



March 2018

ILLICIT OPIOIDS

While Greater
Attention Given to
Combating Synthetic
Opioids, Agencies
Need to Better Assess
their Efforts

GAO Highlights

Highlights of [GAO-18-205](#), a report to congressional requesters

Why GAO Did This Study

Increased illicit use of synthetic (man-made) opioids has contributed to drug-related overdose deaths. Synthetic opioids like fentanyl—a substance 100 times stronger than morphine—accounted for more than 19,000 of the nearly 64,000 overdose deaths in 2016, the most recent year for which federal data are available. GAO was asked to review U.S. agency efforts to combat illicit synthetic opioids.

This report examines how U.S. agencies (1) work with international partners to limit production of illicit synthetic opioids; (2) work domestically to limit the availability of and enhance their response to these drugs and how agencies can improve their effectiveness; (3) measure performance in their documented opioid response strategies; and (4) have adapted their approaches to prevention and treatment.

GAO reviewed documents that described agencies' international coordination efforts, domestic opioid reduction strategies and prevention and treatment approaches, and interviewed international and federal agency officials engaged in drug control policy. GAO also interviewed state and local law enforcement and public health officials in seven states, selected in part for their high rates of overdose deaths.

What GAO Recommends

GAO is making six recommendations, including that agencies develop performance metrics. DHS agreed, ONDCP did not state whether they agreed or disagreed, and DOJ did not agree with GAO's recommendations. GAO continues to believe that these recommendations remain valid.

View [GAO-18-205](#). For more information, contact Diana Maurer at (202) 512-8777 or maurerd@gao.gov.

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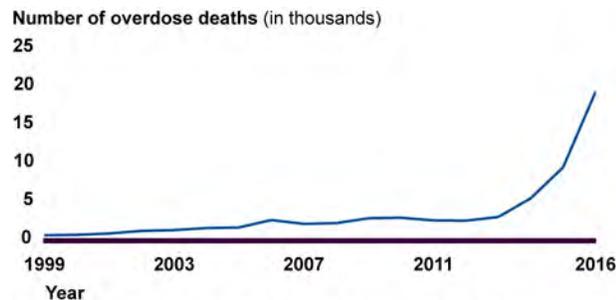
While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts

What GAO Found

Federal agencies collaborate with foreign governments, such as China, Mexico, and Canada, as well as with international organizations, to limit the production of illicit synthetic opioids. They do this by enhancing investigations, sharing information on emerging trends, helping to expand the regulation of illicit substances, and building capacity to thwart the distribution of illicit drugs.

Federal agencies have ongoing efforts to limit the domestic availability of and enhance their response to illicit synthetic opioids. For example, federal efforts include treating overdose death scenes as crime scenes where officers collect evidence to investigate and identify the drug source.

Overdose Deaths Involving Synthetic Opioids and Size of a Lethal Dose of Fentanyl



Source: National Center on Health Statistics; adaptation of U.S. Drug Enforcement Administration information (photo). | GAO-18-205

Federal agencies have also documented specific strategies to combat illicit opioids. However, only one of the five strategies we reviewed included outcome, or results-oriented measures—largely due to agency perceptions that designing such measures posed challenges. The Government Performance and Results Act Modernization Act of 2010 directs agencies to develop goals, as well as performance indicators. Without specific outcome-oriented performance measures, federal agencies will not be able to truly assess whether their respective investments and efforts are helping them to limit the availability of and better respond to the synthetic opioid threat. We also found that while federal law enforcement agencies are increasingly coordinating with the public health sector to share overdose information, both sectors reported ongoing data sharing obstacles and related challenges with the timeliness, accuracy, and accessibility of overdose data. Standards for Internal Control in the Federal Government states that information for decision-making should be appropriate, current, complete, accurate, accessible, and provided on a timely basis. Embarking on a concerted effort, led by the Office of National Drug Control Policy (ONDCP), to examine and address data related concerns will enhance agencies' efforts continue to understand and respond to the opioid epidemic.

Federal agencies have adapted to the opioid epidemic by, among other things, expanding prevention programs and treatment options. For example, agencies have increased engagement with medical professionals about the implications of prescribing practices to help reduce opioid abuse, and provided additional resources to states and localities to expand the distribution and use of overdose reversal and treatment options.

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Abbreviations

AACT	American Academy of Clinical Toxicology
ACMT	American College of Medical Toxicology
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
DARE	Drug Abuse Resistance Education
DEA	Drug Enforcement Administration
DHS	Department of Homeland Security
DOD	Department of Defense
DOJ	Department of Justice

EAD	Electronic Advance Data
EOUSA	Executive Office for United States Attorneys
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
HARP	Heroin Availability Reduction Plan
HHS	Department of Health and Human Services
HIDTA	High-Intensity Drug Trafficking Areas
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRS	Heroin Response Strategy
ICE-HSI	U.S. Immigration and Customs Enforcement – Homeland Security Investigations
INCB	International Narcotics Control Board
LSSD	Laboratories and Scientific Services Directorate
MAT	Medication-Assisted Treatment
NIDA	National Institute on Drug Abuse
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NTC	National Targeting Center
OCDETF	Organized Crime Drug Enforcement Task Forces
ONDCP	Office of National Drug Control Policy
SAMHSA	Substance Abuse and Mental Health Services Administration
UNODC	United Nations Office on Drugs and Crime
USAO	United States Attorney’s Office
USPIS	United States Postal Inspection Service
USPS	United States Postal Service

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March 29, 2018

Congressional Requesters

Though drug misuse and abuse in our nation is not a new phenomenon, the scale and impact of illicit drug use in this country has reached new heights. Policymakers, criminal justice officials, healthcare providers, and the public at large are turning with renewed attention to the drug epidemic and its impact on our nation. Deaths from drug overdoses have risen steadily over the past two decades and are the leading cause of death due to injuries in the United States. In fact, according to the Centers for Disease Control and Prevention (CDC), drug overdose deaths surpass the annual number of traffic fatalities, as well as deaths due to firearms, suicide, and homicide, respectively. According to figures from the CDC's National Center for Health Statistics, in 2016, the most recent year for which national data are available, there were nearly 64,000 deaths from drug overdoses, or approximately 175 people every day.

Recently, there has been a rise in opioid use in the United States involving both the nonmedical use of prescription drugs and more traditional illicit opioids, such as heroin. Coinciding with this increase, there also has been a significant increase in the use of man-made (synthetic) opioids, such as fentanyl and fentanyl analogues, which is a main contributor to the spikes in overdose deaths.¹ For example, according to CDC, of the nearly 64,000 drug overdose deaths in 2016, more than 15,000 involved heroin and more than 19,000 involved synthetic opioids such as fentanyl and fentanyl analogues. Public health and law enforcement experts expect this number to continue to increase.

You asked us to review the federal efforts to combat synthetic opioids. In this report, we examine the following: (1) how U.S. agencies work with international partners to limit the production of illicit synthetic opioids; (2) how U.S. agencies work domestically to limit the availability of and enhance their response to illicit synthetic opioids and how agencies can improve the effectiveness of these efforts; (3) how U.S. agencies' documented opioid-response strategies measure performance; and (4)

¹An analogue is a drug molecule that shares structural similarities with the original compound. It may also share pharmacological similarities.

how U.S. agencies have adapted prevention and treatment approaches in light of the illicit synthetic opioid epidemic.

To understand how U.S. agencies work with international partners to limit the production of illicit synthetic opioids, we collected information and interviewed officials from federal agencies that engage with international organizations and foreign governments on efforts related to international drug control scheduling, information sharing, and capacity building.²

These agencies included the Department of Homeland Security (DHS); Department of Defense (DOD); Department of Justice (DOJ); Department of Health and Human Services (HHS); Department of State (State); and Office of National Drug Control Policy (ONDCP). These agencies collaborate with the United Nations Office on Drugs and Crime (UNODC) and the International Narcotics Control Board (INCB) on issues related to illicit synthetic opioids. We interviewed officials from UNODC and INCB to learn about their roles in limiting the international production of these illicit substances.

Further, we interviewed federal law enforcement officials from the U.S. Drug Enforcement Administration (DEA), U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement-Homeland Security Investigations (ICE-HSI), and Federal Bureau of Investigation (FBI) stationed in China (including Hong Kong), Mexico, and Canada to understand their roles in those countries. This included their efforts to share information, coordinate investigations, encourage capacity building, and engage in drug scheduling efforts with foreign counterparts, including any challenges they may face operating in a foreign environment. We focused our review on these three countries based on documentary and testimonial evidence provided by DHS, DOJ, and State that indicated the majority of illicit synthetic opioids in the U.S. market are produced in China and either shipped directly into the United States or shipped into Mexico or Canada first, before being trafficked across the border.

To examine how U.S. agencies work domestically to limit the availability of and enhance their response to illicit synthetic opioids and to determine how agencies can improve the effectiveness of their efforts, we reviewed various documents that, among other things, outlined federal agencies'

²The process of drug scheduling involves categorizing a drug based on the substance's medical use, potential for abuse, and risk of dependence. This is intended to ensure the continued access and availability of controlled substances for medical purposes while preventing their diversion into illicit channels.

approaches to limit opioid distribution across the country. These documents included federal guidance for first responders on the safe handling of fentanyl and DEA documents that discuss the nature of the drug threats in the United States. Further, we interviewed cognizant law enforcement officials from DEA, CBP, ICE-HSI, and FBI—as well as officials from the United States Postal Service (USPS) and ONDCP, among others, about their efforts to reduce the domestic availability of synthetic opioids and how they coordinate with state and local law enforcement agencies and public health entities, such as medical examiners and coroners. We also interviewed federal officials working to test technologies to identify synthetic opioids, such as researchers from the Department of Commerce’s National Institute of Standards and Technology (NIST), and talked to experts from the American College of Medical Toxicology about the safe handling of synthetic opioids for first responders.

Additionally, we selected states to visit that (1) participate in federal drug control efforts, such as ONDCP’s High Intensity Drug Trafficking Areas’ (HIDTA) program, which coordinates efforts within specifically designated drug trafficking areas, and (2) experienced high rates of overdose deaths attributable to synthetic opioids, based on data from the CDC. These states included New York, New Jersey, Massachusetts, New Hampshire, Ohio, Kentucky, and Tennessee. We interviewed federal, state, and local law enforcement and public health officials to understand any challenges they may be facing in helping to limit illicit synthetic opioids, the unique efforts in which they were engaged, and the extent of their engagement with federal counterparts. Further, to better understand the issues with synthetic opioid trafficking at the southwest border, we visited Los Angeles and San Diego, including the San Ysidro Port of Entry, where CBP had conducted a pilot program using technology to detect illicit synthetic opioids. While there, we interviewed federal law enforcement officials about their actions to reduce the flow of synthetic opioids across the border and how they coordinate their efforts.

To examine how U.S. agencies’ documented opioid-response strategies measure performance, we first queried the federal agencies that are working to limit the domestic availability of synthetic opioids to identify any strategies that they had developed. We then reviewed the five documented strategies that the agencies provided to determine whether the agencies had built-in measures to assess the effectiveness of their efforts. Next, we assessed the nature and scope of the available measures against the Government Performance and Results Act Modernization Act of 2010. This act directs agencies to develop goals, as

well as performance measures, to provide federal agencies with information on how resources and efforts should be allocated to ensure effectiveness and keep program partners focused on the key goals of a program.³

To determine how U.S. agencies have adapted their approaches to prevention and treatment in response to the illicit synthetic opioid epidemic, we reviewed federal agency documents on the types of prevention and treatment now available for opioid abuse. In addition, we interviewed federal officials from agencies such as HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA), about their roles in preventing and treating opioid abuse, and any related initiatives they have that involve synthetic opioids. Further, we interviewed regional HIDTA officials and participants, United States Attorney's Office (USAO) district officials, and other key groups, such as state and local public safety and public health agencies in the states we visited, to better understand how federal, state, and local entities have coordinated across disciplines. We also attended the public sessions of the President's Commission on Combating Drug Addiction and the Opioid Crisis (President's Commission) and reviewed its reports and related recommendations. For additional details on our scope and methodology, see appendix I.

We conducted this performance audit from January 2017 through March 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

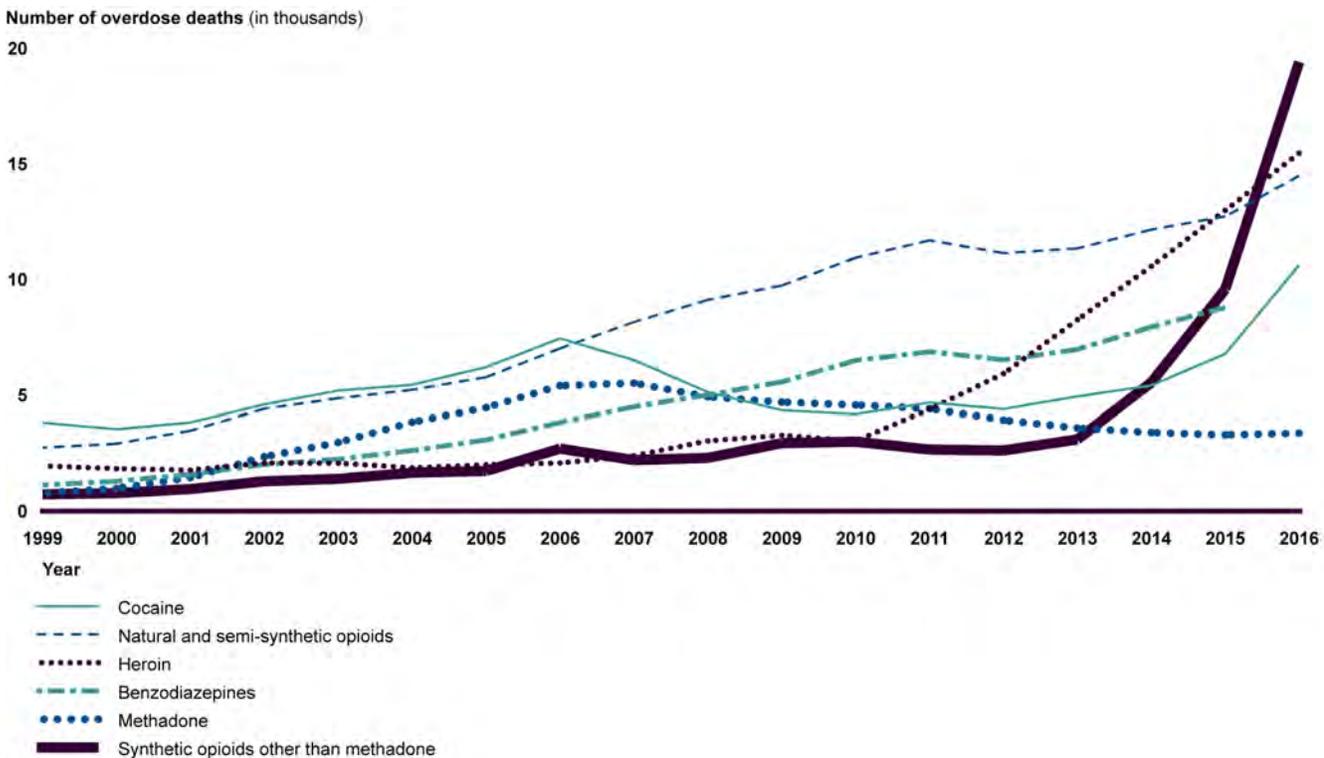
³The Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285 (1993), sets out the performance planning and reporting framework. The Government Performance and Results Act Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866 (2011), enhanced the Government Performance and Results Act by providing important tools that can help decision makers address challenges facing the federal government, help resolve longstanding performance and management problems, and provide greater accountability for results.

Background

Synthetic Opioid Production, Potency, Overdose Trends, and Effects on the Brain

Synthetic opioids are chemically produced in a laboratory, as opposed to opiates derived from the poppy plant, such as heroin and morphine. Their chemical structure can be either identical to or different from naturally occurring opioids and their effects are designed to mimic or even enhance those of natural drugs. According to the CDC, among the nearly 64,000 drug overdose deaths in 2016, the sharpest increase occurred among deaths related to synthetic opioids, such as fentanyl and fentanyl analogues (see fig. 1). These data show that overdose deaths involving synthetic opioids increased from 9,580 in 2015 (18 percent of all overdose deaths) to 19,413 in 2016 (31 percent of all overdose deaths)—an increase of more than 100 percent. A majority of these deaths are likely attributable to illicit fentanyl.

Figure 1: Drugs Involved in U.S. Overdose Deaths (1999-2016)^a

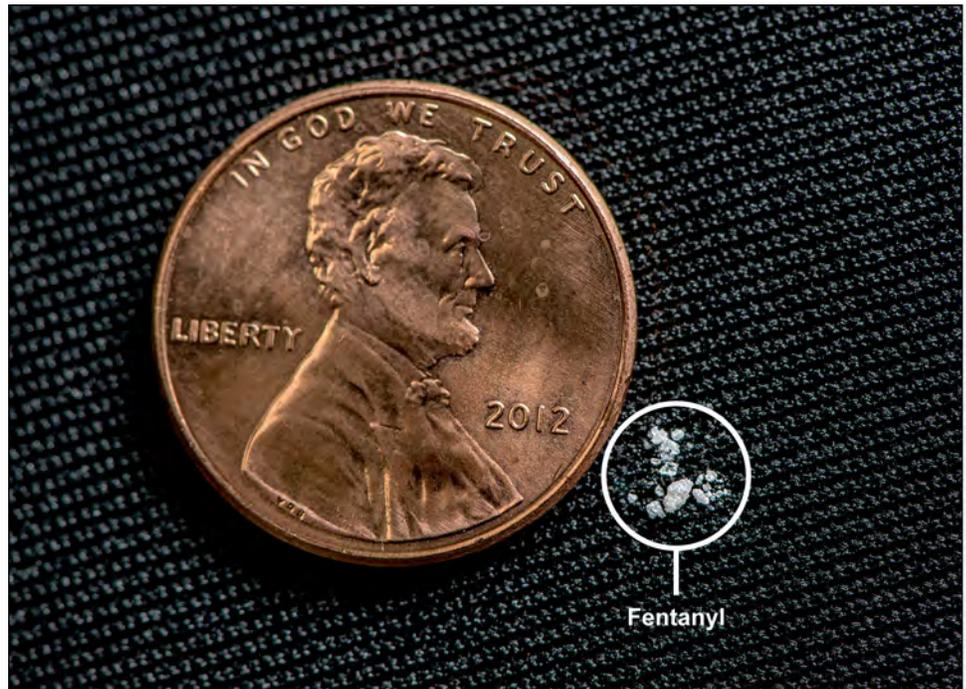


Source: National Center on Health Statistics. | GAO-18-205

^aMeasurement of specific drug death rates can be affected by a number of factors, including that the substances tested for and the circumstances under which the toxicology tests are performed vary by jurisdiction.

The high potency of fentanyl and related synthetic opioids can increase the risk of overdose.⁴ According to DEA, two milligrams of fentanyl can cause a lethal overdose (see fig. 2).

Figure 2: Comparison of a Potentially Lethal Dose of Fentanyl to a U.S. Penny



Source: GAO adaptation of U.S. Drug Enforcement Administration information. | GAO-18-205

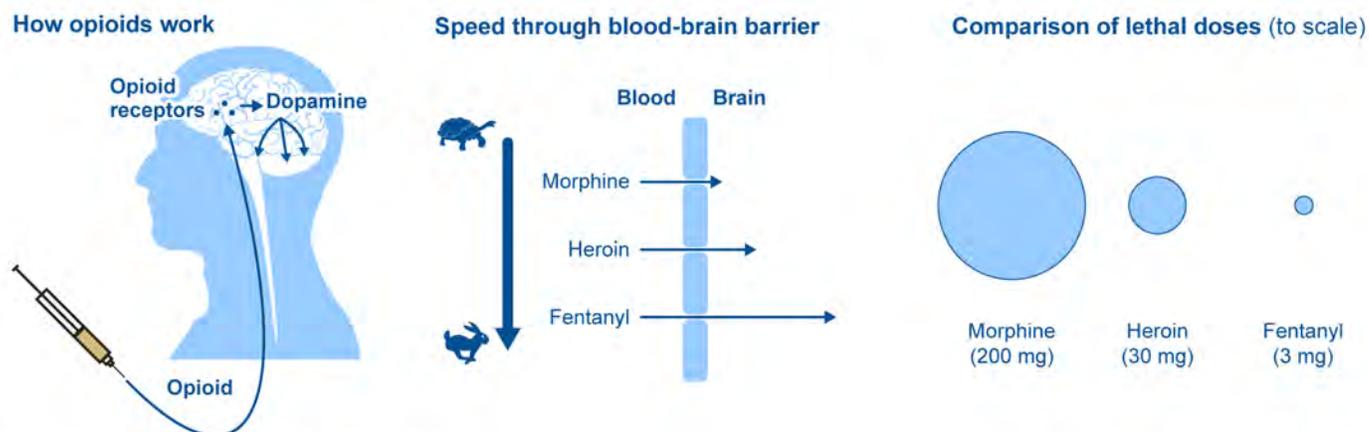
Fentanyl's potency—100 times stronger than morphine and 50 times stronger than heroin—is attributable to its chemical structure. This allows fentanyl to pass the blood-brain barrier much more efficiently than other types of opioids.⁵ Like heroin, morphine, and other opioid drugs, fentanyl works by binding to the body's opioid receptors, which are found in areas of the brain that control pain and emotions. When opioid drugs bind to

⁴For the purposes of our report we are defining potency as a measure of drug activity expressed in terms of the amount required to produce an effect of given intensity. A highly potent drug evokes a given response at low concentrations, while a drug of lower potency evokes the same response only at higher concentrations.

⁵The blood-brain barrier is comprised of a network of blood vessels that create a boundary between the brain and the bloodstream that helps to block harmful substances from entering the brain.

these receptors, they can drive up dopamine levels in the brain, producing a state of euphoria (see fig. 3).

Figure 3: How Opioids Affect the Brain



Source: GAO analysis; Art Explosion (clip art). | GAO-18-205

Fentanyl is a drug that can be legally prescribed by a physician to treat pain, such as from advanced cancer. According to the CDC, the rates for fentanyl prescriptions have remained stable—demonstrating that the recent increase in fentanyl misuse is largely attributable to illicitly produced, non-pharmaceutical fentanyl. When produced clandestinely, synthetic opioids are not typically controlled pharmaceutical substances intended for legitimate medical use. Rather, they have slightly modified molecular structures intended to circumvent the controlled substances specifically listed in drug scheduling laws.

Current Drug Scheduling Laws

In the United States, the Controlled Substances Act regulates drug scheduling.⁶ Enacted in 1970, this act assigns controlled substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids—to one of five schedules based on the substance’s medical use, potential for abuse, and risk of dependence. Schedule I contains drugs or other substances that have been found to have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and have a lack of accepted safety for use of the drug or other substance

⁶Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. § 801 et seq.).

under medical supervision.⁷ As a result, these drugs may not be prescribed, administered, or dispensed for medical use. In contrast, drugs in Schedules II, III, IV, and V include substances that have recognized medical uses and may be manufactured, distributed, and dispensed in accordance with the Controlled Substances Act. Fentanyl is a Schedule II drug under the Controlled Substances Act. A substance is placed on Schedule II if the drug or other substance have been found to (1) have a high potential for abuse, (2) have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and (3) abuse of the drug or substance may lead to severe psychological or physical dependence.⁸ In contrast, cough syrup with the opioid codeine added, is a Schedule V drug.⁹

Under the Controlled Substance Analogue Enforcement Act of 1986, as amended, a “controlled substance analogue”—generally a chemical substantially similar to a controlled substance which has a stimulant, depressant, or hallucinogenic effect on the central nervous system in a manner equivalent to or greater than the controlled substance— is, to the extent intended for human consumption, to be treated under any federal law as if it were a controlled substance in schedule I.¹⁰ In part, this act regulates emerging variations of synthetic opioids that are not yet scheduled. In November 2017, DEA also announced efforts to initiate emergency scheduling for all fentanyl-related analogues, which would subject anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue to the same criminal prosecution as for fentanyl and other controlled substances.¹¹

Internationally, three United Nations conventions establish applicable control measures intended to ensure that narcotic drugs and psychotropic

⁷21 U.S.C. § 812(b)(1).

⁸21 U.S.C. § 812(b)(2).

⁹Generally, the preparation of the drug must have less than 200 milligrams of codeine or per 100 milliliters of nonnarcotic cough syrup to be considered a Schedule V drug.

¹⁰Controlled Substance Analogue Enforcement Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207-13 (1986). See 21 U.S.C. § 813.

¹¹See 21 U.S.C. § 811(h) and 28 C.F.R. § 0.100.

substances are available for medical and scientific purposes,¹² while preventing them from being diverted into illegal channels.¹³ These three conventions are the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol), the 1971 Convention on Psychotropic Substances, and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The 1961 and 1971 Conventions classify controlled substances in four Schedules, according to their perceived therapeutic value and potential risk of abuse. The 1988 Convention also lists precursor chemicals and other substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. It also provides for measures to prevent the diversion of chemicals into illicit channels, including the monitoring of their international trade.

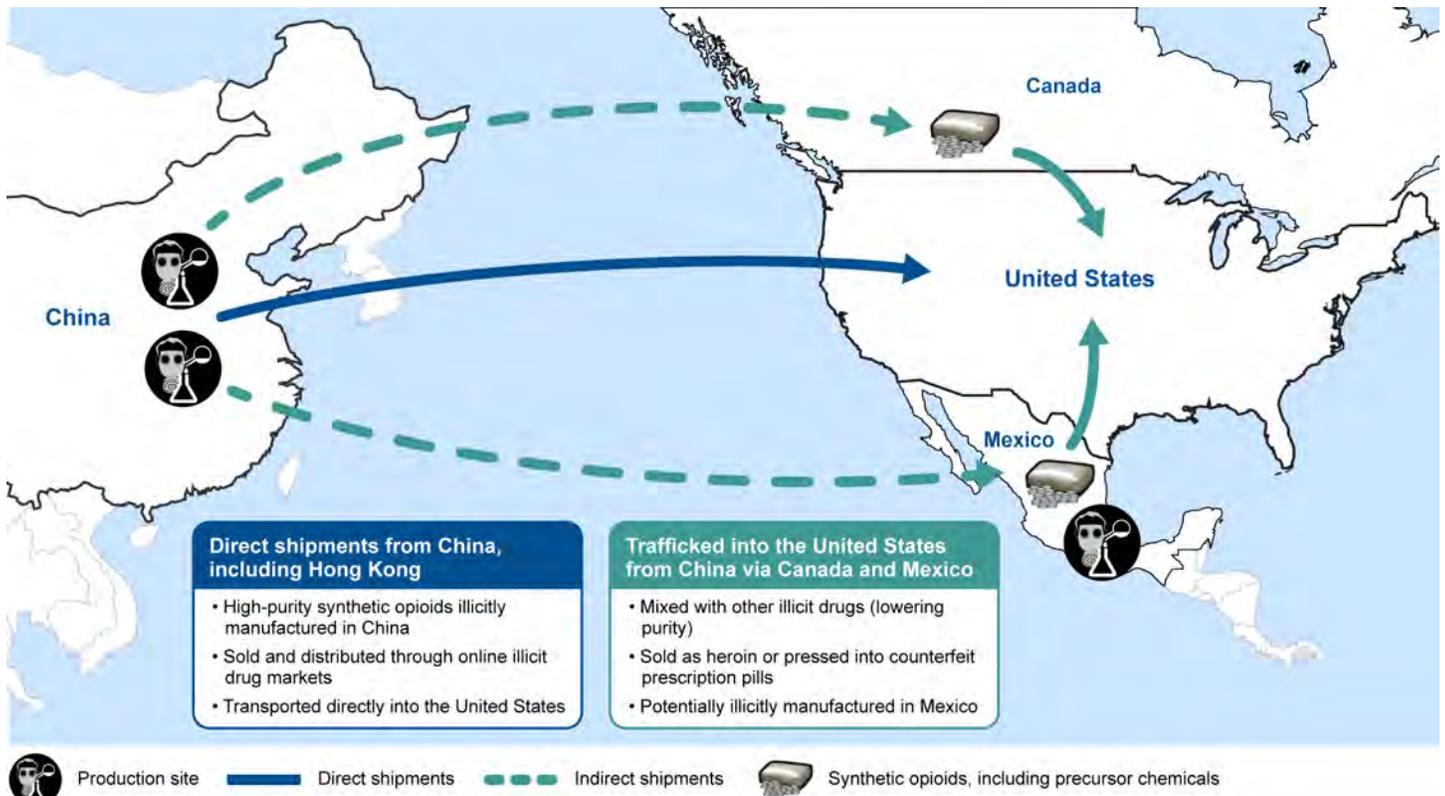
Synthetic Opioids in the United States

According to U.S. law enforcement agencies, the majority of synthetic opioids in the illegal drug market are illicitly produced by foreign sources, primarily in China, and trafficked either directly into the United States or indirectly through Mexico and Canada. Illicit manufacturing and trafficking via these three primary routes is demonstrated in figure 4 and explained below:

¹²In the context of international drug control, “narcotic drug” means any of the substances, natural or synthetic, in Schedules I and II of the 1961 Single Convention on Narcotic Drugs. In medicine, the term usually refers to opiates or opioids. “Psychoactive substances” refer to any chemical agent that affects the mind or mental processes. In the context of international drug control, “psychotropic substances” mean any substance, natural or synthetic, or any natural material in Schedule I, II, III, or IV of the 1971 Convention on Psychotropic Substances.

¹³A convention is a formal agreement between United Nations member states; generally, the generic term ‘convention’ is synonymous with the generic term ‘treaty.’ Conventions are normally open for participation by the international community as a whole, or by a large number of member states. Generally, a convention begins as an international meeting of representatives from many nations that results in general agreement about procedures or actions they will take on specific topics.

Figure 4: Flow of Illicit Synthetic Opioids from China to the United States



Source: GAO analysis of U.S. Drug Enforcement Administration information; Map Resources (map); Art Explosion (clip art). | GAO-18-205

1. Direct from China: China is a global source of fentanyl and other illicit substances. According to the U.S.-China Economic and Security Review Commission, thousands of pharmaceutical and chemical companies operate, both legally and illegally, in the country.¹⁴ Further, these companies produce massive quantities of pharmaceutical and chemical products daily. DEA and others report that certain Chinese chemical exporters utilize various covert methods to ship drugs to the

¹⁴The U.S.-China Economic and Security Review Commission was established on October 30, 2000 pursuant to the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Pub. L. No. 106-398, § 1238, 114 Stat. 1654, 1654A-334 to 1654A-338 (codified as amended at 22 U.S.C. § 7002). The purpose of this Commission is to monitor, investigate, and submit to Congress an annual report on the national security implications of the bilateral trade and economic relationship between the United States and the People’s Republic of China, and to provide recommendations, where appropriate, to Congress for legislative and administrative action.

United States, including sending illicit materials through a chain of forwarding systems, mislabeling narcotic shipments, and modifying chemicals so they are not controlled in the United States. U.S.-based consumers can also purchase fentanyl illicitly through both the Dark and Surface Web in very small, high-purity quantities.¹⁵ These packages are shipped through both express consignment carriers, such as FedEx and the United Parcel Service (UPS), and traditional international mail.

2. From Mexico across the southwest border: Mexico is rarely the final destination for illicit drug shipments; most fentanyl products sent to Mexico are repackaged and smuggled into the United States, according to the U.S.-China Economic and Security Review Commission. Mexican drug trafficking organizations act as the country's primary conduit for Chinese fentanyl destined for the United States, purchasing bulk shipments and trafficking it—either alone or mixed with other drugs like heroin—across the U.S. border along established drug routes. The increasing adulteration of heroin with highly potent fentanyl and other synthetic opioids has exacerbated overdose deaths in the United States, according to DEA. While Mexico is the primary source of heroin for the U.S. market, it is unclear how much market share fentanyl has gained from heroin because the two markets are so intertwined. The illicit nature of these smuggling operations makes it difficult to quantify the volume of fentanyl flowing from Mexico to the United States. U.S. law enforcement agencies suggest that fentanyl may also be produced in Mexico with precursor chemicals sourced from China.
3. From Canada across the northern border: Along with shipments directly to the United States, Chinese producers are also shipping fentanyl to Canada before the drug is trafficked across the U.S. northern border. Collaboration and information sharing between DEA and Canada's Royal Canadian Mounted Police confirms this cross-

¹⁵According to the Congressional Research Service, the layers of the Internet go far beyond the surface content that many can easily access in their daily searches. The Surface Web is a portion of the World Wide Web that is readily available to the general public and searchable with standard web search engines. The Dark Web contains content that has been intentionally concealed and requires specialized software for access. The Dark Web may be used for legitimate purposes; for example, some news organizations have sites on the Dark Web that enable users to transmit information anonymously. However, some users may access the Dark Web to conceal criminal or otherwise malicious activities. Congressional Research Service, Dark Web, R44101 (Washington, DC.: Mar. 10, 2017).

border fentanyl trafficking.¹⁶ However, according to the U.S.-China Economic and Security Review Commission, this occurs less frequently than the trafficking across the U.S. southern border.

DEA reported in its 2017 National Drug Threat Assessment that illicit fentanyl entering into the United States is traditionally mixed into or sold as heroin. Additionally, in recent years, law enforcement agencies have increasingly encountered counterfeit prescription opioid pills and other drugs containing fentanyl, often mixed in without the user's knowledge.

The profitability of synthetic opioids incentivizes drug traffickers since so little of the substance is needed to produce the high users seek. For example, DEA reported that traffickers could purchase a kilogram of illicit fentanyl for a few thousand dollars from a Chinese supplier, create counterfeit prescription pills using illicit pill presses, and collect up to \$20 million in revenue.

Drug interdiction efforts show an increase in smuggling of synthetic opioids. DEA's 2017 National Drug Threat Assessment indicates that U.S. law enforcement agencies seized a record-high 287 kilograms of fentanyl in 2016—a 72 percent increase from the 167 kilograms seized in 2015. For example, according to CBP's National Targeting Center, CBP seizures of synthetic opioids alone increased from approximately 1 kilogram in fiscal year 2013 to nearly 90 kilograms in fiscal year 2015 and nearly 200 kilograms in fiscal year 2016.

Federal Agencies Involved in Combating Drug Trafficking and Misuse

Combating the opioid crisis requires the coordinated efforts of many federal agencies across many levels of government. Overall, the federal government response is not specifically focused on synthetic opioids, but rather the larger opioid issue, which includes heroin and prescription opioids. This is because synthetic opioids are often mixed in or sold as other opioids, the same drug trafficking organizations and trafficking routes are being utilized, and federal agencies want to avoid responses to one type of opioid that may inadvertently have a negative impact on

¹⁶The Royal Canadian Mounted Police is responsible for national law enforcement, including border security, in Canada. The Canada Border Services Agency is Canada's federal customs agency. We have previously reported on the challenges of security along the U.S.-Canadian border. See GAO, *Border Security: Enhanced DHS Oversight and Assessment of Interagency Coordination Is Needed for the Northern Border*, [GAO-11-97](#) (Washington, D.C.: Dec. 17, 2010).

another. Table 1 summarizes some of the federal agencies that are involved in combating drug trafficking and drug use.

Table 1: Examples of Federal Agencies Involved in Combating Drug Trafficking and Drug Use

Agency	Tasks
Department of Defense (DOD)	
Joint Interagency Task Force West & Joint Interagency Task Force South	<ul style="list-style-type: none"> • Detects and monitors illicit drug trafficking, and facilitates international and interagency interdiction
National Guard	<ul style="list-style-type: none"> • Supports the detection, interdiction, disruption, and curtailment of drug trafficking activities and use at all levels of government, through use of military skills and resources
Department of Health & Human Services (HHS)	
Centers for Disease Control and Prevention (CDC)	<ul style="list-style-type: none"> • Detects and responds to new and emerging health threats causing death and disability for Americans • Uses science and technology to prevent disease • Promotes healthy and safe behaviors, communities, and environment
Food and Drug Administration (FDA)	<ul style="list-style-type: none"> • Protects public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices • Coordinates with DEA on scheduling drugs under the Controlled Substances Act^a • Collaborates with CBP to prevent the importation of unapproved drugs and investigates their distribution • Inspects registered facilities that manufacture drugs approved for marketing in the United States
National Institutes of Health	<ul style="list-style-type: none"> • Supports research to protect and improve public health, prevent disease, and expand medical knowledge • Includes the National Institute on Drug Abuse (NIDA), which supports research on the causes and consequences of drug misuse
Substance Abuse and Mental Health Services Administration (SAMHSA)	<ul style="list-style-type: none"> • Develops best practices and expertise in preventing and treating mental and substance use disorders • Evaluates and disseminates evidence-based behavioral health practices • Supports behavioral health programs and services with grant funding • Supports behavioral health with data from national surveys and surveillance

Agency	Tasks
Department of Homeland Security (DHS)	
Customs and Border Protection (CBP)	<ul style="list-style-type: none"> • Manages and controls the border, including the enforcement of customs, immigration, border security, and agricultural laws. This includes screening inbound cargo at ports of entry, including international mail and express consignment carrier items • Collaborates with FDA to prevent the importation of unapproved drugs and investigates their distribution
U.S. Coast Guard	<ul style="list-style-type: none"> • Conducts maritime drug interdiction • Contributes vessels and aircraft deployed to disrupt illicit drug smuggling
U.S. Immigration and Customs Enforcement (ICE)	<ul style="list-style-type: none"> • Enforces federal laws governing border control, customs, trade, and immigration • ICE's Homeland Security Investigations (HSI) investigates the illegal movement of goods within and out of the U.S., including narcotics
Department of Justice (DOJ)	
Criminal Division	<ul style="list-style-type: none"> • Develops, enforces, and supervises application of federal criminal laws except those assigned to other divisions • Advises the Attorney General, Congress, the Office of Management and Budget, and the White House on matters of criminal law and assists federal prosecutors
Drug Enforcement Administration (DEA)	<ul style="list-style-type: none"> • Enforces laws and regulations related to the growing, manufacture, or distribution of controlled substances • Conducts investigations in coordination with international, state, local and tribal law enforcement agencies • Coordinates with FDA on scheduling drugs under the Controlled Substances Act^a
Federal Bureau of Investigation (FBI)	<ul style="list-style-type: none"> • National security organization with intelligence and law enforcement responsibilities, including terrorism, cyber-attacks, and other major criminal threats
Office of Justice Programs	<ul style="list-style-type: none"> • Disseminates information on strategies for crime control and prevention to federal, state, local, and tribal justice systems • Administers grant programs to develop and implement these strategies
Organized Crime Drug Enforcement Task Forces (OCDETF)	<ul style="list-style-type: none"> • Identifies, targets, disrupts, and dismantles major drug trafficking organizations, money laundering organizations, and related criminal enterprises • Coordinates prosecutor-led, intelligence-driven multi-agency and multijurisdictional task forces, including DOJ, DHS, and USPS component agencies
U.S. Attorney's Office (USAO)	<ul style="list-style-type: none"> • Enforces federal laws throughout the country, including drug trafficking and production offenses
Department of State	
Bureau of International Narcotics and Law Enforcement Affairs	<ul style="list-style-type: none"> • Helps foreign governments implement programs to reduce the demand for and supply of illicit drugs

Agency	Tasks
Office of National Drug Control Policy (ONDCP)	<ul style="list-style-type: none"> • Advises the President on drug-control issues • Coordinates drug-control activities and funding across the federal government • Develops the annual National Drug Control Strategy • Administers the High Intensity Drug Trafficking Areas (HIDTA) Program and the Drug-Free Communities grant program^b • Leads the interagency National Heroin Coordination Group, which developed the Heroin Availability Reduction Plan
United States Postal Service (USPS)	
U.S. Postal Inspection Service (USPIS)	<ul style="list-style-type: none"> • Protects against and prevents criminal attacks to postal employees, customers, infrastructure, and the U.S. Mail • Enforces laws that defend the nation's mail system from illegal or dangerous use • As the federal law enforcement arm of the USPS, investigates cases and prepares them for court along with U.S. Attorneys, other law enforcement, and local prosecutors

Source: GAO Analysis of Agency Documents | GAO-18-205

^aEnacted in 1970, the Controlled Substances Act and its implementing regulations establish a framework for the federal government to regulate the use of these substances for legitimate medical, scientific, research, and industrial purposes, while preventing them from being diverted for illegal purposes. This act assigns controlled substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids—to one of five schedules based on the substance's medical use, potential for abuse, and risk of dependence. FDA compiles and transmits to DEA a medical and scientific evaluation regarding a drug or other substance, recommending whether the drug should be controlled, and in what schedule it should be placed.

^bThe Drug-Free Communities Support program provides grants to community coalitions to create and sustain reduction in local youth substance use. For more information, see GAO, *Drug-Free Communities Support Program: Agencies Have Strengthened Collaboration but Could Enhance Grantee Compliance and Performance Monitoring*, [GAO-17-120](#) (Washington, D.C.: Feb. 7, 2017)

Recently Enacted Funding Streams and the Newly Chartered Presidential Commission

Comprehensive Addiction and Recovery Act: Enacted in 2016, this act encompasses six different areas for a coordinated federal response to the opioid epidemic: prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. Generally, the act authorizes nearly \$181 million each year from fiscal year 2017 through fiscal year 2021, to be funded through the annual appropriations process.¹⁷ The funding, if appropriated, would support programs such as those expanding first responders' access to naloxone—an opioid antagonist that is used to reverse the effects of an overdose. It would also fund programs to treat opioid addiction, such as Medication-Assisted

¹⁷Pub. L. No. 114-198, 130 Stat. 695 (2016).

Treatment (MAT)—an evidence-based approach that complements medication with behavioral therapy.¹⁸

21st Century Cures Act: Also enacted in 2016, this act authorizes \$1 billion in new funding to combat the opioid crisis.¹⁹ Early efforts funded expansion of community-based efforts for drug use prevention and access to treatment.²⁰

The President’s Commission on Combating Drug Addiction and the Opioid Crisis: Executive Order 13784 established the President’s Commission in March 2017 to study the scope and effectiveness of the federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving the federal response.²¹ The President’s Commission issued an interim report in July 2017 and its final report in November 2017.²² ONDCP provides administrative support to the President’s Commission.

¹⁸We have done prior work on Medication-Assisted Treatment programs. See GAO, *Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, [GAO-16-833](#), (Washington, D.C., September 27, 2016) and GAO, *Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Medication-Assisted Treatment*, [GAO-18-44](#), (Washington, D.C., October 31, 2017).

¹⁹Pub. L. No. 114-255, 130 Stat. 1033 (2016).

²⁰Further Continuing and Security Assistance Appropriations Act, 2017, Pub. L. No. 114-254, 130 Stat. 1005, 1021 (2016). See 21st Century Cures Act, Pub. L. No. 114-255, §1003, 130 Stat. 1033, 1044-46 (2016).

²¹Exec. Order No. 13,784, 82 Fed. Reg. 16,283 (Mar. 29, 2017).

²²The President’s Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, November 1, 2017.

U.S. Agencies Collaborate with Foreign Governments and International Organizations to Limit Production of Illicit Synthetic Opioids

Federal Agencies Collaborate with Foreign Governments to Enhance Investigations and Share Information

Several U.S. federal agencies, such as DOJ and DHS, collaborate with each other and with foreign governments to (1) enhance drug investigations by building law enforcement capacity and coordinating resources, and (2) share information related to illicit synthetic opioids. According to agency officials working in foreign countries, U.S. officials must pursue investigations alongside their foreign counterparts because they do not have authority to carry out investigations on their own. For example, DEA, ICE-HSI, CBP, and FBI officials stationed at the U.S. embassies in Beijing, Mexico City, and Ottawa, as well as the U.S. Consulate Generals in Hong Kong and Macau, collaborate with their foreign counterparts on issues related to illicit synthetic opioids.²³ Further, these officials are often co-located and work with other federal agencies, such as State, on these issues. U.S. officials that we spoke with acknowledged some difficulties in working with foreign counterparts, such as competing priorities and the inability to share certain information. Despite these difficulties, several federal agencies told us they continue to collaborate with foreign governments to limit the production of illicit synthetic opioids.

²³DEA, ICE-HSI, CBP, and FBI also have officials stationed at other locations around Mexico, Canada, and China, often at one of the U.S. Consulates. In many cases, these four agencies are co-located with each other as well as with other federal law enforcement agencies. Based on prior work, co-locating agencies can lead to information sharing across organizational boundaries. GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012)

Enhancing Investigations in China, including Hong Kong

Combating Synthetic Opioids with China



China is a major source of supply for illicit synthetic opioids bound for the United States, Canada, and Mexico. According to the Department of State's 2017 International Narcotics Control Strategy Report, China's insufficient regulatory oversight of the precursor chemical industry, corruption among government and business officials, lower production costs, myriad transportation options, and illegal factories make it an ideal source for precursor chemicals intended for illicit drug production. The Drug Enforcement Administration's reporting indicates that many Chinese laboratories illicitly manufacturing synthetic drugs also manufacture legitimate chemicals for purchase by U.S. companies. This means that laboratories responsible for supplying illicit synthetic opioids can also run legitimate businesses. State's 2017 Report emphasizes the need for China and the United States to work together to reduce the supply of illicit synthetic opioids to the United States.

Source: U.S. Department of State and Drug Enforcement Administration; Map Resources (map). | GAO-18-205

Cooperation on synthetic opioids between the United States and China has increased over recent years. According to DOJ, this is primarily due to relationships developed by DEA's Beijing Country Office, as well as DHS, at the operational level. However, DEA, ICE-HSI, and CBP officials acknowledged that they face difficulties in targeting and seizing illicit synthetic opioids bound for the United States from China due to the innovative practices of labs and shippers. For example, China can schedule certain drugs or substances in an effort to limit illicit activities and use. Yet, according to DEA, ICE-HSI, and CBP officials, clandestine labs in China can change the molecular structure of a substance so that it is no longer controlled.²⁴ Further, these same officials told us that clandestine labs do this much more quickly than the average length of time it takes to schedule a new or altered substance in China. ICE-HSI officials in China told us that this seriously hinders their ability, as well as DEA, CBP, and FBI's ability, to stem the flow of illicit synthetic opioids into the United States from China. DEA officials stated that this also affects Chinese law enforcement and customs officials because they cannot seize substances, such as those bound for the United States, that are not domestically controlled. Further, DEA's 2017 National Drug Threat Assessment states that drug traffickers can send illicit synthetic opioids from China through freight forwarders, thereby masking the origins of the package.²⁵ ICE-HSI and CBP officials in China also noted that, in their experience, Chinese officials require a substantial amount of law enforcement information on suspected illicit production before they will act on leads from U.S. agencies, which can potentially slow investigations. However, U.S. agencies told us they continue to collaborate with China to schedule synthetic opioids and conduct investigations despite inherent difficulties. Agencies reported the following collaboration:

²⁴For example, furanyl fentanyl is a synthetic opioid and analogue of fentanyl. The molecular structure of furanyl fentanyl and fentanyl differ by one group of atoms in a specific position. Labs can synthesize furanyl fentanyl using similar precursors and methods as those developed for fentanyl by changing one of the precursor chemicals. Furanyl fentanyl was not controlled in China until March 2017.

²⁵Several DEA investigations have revealed that the original supplier will provide an illicit package to a freight forwarding company or individual, who then transfers it to another freight forwarder, who then takes custody and presents the package to customs for export. The combination of a chain of freight forwarders and multiple custody transfers makes it difficult for Chinese and U.S. law enforcement to track these packages. In May 2015, Chinese customs officials seized 46 kilograms of fentanyl and 26 kilograms of acetyl fentanyl hidden in a cargo container destined for Mexico. According to DEA, the substances had been transferred through five different freight forwarders before arriving at Chinese customs.

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- DEA officials in China reported that they work with their Chinese counterparts by providing assistance and information to support regulation of certain synthetic opioids, precursor chemicals, and emerging analogues. This can significantly reduce the illicit movement of that substance to the United States, according to DEA officials. For example, China controlled eight new psychoactive substances,²⁶ such as carfentanil and U-47700 in 2017 and two fentanyl precursors in February 2018.²⁷ According to DEA, these actions were a culmination of ongoing cooperation with Chinese counterparts. Additionally, DEA shares detailed information with the Ministry of Public Security about substances encountered in the United States that they suspect originated in China. DEA coordinates these efforts with ICE-HSI and CBP. According to DEA officials in China, such cooperation is vital given the ability of clandestine labs in China to evade drug-scheduling regulations.
 - DEA exchanges law enforcement information with agency officials in China on seizures of synthetic opioids, which can support investigations in Beijing or the United States into illicit drug shipments from China. Officials explained that based on this information, their counterparts can open an investigation and ask DEA to collaborate on collecting further law enforcement information. Occasionally, this involves officials from DEA's Special Testing and Research Laboratory working with Chinese chemists on seizure and forensic analyses from drug evidence.
 - FBI officials in Beijing told us they support DEA efforts by providing information related to ongoing FBI domestic drug trafficking investigations with a nexus to China. For example, FBI sponsored a working group in September 2017 to discuss issues related to counterterrorism, transnational crimes, and narcotics; Chinese

²⁶New psychoactive substances are substances of abuse, in either a pure form or a preparation, that are not controlled under the 1961 or 1971 Convention, but that may pose a public health threat. In this context, the term "new" does not necessarily refer to new inventions but to substances that have recently become available.

²⁷Carfentanil is a fentanyl-related compound that is 10,000 times more potent than morphine (100 times stronger than fentanyl) and is the most potent commercially used opioid. Carfentanil is controlled in the United States as a Schedule II substance and is not approved for use in humans. It is used as a tranquilizing agent by veterinarians in zoos and other large wildlife environments for elephants and other large mammals. U-47700 is a synthetic opioid that is 7.5 times the potency of morphine and is controlled as a Schedule I substance with no accepted medical use.

Enhancing Investigations in Mexico

Combating Synthetic Opioids with Mexico



Mexico is a major transit country for illicit synthetic opioids destined for the United States. According to the Department of State's 2017 *International Narcotics Control Strategy Report*, increased seizures along the U.S.-Mexico border suggest a rise in fentanyl production and trafficking. Synthetic drugs, such as fentanyl, are increasingly transported in loads with other drugs and sometimes pressed into pills to be sold as legitimate prescription medications. For example, in early 2016, U.S. authorities seized over 1,000 counterfeit oxycodone tablets containing fentanyl as they were being smuggled from Mexico into California. State's 2017 Report emphasizes that the most effective and cost-efficient way to reduce supplies of these drugs in the U.S. market is to collaborate with transit countries, such as Mexico.

Source: U.S. Department of State; Map Resources (map). | GAO-18-205

- officials from the Ministry of Public Security attended.²⁸

In Mexico, U.S. agencies reported efforts to strengthen Mexico's capacity to identify, investigate, interdict, and dismantle clandestine drug laboratories as well as disrupt trafficking networks. According to agency officials, these efforts aim to help Mexican law enforcement in light of unique challenges, such as the large number of active drug trafficking organizations in Mexico, which makes it difficult for U.S. and Mexican federal law enforcement to focus efforts solely on illicit synthetic opioids. Another challenge, according to ICE-HSI officials, is that officers stationed in Mexico must focus on a number of competing priorities in addition to illicit synthetic opioids, such as human trafficking, immigration enforcement, and money laundering. Further, according to ICE-HSI officials, coordination on controlled deliveries can be difficult because Mexican officials, historically, have employed a different approach to these operations.²⁹ Agency efforts have helped address some of these inherent difficulties, such as:

- DEA and State's Clandestine Laboratory Initiative aims to strengthen Mexican law enforcement's capabilities through training and specialized equipment. This initiative aims to target drug trafficking organizations that manufacture and distribute synthetic drugs, such as fentanyl, disrupt and dismantle clandestine labs, develop successful

²⁸FBI convened this working group in advance of the October 2017 meeting of the U.S.-China Law Enforcement and Cybersecurity Dialogue. At this meeting, DOJ and DHS officials met with China's Ministry of Public Security to discuss enhanced cooperation that could include combating the illicit production and trafficking of fentanyl and fentanyl-related substances and precursor chemicals. Discussions addressed, in part, scheduling actions, the use of express mail and consignment services, and the sharing of package tracking information to help identify individuals and criminal networks responsible for narcotics trafficking.

²⁹Law enforcement agencies use the technique of controlled delivery after they detect a package of illicit drugs. A law enforcement agency allows the package to go forward to its destination under the control and surveillance of law enforcement officers in order to secure evidence against the organizers of such illicit drug traffic. ICE-HSI officials we spoke with stated that Mexican law enforcement has traditionally seized and destroyed illicit drugs rather than identifying distribution networks and final destinations.

criminal prosecutions, reduce the overall supply of narcotics, and strengthen law enforcement collection methods.³⁰

ICE-HSI and State officials reported that they provide training and coordinate with law enforcement officers in Mexico to identify targets, collect and share evidence, and facilitate the prosecution of transnational criminal organizations, both in Mexico and through the U.S. judicial system. Specifically, ICE-HSI and State fund training for the Mexican Transnational Criminal Investigative Unit—a unit that was established in 2017, is led by ICE-HSI, and comprises ICE-HSI special agents and U.S.-vetted Mexican law enforcement officers.

To synchronize U.S. and Mexican investigative efforts to combat heroin and fentanyl production and trafficking, DEA established the U.S. Embassy Interagency Heroin-Fentanyl Working Group in Mexico City in 2015.³¹ ONDCP co-chairs the working group, which includes participation from all U.S. federal law enforcement agencies represented in Mexico City (e.g., ICE-HSI, CBP, and FBI) as well as State. In addition, the DEA-led Bilateral Heroin and Fentanyl Investigation Group meets every 2 weeks to discuss ongoing bilateral investigations, according to DEA officials. Mexico's federal police and the Mexican Attorney General's Office co-chair this group.

DEA officials also told us they work directly with the Mexican Attorney General's Office and the Mexican federal police to conduct bilateral investigations with the goal of extraditing individuals suspected of involvement in narcotics trafficking to the United States for prosecution, when appropriate. For example, DEA's Mexico City Heroin Enforcement Group works on fentanyl-related investigations alongside the Mexican Attorney General's Office. In addition, DEA's Mexico City Diversion Investigative Group pursues bilateral investigations with Mexico's federal police targeting Mexico-based organizations involved in fentanyl trafficking, according to DEA officials. In addition, FBI officials in Mexico

³⁰We previously reported on equipment and training provided to Mexico by the United States under the Merida Initiative, a bilateral effort aimed at supporting counternarcotic and related law enforcement activities. The Clandestine Laboratory Initiative is funded through the Merida Initiative. GAO, *Merida Initiative: The United States Has Provided Counternarcotics and Anticrime Support but Needs Better Performance Measures*, [GAO-10-837](#) (Washington, D.C.: July 21, 2010).

³¹Further, DEA established Mexico Sensitive Investigations Units to cooperatively train, equip, mentor, and support specialized units within host nation police forces and to develop and share information in order to thwart major international drug trafficking organizations and transnational criminal organizations impacting the United States.

Enhancing Investigations in Canada



Illicit synthetic opioids, such as fentanyl, transit through Canada before entering the United States. According to the Department of State's 2017 International Narcotics Control Strategy Report, the use of fentanyl among drug users has caused thousands of fatal overdoses in the United States, Canada, and some European countries. Canadian officials report increasing imports of fentanyl from China, largely via mail and courier. According to the Drug Enforcement Administration, Canadian officials have seized fully functional fentanyl synthesis and pill-producing clandestine laboratories. State's 2017 Report emphasizes the need to work with Canada to stem the flow of illegal drugs across the shared border, and enhance regulatory frameworks to prevent access to precursor chemicals and lab equipment for criminal use.

Source: U.S. Department of State and Drug Enforcement Administration: Map Resources (map). | GAO-18-205

reported that they share information regarding clandestine laboratories with DEA and Mexican officials and assist in joint investigations and seizures related to the illicit shipment of narcotics.

U.S. agencies cooperate extensively with Canada on bilateral law enforcement and counterdrug efforts, including conducting joint operations. According to officials, they engage in collaborative efforts despite inherent challenges, such as Canadian privacy laws, which impede the ability of the Royal Canadian Mounted Police to share certain information with U.S. law enforcement agencies. In addition, ICE-HSI officials noted that, historically, it has been difficult to target and interdict small quantities of illicit synthetic opioids shipped from Canada into the United States because the Canada Border Services Agency was previously prohibited from opening packages that weighed less than 30 grams unless they obtained permission from either the addressee or the sender. Further, ICE-HSI officials told us that Canadian law requires the public disclosure of the identities of undercover agents used in investigations. According to ICE-HSI officials in Canada, this can compromise other ongoing investigations and deter U.S. agencies' use of undercover officers in future investigations involving Canada, ultimately limiting investigative capabilities. However, U.S. efforts have helped address some of these unique challenges, such as:

- DEA and the Royal Canadian Mounted Police have a long-standing memorandum of understanding by which their representatives can work directly with each other on drug-related matters. While officials told us that the Royal Canadian Mounted Police is often willing to exchange law enforcement information, U.S. agencies generally run parallel narcotics investigations. For example, DEA officials in Vancouver reported that they work with the Royal Canadian Mounted Police to further investigations related to fentanyl trafficking between Canada and the United States.
- ICE-HSI officials in Canada reported that they engage with their foreign counterparts to target potential shipments of illicit synthetic opioids and perform controlled deliveries. For example, ICE-HSI and DEA officials in Hong Kong worked with local customs and law enforcement authorities in 2017 to seize roughly 50 packages containing fentanyl that were bound for the United States and Canada. ICE-HSI and Canadian officials in Ottawa then collaborated on an international controlled delivery with information provided by USPIS and DEA. State officials also told us that an amendment to Canada's Customs Act in May 2017 gave Canadian border officials the authority to open international mail of any weight if they have

reasonable grounds to suspect the item may contain prohibited, controlled, or regulated goods. Such an amendment could help the Canada Border Services Agency target and interdict shipments of illicit synthetic opioids, thereby increasing information sharing with U.S. law enforcement agencies.

- According to ICE-HSI, the Canada Border Services Agency and Canada Post flag shipments of pill presses bound for the United States and notify ICE-HSI officials in Canada so that ICE-HSI can check for connections to open investigations.³² Further, ICE-HSI officials in Canada reported that they work with the Royal Canadian Mounted Police to investigate companies that produce pill presses and find ways to prosecute individuals in the United States that are suspected of involvement in the smuggling of these machines. According to State officials, Canada's federal government passed legislation in May 2017 to regulate the importation of pill presses and harmonize their rules with those of the United States. Previously, the lack of regulation had posed problems, but such regulation could now help U.S. agencies address the unregistered import of machines into the United States for illicit use.
- FBI and ICE-HSI officials reported that they have met with Canadian officials to share trends and targeting strategies in fentanyl-related investigations. For example, FBI officials told us they facilitated a Virtual Currency Practitioner's Workshop in Ottawa in December 2017 to share investigative best practices and identify opportunities for joint investigations with the Royal Canadian Mounted Police regarding the use of cryptocurrencies and money laundering in conjunction with online illicit opioid investigations.³³

Agencies at the U.S. Embassy in Ottawa also collaborate on counternarcotic efforts through the Law Enforcement Working Group,

³²According to DEA, traffickers purchase industrial pill presses from China to create counterfeit prescription opioid pills containing fentanyl to supply illicit U.S. drug markets. Under U.S. law, DEA must be notified of the importation of a pill press into the United States. However, foreign pill press vendors often mislabel the equipment or send it disassembled to avoid law enforcement detection, according to DEA. See 21 U.S.C. § 830. See also 21 C.F.R. §§ 1310.05, 1310.06.

³³Cryptocurrencies, such as Bitcoin, provide people around the world with new and innovative ways of engaging in legitimate commerce by virtually exchanging currency. However, individuals can subvert these technologies to conduct and obscure criminal activity. According to DOJ, although cryptocurrencies have known legitimate uses, the virtual currency can be used—just like cash—to facilitate illicit transactions and to launder criminal proceeds.

which generally meets twice a month. Participants in the working group told us they have discussed issues related to illicit synthetic opioids since 2016. For example, FBI is actively involved in this working group and exchanges law enforcement information with interagency partners, according to agency officials. In addition, CBP officials in Canada told us they regularly support DEA, ICE-HSI, and FBI enforcement and investigative efforts related to synthetic opioids trafficking by sharing information such as seizure data and trends, and key contacts.

Sharing Information with China (including Hong Kong), Mexico, and Canada

Federal agencies, such as DEA, ICE-HSI, CBP, State, and FBI, stated that they share information with their foreign counterparts to develop bilateral and multilateral approaches to limit the production of illicit synthetic opioids:

- Mexico and State organized the first National Forensic Chemist Fentanyl Conference in May 2017 for U.S. and Mexican law enforcement and regulatory agencies to share best practices for the detection, identification, analysis, and handling of fentanyl. According to State, Mexico committed to improving the exchange of intelligence on illicit opioids between Mexico, the United States, and Canada at this conference. Additionally, officials from Mexico's Attorney General's Office and DEA shared updated fentanyl detection protocols as well as new methods to identify synthetic opioids in laboratory settings.
- The United States joined Mexico and Canada in October 2016 for the first North American Drug Dialogue to exchange information on drug trends in the Northern Hemisphere, illicit opioid use, and shared approaches to addressing the heroin and fentanyl crisis. Members of this tri-lateral group met again in December 2017 in Mexico City to review progress made and discuss the increase in synthetic drugs, the diversion of chemicals from licit to illicit use, and current activities to reduce the demand for drugs. According to State, Canada agreed to host the third North American Drug Dialogue in 2018.
- According to officials, the U.S.-China Joint Liaison Group on Law Enforcement Cooperation (Joint Liaison Group) and its Counter-Narcotics Working Group meets annually to exchange views and information, discuss pertinent laws, regulations, policies, and procedures, seek progress and address challenges, and find mechanisms to cooperate on investigations related to drug use and

trafficking of illicit synthetic opioids.³⁴ The last Joint Liaison Group and Counter-Narcotics Working Group annual meetings occurred between September and November 2016 but State officials told us these groups plan to meet again.

According to officials, prior discussions at Joint Liaison Group and Counter-Narcotics Working Group meetings helped lead China to enact wide-reaching legislation in October 2015 that allowed the Chinese government to schedule new and emerging drugs deemed to have no identified medical use, including substances not used within China.³⁵ According to DOJ officials, this legislation also established immediate controls over 116 new psychoactive substances, such as fentanyl and several fentanyl analogues. DEA reported a marked reduction in seizures and availability of many of the new psychoactive substances newly controlled by China within the United States, according to State's 2017 International Narcotics Control Strategy Report and DEA's 2017 National Drug Threat Assessment. DEA officials told us they expect additional scheduling to yield similar results. Further, according to State, China's enactment of this legislation provides a mechanism for enhanced cooperation with the United States and other international partners to control the spread of new psychoactive substances. Nevertheless, fentanyl and related analogues continue to be a challenge for law enforcement in the United States, according to ONDCP.

U.S. officials acknowledged that some difficulties in working with foreign governments are inherent to operating in an environment that is largely outside their control and are not unique to the issue of limiting the illicit production of synthetic opioids. However, State asserts that partnerships

³⁴State, DOJ, and DHS co-chair the Joint Liaison Group along with China's Ministry of Public Security, Ministry of Foreign Affairs, and Ministry of Supervision. The Counter-Narcotics Working Group is chaired by DOJ and China's Ministry of Public Security. The Ministry of Public Security's Narcotics Control Bureau is the primary national drug enforcement entity in China and works in conjunction with provincial public security bureau offices. The Anti-Smuggling Bureau within the General Administration of Customs is also responsible for the enforcement of China's drug control laws at seaports, airports, and land border checkpoints. DEA officials told us they work with these agencies on investigations, information sharing, and drug control scheduling. DEA also exchanges law enforcement information with the Ministry of Public Security through the Bilateral Drug Intelligence Working Group.

³⁵Further, according to agency officials, DEA and Chinese officials have met regularly over the past year to discuss mutual interests and shared responsibilities in countering the threat from fentanyl-class substances. These discussions included exchanging information on emerging substances' scientific data and trafficking trends, so that they may be considered for control in China.

between the United States and foreign governments are an effective and cost efficient means to reduce the production of illegal drugs at their source and disrupt the movement of drugs in transit.

Federal Agencies
Collaborate with
International
Organizations on Drug
Control Scheduling and
Information Sharing

International Drug Control
Scheduling

Several U.S. federal agencies reported collaboration with UNODC, INCB and the Commission on Narcotic Drugs (Commission) to place synthetic opioids and precursor chemicals and analogues under international control via international conventions.³⁶ Further, these agencies reported that they collaborate with INCB to monitor United Nations member states' compliance with international drug control conventions and prevent the diversion of legitimate chemicals into illicit traffic.³⁷ Agencies reported the following collaboration:

- State leads the U.S. delegation at annual sessions of the Commission during which participants consider and adopt resolutions to reduce the manufacture, distribution, and availability of illicit synthetic drugs and precursor chemicals. Officials told us that in response to the domestic opioid crisis, the U.S. delegation requested in 2016 that the United Nations Secretary-General initiate the process to consider two fentanyl precursor chemicals for international control. As a result, United Nations member states voted in favor of these controls at the Commission's 2017 meeting as well as additional controls for a

³⁶UNODC supports member states, such as the United States, China, Canada, and Mexico, in their efforts against illicit drugs, crime, and terrorism by conducting research and engaging in capacity-building projects, among other things. The United States assists the Commission in fulfilling its mandates to monitor the world drug situation, develop strategies on international drug control, and recommend measures to address the world drug problem.

³⁷The INCB is an independent, quasi-judicial expert body that, among other things, assists member states in monitoring the international trade of precursor chemicals and assesses chemicals used to make illicit drugs, to determine if they should be placed under international control.

Information Sharing and Capacity Building

synthetic opioid analogue.³⁸ Multiple federal agencies told us they hope to schedule additional synthetic opioids at the Commission's March 2018 meeting; for instance, State asserted that it would push for additional international controls on carfentanil at the 2018 meeting.

Federal agencies, such as FDA, DEA, and NIDA, also told us they provide information to the World Health Organization, upon request, regarding synthetic opioids.³⁹ The World Health Organization uses this information to assess these drugs and make recommendations for international drug scheduling.

UNODC and INCB officials told us their collaboration with U.S. federal agencies on illicit synthetic opioids and their precursors has informed law enforcement work around the world and strengthened international information sharing, which has helped to build capacity to thwart the distribution of illicit drugs. Agencies reported the following collaboration:

- State provides funding to support the international detection and tracking of chemicals diverted from their lawful purpose to illicit drug traffic, according to INCB officials. INCB maintains multiple online platforms that facilitate communication on shipments and seizures of the chemicals, including those required for the manufacture of illicit synthetic opioids, such as fentanyl. INCB also facilitates contact between member states to further investigations involving these substances; for example, INCB officials told us they assisted DEA in a 2017 fentanyl seizure by connecting officials with their Hong Kong counterparts. According to INCB officials, State also provided funding in February 2017 to organize an international conference where participating countries, including the United States and China, discussed measures governments could take to prevent the diversion of precursor chemicals and address new psychoactive substances, such as fentanyl analogues.

³⁸Generally, adopted changes are to be incorporated by member states—such as the United States, China, Mexico, and Canada—within 180 days. However, according to INCB, countries often need more than 180 days to implement the changes. For example, China announced that scheduling controls on these two fentanyl precursor chemicals would take effect on February 1, 2018, after the Commission's March 2017 meeting. In such instances, international drug conventions allow member states to apply a minimum set of control measures in the interim, to satisfy their treaty obligations.

³⁹FDA coordinates data collection, including obtaining public comments, and submits this information to the World Health Organization.

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- State, DEA, and UNODC officials told us they provide technical assistance, training, and capacity building to help countries strengthen their law enforcement and judicial capacity to investigate and prosecute offenders before illicit drugs can reach the United States. For example, UNODC partners with U.S. federal agencies to train foreign law enforcement on identifying new psychoactive substances.
 - Federal agencies, such as DEA, provide data to UNODC's Global SMART (Synthetics Monitoring: Analyses, Reporting, and Trends) Program, which captures information on forensics, seizures, chemical names, consumption trends, and trafficking patterns. According to UNODC, this information informs the analysis of synthetic drugs, including opioids, in relevant publications such as its annual World Drug Report. Further, officials reported that DEA's Special Testing and Research Laboratory and Office of Diversion Control have served as advisors for this program and participated in INCB task forces related to new psychoactive substances and precursor chemicals. DEA has also cooperated in related INCB-facilitated investigations; according to INCB, shared information and cooperation helps disseminate practices globally for preventing new psychoactive substances and precursor chemicals from reaching consumer markets.
 - UNODC officials told us that NIDA provides funding support for international research on treatment standards. In addition, UNODC officials reported that they use SAMHSA tools to implement evidence-based practices in prevention and treatment. According to UNODC, these efforts inform proposed resolutions and recommendations at the Commission's annual meetings.

U.S. Agencies Have Modified Practices and Enhanced Coordination Domestically to Limit Illicit Synthetic Opioids, but Could Better Allocate Resources and Enhance Data Usage

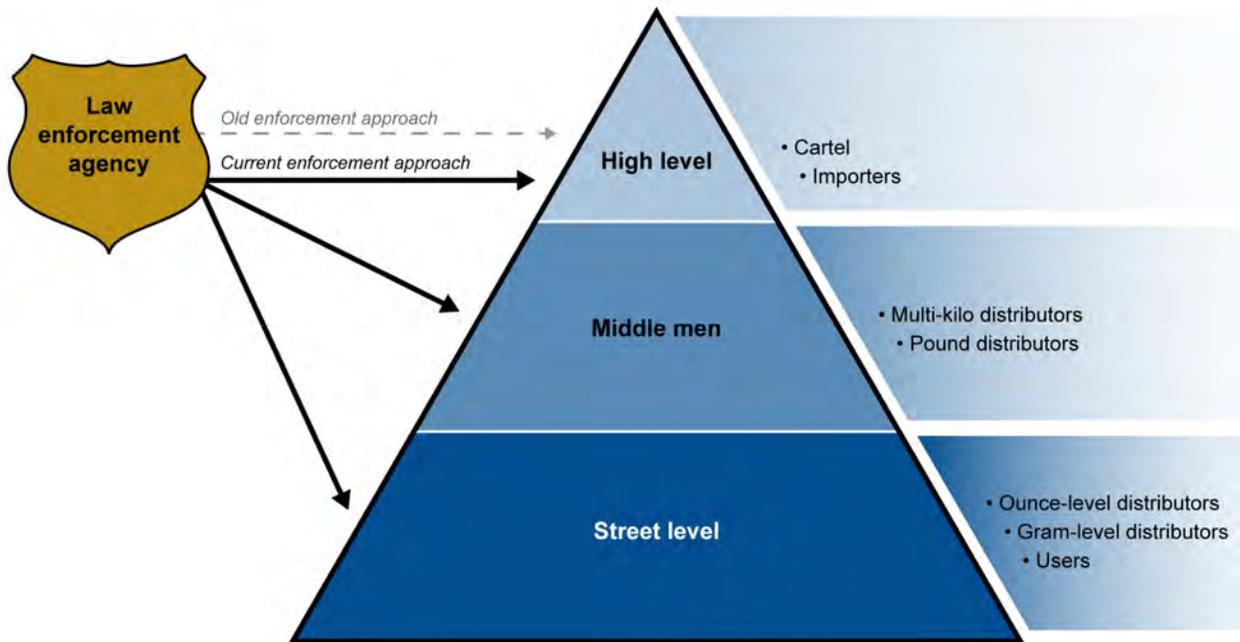
Federal agencies have ongoing efforts to limit the domestic availability of synthetic opioids and to enhance their response to synthetic opioid threats. These efforts include: (1) modifying their approaches to investigating and prosecuting cases, (2) enhancing the targeting, interdiction, and seizure of illicit synthetic opioids, and (3) extending collaboration among law enforcement and public health officials to share information and data. However, federal agencies face continuing challenges and have opportunities to enhance the effectiveness of some of these efforts by better allocating resources and enhancing their use of data.

U.S. Agencies Have Modified Investigative and Prosecutorial Practices Related to Illicit Opioids

The current threat of synthetic opioids and the increase in overdose deaths has resulted in federal agencies modifying their approach to investigations and prosecutions of these cases, such as by reevaluating who they target, adjusting their investigation techniques, and consolidating resources. Federal agencies reported the following actions:

- According to officials, OCEDEF has broadened its scope of targets to encompass the entire supply chain involved in opioid trafficking, due in part to an increased recognition that lower-level suppliers are integral to the causal chain of overdose deaths. To do this, they have deployed personnel and resources to support investigations and prosecutions of doctors, pharmacists, and other medical professionals who illegally divert prescription opioids. They have also targeted street-level and mid-level distributors, rather than focusing more heavily on traditional targets, such as cartels. Other federal law enforcement agencies have taken a similar approach (see fig. 5).

Figure 5: Scope of Federal Law Enforcement Agencies' Targets for Drug Investigations and Prosecutions



Source: GAO analysis. | GAO-18-205

- FBI officials told us that because some drug trafficking has become internet-based, they have had to adjust their investigative approaches in such cases. Officials noted that numerous online vendors are taking advantage of technology to advertise fentanyl and other illicit substances while obfuscating identities and locations. FBI officials noted that online undercover operations and confidential informants must be used to make contact with these sellers and attempt to uncover their true identities and locations.
- In November 2017, the Attorney General and the Acting DEA Administrator announced the formation of a new DEA Field Division, based in Louisville, Kentucky, which will include Kentucky, Tennessee, and West Virginia.⁴⁰ According to the Acting DEA Administrator, DEA anticipates that this consolidation of resources will

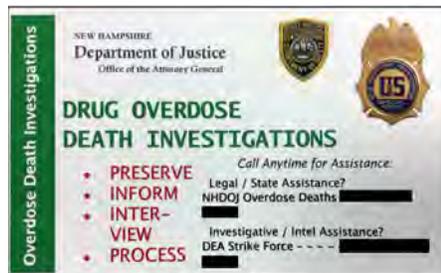
⁴⁰Prior to the addition of this field office, DEA had 21 field divisions. The addition of this field division is the first time a new field division has been added in 20 years. According to DEA officials, making this office a field division will better align DEA with the U.S. Attorney's Office districts in those areas, similar to the current configuration of other agencies like FBI as well as the local HIDTA program.

produce more effective investigations on heroin, fentanyl, and prescription opioid trafficking, as the move will unify drug trafficking investigations under a single Special Agent in Charge.

- Federal agencies have also coordinated to develop guidance to first responders for the safe handling of synthetic opioids during their investigations. In particular, the White House's National Security Council convened a federal working group with the goal of identifying the most up-to-date scientific data regarding fentanyl, while taking into account the uncontrollable environment in which first responders operate. The group was comprised of law enforcement agencies, such as DEA, FBI, DHS, and USFIS, federal health agencies, such as CDC, the National Institute for Occupational Safety and Health (NIOSH) and HHS, and others, such as ONDCP. It also sought the support of expert groups such as the American College of Medical Toxicology and those representing state and local law enforcement agencies, first responder groups, and health officials. Because of the working group's efforts, the National Security Council issued new government-wide guidance in November 2017 to provide an authoritative source for safety recommendations for the first responder community. See appendix II for more information on this effort.
- Federal law enforcement is also changing the way that it approaches overdose deaths. According to some law enforcement officials we spoke with, prior to this change in approach, a law enforcement officer would respond to the scene of an overdose death by calling in the medical examiner or coroner's office to remove the body, disposing of any drug paraphernalia, and completing an incident report. Now however, federal law enforcement agencies are increasingly treating such scenes like crime scene investigations where officers collect evidence to investigate and identify the source of the drugs involved. These agencies are also encouraging state and local law enforcement agencies to adopt the approach. According to the FBI, in Cleveland, Ohio, the USAO, along with state and local law enforcement agencies, the local medical examiner's office, and the FBI combined to devise a coordinated law enforcement response to the heroin epidemic. These partners created the Heroin Involved Death Investigation Team, which responds to every heroin overdose in Cuyahoga County. The team members process the location as a crime scene, attempting to preserve all available evidence and interview as many witnesses as possible to help identify the source of the heroin. In addition, the DEA office in Manchester, New Hampshire and the New Hampshire Department of Justice have created business cards that law enforcement officers can carry in their pockets with

detailed information and techniques on how to collect specific evidence at overdose death scenes (see fig. 6).

Figure 6: Examples of Investigative Approaches that Select Law Enforcement Agencies Encourage Agents to Use at Overdose Death Scenes



Federal law enforcement is changing the way officers respond to overdose death scenes by encouraging them to collect evidence to investigate and identify the source of the drugs involved. For example, some officers receive guidance on how to preserve the crime scene, conduct and document interviews with witnesses, document and photograph observations at the scene, collect physical evidence, and inform other relevant agencies, such as prosecutors and public health officials.

Source: New Hampshire Department of Justice and U.S. Drug Enforcement Administration. | GAO-18-205

- Further, through OCDETF’s National Heroin/Opioid Initiative, federal prosecutors are encouraged to work not only with their component federal agencies, but also with state and local investigators, prosecutors, and teams in other jurisdictions to coordinate opioid investigations and bring prosecutions to the most appropriate judicial venues. For example, the USAO in North Dakota worked with local and state police, DEA, ICE-HSI, their OCDETF counterparts in Oregon, and law enforcement officials in Canada and China to respond to an overdose death of a teenager in Grand Forks, North Dakota. In doing so, they were able to follow the supply chain of the source drugs to Oregon, on to Canada, and ultimately to a Chinese opioid manufacturer.

Additionally, given the rise in deaths attributable to drug overdoses, officials from 8 of the 9 USAOs we spoke with are increasingly pursuing sentencing enhancements when charging drug suppliers in cases where drug distribution results in an overdose causing death or serious bodily injury to the user.⁴¹ Such enhancements carry a higher mandatory minimum sentence than charges for drug possession or distribution that does not cause death or serious injury. USAO representatives told us

⁴¹ A “sentencing enhancement” augments/increases a sentence or term of imprisonment that would be imposed for an underlying criminal act by adding time to the sentence or term of imprisonment under certain defined circumstances. For example, under 21 U.S.C. §§ 841(b)(1)(A)(vi), 841(b)(1)(B)(vi), individuals who distribute particular threshold amounts of fentanyl or certain fentanyl analogues are subject to mandatory-minimum penalties of 5 or 10 years in prison. If the distribution results in death or serious bodily injury, individuals are subject to enhanced mandatory-minimum penalties of at least 20 years in prison.

they are actively pursuing such enhancements for synthetic opioids cases if they can establish a link between an overdose death and the source of the drugs that caused the overdose.⁴² Some USAO officials told us that in the past, these types of charges were typically not pursued for prosecution because it can be difficult in drug cases to link the cause of death to a specific drug beyond a reasonable doubt. One of the reasons given by the USAOs with whom we spoke for why it is difficult to establish such a link is that the “cause of death” that prosecutors receive from medical examiners and coroners often cites more than one drug as the cause if multiple drugs were found in the system. This can make it difficult for prosecutors to make a case that a synthetic opioid like fentanyl was responsible for the death and not the other drugs identified through toxicology testing.

According to a medical examiner we spoke with, medical examiners and coroners may not always order toxicology tests for substances like fentanyl, and it is not always part of the typical battery of drugs included in the standard toxicology test. Some of the reasons for not testing for fentanyl identified by medical examiners and coroners with whom we spoke included the lack of resources to conduct such a test or that there was no indication at the time of an autopsy that a fentanyl test was needed. However, as overdose deaths continue to rise, medical examiners and coroners are starting to test for fentanyl and its analogues more frequently. For example, one medical examiner in New York City told us that, starting in July 2016, fentanyl has been routinely included in the toxicology tests that they perform. Additionally, some USAO officials told us that they are able to use expert witnesses, such as a medical examiner, coroner, or toxicologist during the trial to establish that the synthetic opioid was responsible for the death.

In addition to pursuing such charges, several of the representatives from the USAOs with whom we spoke indicated that the emergence of synthetic opioids like fentanyl has caused them to reevaluate the typical criteria for which they would accept cases for prosecution based on the type of drug and the quantity seized. Specifically, some attorneys in the USAOs we spoke with are now using their discretion to prosecute fentanyl cases, even though such cases involve small quantities of the drug relative to other drugs like heroin or cocaine. In addition, given the

⁴²Representatives from the one USAO of the 9 we met with who were not pursuing homicide charges against suppliers of drugs who cause an overdose are from districts near the southwest border and told us that drug trafficking is their primary concern.

ever-changing nature of synthetic drugs, attorneys in several of the USAOs we spoke with are increasingly relying on the Controlled Substances Analogue Enforcement Act of 1986, as amended, to prosecute cases involving analogues of controlled substances like fentanyl that are not currently scheduled.⁴³ Further, in November 2017, the Attorney General directed each of the 93 U.S. Attorneys to designate an opioid coordinator to work with prosecutors and with federal, state, local, and tribal law enforcement to coordinate federal opioid prosecutions in every district.⁴⁴

U.S. Agencies Have Enhanced Coordination to Limit Illicit Synthetic Opioids, but CBP's Approach to Allocating Resources Has Weaknesses

Federal agencies are working together to coordinate their efforts at the CBP's National Targeting Center (NTC), express consignment carrier facilities, international mail facilities, and land ports of entry to enhance the targeting, interdiction (interception), and seizure of packages. Nevertheless, we found that CBP is not taking a risk-based approach to address the accumulating backlog of suspicious packages waiting for testing at some of its labs.

Increasing Coordination at the National Targeting Center

CBP's NTC coordinates examination of cargo that may be connected to terrorism or other crimes, such as narcotics smuggling, human trafficking, merchandise counterfeiting, and money laundering. To do this, NTC identifies high-risk cargo destined for the United States prior to its arrival. For example, NTC uses a risk-based approach and various information sources to identify shipments that may contain illicit synthetic opioids. The NTC includes participants from across the federal government, such as ICE-HSI, FDA's Office of Criminal Investigation, the USPIS, and FBI, and provides advance targeting and research for CBP field units. The NTC also works with the intelligence community, foreign counterparts, and investigative and law enforcement agencies. In addition, NTC is

⁴³See 21 U.S.C. § 813.

⁴⁴The Attorney General's directive required every U.S. Attorney to designate an Opioid Coordinator by the close of business on Dec. 15, 2017. Each USAO Opioid Coordinator is responsible for facilitating intake of cases involving prescription opioids, heroin, and fentanyl; convening a task force of federal, state, local, and tribal law enforcement to identify opioid cases for federal prosecution, facilitate interdiction efforts, and tailoring his or her district's response to the needs of the community it serves; providing legal advice and training to Assistant United States Attorneys regarding the prosecution of opioid offenses; maintaining statistics on the opioid prosecutions in the district; and developing and continually evaluating the effectiveness of the Office's strategy to combat the opioid epidemic.

Implementing Pilots at International Mail Facilities

increasing its coordination with other federal agencies, like USPS, as well as international partners such as customs officials from Canada. For example, according to USPIS officials, in September 2017, the agency placed an analyst with the narcotics section of the NTC and in January 2018 placed an additional postal inspector at NTC to work with CBP on combating the synthetic opioid problem. Further, ICE-HSI officials told us in June 2017 that a Canadian customs official is posted at the NTC.

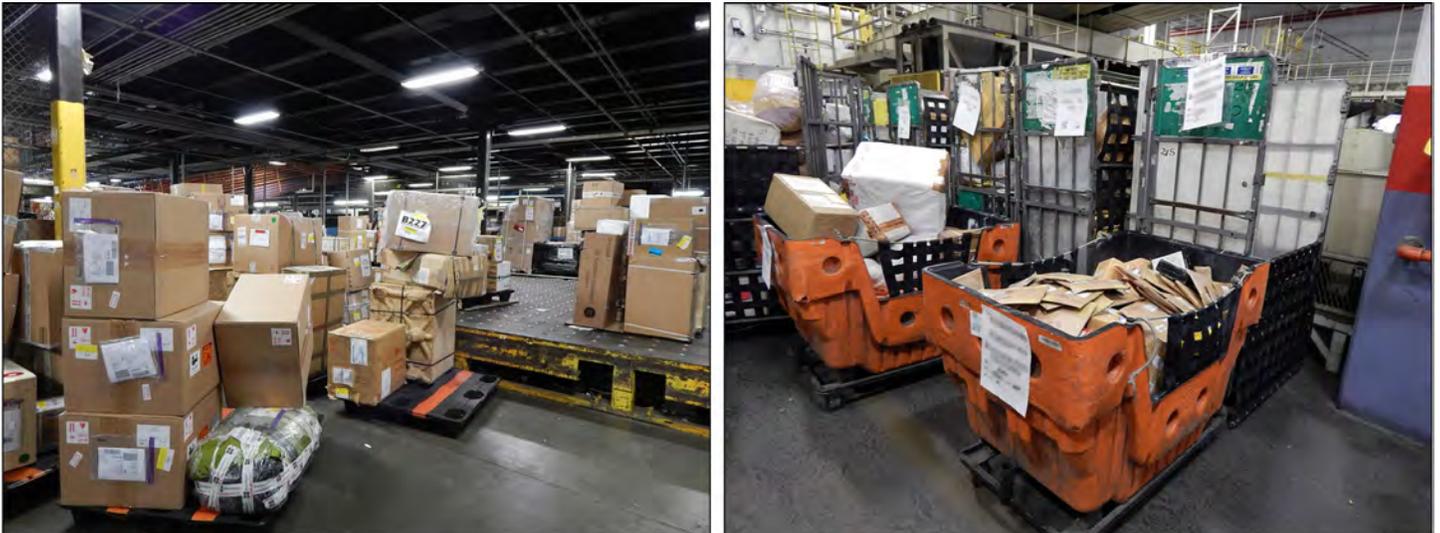
As we reported in August 2017, CBP works with express consignment operators, such as FedEx and UPS as well as the USPS, to inspect express cargo and inbound international mail.⁴⁵ Express consignment operators are required to provide CBP with “electronic advance data” (EAD)—such as the sender’s and recipient’s name and address—for all inbound express cargo. According to officials from State and USPS, international postal arrangements and federal law currently do not require EAD for most mail, although specific bilateral agreements provide for it for a portion of the mail stream from some countries, including China.⁴⁶ According to State, in October 2017, the Universal Postal Union adopted a global messaging standard for EAD for mail items between its 192 participating countries.⁴⁷ This step, combined with the earlier adoption of Universal Postal Union regulations governing the exchange of EAD, will enable the United States and other countries to begin to require EAD for mail from countries with the ability to provide it beginning in January 2018. Nevertheless, according to officials from State, it will take several years for many countries to develop the capacity to provide this data. Because of the lack of EAD, CBP officials explained that the processing of inbound international mail is primarily manual and resource intensive, requiring CBP officers to sort through large bags or bins of parcels. For example, the international mail facility at John F. Kennedy International Airport in New York receives hundreds of thousands of pieces of mail per day.

⁴⁵GAO, *International Mail Security: Costs and Benefits of Using Electronic Data to Screen Mail Need to Be Assessed*, [GAO-17-606](#), (Washington, D.C., August 2, 2017).

⁴⁶See Trade Act of 2002, Pub. L. No. 107-210, § 343, 116 Stat. 933, 981-83 (2002).

⁴⁷The international movement of mail amongst member countries is governed under the Universal Postal Convention by the Universal Postal Union, a United Nations specialized agency with over 190 member countries.

Figure 7: Inbound International Mail at the New York International Mail Facility



Source: GAO. | GAO-18-205

CBP and USPS jointly initiated two ongoing pilot programs at the international mail facilities at John F. Kennedy International Airport in New York (in November 2015) and at Los Angeles International Airport in California (in June 2017) to target mail for inspection using EAD received on inbound mail packages from two countries, including China. We previously examined these pilot programs and found that the agencies could improve implementation. Accordingly, we recommended in August 2017 that CBP and USPS (1) establish measureable performance goals to assess the pilots and (2) evaluate the costs and benefits of using EAD to target mail for inspection compared with other targeting methods. Both CBP and USPS agreed with these recommendations and have begun taking steps to implement them. According to USPS officials, as of the end of 2017, the pilot program had been expanded to all five international mail facilities. Fully implementing our prior recommendations will position these agencies to assess the value of these pilots to their operations and make well-informed decisions in the management of these pilots in the future.

Deploying and Advancing New Drug Detection Technologies at Land Ports

Federal agencies are assessing and deploying new drug detection technologies at land ports. For example, after completing a pilot study in 2016 at the San Ysidro Port of Entry, CBP deployed two new detection devices, TruNarc and Gemini, at ports throughout the country. In addition, researchers at NIST published a study in June 2017 that assessed the

capabilities and sensitivities of existing technologies to detect trace amounts of fentanyl and 16 other analogues, including carfentanil, even when those substances were mixed with other drugs or adulterants, like caffeine. NIST researchers found that the existing technology was capable of presumptively identifying these substances in trace amounts, meaning that officers could detect the substance on the suspect's hands or on the drug's packaging without opening it—enhancing officer safety while providing them with information to begin an investigation without having to wait for results from laboratory analysis.

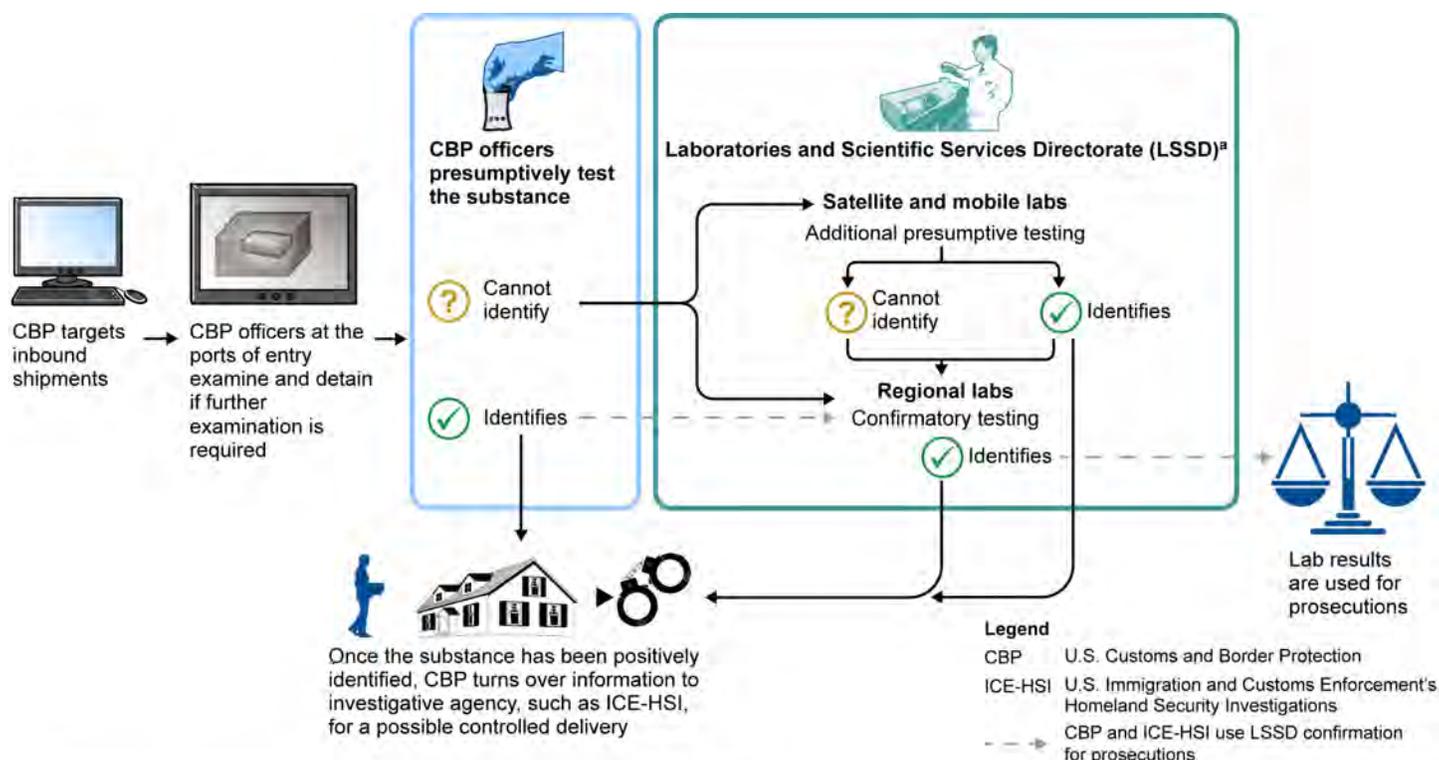
However, agency officials are aware that there are certain limitations in the available detection technologies, such as the inability to see through certain types of packaging and the challenges involved with maintaining up-to-date technology on the emerging drugs of concern. For example, the technology is limited by how extensive the “library” is, which includes all of the drug signatures that the technology can detect. Agencies like NIST, DEA's Special Testing and Research Laboratory, and CBP's Laboratories and Scientific Services Directorate (LSSD) are working to develop new data for the libraries of the various devices. These libraries contain drug-specific characteristics that can be used for drug identification and to deploy the information to manufacturers and forensic labs. Doing this will help keep their technology and testing methods up to date with emergent drug trends. In its final report, the President's Commission acknowledged the importance of such technology and recommended that CBP and the USPIIS use additional technologies and drug detection canines to expand efforts to intercept fentanyl and other synthetic opioids in envelopes and packages at international mail processing distribution centers. As of January 2018, CBP and USPIIS were in the process of evaluating additional methods to detect fentanyl and other synthetic opioids and as of March 2018, CBP was deploying additional devices to aid in the detection of illicit items. In addition, according to CBP, by the end of March 2018, all of the agency's canine teams will be trained to detect fentanyl.

CBP is Not Taking a Risk-Based Approach to Allocating Laboratory Resources

According to CBP officials, as seizures have increased, so has the need for additional laboratory testing at LSSD to confirm the identity of the suspicious substances. When CBP interdicts a suspicious package at the port of entry, officers inspect its contents. They then can use detection technology to conduct a presumptive test to help them determine whether the package might contain illicit materials and therefore should be seized or detained for further analysis. However, in order for law enforcement to be position to prosecute the case, CBP must also send the contents of the seized package to the laboratory for confirmatory testing (see fig. 10).

Across the country, CBP has eight main laboratory facilities—each managed by a Director—and mobile units that can travel and deploy to provide “surge support,” bringing all the necessary personnel and equipment to the desired port of entry. Some of these mobile units have chemists that work at the port of entry full time and others have part-time chemists.

Figure 8: Customs and Border Protection’s (CBP) Process for Identifying Illicit Synthetic Opioids



Source: GAO analysis of CBP information; CBP (adapted photos); Art Explosion (clip art). | GAO-18-205

^aIn each instance, LSSD communicates testing results back to CBP officers at the ports of entry.

According to CBP LSSD officials, the recent surge in narcotics smuggling and interdictions of narcotics, including synthetic opioids is overwhelming the LSSD current capacity load, resulting in significant backlogs at all LSSD facilities. For example, according to CBP, CBP seizures of synthetic opioids alone increased from approximately 1 kilogram in fiscal year 2013 to nearly 90 kilograms in fiscal year 2015 and nearly 200 kilograms in fiscal year 2016.

CBP officials at the ports told us that, depending on the level of support that they receive from LSSD, sometimes they can get testing results in 24 hours and other times it can take months. For example, CBP officials have LSSD staff on-site full time at one international mail facility, which officials said allows them to receive test results back within 24 hours. Alternatively, CBP officials at another international mail facility told us that LSSD's turnaround time for processing and testing samples is much longer. This facility receives hundreds of thousands of pieces of mail per day and about two-thirds of all international mail entering the United States. According to CBP officials there, it can take anywhere from weeks to months to receive testing results, as they only have laboratory staff on-site 2 days a month. While they wait on testing and for LSSD to report back on the parcel's contents, CBP officials at that facility told us they cannot work with ICE-HSI in pursuing their investigations. They also stressed that the testing of these samples are holding up the delivery of packages that recipients are waiting to receive. This can affect USPS or express consignment carrier customer service and may affect the likelihood that a controlled delivery will result in an arrest. They explained that a delay in an investigation may prevent law enforcement officers from taking enforcement action, such as making an arrest.

CBP LSSD officials told us they have taken steps to try and manage their backlog, such as limiting the number of samples that ports of entry can submit for testing per day, reassigning chemists working in other areas to work on narcotics cases or sending samples to labs with a lesser backlog to process.⁴⁸ However, we found that CBP LSSD does not have a documented risk-based process in place to assess how best to allocate its limited staff in consideration of its volume. In particular, CBP LSSD officials acknowledge that they are not allocating their LSSD staff according to the volume at each port and the associated risk of the packages. Instead, CBP LSSD officials told us they prioritize lab work for those seizures that the officers believe are highly suspicious and whose testing (1) will lead to a controlled delivery, (2) confirms whether a person who is detained on account of the seizure can be released, or (3) will provide key information to assist an active investigation.⁴⁹ Further, despite

⁴⁸According to LSSD officials, the limitations on the number of samples that ports of entry can submit for testing per day was removed in January 2018.

⁴⁹Law enforcement agencies use the technique of controlled delivery after they detect a package of illicit drugs. A law enforcement agency allows the package to go forward to its destination under the control and surveillance of law enforcement officers in order to secure evidence against the organizers of such illicit drug traffic.

communicating to us that this was how they prioritized lab work, officials could not provide documentation, such as an operational plan, that this was how they were making their day-to-day decisions. Moreover, despite the steps that LSSD has taken to attempt to better manage their backlogs, significant backlogs for laboratory testing continue to persist, which prevents law enforcement from taking the very actions that LSSD officials have stated influence how they prioritize their lab work.

CBP LSSD officials noted they face challenges retaining and recruiting chemists, such as the time it takes to conduct the necessary security clearances to bring a qualified candidate on board. They also said they have a limited budget to hire new chemists and noted that even if they were fully staffed at their authorized staffing levels, the backlogs and volume of incoming samples to test would still present ongoing challenges.⁵⁰ Nevertheless, the officials could not provide evidence that they were making decisions to allocate positions and personnel across the labs in a way that accounted for factors such as the volume of the incoming packages and risk associated with these packages at each port.

The Office of Management and Budget's guiding principles for risk analysis state that agencies should seek to compare risks to inform priority setting. Further, these principles state that agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement are taken first, accounting for relevant management and social considerations. Given that officials told us that one of LSSD's key priorities is to focus on cases that will result in controlled deliveries, it is critical for CBP to consider volume and risk when determining which ports have the highest need for laboratory staff allocations so that they can reduce the backlogs that are preventing such deliveries from occurring. Moreover, Standards for Internal Control in the Federal Government stress the importance of documenting internal controls to meet operational needs to ensure that controls are communicated to those responsible for executing those controls, and capable of being monitored

⁵⁰In February 2018, the President signed the International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology (INTERDICT) Act, Pub. L. No. 115-112, 131 Stat. 2274, which authorized \$9,000,000 to be appropriated in additional funding to ensure CBP has resources, including chemical screening devices, personnel and scientists, available during all operational hours to prevent, detect, and interdict the unlawful importation of fentanyl, other synthetic opioids, and other narcotics and psychoactive substances. According to CBP officials, once funding is allocated and implementation takes place, these resources should help LSSD significantly reduce its backlog for drug analysis.

and evaluated. Such controls, in this case, could include documenting the key decisions and approaches in developing a risk-based approach to prioritizing laboratory staff allocations. Comparing risks and volume across ports of entry, allocating laboratory resources accordingly, and documenting this process will help CBP ensure that LSSD's priorities can be accomplished as effectively and efficiently as possible, particularly in light of historic backlogs, increasing demand for testing, and limited budgetary resources.

U.S. Law Enforcement and Public Health Officials Have Coordinated to Share Information, but Data Timeliness, Accuracy, and Accessibility Pose Challenges

In response to the current threat of synthetic opioids, federal law enforcement agencies have recognized the importance of expanding their collaboration both within law enforcement, and to those in the public health sector. However, both law enforcement and public health officials we spoke with reported challenges with the timeliness, accuracy, and accessibility of overdose data.

Within law enforcement, federal law enforcement agencies have expanded collaboration by forming working groups and task forces dedicated to combating heroin and illicit fentanyl. For example, in 2014, DEA established the Heroin/Fentanyl Working Group, which includes federal agencies such as DOD, CBP, FBI, USPIS, and ICE-HSI. The group emphasizes the coordination of drug cases involving synthetic opioids, especially those involving major drug trafficking organizations that operate across jurisdictional boundaries on a regional, national, and international level. They also use various techniques to target these organizations to better understand how they operate and develop information that can be passed on to the field. In addition, in October 2017, DEA established six enforcement teams—comprised of DEA agents and state and local task force officers—focused on combating the flow of heroin and illicit fentanyl that are based in communities facing significant challenges with heroin and fentanyl. Law enforcement agencies are also expanding their collaboration under HIDTA's Heroin Response Strategy (HRS), which we discuss in more detail later in this report. For example, each HRS-participating HIDTA has a drug intelligence officer located in each state where the HIDTA operates to help share information across jurisdictions. The drug intelligence officers receive information about felony drug arrests from multiple sources and connect the arresting agency with appropriate in- and out-of-state law enforcement agencies.

Federal law enforcement agencies have also engaged more directly with public health agencies. For example, each HIDTA that participates in

HRS has public health analysts who are managed by the CDC and, according to ONDCP, tasked with enhancing the timeliness and accuracy of state drug use indicator data, such as data on overdose deaths and naloxone distribution. Many of these health analysts have been able to help agencies gain access to fatal and non-fatal overdose data and made use of data in innovative ways. For example, the Washington-Baltimore HIDTA has developed a new technology called ODMAP that provides real-time overdose surveillance data across jurisdictions to support public safety and health efforts to mobilize an immediate response to an overdose spike. It links first responders on the scene to a mapping tool to report overdoses that can then be tracked to stimulate a real-time response and strategic analysis across jurisdictions.

Despite such initiatives, each of the six HIDTAs we spoke with indicated that accessing and analyzing these data continue to pose challenges, a view also shared by nearly all of the law enforcement and public health officials with whom we spoke. In particular, officials cited timeliness, accuracy, and the accessibility of overdose-related data as their primary concerns.

Timeliness

Law enforcement and public health officials indicated that they have a need for fatal overdose death data to help them identify trends, but the lag in receiving it poses a challenge. Overdose data traditionally comes from the official cause of death listed on the death certificate that is prepared by medical examiners or coroners. However, toxicology test results can take months to obtain. For example, officials from the Ohio HIDTA told us that in cases where people die of overdoses at hospitals, the toxicology results can take 2 months or more to be completed. Therefore, it is very difficult for law enforcement and public health officials to have timely data on overdose deaths so they can anticipate and respond to emerging trends.

Accuracy

Law enforcement and public health officials we spoke with also highlighted concerns with the accuracy of the overdose death data they receive. For example, some of the data may be incomplete because medical examiners and coroners may not always test for synthetic opioids like fentanyl in their toxicology tests. For example, an official from the Appalachia HIDTA told us that the underreporting of opioid-related overdoses is an ongoing challenge in the region because, in part, such tests are more often performed by local coroners, rather than by medical examiners who have more training. An undercount of the number of overdose deaths attributable to synthetic opioids like fentanyl may affect the scope of law enforcement and public health officials' response.

Accessibility

In addition to issues with the timeliness and accuracy of data, much of the relevant data for law enforcement and public health officials has legal restrictions for how it can be shared and analyzed to protect patient privacy. For example, by law, the New Hampshire Prescription Drug Monitoring Program may only provide information in the program to authorized law enforcement officials on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause.⁵¹ In addition, no law enforcement agency or official may have direct access to the program. DEA officials told us that obtaining such information is difficult and that as a result, law enforcement agencies have to resort to other means, such as conversations with pharmacists and treatment providers to get information needed to further their investigations.

Further, Massachusetts public health officials told us that, until recently, they had a limited understanding of the extent of the opioid problem in the state because relevant data sets like the state's Prescription Drug Monitoring Program database and cause of death data were legally restricted from being shared. However, officials explained that the Massachusetts Legislature passed Chapter 55 of the Acts of 2015, which required the development of a statewide report on opioid trends, lifted many of the legal restrictions on data, and allowed different law enforcement and public health datasets to be analyzed together for the first time.⁵² As a result, a Massachusetts public health official told us that they were able to identify that cocaine users were overdosing on cocaine laced with fentanyl and planned to target these users with prevention and safe use messaging.

In addition, law enforcement and public health officials we spoke to indicated a need for data on non-fatal overdoses to help them identify and investigate the sources of these drugs in their communities and to be able to direct people to available drug treatment programs. They particularly noted that data of this kind would provide an early warning system for law enforcement and public health officials to anticipate and respond to emerging drug overdose trends. For example, a public health analyst

⁵¹N.H. Rev. Stat. Ann. § 318-B:35. Prescription Drug Monitoring Programs are state-run databases that collect data about controlled substance prescriptions dispensed by pharmacies and doctors. These programs permit authorized users, including prescribers and dispensers, to monitor dispensing activity. In certain states, law enforcement officers may also seek and obtain authorization to access program data.

⁵²2015 Mass. Adv. Legis. Serv. 55.

from the New England HIDTA told us that in Connecticut, officials are unable to estimate the number of non-fatal overdoses because of privacy restrictions on accessing the data. According to law enforcement officials, when medical professionals typically treat a non-fatal overdose, the individual does not directly interact with law enforcement. As a result, those treatment encounters are never officially relayed to law enforcement because of patient protections embedded into laws like the federal Health Insurance Portability and Accountability Act (HIPAA).⁵³ According to some law enforcement officials with whom we spoke, while HIPAA does have a law enforcement exemption if certain requirements are met, such as obtaining a court order, the requirements that must be met are an access challenge that hinders their investigations.

Agencies have taken some steps to improve the quality and timeliness of forensic science and medical examiner and coroner services, such as:

- DOJ's National Institute of Justice has a National Forensic Science Improvement Award grant program that can support data improvements. However, this funding program is not strictly dedicated to medical examiners and coroner services as the grant also provides funding to improve the quality and timeliness for all forensic science services.⁵⁴ In fiscal year 2017, the agency awarded approximately \$10.6 million to 62 grantees under this program.
- As of September 2017, CDC funded 32 states and the District of Columbia under the Enhanced State Opioid Overdose Surveillance program, which aims to improve the timeliness of reporting of both fatal and nonfatal overdoses. Also, through an expansion in funding for this program, all awarded states including the District of Columbia will use the funding to directly support medical examiners and coroners, including for comprehensive toxicology testing.

⁵³See 45 C.F.R. § 164.512(f). HIPAA established national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers, and provided for the establishment of privacy and security standards for handling health information. Generally, HIPAA prohibits the release of information without the authorization of the patient except in specific situations identified in the regulations.

⁵⁴In 2017, the National Institute of Justice also initiated the Strengthening the Medical Examiner-Coroner System Program, a competitive grant program designed to support the enhancement of medicolegal death investigation services and increase the supply of forensic pathologists nationwide by supporting forensic pathology fellowships and providing resources necessary for medical examiner and coroner offices to achieve accreditation.

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- In August 2017, CDC and the Association of State and Territorial Health Officials hosted a meeting regarding citing specific information about drugs on death certificates. According to CDC officials, this meeting brought together local, state, and federal stakeholders to create actionable priorities to improve drug specificity in the death certificate reporting.
 - As reported in September 2016, CDC’s National Center for Health Statistics, the National Institutes of Health, and other federal agencies served on a committee under the auspices of the President’s National Science and Technology Council to address issues related to accessing and working with data that medical examiners and coroners provide during death investigations.⁵⁵ The committee’s work was focused on death investigations overall, and not just on those attributable to overdoses, but the 12 recommendations it made in 2016 have the potential to enhance the capacity and quality of the larger death investigation system that medical examiner and coroner offices, in part, support.

Standards for Internal Control in the Federal Government states that agencies should use quality information to make informed decisions and that quality information is appropriate, current, complete, accurate, accessible, and provided on a timely basis.⁵⁶ While some efforts are newly underway, many federal, state, and local officials acknowledged to us the ongoing need for better data usage—for both fatal and non-fatal overdose cases. In particular, ONDCP officials told us that understanding and improving data collection activities related to the opioid epidemic remains important. Further, the President’s Commission identified a number of challenges in its 2017 report related to agencies having quality information and made a number of recommendations for ways to address

⁵⁵According to the Council’s report, “the nation’s approximately 2,400 medical-examiner and coroner (ME/C) jurisdictions investigate nearly 500,000 deaths each year and perform post-mortem examinations and/or autopsies to determine the cause and manner of death. While the function and organization of these offices vary by state, medical examiners and coroners typically investigate deaths that are sudden and unexpected, deaths that have no attending physician, and all suspicious or violent deaths. Strengthening the ME/C system is critical for improving the accuracy and reliability of these death investigations and will benefit public health and safety programs, law-enforcement investigations, and the development of interventions to prevent deaths nationwide.” See Executive Office of the President National Science and Technology Council, *Strengthening The Medicolegal-Death-Investigation System: Improving Data Systems*. (Washington, D.C., September 2016).

⁵⁶GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#), (Washington, D.C., September 2014).

them. For example, the President’s Commission recommended, broadly, a federal effort to strengthen data collection activities. In its report, the President’s Commission noted this would “enable real-time surveillance of the opioid crisis at the national, state, local, and tribal levels.” As of December 2017, the administration was still considering the these recommendations and how to address them.

As demonstrated through its management of programs like HIDTA’s HRS, an agency like ONDCP is uniquely positioned to collaborate with its law enforcement and public health counterparts to lead a specific review on ways to improve the timeliness, accuracy, and accessibility of fatal and non-fatal overdose data that provide critical information to understand and respond to the opioid epidemic. Such a review should expand on and leverage the findings from previous federal studies. It should also assess the benefits and scalability of ongoing efforts to leverage data systems, such as the Washington-Baltimore HIDTA’s ODMAP program, and examine ways in which laws that restrict access to public health data to protect patient privacy have exemptions for law enforcement entities that could be more widely leveraged while appropriately protecting patient privacy.

Many U.S. Agencies’ Documented Opioid Response Strategies Lack Outcome-Oriented Performance Measures

A number of federal agencies have documented specific strategies to combat illicit opioids.⁵⁷ However, only three of the five strategies we assessed—ONDCP’s Heroin Availability Reduction Plan (HARP); HIDTA’s HRS; and DEA’s 360 Strategy—included performance measures to gauge the effectiveness of the efforts described in each strategy, and only HARP included outcome-oriented performance measures.

We have long reported on the importance of measuring program performance.⁵⁸ Our prior reports and guidance have stated that performance measurement should evaluate both processes (outputs) and

⁵⁷None of the five strategies we reviewed are specifically focused on synthetic opioids but rather on the larger opioid issue, which includes heroin and often prescription opioids. According to ONDCP, this is because (1) synthetic opioids are often mixed in or sold as other opioids, (2) the same drug-trafficking organizations and trafficking routes are being utilized, and (3) federal agencies want to avoid responses to one type of opioid that inadvertently has a negative impact on another. For example, law enforcement would not want to focus all their enforcement efforts on reducing the availability of prescription opioids because it may cause people to seek out illicit drugs like heroin.

⁵⁸[GAO-14-207](#); [GAO-12-208G](#); [GAO-11-646SP](#); and [GAO/GGD-96-118](#).

outcomes related to program activities. Specifically, we have noted that output measures address the type or level of program activities conducted and the direct products or services delivered by a program, such as the number of presentations given, while outcome measures address the results of products and services, such as reductions in overdose deaths. Outcome measures can help in assessing the status of program operations, identifying areas that need improvement, and ensuring accountability for end results. Further, the Government Performance and Results Act Modernization Act of 2010 directs agencies to develop goals, as well as performance measures.⁵⁹ Such measures provide federal agencies with information on how resources and efforts should be allocated to ensure effectiveness and keep program partners focused on the key goals of a program. Without specific goals and outcome-oriented performance measures, federal agencies will not be able to truly assess whether their respective investments and efforts are helping them achieve the goals set out in their strategies. Moreover, as stated in the final report of the President's Commission, "if we are to invest in combating [the opioid] epidemic, we must invest in only those programs that achieve quantifiable goals and metrics."⁶⁰

ONDCP's Heroin Availability Reduction Plan (HARP)

ONDCP's HARP, implemented in 2016, aims to provide a roadmap to guide and synchronize interagency activities, performed through ONDCP's National Heroin Coordination Group, to reduce the supply of heroin, fentanyl, and fentanyl analogues in the U.S. market. The HARP is a 5-year plan, partitioned into 6 month time periods, focused on the following strategic end state goals:

1. A significant reduction in the number of heroin-involved deaths in the United States due to a disruption in the heroin and fentanyl supply chains;
2. A detectable decrease in the availability of those drugs in the U.S. market; and
3. [Agencies experiencing] the complementary effects of international engagement, law enforcement, and public health efforts.

Of the five federal opioid response strategies that we assessed, only ONDCP's HARP contained goals with outcome-oriented performance

⁵⁹Pub. L. No. 111-352, 124 Stat. 3866 (2011).

⁶⁰The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, November 1, 2017.

HIDTA's Heroin Response Strategy (HRS)

measures that aim to assess the effectiveness of these efforts. For example, for its first goal, the HARP includes an outcome-oriented measure related to the rate of heroin-involved overdose deaths that it tracks through the CDC's cause of death data. In addition, officials acknowledged the difficulties in the timeliness of this data, which is released annually, and the strategy establishes incremental metrics that are based off state-level data that are released on a quarterly basis.

The HIDTA program's HRS, started in August 2015, seeks to establish a cross-disciplinary initiative that brings public health and public safety partners together at the federal, state, and local level to reduce drug overdose fatalities and disrupt trafficking in illicit opioids.⁶¹ HRS sets out four overall goals that the participating HIDTAs should be working to:

1. Create and coordinate shared data regimes that allow public health, law enforcement, and others to respond quickly and effectively to the opioid overdose epidemic;
2. Develop and support strategic, evidence-based responses to generate immediate reductions in the number of overdose-related fatalities;
3. Promote and support efforts to prevent or reduce opioid misuse; and
4. Promote the active engagement of local communities in the discussion, planning, and implementation of HRS goals and activities.

HRS does include some output-oriented performance measures, such as the number of individuals referred to public health agencies for follow-up; however, HRS does not include any outcome-oriented performance measures. In the case of HRS, an example of an outcome-oriented performance measure that links closely to its current goals might be the number of overdose deaths.

According to ONDCP and HIDTA officials, it was not possible to set outcome-oriented performance measures for HRS because the program is funded through discretionary funds year-to-year and the funding stream is not guaranteed. However, given that the program competes for limited

⁶¹ Apart from HRS, the HIDTA program as a whole has output-oriented performance measures used to track the effectiveness of their efforts. For example, one of the HIDTA goals is to disrupt the market for illegal drugs by dismantling or disrupting drug trafficking and/or money laundering organizations. One measure that is used to assess effectiveness is to report on the return on investment based on the value of drugs, cash, and assets seized from these organizations.

discretionary funding, it is essential that HRS establish outcome-oriented performance measures so that HIDTA participants can demonstrate whether their goals are being achieved over time and that the program is a worthwhile investment. HIDTA officials also stated that outcome-oriented performance measures, such as reducing overdose deaths, require the collaboration and support of a variety of partners and HIDTA cannot direct their activities. Thus, HIDTA officials believe the measures that HRS has put into place are those that relate to activities for which HIDTA is directly responsible. While we acknowledge that it may be difficult to single out HIDTA's contribution to these activities, the stated goals of HRS revolve around the collaboration between HIDTA and its partners. Therefore establishing outcome-oriented performance measures, such as the number of overdose deaths, would enhance HIDTAs' ability to assess whether these collaborative efforts are producing intended results.

OCDETF's National Heroin Initiative

OCDETF's National Heroin Initiative started in December 2014 with the goal of supporting local and regional initiatives to disrupt the flow of heroin into communities in every OCDETF region across the country. The initiative aims to bring together otherwise disparate agencies, investigations, and information to develop a coordinated law enforcement action plan involving federal, state, tribal, and local authorities. The strategy outlines the mechanisms by which OCDETF will provide its field components with discrete amounts of operational funding.⁶² This funding supports the development of creative strategies and initiatives to identify and exploit the vulnerabilities of criminal organizations responsible for illegal trafficking of opioid drugs in the United States. The supporting objectives to the goal include identifying, disrupting, and dismantling the most significant criminal organizations responsible for the manufacture and distribution of heroin intended for consumption in the United States, collecting intelligence, and facilitating law enforcement coordination, among others. The strategy does not include performance measures, outcome-oriented or otherwise, to assess progress specific to the National Heroin Initiative. However, the initiative does require each field component to submit quarterly reports detailing all of the relevant data that is pertinent to the area where they work. These reports include measures that OCDETF then uses to assess its overall performance,

⁶²OCDETF field components include members of federal, state, and local law enforcement agencies that are investigating and prosecuting OCDETF cases on the local level.

such as OCDETF conviction rates. Field components also participate in a conference call with other funded entities to share information.

According to the OCDETF Heroin Initiative Coordinator, each OCDETF field component operates in a district with unique needs and challenges and therefore there are not overarching performance measures, outcome-oriented or otherwise. However, without establishing outcome-oriented performance measures for the National Heroin Initiative, OCDETF is unable to fully determine whether the resource investment made into the initiative and participating field components achieves the initiative's overall goals. In addition, establishing such outcome-oriented performance measures would allow OCDETF to compare the performance of participating field components to better understand which efforts are working well and what efforts may need additional attention.

DOJ and U.S. Attorneys Offices' Strategies to Address the Opioid Epidemic

In September 2016, the Attorney General announced the Department's strategy to combat the opioid epidemic, which rested on three pillars: prevention, enforcement, and treatment. According to officials from the Office of the Deputy Attorney General, although this strategy started under the prior administration, it is still in effect and DOJ has expanded its opioid efforts in the new administration. In particular, in late December 2017, the Attorney General announced the creation of a new senior-level position—the Director of Opioid Enforcement and Prevention Efforts within the Deputy Attorney General's office. Once selected, the Director will be responsible for assisting the Attorney General, Deputy Attorney General, and department components in formulating and implementing DOJ initiatives, policies, grants, and programs related to opioids, and coordinating these efforts with law enforcement.

Nevertheless, we found that DOJ's department-wide strategy does not outline goals or include outcome-oriented performance measures to assess the impact of their efforts. Accompanying the Attorney General's announcement of the strategy was a memorandum from the Deputy Attorney General to all United States Attorneys directing them to draft a district-specific strategy to address the opioid epidemic that focuses on the same three pillars. Other than indicating that the district-specific strategies should focus on the three pillars, the Deputy Attorney General's memorandum does not set out overall goals and performance measures that the districts should use to assess the effectiveness of their efforts, nor does it direct the Executive Office for the United States Attorneys

(EOUSA)—the office within DOJ that supports the USAOs nationwide—to do so.⁶³

According to DOJ officials, developing goals and outcome-oriented performance measures, such as those related to drug trafficking or overdose rates, for their department-wide opioid strategy is difficult because the federal government still does not have a complete understanding of the opioid problem. From their perspective, the emergence of new opioid threats in recent years, such as new potent fentanyl analogues, pose unique challenges for the USAOs in identifying and prosecuting domestic and international supply sources, deterring trafficking, and preventing public harm. Further, they noted that the nature of the opioid problem varies among the 93 USAOs. However, without establishing goals and outcome-oriented performance measures as a means to assess the effectiveness of its strategy, it is difficult for DOJ to set a course for its efforts and understand whether the efforts the department is undertaking as a part of the strategy are having the intended impact. Further, establishing outcome-oriented performance measures for its efforts will provide DOJ a mechanism to better understand the opioid problem as it continues to progress and adjust its course, if needed, along the way.

DEA's 360 Strategy

U.S. Drug Enforcement Administration 360 Pilot Cities

1. Louisville, Kentucky
2. Milwaukee, Wisconsin
3. St. Louis, Missouri
4. Pittsburgh, Pennsylvania
5. Dayton, Ohio
6. Albuquerque, New Mexico
7. Charleston, West Virginia
8. Manchester, New Hampshire
9. South Jersey, New Jersey
10. Salt Lake City, Utah

Source: U.S. Drug Enforcement Administration. |
GAO-18-205

DEA's 360 Strategy was implemented in November 2015 with the intent to bring together three key DEA activities— enforcement operations, diversion control initiatives, and demand reduction efforts— under one strategy targeted toward opioids. The strategy is currently being rolled out in ten pilot areas throughout the United States, such as Milwaukee, Wisconsin and Manchester, New Hampshire on a 1 year, time-limited basis.

DEA's 360 Strategy has three main goals:

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;

⁶³In March 2017, EOUSA finalized a compilation report of all the individual strategies that each of the 93 USAOs had submitted. It distributed the report to every USAO, as well as to ONDCP, as a means to share promising practices on the unique efforts being taken at the local levels.

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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.

DEA's 360 Strategy includes output-oriented performance measures for these demand reduction efforts, which include measures such as the number of participants in its activities and the number of presentations given. However, the 360 Strategy does not include goals or output-oriented measures for the other two activities embodied in the strategy—enforcement operations and diversion control initiatives—and does not include outcome-oriented measures for any of the three activities.

DEA has issued a solicitation for a Performance Analysis Pilot to assess the reach and impact of outreach activities in Milwaukee using the established performance measures and, according to DEA officials, the agency intends to deploy such assessments in other pilot locations contingent upon the availability of funding. However, given the lack of goals for two parts of the strategy as well as the lack of outcome-oriented performance measures in all three parts of the 360 Strategy, it is unclear the extent to which this pilot can accurately and fully gauge these efforts and their overall effectiveness. According to DEA officials, DEA did not establish outcome-oriented performance measures for the 360 Strategy, since it is a time-limited, 1-year project in each city, and outcomes, such as changes in drug use behavior, are difficult to measure and achieve over such a short period. Further, they believe that the output-oriented measures that are in place for the demand reduction activities position them to understand the reach and impact of their efforts, even though such measures do not speak to the results the strategy aims to achieve. Although DEA has set these pilot programs to be time-limited and measuring outcomes over a short period can be challenging, the programs these pilots develop are intended to be sustained in the communities once the official pilots are complete. Therefore, establishing goals and outcome-oriented performance measures for each of the three parts of the strategy at the pilot's onset will better enable DEA officials to understand what they are trying to achieve and whether or not the activities they have included in their strategy are yielding desired results. Further, having such measures at the pilot's inception will position the local communities to be able to measure progress after the official pilots have ended.

U.S. Agencies Adapted to the Opioid Epidemic by Expanding Education Campaigns, Treatment Options, and Partnerships

As part of their response to the opioid epidemic, agency officials from DHS, DOJ, and ONDCP reported that they have generally continued their prevention efforts, and provided examples of expanded education campaigns in response to the synthetic opioid threat. Further, federal agencies reported providing additional funding for overdose reversal and treatment options, including distribution and use as well as efforts to improve their availability and effectiveness. Lastly, officials reported an increase in partnerships across federal, state, and local agencies and across education, public health, and law enforcement sectors to coordinate their responses to the growth in synthetic opioid use.

Prevention Efforts

As the threat of synthetic opioids has grown more severe, officials have stressed the importance of researching what works in prevention efforts and applying the findings, expanding federal law enforcement agency community outreach, and engaging medical professionals on the subject of addiction.

Researching What Works in Prevention Efforts

Officials with whom we spoke as well as previously issued federal agency reports stressed the importance of researching existing prevention programs to identify what works and replicating the effective programs across the country—particularly in light of the changing nature of drug use. For example, participants at a Comptroller General forum on preventing illicit drug use in June of 2016 stated that widely used programs like Drug Abuse Resistance Education (DARE) have not been proven effective.⁶⁴ Instead, they noted that the research shows that programs in schools and community settings that focus more broadly on combating risky behaviors and strengthening family and community ties have greater benefits than those that are more narrowly targeted to warnings about specific drugs.⁶⁵ Officials stated that since the main risk factors for substance use include impulsivity and high risk-taking, developing skills in youth to control their impulses and understand the

⁶⁴DARE is a school-based substance abuse prevention program taught to students in elementary school, middle school, and high school. A previous GAO report in 2003 reviewed evaluations of DARE's long-term effectiveness and found that there were no statistically significant differences in illicit drug use between students who received DARE lessons in the fifth or sixth grade and those who did not. See GAO, *Youth Illicit Drug Use Prevention: DARE Long-Term Evaluations and Federal Efforts to Identify Effective Programs*, [GAO-03-172R](#) (Washington, D.C.: Jan. 15, 2003)

⁶⁵GAO, *Highlights of a Forum: Preventing Illicit Drug Use*, [GAO-17-146SP](#) (Washington, D.C.: Nov. 14, 2016)

consequences of risk means that they can apply these skills in adolescence when opportunities to engage in substance abuse are more likely to present themselves.

The U.S. Surgeon General's November 2016 report on addiction in America further emphasized that effective prevention programs can reduce substance misuse and related threats to public health by focusing on a skills-development approach.⁶⁶ In addition, NIDA officials we spoke with affirmed this view, and described the funding NIDA provides to research and implement several evidence-based prevention programs that aim to enhance parenting skills and youth behavior management. These include the Nurse-Family Partnership, the Good Behavior Game, and the Strengthening Families Program.⁶⁷

DOJ and HIDTA officials we spoke with acknowledged the importance of education campaigns, and described some of their locally based, expanded community outreach efforts. USAO District of New Hampshire officials stated that they have partnered with DEA as part of DEA's 360 Strategy to conduct outreach to schools in the 360 pilot communities. As part of these efforts, DEA's Manchester field office hosted a youth summit with more than 8,500 youth in attendance and broadcast to over 35,000 youth around the state. The summit included presentations by the Attorney General and families affected by opioid use about the impact of opioids and the need for prevention efforts.

Additionally, USAO Central District of California officials stated that they have focused on sending speakers to conduct trainings for college students about synthetic opioids and why they are a problem, how they differ from prescription drugs, and what to do in the event of an overdose.

⁶⁶U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, DC: HHS, November 2016.

⁶⁷The Nurse-Family Partnership involves nurses providing home visitation interventions for at-risk, first-time mothers during pregnancy to provide ongoing education and support. It has shown significant reduction in the use of alcohol in teenagers compared to those who did not receive the intervention. The Good Behavior Game is a classroom behavior management program that rewards children for acting appropriately during instructional times. It significantly lowered rates of alcohol, other substance misuse, and substance use disorders in the children when they reached ages 19 to 21. The Strengthening Families Program consists of a seven-session, family-focused program to teach parenting skills and adolescent substance refusal skills. It was associated with reductions in tobacco, alcohol, and drug use up to 9 years after the intervention as well as reductions in prescription drug misuse up to 13 years afterwards.

District officials stated they have also previously sent speakers to the University of Southern California's forensic social work school to discuss how to recognize signs of addiction and help drug users. Similarly, DEA makes a variety of resources about drug use publicly available. For example, their Get Smart About Drugs website includes information for parents, educators, and caregivers on how to identify illicit drugs and paraphernalia, emerging drug trends, and the health effects of drug use.

Several HIDTA officials also stated that they provide funding to local programs aimed at at-risk populations. For example, New York and New Jersey HIDTA officials reported that they provide funding to several prevention programs. These included Saturday Night Lights, a program that the Manhattan District Attorney initiated where local YMCAs provide coaches, sports programs, and a safe space for children on Saturday nights, and Harlem Children's Zone, which provides a range of family services, social services, and health programs.⁶⁸ Los Angeles HIDTA officials reported being part of the Safe Med LA coalition, which focuses on reducing prescription drug misuse and overdose deaths. The coalition works on efforts ranging from community education, promoting medication-assisted treatment, safe drug disposal, and safe prescription practices for doctors.

Engaging Medical Professionals in Prevention Efforts

Agency officials also emphasized the emerging need to better train and engage medical professionals in prevention efforts and explained their increasing role in this area. For example, in March 2016 the CDC developed and issued voluntary guidelines for primary care physicians prescribing opioids to patients with chronic pain.⁶⁹ The CDC stated that, among other goals, it intends for the guidelines to help reduce the number of persons who develop opioid use disorder, overdose, or other adverse events related to opioids. CDC officials also reported that after releasing the guidelines, the agency has developed training materials on the topic, including several webinars. Approximately 60 medical schools have signed a pledge to incorporate the guidelines into their educational curriculums. According to CDC officials, they are also in the process of

⁶⁸The Harlem Children's Zone is a non-profit organization that funds and operates a neighborhood-based system of education and social services for the children of low-income families in Harlem, New York.

⁶⁹Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity and Mortality Weekly Report Recommendations and Reports (United States: Centers for Disease Control and Prevention, Mar. 18, 2016).

developing more comprehensive training modules that will qualify as continuing education credits for physicians and nurses.

Additionally, New England HIDTA officials reported that they worked with public health officials in the region on the Safe and Competent Opioid Prescribing Education of Pain training program for physicians. This training includes material on how to assess patients' risk of opioid misuse, how to distinguish drug-seeking behavior from pain, and how to educate patients on the risks of opioids.

Overdose Reversal and Treatment Options

In response to the ongoing opioid epidemic, federal agencies reported providing funding for the distribution and use of naloxone and MAT services, as well as efforts to improve their availability and effectiveness. Officials also reported exploring vaccines to counteract opioid effects in the body.

Naloxone

Naloxone is an opioid antagonist that reverses overdoses by displacing opioids from receptors in the brain and blocking effects on breathing and heart rates.⁷⁰ The FDA originally approved the drug in 1971 and it continues to be used for a variety of opioid overdoses, including illicit synthetic opioids. In 2015, DOJ's Bureau of Justice Assistance developed a Law Enforcement Naloxone Toolkit, which was made available online for state, local, and tribal law enforcement agencies. The toolkit provides answers to frequently asked questions about naloxone and training materials about its use. Over the next 2 years, naloxone use was found to be widespread and support had built for its use among the public. In fact, the Network for Public Health Law (Network) reported in 2017 that all 50 states and the District of Columbia had passed legislation to improve access to naloxone for laypeople.⁷¹ In addition, the Network reported that 40 states and the District of Columbia had passed Good Samaritan laws that provide protection from arrest or prosecution for individuals who report overdoses in good faith. Further, officials with all six HDTAs we interviewed reported efforts in their regions to improve the availability of naloxone to first responders or the public.

⁷⁰The FDA has approved a nasal spray formulation of naloxone hydrochloride known as Narcan. For the purposes of this report, we will refer to the drug as naloxone in general.

⁷¹The Network for Public Health Law, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws* (Edina, MN: Robert Wood Johnson Foundation, 2017).

HHS officials reported taking a number of actions that may improve the availability and effectiveness of naloxone and similar opioid antagonists. FDA officials stated that they have developed model labeling for a potential over-the-counter naloxone that can be sold without a prescription. They also noted that a formal research study is ongoing to determine whether consumers can comprehend that label and understand how to use naloxone in an emergency situation, without any help from a healthcare professional. They have also incentivized the development of new opioid overdose reversal treatments using the FDA's expedited review program. For example, they approved both the first auto-injector of naloxone and a nasal spray formulation of naloxone under the program. Both FDA and NIDA officials reported that there may be a need for new drugs designed to treat overdoses resulting from high-potency opioids such as carfentanil. Naloxone can reverse carfentanil overdoses, but multiple doses may be required. FDA officials stated that they have contracted for a high-priority study of the relationship between the chemical structure of synthetic opioids and their effects in the body to better understand the requirements for reversing this type of overdose.

Medication-Assisted Treatment (MAT)

MAT services, though not specific to synthetic opioids, consist of a combination of medications and behavioral therapies that are used to treat substance use disorders. They have been shown to be more effective than abstinence-based treatments at reducing illicit drug use and overdose deaths, improving retention in treatment, and reducing HIV and hepatitis C transmission.⁷² Medications that the FDA currently approves for use in MAT include methadone, buprenorphine, and naltrexone.⁷³ Examples of behavioral therapies include cognitive behavioral therapy and contingency management.⁷⁴

⁷²U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, DC: HHS, November 2016.

⁷³Methadone is an opioid agonist that helps prevent withdrawal symptoms during detoxification therapy and reduce cravings for opioids during maintenance therapy. Buprenorphine is also an opioid agonist that reduces or eliminates withdrawal symptoms and cravings for opioids. Naltrexone is an opioid antagonist that prevents opioids from binding to and activating opioid receptors. This blocks the effects on the user and is used to prevent relapses after detoxification therapy.

⁷⁴Cognitive behavioral therapy involves modifying behaviors and improving coping skills by identifying and modifying dysfunctional thinking. Contingency management involves giving rewards to support positive behavioral changes.

Prior GAO reports have highlighted that only a portion of individuals who need MAT are receiving it and federal agencies are seeking to expand its availability in response to the opioid epidemic.⁷⁵ According to ONDCP officials, they have formed a MAT working group to raise awareness, increase support for MAT services for opioid users, and coordinate with SAMHSA and Bureau of Justice Assistance to introduce it as an option in drug court cases.⁷⁶ SAMHSA officials stated that they provide funding through several programs that can be used to provide MAT services. One new source of funding is through the State Targeted Response to the Opioid Crisis grant program, which was authorized in the 21st Century Cures Act.⁷⁷ Another funding source is the Medication Assisted Treatment – Prescription Drug and Opioid Addiction grant program. SAMHSA issues this funding to states to provide MAT and recovery support services to individuals with opioid use disorders. According to SAMHSA officials, there are currently 22 states receiving these funds. Officials reported that existing SAMSHA block grants to states might also be used for MAT services.

NIDA officials also stated that they are providing funding for research projects related to MAT. These included projects supporting the development of specific new medications as well as basic medical research that contributes to the future development of new medications. NIDA officials stated that short-term projects include developing improved formulations of existing medications or different delivery methods. For example, they cited a formulation of buprenorphine that lasts for 6 months and is delivered through biodegradable implants. Of the three drugs approved for use in MAT, naltrexone has been available for the shortest amount of time. According to NIDA officials, the oral formulation of naltrexone has not been shown to be particularly effective at treating substance use disorders, but the 30-day injected formulation (XR-NTX) has evidence that it is effective at reducing opioid use. NIDA recently completed a comparison study of the effectiveness of a

⁷⁵GAO, *Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment*, [GAO-18-44](#) (Washington, D.C., Oct. 31, 2017).

⁷⁶Drug courts are designed to offer alternatives to adjudication or incarceration for criminal defendants with substance use disorders, generally requiring participating in substance use treatment programs and other social services. See GAO, *Adult Drug Courts: Studies Show Courts Reduce Recidivism, but DOJ Could Enhance Future Performance Measure Revision Efforts*, [GAO-12-53](#) (Washington, D.C.: Dec. 9, 2011).

⁷⁷Pub. L. No. 114-255, § 1003, 130 Stat. 1033, 1044-1046 (2016).

buprenorphine/naloxone combination and extended release naltrexone that was published in November 2017 and demonstrated that, once initiated, the buprenorphine/naloxone combination and XR-NTX are equally safe and effective.⁷⁸ The National Institutes of Health is also establishing public-private partnerships with pharmaceutical companies to accelerate the development of medications to treat opioid addiction. Further, after two clinical studies, the FDA announced its approval on November 30, 2017 of Sublocade, the first once-monthly injectable buprenorphine that can reduce the burden of daily medication for some eligible patients as part of MAT.

Opioid Vaccines

In addition to funding for MAT-specific research, NIDA has also funded research into several opioid vaccines that attempt to counteract the effects of opioids in the body. NIDA officials stated that they have provided funding to develop a fentanyl vaccine, which is expected to enter primate testing in the fall of 2017 and, if successful, be ready for market in 7 to 10 years. There are also heroin/HIV and oxycodone vaccines being developed, although they are both in the pre-clinical stages.⁷⁹ FDA officials stated that they could not provide details on specific vaccines under development, but that these types of vaccines would be eligible for an expedited development process.

Partnerships

Federal, state, and local agencies have reported enhancing older or more loosely coordinated public safety and public health partnerships. Two examples—the HIDTA program and the use of emergency declarations—illustrate how these stronger partnerships have worked to better target prevention and treatment efforts in light of the emergence of synthetic opioids.

HIDTA Program

In the New York/New Jersey region, HIDTA officials stated that they participate in the RX Stat Initiative, which consists of regular monthly meetings between 44 federal, state, and local government agencies. HIDTA officials stated that the reason for RX Stat's formation was to

⁷⁸Joshua D. Lee et al., "Comparative Effectiveness of Extended-Release Naltrexone Versus Buprenorphine-Naloxone for Opioid Relapse Prevention (X:BOT): A Multicentre, Open-Label, Randomised Controlled Trial", *The Lancet*, vol. 391, no. 10118 (January 2018): 309-318, 27.

⁷⁹C.R. Alving et al., "Heroin-HIV-1 (H2) Vaccine: Induction of Dual Immunologic Effects with a Heroin Hapten-Conjugate and an HIV-1 Envelope V2 Peptide with Liposomal Lipid A as an Adjuvant" *NPJ Vaccines* (2017).

bridge the gap between public health agencies' population-level view of the opioid problem and public safety agencies' case-level view. Participants include DEA, the New York Office of the Chief Medical Examiner, the New York Police Department, and the New York Housing Department. HIDTA officials in the region reported that the initiative has been beneficial because it helped them understand the scope of the opioid abuse problem and target approaches in order to address it more effectively. The RX Stat Operations group has also helped by analyzing data on overdose victims, including information on their medical, criminal, and personal histories. This has allowed RX Stat participants to discuss strategies for preventing future overdoses. According to officials, the New York/New Jersey HIDTA is currently attempting to acquire more data on overdose deaths from the New York Fire Department as well as private ambulance companies for use in RX Stat analysis and discussion.

New England HIDTA officials stated that they began a partnership with the Massachusetts Department of Public Health under the HRS. Prior to the partnership, HIDTA officials reported that they had a more limited understanding of the public health consequences of the opioid epidemic in the region and what data was available. A Massachusetts public health official stated that the New England HIDTA has facilitated communication and information sharing in the region, and a public health analyst added that the New England HIDTA has facilitated aggregation of information on drug overdoses at the state level. As previously mentioned, the Massachusetts Department of Public Health is working on a data linkage project, called Chapter 55, which will link systems, including data on medical examiner toxicology reports, the state's Prescription Drug Monitoring Program, and ambulance and paramedic reports. State and local law enforcement data are currently being added to the project. According to a Massachusetts public health official, the enhanced data allows the agency to identify populations at risk for opioid overdoses. For example, the agency previously received information on instances of cocaine laced with fentanyl, indicating that both heroin and cocaine users needed to receive information about the dangers posed by synthetic opioids.

Appalachia HIDTA officials stated that prior to their partnership efforts there was a lack of communication and information sharing between law enforcement agencies and medical organizations in the region, such as first responders and hospitals. They reported addressing this through collaboration with public health analysts who are co-located with DEA, FBI, National Guard, and the Kentucky State Police. Among other things, this partnership has enabled them to access hospital data more quickly

than they had been able to previously. In another example, San Diego-Imperial County HIDTA officials reported assigning public health analysts to law enforcement agencies in order to help direct individuals to treatment options. This partnership helped avoid potential repeat arrests of the same individuals, who had previously been cycling in and out of the criminal justice system for their drug use and addiction.

Officials in the New England HIDTA and San Diego-Imperial County HIDTA also cited the Police Assisted Addiction and Recovery Initiative program as an example of coordination between public health and public safety agencies in their regions. Under this program, drug users who ask for help at a police department are placed in a treatment program rather than in jail. This program also works to provide naloxone to police departments and overdose victims.

Emergency Declarations

Another approach that demonstrates the gains from partnerships is the use of emergency declarations, which allow for centralized coordination of federal, state, and local agencies' efforts in response to the impact of synthetic opioids and other drugs in certain states. According to the Association of State and Territorial Health Officials, as of January 2018, eight states have issued emergency declarations related to the opioid epidemic: Massachusetts, Virginia, Alaska, Maryland, Florida, Arizona, South Carolina, and Pennsylvania.⁸⁰ The Alaska emergency declaration authorized the Commissioner and State Medical Officer of the Alaska Department of Health and Social Services to coordinate a statewide Overdose Response Program. The declaration also issued a standing order that allows local and regional overdose response programs, healthcare officials, first responders, and the public to dispense and administer naloxone. A follow-up administrative order directed the State Medical Officer to establish, coordinate, and manage an incident command structure to address the opioid epidemic. The Arizona emergency declaration required the Director of Arizona's Department of Health Services to develop guidelines for healthcare providers on responsible prescribing practices, as well as to develop and provide training to local law enforcement agencies on protocols for carrying, handling, and administering naloxone for overdoses.

⁸⁰The emergency declaration in Virginia was issued by the State Health Commissioner, who later clarified that it was not a Governor's emergency declaration and does not have the force of law. However, it also included a standing order to state pharmacists allowing individuals to purchase naloxone without having to get a prescription.

Officials with the Maryland Opioid Operational Command Center stated that the Governor of Maryland first engaged emergency managers about organizing coordinated efforts to address the opioid epidemic using FEMA's National Incident Management System framework.⁸¹ The Governor subsequently declared a state of emergency in March 2017. According to Maryland officials, they are using a modified version of this framework because it is scalable and allows them to integrate state and local efforts. Maryland officials are also currently using the HIDTA program to help facilitate coordination because it already offers information sharing between public safety and public health agencies.

Maryland officials told us in the summer of 2017 that a federal emergency declaration would allow the federal government to centralize state efforts and address the opioid epidemic as a crisis. For example, it could allow the HHS Secretary to negotiate reduced pricing on naloxone for all government agencies. On July 31, 2017, the President's Commission released an interim report that included a recommendation for the President to declare a national emergency under either the Public Health Service Act⁸² or the Stafford Act.⁸³ On October 26, 2017, the President directed the Acting HHS Secretary to declare the drug demand and opioid crisis to be a public health emergency. The President also issued a memorandum to the heads of executive departments and agencies

⁸¹According to FEMA, the National Incident Management System is intended to provide a consistent national framework and approach for governments, the private sector, and nongovernmental organizations to work together to respond to incidents regardless of the cause, size, location, or complexity. This allows them to integrate their efforts and establish a unified command.

⁸²The Public Health Service Act, as amended, includes the ability for the HHS Secretary to declare a public health emergency presented by a disease or disorder, or by significant outbreaks of infectious disease or bioterrorist attacks. Among other things, the declaration allows the Secretary to respond to the emergency by making grants and entering contracts, accessing appropriated funds in the Public Health Emergency Fund, and waiving or modifying some requirements. Public health emergencies terminate when the HHS Secretary declares that the emergency no longer exists, or 90 days after the initial determination. The HHS Secretary may renew determinations. See 42 U.S.C § 247d.

⁸³The Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 100-707, 102 Stat. 4689 (1988), allows the President to declare an "emergency" or "major disaster." "Emergencies" consist of "any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States." In declared emergencies, the President may direct federal agencies to support state and local assistance efforts, coordinate disaster relief assistance, remove debris, and assist in distribution of supplies. See 42 U.S.C. §§ 5121-5206.

directing them to exercise all appropriate emergency authorities to reduce the number of deaths and minimize the devastation inflicted on American communities. That same day, the Acting HHS Secretary declared the public health emergency under the Public Health Service Act.⁸⁴

While it is too soon to tell what specific actions will be taken in response to the public health emergency declaration, the President's remarks mentioned several new measures that the administration plans to undertake, including:

- Removing a restriction on providing care at treatment facilities with more than 16 beds;⁸⁵
- Implementing recommendations based on a review and evaluation of the President's Commission final report;
- Developing and conducting an advertising campaign aimed at preventing people from initially using drugs.

Conclusions

In 2016, 19,413 Americans died from an overdose involving synthetic opioids. This was more than double the number in 2015 and a dramatic increase of over 525 percent from the 3,105 overdose deaths involving synthetic opioids in 2013. Combating this alarming trend is a government-wide responsibility that requires contributions from departments and agencies working in a coordinated effort. While federal agencies have in many ways enhanced their approaches to limit the production, availability, and demand for potent synthetic opioids, further efforts are needed to assess the effectiveness of these approaches and to ensure that the invested resources are yielding intended results. In particular, better prioritizing investments in resources and staff that exist at many of CBP's laboratories will help address backlogs and thus help law enforcement agencies better investigate and consider prosecution in drug-related cases. Moreover, embarking on a concerted effort to examine and address data related concerns, such as timeliness and accuracy, will allow law enforcement and public health agencies to better share information as they continue to understand and respond to the opioid

⁸⁴The Acting HHS Secretary renewed the October 26, 2017 determination on January 19, 2018 for another 90-day period.

⁸⁵This would allow for state waivers of the "Institutes for Mental Diseases" exclusion, which prohibits federal Medicaid funds from being used to reimburse inpatient facilities with more than 16 beds that treat "mental diseases."

epidemic. Furthermore, establishing goals and outcome-oriented performance measures for some of the existing strategies will help agencies assess whether the resources they have invested in their efforts are yielding their intended results.

Recommendations for Executive Action

We are making a total of six recommendations, including one to CBP, two to ONDCP, one to OCDETF, one to DOJ, and one to DEA. Specifically:

We are making one recommendation to CBP:

The Commissioner of CBP should, in consultation with the Executive Director of CBP's LSSD and the Laboratory Directors, assess volume and risk at each port of entry to determine those with the greatest need for resources, use this information as a basis for staff allocations, and document its risk-based, staff allocation process to ensure that CBP and LSSD priorities can be accomplished as effectively and efficiently as possible. (Recommendation 1)

We are making two recommendations to ONDCP:

The Director of ONDCP, in collaboration with law enforcement and public health counterparts, should lead a review on ways to improve the timeliness, accuracy, and accessibility of fatal and non-fatal overdose data from law enforcement and public health sources that provide critical information to understand and respond to the opioid epidemic. Such a review should expand on and leverage the findings from previous federal studies. It should also assess the benefits and scalability of ongoing efforts to leverage data systems, such as the Washington-Baltimore HIDTA's OD MAP program, and examine ways in which laws that restrict access to public health data to protect patient privacy have exemptions for law enforcement entities that could be more widely leveraged while protecting patient privacy. (Recommendation 2)

The Director of ONDCP should work with the HIDTAs participating in the Heroin Response Strategy to establish outcome-oriented performance measures for the four main goals set out in the strategy. (Recommendation 3)

We are making one recommendation to OCDETF:

The Executive Director of OCDETF should work with the National Heroin Initiative Coordinator to establish outcome-oriented performance measures for the goals set out for National Heroin Initiative. (Recommendation 4)

We are making one recommendation to DOJ:

The Attorney General should, in consultation with its relevant components such as DEA and EOUSA, establish goals and outcome-oriented performance measures for its Strategy to Combat the Opioid Epidemic. (Recommendation 5)

We are making one recommendation to DEA:

The DEA Administrator should establish goals and outcome-oriented performance measures for the enforcement and diversion control activities within the 360 Strategy and establish outcome-oriented performance measures for the community engagement activities within the 360 Strategy. (Recommendation 6)

Agency Comments, Third Party Views, and Our Evaluation

We provided a draft of this product to DHS, ONDCP, DOJ, Commerce, DOD, HHS, State, and USPS for comment. Each agency provided technical comments, which we incorporated as appropriate. DHS, ONDCP, and DOJ provided written comments which are reproduced in appendices III, IV, and V, respectively. In addition, we also obtained third-party comments from UNODC, INCB, and the ACMT, which we incorporated as appropriate.

In its written comments, DHS concurred with our recommendation that CBP assess the volume and risk at each port of entry to determine those ports with the greatest need for laboratory resources, use this information as a basis for staff allocations, and document the process. Specifically, the Department stated that CBP plans to establish a working group to assess LSSD risk and resource allocations, analyze and assess its current program to support analysis and triage of suspected chemical parcels and determine whether the program can be expanded for 24/7 operations. CBP plans to then finalize and implement any necessary changes to policies and procedures by the end of fiscal year 2018.

In its written comments, ONDCP did not explicitly state whether it concurred with the two recommendations directed to the agency. However, ONDCP raised concerns but said it will take the recommendations under consideration. We first recommended that ONDCP lead a review on ways to improve the timeliness, accuracy and accessibility of overdose data from law enforcement and public health sources. In response, ONDCP stated that the agency already conducts activities where it brings together public health and public safety experts through its National Heroin Coordination Group to, among other things, share useful practices and relevant data. We agree that the National Heroin Coordination Group provides a mechanism to discuss these issues across the public health and public safety disciplines, which is consistent with its broad mission to lead interagency efforts to reduce the supply of heroin and fentanyl in the United States. However, the National Heroin Coordination Group and ONDCP have not taken action to specifically address our recommendation, which is focused on reviewing ways to improve overdose data in a more concerted manner. Further, ONDCP's response did not address how the office is working to find ways to improve the timeliness, accuracy, and accessibility of data that provide critical information to understanding and responding to the opioid epidemic. During our review, the lack of timely, accurate, and accessible information was one of the most pervasive concerns we heard from the public health and law enforcement officials with whom we spoke. As we note in our report, ONDCP is uniquely positioned to bring together law enforcement and public health officials in a concerted effort to better understand the specific obstacles involved and how the federal government can work to improve national-level data and support the data improvement efforts occurring at the state and local levels.

We also recommended that ONDCP coordinate with the HIDTAs participating in the Heroin Response Strategy (HRS) to establish outcome-oriented performance measures to assess progress towards the four main goals set out in the strategy. In its response, ONDCP stated that HRS's output-oriented performance metrics comprise activities for which HIDTAs are directly responsible and HIDTAs cannot set performance metrics aimed at goals for which they are not solely responsible. We disagree. Because the stated goals of HRS revolve around the collaboration between HIDTA and its partners, establishing outcome-oriented performance measures, such as the number of overdose deaths, would enhance HIDTAs' ability to assess whether these collaborative efforts are producing intended results. This is especially true because, as ONDCP notes in its response, the mission of the HRS is to reduce overdose deaths, so the agency should establish a way to track its

progress in achieving this mission. Further, in its response, ONDCP states that “[s]olutions for ending this crisis can be enhanced by such information gathering, but cannot wait in the development and perfection of techniques before taking action.” Our draft report did not state that actions should cease while addressing our recommendations. We believe that ONDCP should continue to take action to address the synthetic opioid crisis while also developing performance measures to help ensure that the activities we highlight in our report are making progress toward the intended results.

In its written comments, DOJ disagreed with our three recommendations related to the establishment of goals and/or outcome-oriented performance metrics for (1) OCDETF’s National Heroin Initiative, (2) the DOJ-wide opioid strategy, and (3) DEA’s 360 Strategy. In general, the Department stated that it is difficult to develop outcome-oriented performance measures because:

- the opioid threat continues to emerge;
- the nature of the opioid threat varies amongst districts and cities; and districts and cities have their own unique sets of risk and protective factors that contribute to and help mitigate local drug use;
- local sub-initiatives do not lend themselves to having long-term performance measures; and
- it is difficult to measure the success of any one strategy in isolation.

While we acknowledge in our report that developing meaningful outcome-oriented performance measures can be challenging given the nature of the opioid threat, we also note that other agencies have been able to create such measures with success. For example, ONDCP’s Heroin Availability Reduction Plan includes an outcome-oriented measure related to the rate of heroin-involved overdose deaths. Furthermore, while we acknowledge in our report that it may be difficult to single out an individual agency’s contribution to these activities, we continue to believe that finding meaningful ways to measure any federal strategy designed to combat it is important, particularly *because* the threat is imminent and evolving. With a growing number of overdose deaths in recent years, establishing outcome-oriented performance measures for its efforts under the three strategies will help DOJ establish a baseline, chart its progress, and adjust its course as needed. Without goals and measures in place, DOJ and its cognizant agencies will not have the information needed to

assess whether the resources they have invested—and continue to invest—in these local efforts are yielding their intended results.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 14 days from the report date. At that time, we will send copies to the appropriate congressional committees and members, the Secretary of the Department of Homeland Security, the Director of the Office of National Drug Control Policy, the Assistant Attorney General for Administration, the Secretary of the Department of Commerce, the Secretary of the Department of Defense, Secretary of the Department of Health and Human Services, Secretary of the Department of State, and the Postmaster General of the United States Postal Service, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-8777 or maurerd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.



Diana Maurer, Director
Homeland Security and Justice Issues

List of Requesters

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Ron Johnson
Chairman
The Honorable Claire McCaskill
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rob Portman
Chairman
The Honorable Thomas Carper
Ranking Member
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Christopher Coons
United States Senate

The Honorable Bill Cassidy
United States Senate

Appendix I: Objectives, Scope, and Methodology

In this report, we examine how U.S. agencies:

1. work with international partners to limit the production of illicit synthetic opioids;
2. work domestically to limit the availability of and enhance their response to illicit synthetic opioids and how they can improve the effectiveness of their efforts;
3. measure performance in their documented opioid-response strategies; and
4. adapted their prevention and treatment approaches in light of the illicit synthetic opioid epidemic.

To understand how U.S. agencies work with international partners to limit the production of illicit synthetic opioids, we collected information from federal agencies that are engaged in foreign or domestic drug control activities, including the Department of Defense (DOD); Department of Justice (DOJ); the Department of State (State); and the Office of National Drug Control Policy (ONDCP). For example, we reviewed State's 2017 International Narcotics Control Strategy Report, the Drug Enforcement Administration's (DEA) 2017 National Drug Threat Assessment; and ONDCP's 2016 National Drug Control Strategy which helped explain bilateral and multilateral engagement on issues related to illicit synthetic opioids. To learn about federal efforts to engage with international organizations and foreign governments on efforts related to international drug control scheduling, information sharing, and capacity building, we interviewed officials from Department of Health and Human Services (HHS); the Department of Homeland Security (DHS); DOJ; State; and ONDCP. In addition, we interviewed officials from the United Nations Office on Drugs and Crime and the International Narcotics Control Board to learn about their functions and the role of these organizations in limiting the international production of these illicit substances.

Further, we interviewed federal law enforcement officials from DEA, U.S. Customs and Border Protection (CBP), the Federal Bureau of Investigation (FBI), and U.S. Immigration and Customs Enforcement-Homeland Security Investigations (ICE-HSI) stationed in Mexico, Canada, and China as well as DEA officials stationed in Hong Kong to understand their roles in those specific countries. This included their efforts to share information, coordinate investigations, encourage capacity building, and engage in drug scheduling with foreign counterparts as well as any challenges they may face operating in a foreign environment. We also interviewed officials from DEA, CBP, ICE-HSI, State, and the FBI located

in the United States to learn more about their efforts with Mexico, Canada, and China. We focused our review on these three countries based on documentary and testimonial evidence provided by DHS, DOJ, and State, which showed that the majority of illicit synthetic opioids in the U.S. market are produced in China and either shipped directly into the United States or shipped into Mexico or Canada before being trafficked across the border. Finally, we coordinated with the inspector general (IG) offices at the relevant agencies and with the Supreme Audit Institutions of Mexico, Canada, and China to identify any past or ongoing related work related to the international production of illicit synthetic opioids.

To examine how U.S. agencies work domestically to limit the availability of and enhance their response to illicit synthetic opioids and how they can improve the effectiveness of their efforts, we reviewed a number of pertinent documents. These included federal agency guidance for first responders on the safe handling of fentanyl; DEA documents which aim to further understanding on the drug threat in the United States; and ONDCP's High Intensity Drug Trafficking Areas' (HIDTA) Annual Performance Reports, which describe the actions each HIDTA—the organization tasked with coordinating efforts within the designated drug trafficking area—has undertaken.

Further, we interviewed cognizant federal law enforcement officials from DEA, CBP, ICE-HSI, and FBI—as well as officials from the DOD's National Guard Counterdrug Program; the United States Postal Service and the United States Postal Inspection Service; and ONDCP to understand their actions to reduce the availability of synthetic opioids domestically and how they coordinate with state and local law enforcement agencies and public health entities, such as medical examiners and coroners. We also interviewed federal officials working to test technologies to identify synthetic opioids, such as researchers from the Department of Commerce's National Institute of Standards and Technology, and talked to experts from the American College of Medical Toxicology about the safe handling of synthetic opioids for first responders.

Additionally, we selected states to visit that (1) participate in federal drug control efforts, such as ONDCP's HIDTA program, and (2) experience high rates of overdose deaths, based on data from the Centers for Disease Control and Prevention (CDC). These states included New York, New Jersey, Massachusetts, New Hampshire, Ohio, Kentucky, and Tennessee. While on-site, we interviewed state and local law enforcement and public health officials to understand the challenges they

were facing, the unique efforts in which they were engaged, and the nature and extent of their engagement with federal counterparts.

In addition, we interviewed representatives from the United States Attorney's Offices (USAO) and HIDTAs with jurisdictions in the states to learn more about their engagement therein. Similarly, we visited California to learn about federal drug control efforts in relation to synthetic opioids and interviewed law enforcement officials from DEA, USAOs, CBP, and ICE-HSI—as well as HIDTA officials—to understand their actions to reduce the flow of illicit synthetic opioids coming across the southwest border and how they coordinate these efforts. While HIDTA officials stated that California does not experience high rates of overdose deaths attributable to synthetic opioids, other officials stated that drug trafficking organizations move illicit synthetic opioids from Mexico into California; we visited and interviewed officials at the San Ysidro Port of Entry to better understand these issues. Further, CBP conducted a pilot of drug detection technologies at the San Ysidro Port of Entry. Finally, we coordinated with the IG offices at the relevant federal and state audit offices to identify any past or ongoing related work related to the efforts to limit the domestic availability of illicit synthetic opioids.

To examine how U.S. agencies' documented opioid-response strategies measure performance, we queried the federal agencies that are working to limit the domestic availability of synthetic opioids to identify any strategies that they had developed. We then reviewed the five federal opioid strategies that were identified to determine whether agencies had built-in measures to assess the effectiveness of their efforts. The Government Performance and Results Act Modernization Act of 2010 requires that agencies establish goals and performance indicators to measure their progress in achieving agency objectives.

To determine how U.S. agencies have adapted their approaches to prevention and treatment in light of the illicit synthetic opioid epidemic, we reviewed documents on the types of prevention and treatment for opioid use, as well as related efforts by federal agencies. These included CDC's Guidelines for Prescribing Opioids for Chronic Pain; the Substance Abuse and Mental Health Services Administration's (SAMHSA) Opioid Overdose Prevention Toolkit; ONDCP's Heroin Response Strategy; the Surgeon General's Report on Alcohol, Drugs, and Health; and prior work we issued related to illicit drug treatment and prevention. In addition, we interviewed officials at the CDC; the Food and Drug Administration; the National Institutes of Health's National Institute on Drug Abuse; and SAMHSA about their agencies' roles in preventing and treating opioid use

as well as what initiatives, if any, they have that are specifically related to synthetic opioids. In addition, we talked with academics we identified through their published research on opioid issues and with organizations that have provided technical assistance to federal agencies on drug prevention and treatment. In the states we selected for our visits, we interviewed state and local officials at public safety and public health agencies to collect information on their prevention and treatment efforts to address the opioid epidemic. Further, we interviewed regional HIDTA officials and participants, USAO district officials, and other key groups to better understand how federal, state, and local efforts have been coordinated across disciplines. We also attended the public sessions of the President's Commission on Combating Drug Addiction and the Opioid Crisis and reviewed their reports and related documents. Finally, we coordinated with the IG offices at the relevant agencies to identify any past or ongoing related work related to opioid-related drug prevention and treatment programs.

We conducted this performance audit from January 2017 through March 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: The Evolution of Federal Guidance for the Safe Handling of Synthetic Opioids for First Responders and Continuing Efforts to Enhance the Evidence Basis for Safe Handling Measures

Given the exceptional potency of synthetic opioids, law enforcement and public health officials have become increasingly concerned about the risks from potential exposures, such as breathing in minute quantities of synthetic opioids while responding to medical calls, crime scenes, or during drug raids. Federal agencies (e.g. the Drug Enforcement Administration (DEA) and the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention (CDC)); organizations (e.g. the Interagency Board¹); and expert groups (e.g. the American College of Medical Toxicology (ACMT) and American Academy of Clinical Toxicology (AACT)²) have each developed written guidance and standard operating procedures that modified work practices for handling substances known or suspected to be fentanyl.³ However, the intended audience for the guidance, the approaches that these federal agencies used to develop the guidance, and the recommendations included in the guidance differed. According to the Office of National Drug Control Policy (ONDCP), these differences in various agencies' guidance have resulted in confusion among the first responder community.

In part to address this confusion, during our review, the White House's National Security Council (NSC) convened a federal working group with the goal of identifying the most up-to-date scientific data regarding fentanyl, while taking into account the uncontrollable environment in which first responders operate. The group was comprised of federal law enforcement agencies, such as DEA, the Federal Bureau of Investigation, the Department of Homeland Security, and the United States Postal Inspection Service, federal health agencies, such as CDC, NIOSH, and the Department of Health and Human Services (HHS), and others, such as ONDCP. It also sought the support of expert groups such as ACMT and those representing state and local law enforcement agencies, first responder groups, and health officials.

¹The Interagency Board is a voluntary collaborative panel of more than 150 emergency preparedness and response practitioners that represent federal, state, and local first responders from fire service, law enforcement, medical/health, and military sectors.

²The ACMT is a professional, nonprofit association of physicians with recognized expertise in medical toxicology—a medical subspecialty focusing on the diagnosis, management and prevention of poisoning and other adverse health effects due to medications, occupational and environmental toxins, and biological agents. The AACT is a non-profit multi-disciplinary organization that aims to unite scientists and clinicians in the advancement of research, education, prevention and treatment of diseases caused by chemicals, drugs and toxins.

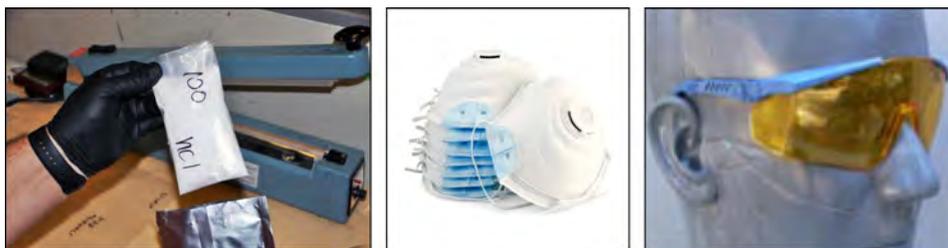
³Other agencies, such as CBP and the U.S. Coast Guard, have also developed guidance for the safe handling of fentanyl; however, their guidance is largely based on those produced by DEA, with special processes that are agency-specific.

Appendix II: The Evolution of Federal Guidance for the Safe Handling of Synthetic Opioids for First Responders and Continuing Efforts to Enhance the Evidence Basis for Safe Handling Measures

Because of the working group's efforts, the NSC issued new government-wide guidance in November 2017 to provide an authoritative source for safety recommendations for the first responder community. In particular, the guidance addresses:

- the common ways that first responders may encounter fentanyl in the field;
- the basic personal protective equipment that can protect first responders from most encounters with fentanyl, such as nitrile gloves, NIOSH-approved respirator masks, and eye protection (see fig. 9);
- the symptoms of opioid exposure, such as slow breathing and drowsiness; and
- ways to respond to such exposure, such as by administering the opioid reversal medication naloxone.

Figure 9: Examples of Personal Protective Equipment Used to Respond to Most Fentanyl Encounters



Source: Centers for Disease Control and Prevention and U.S. Drug Enforcement Administration. | GAO-18-205

Further, in cases where the level of exposure may be higher than the first responder may routinely encounter, such as at a location where fentanyl is being mixed with other drugs, it directs the reader to follow his or her agency guidelines. For example, DEA's guidance notes that if someone encounters a situation of where the scene is highly contaminated from fentanyl, then he or she needs to wear a specialized full-body suit with a self-contained breathing apparatus, such as a Level A suit (see fig. 10).

Appendix II: The Evolution of Federal Guidance for the Safe Handling of Synthetic Opioids for First Responders and Continuing Efforts to Enhance the Evidence Basis for Safe Handling Measures

Figure 10: Example of a Specialized Full-Body Suit Used to Respond to Scenes of Gross Fentanyl Contamination



Source: GAO. | GAO-18-205

According to ONDCP, the 2017 National Security Council guidance is now the standard, evidence-based federal government baseline for safe handling of fentanyl. ONDCP officials said they anticipate that this guidance could supersede federal agencies' previously developed guidance and that agencies can add to the Council's guidance as they see fit. The final report for the President's Commission on Combating Drug Addiction and the Opioid Crisis, which was issued in November 2017, recommended that the White House develop a national outreach plan for the Council's guidance and that federal agencies should partner with states to develop and standardize data collection, analytics, and information-sharing related to first responder opioid-intoxication incidents. As of December 2017, the Administration has published the guidance on its website, and according to ONDCP officials, the participating agencies and stakeholder groups have shared the guidance. Further, according to ONDCP, a short instructional video on fentanyl handling is in development to maximize awareness across the first responder community.

**Appendix II: The Evolution of Federal
Guidance for the Safe Handling of Synthetic
Opioids for First Responders and Continuing
Efforts to Enhance the Evidence Basis for Safe
Handling Measures**

Although the NSC effort has resulted in the issuance of government-wide evidence-based guidance, the officials we spoke with whose agencies were involved in the effort acknowledged that the evidence base in this arena is still developing as the data regarding actual incidents of accidental exposure is somewhat limited. To address the data gaps, agencies like NIOSH are taking several steps. For example, NIOSH officials told us that they have spoken to dozens of law enforcement officers and emergency medical service providers at the state and local level to gather “real world” information needed to provide recommended protective measures. In addition, they stated that NIOSH partnered with HHS to gather news reports of potential exposure to law enforcement and emergency medical service providers and followed up on these reports to gather additional information.

According to the ACMT expert we spoke with, developing an evidence base to craft reasonable guidance for personal protective equipment could be done by collecting blood and urine samples from first responders who are believed to have had accidental exposure. The clinicians would then compare the results to the sample of the drug taken for testing by law enforcement. If the two matched, then it would be clear that the drug had permeated the first responder’s skin and bloodstream. These occupational exposure evaluations would also note the symptoms the first responder experienced and the circumstances of the exposure and analyze that information to look for common scenarios in which exposure caused harm. ACMT is encouraging this type of data collection and analysis among those working in emergency medicine and poison control centers.

Appendix III: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

March 5, 2018

Diana Maurer
Director, Homeland Security and Justice
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Management's Response to GAO Draft Report GAO-18-205, "Illicit Opioids – While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts"

Dear Ms. Maurer:

Thank you for the opportunity to review and comment on this draft report. The U.S. Department of Homeland Security (DHS) appreciates the U.S. Government Accountability Office's (GAO) work in planning and conducting its review and issuing this report.

DHS is pleased to note GAO's positive recognition of U.S. Customs and Border Protection's (CBP) efforts to limit the availability of illicit synthetic opioids. DHS remains committed to addressing the opioid crisis with our federal, state, local, tribal, and international partners and provides critical capabilities toward the whole-of-government approach to address drug trafficking and other transnational threats at ports of entry and along the southwest border, northern border, and coastal approaches.

For example, America's unified border agency, CBP fulfills a critical role in the Nation's efforts to keep dangerous synthetic drugs out of the hands of the American public. Interdicting drugs at and in between our ports of entry, leveraging targeting and intelligence-driven strategies, and working with our partners to combat drug trafficking organizations are key components of our multi-layered, risk-based approach to enhance the security of our borders. This layered approach reduces our reliance on any single point or program and extends our zone of security outward ensuring our physical border is not the first or last line of defense, but one of several.

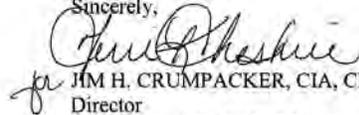
As noted in the draft report, CBP's National Targeting Center is leading efforts to expand interagency coordination to enhance targeting, interdiction, and seizure of international packages containing illicit synthetic opioids. CBP has a unique responsibility and critical role in preventing these threats to the public from entering our country. CBP continues its efforts to target international mail packages for inspection using "electronic advance data" on inbound international packages and assess the value to operations. The CBP Laboratories and Scientific Services Directorate contributes to combatting synthetic opioids by providing information to

CBP's Office of Field Operations for operational decision making; intelligence on new synthetic narcotics to Federal, state and local law enforcement; and, leads for law enforcement agencies for enforcement actions, controlled deliveries and prosecutions.

The draft report contained one recommendation for CBP, with which the Department concurs. Please see the attached for our detailed response to the recommendation. Technical comments were previously provided under separate cover.

Again, thank you for the opportunity to review and comment on this draft report. Please feel free to contact me if you have any questions. We look forward to working with you again in the future.

Sincerely,


J. M. H. CRUMPACKER, CIA, CFE
Director
Departmental GAO-OIG Liaison Office

Attachment

**Attachment: Management Response to Recommendations
Contained in GAO-18-205**

GAO recommended that the Commissioner of U.S. Customs and Border Protection (CBP), in consultation with the Executive Director of CBP's Laboratory Scientific Service Division (LSSD) and the Laboratory Directors:

Recommendation: Assess volume and risk at each port of entry to determine those with the greatest need for resources, use this information as a basis for staff allocations, and document its risk-based, staff allocation process to ensure that CBP and LSSD priorities can be accomplished as effectively and efficiently as possible.

Response: Concur. During fiscal year (FY) 2015 CBP's LSSD established the Field Triage Infrared Reachback (FTIR) program to support operations with remote analysis and triage of suspect chemical parcels. In FY 2017 LSSD analyzed over 26,000 suspected controlled substances, of which 12,800 were handled by the FTIR. LSSD will analyze its current reachback program to identify best practices that may be applied to a more effective operational posture and assess an expansion of the program for 24/7/365 operations. LSSD, in coordination with the CBP, Office of Field Operations, will also assess risks per port of entry and establish policy and procedures to address resource allocations for LSSD.

Specifically, CBP will:

Establish a working group to assess LSSD risk and resource allocations.	March 30, 2018
Complete analysis and assessment of current FTIR.	July 31, 2018
Finalize and implement policy and procedures for risk-based resource allocations for operational effectiveness and efficiency.	September 28, 2018

Estimated Completion Date: September 28, 2018.

Appendix IV: Comments from the Office of National Drug Control Policy



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

March 13, 2018

Diana Maurer
Director, Homeland Security and Justice
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Maurer:

Thank you for the opportunity for the Office of National Drug Control Policy (ONDCP) to review and comment on the proposed report from the General Accountability Office (GAO) entitled, *ILLICIT OPIOIDS: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts (GAO-18-205)*. The report provides an excellent overview of the efforts being made by Federal agencies to address the public health and public safety issues caused by existing and emerging synthetic opioids. Please consider this letter our response to be included in the report.

This report focuses on performance reporting and data collection as a means to evaluate the Government's success in addressing synthetic opioid use in this nation. While such information gathering has utility in assessing best practices, ultimately achievement in addressing this problem can be assessed on very basic criteria: is access to these synthetic compounds being curtailed, and are people less frequently using and dying from synthetic opioid use? The current opioid crisis began and still largely arises through the misuse of prescription opioid medications, but it has now evolved to include reemerging use of heroin and use of synthetic and semi-synthetic opioid compounds like fentanyl and fentanyl analogues. Solutions for ending this crisis can be enhanced by such information gathering, but cannot wait on the development and perfection of these techniques before taking action.

ONDCP's comments on the proposed report address the general recommendations made for the agency and then provide more specific observations, making reference to page numbers in the draft report. The report makes two recommendations specifically relating to ONDCP activities. We note that both recommendations make reference to an "Executive Director of ONDCP," a position that does not exist, and should instead refer to the "Director of National Drug Control Policy" or "Director of ONDCP."

1. The Director of National Drug Control Policy, in collaboration with law enforcement and public health counterparts, should head a review on ways to improve the timeliness, accuracy, and accessibility of fatal and non-fatal overdose data from law enforcement and public health sources that provide critical information to understand and respond to the opioid epidemic. Such a review should expand on and leverage the findings from previous Federal studies. It should also assess the benefits and scalability of ongoing efforts to leverage data systems, such as the Washington-Baltimore HIDTA's OD MAP [High Intensity Drug Trafficking Area Overdose Mapping Application Program], and

examine ways in which laws that restrict access to public health data to protect patient privacy, have exemptions for law enforcement entities that could be more widely leveraged, while protecting patient privacy.

We take issue with this recommendation, as ONDCP already conducts activities where it brings together public health and public safety experts to provide information on promising practices and methods to improve data reporting. ONDCP's National Heroin Coordination Group (NHCG), as part of Heroin Availability Reduction Plan (HARP) implementation, conducts regular gatherings of public health and public safety experts to share "lessons learned in the field" and to share useful practices and relevant data, where available, about addressing heroin, fentanyl, and fentanyl analogue use. In many instances, this information is provided in a confidential setting, well before it can be gathered and disseminated publically. The NHCG provides an annual report assessing its accomplishments in implementing the HARP. Other agencies are also engaged in finding beneficial uses of existing data systems; for example, the National Security Council recently conducted an interagency work group on the ODMAP.

2. The Director of National Drug Control Policy should work with the HIDTAs participating in the *Heroin Response Strategy* to establish outcome-oriented performance measures for the four main goals set out in the strategy.

As GAO observes in the report, ONDCP and the HIDTAs participating in the *Heroin Response Strategy* (HRS) have developed output-oriented performance measures to ensure progress is being made toward the stated objectives of the HRS. Although the performance metrics that are tracked by the regional HIDTAs participating in the HRS do not include a reduction of overdose deaths as a formal outcome measure, this is the mission of the initiative, so all of the work conducted under the HRS supports this outcome. Consistent with the broader HIDTA program, the HRS's performance metrics comprise activities for which HIDTAs are directly responsible. Broader goals, such as reducing overdose deaths, involve the collaboration and support of a variety of partners in both the public safety and public health communities. While HIDTA HRS participants facilitate that collaboration and strive to reduce heroin deaths and heroin use, they cannot set performance metrics aimed at goals for which they are not solely responsible.

In addition to these two comments, ONDCP also makes the following specific observations on the text of the report:

- Page 2 – In the first sentence, change "drug abuse misuse" to "drug abuse and misuse."
- Page 2 – Footnote 1 should be clarified to state that analogues share structure similarities and may produce similar pharmacological effects.
- Pages 6-7 – The report appears to make a correlation of potency to lethality, which is not necessarily true for every compound. Since the report discusses "potency" at length, it should define the term.
- Page 11 – In the first paragraph, the phrase "yet exceedingly deadly" should be removed as it pertains to dosing by the user and has nothing to do with the transaction.

- Page 18 – Footnote 25 – There are other more potent fentanyl-related compounds, although their uses in commerce may not be fully ascertained. Additionally, the footnote is again making the erroneous assertion that increased potency equals lethality, further emphasizing the need to define “potency” as discussed above.
- Page 30 – The model in Figure 5 fails to capture the fentanyl problem, as pound distributors of drugs of the 1980s do not equate to pound distributors of fentanyl class compounds (middle tier) today. The same disproportionation exists in the bottom tier in regard to gram-quantities of drugs.
- Page 47 – The end of the first sentence (following “Group”) should read, “to reduce the supply of heroin, fentanyl, and fentanyl analogues in the U.S. market. The HARP is a 5-year plan focused on the following strategic end states.”
- Page 56 – In paragraph 2, at the end of sentence 5 consider deleting “such as carfentanil.” Carfentanil is not the only fentanyl class compound that requires multiple doses as it has been used for fentanyl and its analogues.

In conclusion, ONDCP appreciates GAO’s efforts to inform Federal agencies where further assessment of their activities could prove useful. We will take the recommendations under consideration. We thank you and your staff for their efforts in developing this report, and we look forward to continuing to work with you in our work to address the opioid epidemic.

Sincerely,



James W. Carroll
Acting Director

Appendix V: Comments from the Department of Justice



U.S. Department of Justice

Washington, D.C. 20530

FEB 28 2018

Diana C. Maurer
Director, Homeland Security and Justice
Government Accountability Office
441 G Street, NE
Washington, DC 20548

Dear Ms. Maurer:

Thank you for the opportunity to review and comment on GAO's draft report entitled *ILLICIT OPIOIDS: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts* (GAO-18-205). The Department of Justice (DOJ) appreciates the significant work that your team put into this review. While DOJ agrees with the effort to measure the success of these strategies, we disagree with your recommendations as outlined below because establishing a universal set of outcome-oriented performance measures is not a viable means to measure the success of these strategies.

Recommendation Number 1: The Executive Director of the Organized Crime Drug Enforcement Task Force (OCDETF) should work with the National Heroin Initiative Coordinator to establish outcome-oriented performance measures for the goals set out for the National Heroin Initiative.

Response: The OCDETF disagrees with this recommendation as written, as it misstates the performance measures that were established for this Initiative. The OCDETF Program established the National Heroin Initiative to generate an increased level of federal law enforcement efforts at the local level and to identify those international criminal entities trafficking illicit opioids. As the Initiative was expected to produce positive results from both OCDETF and non-OCDETF perspectives, we needed to craft a process that measured both types of federal efforts. To measure the success of this Initiative, the OCDETF Executive Office developed a two-part method for measurement; (1) measuring OCDETF performance, and; (2) measuring non-OCDETF performance.

First, the primary expected outcome of the National Initiative was to increase the number of OCDETF investigations with heroin/opioids as the targeted drug and, accordingly, increase the number of defendants charged and indicted for heroin/opioid related offenses. Second, the OCDETF Program developed a method to track those federal law enforcement efforts that did not ultimately generate an OCDETF case. Measuring non-OCDETF effectiveness of the Initiative was a broadening of our scope to include the positive effects of our efforts outside of

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the primary OCDETF focus. Both of these measures have shown a strong and positive increase in overall performance since the Initiative was first announced. Our National Coordinator's statement quoted in the report about not having long-term goals was referring to the specific actions planned for the individual, localized sub-initiatives. Those local sub-initiatives did not lend themselves to having long-term performance measures but were part of the overall National Initiative, for which the long-term expectation was the increase of OCDETF investigations and defendants charged that did result from the combination of sub-initiatives.

Recommendation Number 2: The Attorney General should, in consultation with the relevant components such as the Drug Enforcement Administration (DEA) and the Executive Office for United States Attorneys, establish goals and outcome-oriented performance measures for its Strategy to Combat the Opioid Epidemic.

Response: The DOJ maintains that it is difficult to develop outcome-oriented performance measures, such as those related to drug trafficking and overdose rates, because of the continuing emergence of new opioid threats in recent years. Further, as noted in the GAO report, the nature of the opioid threat varies among districts. Due to these differences, the DOJ's Department-wide strategy announced in September 2016 and enhanced in November 2017, directed the United States Attorney's Offices (USAO) to consult with local stakeholders and develop district-specific strategies tailored to the issues of each district.

The DOJ initiated its Department-wide strategy to help end the opioid epidemic and reduce the number of opioid overdose deaths. The DOJ will look to the trend in opioid overdose deaths as a means of assessing its continued response to the emerging threat of opioids. Nonetheless, given the multitude of overlapping national and district-specific strategies the DOJ and its components are pursuing and of other strategies being pursued across the government, it is difficult to measure the success of any one strategy in isolation based on the number of opioid overdose deaths.

Pursuant to the directive of the Deputy Attorney General, each USAO has designated an opioid coordinator. Each USAO Opioid Coordinator is responsible for facilitating intake of cases involving prescription opioids, heroin, and fentanyl; convening a task force of federal, state, local, and tribal law enforcement to identify opioid cases for federal prosecution, facilitating interdiction efforts, and tailoring their district's response to the needs of the community; providing legal advice and training to AUSAs regarding the prosecution of opioid offenses; maintaining statistics on the opioid prosecutions in the district; and developing and continually evaluating the effectiveness of the office's strategy to combat the opioid epidemic. Since November 2017, each USAO has reviewed its district-specific strategy to determine if it needed revision in light of current local opioid trends.

The DOJ will continually evaluate the effectiveness of its Department-wide strategy through measures such as the number of opioid-related prosecutions, the number of indictments/criminal informations and convictions in such cases, and the number of civil enforcement actions. The DOJ will monitor the USAOs' opioid-prosecution statistics through EOUSA's case-tracking system. Each USAO also will consider emerging threats in the opioid epidemic and the trends in opioid overdose deaths in evaluating the success of its strategy and determining whether

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adjustments are necessary.

Recommendation Number 3: The DEA Administrator should establish goals and outcome-oriented performance measures for the enforcement and diversion control activities within the 360 Strategy and establish outcome-oriented performance measures for the community engagement activities within the 360 Strategy.

Response: A key component of DEA 360 Strategy is the community outreach effort, which brings together a community's key stakeholders such as the U.S. Attorney's Office, state and local law enforcement, faith-based organizations, schools, the business community, and prevention and treatment providers to reduce the impact of opioid addiction. After an enforcement action occurs in the community, DEA strongly encourages the community to develop and/or maintain a focus on implementing evidence-based programs to help prevent the drug and violent crime problems from resurfacing. Using a strategic planning process, stakeholders collaborate to develop a plan of action for the community, resulting in outcomes that have a positive impact in the DEA 360 communities.

For the 360 Strategy, DEA identified youth and their circle of influence—parents, caregivers, and educators—as the primary target audiences. The 360 Strategy uses a comprehensive communication approach by deploying an aggressive 13-week media campaign through television, radio, print, and social media outlets, as well as creating a grassroots movement within each community to empower its citizens to take back their neighborhood and create a safer place for their children. DEA also identified national partners that work to develop new or enhance existing community coalitions in each pilot city, which are intended to be sustained beyond the initial one year 360 Strategy deployment.

When DEA created its 360 Strategy, a comprehensive set of universal metrics were developed, with the intent to create a change in attitude and perception regarding the threat to the community posed by the rise in prescription opioid misuse and heroin use among target audiences. The 360 Strategy, as well as DEA's other community outreach and prevention support efforts, are built around three prevention principles: local people solve local problems best, people support what they help create, and science matters. In line with these principles, it was not advisable for DEA to establish a universal set of outcome-oriented performance measures from the onset of the 360 Strategy's deployment, since each of the cities in which the 360 Strategy is implemented is unique, complete with its own set of risk and protective factors that contribute to and help mitigate drug abuse in the community. Therefore, during the 360 Strategy's 1-year period of implementation in each city, DEA provides intensive training and technical assistance resources to help the community establish a sustainable plan of action to achieve long-term outcome-oriented performance measures, such as decreases in prescription drug misuse and heroin use among target populations. To date, performance analyses were conducted for two of the cities in which the DEA 360 Strategy was implemented (i.e., Milwaukee, Wisconsin; Manchester, New Hampshire) to document the reach and impact of the community outreach strategies in each city, and how those strategies created an impetus for change.

Ms. Diana Maurer

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Thank you again for the opportunity to comment on this report. We look forward to working with the GAO as we strive to improve our programs and further our mission.

Sincerely,



Lee J. Lofthus
Assistant Attorney General
for Administration

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Diana Maurer, (202) 512-8777 or maurerd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Joy Booth (Assistant Director), Julia Vieweg (Analyst-in-Charge), Jane Eyre, Steve Komadina, Sylvia Bascope, and Mara McMillen made key contributions to this report. Willie Commons III, Dominick Dale, Eric Hauswirth, Amanda Miller, and Rebecca Parkhurst, also contributed to the work.

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