United States Government Accountability Office

Report to Congressional Addressees

April 2021

# SYNTHETIC OPIOIDS

# Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances


GAO-21-499

GAO@100 Highlights

Highlights of GAO-21-499, a report to congressional addressees

April 2021

# SYNTHETIC OPIOIDS

## Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances

### Why GAO Did This Study

Fentanyl-related substances are powerful synthetic opioids that can be significantly more potent than morphine. The number of deaths from fentanyl-related substances is unknown, but the Centers for Disease Control and Prevention reports that there were more than 50,000 deaths involving all synthetic opioids in the 12-month period ending July 2020.

The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act included a provision for GAO to study the classification of fentanyl-related substances and considerations for future scheduling. GAO focused on effects related to drug classification, research, and federal law enforcement, and effects from the classification of similar substances in China.

GAO analyzed documents, data, and statements from federal agencies, such as the Departments of Homeland Security (DHS), Health and Human Services (HHS), Justice (DOJ), and State; ONDCP; and Federal Public and Community Defenders. GAO also interviewed representatives of research, professional, state and local law enforcement, civil rights and criminal justice, industry, and international organizations.

In written comments, ONDCP noted the report identifies the issues to be considered for scheduling. DOJ and the Federal Public and Community Defenders commented on the report's emphasis on different stakeholder perspectives. GAO addressed these comments as appropriate and incorporated technical comments from ONDCP, HHS, DHS, and DOJ.

View GAO-21-499. For more information, contact Alyssa M. Hundrup at 202-512-7114 or hundrupa@gao.gov, Triana McNeil at (202) 512-8777 or McNeilT@gao.gov or Kimberly M. Gianopoulos at (202) 512-8612 or GianopoulosK@gao.gov.

### What GAO Found

In 2018, the Drug Enforcement Administration (DEA) temporarily classified fentanyl-related substances as Schedule I under the Controlled Substances Act, based on their chemical structure, designating them illicit drugs with high abuse potential and no medical use. GAO identified possible considerations for scheduling decisions when the temporary classification expires on May 6, 2021.

**Allow the temporary scheduling order to expire.** Without the temporary scheduling order, DEA could individually schedule specific fentanyl substances or use the analogue provisions in the Controlled Substances Act to prosecute cases involving unscheduled substances.

- Individually scheduling substances would require evidence of abuse potential and no accepted medical use to classify each substance as Schedule I. This reduces the likelihood of misclassifying substances, as may occur in class-wide scheduling, according to some federal officials.
- Federal law enforcement officials expressed concern that individual scheduling or prosecuting cases as analogues would not be sufficient to deter the creation of new, potentially dangerous substances.

**Schedule as a class without modifications.** The current temporary scheduling order could be made permanent, such as through legislative scheduling.

- Some substances with unknown potential medical uses or unknown abuse risk could be included in Schedule I.
- Law enforcement officials said that class-wide scheduling has reduced incentives to make new and existing fentanyl substances. GAO's analysis showed a reduction in law enforcement encounters with fentanyl analogues not scheduled individually, but did not determine the cause.
- DEA has approved all 28 researchers who applied to study fentanyl-related substances since 2018, but researchers identified a variety of challenges with research on Schedule I substances, including the time required to obtain approval to conduct such research.
- Civil rights and criminal justice stakeholders cited concerns that class-wide scheduling could result in convictions for substances that may not be harmful and lengthy sentences for trace amounts of fentanyl-related substances and exacerbate racial disparities in federal sentencing.

**Legislatively schedule as a class with modifications.** Fentanyl-related substances could be legislatively scheduled with modifications to the temporary scheduling order. Potential modifications include those recommended by an interagency workgroup convened by the Office of National Drug Control Policy (ONDCP), such as removing barriers to research and streamlining the process for removing substances from Schedule I if they are discovered to have no abuse potential.

This is a public version of a sensitive report GAO issued in April 2021. Information on China's class-wide scheduling that DOJ deemed sensitive has been omitted from this report.

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## Abbreviations

| | |
|---|---|
| CBP | U.S. Customs and Border Protection |
| CDC | Centers for Disease Control and Prevention |
| China | People's Republic of China |
| COVID-19 | Coronavirus Disease 2019 |
| CSA | Controlled Substances Act |
| DEA | Drug Enforcement Administration |
| DHS | Department of Homeland Security |
| DOJ | Department of Justice |
| EOUSA | Executive Office for United States Attorneys |
| FDA | Food and Drug Administration |
| Federal Analogue Act | Controlled Substance Analogue Enforcement Act of 1986 |
| HHS | Department of Health and Human Services |
| NIH | National Institutes of Health |
| OFO | Office of Field Operations |
| OCDETF | Organized Crime Drug Enforcement Task Forces |
| ONDCP | Office of National Drug Control Policy |
| SEACATS | Seized Assets and Case Tracking System |
| State | Department of State |
| UNODC | United Nations Office on Drugs and Crime |
| USAO | United States Attorney's Offices |
| USPS | U.S. Postal Service |

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Congressional Addressees

Fentanyl—a synthetic opioid—is a pain reliever approved for treating severe pain, such as advanced cancer pain. It is 50 to 100 times more potent than morphine.[1] Fentanyl analogues are synthetic opioids with chemical structures related to fentanyl, and can have similar effects. The potency of these fentanyl analogues is often unknown because they have not been evaluated, but they can range from less potent than fentanyl to much more potent, with one of the most potent known fentanyl analogues—carfentanil—estimated to be 10,000 times more potent than morphine.

Both the Centers for Disease Control and Prevention (CDC) and the Drug Enforcement Administration (DEA) have noted that increases in deaths attributed to synthetic opioids are associated with fentanyl and fentanyl analogues. While the number of deaths specifically from fentanyl analogues is unknown, preliminary data from CDC suggest that there were more than 50,000 deaths involving all synthetic opioids except methadone in the United States during the 12-month period ending in July 2020, the latest period for which data are available.[2] CDC also noted that overall drug overdose deaths have accelerated during the Coronavirus Disease 2019 (COVID-19) pandemic, and that synthetic opioids are the primary driver of this increase.[3]

Substances that are deemed to pose a risk of abuse and dependence, such as fentanyl, are regulated under the Controlled Substances Act

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[1]For purposes of this report, potency refers to a substance's analgesic or other pharmacological effects on people, including pain relief, respiratory depression, short-term euphoria, and dependence.

[2]CDC data are based on synthetic opioids excluding methadone, as methadone is tracked separately. Centers for Disease Control and Prevention, *Opioid Overdose: Synthetic Opioid Overdose Data.* accessed June 23, 2020, http://www.cdc.gov/drugoverdose/data/fentanyl.html. Centers for Disease Control and Prevention, *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts*, accessed March 4, 2021, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

[3]Centers for Disease Control and Prevention, *Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVVID-19 Pandemic*, CDCHAN-00438, Dec. 17, 2020.

(CSA).[4] The CSA divides these substances into categories known as schedules. Controlled substances can be administratively or legislatively placed in these schedules that range from I through V – with Schedule I having the greatest restrictions. Schedule I controlled substances are those that have been found by the federal government to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Schedule I substances include heroin and D-lysergic acid diethylamide (LSD), among others. Once placed in Schedule I, evidence of medical use or no abuse potential is required to administratively reschedule a drug into a less restrictive category or to remove it from scheduling. Fentanyl is placed in Schedule II because it has been found by the federal government to have a high potential for abuse, a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse of fentanyl may lead to severe psychological or physical dependence. Some individual fentanyl analogues have been scheduled under the CSA in either Schedule I or Schedule II.

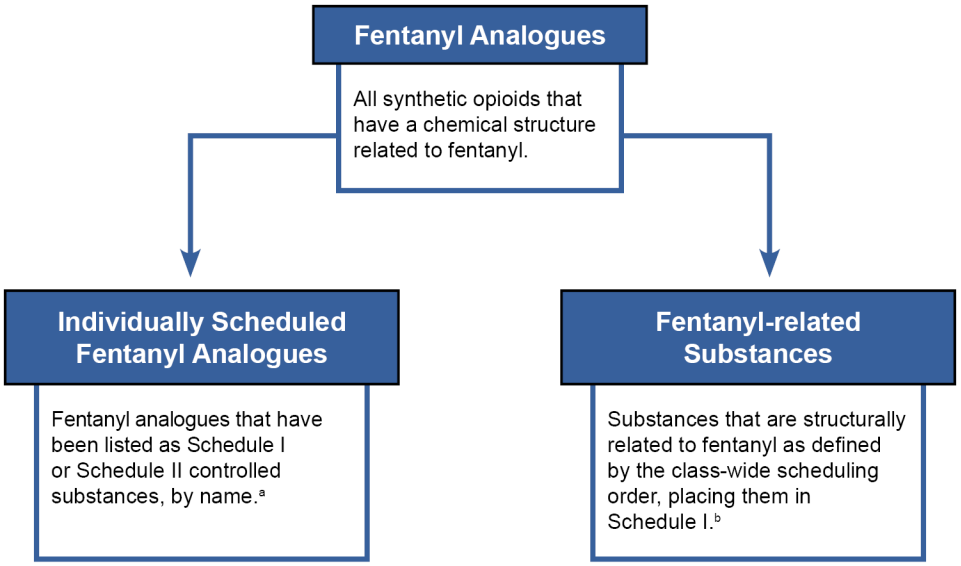
To address new and emerging substances related to fentanyl, DEA issued a temporary scheduling order on February 6, 2018, to control a group of fentanyl analogues—called fentanyl-related substances—that had not already been scheduled under the CSA. In its temporary scheduling order, DEA stated that its action was necessary to avoid an imminent hazard to the public safety, and that the previous approach was not as effective in preventing deaths and serious injuries from these substances. The temporary scheduling order defined the class of fentanyl-related substances as those structurally related to fentanyl by one or more of five chemical structural modifications and not otherwise controlled in any schedule, and classified these fentanyl-related substances as Schedule I through February 6, 2020.[5] For purposes of this report, we define fentanyl analogues as those synthetic opioids with chemical structures related to fentanyl. These analogues include both fentanyl-related substances—which are controlled under the temporary scheduling order and are the focus of this report—and other fentanyl analogues that have been individually scheduled by DEA and therefore also are controlled substances under the CSA. (See fig. 1.) We use

[4]Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (1970) (codified as amended at 21 U.S.C. § 801 et seq.).

[5]83 Fed. Reg. 5188 (Feb. 6, 2018).

DEA's definition of fentanyl-related substances, as described in the temporary scheduling order.

**Figure 1: Fentanyl Analogues and Their Definitions**




Source: GAO analysis of DEA documents and GAO's definition. | GAO-21-499

Note: Fentanyl analogues benzylfentanyl and thenylfentanyl have been found to have no abuse potential and are not included in Schedule I or Schedule II nor are they included in the fentanyl-related substances definition. In May 2020, DEA controlled benzylfentanyl as a List I chemical due to it being a precursor chemical used to produce fentanyl.

[a]The Controlled Substances Act classifies controlled substances into categories known as schedules. These schedules range from I through V – with Schedule I having the greatest restrictions. Schedule I substances are those that have been found to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision, while Schedule II drugs have been found to have a high potential for abuse but have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse may lead to severe psychological or physical dependence.

[b]In 2018, DEA issued a temporary scheduling order to control fentanyl-related substances, defined as those substances not otherwise controlled in any schedule that are structurally related to fentanyl by one or more of five chemical structural modifications. See 83 Fed. Reg. 5188 (Feb. 6, 2018).

DEA implemented the temporary scheduling order to prevent illicit drug traffickers from creating new fentanyl analogues as DEA administratively scheduled other fentanyl analogues in Schedule I. The challenge of keeping up with traffickers who create new fentanyl analogues has been likened to a game of "whack-a-mole" by at least one federal researcher

and U.S. Attorney, as well as members of Congress.[6] Attorneys General from all states also noted in a letter to Congress that they view the scheduling system as being a step behind those who manufacture fentanyl analogues.[7]

Prior to the expiration of the temporary scheduling order, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extended the classification through May 6, 2021.[8] Unless fentanyl-related substances are scheduled as a class before this date, DEA will revert to beginning the scheduling process for individual fentanyl analogues as they are discovered. In addition, under the Controlled Substance Analogue Enforcement Act of 1986, Department of Justice (DOJ) could prosecute cases for offenses involving unscheduled fentanyl analogues.[9] The act requires prosecutors to prove multiple elements related to chemical structure and psychoactive effect, among other things, for the analogue to be treated as a controlled substance in Schedule I in a particular criminal case.

In January 2020, DEA reported that the People's Republic of China (China) and Mexico were the primary source countries for fentanyl and fentanyl-related substances trafficked directly into the United States.[10] According to the Department of State (State), on May 1, 2019, China implemented class-wide controls over fentanyl and many of its analogues

[6]See National Institute of Standards and Technology, *Free Software Can Help Spot New Forms of Fentanyl and Other Illegal Drugs* (Mar. 7, 2018) accessed October 26, 2020 at https://www.nist.gov/news-events/news/2018/03/free-software-can-help-spot-new-forms-fentanyl-and-other-illegal-drugs; United States Department of Justice, *U.S. Attorney Scott Brady Statement on Expiration of Fentanyl Analogue Emergency Scheduling* (Jan. 29, 2020) accessed October 26, 2020 at https://www.justice.gov/usao-wdpa/pr/us-attorney-scott-brady-statement-expiration-fentanyl-analogue-emergency-scheduling, and Congressional Record, *Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act* (Jan. 29, 2020, pages H647-H653), accessed October 26, 2020 at https://www.congress.gov/116/crec/2020/01/29/modified/CREC-2020-01-29-pt1-PgH647-2.htm

[7]https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/Letter-to-Congress-SOFA-Act-8.23-1.pdf (accessed March 9, 2021).

[8]Pub. L. No. 116-114, § 2, 134 Stat. 103 (2020).

[9]Pub. L. No. 99-570, 100 Stat. 3207-13. See 21 U.S.C. §§ 802(32), 813.

[10]DEA Intelligence Report, *Fentanyl Flow to the United States*, DEA-DCT-DIR-008-20 (Jan. 2020).

and increased screening and inspections of chemical centers and sales sites.[11]

The law extending the temporary scheduling order of fentanyl-related substances included a provision that we study various issues related to the classification of fentanyl-related substances.[12] This report examines what is known about the class-wide scheduling of fentanyl-related substances including its potential effects and considerations for future scheduling decisions.

This report is a public version of a sensitive report that was issued in April 2021.[13] DOJ deemed some of the information in our April report to be sensitive, which must be protected from public disclosure. Therefore, this report omits sensitive information related to China's class-wide scheduling of fentanyl analogues. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

This report is part of GAO's continuing body of work related to drug misuse. In March 2020, we determined that this issue should be on our High-Risk List, because the nation is at a critical juncture where a strategic, coordinated, and effective national response to drug misuse is

[11]China is a party to the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (1961 Single Convention). DEA officials confirmed that fentanyl and 26 specific analogues are currently controlled under the terms of the 1961 Single Convention. On April 1, 2019, China announced that it was placing "fentanyl-related substances" as a class on its list of scheduled substances effective May 1, 2019. The announcement noted the government was doing so in accordance with its *Regulations on the Administration of Narcotic Drugs and Psychotropic Substances* and *Regulations on the Administration of Narcotic Drugs and Psychotropic Substances with Non-medical Use*. Moreover, the announcement stated that fentanyl and its analogues previously scheduled in accordance with this law would remain on the list of scheduled substances. According to U.S. officials, China's law defines fentanyl-related substances more broadly than the U.S. government defines fentanyl-related substances. The DEA's temporary scheduling order defined fentanyl-related substances as those substances not otherwise controlled in any schedule that are structurally related to fentanyl by one or more of five chemical structural modifications. See 83 Fed. Reg. 5188. China's law defines only four such structural relationships, according to U.S. officials. According to U.S. officials, China's definition is slightly broader than the U.S. definition and includes some fentanyl precursors.

[12]Pub. L. No. 116-114, § 3, 134 Stat. at 103-105.

[13]GAO, *Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-related Substances,* GAO-21-301SU (Washington, D.C.: April 8, 2021).

needed.[14] In 2021, we included drug misuse on our High Risk List, noting that federal agencies must effectively implement a strategic national response to drug misuse and make progress toward reducing rates of drug misuse and the resulting harmful effects to society.[15]

To examine what is known about the class-wide scheduling of fentanyl-related substances, including its potential effects and considerations for future scheduling decisions, we reviewed the U.S. class-wide scheduling of fentanyl-related substances as well as the potential effects of China's class-wide controls on the flow of these substances entering the United States. We analyzed documents from, and interviews with, federal agencies, including State, Department of Health and Human Services (HHS), Department of Homeland Security (DHS), DOJ, Office of National Drug Control Policy (ONDCP), and Federal Public and Community Defenders. We also interviewed representatives of 21 stakeholder organizations knowledgeable on this topic (such as those representing researchers, professional associations, state and local law enforcement officials, criminal justice and civil rights organizations, international organizations, and industry). We conducted a literature search to identify articles published from 2010 through July 2020 on the process of obtaining approval to research Schedule I substances.

We analyzed DEA data on time frames for approving applications to research fentanyl-related substances from February 2018 through January 2020 and on law enforcement encounters with fentanyl analogues and fentanyl-related substances from 2016 through 2019. We also analyzed data from the Executive Office for United States Attorneys (EOUSA) on related prosecutions from fiscal year 2019 through fiscal year 2020. We also analyzed seizure data from U.S. Customs and Border Protection (CBP) from fiscal years 2018 through July 2020. We assessed the reliability of DEA, EOUSA, and CBP data and determined that they were sufficiently reliable for our purposes. More details about our methodology, including a list of all organizations we interviewed, are in appendix I.

We conducted this performance audit from March 2020 to April 2021 in accordance with generally accepted government auditing standards.

[14]GAO, *Drug Misuse: Sustained National Efforts Are Necessary for Prevention, Response, and Recovery*, GAO-20-474 (Washington, D.C.: March 26, 2020).

[15]GAO, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas,* GAO-21-119SP (Washington, D.C.: March 2, 2021).

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.

# Background

## Federal Agencies Involved in Research, Regulation, and Control of Fentanyl-Related Substances

A number of federal agencies are involved in the regulation and control of controlled substances, including fentanyl-related substances, in the United States. They include ONDCP, as well as agencies in HHS, such as the Food and Drug Administration (FDA) and National Institutes of Health (NIH); agencies in DHS, such as CBP and U.S. Immigration and Customs Enforcement; agencies in DOJ, such as DEA, EOUSA, the Federal Bureau of Investigation, and the Organized Crime Drug Enforcement Task Forces (OCDETF); agencies in State, including the Bureau of International Narcotics and Law Enforcement Affairs; and the United States Postal Services' U.S. Postal Inspection Service. (See table 1).

**Table 1: Examples of Key Federal Agencies Involved in Combating the Use, Enforcement, and Tracking of Controlled Substances, Including Fentanyl-Related Substances**

| Agency | Tasks |
|---|---|
| **Executive Office of the President** | |
| Office of National Drug Control Policy (ONDCP) | • Leads the national drug control effort, including coordinating with the National Drug Control Program agencies<br>• Develops the National Drug Control Strategy<br>• Coordinates and oversees implementation of national drug control policy |
| **Department of Health & Human Services (HHS)** | |
| Food and Drug Administration (FDA) | • Protects public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices<br>• Coordinates with Drug Enforcement Administration (DEA) on scheduling drugs under the Controlled Substances Act<br>• Collaborates with Customs and Border Protection and Immigration and Customs Enforcement's Homeland Security Investigations to prevent the importation of unapproved drugs and investigates their distribution<br>• Inspects registered facilities that manufacture drugs approved for marketing in the United States |

| Agency | Tasks |
|---|---|
| National Institutes of Health (NIH) | • Supports research to protect and improve public health, prevent disease, and expand medical knowledge<br>• Includes the National Institute on Drug Abuse, which supports research on the causes and consequences of drug misuse<br>• Coordinates with FDA on scheduling drugs under the Controlled Substances Act |
| Centers for Disease Control and Prevention (CDC) | • Detects and responds to new and emerging health threats causing death and disability for Americans<br>• Uses science and technology to prevent disease<br>• Promotes healthy and safe behaviors, communities, and environment |
| **Department of Homeland Security (DHS)** | |
| U.S. Customs and Border Protection (CBP) | • Manages and controls the border, including the enforcement of customs, immigration, border security, and agricultural laws<br>• Inspects inbound and outbound cargo at ports of entry, including international mail and express consignment carrier facilities<br>• Collaborates with FDA, U.S. Immigration and Customs Enforcement's Homeland Security Investigations, and DEA to prevent the importation of unapproved drugs and controlled substances and facilitate investigations regarding their distribution |
| U.S. Immigration and Customs Enforcement | • Enforces federal laws governing border control, customs, trade, and immigration<br>• Homeland Security Investigations investigates the illegal movement of goods into and out of the United States, including narcotics<br>• Collaborates with FDA and CBP to prevent the importation of unapproved drugs and investigates their distribution |
| **Department of Justice (DOJ)** | |
| Drug Enforcement Administration (DEA) | • Enforces laws and regulations related to the growing, manufacture, or distribution of controlled substances<br>• Collaborates with foreign partners to counter illicit organizations and drugs<br>• Collects and disseminates intelligence globally from foreign partners<br>• Conducts investigations in coordination with international, state, local, and tribal law enforcement agencies<br>• Coordinates with FDA on scheduling drugs under the Controlled Substances Act<br>• Implements and conducts counter-narcotics and law enforcement capacity development training programs in other countries |
| Federal Bureau of Investigation | • Conducts investigations on a broad range of criminal threats including transnational organized crime, terrorism, violent crime, and cybercrime. |
| Executive Office for United States Attorneys | • Provides executive and administrative support for U.S. Attorney's Offices across the United States |

| Agency | Tasks |
|---|---|
| U.S. Attorney's Offices (USAO) | • Enforces federal laws throughout the country, including drug trafficking and production offenses<br>• U.S. Attorneys serve as the nation's principal litigators and conduct most of the trial work in which the United States is a party, including prosecuting drug cases<br>• There are 93 U.S. Attorneys stationed in districts throughout the United States and its territories |
| Organized Crime Drug Enforcement Task Forces (OCDETF) | • Identifies, targets, disrupts, and dismantles major drug trafficking organizations, money laundering organizations, and related criminal enterprises<br>• Coordinates prosecutor-led, intelligence-driven, multi-agency and multijurisdictional task forces and includes member agencies from DOJ (e.g., DEA, Federal Bureau of Investigation, USAOs), DHS (e.g., Homeland Security Investigations), the U.S. Postal Service, and state and local law enforcement agencies, among others<br>• There are 19 OCDETF strike forces located across the country |
| Narcotic and Dangerous Drug Section of the Criminal Division | • Investigates and prosecutes priority national and international drug trafficking groups and provides legal, strategic, and policy guidance in support of that end |
| **Department of State** | |
| Bureau of International Narcotics and Law Enforcement Affairs | • Helps foreign governments implement programs to reduce the demand for and supply of illicit drugs<br>• Funds counternarcotic and law enforcement programs in nations where illicit drug-producing and trafficking has been identified, among other things |
| **United States Postal Service** | |
| U.S. Postal Inspection Service | • Protects against and prevents criminal attacks to postal employees, customers, infrastructure, and the U.S. Mail<br>• Enforces laws that defend the nation's mail system from illegal or dangerous use<br>• As the federal law enforcement arm of the U.S. Postal Service (USPS), investigates cases and prepares them for court along with U.S. Attorneys, other law enforcement, and local prosecutors |

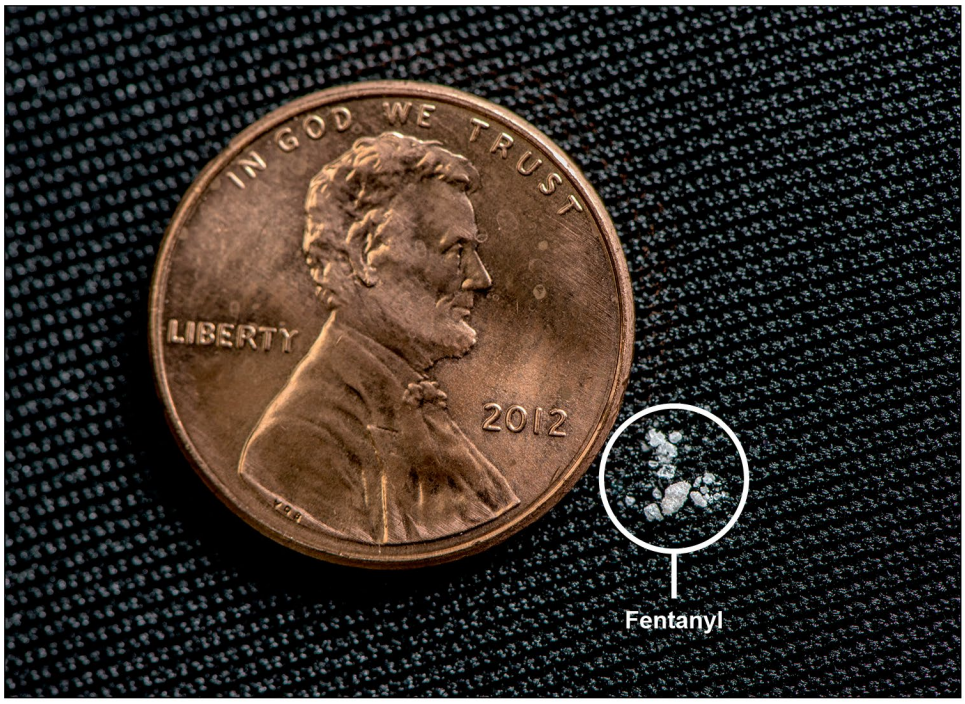
Source: GAO analysis of agency documents. | GAO-21-499

In June 2019, ONDCP convened an interagency workgroup with representatives from HHS (including FDA, NIH's National Institute on Drug Abuse, and the Assistant Secretary for Health) and DOJ (including DEA) to develop recommendations intended to mitigate potential negative effects of permanently scheduling fentanyl-related substances on research or development of therapeutics. The interagency workgroup brought together agencies that have diverse perspectives on the relevant issues to reach agreement on the recommendations. The interagency workgroup submitted its recommendations to Congress in September 2019.

## Effects of Synthetic Opioids

Synthetic opioids, such as fentanyl and fentanyl analogues, are produced in a laboratory, as opposed to opiates, such as morphine and codeine, that are derived from the poppy plant or semi-synthetic opioids, such as heroin or oxycodone, that are synthesized from opium products. Fentanyl is more potent than heroin or morphine and is able to pass its pharmacological effects onto the body more efficiently. These effects can include pain relief, respiratory depression, short-term euphoria, and dependence. Respiratory depression, in particular, can lead to death in overdose, and NIH reported that in 2019, synthetic opioids were involved in over half of opioid-involved overdose deaths.[16] Fentanyl is 100 times more potent than morphine and 50 times more potent than heroin. As a result, a very small amount of fentanyl or its analogues can increase the risk of overdose. DEA has reported that 2 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-21-499

[16]National Institute on Drug Abuse, *Overdose Death Rates,* accessed March 8, 2021, https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates.

## Deaths Related to Fentanyl-Related Substances

Although deaths from synthetic opioids such as fentanyl have been rising in recent years, it is unknown how many of these deaths may be attributable specifically to fentanyl-related substances. CDC does not have and has not published nationwide data on deaths related to fentanyl-related substances or fentanyl analogues in their own category, and its ability to do so is limited by the data available from post-mortem toxicology screenings across the United States.[17] However, CDC has studied a group of drugs referred to as fentanyls, which include fentanyl as well as fentanyl metabolites, precursors, and analogues.[18] The most recent data show that this group of fentanyls was the drug most frequently involved in overdose deaths in the United States in 2017, accounting for 27,299 deaths (almost 39 percent of all drug overdose deaths that year).[19]

To help examine deaths associated with fentanyl and fentanyl analogues—which it labeled as "illicitly manufactured fentanyls"—CDC reported data from 20 states and the District of Columbia, and partial data from four additional states, from January 2019 through June 2019. It found that almost 62 percent of overdose deaths during that period involved illicitly manufactured fentanyls.[20] CDC had previously reported data from 28 states and the District of Columbia from July through December 2018, showing that one or more fentanyl analogues were

[17]According to ONDCP, data from post-mortem toxicology screenings are limited because these screenings vary across states and local jurisdictions, with different coroners and medical examiners making different determinations of what substances to look for and how to report them.

[18]Metabolites are substances in the body that are produced when drugs are chemically altered, or metabolized, by the body, and a precursor is any chemical substance that may be used in any part of the manufacturing process of narcotic drugs and psychotropic substances such as fentanyl and fentanyl-related substances.

[19]H. Hedegaard, B. A. Bastian, J. P. Trinidad, M. R. Spencer, and M. Warner, "Regional Differences in the Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2017." National Vital Statistics Reports; vol. 68 no. 12. Hyattsville, MD: National Center for Health Statistics (2019).

[20]J. O'Donnel, R. M. Gladden, C. L. Mattson, C. T. Hunter, and N. L. Davis, "Vital Signs: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants – 24 States and the District of Columbia, January-June 2019." *MMWR Morbidity and Mortality Weekly Report,* vol. 69, no. 35 (2020), 1188-1197.

detected in almost 20 percent of the opioid-related deaths.[21] The report noted that deaths involving fentanyl increased in 2018, while deaths associated with fentanyl analogues decreased, suggesting an increase in the distribution of fentanyl that was illicitly manufactured, rather than the distribution of illicit fentanyl analogues.

## Federal Laws and Regulations Related to Controlled Substances

The CSA, enacted in 1970, 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. Generally, the Controlled Substance Analogue Enforcement Act of 1986 (hereinafter referred to as the "Federal Analogue Act"), amended the CSA to allow prosecution of cases involving substances that are not otherwise scheduled or FDA-approved that are intended for human consumption and have (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, and (2) an actual, represented, or intended effect that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance in Schedule I or II.[22] A substance that meets those criteria and is intended for human consumption is considered a controlled substance analogue and is treated as a controlled substance in Schedule I.[23]

In part, the Federal Analogue Act allows for prosecution of emerging variations of synthetic opioids that have not yet been scheduled. Prior to the class-wide scheduling of fentanyl-related substances in 2018, DOJ officials said that they used the Federal Analogue Act to prosecute cases for offenses involving unscheduled fentanyl analogues, which required prosecutors to prove the elements above in a court of law on a case-by-case basis.

Substances may be scheduled through legislation, administrative scheduling, or emergency temporary scheduling.

[21]J. O'Donnell, R. M. Gladden, B. A. Goldberger, C. L. Mattson, and M. Kariisa, "Notes From the Field: Opioid-Involved Deaths with Fentanyl or Fentanyl Analogs Detected – 28 States and the District of Columbia, July 2016-December 2018." *MMWR Morbidity and Mortality Weekly Report*, vol. 69 (2020), 271-273.

[22]See Pub. L. No. 99-570, subtit. E, 100 Stat. 3207, 3207-13 (1986).

[23]21 U.S.C. §§ 802(32), 813.

- Laws can be enacted to control a substance, change its classification, or remove it from control. Congress may use legislative scheduling to respond quickly to a drug it views as posing an urgent concern.
- Administrative scheduling occurs when DEA either initiates the action or responds to a request from HHS or an interested party. DEA receives a scheduling recommendation based on a scientific and medical evaluation of the substance at issue from the Assistant Secretary for Health, which relies on FDA to conduct this evaluation. FDA's scientific and medical evaluation, called an Eight-Factor Analysis, considers:

  1. the substance's actual or relative potential for abuse;
  2. scientific evidence of its pharmacological effect, if known;
  3. the state of current scientific knowledge regarding the substance;
  4. the substance's history and current pattern of abuse;
  5. the scope, duration, and significance of abuse;
  6. any risk the substances poses to the public health;
  7. the substance's psychic or physiological dependence liability, which refers to the potential for users to become psychologically or physically dependent on a substance; and
  8. whether the substance is an immediate precursor of an existing controlled substance.

  As part of this evaluation, FDA consults with NIH's National Institute on Drug Abuse. The HHS Assistant Secretary for Health is to consider the scientific and medical evaluation from FDA and the National Institute on Drug Abuse and make a recommendation about scheduling. This recommendation is binding on DEA, such that if the Assistant Secretary for Health recommends against controlling a substance, DEA may not schedule it. Finally, DEA's decision about scheduling, rescheduling, or descheduling a substance is subject to judicial review.
- Emergency scheduling allows the DEA Administrator to place a substance in Schedule I temporarily to avoid an imminent hazard to public safety. When so doing, DEA is required to conduct a Three-Factor Analysis, which is a subset of the eight factors relevant to permanent administrative scheduling—specifically the history and current pattern of abuse of the substance; the scope, duration, and significance of abuse; and the risk to public health. A substance may be temporarily scheduled for up to 2 years and extended for an additional year if administrative scheduling proceedings are pending.

DEA used this emergency scheduling authority for fentanyl-related substances when it temporarily scheduled them in 2018, and then the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extended the scheduling through May 6, 2021.

## Registration Requirements

Individuals or entities—such as manufacturers, distributors, researchers, practitioners, and pharmacists—that work with controlled substances—including fentanyl, individually scheduled fentanyl analogues, and now, fentanyl-related substances—must register with DEA. These registrations last between 1 and 3 years. Separate registrations are required for each place of business where the controlled substance is manufactured, distributed, imported, exported, or dispensed.

Registrants have a variety of obligations related to recordkeeping and reporting of the inventory and distribution of substances, and must submit a modification to DEA if they wish to add new controlled substances to their registration or change the amounts of approved substances. Additionally, they are subject to DEA inspection of the place of business and they must implement controls to guard against theft or diversion of controlled substances. Specifically, nonpractitioners—such as researchers—must follow certain specifications when storing controlled substances and limit access to that storage to a minimum number of certain authorized employees. Before researchers can register with the DEA, they must possess the relevant authorizations rom their respective states and institutions (such as universities) where they conduct their work.

## China's Class-Wide Control of Fentanyl-Related Substances

China reported that it would implement class-wide controls over many fentanyl analogues that had not already been controlled individually on May 1, 2019.[24] According to U.S. officials, China's law defines fentanyl-related substances more broadly than the U.S. government defines fentanyl-related substances, and China's definition also includes some

[24]On April 1, 2019, China announced that it was placing "fentanyl-related substances" as a class on its list of scheduled substances effective May 1, 2019. The announcement noted the government was doing so in accordance with its R*egulations on the Administration of Narcotic Drugs and Psychotropic Substances* and *Regulations on the Administration of Narcotic Drugs and Psychotropic Substances with Non-medical Use.* Moreover, the announcement stated that fentanyl and its analogues previously scheduled in accordance with this law would remain on the list of scheduled substances.

fentanyl precursors.[25] According to a 2020 State report on international drug and chemical controls, China also increased screening and inspections of chemical centers and sales sites. According to a Chinese government announcement, this law officially regulated what it called "fentanyl-related substances" and was referred to as an important measure to prevent and respond to the risks and harms brought about by new drug problems in advance. ONDCP officials told us that the U.S. government strongly supported China's decision to implement class-wide controls and that these controls had been a top U.S. priority, and that U.S. officials, including the President and the Ambassador to China, had engaged with Chinese officials to encourage the decision.

## Potential Effects of Class-Wide Scheduling of Fentanyl-Related Substances Show Possible Tradeoffs for Future Scheduling Decisions

The temporary class-wide scheduling of fentanyl-related substances in the United States since 2018 has likely had effects on drug classification, research, and federal law enforcement. We also identified potential effects from China's reported permanent classification and scheduling of many fentanyl analogues that had not already been controlled individually. These potential effects show possible tradeoffs for future scheduling decisions for fentanyl-related substances.

### Potential Effects of U.S. Class-Wide Scheduling

The temporary class-wide scheduling of fentanyl-related substances since 2018—designating them as illicit drugs with high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision—has likely had several effects on drug classification, research, and law enforcement, among other issues.

**Drug classification.** DEA's use of a structural definition for fentanyl-related substances classifies potentially harmful substances as Schedule I under the Controlled Substances Act, preemptively including an unknown number—potentially thousands—of substances that have not yet been identified by DEA and may not yet have been developed. According to ONDCP and HHS officials, it is possible that some

[25]The DEA's temporary scheduling order defined fentanyl-related substances as those substances not otherwise controlled in any schedule that are structurally related to fentanyl by one or more of five chemical structural modifications. See 83 Fed. Reg. 5188. China's law defines only four such structural relationships, according to U.S. officials.

substances in the class may be discovered to have low or no abuse potential or have a medical use. HHS had not completed an Eight-Factor Analysis evaluating the entire class requested by DEA as of March 2021, and HHS officials indicated that they are not certain such an analysis can be completed due to the large number of potential substances in the class, including those yet to be identified. According to HHS officials, as of March 2021 discussions within HHS regarding this analysis are ongoing, and HHS officials expect to provide an update to DEA prior to the expiration of the temporary scheduling order on May 6, 2021. Without the Eight-Factor Analysis, DEA would be precluded from administratively scheduling fentanyl-related substances as a class.

If the temporary scheduling order were to be made permanent, any individual fentanyl-related substances that are later discovered to have medical uses or low or no abuse potential would have to be rescheduled or descheduled based on new evidence. Rescheduling or descheduling of such substances can occur either legislatively, or administratively by DEA—based on HHS's recommendation and Eight-Factor Analysis of that substance. As a result, although fentanyl-related substances may be legislatively scheduled without an HHS recommendation or an Eight-Factor Analysis, any effort to administratively reschedule or deschedule specific substances will require such a recommendation and analysis.

In 2019, a federal interagency workgroup—led by ONDCP with agencies from DOJ and HHS—recommended the use of class-wide scheduling for fentanyl-related substances along with legislative modifications to allow for the rescheduling or descheduling of any fentanyl-related substances with low or no abuse potential with less scientific and medical evidence than currently required. This would allow rescheduling or descheduling to happen in a more timely manner. (See appendix II for more information on the classification of fentanyl-related substances.)

**Research.** Classifying fentanyl-related substances as Schedule I presents challenges related to research that exist for all Schedule I substances. While DEA has approved all 28 researchers who applied to study fentanyl-related substances since 2018, representatives from research organizations we interviewed and articles we reviewed indicated that a Schedule I designation can hinder research on such substances. For example, according to federal officials and representatives from three research organizations, the process for obtaining approval from DEA to conduct research on Schedule I substances can be time consuming and confusing. This process includes the need to obtain approval from states and institutions (such as universities), as well as the time for DEA and

FDA to conduct their reviews. In addition, according to representatives from five research organizations we met with and articles we reviewed, the time and resources it takes to meet these requirements may result in less research being conducted on both what makes these substances dangerous as well their possible use in medical treatments.[26] Officials at NIH and some research organizations we spoke with stated that it can take more than a year to gain all of the necessary approvals to conduct research on Schedule I substances in general. In terms of the federal portion of the review process specifically, DEA data indicate that median overall review time for complete new applications for fentanyl-related substances was about 2 months, though there was wide variation. Representatives from two research organizations also stated that the process of modifying an existing registration is also time consuming and challenging. DEA officials stated, however, that class-wide scheduling could have the benefit of allowing researchers the possibility of using a research protocol broadly focused on the class of fentanyl-related substances, and in this case their DEA registration could allow them to study additional fentanyl-related substances without the need for modification.

The federal interagency workgroup led by ONDCP provided Congress with recommendations to facilitate research on Schedule I substances and to clarify what is already allowed. According to ONDCP officials, the interagency workgroup's recommendations were intended to ensure that research on fentanyl-related substances could continue after their classification as Schedule I substances or allow a substance to be removed from scheduling for research purposes only. (See appendix III

[26]The following articles describe the time and resources required to meet Schedule I registration requirements: J. Dodge, "When the DEA comes knocking," *Journal of Chemical Health & Safety*, vol. 18, no. 3, (2011): p. 23-27; Editors, "End the Ban on Psychoactive Drug Research," *Scientific American*, vol. 310, no. 2, (2014): p. 10-11; S. J. Belouin, and J. E. Henningfield, "Psychedelics: Where we are Now, Why we Got Here, what we Must Do," *Neuropharmacology*, vol. 142, (2018): p. 7-19; M. Marks, "Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles," *Journal of Legislation and Public Policy*, vol. 21, (2018): p. 69 – 140. The following articles describe how Schedule I registration requirements result in less research on these substances: D. L. Nutt, L. A. King and D. E. Nichols, "Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation," Nature Reviews Neuroscience, vol. 14, August 2013, p. 577-585, A. Kreit, "Controlled Substances, Uncontrolled Law," *Albany Government Law Review*, vol. 6 (2013): p. 331-357; M. H. Andreae, et al., "An Ethical Exploration of Barriers to Research on Controlled Drugs," American Journal of Bioethics, vol. 16, no. 4, (2016): p. 36–47; J. M. Bostwick, "Blurred Boundaries: The Therapeutics and Politics of Medical Marijuana," *Mayo Clinic Proceedings*, vol. 87, no. 2, (2012) p. 172-186.

for more information on the potential effects of class-wide scheduling of fentanyl-related substances on research.)

**Federal law enforcement.** Law enforcement officials and other stakeholders we interviewed had competing views on the potential effects of class-wide scheduling on investigations and prosecutions of fentanyl-related substance cases. For example, DEA and other federal law enforcement officials we interviewed reported that class-wide scheduling of fentanyl-related substances reduces incentives for criminal organizations to manufacture and traffic these substances to circumvent law enforcement, and that such scheduling has helped reduce the number of reports of law enforcement encounters with fentanyl-related substances.

Our analysis of DEA data on these reports show that encounters with fentanyl analogues that were not individually scheduled by name—which is what class-wide scheduling was intended to target—decreased from 7,058 reports in 2016 and 2017 to 787 reports in 2018 and 2019. This decrease coincided with DEA's class-wide scheduling order in February 2018 and the individual scheduling of 11 fentanyl analogues shortly before DEA's order.[27] However, we did not conduct an analysis to determine the cause of the decrease due to the short time period that the temporary scheduling order has been in effect and the numerous other factors that could affect law enforcement reports of encounters with these analogues.[28] Nonetheless, DEA officials stated that class-wide scheduling, individually scheduling some analogues by name, and China's class control law, which we discuss later in this report, all contributed to the low number of law enforcement encounters with fentanyl-related substances after DEA's temporary scheduling order went into effect. According to other DOJ officials, this likely reduced overdose deaths from these substances.

Officials from EOUSA and the U.S. Attorney's Offices we interviewed also cited a number of benefits with prosecuting cases under class-wide

[27]There were 5,065 reports of encounters with these 11 fentanyl analogues in 2018 and 2019 that were excluded from the reports for those years (i.e., not part of the 787 reports of encounters classified as fentanyl-related substances under DEA's order) because the analogues were already scheduled.

[28]Only 2 years of data on law enforcement encounters after class-wide scheduling were available.

scheduling.[29] For example, because such scheduling classifies all fentanyl-related substances as Schedule I drugs, the officials told us that technical testimony from multiple expert witnesses is not required to prove to a jury that an analogue involved has substantially similar chemical and psychoactive properties as fentanyl. Officials said that class-wide scheduling could save considerable resources involved with expert witnesses necessary for such prosecutions. They also said class-wide scheduling could reduce the possibility of inconsistent case outcomes that may result when different juries reach different conclusions about the similarity of a substance to fentanyl when prosecuting cases under the Federal Analogue Act.

However, representatives from the five criminal justice and civil rights organizations we interviewed expressed concerns over the effects of class-wide scheduling on defendants' rights and sentence lengths. For example, representatives from all of these organizations stated that class-wide scheduling may deprive accused persons of the ability to mount an effective defense because it removes the prosecutorial burden of having to prove that a substance has a psychoactive effect substantially similar to fentanyl. According to one representative, this could potentially lead to defendants being convicted for offenses involving fentanyl-related substances that do not have a harmful effect. Representatives from all five organizations also raised concerns that defendants may be subjected to mandatory minimum sentences for trace amounts of fentanyl-related substances.[30] In addition, representatives from four of these organizations and the federal public defenders we spoke with cited concerns with racial disparities in federal sentencing of cases involving illicit fentanyl and fentanyl analogues and said these disparities could be exacerbated under class-wide scheduling. (See appendix IV for more information on the potential effects of class-wide scheduling of fentanyl-related substances on federal law enforcement efforts.)

## Potential Effects of China's Class-Wide Scheduling

In May 2019, China announced the permanent classification and scheduling of many fentanyl analogues that had not already been controlled individually in the country. Our analysis of CBP seizure data shows that the number of seizures of fentanyl and its analogues entering the United States from China decreased from 352 seizures in fiscal year 2018—before the announcement—to 10 seizures in fiscal year 2020

[29]EOUSA reported that, as of December 2020, U.S. Attorney's Offices have prosecuted eight cases under class-wide scheduling.

[30]See 21 U.S.C. § 841.

through July. However, this decrease was offset by increased seizures of fentanyl and its analogues entering the United States from Mexico and, to a lesser degree, Canada. U.S. officials and documents noted since at least 2018 that transnational criminal organizations are importing more precursors to manufacture fentanyl within Mexico to traffic to the United States. Our analysis of CBP seizure data at U.S. ports of entry shows that seizures from Mexico increased by more than 200 percent from 220 seizures in fiscal year 2018 to 669 seizures in fiscal year 2020 through July.

According to our analysis of CBP seizure data and discussions with U.S. officials, the extent to which these changes in the flow of seizures to the United States are a direct result of the China's 2019 class-wide scheduling law is unclear, because multiple factors likely contributed to the decline in seizures from China. For example, U.S. officials noted two potential factors, among others, that might help to explain the decline in seizures in the 16 months prior to the law's stated date of effectiveness, including the anticipation of China's law on the part of manufacturers in China and U.S. control and enforcement efforts, such as enhanced detection capabilities at U.S. ports of entry. There are also limitations of CBP seizure data, which do not separate fentanyl from fentanyl analogues or fentanyl related substances. (See appendix V for more information on China's class-wide scheduling of fentanyl-related substances.)

## Possible Tradeoffs for Future Scheduling Decisions

The potential effects we identified show possible tradeoffs for decisions on the scheduling of fentanyl-related substances when the current temporary scheduling order expires in May 2021. Below, we discuss potential scheduling decisions, along with tradeoffs associated with those decisions.

**Allow the temporary scheduling order to expire.** Without the temporary scheduling order, DEA could individually schedule specific fentanyl analogues, as was done prior to the temporary scheduling order, and unscheduled fentanyl analogues may be prosecuted under the Federal Analogue Act. Allowing the temporary scheduling order to expire without legislative or administrative class-wide scheduling could have the following effects, as discussed. Our work shows that this approach may

- reduce the risk of including substances with potential medical use, or with no or low risk of abuse, in Schedule I.

- eliminate a benefit of class-wide scheduling—reduced incentives for illegal drug manufacturers to make new and existing fentanyl-related substances to circumvent the law—according to federal law enforcement officials.
- result in inconsistent case outcomes for prosecutions of fentanyl-related substance offenses under the Federal Analogue Act where the same substance is determined to be an analogue in one case but not another, according to federal law enforcement officials.

**Schedule as a class without modifications.** The temporary scheduling order in effect until May 6, 2021, could be made permanent through legislative scheduling.[31] Scheduling fentanyl-related substances as a class without modifications could have the following effects, as discussed.

- It could increase the risk of including substances with potential medical use or without a known risk of abuse in Schedule I.
- According to law enforcement officials, this approach would retain reduced incentives for illicit drug manufacturers to circumvent law enforcement by creating new and existing fentanyl-related substances.
- It would not address existing challenges identified by researchers related to obtaining approval to conduct research.
- It would not address concerns expressed by criminal justice and civil rights organizations about convictions for substances that may not have a psychoactive effect substantially similar to fentanyl, lengthy sentences for trace amounts of fentanyl-related substances resulting from mandatory minimum sentencing requirements, and racial disparities in federal sentencing.

**Legislatively schedule as a class with modifications.** Fentanyl-related substances could be legislatively scheduled with modifications to the temporary scheduling order. For instance, the interagency workgroup convened by ONDCP recommended some modifications that could be made to address some of the tradeoffs involved in permanent scheduling, and presented those recommendations to Congress in September 2019.

[31]The temporary scheduling order could also be made permanent through administrative scheduling, but a complete HHS Eight-Factor Analysis would be required. As of March 9, 2021, HHS officials told us that the analysis had not be completed. While HHS officials noted that there are ongoing discussions within HHS and the agency hopes to have a response to DOJ and DEA prior to May 6, 2021, DEA officials told us they believed that HHS would not be able to perform that analysis. The Assistant Secretary for Health had also expressed such concerns in January 2020 testimony before Congress.

These modifications have not been included in enacted legislation as of March 2021. The list of recommended modifications is included in Appendix III and includes:

- removing barriers to and clarifying the process for conducting research, and
- streamlining the process for removing from Schedule I any substances that are discovered to have low or no abuse potential.

## Agency Comments and Our Evaluation

We provided a draft of the sensitive report to HHS, DHS, DOJ, ONDCP, State, and the Federal Public and Community Defenders. ONDCP, DOJ, and the Federal Public and Community Defenders provided written comments, which are reprinted in appendixes VI, VII, and VIII, respectively. DOJ's written comments have been updated for this report to omit information it considered sensitive. ONDCP, HHS, DHS and DOJ provided technical comments, which we incorporated as appropriate. State did not provide comments.

In its written comments, ONDCP stated that the draft report identified the issues to be considered with regard to permanent scheduling of fentanyl-related substances. It stated that permanent scheduling would facilitate law enforcement investigations and prosecutions for trafficking in fentanyl-related substances, among other things. However, it also stated that the ancillary effects of permanent scheduling on research to examine medically beneficial uses of fentanyl-related substances, as well as mandatory minimum sentencing, must be addressed and mitigated.

DOJ and the Federal Public and Community Defenders, in their written comments, stated that the draft report placed either too much or too little emphasis on perspectives from certain stakeholders. For example, DOJ stated that the draft report appeared to give little weight to the data and perspectives provided by law enforcement professionals and prosecutors—which, as the report describes, generally support the positive effects of class-wide scheduling on law enforcement and public health—while giving undue credence to assertions made by advocates who disfavor scheduling. In our report, we provide data showing that law enforcement encounters with fentanyl-related substances have declined since the temporary scheduling order, but also clarify that our own analysis did not determine the specific cause of these reductions, noting that there were multiple possible factors involved.

In contrast, the Federal Public and Community Defenders stated that the draft report placed too much emphasis on assertions by law enforcement about the utility and effect of class-wide scheduling and not enough on evidence that class-wide scheduling is unnecessary and could lead to overcriminalization—a viewpoint that we also describe in the report. The Federal Public and Community Defenders also stated that the beginning of the report should specify that harmful fentanyl-related analogues are illegal, even without class-wide scheduling. The report includes information on the Federal Analogue Act, which would apply without class-wide scheduling, but we made revisions to clarify this point earlier in the report. The report also includes perspectives from DOJ officials regarding limitations of this act.

We considered each of the agencies' comments and made revisions, as appropriate, to ensure that the report presents the available evidence in an accurate and balanced manner by including a variety of viewpoints and perspectives along with supporting data, where available. As a result, we believe that the report describes the important tradeoffs to be considered when making decisions about the scheduling of fentanyl-related substances.

We are sending copies of this report to the appropriate congressional committees; the Secretaries of HHS, DHS, and State; the Attorney General; the Acting Director of ONDCP; the Administrative Offices of the United States Courts; and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff members have any questions about this report, please contact Alyssa M. Hundrup at (202) 512-7114 or HundrupA@gao.gov, Triana McNeil at (202) 512-8777 or McNeilT@gao.gov or Kimberly M. Gianopoulos at (202) 512-8612 or GianopoulosK@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 IX.

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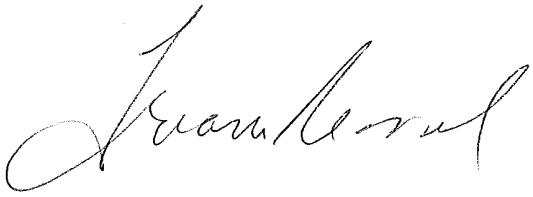

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# Appendix I: Objective, Scope, and Methodology

## Objective and Scope

Our report examined what is known about the U.S. class-wide scheduling of fentanyl-related substances including its potential effects and considerations for future scheduling decisions. We focused on issues such as drug classification, research, and federal law enforcement, as well as The People's Republic of China's (China) class-wide scheduling on the flow of these substances entering the United States. For purposes of this report, we focused on fentanyl-related substances as defined by the Drug Enforcement Administration (DEA) in its 2018 temporary scheduling order classifying these substances as Schedule I.[1]

This report is a public version of a sensitive report that was issued in April 2021.[2] DOJ deemed some of the information in our April report to be sensitive, which must be protected from public disclosure. Therefore, this report omits sensitive information related to China's class-wide scheduling of fentanyl analogues. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

## Interviews with Federal Agencies

We interviewed numerous officials from federal agencies that have a role in the scheduling or control of illicit drugs, as well as those involved with international aspects of drug control. We focused our interviews on the temporary scheduling order and its potential effects on classification, research, and federal law enforcement, as well as the interagency workgroup examining the temporary class-wide scheduling (though we did not review the workgroup's methodology or process used to develop its recommendations). The federal officials we interviewed were from:

- Office of National Drug Control Policy (ONDCP)
- Department of Health and Human Services (HHS): Food and Drug Administration (FDA), National Institutes of Health (NIH), Office of the Assistant Secretary for Health
- Department of Justice (DOJ): DEA, the Federal Bureau of Investigation, Executive Office for United States Attorneys (EOUSA)
- Department of Homeland Security (DHS): U.S. Customs and Border Protection (CBP)

[1]83 Fed. Reg. 5188 (Feb. 6, 2018).

[2]GAO, *Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-related Substances,* GAO-21-301SU (Washington, D.C.: April 8, 2021).

- Department of State's (State) Bureau of International Narcotics and Law Enforcement Affairs

To assess the potential effects of class-wide scheduling on federal law enforcement investigations and prosecutions of fentanyl-related substance cases, we also conducted semi-structured interviews with federal officials in four DEA field division offices, four U.S. Attorney's Offices, and four Organized Crime Drug Enforcement Task Forces (OCDETF) strike forces that cover four selected states—Maryland, Massachusetts, Missouri, and Ohio.[3] We selected these states because they had high overdose death rates from synthetic opioids other than methadone in 2018, as well as increasing overdose death rates from 2017 to 2018 and/or a high number of law enforcement reports of fentanyl and fentanyl-related compounds in 2018, among other factors.[4] In addition, we interviewed Federal Public and Community Defenders who are knowledgeable about class-wide scheduling, as well as officials from the U.S. Sentencing Commission.[5]

To further understand the potential effects of China's class-wide scheduling law, we interviewed officials from CBP, DEA, and State's

[3]Specifically, we interviewed field officials from DEA's District of Columbia field division office, which covers the District of Columbia, Maryland, and Virginia; New England field division office, which covers Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, and Vermont; St. Louis field division office, which covers Illinois, Kansas, and Missouri; and Detroit field division office, which covers Ohio and Michigan. We also interviewed U.S. Attorney's Offices for the District of Massachusetts, District of Maryland, the Eastern District of Missouri, and the Northern District of Ohio; as well as OCDETF strike forces in Baltimore, Boston, Cleveland, and St. Louis.

[4]N. Wilson, M. Kariisa, P. Seth, H. Smith IV, and N. L. Davis, "Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018," *CDC Morbidity and Mortality Weekly Report*, vol. 69, no. 11 (2020): pp. 294-295. See also DEA Diversion Control Division, Table 3. State Counts for Fentanyl and Fentanyl-related Compounds: 2018. accessed June 11, 2020, https://www.nflis.deadiversion.usdoj.gov/Resources/NFLISPublicResourceLibrary.aspx. These were the most recent data that were publicly available when we selected the states.

[5]Under the Criminal Justice Act of 1964, Pub. L. No. 88-455, 78 Stat. 552 (Aug. 20, 1964), federal public defenders are appointed to represent defendants financially unable to retain counsel in federal criminal proceedings. See 18 U.S.C. § 3006A. The Administrative Office of the U.S. Courts administers the federal defender program on a national basis. According to the office, federal public defenders represent the majority of individuals who are prosecuted in the nation's federal courts. The United States Sentencing Commission is a bipartisan, independent agency located in the judicial branch of government. The Sentencing Reform Act of 1984, Pub. L. No. 98-473, § 217, 98 Stat. 1987, 2017 (Oct. 12, 1984), created the commission in 1984 to reduce sentencing disparities and promote transparency and proportionality in sentencing. See 28 U.S.C. § 991.

Bureau of International Narcotics and Law Enforcement Affairs and the U.S. Embassy in Beijing.

## Interviews with Stakeholders

We interviewed numerous stakeholders who could provide a variety of perspectives on the process of scheduling fentanyl-related substances, as well as the effect of such scheduling on research, public health, criminal justice, civil rights, and law enforcement, as well as international issues. When selecting these stakeholders, we considered the extent to which they were active or engaged in the scheduling of fentanyl-related substances or other synthetic opioids.

We interviewed representatives—including officials, members, or both—of various types of research organizations to learn about the potential implications of scheduling fentanyl-related substances on research and drug classification. We identified organizations with knowledge of fentanyl analogues and research on controlled substances from disciplines that include medicine, public health, toxicology, and pharmacology. We identified organizations that were engaged with fentanyl analogues or synthetic opioids through prior related work with GAO, as well as through interviews with federal officials and other stakeholders. From that list, we chose those that appeared most knowledgeable on the topics of this report based on publicly available information on their websites and interviews with others to ensure a range of perspectives.

We selected 11 organizations that represent a range of perspectives in the research community, including those representing professional associations, research institutions, and the pharmaceutical industry, as well as researchers. The organizations were:

- Professional associations and associated researchers: American Society of Addiction Medicine, The College of Problems on Drug Dependence, and the American Society of Pharmacology and Experimental Therapeutics
- Research institutions and associated researchers: NMS Labs, RAND, University of California San Francisco, and Scripps Foundation
- Pharmaceutical industry research organizations: Pistoia Alliance and PhRMA
- Research-related interest groups: Friends of NIDA and Council on Government Relations

We also interviewed representatives from various criminal justice reform, civil rights, and law enforcement organizations to obtain information and

perspectives on the potential effects of class-wide scheduling of fentanyl-related substances. These organizations were chosen based on their recent research and other related work on such scheduling.[6] The organizations were:

- Criminal justice reform and civil rights: American Civil Liberties Union, Drug Policy Alliance, Leadership Conference on Civil and Human Rights, National Association of Criminal Defense Lawyers, and Sentencing Project
- Law enforcement: National Narcotic Officers' Associations' Coalition, National Sheriffs' Association, and National District Attorneys Association, which represent state and local law enforcement officials

We also interviewed officials from international organizations, including the International Narcotics Control Board and United Nations Office on Drugs and Crime (UNODC) in Vienna, Austria—the international organizations with primary responsibility for monitoring international drug conventions and international drug flows—to discuss the international scheduling process and precursor flows.

## Analysis of Data and Documents

In addition to the interviews noted above, we analyzed data and conducted additional research activities to assess the potential effects of class-wide scheduling of fentanyl-related substances on researchers and federal law enforcement. We also analyzed data related to the potential effect of China's class-wide scheduling on the flow of these substances entering the United States.

To assess the potential effects of class-wide scheduling of fentanyl-related substances on research, we conducted a literature search for articles regarding challenges to research on Schedule I substances and the registration process. We considered articles that met the following criteria: published from 2010 through July 2020 in the news media, academic journals, or by government agencies and nonprofit organizations. Of the 780 results produced by this search, we chose 85 of the most relevant articles to consider and selected 14 articles to review that included either researcher perspectives or findings regarding the effects of a Schedule I classification on research. Selected articles

[6]We conducted online searches for research and work related to class-wide scheduling of fentanyl-related substances, such as letters in support of or opposing class-wide scheduling legislation, and solicited recommendations from the organizations we interviewed.

provided an illustration of the effects of a Schedule I classification on research from the perspective of those engaged in this research.

We also analyzed DEA data on federal Schedule I research registration processing time. These data include information on 28 applications to conduct research on fentanyl-related substances that were submitted between February 2018 and January 2020.[7] We assessed the reliability of these data by interviewing DEA officials about how the data were collected and used and the DEA's data quality control procedures. We found these data to be sufficiently reliable for the purposes of this report, to describe processing time for applications to register to conduct research on fentanyl-related substances with DEA.

To assess the potential effects of class-wide scheduling on federal law enforcement efforts, we analyzed DEA data on domestic law enforcement encounters with fentanyl analogues and fentanyl-related substances from 2016 through 2019 (2 years before and 2 years after DEA's temporary class-wide scheduling order).[8] DEA measures these encounters through its National Forensic Laboratory Information System, which collects reports from participating federal, state, and local laboratories of drugs obtained in law enforcement operations.[9] We obtained perspectives on

[7]These data include registrations to research fentanyl-related substances scheduled as a class. Data for each application includes dates such as when the application was first received, when the application was received in full, when the application was sent to FDA for review, the date of FDA approval, and the date of the DEA's final determination. These data did not identify these researchers by name, and GAO did not solicit input from these 28 researchers. Instead, as described above, we received input from 11 organizations that represent a range of perspectives in the research community, including those representing professional associations, research institutions, and the pharmaceutical industry, as well as researchers.

[8]According to DEA officials, data from the National Forensic Laboratory Information System are reliable and complete through 2019. They noted that the 2020 data are still pending as laboratories continue to process submissions and will not be complete until spring 2021, or possibly later due to the Coronavirus Disease 2019 (COVID-19) pandemic.

[9]DEA's National Forensic Laboratory Information System collects drug identification results and associated information from drug cases submitted to and analyzed by federal, state, and local forensic laboratories. These laboratories analyze controlled and noncontrolled substances obtained in law enforcement operations across the country, such as through seizures or undercover buys, and produce confirmed reports of substances that are included in the system's database. Laboratory participation in the system is voluntary. The system includes DEA and Customs and Border Protection laboratories, and as of June 2020, 50 state laboratory systems and 104 local laboratory systems, representing 279 individual laboratories.

what factors potentially contributed to changes in the number of reported encounters before and after class-wide scheduling, but did not conduct a causal analysis to determine the effects of class-wide scheduling on reports of law enforcement encounters.[10] We also analyzed data from the Executive Office for United States Attorneys (EOUSA) on the number of fentanyl analogue cases prosecuted from fiscal year 2019, the first year that data were available, through fiscal year 2020.[11] We assessed the reliability of both these data sources by reviewing documentation on the data systems, conducting manual tests of the data, and interviewing DEA and EOUSA officials about how the data were collected and their data quality control procedures. We found these data to be sufficiently reliable for the purposes of analyzing reports of law enforcement encounters with fentanyl analogues and prosecutions of fentanyl analogue cases. In addition, we analyzed documentation related to federal investigations and prosecutions of fentanyl-related substances, such as DEA's annual drug threat assessments and publicly available court filings and charging documents for cases prosecuted under the class-wide scheduling provision.

To assess the potential effects of China's class-wide scheduling law on the flow of fentanyl-related substances into the U.S., using data from CBP's Seized Assets and Case Tracking System (SEACATS) covering fiscal years 2018 through July 2020,[12] we analyzed the frequency of seizures of fentanyl and its analogues, methods of transportation, main countries from where the drugs came, and any shifts related to China's

[10]We did not conduct an analysis to draw causal conclusions related to class-wide scheduling because of the short time period that DEA's temporary order has been in effect—only 2 years of data on law enforcement encounters after class-wide scheduling were available—and the various other factors, such as international regulatory controls, that could affect law enforcement reports of fentanyl analogues, including fentanyl-related substances.

[11]According to EOUSA officials, EOUSA established a "fentanyl analogue" field in its case management system at the start of fiscal year 2019. This category does not distinguish between individually scheduled fentanyl analogues and fentanyl-related substances.

[12]We analyzed data from fiscal year 2018 through July of fiscal year 2020 for two reasons. First, according to CBP officials, limited field testing and officer experience following the introduction of the fentanyl field in SEACATS in March 2016 limited the amount of fentanyl reported in 2016 and likely into 2017. Second, we analyzed data through July 31 of fiscal year 2020 because it was the latest data available at the time of analysis.

class-wide scheduling law.[13] We analyzed data from SEACATS because officials from CBP, State, DEA and ONDCP agreed it was the best available data for our purposes and they rely on it to monitor international drug trafficking trends. There are three main limitations with using SEACATS data for this review. First, seizure data do not represent the actual supply or flows of fentanyl and its analogues entering the United States. According to CBP and ONDCP officials, seizure data only allows us to analyze what has been seized. Due to the illicit nature of drug trafficking, seizure data is unable to estimate total drug supply. Therefore, we analyzed 2,509 seizures of fentanyl and its analogues that were marked as inbound to the United States and seized by CBP's Office of Field Operations (OFO).[14] Second, SEACATS does not distinguish fentanyl from fentanyl analogues or fentanyl-related substances and categorizes them all as fentanyl—which means we are unable to separate the potential effects of China's class-wide scheduling law solely on flows of fentanyl-related substances. Third, according to CBP officials, it is not possible for agents to determine a synthetic drug's origin or point of manufacture with certainty.

Therefore, we constructed a country of transport variable, which indicates the locations of origin or last known country associated with the fentanyl seizure.[15] We focused our analysis on the three countries of transport where, collectively, over 80 percent of seizures of fentanyl and its analogues came from each year from fiscal year 2018 through July 2020: Canada, China, and Mexico. The actual proportion of seizures from each

[13]CBP categorizes all seizures of fentanyl, scheduled fentanyl analogues, and fentanyl-related substances as fentanyl within SEACATS. According to CBP officials, SEACATS data may also include seizures of inactive fentanyl analogues if presumptive field testing or laboratory testing confirmed the presence of fentanyl. We included all seizures categorized as fentanyl within the description field in SEACATS and any other observations with the word "fentanyl" in its description. Therefore, our analysis may also include precursor chemicals if either of those parameters apply. We refer to this combined category in this report as fentanyl and its analogues.

[14]CBP's OFO is responsible for inspections at the 328 U.S. land, sea, and air ports of entry. CBP's border security mission is led by officers from the OFO at land ports of entry and screen inbound and outbound international mail and express consignment carrier items at U.S. ports of entry. We used seizure data from OFO because they account for the majority of CBP seizures of fentanyl marked as inbound to the US. We excluded seizures by agents from the U.S. Border Patrol, Air and Marine Operations, and Immigration and Customs Enforcement Homeland Security Investigations as these groups are seldom associated with inbound seizures.

[15]Country of transport refers to a seizure that is associated with a particular country identified in the following fields from SEACATs, listed in order of prioritization: origin, from, departure, sender, or export. We verified the validity of this approach with CBP.

country varied over time. We reviewed the data, conducted electronic tests of the data, and interviewed knowledgeable agency officials to determine that these data were sufficiently reliable for our purposes.

We conducted this performance audit from March 2020 to April 2021 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: Potential Effects of Class-Wide Scheduling on Drug Classification

This appendix includes information on the potential effects of the U.S. class-wide scheduling of fentanyl-related substances on drug classification, based on the 2018 temporary scheduling of these substances. The Drug Enforcement Administration's (DEA) use of a structural definition for fentanyl-related substances classifies potentially harmful substances as Schedule I under the Controlled Substances Act, but also includes an unknown number—potentially thousands—of substances that have not yet been identified by DEA. If the temporary scheduling order were to be made permanent, any individual fentanyl-related substances that are later discovered to have medical uses, or low or no abuse potential, would have to be rescheduled or descheduled based on new evidence.

**Definition.** In its temporary scheduling order, DEA defined fentanyl-related substances based on their chemical structure alone and did not define them based on their pharmacological activity—the resulting physical and psychoactive effects on humans.[1] Specifically, the temporary scheduling order defined fentanyl-related substances as any substance that is structurally related to fentanyl by one or more of five chemical modifications and is not otherwise controlled in any of the schedules (I through V). All fentanyl-related substances that meet this structural definition, even if such substances have not yet emerged on the illicit market in the United States, have been placed in Schedule I until May 6, 2021, which restricts access to these substances and labels them as having high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.[2] According to DEA, the agency developed the definition to target substances with a known or predicted risk of abuse, and to exclude substances with no known risk of abuse. In addition to targeting substances in this way, however, this use of a structural definition also captures potentially thousands of substances with unknown effects. As of March 2021, HHS has analyzed 15 fentanyl-related substances, all of which have been found to have high abuse potential and no accepted medical uses—consistent with their placement in

[1]83 Fed. Reg. 5188 (Feb. 6, 2018). According to DEA, the predicted pharmacological activity of fentanyl-related substances at the opioid receptors is associated with the effects in humans of pain relief, respiratory depression, and dependence, as is the case with fentanyl and other opioids.

[2]DEA's temporary scheduling order expired after 2 years. In February 2020, the Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act extended the temporary scheduling order through May 6, 2021. Pub. L. No. 116-114, § 2, 134 Stat. 103 (2020).

Schedule I under the temporary scheduling order. However, according to Office of National Drug Control Policy (ONDCP) and HHS officials, it is possible that other substances in the class may be discovered to have low or no abuse potential or an accepted medical use. As part of preparations for the temporary scheduling order, in November 2017, HHS confirmed to DEA that no fentanyl-related substances were part of any approved new drug applications or active investigations for new drug applications.

According to DEA, the agency based its decision to use a structural definition for its temporary scheduling order on the premise of structure-activity relationships, which predicts that substances similar in chemical structure have similar pharmacological activity.[3] DEA officials told us that structure-activity relationships are commonly used in academic and pharmaceutical drug discovery research as well as by drug traffickers to design new substances for the illicit market. According to DEA, the structure-activity relationships for opioids, but their neurological receptors have been intensively studied and are well understood, and there may be exceptions where structure does not accurately predict pharmacological activity. For example, DEA temporarily scheduled two fentanyl analogues in 1985 based on their similarity in structure to that of controlled substances, the likelihood that they would produce pharmacological effects similar to Schedule I or II substances, and their appearance in the illicit market.[4] The agency then removed these substances from control in 1986 because, upon further evaluation, they were determined to have no evidence of abuse potential.

DEA officials told us that for the temporary scheduling order, the agency chose a definition based on structure to provide clarity that all fentanyl-related substances are scheduled. They said that including pharmacological activity in the definition would have introduced uncertainty about the scheduling status of new substances because under such a definition it would be unclear if a substance was controlled

[3]According to DEA, the agency based its structural definition of fentanyl-related substances on the U.K.'s structural definition of fentanyl analogues that has controlled those substances since 1986.

[4]The two substances are benzylfentanyl and thenylfentanyl. DEA excluded the structural modifications that result in these fentanyl analogues from the fentanyl-related substances definition because they were already determined to not have abuse potential and therefore do not fit the definition of a Schedule I substance. According to DEA, the removal of these two substances from control demonstrates that the scheduling process functions appropriately. In May 2020, DEA controlled benzylfentanyl as a List I chemical due to it being a precursor chemical used to produce fentanyl.

prior to determining its pharmacological activity. On the other hand, HHS officials told us that including pharmacological activity in the fentanyl-related substances definition would minimize the need to reschedule or deschedule substances later found to have low or no abuse potential, because substances placed in Schedule I would already have shown pharmacological activity associated with high abuse potential. Substances have been legislatively scheduled as a class based on a combination of structure and pharmacological activity. For example, the Synthetic Drug Abuse Prevention Act of 2012 added the class of synthetic cannabinoids to Schedule I by a definition that includes five structural classes and pharmacological activity at the cannabinoid receptor—which produces an effect similar to delta-9-tetrahydrocannabinol, the primary psychoactive agent in marijuana.[5]

Representatives of eight research organizations we spoke to expressed concerns about the potential effects of class-wide scheduling, particularly when relying on a structural definition as in the temporary scheduling order. The class of fentanyl-related substances may include medically useful substances or ones with low abuse potential, according to representatives of most of these research organizations. Furthermore, most of them also expressed concern that including unknown substances in Schedule I may dampen research efforts and subsequently may delay the development or discovery of medically useful substances. In particular, they highlighted the possibility that the class of fentanyl-related substances may include the following undiscovered substances:

- A pain treatment, similar to the fentanyl analogue, remifentanil, a Schedule II opioid analgesic used for pain relief during surgery. If it had not already been classified as Schedule II, remifentanil would have been included in Schedule I as fentanyl-related substances under the temporary scheduling order.[6]
- An overdose treatment, similar to naloxone, which reverses the effects of opioids. While naloxone is not a fentanyl-related substance,

[5]See Pub. L. No. 112-144, § 1152, 126 Stat. 993, 1130 (2012).

[6]DEA has scheduled 31 fentanyl analogues by name that would have otherwise met the definition of fentanyl-related substances. Five of those substances (16 percent) were classified as Schedule II because of their medical use. The remaining 26 substances were classified as Schedule I.

it is structurally similar to other opioids with negative effects, like oxycodone.[7]

**Assessment of fentanyl-related substances.** Since the temporary scheduling of fentanyl-related substances took effect, DEA requested that HHS conduct an Eight-Factor Analysis of 16 individual fentanyl-related substances in April and October 2019, and of fentanyl-related substances as a class in February 2020.[8] The Eight-Factor Analysis—which includes an evaluation of pharmacological activity, if known, and abuse potential—forms the basis of HHS's scheduling recommendation.[9] Of these requests, HHS completed an analysis of 11 fentanyl-related substances in July 2020 and 4 in March 2021. HHS recommended that these 15 substances be included in Schedule I, as it found all were active opioid agonists with high abuse potential.[10] As of March 2021, HHS officials shared that the Eight-Factor Analyses of the one other substance for which DEA requested an analysis was in progress.

In addition, HHS has not completed the Eight-Factor Analysis of the entire class of fentanyl-related substances as of March 2021. According to HHS officials, while the Eight-Factor Analysis for fentanyl-related substances is underway and a high priority for the agency, HHS is not certain it can be completed. The Assistant Secretary for Health testified before Congress in January 2020 that analyzing a class of substances rather than a specific substance would be a significant change for HHS, and that doing so might not be feasible due to the large number of substances in the class. According to HHS officials as of March 2021, discussions within

[7]Naloxone was descheduled from its prior Schedule II placement in 1974. According to DEA, this descheduling suggests that the rescheduling mechanism within the CSA functions appropriately.

[8]Between 2017 and 2019, DEA identified 27 fentanyl-related substances through forensic laboratory reports, according to DEA officials. While DEA requested an evaluation of 16 of these fentanyl-related substances by name, DEA expects that the other 11 substances would be evaluated in the Eight-Factor Analysis for fentanyl-related substances as a class, if HHS is able to conduct such an analysis.

[9]A subset of the Eight-Factor Analysis, called a Three-Factor Analysis is required for DEA to temporarily schedule any substance. The Three-Factor Analysis considers the following factors: (1) history and current pattern of abuse; (2) scope, duration, and significance of abuse; and (3) any risk the substances poses to the public health. DEA completed the Three-Factor Analysis on fentanyl-related substances prior to temporarily scheduling them.

[10]As of September 2020, DEA told us that it had initiated the process of permanently scheduling these 11 substances based on HHS's July 2020 recommendation.

HHS regarding this analysis are ongoing, and HHS expects to provide an update to DEA on its progress prior to the expiration of the temporary scheduling of fentanyl-related substances on May 6, 2021.

HHS's completion of the Eight-Factor Analysis would be required for DEA to administratively schedule fentanyl-related substances, but it would not be required to legislatively schedule them.[11] Representatives of six of the 11 research organizations we interviewed emphasized the importance of considering the scientific evidence, including pharmacological activity, in any scheduling decision. For example, a stakeholder told us that a scheduling decision made without the Eight-Factor Analysis would be based on insufficient evidence. Another representative of a research organization told us that the scientific expertise of HHS, FDA, and the National Institute on Drug Abuse (NIDA) should be used in making scheduling decisions.

**Rescheduling and descheduling.** If the class of fentanyl-related substances—as currently defined—is permanently placed in Schedule I, then rescheduling (moving a substance to a different schedule) or descheduling (removing a substance from control) would be necessary for any individual fentanyl-related substance that is later discovered through research to have medical use or low or no abuse potential. Such a substance may be rescheduled or descheduled by the same processes used to schedule substances, either legislatively or administratively by DEA with input from HHS. DEA officials told us that they were unaware of any instances where Congress had rescheduled a substance.

To reschedule or deschedule a substance administratively, DEA would require evidence from HHS's Eight-Factor Analysis—and from an FDA approval, in the case of establishing a medical use—to establish that a fentanyl-related substance does not belong in Schedule I. For a substance placed in Schedule I administratively, an Eight-Factor Analysis to support rescheduling or descheduling would need to provide new evidence that refutes the earlier recommendation to place it in Schedule I. However, for a substance placed in Schedule I legislatively, an Eight-Factor Analysis to support rescheduling or descheduling may be the first such assessment of the substance's pharmacological activity, as legislative scheduling does not require completion of an Eight-Factor Analysis.

[11]See 21 U.S.C. § 811(b)-(c).

- DEA may remove a substance from Schedule I if the substance has an accepted medical use based on HHS's analysis and recommendation. For example, DEA moved one substance unrelated to fentanyl, Epidiolex—which contains cannabidiol, at the time a Schedule I substance—to Schedule V following Food and Drug Administration (FDA) approval of the substance for the treatment of seizures.[12] Apart from FDA approval, DEA and HHS may determine that a substance has an accepted medical use in treatment in the United States if it meets a five-part test, which includes that scientific evidence must be widely available.[13]
- DEA may remove a substance from Schedule I if the substance has low abuse potential based on HHS's analysis and recommendation. DEA has not removed an administratively scheduled substance from Schedule I because of its low abuse potential, but it has removed temporarily scheduled substances from Schedule I for that reason. For example, in September 2002, DEA temporarily placed a substance called TFMPP in Schedule I, then removed it from control in March 2004 after HHS completed its evaluation and did not recommend its scheduling.[14]

Representatives of five research organizations whose work may be affected by scheduling and rescheduling actions told us that the rescheduling process takes a long time and the evidence can be difficult to gather.[15] Therefore, three of these research organizations suggested the process be modified to allow for expedited rescheduling of substances with medical uses or low abuse potential. DEA officials told us that the rescheduling process would generally be triggered by FDA

[12]See 83 Fed. Reg. 48,950 (Sept. 28, 2018). Following DEA's classification of Epidiolex as a Schedule V substances, Epidiolex was removed from classification as a controlled substance based on the Agricultural Improvement Act of 2018, which removed cannabidiol from Schedule I. See Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018 (2018).

[13]To meet the five-part test, all of the following must be demonstrated: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.

[14]TFMPP in combination with BZP (currently controlled in Schedule I) was found to be promoted as an alternative to MDMA or Ecstasy. Similarly, DEA temporarily placed benzylfentanyl and thenylfentanyl in Schedule I based on structure, but removed them when further research found no evidence of abuse potential.

[15]For example, in a challenge to the classification of marijuana as a Schedule I substance that was dismissed, plaintiffs documented that the average time in deciding petitions to reclassify drugs under the CSA is approximately 9 years.

approval of a drug, and that the evidence required for rescheduling a Schedule I drug is necessary and appropriate considering the potential danger of these substances.

An interagency workgroup—coordinated by ONDCP with DEA, Office of the Assistant Secretary for Health, National Institutes of Health, NIDA, and FDA—provided a recommendation to Congress to modify the process to reschedule or deschedule fentanyl-related substances, according to ONDCP officials.[16] While recommending the adoption of class-wide scheduling for fentanyl-related substances, the workgroup also recommended Congress make changes to enable rapid removal from Schedule I of any fentanyl-related substances that HHS determines to have low or no abuse potential. According to ONDCP, this recommendation reflects the agencies' expectation that HHS continues to research fentanyl-related substances, and that it may identify fentanyl-related substances with low or no abuse potential that should be rescheduled or descheduled in a timely manner. Specifically, the workgroup's recommendation would reduce the scientific and medical evidence HHS must compile for rescheduling or descheduling to four of the eight factors currently required—(1) the state of current scientific knowledge regarding the substance, (2) the substance's actual or potential for abuse, (3) scientific evidence of its pharmacological effect, and (4) any risk the substance poses to the public health. Additionally, the workgroup's recommendation would require DEA to act on HHS's recommendation within 90 days of receiving HHS's conclusions for substances with no abuse potential and 180 days for substances with low abuse potential.

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[16] See Appendix III for more detail on the interagency workgroup's recommendations related to research.

# Appendix III: Potential Effects of Class-Wide Scheduling on Research

This appendix includes information on the potential effects of the U.S. class-wide scheduling of fentanyl-related substances on research, based on the temporary scheduling of these substances that is due to expire in May 2021. To study Schedule I substances, researchers must follow Drug Enforcement Administration (DEA) requirements to receive authorization from their states and institutions (such as universities) and apply for a registration with DEA. Our interviews with federal officials and representatives from research organizations and our review of related literature and DEA data suggest that registration requirements may present challenges that may reduce opportunities for research on potential dangers or medical uses of fentanyl-related substances, and federal agencies have made recommendations to help address these challenges and make it easier to obtain approval to research Schedule I substances.

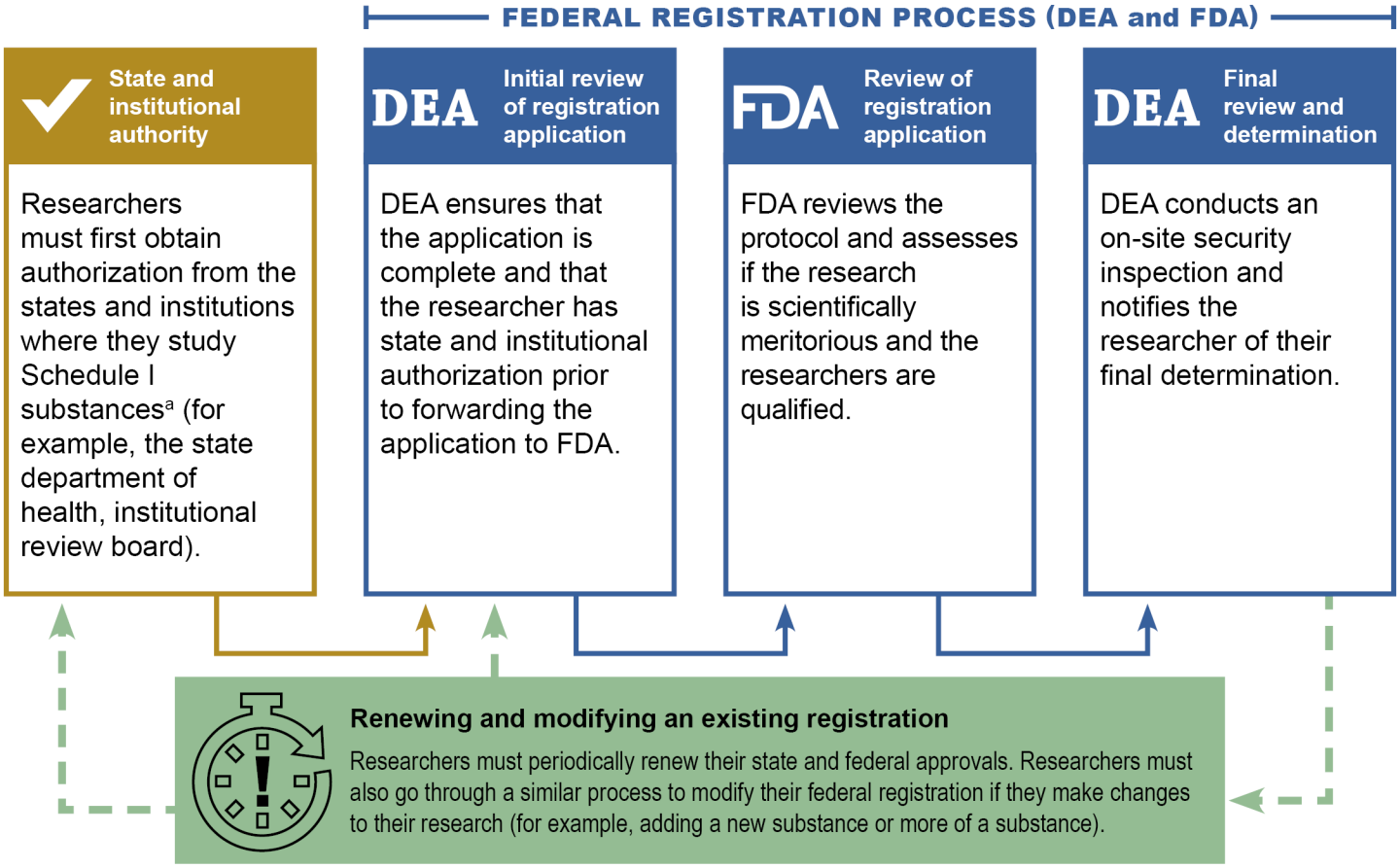
**Role of research.** Research has shown that the functional effects of drugs with similar structures may vary significantly. Small changes in the chemical structure of opioids can produce substances with increased potency—such as carfentanil, which is 100 times more potent than fentanyl.[1] Similarly, small changes can produce substances with little to no pharmacological potential for abuse—as was found for two fentanyl analogues cited by DEA in the temporary scheduling order for fentanyl-related substances. Other changes in the chemical structure of some opioids have produced medications used in treating opioid use disorder—the misuse of, or addiction, to opioids—and preventing opioid overdoses. For example, naloxone—used to treat heroin and other opioid overdoses—is structurally similar to heroin but has a very different effect. An injection of naloxone can almost immediately neutralize a heroin overdose. As a result, the Assistant Secretary for Health testified in January 2020 that research on fentanyl-related substances and other synthetic opioids is important in the development of new and improved treatments for opioid addiction and overdose, chronic pain, and other medical conditions.

**Research registration requirements.** To study Schedule I substances, including fentanyl-related substances, researchers must obtain the relevant authorities from the states and institutions where they conduct their work and then apply for a registration with the DEA, which entails a review by both DEA and the Food and Drug Administration (FDA).

[1]For example, carfentanil has the same chemical structure as fentanyl, with the addition of two carbon, two hydrogen, and two oxygen atoms.

Researchers must also periodically renew their state and federal authorities as well as modify their registration with DEA if they make changes to their approved research. Figure 3 below depicts this process.

**Figure 3: Researchers Require Institutional, State, and Federal Approval to Study Schedule I Substances**




Legend: DEA= Drug Enforcement Administration; FDA=Food and Drug Administration.

Source: GAO interviews with Department of Justice and DEA officials and review of DEA and Washington State Department of Health documents. | GAO-21-499

[a]Schedule I substances are those that have been found to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

- **State and institutional authorization:** Researchers must first obtain authorization from the states and institutions where they will study Schedule I substances, before applying for DEA registration. Specific requirements vary by state and institution, according to researchers we spoke with and agency officials. A researcher may have to

demonstrate compliance with rules regarding clinical research and the security of the controlled substances that will be used in the research, as well as demonstrate the scientific validity of the proposed work. The researcher may be required to register with the state Department of Health and hold a license from the agency that regulates a researcher's particular discipline, such as a state board of medicine. Research facilities may be subject to inspection by state officials, and state registrations require periodic renewal. Similarly, researchers must also receive authorization from their institution. For example, Institutional Review Boards at hospitals and universities examine research protocols to ensure that research subjects are adequately protected.

- **Initial DEA review of registration application**: After obtaining the necessary state and institutional authorization, a researcher must apply to receive a registration from DEA. Registration applications include information such as the researcher's professional curriculum vitae, substances being studied and their amounts, and the location(s) where the research will take place, according to DEA officials. Schedule I research registration applications encompass a wide range of research, detection, synthesis, or pharmacological studies, according to DEA officials. Researchers must state the security provisions in place to securely store and handle Schedule I substances and are subject to on-site DEA inspections. According to DEA officials, the agency reviews submitted applications to ensure that all the necessary information is included and communicates with the applicant if any additional information is required.
- **FDA review of registration application:** Once DEA completes its initial review to ensure the application is complete, it sends the application to FDA for review and determination. In this step, FDA assesses the scientific merit of the research and the qualifications of the researchers, according to DEA and FDA officials. FDA then makes a recommendation about whether the research should be approved for a registration and returns the application to DEA. Per regulation, DEA is to process and forward a completed application to FDA within 7 days, and FDA is to review and notify DEA of its determination within 21 days for preclinical studies and 30 days for clinical studies.[2]
- **DEA final review and determination:** Following FDA approval, the application then returns to DEA for final review and determination. This includes an on-site inspection of research facilities for security of

[2]21 C.F.R. § 1301.32(a). Clinical studies involve research on human subjects.

the controlled substances and a background inspection of the researcher and individuals handling the controlled substances. DEA then notifies the researcher of its final determination.

**Maintaining and modifying an existing registration.** Researchers must periodically renew their registration. States vary with regard to how often researchers must renew their authorization with the relevant state agencies, while a DEA registration must be renewed annually, according to DEA officials. According to these officials, researchers must also go through a process similar to that for the initial registration application to modify their registration if they plan to make changes to their research, including when a researcher increases the amount of a Schedule I substance being studied, works with a substance that has been newly scheduled, or changes their research protocol. According to DEA officials, researchers typically go through multiple modifications as they change the amounts of a substance they are using in their work. DEA officials noted that class-wide scheduling could have the benefit of allowing researchers the possibility of using a research protocol broadly focused on the class of fentanyl-related substances, and in this case, their DEA registration could allow them to study additional fentanyl-related substances without the need for modification. However, the officials noted that the researcher would still have to have the revised research protocol reviewed and approved by HHS.

**Challenges for researchers studying Schedule I substances.** There are a number of challenges associated with research on Schedule I substances, according to representatives from research organizations and articles we reviewed.

- **The registration process may be confusing:** The combination of state and federal requirements to research Schedule I substances may be challenging for researchers and can create confusion, according to federal officials and representatives from three research organizations. For example, according to NIH officials, some researchers are unclear about whether multiple researchers could work under a principal investigator's registration and whether there can be institution-wide registration, or if a registration is needed for all locations where work is being done. Both are allowed, according to DEA officials. According to DEA officials, 70 percent of registration applications submitted in 2019 were incomplete when first submitted, which could be a result of researchers' confusion. Many applications do not include required information such as the source of a controlled substance, or documentation of state and institutional authorization. The back and forth between the agency and the researchers to

complete these applications takes time, DEA officials said. The officials acknowledged that there is some confusion regarding Schedule I registration requirements among researchers, and that the agency could do a better job communicating the requirements and options to researchers. According to DEA officials, DEA is willing to work with researchers to accomplish their research goals. For example, DEA provides researchers with a checklist at its Diversion Control Division website to help them prepare for and navigate the application process to research Schedule I drugs.

- **The Schedule I registration process can be resource intensive.** According to representatives from five research organizations and two articles we reviewed, the registration process can be aided by resources that are not available to all researchers or institutions.[3] For example, some institutions, such as research universities, have established compliance offices to help researchers navigate the registration process.[4] These programs require financial and personnel resources that may be a challenge for other, smaller institutions. One researcher told us he does not have a Schedule I registration because he is at a small institution that lacks the resources to manage the registration process, and he is unable to manage it without that support. Two research organizations we spoke with also stated that the process to modify an existing registration can be especially challenging for those studying fentanyl-related substances, because new fentanyl-related substances are discovered frequently, and research may involve the search for new substances, which could require researchers to modify their registrations when they find such new substances.
- **The registration process can be time consuming.** Federal officials, representatives from six research organizations, and articles we reviewed identified ways in which the process to gain approval to research Schedule I substances is time consuming.[5] This process includes many components and requirements at the institutional, state, and federal level. Each stage in the process takes time, and the

[3]J. Dodge, "When the DEA comes knocking," *Journal of Chemical Health & Safety*, vol. 18, no. 3, (2011): p. 23-27; M. Marks, "Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles," *Journal of Legislation and Public Policy*, vol. 21, (2018): p. 69 – 140.

[4]Dodge, "DEA comes knocking," p. 23-25.

[5]Editors, "End the Ban on Psychoactive Drug Research," *Scientific American*, vol. 310, no. 2*,* (2014); D. J. Nutt, L. A. King and D. E. Nichols, "Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation," *Nature Reviews Neuroscience,* vol. 14, August 2013, p. 577-585.

federal portion of the approval process cannot proceed unless researchers first have state and institutional authorization, according to DEA officials. The need to secure these authorities takes time and can result in delays. For example, Institutional Review Boards may not meet frequently, which leads to delays in securing institutional authorization and beginning the federal registration process, according to DEA officials. Officials at the National Institutes of Health (NIH) and some research organizations we spoke with stated that it can take more than a year to gain all of the necessary approvals to conduct research on Schedule I substances. In terms of the federal portion of the review process specifically, DEA data indicate that median overall review time for complete applications was about 2 months, though there was wide variation.[6] See Table 2 below for information on application processing time for applications to research fentanyl-related substances from February 2018 through January 2020.[7] In addition, the process to modify an existing registration is similar to applying for a new registration according to DEA officials, and our analysis of DEA data show that median overall review time to modify an existing registration is longer than that of new applications.

**Table 2: Federal Research Registration Application Processing for Fentanyl-Related Substances, February 2018 through January 2020**

| Time Frame | Median | Minimum | Maximum |
|---|---|---|---|
| Days between application received and application received in full | 2 | 0 | 120 |
| Days between application received in full and researcher notified of result | 56 | 19 | 216 |
| Days between application received in full and sent to FDA | 5 | 0 | 75 |
| Days between application sent to FDA and FDA approval | 29 | 8 | 141 |

Source: GAO review of DEA data on processing of applications to register to conduct research on fentanyl-related substances, February 2018 through January 2020 (N=28). These data include applications from researchers seeking new Schedule I registrations (N=9) as well as researchers modifying existing Schedule I registrations (N=19). | GAO-21-499

- **There may be a stigma associated with studying Schedule I substances.** According to representatives from three research organizations and articles we reviewed, the study of Schedule I substances comes with a stigma and concern for the reputations of

[6]There is wide variation with regard to how long it takes a registration application to move through each stage in the process. While median review times for DEA to pass an application to FDA and for FDA to make its determination fall within required time frames, some instances took longer than allowed by regulation. According to DEA, these delays are the result of the need to communicate with the applicants to resolve missing information or other errors, and the result of competing workloads and priorities.

[7]DEA did not provide detailed application timeline information for all Schedule I applications.

researchers, institutions, clinical trial participants, and funders, because these substances are designated as illicit drugs with no currently accepted medical use in treatment.[8] Researchers and institutions may be concerned about being associated with research on a Schedule I substance.

**Research on potential medical uses of controlled substances.** Research on Schedule I substances does occur, but the challenges of obtaining the necessary approval to do so may result in less research on Schedule I substances, according to research organizations we spoke with and articles we reviewed. As a result, according to these sources, there are fewer opportunities to study what makes these substances dangerous as well as their possible medical benefits compared to other substances. For example, according to some research organizations we spoke with, researchers—particularly students and junior scientists—will avoid these challenges by focusing their research projects on substances that do not require a Schedule I registration.

According to some research organizations and articles we reviewed, these challenges present a "catch-22," in which a Schedule I designation labels a substance as having no medical value, and this designation makes it difficult for researchers to study the possibility that a substance may indeed have medical value.[9] Representatives from research organizations we interviewed and articles we reviewed stated that research is needed to help understand why Schedule I substances may be toxic, how to mitigate the risk of overdose, and their potential ability to be used as treatments for a variety of medical issues.[10] One representative from a research organization described how fentanyl-based compounds are used to synthesize vaccines against opioid misuse and in antibody-based diagnostic kits, and therefore stated that a

[8]M. H. Andreae, et al., "An Ethical Exploration of Barriers to Research on Controlled Drugs," *American Journal of Bioethics*, vol. 16, no. 4, (2016): p. 36–47; S. J. Belouin, and J. E. Henningfield, "Psychedelics: Where we are Now, Why we Got Here, what we Must Do," *Neuropharmacology*, vol. 142, (2018): p. 7-19; Nutt et al., "Effects of Schedule I Drug Laws," p. 577; Rhodes et al., "Stakeholders' Views on Barriers to Research on Controversial Controlled Substances," *Journal of Clinical Ethics,* vol. 27, no. 4 (2016): p. 308–321; Marks, "Psychedelic Medicine," p. 93.

[9]Nutt et al., "Neuroscience Research," p. 578; A. Kreit, "Controlled Substances, Uncontrolled Law," Albany *Government Law Review*, vol. 6 (2013): p. 331-357; Andreae, "Ethical Exploration," p. 40.

[10]Kreit, "Controlled Substances, Uncontrolled Law," p. 353; Andreae et al, "Ethical Exploration," p. 6; Nutt et al., "Neuroscience Research," p. 577.

Schedule I classification could be an obstacle in the development of life-saving drugs or other diagnostic tools.[11] Another representative from a research organization we spoke with raised the example of naloxone, an opioid that is used to reverse overdoses, as an example of how a substance similar in structure to a controlled substance may have therapeutic value. Because evidence-based research is required to change how a substance is scheduled, research organizations also noted that the challenges of researching Schedule I drugs also make it more difficult to generate the evidence needed to reschedule these substances, as may be appropriate.

Officials from DEA and research organizations we spoke with provided mixed views with regard to the extent to which registration requirements hinder research on Schedule I substances. Officials from DEA and the Office of National Drug Control Policy (ONDCP) stated that classifying a substance into Schedule I is not intended to inhibit research. DEA officials told us that, as of July 16, 2020, there were 819 active registrants approved to conduct research with Schedule I substances, and that these approvals indicate that researchers interested in studying Schedule I substances are doing so. These active registrants included 27 researchers who applied for and received approval to study fentanyl-related substances since they were temporarily scheduled in 2018, and all researchers who applied to study these substances were approved.[12] However, representatives from three research organizations and two articles we reviewed also describe how a Schedule I designation has stalled research of specific substances and their ability to be used as treatments for a variety of medical issues. For example, these articles indicate that a Schedule I designation has impeded research on treatment for HIV, depression, and post-traumatic stress disorder.[13] Three articles also argue that a Schedule I designation has limited research on the potential medical uses of Schedule I drugs including marijuana and

[11]For more information on opioid vaccines, see GAO, *Science and Tech Spotlight: Opioid Vaccines*, GAO-19-706SP (Washington, D.C.: September 2019).

[12]There was one additional researcher approved to study fentanyl-related substances that did not have an active registration as of June 12, 2020. Among the 27 active registrations, 11 were for “Research for detection, detection devices, or analytical techniques,” 2 were for “Research for detection, detection devices, or analytical techniques – Department of Defense grant,” 4 were for “Synthesis and Pharmacology research,” 4 were for “Pharmacology research,” 1 was for “Pharmacology research - for DEA Contract,” and 5 were for “DEA Contractor- Pharmacology Studies.”

[13]Andreae et al., “Ethical Exploration,” p. 5-6; Nutt et al., “Neuroscience Research,” p. 582.

psychedelics.[14] In written comments, DEA disputed these assertions and stressed that there have been no impediments pertaining to research of fentanyl-related substances.

**Proposed measures to facilitate research on Schedule I substances.** Federal officials and researchers have proposed measures to facilitate research on Schedule I substances and address some of the challenges outlined above. These proposals include recommendations from an interagency workgroup facilitated by ONDCP as well as other proposals suggested by representatives of research organizations we spoke with and articles we reviewed.

ONDCP officials said that they organized the interagency workgroup to help generate recommendations for possible inclusion in legislation to permanently schedule fentanyl-related substances as Schedule I. Their recommendations included modifications to facilitate research on the class of fentanyl-related substances placed in Schedule I and to clarify existing provisions related to research on Schedule I substances.[15] According to these officials, the interagency workgroup included DEA, the Department of Health and Human Services, NIH, the National Institute on Drug Abuse, and FDA. The interagency workgroup recommendations included enacting legislation to accomplish the following goals:

- Enable rapid and mandatory removal from schedule I of drugs certified by HHS to have no potential for abuse.
- Based on scientific evaluation by HHS, allow DOJ to remove a substance from scheduling, for research purposes only.
- Clarify that individuals who are agents or employees of the person holding the research registration are not required to have a separate registration.

[14]See J. M. Bostwick, "Blurred Boundaries: The Therapeutics and Politics of Medical Marijuana," *Mayo Clinic Proceedings*, vol. 87, no. 2, (2012) p. 172-186. See also National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Researc*h. (Washington, D.C.: The National Academies Press, 2017). Examples of psychedelic drugs include D-lysergic acid diethylamide (LSD), psilocybin, and methylenedioxymethamphetamine (MDMA).

[15]See Appendix II for more detail on the interagency workgroup's recommendations related to rescheduling.

- Allow registered researchers to store, administer, and otherwise work with any substances for which they hold a researcher registration at multiple practice sites on a single contiguous campus.
- Allow a researcher who is registered to study a controlled substance to perform limited manufacturing activities on small quantities of that substance consistent with their research protocol (for example, creating a particular dosage formulation for research purposes), and to do so without having to obtain a separate manufacturing registration.
- Allow individuals conducting research with a substance subsequently placed into Schedule I, who hold a registration to conduct research with any other Schedule I or Schedule II substance, to continue work on the newly scheduled substance until their new or amended registration application is approved or denied.
- Clarify that if a person is registered to conduct research with a controlled substance and applies to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, the inspection that was performed for purposes of the existing registration shall be sufficient to support the application.
- Require the Attorney General and the Secretary of Health and Human Services to conduct a review of the process for obtaining or modifying a research registration under the Controlled Substances Act to identify redundancies, inefficiencies, or burdens on persons seeking registrations that can be reduced while ensuring public safety; subsequently require the Attorney General and the Secretary of Health and Human Services to issue joint guidance clarifying the registration process.

According to ONDCP officials, class-wide scheduling in Schedule I under the temporary scheduling order provides an unprecedented level of control over fentanyl-related substances. The interagency workgroup's recommendations were intended to ensure that research on fentanyl-related substances could continue amidst their classification as Schedule I substances, according to these officials. These proposals have not been included in enacted legislation as of March 2021, but these officials told us that implementing such proposals would be important if class-wide scheduling becomes permanent. Other proposals to facilitate research on

Schedule I substances were suggested by representatives from research organizations we spoke with and articles we reviewed.[16] These include:

- Creating a new type of registration for scientists using small amounts of substances.
- Establishing a new scheduling category for all analogues.
- Simplifying the registration/modification process.
- Allowing concurrent review of state, federal, and institutional applications.

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[16]Nutt et al., "Neuroscience Research," p. 587; 2013; Dodge, "DEA Comes Knocking," p. 24.

# Appendix IV: Potential Effects of Class-Wide Scheduling on Federal Law Enforcement Efforts

This appendix includes information on the potential effects of the U.S. class-wide scheduling of fentanyl-related substances on federal law enforcement efforts, based on the 2018 temporary scheduling of these substances that is due to expire in May 2021. Law enforcement officials and other stakeholders had competing views on the potential effects of class-wide scheduling on investigations and prosecutions of fentanyl-related substance cases. For example, officials from the Drug Enforcement Administration (DEA), Executive Office for United States Attorneys (EOUSA), and other law enforcement agencies reported that such scheduling reduces incentives to illicitly manufacture fentanyl-related substances; has led to a decrease in reports of law enforcement encounters (e.g., seizures) with these substances, which could reduce overdose deaths; and could result in more consistent outcomes for prosecutions involving these substances. However, other stakeholders stated that class-wide scheduling could result in convictions for substances that may not have a psychoactive effect substantially similar to fentanyl, impose lengthy sentences for offenses involving trace amounts of fentanyl-related substances, and perpetuate racial disparities in sentencing, among other concerns.[1]

**Reduced incentives to manufacture fentanyl-related substances.** Officials from almost all of the federal law enforcement agencies and law enforcement associations we spoke with—such as the DEA, Federal Bureau of Investigation, EOUSA, and Organized Crime Drug Enforcement Task Forces (OCDETF) strike forces—stated that class-wide scheduling reduces incentives for criminal entities to create, manufacture, and traffic fentanyl-related substances to circumvent law enforcement.[2] For example, officials from one DEA field division office stated that, because all fentanyl-related substances are Schedule I drugs under class-wide scheduling, criminal organizations have fewer incentives to attempt to evade prosecution by manufacturing these substances or making minor structural modifications to fentanyl to produce new

[1]We spoke with federal public defenders and representatives from five criminal justice reform and civil rights organizations.

[2]We interviewed headquarters officials from the DEA, Federal Bureau of Investigation, and EOUSA and field officials in four DEA field division offices, four U.S. Attorney's offices, and four OCDTEF strike forces. We also interviewed representatives from three law enforcement associations. See appendix I for the offices, strike forces, and associations we interviewed and our selection methodology.

analogues that are not individually scheduled.[3] In addition, officials from two of the three law enforcement associations we interviewed likened drug control efforts prior to class-wide scheduling to a game of "whack-a-mole," in which DEA would individually schedule analogues but face the constant challenge of keeping up with new ones that emerged. DEA headquarters officials stated that, prior to class-wide scheduling, DEA was continually in a reactive position when trying to control these highly potent substances. According to these officials, individually scheduling a new analogue that emerged using a temporary order typically took over a year to complete and during that time, more new analogues would be reported.[4] They noted that if class-wide scheduling expires, fentanyl-related substances would no longer be scheduled and criminal organizations would likely resume or increase production of these substances.[5] According to other Department of Justice (DOJ) officials, because very small amounts of fentanyl-related substances can be lethal, this could lead to increases in overdose deaths.

**Law enforcement encounters with fentanyl-related substances.** According to DEA headquarters officials, class-wide scheduling has helped reduce the number of reports of domestic law enforcement encounters with fentanyl-related substances. As previously discussed, fentanyl-related substances are defined as substances with a chemical structure related to fentanyl that have not been individually scheduled.[6]

[3]Prior to class-wide scheduling, fentanyl-related substances were unscheduled, and prosecuting offenses involving these substances could be complex and resource intensive, as discussed later in this appendix.

[4]As discussed earlier in this report, DEA must complete a Three-Factor Analysis to temporarily schedule illicit substances under its emergency scheduling authority, which officials noted requires a multi-step process and 30-day notice period. According to DEA officials, documenting the actual or potential harm of a substance for this analysis can be challenging depending on the availability of detection methods and data or studies on pharmacological activity and overdose deaths. DEA has generally temporarily scheduled fentanyl analogues to control them before permanently scheduling them.

[5]As discussed earlier in this report, prior to class-wide scheduling, DOJ officials said that they used the Controlled Substance Analogue Enforcement Act of 1986 (Federal Analogue Act) to prosecute cases for offenses involving unscheduled fentanyl analogues. The act requires prosecutors to prove multiple elements related to chemical structure and psychoactive effect, among other things, for the analogue to be treated as a Schedule I controlled substance in the particular criminal case. See 21 U.S.C. §§ 802(32), 813.

[6]After class-wide scheduling, fentanyl analogues that are not individually scheduled by name and structurally related to fentanyl by one or more modifications to its chemical structure, as outlined in DEA's temporary order, are considered fentanyl-related substances and controlled as a class under Schedule I of the Controlled Substances Act.

Class-wide scheduling is intended to more effectively control these analogues by classifying them collectively as Schedule I drugs. Our analysis of DEA data on reports of law enforcement encounters with fentanyl analogues not individually scheduled indicates that reports have decreased since 2018. However, we did not conduct an analysis to determine the cause of the decrease due in part to the short time period that class-wide scheduling has been in effect and the multiple other factors that could affect the number of encounters with these substances.

DEA measures domestic law enforcement encounters with illicit substances through its National Forensic Laboratory Information System (laboratory information system), which collects reports from participating federal, state, and local laboratories of drugs obtained in law enforcement operations (e.g., seizures and undercover buys).[7] Specifically, a law enforcement encounter resulting in seizure of an illicit substance that is submitted to one of these laboratories and analyzed produces a confirmed report of this substance in DEA's laboratory information system.[8] Our analysis of data provided by DEA from this system indicates that the number of reports of fentanyl analogues not individually scheduled have decreased since 2018, after DEA's temporary class-wide scheduling order and the scheduling of 11 fentanyl analogues by name shortly before the order was issued.[9] Specifically, in 2016 and 2017, there were 7,058 law enforcement reports of encounters with fentanyl

[7]Participation in the DEA's laboratory information system is voluntary, but DEA reported that, as of June 2020, more than 98 percent of the national drug caseload is represented by laboratories that have joined the system.

[8]DEA officials noted that not all law enforcement encounters with illicit substances are submitted to laboratories and about 30 percent of submissions are not analyzed. For example, officials said that laboratories with large backlogs may not analyze all substances submitted, and investigators and prosecutors may not request laboratory analyses if a plea deal is made.

[9]The majority of law enforcement reports during these years were for encounters with fentanyl analogues that have been individually scheduled, which is not the focus of this appendix. DEA laboratory information system tables show that overall, the number of reports of all fentanyl analogues and other related compounds (e.g., precursors), including individually scheduled analogues, have increased since 2018. Specifically, there were 28,464 total reports of fentanyl analogues and other related compounds in 2016 and 2017 and 43,967 reports in 2018 and 2019. DEA Diversion Control Division, Table 3. State Counts for Fentanyl and Fentanyl-related Compounds, 2016-2019, accessed on June 11, 2020 and September 16, 2020, https://www.nflis.deadiversion.usdoj.gov/Resources/NFLISPublicResourceLibrary.aspx. However, our analysis focuses on fentanyl analogues that are not individually scheduled because class-wide scheduling specifically applies to only these substances.

analogues that were not individually scheduled by name when submitted to forensic laboratories for analysis. In contrast, there were 787 reports of encounters with these analogues—now classified as fentanyl-related substances—in 2018 and 2019.[10] Law enforcement reports of encounters with the 11 analogues scheduled by name totaled 2,633 in 2018 and 2,432 in 2019 and were not included as fentanyl-related substances under DEA's order because they were already scheduled. While excluding these reports in 2018 and 2019 substantially contributed to the lower number of analogue reports classified as fentanyl-related substances, DEA officials stated that the sustained reduction in fentanyl-related substance encounters after the agency's temporary order indicates that class-wide scheduling has been effective in reducing incentives to manufacture these substances. According to other DOJ officials, this likely reduced overdose deaths from fentanyl-related substances.

In addition, DEA reported that the number of new fentanyl analogues the agency has identified decreased since the temporary class-wide scheduling order was issued in February 2018, which according to officials, helps demonstrate that the order is working as intended. Specifically, on the basis of its laboratory information system data and other sources, DEA identified 26 new fentanyl analogues (e.g., phenyl fentanyl) from 2016 through January 2018 and 12 new fentanyl analogues (e.g., para-fluoro furanyl fentanyl) after class-wide scheduling, as of July 31, 2020.[11] DEA noted that many of the new fentanyl analogues identified in 2016 and 2017 were encountered at high rates compared to the new analogues identified after class-wide scheduling. For example, DEA laboratory information system data show that there were 2,149 law enforcement reports of acryl fentanyl in 2016 and 2017,

[10]According to DEA officials, data from the National Forensic Laboratory Information System are reliable and complete through 2019. They noted that the 2020 data are still pending as laboratories continue to process submissions and will not be complete until spring 2021, or possibly later due to the Coronavirus Disease 2019 (COVID-19) pandemic.

[11]As of August 2020, nine of the new fentanyl analogues identified in 2016 and 2017 have been individually scheduled by name.

which was more than four times the total number of reports for all 12 new fentanyl analogues identified after class-wide scheduling.[12]

Although the timing of DEA's temporary order corresponds to a decrease in law enforcement reports of encounters with fentanyl analogues that are not individually scheduled and the number of new fentanyl analogues identified, we did not conduct an analysis to draw conclusions about the extent to which the cause of the decrease is related to class-wide scheduling. This is because of the short time period that the order has been in effect—only 2 years of data on law enforcement encounters after class-wide scheduling were available—and the numerous other factors that could affect law enforcement reports of these analogues, including fentanyl-related substances. Specifically, as discussed above, DEA individually scheduled 11 fentanyl analogues by name shortly before class-wide scheduling took effect in 2018, which were subsequently not included as fentanyl-related substances. In addition, DEA headquarters officials noted that international regulatory controls, such as class-wide scheduling of fentanyl analogues in China, could affect law enforcement encounters with fentanyl analogues, and that China's class control has worked collectively with class-wide scheduling in the United States to deter the production of fentanyl-related substances.[13]

DEA officials stated that it is highly likely that class-wide scheduling, individually scheduling analogues by name, and international controls all contributed to the low number of law enforcement reports of encounters with fentanyl-related substances after DEA's temporary scheduling order took effect. Further, DEA headquarters and field officials, as well as officials from the Department of Homeland Security, told us that many other factors, such as the price and availability of fentanyl analogues and other drugs, drug screening and detection capabilities, and law enforcement priorities could also have an effect on reports of fentanyl analogues. However, DEA officials stated that, notwithstanding the

[12]The number of law enforcement reports of new fentanyl analogues identified after class-wide scheduling include reports of two substances that, according to DEA officials, do not have specific names or a defined chemical structure but would fall under the definition of fentanyl-related substances.

[13]According to DEA intelligence Report, *Fentanyl Flow to the United States*, DEA-DCT-DIR-008-20 (Jan. 2020), China was a major source country for fentanyl-related substances that were trafficked into the United States. The Chinese government reported that it placed "fentanyl-related substances" as a class on its list of scheduled substances effective May 1, 2019. See appendix V for more information on China's class-wide scheduling law and its potential effect on the flow of fentanyl and its analogues to the United States.

potential effects of other factors, class-wide scheduling has been the primary contributor to lowering the number of new fentanyl analogues encountered in the United States.

**No major effects on conducting investigations**. Officials from all four DEA field division offices and four OCDETF strike forces we interviewed indicated that, overall, class-wide scheduling has not or would not have a substantial effect on how they conduct investigations involving fentanyl-related substances, such as the time and resources needed to investigate cases. Officials from seven of these eight field offices and strike forces stated that, in most cases, agents seize substances that are composed of a mixture of different drugs and do not know whether a fentanyl-related substance is involved until forensic laboratories analyze the results. In addition, officials from four of these field offices and strike forces noted that investigations are generally focused on drug trafficking organizations and not the specific drugs involved.

Further, according to DEA headquarters officials, class-wide scheduling has had no effects on drug diversion investigations of fentanyl-related substances because these investigations are primarily focused on pharmaceuticals from legitimate sources (e.g., prescription drugs) and not substances classified under Schedule I.[14] These officials also stated that there have been no known instances of diversion of fentanyl-related substances from researchers approved to study them since class-wide scheduling was implemented.

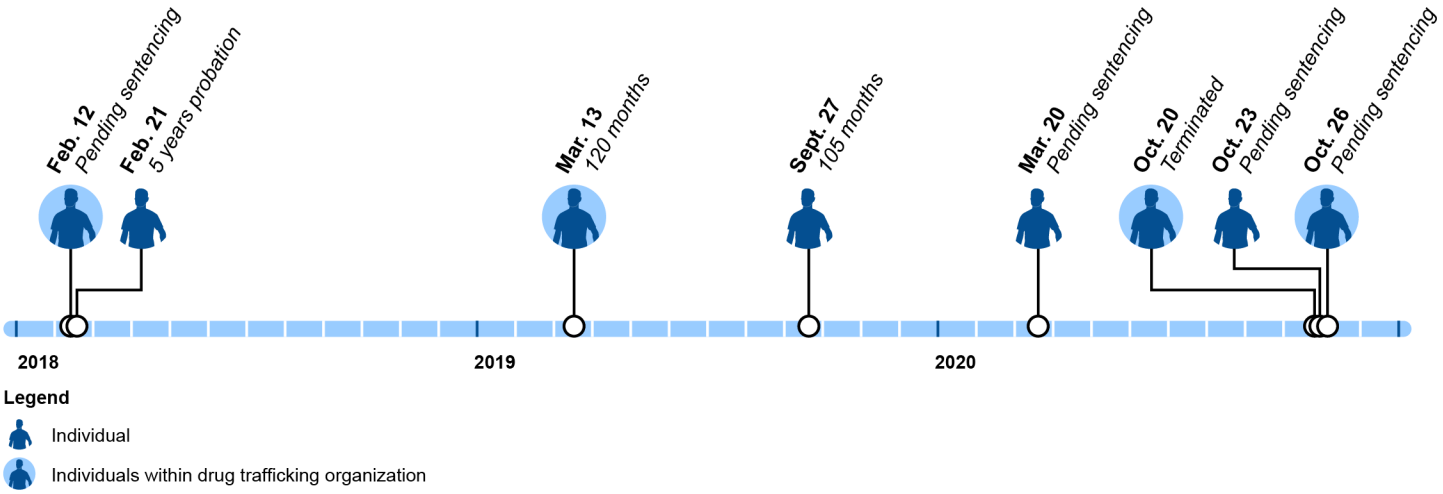
**Prosecutions under class-wide scheduling.** Since DEA's temporary scheduling order in 2018, EOUSA officials reported that eight cases were prosecuted using the class-wide scheduling provision. Law enforcement officials cited potential benefits for prosecuting fentanyl-related substance cases, such as reduced inconsistencies in case outcomes and a reduction in the time and resources needed for prosecuting these cases.

- **Cases prosecuted under class-wide scheduling.** EOUSA officials reported that since DEA's temporary scheduling order in 2018, their U.S. Attorney's Offices prosecuted eight cases using the class-wide

[14]DEA's drug diversion efforts involve preventing, detecting, and investigating the diversion of controlled pharmaceuticals and chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

scheduling provision.[15] Of these cases, four involved individual offenders and four involved individuals who were part of what could be considered larger drug trafficking organizations as street-level dealers.[16] (See fig. 4.)

**Figure 4: Individuals Prosecuted by U.S. Attorney's Offices Using the Class-Wide Scheduling Provision and Sentence Length, as of December 2020**




Source: Analysis of cases identified by the Executive Office for United States Attorneys and Public Access to Court Electronic Records docket information and charging documents. | GAO-21-499

Note: The October 20, 2020 case was dismissed when the defendants were indicted and the case moved to district court where the indictment was sealed. Cyclobutyl fentanyl, the fentanyl-related substance identified in the original complaint, is still charged in the sealed indictment. Additionally, case information is current as of the date it was retrieved from the Public Access to Court Electronic Records system; therefore, some cases may have reached a final disposition and individuals sentenced. Four cases are current as of September 2020, and four are current as of January 2021.

[15]EOUSA officials told us that this information was collected based on its analysis of U.S. Sentencing Commission data, charging documents, and information provided from a data call to all U.S. Attorney's Offices and DEA.

[16]Fentany-related substances from these cases included phenyl fentanyl and cyclobutyl fentanyl, among others. Phenyl fentanyl was the most common fentanyl-related substance present among all cases. For the cases involving drug trafficking organizations, one case involved 22 defendants charged with selling a variety of controlled substances, primarily heroin, fentanyl, fentanyl analogues, crack cocaine, and cocaine. Another case involved a defendant who possessed a substance containing a fentanyl-related substance and conspired with others to import a controlled substance containing a fentanyl-related substance. For the cases involving individuals acting alone, one case involved an individual initially charged with importing a controlled substance including a fentanyl-related substance. Another case involved a street-level dealer charged with possession and distribution of heroin, fentanyl, fentanyl analogues previously scheduled, and a fentanyl-related substance.

- **Potential benefits for conducting prosecutions.** EOUSA officials said that class-wide scheduling could reduce inconsistencies in case outcomes for fentanyl-related substance offenses and reduce the time and resources needed to prosecute these cases. Specifically, without class-wide scheduling, officials told us that prosecutors would need to rely on the Controlled Substance Analogue Enforcement Act of 1986 (Federal Analogue Act) to charge offenses involving fentanyl-related substances and cases for the same substance could generate inconsistent jury findings.[17]

Officials from two U.S. Attorney's Offices and three OCDETF strike force teams we met with said that prosecutors who use the Federal Analogue Act have little certainty that a jury will find the substance is an analogue though they are expending a great deal of time and resources to prosecute cases. According to most of these officials, prosecutors would need to provide expert witnesses to confirm that both the chemical structure and psychoactive effects of the substance were substantially similar to fentanyl. Alternately, officials told us that defendants may also provide similar experts to argue that the substance was dissimilar or does not have a psychoactive effect.[18] Officials stated that because every jury is different and the information jurors must evaluate is very technical, it becomes a "battle of the experts." They noted that juries must assess information from both sets of experts and make a determination on whether or not the information collectively confirms that the substance is a controlled substance analogue.[19] As a result, officials told us that the same substance could be found to be an analogue in one case or jurisdiction but not in another, which could pose potential legal issues for

[17]Controlled Substance Analogue Enforcement Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207-13. See 21 U.S.C. §§ 802(32), 813.

[18]OCDETF officials told us that there is not a definitive test for psychoactive effect since testing on humans is ethically prohibited, so experts must extrapolate the effect.

[19]As discussed earlier in this report, a controlled substance analogue is generally defined as a substance that is not otherwise scheduled or approved by the Food and Drug Administration that is intended for human consumption and has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, and (2) an actual, represented, or intended effect that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance in Schedule I or II. See 21 U.S.C. §§ 802(32), 813.

prosecutors in the future.[20] Under class-wide scheduling, since all fentanyl-related substances are under Schedule I of the Controlled Substances Act, prosecutors do not need to prove that these substances are fentanyl analogues with similar chemical and psychoactive properties as fentanyl. Rather, prosecutors may charge the individual with a Schedule I drug offense as appropriate.

As a result of the difficulties associated with prosecuting cases under the Federal Analogue Act, officials from two U.S. Attorney's Offices and two OCDETF strike force teams said that they avoid prosecuting cases using the act when possible. One official stated that if multiple substances are involved in a case, prosecutors opt to charge the offense under a drug that has already been scheduled, which DOJ officials said may result in charges for less potent drugs and lighter sentences than charges for fentanyl analogues. Based on our review of EOUSA data in fiscal year 2019, at least 143 of 194 reported fentanyl analogue drug cases included one or more Schedule I drugs.[21] In fiscal year 2020, at least 144 of 194 reported fentanyl analogue drug cases included another Schedule I drug.

**Selected stakeholders' concerns about prosecutions.** Representatives from all five civil rights and criminal justice organizations and the federal public defenders we spoke with noted several concerns with class-wide scheduling and its effect on accused persons: no requirement to prove similar psychoactive effect to fentanyl, effect on mandatory minimum sentencing, racial disparities in sentencing, and targets on low-level offenders for prosecution.

- **No requirement to prove similar psychoactive effect to fentanyl.** Representatives from all five civil rights and criminal justice organizations stated that class-wide scheduling may deprive accused persons of the ability to mount an effective defense since class-wide scheduling removes the burden from the federal government to prove that a substance has a substantially similar psychoactive effect as fentanyl and is intended for human consumption. As previously mentioned, under class-wide scheduling, the government does not need to prove that the substance has similar chemical and

[20]EOUSA officials provided an example of three cases prosecuted under the Federal Analogue Act where a substance was found to be an analogue in two cases and determined not to be an analogue in the other case. None of these cases involved a fentanyl analogue or fentanyl-related substance.

[21]Other Schedule I drugs include heroin, ecstasy, and marijuana, among others.

psychoactive properties as fentanyl; rather, the government can charge the individual with a Schedule I drug offense. Because there is no requirement to confirm that the substance has a similar psychoactive effect as fentanyl, representatives from one organization told us that class-wide scheduling assumes that all fentanyl-related substances are harmful with no opportunity to prove otherwise.[22] A representative stated that since Schedule I drugs are determined to be harmful, this classification limits the defendant's ability to challenge criminal charges involving substances that may not have a psychoactive effect substantially similar to fentanyl.[23] Another representative also stated that individuals could be convicted of fentanyl-related substance offenses for these substances despite an unknown psychoactive effect. Representatives we met with from another organization told us that class-wide scheduling creates the risk that people may be convicted and sentenced harshly for offenses involving a substance that may not affect the body or could have beneficial effects such as reversing or blocking the effects of other opioids. Representatives knew of at least three cases where individuals were prosecuted after 2018 for Schedule I offenses involving benzylfentanyl, which has no pharmacological effect.[24] They stated that, in one instance, prosecutors sought the mandatory minimum sentence associated with the charge.

- **Effect on mandatory minimum sentencing.** In addition, representatives from all five civil rights and criminal justice organizations we met with told us that more defendants may be subject to enhanced mandatory minimums for trace amounts of

[22]As mentioned previously, fentanyl is placed in Schedule II because, even though it has high potential for abuse, it also is approved for medical use.

[23]EOUSA officials told us that, in their opinion, it is unlikely that a person would be prosecuted for an offense involving a fentanyl-related substance that did not have a psychoactive effect. If this was to occur, officials told us that they would consult with DOJ, DEA chemists, and others in headquarters to work through the policy issues. Officials confirmed that there is not guidance governing this specific process; however, there is general guidance on steps to take when evidence could be exculpatory.

[24]As discussed earlier in this report, DEA temporarily scheduled benzylfentanyl in 1985 based on its similarity in structure to that of a controlled substance, the likelihood that it would produce pharmacological effects similar to Schedule I or II substances, and its appearance in the illicit market. The agency then removed this substance from control in 1986 because, upon further evaluation, it was determined to have no evidence of abuse potential. In May 2020, DEA controlled benzylfentanyl as a List I chemical due to it being a precursor chemical used to produce fentanyl and DOJ officials noted that this use would be subject to the mandatory minimum if charged in an attempt to produce fentanyl.

fentanyl-related substances under class-wide scheduling.[25] For example, according to representatives from three of these organizations, offenses prosecuted under class-wide scheduling can trigger a mandatory minimum sentence of 5 years for 10 grams or 10 years for 100 grams of a drug mixture containing a detectable amount of a fentanyl analogue. A representative from one of these organizations noted that the 100 grams applies to the entire drug mixture, and because fentanyl-related substances are generally mixed with other drugs, trace amounts of these substances can trigger lengthy sentences.[26] Representatives from four organizations told us that class-wide scheduling may expose more people to mandatory minimum sentences since more substances are classified in Schedule I. Representatives from four of these civil rights and criminal justice organizations specifically noted that, according to their research on U.S. Sentencing Commission data, a substantial proportion of individuals convicted in federal sentencing cases involving illicit fentanyl and fentanyl analogues received a mandatory minimum

[25]Generally, federal judges must impose a statutory minimum term of imprisonment on defendants convicted of various controlled substance offenses and drug-related events. The severity of these sentences depend on a variety of factors, including the nature and amount of drugs involved, the defendant's prior criminal record, and any resulting injuries or death, among other things. These mandatory minimums can range anywhere from 5 years to imprisonment for life but are contingent upon the criminal charges and individuals' circumstances or conduct.

[26]Pursuant to 21 U.S.C. § 841, generally it is unlawful for any person to knowingly or intentionally (1) manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance. Generally, any person who violates this prohibition, shall be sentenced in the case of a violation involving 400 grams or more of a mixture or substance containing a detectable amount of fentanyl [N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide] or 100 grams or more of a mixture or substance containing a detectable amount of any fentanyl analogue [analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide] to a term of imprisonment which may not be less than 10 years or more than life, and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 of the United States Code or $10 million if the defendant is an individual or $50 million if the defendant is other than an individual, or both. Additional mandatory penalties may be imposed depending upon each person's particular circumstances based upon factors such as prior criminal history.

sentence.[27] Representatives from one organization stated that, in some instances, these individuals did not know that the drugs they possessed contained a fentanyl analogue or fentanyl-related substance, but they would still be subject to mandatory minimums. Additionally, the representatives stated that because judges must impose a specific sentence, mandatory minimums generally deny the judge the ability to use discretion to set a lower sentence based on the circumstances of the case and the role of the individual.[28]

- **Racial disparities in sentencing.** Representatives from four of five criminal justice and civil rights organizations and the federal public defenders cited concerns with racial disparities in federal sentencing of cases involving illicit fentanyl and fentanyl analogues. For example, one organization's representative stated that class-wide scheduling perpetuates what previously occurred from the "War on Drugs," which resulted in the disproportionate incarceration of Black and Brown people.[29] Additionally, representatives from these organizations noted that in their research of U.S. Sentencing Commission data, people of color comprised a far larger percentage of those prosecuted for cases involving illicit fentanyl and fentanyl analogues during fiscal year 2019 than their percentage of the U.S. population.
- **Targeting low-level offenders for prosecution.** Representatives from four of the five criminal justice and civil rights organizations and the federal public defenders we spoke with told us that they were concerned that individuals targeted for prosecution of drug offenses

[27]U.S. Sentencing Commission, *Quick Facts – Fentanyl Trafficking Offenses*. June 2020 (Washington, D.C.). In addition, a 2019 U.S. Sentencing Commission report references the addition of fentanyl analogue cases to the overall count of illicit fentanyl drug trafficking cases. While the report does not break out sentencing data for fentanyl, fentanyl analogues, and fentanyl-related substances, representatives noted that class-wide scheduling is likely to expand the number of drug-related prosecutions that will seek mandatory minimum penalties.

[28]DOJ officials noted that judges may sentence below the mandatory minimum if the defendant has provided substantial assistance to law enforcement or under the safety valve provision. See 18 U.S.C. § 3553(e) and (f).

[29]The "War on Drugs" refers to a government-led initiative, launched in the 1970s, to stop illegal drug use, distribution and trade. Federal drug convictions rose in the 1980s possibly due to increased federal attention on all drug cases and the expansion of federal resources for drug prosecutions. A Bureau of Justice Statistics report published in 1988 noted that prison sentences for persons charged with drug offenses were longer, on average, than for all other categories of convicted federal offenders except those charged with violent crimes. Bureau of Justice Statistics, *Federal Offenses and Offenders: Drug Law Violators 1980-86*. June 1988.

were low-level users or dealers.[30] However, in a January 2020 written testimony supporting the extension of class-wide scheduling, DOJ officials stated that one of the goals of class-wide scheduling was to disincentivize drug trafficking organizations to invent new fentanyl-related substances to evade DEA's control. Additionally, officials from an OCDETF strike force team stated that their goal is to dismantle the entire organization. As discussed above, out of the eight cases we reviewed that were prosecuted under class-wide scheduling, four involved a defendant who was part of larger drug trafficking organization.

We determined from analysis of EOUSA data on filed drug cases that from fiscal year 2019 through fiscal year 2020, a total of at least 388 drug cases included a fentanyl analogue.[31] EOUSA officials told us that most of the fentanyl analogue cases prosecuted were for offenses involving analogues that had been individually scheduled prior to class-wide scheduling; however, officials from one U.S. Attorney's Office and one OCDETF strike force team we spoke to could not confirm this statement because they generally do not track this information. An official from one U.S. Attorney's Office said these data may be helpful but could be difficult to maintain since prosecutors may note what substances are involved in a case initially; however, confirmation from lab results may come later.

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[30]A 2021 U.S. Sentencing Commission report notes that in fiscal year 2019, 45.5 percent of offenders in fentanyl analogue cases were street-level dealers. The Sentencing Commission report defines fentanyl analogues as substances chemically or pharmacologically similar to fentanyl but does not distinguish between fentanyl-related substances and individually scheduled analogues. U.S. Sentencing Commission, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns*. January 2021 (Washington, D.C.).

[31]EOUSA officials told us that fentanyl analogue data is not inclusive of all fentanyl analogue cases since the "fentanyl analogue" field is optional. Additionally, the denotation of "fentanyl analogues" includes individual fentanyl analogues that have been previously scheduled and fentanyl related substances, as defined by DEA that were previously unscheduled prior to class-wide scheduling. Fiscal year 2019 was the first year that data on fentanyl analogue cases were available.

# Appendix V: Potential Effects of China's Class-Wide Scheduling on the Flow of Fentanyl and Its Analogues to the United States

This appendix includes information on the flow of fentanyl and its analogues to the United States in total and from the People's Republic of China (China), Mexico, and Canada, and the potential effects of China's announced 2019 decision to implement class-wide scheduling of these substances.[1] Seizures of fentanyl and its analogues entering the United States through U.S. ports of entry have increased from the beginning of fiscal year 2018 through July 31, 2020, with the largest share of seizures shifting from shipments from China to shipments from Mexico.[2] The number of seizures entering the United States from China decreased substantially over the 16 months before China's stated date of effectiveness for the law—but this decrease was offset by increased seizures from Mexico and, to a lesser degree, Canada. This shift largely coincided with a decrease in seizures entering the United States via mail and express consignment carriers and an increase in seizures from vehicles and pedestrians. U.S. officials and documents noted that since at least 2018 transnational criminal organizations are importing more precursors to manufacture fentanyl and its analogues within Mexico to

[1]Canada, China, and Mexico are the three countries of transport where, collectively, over 80 percent of seizures of fentanyl and its analogues came from each year from fiscal year 2018 through July 2020. The actual proportion of seizures from each country varied over time.

[2]U.S. Customs and Border Protection's (CBP) Office of Field Operations (OFO) is responsible for inspections at the 328 U.S. land, sea, and air ports of entry. CBP's border security mission is led by OFO officers at ports of entry, by agents from the United States Border Patrol between the U.S. land border ports of entry, and by agents from Air and Marine Operations from the air and sea. OFO responsibilities also include screening of inbound and outbound international mail and express carrier items at U.S. ports of entry. CBP officers and agents enter data related to seizures into their Seized Assets and Case Tracking System (SEACATS). We use the term "fentanyl and its analogues" to describe the results of our analysis of SEACATS data because the data do not differentiate between seizures of fentanyl and seizures of fentanyl-related substances. Specifically, CBP categorizes all seizures of fentanyl, individually scheduled fentanyl analogues, and fentanyl related substances as fentanyl within SEACATS. SEACATS data may also include other fentanyl analogues if presumptive field testing or laboratory testing identified the presence of fentanyl. Analysis produced from seizure data does not represent the actual supply or flows of fentanyl and its analogues entering the United States. Seizure data simply represent the known amount of drugs seized.

traffic to the United States.[3] U.S. officials attribute increased seizures in shipments from Canada to a few individual traffickers. According to Department of Justice (DOJ) officials, they have no evidence indicating that the fentanyl seized coming to the U.S. from Mexico or Canada is still being produced in China.

According to our analysis of U.S. Customs and Border Protection (CBP) seizure data and U.S. officials, the extent to which changes in the flow of seizures to the United States are a direct result of China's 2019 class-wide scheduling law is unclear because multiple factors likely contributed to the decline in seizures from China. For example, U.S. officials identified, among others, two potential explanations—anticipation of China's law and U.S. control and enforcement efforts (including U.S. class scheduling)—that may help explain the decline in the seizures coming from China during the 16 months before China's law went into effect in 2019, as announced by China.[4] However, we cannot distinguish the individual effects of each explanation on the decline in the seizures of fentanyl and its analogues coming from China. Additionally, there are limitations of CBP seizure data, which does not separate fentanyl from its

[3]According to the United Nations Office on Drugs and Crime (UNODC), a precursor is any chemical substance that may be used in any part of the manufacturing process of narcotic drugs and psychotropic substances such as fentanyl and fentanyl-related substances. UNODC identifies three types of precursors: 1) a non-scheduled precursor is a substance not under international control, largely because of its universal industrial uses; 2) a scheduled precursor is a substance subject to international control; and 3) a "designer" precursor is any chemical substance made intentionally to allow for the subsequent manufacture of scheduled precursors or controlled drugs, and usually has no legitimate use. UNODC also refers to designer precursors as a type of "pre-precursors," as they are chemicals specifically designed to circumvent existing precursor control systems.

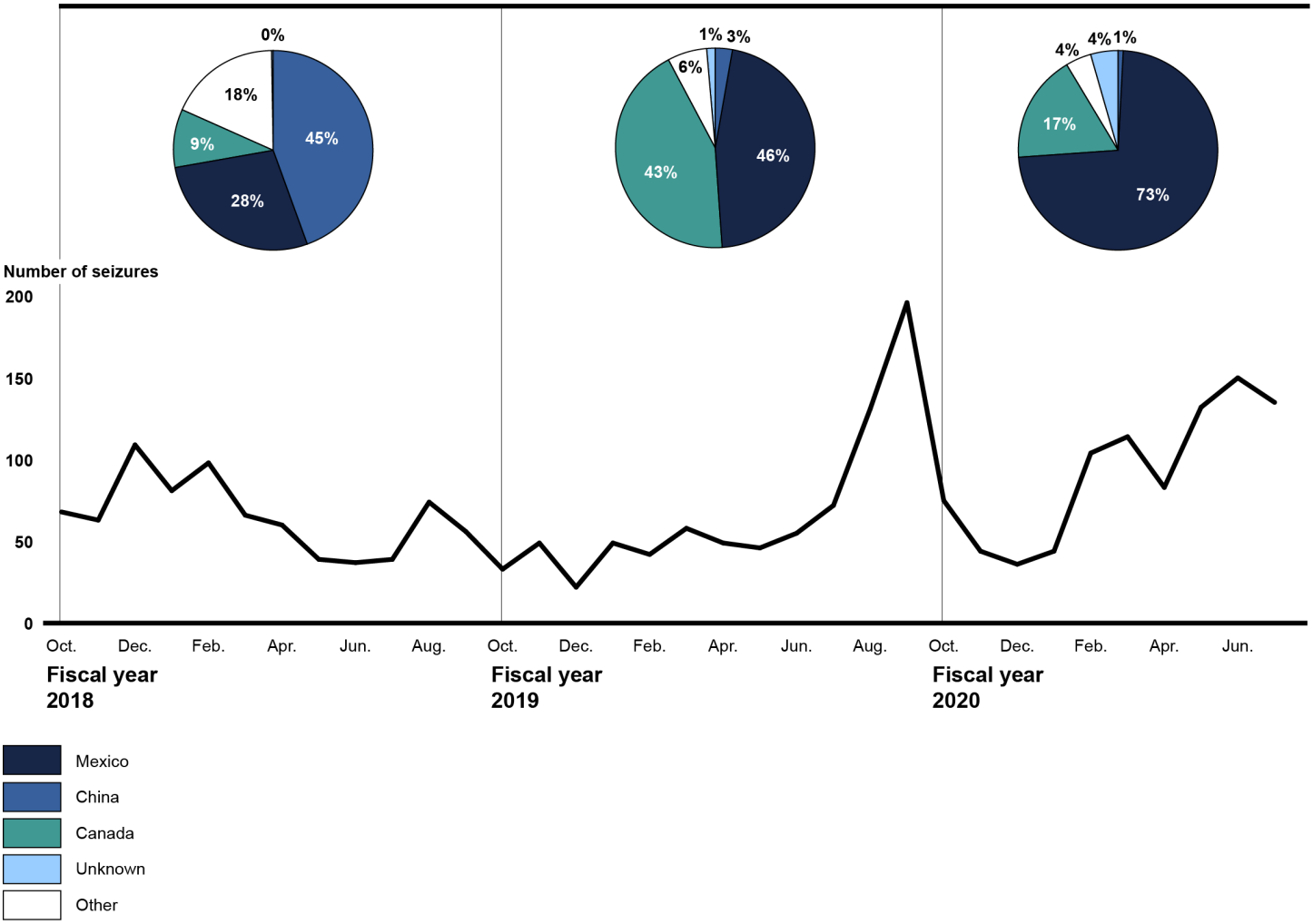
[4]On April 1, 2019, China announced that it was placing "fentanyl-related substances" as a class on its list of scheduled substances effective May 1, 2019. The announcement noted the government was doing so in accordance with its R*egulations on the Administration of Narcotic Drugs and Psychotropic Substances* and *Regulations on the Administration of Narcotic Drugs and Psychotropic Substances with Non-medical Use*. Moreover, the announcement stated that fentanyl and its analogues previously scheduled in accordance with this law would remain on the list of scheduled substances. According to U.S. officials, China's law defines fentanyl-related substances more broadly than the U.S. government defines fentanyl-related substances. The Drug Enforcement Administration's (DEA) temporary scheduling order defined fentanyl-related substances as those substances not otherwise controlled in any schedule that are structurally related to fentanyl by one or more of five chemical structural modifications. See 83 Fed. Reg. 5188 (Feb. 6, 2018). China's law defines only four such structural relationships, according to U.S. officials. According to U.S. officials, China's definition is slightly broader than the U.S. definition and includes some fentanyl precursors.

analogues. U.S. officials stated that the U.S. government continues to work with officials in Mexico and China to address the flow of precursors.

**Overall seizures of fentanyl and its analogues.** Overall seizures of fentanyl and its analogues entering at U.S. ports of entry increased substantially from fiscal year 2018 through fiscal year 2020, as the largest share of seizures shifted from shipments from China to shipments from Mexico well before China's stated date of effectiveness for the law.[5] Specifically, we found that seizures of fentanyl and its analogues increased 39 percent—from a monthly average of 66 seizures in fiscal year 2018, to an average of 92 seizures per month in fiscal year 2020 through July. More seizures (45 percent) of fentanyl and its analogues came from China in fiscal year 2018 than from any other country. By July 2020, most seizures (73 percent) came from Mexico. (See fig. 5.)

[5]We included all observations of seized fentanyl and its analogues that CBP officers indicated as inbound because they account for the majority of CBP seizures of fentanyl marked as inbound to the United States. While it is not possible to determine the origin or point of manufacture of synthetic substances with certainty, we constructed a variable indicating the potential origin or last known country of departure using several variables from CBP's SEACATS data that reflect the locations associated with the fentanyl seizure. Specifically, our constructed variable refers to a seizure that is associated with a particular country identified in the origin, from, departure, sender, or export fields for SEACATS in that order. We verified the validity of this approach with CBP.

**Figure 5: U.S. Customs and Border Protection (CBP) Seizures of Inbound Fentanyl and Its Analogues at U.S. Ports of Entry from Fiscal Year 2018 to July 2020 by Month and by Countries of Transport**




Source: GAO analysis of CBP data. | GAO-21-499

Notes: For fiscal year 2020, we present data from October 1, 2019, through July 31, 2020. We are unable to present full data for the entire fiscal year because it was unavailable at the time of analysis.

"Countries of Transport" is a variable we constructed using a variety of fields found within CBP's seizure data to describe how a seizure is associated with a particular country in that data. Specifically, we constructed a variable that combined data from fields that a CBP officer may enter into the database when reporting a drug seizure. These entries may include variables such as origin country, from country, departure country, sender country, or export country.

We focused our analysis on Canada, China, and Mexico, which are the three countries of transport where, collectively, over 80 percent of seizures of fentanyl and its analogues came from each year from fiscal year 2018 through July 2020. The actual proportion of seizures from each country varied over time.

Seizures from countries other than China, Mexico, Canada, or from unknown countries constituted about 11 percent of the total seizures we analyzed in this period.

**Methods of transportation.** CBP seizure data indicate methods of transporting fentanyl and its analogues into the U.S. have changed over time from using mostly mail and express carriers to using mostly vehicles and pedestrians.[6] Seizures at U.S. ports of entry transported by mail and express carriers decreased by 59 percent from fiscal year 2018 to fiscal year 2020 through July 2020.[7] Seizure data from CBP indicate that 96 percent of seizures of fentanyl and its analogues from China came by mail or express carriers in this same period, compared with 39 percent of fentanyl from all other countries. According to Office of National Drug Control Policy (ONDCP) officials, fentanyl and its analogues that come through the mail are of higher purity but in smaller quantities than those trafficked using other methods. ONDCP officials stated that because of their higher purity levels, shipments coming via mail have a higher potential for lethality than lower-purity shipments coming via other modes of transportation. As CBP increasingly seized fentanyl and its analogues coming from Mexico, the number of seizures from vehicles and pedestrians increased by 114 percent and 893 percent, respectively.[8] According to U.S. government documents and officials, Mexican traffickers mainly used vehicles and pedestrians to transport larger shipments of fentanyl and its analogues across the border, often in a lower purity form mixed in with other narcotics.

ONDCP officials cautioned that it is difficult to compare transport methods against each other because detection capabilities at different ports of entry have varied over time to account for new trafficking trends. For example, after the U.S. government publicly announced improvements in its capabilities to detect fentanyl and its analogues being trafficked through the mail, ONDCP officials said that traffickers changed their routes to avoid increased scrutiny in mail facilities. Additionally, ONDCP officials stated that the weight or amount of drugs seized at U.S. ports of entry differs across transport methods. For example, ONDCP officials

[6]CBP, in coordination with the United States Postal Service (USPS) and its U.S. Postal Inspection Service, screens inbound international mail. CBP also screens inbound express carrier (such as FedEx and DHL) shipments.

[7]Specifically, our analysis of seizure data indicated that seizures of fentanyl and its analogues transported by mail and express carriers decreased from 550 in fiscal year 2018 to 228 in fiscal year 2020 through July 2020.

[8]Specifically, our analysis of seizure data indicated that that seizures of fentanyl and its analogues transported by vehicle increased from 181 in fiscal year 2018 to 388 in fiscal year 2020 through July 2020. Seizures transported by pedestrians increased from 27 to 268 during the same period.

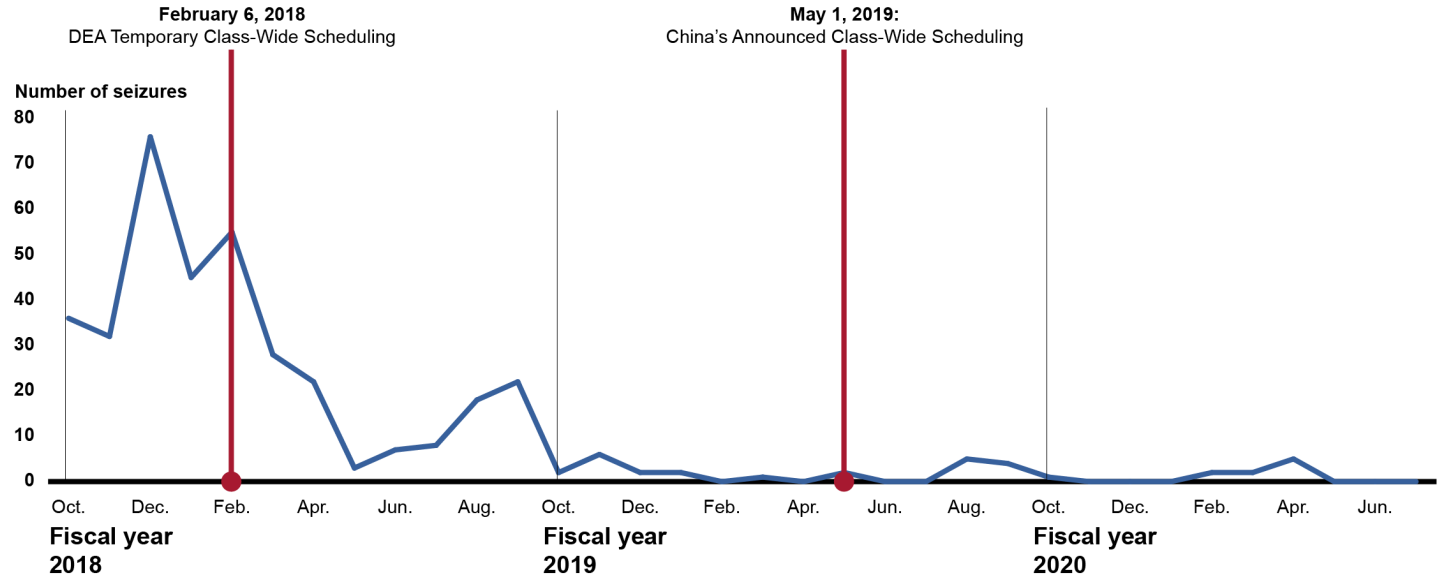
said that the size of drug seizures at the border ports are much larger—and therefore, easier to detect—than the smaller size of packages CBP seizes at international mail facilities. According to CBP's published statistics, the quantity of fentanyl seized more than doubled from fiscal year 2018 to fiscal year 2020. Specifically, CBP reported Office of Field Operations seized 1,895 pounds of fentanyl at ports of entry in fiscal year 2018 and 3,967 pounds in fiscal year 2020.

**Seizures from China.** Overall seizures of fentanyl and its analogues from China decreased from 352 seizures in fiscal year 2018 to 10 seizures in fiscal year 2020 through July.[9] (See fig. 6.) CBP seizures of fentanyl and its analogues at U.S. ports of entry from China decreased substantially in the 16 months leading up to China's announced May 1, 2019 class-wide scheduling law. Specifically, the largest decrease in monthly seizures occurred from December 2017 to January 2018, when seizures fell from 76 to 45. After a slight increase to 55 in February 2018, seizures fell again until May 2018, when there were only three.

[9]U.S. and international agencies indicate that the quantity of seized fentanyl from China declined along with the number of seizures. According to CBP, the quantity of seizures of fentanyl directly shipped from China to the United States also shrank dramatically—from over 116 kilograms (256 pounds) seized in fiscal year 2017 to less than 200 grams (7 ounces) in fiscal year 2019. Moreover, officials from the International Narcotics Control Board and UNODC noted in 2020 that data received from China also indicate a decrease in fentanyl-related substances flowing from China to the United States after China's ban went into effect. UNODC and the International Narcotics Control Board officials indicated that other nations manufacture and traffic only small amounts of fentanyl and fentanyl-related substances compared to China.

Out of the 10 seizures from China in fiscal year 2020 through July, four drugs were seized and marked as fentanyl by the seizing officer, but are not actually controlled because they are not biologically active. Three seizures of fentanyl and its analogues were seized in 2017 when they were not controlled by China at the time, and were not entered into the SEACATS data system until 2020.

**Figure 6: Monthly U.S. Customs and Border Protection (CBP) Seizures of Inbound Fentanyl and Its Analogues at U.S. Ports of Entry from China from Fiscal Year 2018 through July 2020**




Source: GAO analysis of CBP data. | GAO-21-499

Notes: For fiscal year 2020, we present data from October 1, 2019, through July 31, 2020. We are unable to present full data for the entire fiscal year because it was not available at the time of analysis. Both China and the U.S. government gave advance warnings of the class-wide scheduling laws. For example, before the Drug Enforcement Administration's (DEA's) temporary class-wide scheduling order in February 2018, they also issued a notice of intent to schedule temporarily fentanyl analogues in December 2017.

DEA's order temporarily classified a group of fentanyl analogues—called fentanyl-related substances—that had not already been scheduled under the Controlled Substances Act as Schedule I substances 83 Fed. Reg. 5188 (Feb. 6, 2018).

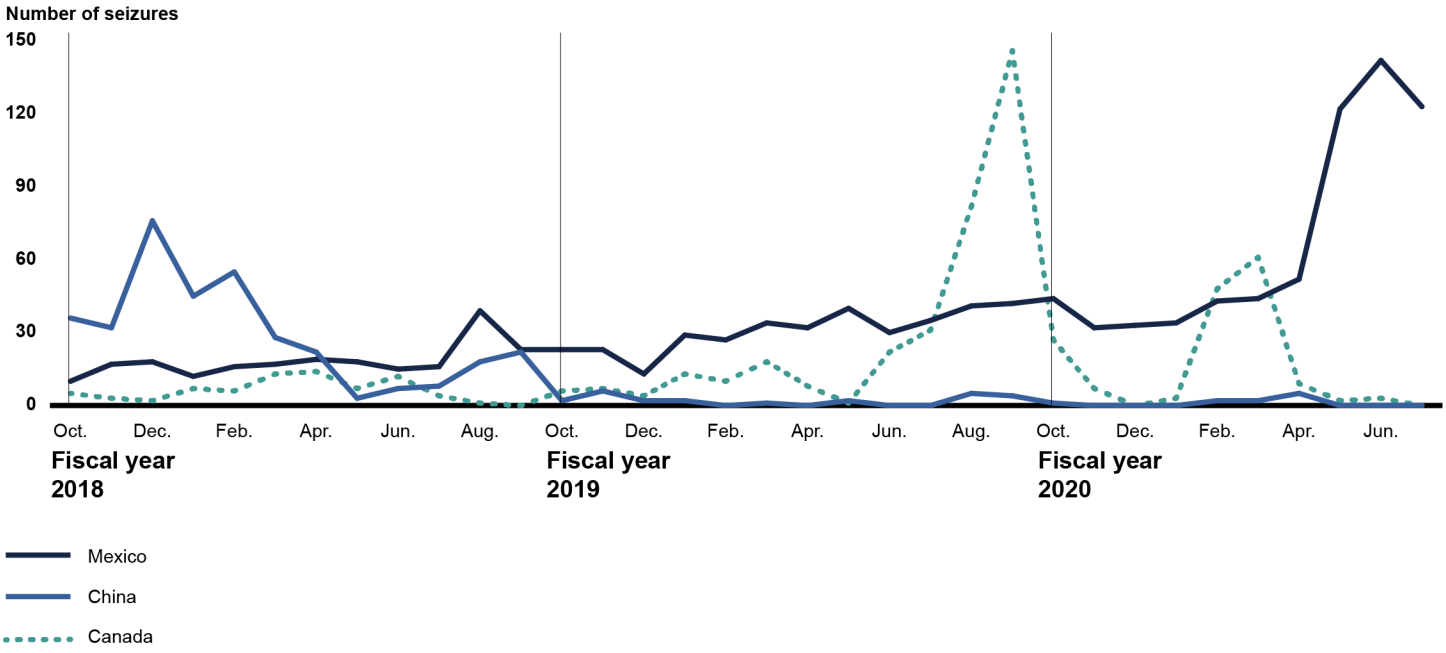
**Seizures from Mexico.** Seizures from Mexico increased substantially from fiscal year 2018 through July 2020. Our analysis of CBP seizure data at U.S. ports of entry found that seizures of fentanyl and its analogues from Mexico increased by more than 200 percent from 220 seizures in fiscal year 2018 to 669 seizures in fiscal year 2020 through July. (See fig. 7.) We found that the monthly number of seizures of fentanyl and its analogues from Mexico from May through July 2020 was larger than the number from China in any month from fiscal year 2018 through July 2020. Specifically, seizures of fentanyl and its analogues from China peaked at 76 seizures in December 2017, while seizures of fentanyl and its analogues from Mexico equaled or exceeded 122 seizures per month from May through July 2020. CBP officials attribute this steep increase, in part, to transnational criminal organizations adapting their behavior in response to the Chinese law. For example,

U.S. officials and documents noted that transnational criminal organizations are manufacturing fentanyl within Mexico using imported precursors from China and elsewhere.[10] According to DOJ officials, however, they have no evidence indicating that the fentanyl seized coming to the U.S. from Mexico is still being produced in China. ONDCP officials emphasized that comparisons between the increasing share of seizures from Mexico and the decreasing share from China should take into account other factors, such as the effect of this shift on the threat to the health and safety of Americans. For example, they noted that given the potential dangers of properly dosing pure fentanyl, large seizures from Mexico involving low-purity fentanyl might have less of an effect on the safety of Americans than one small seizure of high-purity fentanyl seized at an international mail facility.[11]

[10]According to the UNODC, pre-precursors are non-scheduled chemical intermediates made intentionally to allow for the subsequent manufacture of scheduled precursors or controlled drugs, and usually have no legitimate use. Pre-precursors can first be converted into scheduled precursors and then into drugs.

[11]A 2019 DEA report indicated that fentanyl shipped directly from China is typically seized in smaller quantities with purities commonly testing above 90 percent. By comparison, fentanyl trafficked overland into the United States from Mexico is typically seized in larger, bulk quantities with much lower purity, on average testing at less than 10 percent pure.

**Figure 7: U.S. Customs and Border Protection (CBP) Seizures of Inbound Fentanyl and Its Analogues at U.S. Ports of Entry from the Top Three Countries, Fiscal Year 2018 to July 2020**




Source: GAO analysis of CBP data. | GAO-21-499

Note: For fiscal year 2020, we present data from October 1, 2019, through July 31, 2020. We are unable to present full data for the entire fiscal year because it was not available at the time of analysis. For this figure, we omitted seizures from countries other than China, Mexico, and Canada where the country of origin was unknown, or because they were few in number. Of the 2,509 seizures we analyzed during this period, 233 came from other countries and 50 involved seizures not associated with a particular country.

**Seizures from Canada.** Seizure data shows that the number of overall seizures from Canada increased after fiscal year 2018. Our analysis of CBP seizure data at U.S. ports of entry found that 9 percent of all seizures of fentanyl and its analogues came from Canada in fiscal year 2018. Seizures from Canada increased to about 43 percent of all seizures in fiscal year 2019, before decreasing to 17 percent in fiscal year 2020 through July. (See fig. 5.) According to CBP and Department of State officials, the steep increase in seizures for fiscal year 2019 was likely due to a few individual traffickers, at least one of whom was arrested in the Toronto area attempting to mail fentanyl to the United States.

Our analysis of seizure data also confirms that more seizures of fentanyl and its analogues occurred as they were attempting to enter the United States from Canada than from other countries since China's class-wide

scheduling went into effect.[12] However, Mexico still had th9999e largest number of seizures between fiscal year 2018 and July 2020 with 1258 seizures—in contrast to Canada's 582 seizures. A CBP official noted that the amount of fentanyl and its analogues in each seizure from Canada was generally much smaller compared to the amount coming from Mexico. According to the CBP official, most seizures from Canada have been very small amounts measured in gram quantities or less in small parcels and letter class mail. In contrast, Drug Enforcement Administration (DEA) documents noted that fentanyl seizures from Mexico often are measured in kilograms.[13] According to DOJ officials, they have no evidence indicating that the fentanyl seized coming to the U.S. from Canada is still being produced in China.

**Effects of China's class-wide scheduling law.** We were unable to determine the extent to which the Chinese law directly affected the number of seizures coming from China for three primary reasons, as laid out below. U.S. officials identified two potential explanations, among others, for the decline in seizures from China during the 16 months prior to China's class-wide scheduling law going into effect. However, we cannot distinguish the individual effects of these potential explanations on the decline in the seizures of fentanyl and its analogues coming from China. There are also limitations of CBP seizure data, which also prevent us from drawing conclusions on what effect can be directly attributed to China's law.

- **Anticipation of China's law.** As noted above, the decline in CBP seizures at U.S. ports of entry from China occurred in the 16 months before the class-wide scheduling law went into effect in China on May 1, 2019, as announced by China. Because the decline predated the law, we are unable to determine the extent to which the law affected this decline. According to U.S. officials, one potential explanation for the decline in seizures prior to the ban may be that the Chinese government gave legitimate chemical companies in China warnings that it would soon implement the law—and its penalties—if they continued to manufacture fentanyl and its analogues after the new law went into effect. However, U.S. officials were unable to give us a specific date of notice for when companies received warnings.

[12]We use the term other countries to describe seizures from countries other than China, Mexico or Canada.

[13]For example, see DEA Intelligence Report, *Fentanyl Flow to the United States*, DEA-DCT-DIR-008-20 (Jan. 2020),

- **U.S. enforcement efforts.** Beginning in fiscal year 2018, according to CBP officials, enhanced detection capabilities at U.S. ports of entry may have helped law enforcement increase its seizures of fentanyl and its analogues, and may have affected how the drugs were then trafficked into the United States. Although CBP officials have found it difficult to measure the deterrence effect of screening, they stated that enhanced detection capabilities—including technology to find trace amounts of fentanyl and its analogues and the use of canines—have helped to improve intelligence and targeting efforts that can lead to more seizures.[14] For example, CBP officials noted that the number of fentanyl seizures increased when authorities deployed canines trained to detect fentanyl at the international mail facility at the John F. Kennedy airport.[15] Moreover, these officials noted that restrictions put in place to address the Coronavirus Disease 2019 (COVID-19) significantly reduced lawful trade and travel, allowing CBP to focus more resources on interdiction efforts. However, CBP officials also stated that traffickers changed their routes and methods of transport in response to increased seizures. For example, when CBP officials noticed an increase in fentanyl and its analogues entering the United States from China through mail and express carrier shipments, they

[14]Specifically, at the ports of entry, CBP uses an electronic, handheld device that can identify hazardous chemicals and drugs, including fentanyl, coming into the United States. CBP piloted the tool at a port of entry in 2016, and as of October 2020, deployed 334 units to the ports of entry. In June 2019, CBP also approved deployment of a fentanyl testing strip kit to detect low purity levels of fentanyl. According to CBP officials, CBP deployed 1,452 of these kits to field offices and ports of entry as of October 2020. We have ongoing work on CBP's field drug testing capabilities. In addition to these technologies, CBP officials stated that the OFO had trained all of its detector canines by April 2018 to detect concealed fentanyl and some fentanyl analogues.

[15]CBP also began to receive more data on international mail shipments starting in 2019, which could aid in targeting fentanyl shipments. Specifically, while express carrier operators are required to provide advance electronic data (AED)—such as the shipper's and recipient's name and address—for all inbound express cargo, USPS was not required to submit these data to CBP prior to December 31, 2018. This changed with the passage of the Synthetics Trafficking and Overdose Prevention Act of 2018 (STOP Act of 2018). Pub. L. No. 115-271, § 8003(a)(1), 132 Stat. 4075. In particular, the act initially required USPS to transmit AED to CBP for at least 70 percent of aggregate international mail shipments it receives, but 100 percent of mail shipments from China, starting no later than December 31, 2018. Moreover, the act requires USPS, in consultation with CBP, to take enforcement action against international mail shipments received without required AED after December 31, 2020. In our December 2019 report, we found that although USPS transmitted some data to CBP before the enactment of this act, it had not met transmission requirements included in the act. However, we also found that USPS's transmission rates of data to CBP had generally increased from January 2019 through August 2019. See GAO, *International Mail: Progress Made in Using Electronic Data to Detect Illegal Opioid Shipments, but Additional Steps Remain*, GAO-20-229R (Washington, D.C.: December 18, 2019).

began to refocus their enforcement efforts on these routes. According to CBP officials, seizures at mail and express carrier facilities then decreased as the traffickers shifted their routes and transportation methods through Mexico. According to DEA officials, however, the fentanyl coming from Mexico to the United States likely was not produced in China. In addition, U.S. officials told us that the U.S. government actions prior to the Chinese law going into effect might have contributed to this decrease as traffickers adapted their operations in anticipation of these pending changes, including DEA's notice of intent in December 2017 to temporarily schedule fentanyl-related substances as a class. DOJ officials noted that this notice of intent and DEA's February 2018 temporary class-wide scheduling action coincided with the decline in seizures of fentanyl and fentanyl analogues entering the United States from China.

- **Data limitations.** While we are able to report on increases and decreases in seizures of fentanyl and its analogues as a whole, limitations of seizure data do not allow us to determine the extent to which the Chinese law directly affected the number of seizures of fentanyl-related substances, specifically, coming from China. According to DEA officials, seizure data that separated fentanyl from its analogues would help to better determine the direct effect of China's class wide scheduling law on seizures of fentanyl-related substances from China. According to CBP officials, Seized Assets and Case Tracking System (SEACATS) seizure data cannot separate fentanyl from its analogues.[16]

**Addressing the flow of precursors.** U.S. officials stated that Chinese producers largely ceased producing finished fentanyl products for export to the U.S. market. However, U.S. government documents and officials noted that challenges remain in addressing the flow of precursors from China to Mexico, which criminal groups use to manufacture fentanyl and its analogues and traffic into the United States. They noted that in recent years, the fentanyl-related substances market in China has shifted from exporting finished fentanyl and its analogues to exporting precursors or

[16]According to CBP officials, SEACATS does not separate out fentanyl, fentanyl analogues, and fentanyl-related substances for at least two reasons. First, stakeholder organizations agreed upon broad categories of drugs to allow them to track trends in trafficking more easily. Second, a laboratory would have to determine whether a drug is fentanyl, or a specific individually scheduled fentanyl analogue, or a fentanyl-related substance. According to CBP officials, they do not send all seizures to laboratories for analysis. According to DOJ officials, however, lab data indicated that seizures from Mexico were more commonly actual fentanyl and not analogues. They stated this could indicate that U.S. class wide scheduling may have reduced the incentive for traffickers to create new analogues and fentanyl-related substances.

even pre-precursors to other countries, such as Mexico, where they can be synthesized into analogues. For example, according to State, CBP, and DEA documents and officials:

- Transnational criminal organizations have established labs in Mexico that not only mix imported fentanyl and its analogues with other drugs—or dilute them with inert materials such as lactose and mannitol—to traffic into the United States, but also increasingly synthesize fentanyl and its analogues from precursors.
- While the Mexican government is working with the U.S. government to improve national data collection on illicit drug seizures and to schedule fentanyl precursors, the transnational criminal organizations take advantage of the country's uneven precursor chemical controls to manufacture increasing amounts of deadly drugs such as fentanyl and traffic them in the United States.[17] A U.S. Presidential Determination from 2020 found that unless the Mexican government demonstrates substantial progress in 2021 in addressing this "alarming trend" in fentanyl production and other drug-related challenges, Mexico would be at serious risk of having failed to uphold its international drug control commitments.[18]

U.S. officials and documents noted the U.S. government also continues to work with its Chinese counterparts on controlling the flow of precursor chemicals from China.[19]

[17]The U.S. government has invested substantial resources to develop the Mexican government's capacity to detect and interdict the flow of illegal narcotics trafficked across the U.S. border under the terms of the 2007 Mérida Initiative, a bilateral partnership to address crime and violence and enhance the rule of law in Mexico. See GAO, *U.S. Assistance to Mexico: State and USAID Allocated over $700 Million to Support Criminal Justice, Border Security, and Related Efforts from Fiscal Year 2014 through 2018*, GAO-19-647 (Washington, D.C.: Sept. 10, 2019). According to State documents, recent counternarcotics programs under this initiative included training and equipping Mexican forensic laboratories, law enforcement agencies, and prosecutors to improve their ability to detect and interdict the production of fentanyl and its analogues and prevent its trafficking across U.S. borders.

[18]Presidential Determination on Major Drug Transit or Major Illicit Drug Producing Countries for Fiscal Year 2021, September 16, 2020.

[19]In addition, according to ONDCP and State officials, the United States, Canada, and Mexico took steps to coordinate better their efforts to address the challenge posed by the importation of precursors from China and elsewhere at the December 2019 annual meeting of the North American Drug Dialogue. The Dialogue is a forum through which the United States government engages with both Mexico and Canada to share information and to coordinate polices to combat fentanyl and fentanyl analogue production and trafficking.

**Contact Information:** Kimberly Gianopoulos at (202) 512-8612, GianopoulosK@gao.gov

# Appendix VI: 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 5, 2021

Alyssa M. Hundrup
Acting Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC. 20548

Dear Acting Director Hundrup,

The Office of National Drug Control Policy (ONDCP) hereby provides our response to the draft final report entitled, *Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl Related Substances*, GAO-21-301. We have provided clarifying information on some elements of the factual information contained in the report. ONDCP believes that the draft final report identifies the issues to be considered with regard to permanent legislative or administrative scheduling of fentanyl related substances. While permanent scheduling would facilitate law enforcement investigations and prosecutions for trafficking in fentanyl related substances as well as promote consistency with the laws of other nations like China that have permanently scheduled such substances, ONDCP acknowledges the ancillary effects of permanent scheduling on research to examine medically beneficial uses of fentanyl related substances, as well as mandatory minimum sentencing. ONDCP believes that these negative implications must be addressed and mitigated.

ONDCP believes that the information contained in the Report and its accompanying Appendices does not contain confidential or sensitive information such that redactions or having a restricted version and a public version of the report are necessary. Please find attached ONDCP's Technical Comments on the draft report which contains our recommended edits. Thank you for the opportunity to review and comment on the draft final report. Feel free to contact ONDCP General Counsel, Robert Kent at (202) 881-8815 or Robert.A.Kent@ondcp.eop.gov if you would like to further discuss our response.

Respectfully,

Regina M. LaBelle, Acting Director
Office of National Drug Control Policy

# Appendix VII: Comments from the Department of Justice

**U.S. Department of Justice**

Office of the Deputy Attorney General

*Bradley Weinsheimer*
Associate Deputy Attorney General

*Washington, D.C. 20530*

March 31, 2021

Alyssa M. Hundrup
Acting Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Hundrup:

Thank you for the opportunity to review and comment on the Government Accountability Office (GAO) draft report, entitled "*Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-Related Substances (FRS)*." The Department of Justice (Department) has reviewed the report and provides the following response.

GAO provided the Department with a copy of its draft final report for review, and the Department communicated multiple pages of concerns and technical corrections. Prior to that, the GAO had provided the Department an earlier draft report, and the Department provided numerous technical corrections and comments, many of which were not incorporated into GAO's draft final report. Because the Department did not have an opportunity to review changes GAO may have made in the final report as the result of the Department's detailed comments, we are unable to determine whether our concerns were addressed. Accordingly, we restate them here.

First, the draft final report erroneously leads the reader to believe that DEA can *administratively* address class-wide scheduling of fentanyl-related substances before the scheduling order expires on May 6, 2021, and that legislation is only one possible answer to the expiration of the DEA's temporary class-wide scheduling order. However, the Department and DEA conveyed to GAO that in the absence of a medical and scientific evaluation and scheduling recommendation from the Department of Health and Human Services (HHS) to place the class of fentanyl-related substances in schedule I (typically called the "8-factor analysis"), the Department is not aware of an administrative method to extend the control of the class beyond May 6, 2021, when the legislative extension expires. To date, the Department has not received this analysis from HHS, nor does it believe that one is underway. If HHS declines to conduct the requested 8-factor analysis on fentanyl-related substances, the Department would never be able to administratively schedule fentanyl-related substances as a class.

Accordingly, the Department strongly believes that legislatively scheduling fentanyl-related substances is the only viable near-term solution—it certainly is the only solution that can

be adopted prior to the temporary scheduling order's expiration. The GAO report ignores these realities and makes it seem as though continued administrative scheduling by DEA is an alternative to legislative scheduling by Congress. It is not. On May 6, 2021, absent a statutory fix, fentanyl-related substances that have not been permanently scheduled individually will no longer be controlled under the Controlled Substances Act (CSA).

Second, the draft report minimizes the benefits of class-wide scheduling of fentanyl-related substances by disregarding the compelling evidence shared by the Department and other stakeholders of the positive impact that the temporary class-wide scheduling order, in effect since February 2018, has had on reducing the circulation of fentanyl-related substances in the United States. The Department provided GAO with more than four years of data demonstrating that class-wide control works and has helped substantially reduce the number of fentanyl analogue encounters in the United States. For example, GAO analysis of DEA National Forensic Laboratory Information System (NFLIS) data shows that law enforcement encounters of fentanyl analogues that were not individually scheduled declined by almost 90%, when comparing total encounters of uncontrolled fentanyl analogues from 2016 and 2017 (before temporary class-wide scheduling of fentanyl-related substances was in effect) to total encounters of uncontrolled fentanyl analogues from 2018 and 2019 (after temporary class-wide scheduling was in effect). That is a striking decline, and it speaks to the deterrent effect that the DEA's class-wide scheduling order had on manufacturers, importers, and would-be traffickers of fentanyl-related substances. DEA NFLIS data also shows that the number of new fentanyl analogues identified by the agency fell sharply after the temporary scheduling order was issued in February 2018—specifically, new fentanyl analogues detected by the DEA numbered 32 between 2016 and January 2018, but that number fell to 12 between February 2018 through July 2020.

Were class-wide scheduling of these substances allowed to expire in May 2021 without a legislative solution enacted in its place, these positive trends could be reversed. The myriad fentanyl-related substances that manufacturers could concoct – and that illicit traffickers could try to peddle into the United States – would no longer be scheduled substances under the CSA. Customs and Border Protection's (CBP) authority to seize these substances at the border would be dramatically reduced; law enforcement officers' abilities to intercept and stop traffickers from circulating these substances in our communities would be curtailed; and, most alarming, consumption of these deadly substances and overdose deaths could skyrocket.

Another reason the Department strongly believes that class-wide scheduling is necessary—and which the draft GAO report failed to convey—is because in the Department's experience, the *alternatives* to class-wide scheduling are inadequate to address the opioid epidemic. Relying on individual scheduling is not an effective substitute; DEA's experience has been that individually scheduling a new fentanyl analogue takes many months, and during that time, the harm continues and new analogues rapidly proliferate in its place. Similarly, relying on the CSA's analogue provisions to charge offenses involving unscheduled fentanyl-related substances is likewise inadequate. Those prosecutions require a great deal of time and resources, necessitate expert testimony to prove that the chemical structure and pharmacological effects of the substance are substantially similar to fentanyl, and can result in inconsistent jury verdicts.

Moreover, prosecutions under the analogue provisions operate at the back end—oftentimes after the damage has already occurred—and provide for retroactive treatment as a controlled substance only after the jury verdict.

Third, the draft report appears to give little weight to the substantial data and sound perspectives of seasoned law enforcement professionals and prosecutors working in the field, all supporting the positive impact of class-wide scheduling on law enforcement and public health, while giving undue credence to claims and assertions made in interviews with advocates who disfavor scheduling – even where no evidence was provided to demonstrate that such claims were accurate, evidence-based, or likely to occur. Accordingly, the report fails to appropriately or fairly balance the considerations for and against class-wide scheduling of fentanyl-related substances. It creates a highly skewed impression of the relative costs and benefits, emphasizing speculative and in some cases unlikely harms from continued class-wide scheduling while minimizing concrete risks.

As noted above, the Department provided detailed comments to GAO's draft final report and has offered to meet with the GAO team to discuss areas of the report that require clarification. It is the Department's hope that its input will be taken into account so that the final report fairly and accurately describes the Department's efforts to control fentanyl- related substances and what actions are needed to protect our communities from their deadly and devastating impact.

If the Department may be of further assistance to you, please do not hesitate to contact Louise Duhamel, Acting Assistant Director, Audit Liaison Group on 202-514-4006.

Sincerely,

Bradley Weinsheimer

Bradley Weinsheimer
Associate Deputy Attorney General
United States Department of Justice

cc: The Honorable Gene L. Dodaro
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# Appendix VIII: Comments from the Federal Public and Community Defenders

**Federal Public & Community Defenders**
**Legislative Committee**

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Co-Chairs

**David Patton**
**Executive Director**
**Federal Defenders of New York**

**Jon Sands**
**Federal Defender**
**District of Arizona**

March 2, 2021

Alyssa M. Hundrup
Acting Director, Health Care, United States Government Accountability Office (GAO)
441 G St. N.W.
Washington, D.C. 20548

Re: Response to GAO Report on Synthetic Opioids: Considerations for Class-Wide Scheduling of Fentanyl-Related Substances (GAO-21-301SU)

Dear Ms. Hundrup:

Thank you for providing the Federal Public and Community Defenders a copy of GAO's draft report on the class-wide scheduling of fentanyl-related substances ("Report")[1] and for the opportunity to comment on its findings. The Report has the potential to offer a critical contribution to the policy discussion surrounding class-wide scheduling of fentanyl-related substances and the best way to respond to fentanyl and its analogues.[2] Unfortunately, the Report places too much emphasis on assertions by law enforcement about the utility and effect of class-wide scheduling and not enough on the GAO's carefully gathered evidence and findings that demonstrate class-wide scheduling is unnecessary and could lead to over-criminalization. As detailed below, we urge the GAO to revise the Report to provide more emphasis on its own core findings.

**I. The Report confirms that the government is well-equipped to prosecute fentanyl analogues without class-wide scheduling.**

The Report's Executive Summary ("Highlights") should specify that harmful fentanyl-related substances are already illegal even without class-wide scheduling. Presently, the Highlights section states that "allowing the temporary scheduling order to expire . . . would mean relying on DEA to

[1] U.S. Gov't Accountability Office, GAO-21-301SU, Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-Related Substances (Feb. 2021) (Draft) ("Report").

[2] This comment refers to "fentanyl-related substances" and "fentanyl analogues." The term "fentanyl-related substances" refers to the specific substances that are defined in the temporary scheduling order that was codified, temporarily, by legislation. *See,* 83 Fed. Reg. 5188 (Feb. 6, 2018); Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020). The term "fentanyl analogues" refers to "synthetic opioids with chemical structures related to fentanyl—including fentanyl analogues that have been scheduled and fentanyl-related substances." Report at 3.

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individually schedule specific fentanyl substances, as DEA has done in the past."[3] This framing perpetuates the false claim[4] that the government cannot already effectively prosecute cases involving fentanyl-related substances and fentanyl analogues.

The Report feeds this false claim in two ways. First, the Report fails to adequately emphasize that the Department of Justice ("Department") and federal law enforcement agencies have rarely relied on class-wide scheduling. From 2019 to 2020, most fentanyl-analogue prosecutions involved "analogues that had been individually scheduled prior to class-wide scheduling."[5] In contrast, the Department prosecuted only eight cases under the class-wide control since its adoption in 2018.[6] This breakdown confirms that most fentanyl-analogue prosecutions have involved substances that the government used long-existing scheduling authorities[7] to individually control and that the Department's repeated claim that class-wide scheduling is necessary for effective enforcement lacks factual support.[8]

Second, the Highlights section omit any mention of the Analogue Act. The Analogue Act equips federal law enforcement to interdict and prosecute fentanyl analogues that are not already

[3] Report, Highlights. The Report includes other similarly misleading statements. For instance, the DEA told GAO "if class-wide scheduling expires, fentanyl-related substances would no longer be scheduled and criminal organizations would likely resume or increase production of these substances." Report, App. IV at 50. The Report footnotes DEA's statement with a reference to the Analogue Act, but in that note, reiterates law enforcement complaints about the Analogue Act.

[4] See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 n.18 (Jan. 2020)(Testimony of Kevin L. Butler, Fed. Pub. Defender for the Northern District of Alabama,) ("Butler Test."), https://www.congress.gov/116/meeting/house/110392/witnesses/HHRG-116-JU08-Wstate-ButlerK-20200128.pdf (summarizing claims by law enforcement and the Department of Justice that harmful fentanyl analogues would be legalized without class-wide control); Nancy Gertner, *William Barr's New War on Drugs*, Wash. Post, Jan. 26, 2020, https://www.washingtonpost.com/opinions/2020/01/26/william-barrs-new-war-drugs/ ("[Attorney General] Barr recently warned that if his request were not granted, illicit fentanyl analogues would be 'legal.' That is false. Dangerous fentanyl analogues have long been illegal and will continue to be under existing laws.").

[5] Report, App. IV at 60 ("EOUSA officials told us that most of the fentanyl analogue cases prosecuted were for offenses involving analogues that had been individually scheduled prior to class-wide scheduling.").

[6] *Id.* at 54; *see also* U.S. Sentencing Comm'n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* at 23 (Jan. 2021) ("USSC Report"), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf ("Most of the substances identified in the fiscal year 2019 sentencing documents as "fentanyl analogues" are substances listed in a schedule of the CSA before publication of the DEA's [class-wide scheduling] order.").

[7] DEA has been empowered to schedule substances administratively based on a scientific and medical evaluation of a substance from the Assistant Secretary for Health since 1970 and to do so on an accelerated basis since 1984. *See* 21 U.S.C. § 811; Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 Cath. U. L. Rev. 586, 607–08 (1973); Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, tit. II, 98 Stat. 1976 (Oct. 12, 1984).

[8] Nor has class-wide control meaningfully impacted law enforcement investigations. "Officials from all four DEA field division offices and four OCDETF strike forces . . . indicated that, overall, class-wide scheduling has not or would not have a substantial effect on how they conduct investigations involving fentanyl-related substances, such as the time and resources needed to investigate cases." Report, App. IV at 53.

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scheduled—further undermining the need for class-wide scheduling.[9] We would expect this existing statutory method of prosecuting unscheduled fentanyl analogues to be at the forefront of the Report's discussion. It is not mentioned until page 12. And the Report emphasizes Department complaints that Analogue Act prosecutions for fentanyl analogues will be unwieldy and unnecessarily resource-intensive—concerns that lack factual support.[10] According to the Department, prosecutor reliance "on the [Analogue Act] to charge offenses involving fentanyl-related substances and cases for the same substance could generate inconsistent jury findings,"[11] and "prosecutors who use the [Analogue Act] have little certainty that a jury will find the substance is an analogue though they are expending a great deal of time and resources to prosecute cases."[12] But despite these concerns, there is little information about how often the Department has relied on the Analogue Act to prosecute fentanyl analogues and the Department did not provide to GAO any case-specific examples to support its claims.[13] Further, the Report does not include Defender statements that we were unable to identify any examples of cases that support the Department's concerns. We found no cases involving a resource-intensive "battle of the experts" over the identity of a purported fentanyl-related substance, nor examples where juries or courts reached different conclusions about whether a fentanyl-related substance was or was not an analogue.

Overcoming an individual's presumption of innocence is not intended to be convenient for the government. The Analogue Act requires the government to prove that a novel substance meets the Controlled Substance Act's definition of "controlled substance analogue" before that person can be convicted and punished.[14] Congress carefully designed the elements of that definition to secure convictions for dangerous novel substances while shielding harmless conduct from criminal sanctions.[15] The Report should emphasize that despite the Department's claims to the contrary, all evidence indicates the implementation of the Analogue Act has successfully achieved this balance, and that class-wide scheduling would disrupt it.

[9] The Analogue Act, 21 U.S.C. § 813, controls substances that are not otherwise scheduled or FDA-approved that are intended for human consumption if it has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, and (2) an actual, represented, or intended effect that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance in Schedule I or II. Report at 12–13. As in every criminal case, prosecutors are required to meet their burden of proof with respect to the elements of the offense under the Analogue Act.

[10] *See e.g.*, Report at 18; App. IV at 55-56.

[11] *See* Report, App. IV at 55, Report at 18.

[12] *Id.*

[13] *See Id.* at 55 n. 85 (The Department provided GAO an example of three Analogue Act cases that resulted in inconsistent outcomes, but "[n]one of these cases involved a fentanyl analogue or fentanyl-related substance.").

[14] *See id.* at 12–13.

[15] Butler Test. at 9-10 (summarizing legislative history of the Analogue Act, including consideration by Congress of testimony from the American Chemical Society).

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**II. The Report should prominently state that GAO could not substantiate law-enforcement claims that class-wide scheduling has a causal connection to reduced encounters with novel fentanyl-related substances.**

The Report repeatedly highlights law enforcement claims about the efficacy of class-wide scheduling but buries the finding that GAO could not substantiate those claims. The Report's Highlights and body repeat that "Federal law enforcement officials said that a benefit of class-wide scheduling—reduced incentives for traffickers to make new and existing fentanyl-related substances to circumvent the law—would be lost if substances were scheduled individually."[16] In contrast, the Report obscures in footnotes and appendices that GAO was "unable to draw any causal conclusions related to class-wide scheduling" and law enforcement encounters,[17] and that "the number of reports of all fentanyl analogues and other related compounds (e.g., precursors), including individually scheduled analogues, have *increased* since the implementation of class-wide scheduling."[18] Front-loading law enforcement's claims, without similar attention to these important factual findings, may lead many readers to wrongly conclude that GAO substantiated these law enforcement assertions.

We urge the authors to add language in the Highlights and in the body of the Report to clarify its findings and directly confront these claims with the absence of factual support.

**III. The Report should highlight evidence that class-wide scheduling would improperly criminalize helpful and harmless substances.**

The Report should emphasize that class-wide scheduling "preemptively classifi[es] an unknown number of similar substances with unknown effects,"[19] including harmless and therapeutic substances. The class-wide control defines fentanyl-related substances "based on their chemical structure alone and [does] not define them based on their pharmacological activity—the resulting physical and psychoactive effects on humans."[20] This is a flawed approach because chemical structure alone cannot predict how a drug will affect the human brain.[21] The relative potency of fentanyl and fentanyl analogues varies widely: "[s]ome analogues, like acetyl fentanyl, are less potent

[16] *See* Report at "Highlights"; 20.

[17] Report, App. I: at 28 n.27; *see also*, Report, App. IV at 50, 52–53 ("Although the timing of DEA's temporary order corresponds to a decrease in law enforcement reports of new and existing fentanyl analogues that are not individually scheduled, we are unable to draw conclusions about the extent to which the cause of the decrease is related to class-wide scheduling. This is because of the short time period that the order has been in effect and the numerous other factors that could affect law enforcement reports of these analogues, including fentanyl-related substances.").

[18] Report, App. IV at 51 n.73 (emphasis added); *see also, id.* at 62 ("Overall seizures of fentanyl and its analogues entering at U.S. ports of entry increased substantially from fiscal year 2018 through fiscal year 2020.")(emphasis added).

[19] *Id.* at 16.

[20] Report, App. II at 31.

[21] See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 (Testimony of Dr. Sandra D. Comer, Professor of Neurobiology (in Psychiatry), Columbia University Irving Medical Center, New York State Psychiatric Institute) (Jan. 28, 2020), https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf.

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than fentanyl; others, like carfentanil, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive."[22] There are already examples of the class-wide control's overbreadth: the Report identifies specific substances that meet the criteria for class-wide control that have "little to no pharmacological potential for abuse,"[23] as does recent scientific research.[24]

Under the class-wide control, any offense involving a fentanyl-related substance is subject to federal criminal prosecution, even if the substance in question has no potential for abuse. This approach would result in convictions for substances that may not have a psychoactive effect similar to fentanyl.[25] The Report minimizes these concerns and repeats the Department's assertions that it will not prosecute individuals for substances that are not harmful.[26] But a careful reading of the Report also shows that these assurances cannot be credited: as acknowledged (in a footnote), after 2018, the government prosecuted cases involving benzyl fentanyl,[27] a substance long known to have no potential for abuse.[28] If class-wide scheduling becomes permanent, prosecutors will have no incentive to determine whether or not a substance has abuse potential. Nor are prosecutors

[22] Kemp Chester, Assoc. Dir., Nat'l Heroin Coordination Grp., Off. of Nat'l Drug Control Pol'y, Response to Questions for the Record Following Hearing Entitled, The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary (June 4, 2019) at 3, https://www.judiciary.senate.gov/imo/media/doc/Chester%20Responses%20to%20QFRs1.pdf.

[23] Report, App. III ("[S]mall changes can produce substances with little to no pharmacological potential for abuse—*as was found for two fentanyl analogues cited by DEA in the temporary scheduling order for fentanyl-related substances*.").

[24] Dr. Sandra D. Comer et. al., *Potential unintended consequences of class-wide drug scheduling based on chemical structure: A cautionary tale for fentanyl-related compounds*, Drug and Alcohol Dependence, 3 (2021), https://www.sciencedirect.com/science/article/pii/S0376871621000259.

[25] Report, App. IV at 57.

[26] *Id.* at 57 n.88.

[27] In 1985, the DEA temporarily placed benzyl fentanyl on Schedule I based on its structure, but later removed it from control after "further research found no evidence of abuse potential." Drug Enf't Admin. Correction of Code of Federal Regulations: *Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances*, 21 C.F.R. § 1308 (2010).. In 2019, DEA classified benzyl fentanyl as a "List I" chemical, meaning that it is an ingredient that can be used to create fentanyl analogues. *See* Drug Enf't Admin., *Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 Federal Register 73 at 20822-20829, (April 15, 2020), https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0415.htm. In contrast to Schedule I fentanyl analogues, the potential sentences for distribution of List I chemicals are largely capped at five years. *See* 21 U.S.C. § 841(f)(1) ("Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall, except to the extent that paragraph (12), (13), or (14) of section 842(a) of this title applies, be fined under title 18 or imprisoned not more than 5 years, or both.")

28 Report, App. IV at 57 n.89 ("[r]epresentatives provided [the GAO] examples of at least three cases where individuals were prosecuted for the substance benzyl fentanyl which has no pharmacological effect. They stated that, in one instance, prosecutors sought the mandatory minimum associated with the charge"). The USSC Report confirms this, finding that after the 2018 temporary control, the government prosecuted "several cases involving . . . benzyl fentanyl." *See* USSC Report at 23.

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equipped to make such assessments, particularly for substances under class-wide control, which would be scheduled without gathering and reviewing scientific evidence.[29]

The Report should highlight the implications of criminalizing substances with no potential for abuse.

**IV. The Report minimizes concerns that fentanyl and fentanyl-analogue prosecutions would continue to target minimally-involved individuals and street-level dealers, an enforcement approach that exacerbates racial disparities and does not deter drug trafficking organizations.**

We urge the GAO to devote further discussion and analysis to the fact that prosecutions for fentanyl analogues disproportionately target minimally-involved individuals and street-level dealers.[30] The evidence compiled in the Report and in a recently-published report by the United States Sentencing Commission shows that most enforcement efforts have targeted low-level individuals.[31] And there is overwhelming evidence that incapacitating low-level individuals does not disincentivize drug trafficking organizations.[32] Class-wide scheduling needs to be understood, and should be framed in the Report, as another failed effort to fight the war on drugs by prosecuting low-level individuals and punishing them with disproportionately long sentences.[33]

The Report presently cabins these systemic concerns to a few sentences,[34] but devotes significant discussion to uncritically highlighting statements from law enforcement that "one of the goals of class-wide scheduling was to disincentivize drug trafficking organizations to invent new fentanyl-related substances to evade DEA's control," and that law enforcement's goal is to "dismantle the entire organization."[35] The Report also includes a potentially misleading note that "out of the eight cases we reviewed that were prosecuted under class-wide scheduling, four involved a defendant who was part of a larger drug trafficking organization." [36] This characterization omits the fact, included

[29] *See* Report at 16 ("If fentanyl-related substances are legislatively scheduled without an Eight-Factor Analysis being conducted, the Eight-Factor Analysis needed for administratively rescheduling these substances could involve more evidence than was required for the initial legislative scheduling.").

[30] *Id.*, Report, App. IV at 59.

[31] *See id.* at 54; USSC Report at 28.

[32] Nat'l Resch. Council, The Growth of Incarceration in the United States: Exploring Causes and Consequences 146 (Jeremy Travis et al. eds., 2014), http://nap.edu/catalog.php?record_id=18613; Pew, *More Imprisonment Does Not Reduce State Drug Problems*, (March 8, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems; USSC, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* 131 (2004), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-projects-and-surveys/miscellaneous/15-year-study/15_year_study_full.pdf; *see also* Butler Test. at 12-14.

[33] Butler Test. at 7.

[34] *See id.* at 19, Report, App. IV at 59.

[35] *See, e.g.*, Report, App. IV at 59.

[36] *Id.*

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elsewhere in the Report, that each of those four individuals was a street-level dealer, and that the government has not used class-wide scheduling to prosecute even one high-level importer, supplier, or drug kingpin.[37] Targeting street-level dealers for prosecution disproportionately impacts people of color, particularly Black Americans, all while failing to reduce the supply of or demand for illegal drugs.[38]

**V. The Interagency Working Group's ("Interagency Group") proposal would not address the criminal justice implications of class-wide scheduling.**

The Report suggests that "fentanyl-related substances could be legislatively scheduled with modifications"[39] to the class-wide control, and points to recommendations made by an "interagency workgroup convened by ONDCP . . . such as removing barriers to obtaining approval to conduct research and streamlining the process for removing from Schedule I . . .substances discovered to have low abuse potential."[40] We request GAO include both in the Highlights and in the Report Defenders' concerns that the Interagency Group's proposal would not remediate the flawed enforcement-first approach embraced by class-wide control, would lead to lengthy sentences for trace amounts of fentanyl-related substances, and would exacerbate racial disparities in federal sentencing. The Interagency Group's proposal also does not relieve concerns that class-wide scheduling would criminalize substances with no potential for abuse. Although it would attempt to "streamlin[e] the process for removing from Schedule I [] substances discovered to have low abuse potential," de-scheduling would not vacate sentences imposed for such substances.[41]

The shortcomings in the Interagency Group's proposal may be the result of its failure to seek the views of Federal Public and Community Defenders or of the civil rights and criminal justice community. Similarly, the GAO did not seek these perspectives on the Interagency Group's Proposal. The Report should note that these critical voices were neither present during the creation of the Interagency Group recommendations nor were we given an opportunity to comment on the proposal through the Report.

[37] *Id.* at 54.

[38] Pew, *More Imprisonment Does Not Reduce State Drug Problems* (March 8, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems.

[39] Report, Highlights.

[40] *Id.*

[41] *See* 1 U.S.C. § 109 (providing that if a statute is changed or repealed after a crime is committed, "it shall not have the effect to release or extinguish any penalty, forfeiture, or liability incurred under such statute").

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We hope that the GAO will modify the Report to reflect our comments. We remain available to discuss our perspectives and experience on this issue as needed.

Sincerely,

/s/
David Patton
Executive Director, Federal Defenders of New York
Co-Chair, Federal Defender Legislative Committee

/s/
Jon Sands
Federal Public Defender for the
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# Appendix IX: GAO Contact and Staff Acknowledgements

## GAO Contacts

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## Staff Acknowledgments

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