and Abuse Detection Unit also began providing targeting packages to 12 U.S. Attorney's Offices across the country, which, we were told, produced leads and supplemented ongoing opioid-related investigations. Finally, the enactment of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act in October 2018 directed the Department and DEA to take several important steps to enhance enforcement efforts to combat the opioid epidemic. We believe that these legislative changes are a positive step; however, more must be done, including the possibility of additional regulatory changes, for the Department and DEA to effectively target registrants that engage in the diversion of opioids.

## **Recommendations**

To more effectively target registrants that engage in the diversion of opioids, we recommend that DEA:

1. Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combating the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.
2. Require criminal background investigations of all new registrant applicants.
3. Implement electronic prescribing for all controlled substance prescriptions.
4. Require that all suspicious orders reports be sent to DEA headquarters.
5. Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants'

history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.

6. Revise field division work plan requirements to allow the flexibility to target registrants for investigation.
7. Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues and respond to these threats in a timely manner.

To improve its efforts to combat the diversion of pharmaceutical opioids, as well as prosecute registrants that divert pharmaceutical opioids, we recommend that the Department:

8. Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs.
9. Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.

**PURPOSE, SCOPE, AND METHODOLOGY****Standards**

OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation* (January 2012).

**Data Analysis**

We reviewed data related to all opioid anti-diversion activities from FY 2010 through FY 2017. Data included all investigations opened and closed by the Office of Diversion Control (OD); civil and criminal case filings against distributors, manufacturers, pharmacies, and doctors; Immediate Suspension Orders (ISO), Orders to Show Cause (OTSC), Letters of Admonition, and Memoranda of Agreement against registrants; voluntary surrenders; and other administrative enforcement actions brought against opioid distributors and manufacturers. We also reviewed all fines that DEA levied against opioid manufacturers, distributors, doctors, and pharmacies, including the amount, date, and recipient of each fine.

**Site Visits**

We visited or conducted virtual site visits with eight DEA field divisions: (1) Washington, D.C.; (2) New England; (3) San Diego; (4) Los Angeles; (5) Miami; (6) New York; (7) Detroit; and (8) Denver. We selected these sites based on our analysis of opioid overdose data from the Centers for Disease Control and Prevention. In total, we spoke to DEA staff in 17 states and territories that were impacted by the opioid epidemic: (1) California; (2) Connecticut; (3) Denver; (4) Florida; (5) Maine; (6) Maryland; (7) Massachusetts; (8) Michigan; (9) New Hampshire; (10) New York; (11) Ohio; (12) Rhode Island; (13) Utah; (14) Vermont; (15) Virginia; (16) Washington, D.C.; and (17) West Virginia.

**Interviews**

The team conducted 252 interviews during the course of our review, including interviews with DEA Diversion Investigators, Special Agents, Task Force Officers, Intelligence Analysts, Diversion Program Managers, Assistant Special Agents in Charge, and Special Agents in Charge. We also conducted interviews with senior officials at DEA headquarters, including the former acting DEA Administrator; the Principal Deputy Assistant Administrator; the Chief of Operations; current and former Assistant Administrators for the OD; the Deputy Chief Counsel; Section Chiefs or Associate Section Chiefs for the United Nations Reporting and Quota Section, Pharmaceutical Investigations Section, Planning and Resources Section, Community Outreach and Prevention Support Section, Liaison and Policy Section, Regulatory Drafting and Policy Support Section, Regulatory Section, Diversion & Regulatory Litigation Section, and Registration and Program

Support Section; and Chief Counsel attorneys.<sup>125</sup> In addition, we interviewed officials and staff across 31 U.S. Attorney's Offices, including Assistant U.S. Attorneys, Narcotics Chiefs, Criminal Chiefs, Civil Chiefs, and the U.S. Attorney for the District of New Hampshire. Finally, we interviewed senior officials in the Department's Office of the Deputy Attorney General and the Section Chief for the Criminal Division's Narcotic and Dangerous Drug Section.

## **Policy and Document Review**

We reviewed diversion control regulations, policies, procedures, and charging documents, including every ISO and OTSC that DEA issued from FY 2010 through FY 2017. In addition, we reviewed case file documents for eight cases, as well as corresponding case emails.

### *Timeliness Analysis*

To evaluate DEA's timeliness in adjudicating administrative enforcement actions against registrants, we reviewed 642 ISOs and OTSCs, as well as subsequent DEA Administrator decisions provided to us by DEA. During our review of these documents, we captured many fields of information, including but not limited to the name of the registrant, the type of registrant, the type of administrative enforcement action, the date that the administrative enforcement action was issued, the registrant's proposed hearing date, the submission date of the Administrative Law Judge's (ALJ) recommendation to the Office of the Administrator (when available), and the date of the DEA Administrator's final decision (when applicable). To assess DEA's timeliness, we calculated the length of time it took for the Office of the Administrator to issue a final decision after receiving the ALJ's recommendation and the total length of time to complete the administrative process (from issuance to final decision).

Although our methodology allowed for both qualitative and quantitative analysis, it also produced several limitations. First, we could measure the total length of time for only about 40 percent (265 out of 642 cases) of all cases we reviewed because many cases did not culminate with a final decision by the DEA Administrator during our scope. For instance, we excluded from our analysis registrants that surrendered their DEA registration after receiving the charging document or whose case remained pending at the end of our scope. Second, we were able to determine the submission date of the ALJ's recommendation for only about 35 percent (97 out of 265 cases) of all cases that resulted with a final decision by the DEA Administrator during our scope because that information was not regularly provided in the DEA Administrator's decision. In addition, even when we could determine the ALJ's submission date for certain cases, the majority of these cases arose during the first half of our scope, which made it more difficult for us to conduct a reliable annual assessment of DEA's timeliness efforts. Lastly, due to differences in methodology, we were unable to compare our timeliness analysis

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<sup>125</sup> The OIG made several attempts to obtain technical comments and feedback from former acting DEA Administrator Robert Patterson on our working draft report. Despite our efforts, we were unable to obtain Patterson's comments and input.



to OIG's 2014 report, which also assessed DEA's timeliness in adjudicating enforcement actions against registrants.

## DEA DATABASES USED TO COMBAT THE DIVERSION OF CONTROLLED SUBSTANCES

In the Introduction for this report, we briefly describe a number of databases that DEA uses to combat the diversion of controlled substances and to target registrants that may be diverting pharmaceutical opioids. We discuss these systems in greater detail below.

### Automated Reports and Consolidated Orders System

The Automated Reports and Consolidated Orders System (ARCOS) is DEA's automated system to monitor Schedule II and some Schedule III controlled substances. ARCOS reporting requirements are specific to manufacturers and distributors under 21 C.F.R. § 1304. Manufacturers and distributors must use ARCOS to report inventories, acquisitions, and dispositions to DEA. ARCOS allows DEA to maintain current and historical records of inventories and transactions of selected controlled substances from drug manufacturers to distributors and other entities within the closed system of distribution, including pharmacies at the dispensing level.

### Drug Theft or Loss Reporting Requirements

DEA requires all registrants that handle controlled substances to report theft or loss of a controlled substance to their local DEA field division in writing within 1 business day of discovering the loss, according to the *Code of Federal Regulations*.<sup>126</sup> Registrants have the option to report a lost or stolen controlled substance to DEA by paper submission; however, to minimize errors, DEA encourages registrants to report theft or loss of a controlled substance through the online Theft or Loss System.<sup>127</sup>

### Registrant Information Consolidated System

The Registrant Information Consolidated System (RICS), also known as CSA II, is a database that consolidates several of DEA's internal systems, including the Quotas, ARCOS, and CSA databases, providing real-time access to registrant actions and information. DEA uses RICS to manage all registrant records. In addition, RICS allows DEA field divisions to know when registrants are being investigated at the national level to avoid duplicate efforts.

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<sup>126</sup> 21 C.F.R. § 1301.76(b).

<sup>127</sup> Registrants may also report the theft or loss of controlled substances regulated by DEA using DEA Form 106. DEA's Theft or Loss System, the online equivalent to the DEA Form 106, allows registrants to report information with fewer errors using the National Drug Code to populate fields that would identify the manufacturer, product, dosage format, and size of the package.

## Suspicious Order Reporting System

Under the *Code of Federal Regulations*, manufacturers and distributors are required to develop and maintain a system to identify suspicious order requests and to report the information to DEA.<sup>128</sup> Manufacturers and distributors are further required, in accordance with the *U.S. Code*, to maintain effective controls to keep substances from being diverted outside of legitimate medical, scientific, or industrial needs.<sup>129</sup> Most suspicious orders should be reported directly to the local DEA field division unless the registrant has been directed through a Memorandum of Agreement to submit such activity to the Suspicious Order Reporting System (SORS) overseen by DEA headquarters. Suspicious orders are defined as unusual quantities or deviations from normal ordering practices. DEA registrant numbers are linked to suspicious order reports and, once such reports are populated in SORS, the system can show suspicious order activity throughout the nation.

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<sup>128</sup> 21 C.F.R. § 1301.74(b).

<sup>129</sup> 21 U.S.C. § 823.

**PRIOR WORK ON DEA DIVERSION EFFORTS**

Related to opioid enforcement, DOJ OIG and the U.S. Government Accountability Office (GAO) have conducted eight previous reviews, which examined whether DEA has taken steps to improve its ability to control the diversion of opioids:

1. DOJ OIG, *Review of the Drug Enforcement Administration's Control of the Diversion of Controlled Pharmaceuticals* (September 2002).<sup>130</sup> The review concluded that DEA was slow to commit sufficient resources to address the widespread problem of controlled pharmaceutical diversion and abuse. We also found that DEA continued to devote a significantly lower percentage of its criminal investigation resources to controlled pharmaceutical diversion than to criminal investigations of illicit drugs, such as cocaine, heroin, and methamphetamines.
2. DOJ OIG, *Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals* (July 2006).<sup>131</sup> The review concluded that although DEA had taken steps to combat the diversion of controlled pharmaceuticals, some areas needed further improvement. We also found that, since our September 2002 review, diversion using the internet had become a growing threat and that DEA had not provided Diversion Investigators with the tools necessary to conduct successful investigations.
3. DOJ OIG, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014).<sup>132</sup> The review concluded that DEA's process to adjudicate registrants' actions and issue final decisions was compliant with applicable laws and regulations. However, the review found that DEA did not have timeliness standards for the adjudication process and that DEA was slow to reach final adjudication.
4. GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (December 2003).<sup>133</sup> This review concluded that although federal and state agencies and Purdue Pharma, OxyContin's manufacturer, had taken actions to address the abuse and diversion of OxyContin, there was room for improvement. GAO recommended that the U.S. Food and Drug Administration and Purdue Pharma implement a stronger safety warning on OxyContin's label and that both use a coordinated risk

<sup>130</sup> See DOJ OIG, *Review of the Drug Enforcement Administration's Control of the Diversion of Controlled Pharmaceuticals*, E&I Report I-2002-010 (September 2002), [www.oig.justice.gov/reports/DEA/e0210/index.htm](http://www.oig.justice.gov/reports/DEA/e0210/index.htm) (accessed September 25, 2019).

<sup>131</sup> See DOJ OIG, *Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals*, E&I Report I-2006-004 (July 2006), [www.oig.justice.gov/reports/DEA/e0604/index.htm](http://www.oig.justice.gov/reports/DEA/e0604/index.htm) (accessed September 25, 2019).

<sup>132</sup> See DOJ OIG, *The Drug Enforcement Administration's Adjudication of Registrant Actions*, E&I Report I-2014-003 (May 2014), [www.oig.justice.gov/reports/2014/e1403.pdf](http://www.oig.justice.gov/reports/2014/e1403.pdf) (accessed April 16, 2019).

<sup>133</sup> See GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (December 2003), [www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf](http://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf) (accessed September 25, 2019).

management plan to help detect and prevent OxyContin abuse. DEA's OxyContin National Action Plan and its successes were highlighted as an effective means of addressing the abuse and diversion of this drug.

5. GAO, *Controlled Substances: DEA Should Take Additional Actions to Reduce Risks in Monitoring the Continued Eligibility of Its Registrants* (May 2016).<sup>134</sup> The review concluded that DEA had established controls for determining registrant eligibility to handle and prescribe controlled substances. However, limitations in DEA's controls did not help to ensure that individual registrants were and remained eligible and did not present issues that may increase the risk of illicit diversion.
6. GAO, *Department of Justice, Drug Enforcement Administration: Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder* (February 2018).<sup>135</sup> The review found that a new provision in statute allowed DEA to expand the categories of practitioners that may dispense Schedule III, IV, and V narcotic drug treatments for opioid abuse.
7. GAO, *Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries* (May 2018).<sup>136</sup> The review concluded that while the Centers for Medicare and Medicaid Services provided guidance to opioid prescription plan sponsors, recent criteria did not provide sufficient information on the large population of beneficiaries at risk of harm from opioid use.
8. GAO, *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access* (June 2015).<sup>137</sup> The review found that some DEA registrants, particularly chain pharmacy and distributor corporate offices, had better communication with DEA about their regulatory roles and responsibilities. The review concluded that some chain and individual pharmacies, distributors, and practitioners wanted improved communication and guidance from DEA regarding regulatory requirements.

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<sup>134</sup> See GAO, *Controlled Substances: DEA Should Take Additional Actions to Reduce Risks in Monitoring the Continued Eligibility of Its Registrants*, GAO-16-310 (May 2016), [www.gao.gov/products/GAO-16-310](http://www.gao.gov/products/GAO-16-310) (accessed September 25, 2019).

<sup>135</sup> See GAO, *Department of Justice, Drug Enforcement Administration: Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder*, B-329747 (February 2018), [www.gao.gov/products/D18622](http://www.gao.gov/products/D18622) (accessed September 25, 2019).

<sup>136</sup> See GAO, *Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries*, GAO-18-585T (May 2018), [www.gao.gov/products/GAO-18-585T](http://www.gao.gov/products/GAO-18-585T) (accessed September 25, 2019).

<sup>137</sup> See GAO, *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (June 2015), [www.gao.gov/products/GAO-15-471](http://www.gao.gov/products/GAO-15-471) (accessed September 25, 2019).

## DEA'S RESPONSE TO THE DRAFT REPORT




U. S. Department of Justice  
Drug Enforcement Administration

[www.dea.gov](http://www.dea.gov)

SEP 25 2019

MEMORANDUM

TO: Nina Pelletier  
Assistant Inspector General for  
Evaluation and Inspections  
Office of the Inspector General

FROM: Mary B. Schaefer   
Chief Compliance Officer  
Office of Compliance

SUBJECT: DEA Response to the OIG Final Report, "Review of Regulatory and Enforcement Efforts to Control the Diversion of Opioids"

The Drug Enforcement Administration (DEA) has reviewed the Department of Justice (DOJ) Office of the Inspector General's (OIG) Evaluation and Inspections Division report entitled, "Review of Regulatory and Enforcement Efforts to Control the Diversion of Opioids." DEA appreciates the OIG's assessment of DEA's ongoing efforts to combat the diversion of prescription opioids. While the report rightly identifies areas for improvement, we believe that it is important to both highlight the positive progress that DEA has made in the last several years, and to provide context to some of the key observations made in the report.

The DEA uses a wide array of tools – administrative, civil, and criminal – to fight the diversion of controlled substances. While only a minute fraction of the more than 1.8 million DEA registrants are involved in unlawful activity of this nature, DEA works to identify and root out the bad actors – whether they are manufacturers, distributors, pharmacies, or prescribers. In the past eight years, DEA has removed approximately 900 registrations annually, preventing further diversion of controlled substances. Working with United States Attorney's Offices across the country, an increasing number of individuals and corporations are facing civil and criminal charges for actions that have fueled the opioid crisis. The information below provides recent highlights of DEA's efforts in this area:

- In July 2019, two former corporate officers of Miami-Luken, a pharmaceutical distributor, and two pharmacists were indicted on charges that they conspired to illegally distribute and dispense controlled substances. The indictment alleges that the distributor and its officials filled suspicious orders, including distributing over a four year period more than 3.7 million hydrocodone pills to a pharmacy in a town of 400 people.

- In April 2019, in a first-of-its-kind prosecution, two executives of Rochester Drug Cooperative (RDC), one of the ten largest pharmaceutical distributors in the United States, and the distributor itself were charged with drug trafficking and conspiring to defraud the DEA. As alleged, RDC knowingly and intentionally violated the federal narcotics laws by distributing dangerous, highly addictive opioids to pharmacy customers that it knew were being sold and used illicitly.
- DEA has pursued civil actions against some of the nation's largest drug distributors. In FY 2017, DEA secured more than \$194 million in civil penalties, which is more than the total of the prior seven years combined. As of August 2019, DEA has secured over \$51 million in civil penalties.
- In the last three years, DEA has reduced by over 45% the aggregate production quota for the seven most frequently diverted controlled substance opioids. DEA's 2020 quota proposal would bring this to 53% if implemented. There has been a precipitous decline in the number of opioid prescriptions since the beginning of this Administration as well: comparing January 2017 to August 2019, the number of prescriptions for those seven opioids has decreased by nearly 30%.
- DEA also works to educate its registrant community in an effort to stop potential diversion before it occurs. DEA has educated over 13,000 pharmacists and other pharmacy personnel in all 50 states, D.C., and Puerto Rico, and is now hosting similar events for practitioners (e.g., doctors, dentists, veterinarians) to educate them on pre-emptive steps that can be taken to prevent diversion. Since May 2018, DEA has held 25 conferences in 13 locations, reaching over 5,800 healthcare professionals.
- DEA also utilizes its administrative authority to remove registrations from individuals or entities who act contrary to the public interest. Last fiscal year, DEA issued 20 Immediate Suspension Orders (ISOs), 71 Orders to Show Cause (OTSC), and obtained 774 surrenders for cause. The statistics for this fiscal year are likely to meet or exceed those from FY 2018.

These recent accomplishments build on several years of impactful partnership between DEA's Diversion Control Division and the Office of Chief Counsel. Below, we provide additional information in response to the report's findings that DEA did not use its available resources, including its administrative enforcement tools and data systems, to detect and regulate diversion effectively.

In finding that DEA's use of the ISO enforcement tool decreased from FY 2011 through FY 2015, and again in FY 2017, as compared to prior years, the report does not fully take into account the factors that contributed to that decline. As acknowledged in the report, DEA previously identified several factors relevant to the decrease.<sup>1</sup> These included: the substantial decline in opioid prescriptions since 2012 and the concomitant shift in diversion from prescription opioids to heroin/fentanyl, the past reluctance of U.S. Attorney's Offices to allow DEA to proceed administratively if parallel criminal investigations/matters were pending, DEA's strategic shift in 2011-2012 to target "upstream" registrants, the increase of registration surrenders, and the lack of

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<sup>1</sup> See Report at 23-24, nn. 67 & 69.



adequate training of DEA investigation personnel on administrative remedies (including ISOs).

The report focuses only on two of these factors—“the end of DEA’s successful efforts to take down ‘pill mills’ and the poor working relationship between DEA’s Office of Chief Counsel and Diversion Control staff.”<sup>2</sup> While DEA concurs that the end of Operations Pill Nation I & II in Florida, and other large-scale DEA enforcement operations was unquestionably significant in terms of the decline in ISOs after 2012, DEA believes that the report overstates the purported impact of the working relationship between the Office of Chief Counsel and the Office of Diversion Control on the decline in ISOs.

For example, although DEA produced files on 992 cases, the report discusses only two of them. Thus, in over 99% of the cases, the OIG appears to have found no evidence that discord between the Office of Chief Counsel and Diversion Control Division played a role in the decision to pursue an ISO. Moreover, even in the two cases discussed in the report, a lack of cooperation was not the reason that an ISO was not issued in either case. In one case, investigative personnel did not seek administrative action against the target for over a year after the alleged misconduct occurred. The ISO was not issued because at that point it was too late to show “imminent danger” based on the evidence presented. In the second case, as the report correctly recognizes, the Office of Chief Counsel was denied access to a medical expert. In that case, the testimony was essential to support administrative action and the ISO could not be issued without it.<sup>3</sup>

The report accurately observes that federal courts reviewing DEA ISOs had previously faulted DEA for presenting insufficient evidence.<sup>4</sup> In response to this criticism, DEA redoubled its efforts to ensure that the cases it presented were supported by adequate evidence. Though two subsequent cases were discussed where further information was requested by the Office of Chief Counsel, these requests were consistent with what the courts and pertinent case law require.

In failing to give adequate consideration to the other factors contributing to the decline in ISOs, the report disproportionately suggests that the decline in ISOs was due primarily to shortcomings at DEA. In fact, as the additional information DEA provided demonstrates, positive factors such as the decline in opioid prescriptions since 2012 and the increase in registration surrenders also contributed to the decline in ISOs.

As the case disposition data that DEA provided to OIG shows, although DEA issued fewer ISOs after 2012, between FY 2010 and FY 2019, the DEA charged 68.5% of the cases presented. This number rises to 82.6% when one accounts for cases that were favorably terminated prior to the issuance of a charging document (e.g., registrants surrendered their registration prior to charging).<sup>5</sup>

Additionally, the Office of Chief Counsel has declined only 7.6% of the cases opened during the review period, and when years FY 2018 and FY 2019 are included, that number drops to 6.5%.<sup>6</sup>

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<sup>2</sup> Report at 47.

<sup>3</sup> Report at 25, n.71.

<sup>4</sup> See Report at 23-24 (discussing *Cardinal* ISO federal court litigation).

<sup>5</sup> *Id.* FY2019 data was provided through June 26, 2019.

<sup>6</sup> *Id.* Since DEA charged or terminated 82.6% of the cases and declined to charge 7.6% of them, the remaining cases were either settled prior to the issuance of a charging document (4%) (e.g., McKesson), held at the request of DEA investigators

Importantly, the percentage of cases declined has decreased by over 60% during the review period. For the first half of the review period (FY 2010-FY 2013), the declination rate was 9.7%. For the second half (FY 2014-FY 2017), the declination rate was less than half that, or 4.0%. When the second portion of the review period is extended to include FY2018 and FY2019 to date, the percentage of cases declined drops to 2.8%. No case has been declined since FY 2016.

DEA believes that this additional context is important to clarify the reasons for the declines in ISOs during the review period. DEA appreciates OIG's recognition that although discord once existed between the Office of Chief Counsel and the Diversion Control Division, it does not exist today, and has not for years. DEA further believes that collaboration between the Office of Chief Counsel and the Diversion Control Division has produced demonstrable results. Changes in DEA senior leadership in 2015-2016 substantially improved the relationship between the two offices, which currently enjoy a productive, collaborative working relationship.

Other factors also enhanced the working relationship between the offices. For more than three years now, the Office of Chief Counsel's Diversion & Regulatory Litigation Section (CCD) and the Diversion Control Division's Pharmaceutical Investigations Section (DOP) have partnered to provide additional training and assistance to DEA investigators, jointly conducting hundreds of site visits and trainings to increase field investigative personnel's awareness of, and familiarity with, DEA administrative proceedings and the associated evidentiary requirements.

This training regarding case investigation and preparation, in combination with the revised case intake process, has significantly improved the quality of case files presented for administrative action, which in turn speeds case initiation. As the quality of case files improves, cases can be charged more quickly. In FY 2016, for example, the median amount of time between receiving a case file and issuing a charging document was 24 days. By FY 2018, that time had declined to 15 days. As of the end of FY 2018, there were no uncharged cases pending in the Office of Chief Counsel, which has the capacity and capability to review additional cases.

These improvements in training and process have yielded results. In FY 2018, for example, DEA charged 91 cases administratively (71 OTSCs, 20 ISOs). This upward trend continues, as DEA has charged 100 cases (72 OTSCs, 28 ISOs) in FY2019 to date.<sup>7</sup> And as noted previously, no cases have been declined since FY 2016.

DEA anticipates that this positive cycle will continue. Many investigative personnel who previously worked in DOP and alongside CCD have now been promoted to senior leadership positions in various field divisions. Due to their expertise in administrative revocation proceedings, these personnel are working to remedy many of the training issues noted in the past. These personnel are also poised to collaborate with CCD and facilitate even greater use of the DEA administrative process.

With respect to parallel proceedings, the Office of Chief Counsel and Diversion Control Division have jointly worked with field investigative personnel to ensure that DEA pursues ISOs when feasible in parallel with criminal investigations/matters. As such collaborations continue to be

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or US Attorney's Offices (5.5%), or are cases in which investigative personnel are working to obtain additional materials (0.3%).

<sup>7</sup> FY2019 aggregate case data through September 12, 2019.

successful, DEA is optimistic that the historical reticence to allow DEA to proceed administratively in parallel with criminal proceedings will dissipate.

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OIG made a total of nine recommendations in this report, in which seven recommendations are directed to DEA. DEA provides the following responses to its recommendations:

**Recommendation 1. Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combatting the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.**

#### **DEA RESPONSE**

DEA concurs with this recommendation. Although the Office of National Drug Control Policy is the entity within the federal government responsible for developing a national opioid enforcement strategy, DEA will undertake an internal review to develop a DEA-wide national prescription opioid enforcement strategy that incorporates the work of all DEA field divisions, to include metrics of performance to measure the strategy's progress.

**Recommendation 2. Require criminal background investigations of all new registrant applicants.**

#### **DEA RESPONSE**

DEA concurs with the recommendation. DEA agrees that it would be useful to require background investigations of all new registrant applicants. Currently, Diversion Control Division's Registrant Program Specialists (RPS) are authorized to request background checks on new registrant applications through a third party company. The Diversion Control Division is in the final approval process of issuing a guidance memorandum to its RPS staff that background checks on new registrant applications are mandatory, effective immediately. The scheduled issue date of the memorandum is anticipated to be October 1, 2019. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

**Recommendation 3. Implement electronic prescribing for all controlled substance prescriptions.**

#### **DEA RESPONSE**

DEA concurs with the recommendation. The electronic prescribing of controlled substance prescriptions is already authorized for those practitioners who wish to do so. On March 31, 2010, DEA published in the Federal Register an interim final rule entitled, "Electronic Prescriptions for Controlled Substances." The effective date of this rule was June 1, 2010. Additionally, the SUPPORT Act (PL 115-271) signed into law on October 24, 2018, requires DEA, within one year of the law's enactment, to update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances. DEA is working to publish a final rule on the electronic prescribing of controlled

substances. This rule is on the Unified Agenda as a DOJ and Administration priority.

**Recommendation 4: Require that all suspicious orders reports be sent to DEA headquarters.**

**DEA RESPONSE**

DEA concurs with the recommendation. DEA agrees that all suspicious order reports should be sent to DEA headquarters. Registrants are currently required to report suspicious orders to the Field Division Office. 21 C.F.R. 1301.74(b). The SUPPORT Act requires that DEA establish a centralized database for collecting reports of suspicious orders within one year of the law's enactment. DEA is currently working to finalize the database for release by the statutorily mandated deadline of October 23, 2019. Additionally, DEA is drafting regulations pertaining to suspicious orders. This regulation is on the Unified Agenda as a DOJ and Administration priority.

**Recommendation 5. Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants' history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.**

**DEA RESPONSE**

DEA concurs with the recommendation. DEA's current registration application forms already include a set of liability questions that require the applicant to disclose, on pain of a material falsification charge, information including registration revocations/surrenders and state licensure actions.

When an applicant answers any liability question in the affirmative, DEA initiates a pre-registration inquiry to further explore the applicant's response.

It is important to note that DEA lacks the authority to amend or alter the Controlled Substances Act (CSA) via guidance documents. Rather, guidance must come from agency case law applying the CSA, which specifies the legal considerations that guide the public interest analysis in DEA administrative proceedings, including reapplications. This case law provides extensive guidance on the application of the CSA's remedial framework and the relevant factors that DEA must consider under the CSA. For many years, DEA's Diversion Control Division has published all registration adjudication opinions on its website, which is available to the public and DEA investigative personnel.

Since 2015, DEA's Office of Chief Counsel has also produced its Deskbook, a reference handbook for diversion investigative personnel that is intended to address common questions and issues that frequently arise in registration investigations/adjudications. The Office of Chief Counsel has revised and disseminated the Deskbook three times. The Deskbook explains the pertinent criteria and legal analysis that DEA must apply under the CSA.

In response to this recommendation, DEA will examine the current pre-registration inquiry process and guidance to see if improvements can be made to better ensure that DEA Diversion Control Division personnel responsible for adjudicating registrant reapplications are fully informed of the standards for review when conducting a pre-registration inquiry. DEA will then report to the OIG on any changes that are deemed necessary.

**Recommendation 6. Revise field division work plan requirements to allow the flexibility to target registrants for investigation.**

**DEA RESPONSE**

DEA concurs with the recommendation. DEA agrees that it is important to allow flexibility to target registrants for investigation. The 2019 work plan was modified to allow the flexibility for the field to investigate threats in their area of responsibility. Per the FY 2019 work plan parameters, scheduled investigations were required to be completed on a registrant within five years of the last completed scheduled investigation. As such, the FY 2019 work plan covered FY 2019 – FY 2023. It allowed each division to have the flexibility to create their scheduled investigation work plan, based on identified concerns by division management and to choose a time frame for a scheduled investigation between one to five years. It is important to note that these dates are fluid and can be modified at any time to meet the threat assessment in each field division's area of responsibility. The Diversion Control Division has the authority to issue new work plans as needed to outline any changes that are determined to be necessary to address the ever changing landscape of diversion of controlled substances. The Diversion Control Division's strategy is to focus efforts on investigations that will aggressively combat the opioid epidemic and emerging drug threats. The Diversion Control Division is in the final approval stages of issuing a memorandum with new scheduled investigation guidance for FY2020. The anticipated issue date of this memorandum is October 1, 2019, and it will be distributed to all of the Diversion Control Division field offices. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

**Recommendation 7. Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues, and respond to these threats in a timely manner.**

**DEA RESPONSE**

DEA agrees that identifying and responding to emerging drug abuse trends is important to protect public health and safety, and the Diversion Control Division has a number of existing programs and initiatives to identify new and emerging drug threats.

The National Forensic Laboratory Information System (NFLIS) began in September 1997 as a single data collection effort of drug chemistry analysis results from local, state, and federal forensic laboratories (now called NFLIS-Drug). These laboratories analyze substances recovered/seized in law enforcement operations across the country. NFLIS-Drug is a valuable resource for monitoring illegal drug abuse and trafficking, including the diversion of legally manufactured pharmaceutical drugs into illegal markets. NFLIS-Drug data is used to support drug regulatory and scheduling efforts and to inform drug policy and drug enforcement initiatives nationally and in local communities.

NFLIS-Drug includes data from forensic laboratories that conduct analyses of approximately 98% of the Nation's approximate 1.5 million annual drug cases. As of February 2019, NFLIS-Drug includes 50 State systems and 104 local or municipal laboratories/laboratory systems, representing a total of 283 individual laboratories. A recent example of how NFLIS data is used is the NFLIS-Drug Special Release Maps, which highlight fentanyl and selected fentanyl-related substances reported to NFLIS-Drug in 2016 and 2017, and can be found on the NFLIS website.

Recently, DEA expanded the NFLIS program to include (1) public and private toxicology laboratory (NFLIS-Tox) data regarding postmortem and antemortem toxicological testing, and (2) medical examiner and coroner office (NFLIS-MEC) data regarding deaths in which drugs were identified. These two continuous data collection programs complement NFLIS-Drug and further support the DEA's drug regulatory and scheduling efforts. NFLIS recently reported findings from the 2017 Toxicology Laboratory Survey and 2017 Medical Examiner and Coroner Survey in support of starting the NFLIS-Tox and NFLIS-MEC programs.

In addition to the existing NFLIS system and our NFLIS enhancements, DEA recently initiated a contract with the University of California at San Francisco (UCSF) whereby biological samples generated from overdose victims of synthetic drugs can be further analyzed. This program's goal is to connect symptom causation and newly emerging synthetic drugs (i.e. synthetic cannabinoids, synthetic cathinones, fentanyl-related substances, other hallucinogens etc.). In addition to identifying new and emerging drugs of abuse, this program will assist investigators in building "death resulting from" cases against those who traffic controlled substances.

DEA will work with OIG to provide proof of these efforts and move towards closure of this recommendation.

Thank you for the opportunity to respond and address the OIG's concerns. If you have any questions regarding this response, please contact DEA's Audit Liaison Team at 202-307-8200.

## **OIG ANALYSIS OF DEA'S RESPONSE**

OIG provided a draft of this report to DEA. DEA's formal response to the recommendations in the report is included in Appendix 4. DEA concurred with all of OIG's recommendations. Below, we discuss OIG's analysis of DEA's formal response and actions necessary to close the recommendations.

Separately, DEA's response questions the report's finding that a historically poor working relationship between the Office of Chief Counsel (CCD) and the Office of Diversion Control (OD) impacted DEA's use of Immediate Suspension Orders (ISO). In support of its position, DEA states that it "produced files on 992 cases [and] the report discusses only two of them. Thus, in over 99% of the cases, the OIG appears to have found no evidence that discord between [CCD] and [OD] played a role in the decision to pursue an ISO." We do not agree with DEA's position. First, DEA's response fails to mention what we were told by former long-time DEA agent and acting DEA Administrator Patterson, namely that the relationship between field division Diversion Control staff, OD, and CCD had historically been "toxic." Second, as clearly stated in the report, the two cases discussed were cited as examples of the discord we found, consistent with former acting Administrator Patterson's statement. The fact that the report does not discuss the remaining 990 cases does not support a conclusion that "OIG appears to have found no evidence of discord" in those cases. We continue to believe that our finding is supported by the evidence we obtained during our review; however, as stated in the report, and as DEA describes in its response, we believe that DEA has taken recent steps to address the issue and improve this relationship.

**Recommendation 1:** Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combating the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.

**Status:** Resolved.

**DEA Response:** DEA concurred with the recommendation and stated that it will undertake an internal review to develop a national prescription opioid enforcement strategy that incorporates the work of all DEA field divisions and includes performance metrics to measure the strategy's progress.

**OIG Analysis:** DEA's actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a status update regarding DEA's efforts to develop a national prescription opioid enforcement strategy that includes performance metrics to measure the strategy's progress and incorporates the work of all DEA field divisions.

**Recommendation 2:** Require criminal background investigations of all new registrant applicants.

**Status:** Resolved.



**DEA Response:** DEA concurred with the recommendation and agrees that it would be useful to require background investigations on all new registrant applicants. Currently, the Diversion Control Division's Registrant Program Specialists (RPS) are authorized to request background investigations on new registrant applications through a third party company. On October 1, 2019, the Diversion Control Division plans to issue a guidance memorandum to its RPS staff requiring mandatory background investigations on new registrant applications. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

**OIG Analysis:** DEA's actions are responsive to our recommendation, provided that the anticipated guidance memorandum requires RPS staff to request "criminal" background investigations on all new registrant applications. By January 3, 2020, please provide a copy of the guidance memorandum to RPS staff and confirm that the type of background investigations now required are in fact "criminal" background investigations.

**Recommendation 3:** Implement electronic prescribing for all controlled substance prescriptions.

**Status:** Resolved.

**DEA Response:** DEA concurred with the recommendation. The electronic prescribing of controlled substance prescriptions is already authorized for those practitioners who wish to do so. On March 31, 2010, DEA published in the *Federal Register* an interim final rule entitled, "Electronic Prescriptions for Controlled Substances," which became effective on June 1, 2010. Additionally, the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (PL 115-271), signed into law on October 24, 2018, requires DEA, within 1 year of the law's enactment, to update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances. DEA is working to publish a final rule on the electronic prescribing of controlled substances. This rule is on the Unified Agenda as a Department and Administration priority.

**OIG Analysis:** DEA's anticipated actions are partially responsive to our recommendation. While there are several rules DEA proposed on the Unified Agenda of the Office of Management and Budget at various stages in the rulemaking process, the OIG was unable to locate publicly available documentation that pertains to the publication of a final rule on mandatory electronic prescribing for all controlled substances. By January 3, 2020, please provide a status update and clarification regarding the publication of this anticipated final rule.

**Recommendation 4:** Require that all suspicious orders reports be sent to DEA headquarters.

**Status:** Resolved.

**DEA Response:** DEA concurred with the recommendation and agrees that all suspicious order reports should be sent to DEA headquarters. In accordance

with 21 C.F.R. 1301.74(b), registrants are currently required to report suspicious orders to DEA Field Divisions. However, since the enactment of the SUPPORT Act, DEA is required to implement the use of a centralized database for the collection of suspicious order reports. The statute requires that the database is functional by October 23, 2019. Additionally, DEA is drafting regulations pertaining to suspicious orders. This regulation is on the Unified Agenda as a Department and Administration priority.

**OIG Analysis:** DEA's actions are responsive to our recommendation. The OIG has confirmed that the proposed rule, which defines the term "suspicious order" and provides clarity to the registrant community on its reporting obligations, directly addresses the corrective action recommended in our report. In addition, the implementation of a centralized database for the collection of suspicious order reports also directly addresses the corrective action recommended. By January 3, 2020, please provide documentation confirming that suspicious order reports are being collected and housed in the new database and provide a status update regarding the proposed rulemaking regarding suspicious orders.

**Recommendation 5:** Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants' history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.

**Status:** Resolved.

**DEA Response:** DEA concurred with the recommendation. DEA's current registration application forms already include a set of liability questions that require the applicant to disclose, on pain of a material falsification charge, information including registration revocations/surrenders and state licensure actions. When an applicant answers any liability question in the affirmative, DEA initiates a pre-registration inquiry to further explore the applicant's response.

It is important to note that DEA lacks the authority to amend or alter the Controlled Substances Act (CSA) via guidance documents. Rather, guidance must come from agency case law applying the CSA, which specifies the legal considerations that guide the public interest analysis in DEA administrative proceedings, including reapplications. This case law provides extensive guidance on the application of the CSA's remedial framework and the relevant factors that DEA must consider under the CSA. For many years, DEA's Diversion Control Division has published all registration adjudication opinions on its website, which is available to the public and DEA investigative personnel.

Since 2015, DEA's CCD also produced, revised, and disseminated its Deskbook, a reference handbook for diversion investigative personnel that is intended to address common questions and issues that frequently arise in

registration investigations/adjudications. The Deskbook explains the pertinent criteria and legal analysis that DEA must apply under the CSA.

In response to this recommendation, DEA will examine the current pre-registration inquiry process and guidance to see whether improvements can be made to better ensure that DEA Diversion Control Division personnel responsible for adjudicating registrant reapplications are fully informed of the standards for review when conducting a pre-registration inquiry. DEA will then report to OIG on any changes that are deemed necessary.

**OIG Analysis:** DEA's actions are responsive to our recommendation. By January 3, 2020, please provide a status update regarding DEA's examination of the current pre-registration inquiry process and guidance documents associated with that process and describe any improvements DEA plans to make.

**Recommendation 6:** Revise field division work plan requirements to allow the flexibility to target registrants for investigation.

**Status:** Resolved.

**DEA Response:** DEA concurred with the recommendation and reported that its FY 2019 Diversion Control work plan was modified to allow flexibility for each field division to investigate threats in its area of responsibility. More specifically, DEA stated that the FY 2019 work plan allowed each division to create its scheduled investigation work plan based on concerns identified by division management and to choose a time frame for a scheduled investigation between 1 to 5 years. DEA also acknowledged that these dates are fluid and can be modified at any time to meet the threat assessment in each field division's area of responsibility. Further, DEA stated that the Diversion Control Division has the authority to issue new work plans as needed to outline any changes that are determined to be necessary to address the ever changing landscape of the diversion of controlled substances. Moreover, DEA reported that the Diversion Control Division is in the final approval stages of issuing a memorandum with new scheduled investigation guidance for FY 2020. DEA anticipates that this guidance will be issued to all Diversion Control Division field offices on October 1, 2019. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

**OIG Analysis:** DEA's anticipated actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a copy of the FY 2020 scheduled investigation guidance memorandum that extends the flexibilities outlined in the FY 2019 work plan.

**Recommendation 7:** Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues and respond to these threats in a timely manner.

**Status:** Resolved.

**DEA Response:** DEA agreed with the recommendation and reported that its Diversion Control Division uses a number of programs and initiatives to identify new and emerging drug threats. Specifically, DEA stated that it uses the National Forensic Laboratory Information System (NFLIS), established in September 1997 and now called NFLIS-Drug, as a single data collection effort of drug chemistry analysis results from local, state, and federal forensic laboratories. In addition, DEA noted that these laboratories analyze substances recovered and seized in law enforcement operations across the country and monitor trafficking and illegal drug abuse, including the diversion of legally manufactured pharmaceutical drugs into illegal markets. Further, DEA reported that NFLIS-Drug includes data from forensic laboratories that conduct analyses of approximately 98 percent of the nation's annual drug cases and that as of February 2019 included 283 laboratories across the nation. DEA also stated that NFLIS-Drug data is used to support drug regulatory and scheduling efforts to inform drug policy and drug enforcement initiatives nationally and in local communities.

In addition, DEA stated that it recently expanded the NFLIS program to include (1) public and private toxicology laboratory data regarding postmortem and antemortem toxicological testing and (2) medical examiner and coroner office data regarding deaths in which drugs were identified. Moreover, DEA reported that it recently initiated a contract with the University of California at San Francisco whereby biological samples generated from overdose victims of synthetic drugs can be further analyzed. DEA stated that the goal of the program is to connect symptom causation and newly emerging synthetic drugs (i.e., synthetic cannabinoids, synthetic cathinones, fentanyl-related substances, other hallucinogens, etc.). The program will assist investigators in building "death resulting from" cases against those who traffic controlled substances.

**OIG Analysis:** DEA's actions are responsive to our recommendation. By January 3, 2020, please provide OIG with documentation supporting DEA's efforts to expand the NFLIS program to include public and private toxicology laboratory data regarding postmortem and antemortem toxicological testing and medical examiner and coroner office data regarding deaths in which drugs were identified. Also, please provide OIG with information regarding the quality and frequency with which these types of data will be entered into the NFLIS system, and how DEA will use this information to respond to emerging drugs threats.

# THE DEPARTMENT'S RESPONSE TO THE DRAFT REPORT



U.S. Department of Justice

Office of the Deputy Attorney General

Bradley Weinsheimer  
Associate Deputy Attorney General

Washington, D.C. 20530

## MEMORANDUM

**TO:** Nina S. Pelletier  
Assistant Inspector General  
Evaluation and Inspections Division  
Office of the Inspector General

**FROM:** *g. Bradley Weinsheimer*  
Bradley Weinsheimer  
Associate Deputy Attorney General  
Office of the Deputy Attorney General

**DATE:** September 25, 2019

**SUBJECT:** Response to OIG's Draft Report: "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, Assignment Number A-2017-003"

The Office of the Deputy Attorney General (ODAG) appreciates the review undertaken by the Office of the Inspector General (OIG) and the opportunity to comment on OIG's draft report, "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, Assignment Number A-2017-003" (the "Report").

The Report sets forth several recommendations. Recommendations One through Eight are directed at the Drug Enforcement Administration (DEA). However, the Report also directs two separate recommendations for the Department below.

1. **Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs**

While the Department concurs with this recommendation, and will coordinate with DEA and state and local partners to effectuate it, we do wish to raise a few practical and legal concerns. As the OIG Report itself notes, state jurisdictions substantially limit law enforcement access to its Prescription Drug Monitoring Programs (PDMP). State authorities often require heightened legal cause (e.g. search warrant) to access PDMPs and sometimes prohibit access altogether. In jurisdictions that provide greater access to "state and local partners" than federal law enforcement, state law enforcement may not be able to share PDMP information with the DEA under state and local law.

Accordingly, we request that OIG's assessment of Department "efforts" recognize that it may not be feasible or legal for state law enforcement to afford DEA complete access to PDMPs in the manner contemplated by this recommendation.

2. **Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.**

The Department concurs with the recommendation. While the Department certainly will consider expanding the Opioid Fraud and Abuse Detection Unit pilot program upon its conclusion and will determine whether it would be feasible and appropriate to increase the number of federal prosecutors dedicated to prosecuting opioid-related cases, the allocation of limited prosecutorial resources is a matter reserved to the discretion of Department leadership. These decisions require policy determinations entailing careful cost and resource balancing of different strategic priorities and objectives.

**OIG ANALYSIS OF THE DEPARTMENT'S RESPONSE**

OIG provided a draft of this report to the Office of the Deputy Attorney General (ODAG). ODAG's formal response is included in Appendix 6. ODAG concurred with all of OIG's recommendations. Below, we discuss OIG's analysis of ODAG's formal response and actions necessary to close the recommendations.

**Recommendation 8:** Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs.

**Status:** Resolved.

**ODAG Response:** While the Department concurs with this recommendation and will coordinate with DEA and state and local partners to effectuate it, the Department wishes to raise a few practical and legal concerns. As the OIG report notes, state jurisdictions substantially limit law enforcement access to their Prescription Drug Monitoring Programs (PDMP). State authorities often require heightened legal cause (e.g., search warrants) to access PDMPs and sometimes prohibit access altogether. In jurisdictions that provide greater access to "state and local partners" than federal law enforcement, state law enforcement may not be able to share PDMP information with the DEA under state and local law.

Accordingly, we request that OIG's assessment of Department "efforts" recognize that it may not be feasible or legal for state law enforcement to afford DEA complete access to PDMPs in the manner contemplated by this recommendation.

**OIG Analysis:** ODAG's planned actions are responsive to our recommendation. OIG understands the limitations that the Department and DEA face in obtaining greater access to PDMP information. By January 3, 2020, please provide OIG with a status update regarding the efforts that the Department has made to enhance coordination between DEA and its state and local partners to obtain greater access to this information.

**Recommendation 9:** Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.

**Status:** Resolved.

**ODAG Response:** The Department concurred with the recommendation. While the Department certainly will consider expanding the Opioid Fraud and Abuse Detection Unit pilot program upon its conclusion and will determine whether it would be feasible and appropriate to increase the number of federal prosecutors dedicated to prosecuting opioid-related cases, the allocation of limited prosecutorial resources is a matter reserved for the discretion of Department leadership. These decisions require policy determinations entailing careful cost and resource balancing of different strategic priorities and objectives.

**OIG Analysis:** ODAG's planned actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a status update regarding any future plans for the maintenance and expansion of the Opioid Fraud and Abuse Detection Unit pilot program.





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