U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

JAN 1 1 2021

The Honorable Lindsey Graham
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed responses to questions for the record arising from the appearance of Ms. Amanda Liskamm, Director of Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General, and Mr. William T. McDermott, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, before the Senate Judiciary Committee on December 17, 2019, at a hearing entitled, "Tackling the Opioid Crisis: A Whole-of-Government Approach."

Please do not hesitate to contact this office if we can be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Mary Blanche Hankey
Acting Assistant Attorney General

Enclosure

cc: The Honorable Dianne Feinstein
Ranking Member

The Honorable Mike Lee
Subcommittee Chairman

The Honorable Amy Klobuchar
Subcommittee Ranking Member

Questions for the Record for
Tim McDermott
Assistant Administrator
Drug Enforcement Administration
U.S. Department of Justice

From a Hearing Before the
United States Senate
Committee on the Judiciary
Entitled
"Tackling the Opioid Crisis: A Whole-of-Government Approach"
December 17, 2019
Part I

Questions from Senator Harris

1. **The Drug Enforcement Administration is responsible for establishing production and manufacturing quotas for Schedule I and Schedule II Controlled substances, including opioids. In your testimony before the Senate Judiciary Committee, you said current DEA quota determinations are based on "what we think is necessary for the medical use, as well as research, as well as exportation." You also stated that the DEA's quota determination is the result of a "balanced approach."**

    a. **Please describe the approach taken by DEA to determine opioid production and manufacturing quotas.**

    b. **Please describe the approach taken by DEA to determine the 2020 aggregate production quotas for oxycodone, hydrocodone, oxymorphone, hydromorphone, and fentanyl.**

        i. **Please also describe what percentage of each quota has been allotted for (1) medical use, (2) research, and (3) export.**

RESPONSE: The factors that DEA considers in setting aggregate production quotas have changed as a result of new laws and regulations. First, under DEA's regulations as amended effective August 15, 2018 (83 C.F.R. § 32784 (2018)), when setting an aggregate production quota for any basic class of controlled substance listed in schedule I or II, DEA must now consider (in addition to the previously existing regulatory factors): (i) "[t]he extent of any diversion of the controlled substance in the class," and (ii) "[r]elevant information obtained from the Department of Health and Human Services [HHS], including from the Food and Drug Administration [FDA], the Centers for Disease Control and Prevention [CDC], and the Centers for Medicare & Medicaid Services [CMS], and relevant information obtained from the states." 21 CFR 1303.11(b)(5) and (b)(6).

As a result, DEA regulations now list the following factors that the Administrator must consider in determining the aggregate production quotas: (1) total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years: (2) trends in the national rate of net disposal of the class or chemical: (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and import quotas requested in accordance with 21 C.F.R. §§ 1303.12, 1315.32, and 1315.34; (5) the extent of any diversion of the controlled substance in the class; (6) relevant information obtained from HHS, including from the FDA, CDC, CMS, and relevant information obtained from the states; and (7) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 C.F.R. § 1303.11(b)(1-7) and 1315.11(b)(1-5). These quotas do not include imports of controlled substances for use in industrial processes.

2. **Please describe the approach taken by DEA to determine the 2020 aggregate production quotas for oxycodone, hydrocodone, oxymorphone, hydromorphone, and fentanyl.**

RESPONSE: In addition to the foregoing regulatory changes, on October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Pub. L. 115-271, 132 Stat. 3894. The SUPPORT Act, which became effective upon its enactment, changed the way DEA establishes quotas with respect to five controlled substances: fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. These five substances are referred to in the statute as "covered controlled substances." The new law specifically provides that in establishing any quota under 21 U.S.C. § 826, DEA is required to "estimate the amount of diversion of the covered controlled substance that occurs in the United States" and "make appropriate quota reductions, as determined by the [Administrator], from the quota the [Administrator] would have otherwise established had such diversion not been considered." 21 U.S.C. § 826(i)(1)(A) and (C). The SUPPORT Act further provides: "In estimating diversion under this paragraph, the [Administrator] shall consider information the [Administrator], in consultation with the Secretary of [HHS], determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and (ii) may take into consideration whatever other sources of information the Administrator determines reliable." 21 U.S.C. § 826(i)(1)(B).

For the factors listed in 21 C.F.R. §§ 1303.11(b)(1) and (2), the DEA solicited information from the FDA. In May 2019, DEA received FDA estimates of legitimate medical need for calendar years 2019 and 2020, as required by the statutes of both agencies. *See* 21 U.S.C. § 826 and 42 U.S.C. § 242.

For the factors listed in 21 C.F.R. §§ 1303.11(b)(3) and (4), DEA-registered manufacturers of controlled substances in schedules I and II provided the information by submitting their individual data to several DEA database systems used for reporting inventory, distribution, manufacturing, and estimated quota requirements to meet sales forecasts for each class of controlled substance as required by regulations.

Factor 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances. The estimates of diversion as required by the SUPPORT Act are discussed later in the document. Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than a legitimate medical purpose. In order to consider the extent of diversion, federal, state, and local law enforcement seizures and registrant reports of diversion of controlled substances from 2018 were extracted from several DEA supported databases. As a result of considering the extent of diversion, DEA notes that the quantity of FDA-approved drug products that correlate to diverted controlled substances in 2018 represents less than one percent of the total quantity of controlled substances distributed to retail purchasers. The databases used include:

- Theft Loss Report database comprised of DEA registrant reported entries documenting diversion consisting of employee theft break-ins, armed robberies, and material lost in transit;

- Statistical Management Analysis & Reporting Tools System (SMARTS) database comprised of laboratory drug submissions from seizure data and drug purchases made by DEA task force groups, tactical diversion squads, enforcement groups, and High Intensity Drug Trafficking Area (HIDTA) task force groups;

- System to Retrieve Information on Drug Evidence (STRIDE) database comprised of material seized by numerous law enforcement groups across the country, including the Federal Bureau of Investigation (FBI) field offices, DEA field offices, U.S. Immigration and Customs Enforcement (ICE) offices, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) offices, and metropolitan police departments.

The DEA identified usable information contained in the databases noted above. The data was categorized by basic drug class and the amount of active pharmaceutical ingredient (API) in the dosage form was delineated with an appropriate metric for use in proposing aggregate production quota values (*i.e.*, weight).

Data from DEA's internal Automation of Reports and Consolidated Orders System (ARCOS) database was considered as well. However, it was determined to contain identical information to the Theft Loss Report database because both are registrant reported databases, and therefore ARCOS data was excluded. Additionally, both the National Seizure System (NSS) and the National Forensic Laboratory Information System (NFLIS) databases were reviewed. The NSS and NFLIS data reports included total seized weight without reference to whether it is finished dosage forms, container weight, tablets or pill weight which in turn provides no reference to specific API concentrations; furthermore, the databases do not distinguish between pharmaceutically and illicitly manufactured controlled substances.

To consider the factors required by 21 C.F.R. § 1303.11(b), DEA formally solicited HHS, CDC, CMS, and the states in August 2018, requesting information including rates of overdose deaths and abuse and overall public health impact related to controlled substances. This information was also considered pursuant to the SUPPORT Act. Based on the level of response, DEA sent a second letter to the states in October 2018. DEA also sent a second letter to the CDC in April 2019, and CDC responded in June 2019. DEA, in consultation with HHS and CDC, discussed the requirements under the SUPPORT Act in June 2019.

As a result of these solicitations, DEA received Medicaid sales data from CMS, and drug overdose and death data from the CDC and seven state Attorneys General. The CMS data consisted of aggregated sales of controlled substances to Medicaid patients. This information could not be used to determine diversion and therefore was not used in setting the aggregate production quotas. The CDC and HHS do not have mortality data by individual controlled substance, but provide documents and links to data sets and scholarly articles containing overdose and death rates at the national level. DEA determined that the current data could not be used to estimate diversion for the purpose of setting the aggregate production quotas. One major drawback is that the data does not examine each controlled substance individually (*i.e.*, as a basic class and the quantity ingested), but groups them together chemically, making it difficult to determine which basic class was involved and to what extent its aggregate production quotas should be lowered.

For example, patients that overdose from hydrocodone, oxycodone, or hydromorphone are grouped together under natural and semi-synthetic overdose. DEA is unable to determine the basic class that led to the overdose from this information. Additionally, DEA cannot determine from the data if the patient overdosed on an illicit opioid or an FDA-approved opioid product. For purposes of setting the aggregate production quotas for each basic class of controlled substance, DEA would benefit more from the drug overdose and mortality data if it precisely identified the controlled substance(s) believed to be the cause of overdose or death and if it included the quantity of the substance ingested. DEA and HHS are working together to determine if this data currently exists in any reliable databases.

Nine state Attorneys Generals responded to the DEA's request for information. Seven provided, in general, prescription data (from prescription drug monitoring programs), and overdose and death rate data, in addition to statements regarding the over prescription of opioid medications and its effect on public health. The other states were not able to, or did not, provide the requested data. DEA examined the information submitted and determined that it is too generalized to use in estimating diversion because the controlled substances are grouped together chemically. Toxicity reports, moreover, show all the drugs in a patient's system when arriving at the hospital or emergency room, which makes it difficult to know how much, and which drug, is responsible for the visit and consequently adjust its individual aggregate production quota. Additionally, there is no way to determine if the substance was manufactured illicitly or was an FDA-approved drug product. The manufacturing of illicit substances is not considered when determining the aggregate production quotas because such illicit manufacturing cannot be tempered by adjusting the aggregate production quotas. The information provided is highly valuable to understanding the impact of substance use, misuse, and abuse on the public health, but in its current form is not usable for the aggregate production quota analysis.

Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2020 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 C.F.R. § 60294 (2009) and 75 C.F.R. § 79407 (2010), respectively).

3. **Please also describe what percentage of each quota has been allotted for (1) medical use, (2) research, and (3) export.**

RESPONSE: DEA does not determine what percentages of aggregate production quota will be utilized for specific categories such as medical, scientific, research, industrial needs, and export. An aggregate production quota is DEA's estimation of legitimate need based on the cumulative individual, independent business decisions of DEA registered manufacturers and data from other federal agencies. The manufacturers provide DEA with an estimation of individual quota requirements to meet their forecasted business activity that are captured within the criteria set by Congress as a manufacturing activity. DEA registrants may submit amendments to their estimation of quota throughout the calendar year as they modify their business plans. The modifications may be due to internal business decisions, responses to market forces, requests by other domestic federal agencies, or requirements from foreign agencies. The FDA provides DEA its estimations of legitimate domestic medical need on an annual basis as required by statutes.

The term "research" encompasses a wide variety of activities, from the manufacture of reference standards to the manufacture of commercial-sized batches prior to FDA approval. The portion of the aggregate production quota utilized for such research purposes will vary each calendar year based on individual manufacturers' responses to other criteria. Manufacturers may also amend the research quota requests throughout the calendar year as they find necessary.

4. **Does the DEA have any concerns about the impact of permanent scheduling on fentanyl and fentanyl analogue research?**

RESPONSE: The control of fentanyl-related substances as a class does not prohibit research; the Controlled Substances Act of 1970 (CSA) provides a regulatory framework to conduct scientific investigations with fentanyl-related substances, just as with any other controlled substance. By introducing these substances to a regulatory scheme, the CSA provides for research, and these substances are then subject to the closed system of distribution and record keeping, which provides authorities the means to address those bad actors jeopardizing valuable research. As of May 1, 2020, there were 27 schedule I research registrations to study "fentanyl-related substances." Of these 27 registrations, nine were new applicants and 18 were updates to existing schedule I research registrations. Of the 18 existing researchers, four researchers are under contract with DEA to assist with conducting pharmacology studies on these substances to assist in providing data to other Federal agencies as to drug effect to inform regulatory decisions. Furthermore, DEA establishes annual quotas for all controlled substances including schedule I controlled substances and will establish appropriate quotas for research purposes for all fentanyl-

related substances and continue to work with our colleagues in the research community to assist in facilitating their research efforts.

5. **Given DEA's track record, what reassurance do we have that DEA will put this data to good use?**

RESPONSE: On October 1, 2019, the Department's Office of the Inspector General (OIG) published its review of the DEA's Regulatory and Enforcement Efforts to Control the Diversion of Opioids. The report identifies ways the Department and DEA can enhance their abilities to detect the diversion of controlled substances such as opioids. The Department and DEA appreciate the OIG's assessment of the programs involved in the report and the opportunity to discuss improvements made to increase the regulatory and enforcement efforts to control the diversion of opioids.

Although the report references data as far back as 1999, the scope of the report starts in Fiscal Year (FY) 2010 through FY 2017 and addresses a review of DEA's Diversion Control Division (DC). DC is responsible for regulating and enforcing Titles II and III of the CSA, which requires importers, exporters, manufacturers, distributors, dispensers, and healthcare practitioners that handle controlled substances to register with DEA. When controlled substance transactions fall outside the closed system of distribution, the activity constitutes diversion. DEA is working diligently to put in place additional tools, and on October 23, 2019, DEA launched a new centralized database for distributors to report Suspicious Order Reports, along with other regulatory improvements that will better allow DEA to identify and investigate registrants that violate the CSA. The passage into law of H.R. 6, the SUPPORT for Patients and Communities Act of 2018 (P.L. 115-271), has enhanced DEA's ability to better detect and combat diversion of pharmaceutical opioids. Implementation continues, and DEA, in consultation with the Department, will work with OIG to update its processes and will provide routine updates on its progress.

The OIG report identified other areas for improvement, including revising field division work plans to allow more flexibility to target registrants for investigation and a recommendation to revive a drug abuse warning network to identify and respond to emerging drug abuse trends and new drug analogues. In fact, DEA has already modified the Controlled Substance and Chemical Regulatory Work Plan to allow for greater flexibility of investigators. Additionally, DEA has begun to develop a program to connect symptom causation and newly emerging synthetic drugs such as synthetic cannabinoids, synthetic cathinones, fentanyl-related substances, and other hallucinogens.

6. **I have a concern about scheduling drugs, such as fentanyl analogues, on a class-wide basis, particularly where some of the scheduled substances may not have psychoactive effects at all or may even have beneficial effects. Last year, I joined with Sen. Durbin and some of my other colleagues on a letter to Health and Human Services Secretary Azar to get HHS's feedback on scheduling these substances as a class. In response, HHS expressed a real concern about the impact class-wide scheduling would have on scientific research. Specifically, the letter emphasized that "research with fentanyl-related substances and other synthetic opioids may be**

important in the development of new and improved treatments for opioid addiction and overdose, chronic pain, and other neurological and psychiatric conditions." If the so-called "war on drugs" taught us anything, it's that we can't arrest our way out of a drug crisis. We have to make treatment—among other things—a real part of the equation. How can we schedule dangerous fentanyl analogues while ensuring that (a) we are not arresting and prosecuting people for possession of substances that may not have any psychoactive effect; and (b) we allow research into the potential beneficial uses of certain fentanyl analogues?

RESPONSE: The two parts of your question are related, and the answer to the second part informs the answer to the first part.

With respect to the second part of your question about research, DEA appreciates your concern regarding a balanced approach to protecting the public the risk of diversion of highly potent and lethal opioids procured for the purposes of scientific research. We are pleased to learn that this class is now being considered for additional research for new potential medical uses. Effective fentanyl class control can coexist with critical drug research in a regulated environment.

With regard to the DEA's temporary scheduling action of fentanyl-related substances (FRS), DEA reviewed and applied available scientific information to update an existing definition describing fentanyl-related substances. Our scientific team took pains to describe structural modifications to fentanyl that are likely to cause psychoactive effects. The review and application of structure activity relationships is a well-established and common practice by academic and pharmaceutical entities.

Before taking action to permanently control a substance – or in this case a class of substances – data is collected to evaluate the abuse potential, and what, if any, impacts the substance will have on public health and safety. Data from scientific researchers and public health are critical to the evaluation. Between 2015 and 2018, DEA issued a series of temporary (emergency) scheduling orders to control 17 fentanyl class substances. For many of these substances, numerous fatalities were associated with their rapid introduction on the illicit market. Based on the structural modifications that define the class of fentanyl-related substances under consideration for class-wide scheduling, it was determined a proactive approach was required to protect the public from those trafficking in these substances after numerous substances were encountered on the illicit market. A scientific review provided an evidence-based definition with these substances likely to pose an imminent hazard to the public safety. The class control definition was the result of an extensive review of the scientific and patent literature and findings from these publications were utilized to establish the boundaries of the structural definition. This is a common practice. The United Kingdom's 1986 Modification to the Misuse of Drugs Act provided a fentanyl class control; this was the basis for the DEA definition. DEA made minor modifications to the definition to exclude pharmacologically inactive substances, such as norfentanyl and *N*-benzylfentanyl, per the scientific literature and DEA pharmacological studies. In an effort to move from a reactive approach driven by mortality reporting to proactively protecting the public, DEA temporarily controlled fentanyl-related substances, as a class, in February 2018. In a continued effort to protect the public, DEA supplemented the fentanyl-related substance class control with fentanyl precursor chemical controls in 2020. These actions controlled norfentanyl,

N-benzylfentanyl, and 4-anilinopiperidine, which have been encountered in clandestine fentanyl manufacturing operations.

As is clear from the statement of Administrator Giroir, Assistant Secretary for Health, before the House Judiciary Committee on January 28, 2020, HHS agrees with DEA that, as the leading cause of overdose deaths in our nation, and in many nations around the world, keeping fentanyl and fentanyl analogues off the streets must be our highest priority. DEA and HHS further agree that we must ensure access to these substances for legitimate research to develop new therapies for opioid addiction and overdose, chronic pain, and other neurologic and psychiatric conditions and improve scientific understanding of the effects of these substances on human health. Working together with colleagues at ONDCP, DOJ, and HHS, the interagency developed an interagency legislative proposal that balances the need to control these substances as a class, with critical protections for researcher access necessary to study these substances. The interagency proposal was shared with House and Senate Committee staff in early September 2019 and remain available for further discussion. This proposal worked toward accomplishing the Administration's objectives to ensure researcher access and demonstrates that the permanent scheduling of fentanyl related substances need not be an impediment to research.

The regulatory framework of the CSA exists as an underlying platform for research studies to be undertaken. DEA is pleased HHS has been engaged and looks forward to learning about current funding outcomes related to research with FRS and other synthetic opioids that may be important in the development of new and improved treatments for opioid addiction and overdose, chronic pain, and other neurological and psychiatric conditions. This research remains of great interest to DEA because it informs the mechanism, provided by Congress under the CSA to move an FDA-approved drug to another schedule or decontrol upon HHS' recommendation. In this respect, the FDA and DEA regulatory schemes are interrelated.

As noted above, this critical research can co-exist with class-wide scheduling, and there need not be friction between agencies' objectives and interests. Few would dispute that fentanyl-related substances as defined may produce unpredictable and often deadly results. DEA anticipates that researchers would be troubled to learn current FRS encounters appear on the illicit market prior to any legitimate investigations.

The temporary class control is one of many examples highlighting that regulatory controls are effective in reducing illicit drug supply and balanced approach to protect public safety. As of April 30, 2020, 27 substances have been reported to drug seizure databases and by other drug identification efforts meeting the definition of a fentanyl-related substance (FRS) in the February 2018 temporary order (phenyl fentanyl, *para*-fluoro furanyl fentanyl, crotonyl fentanyl, thiofuranyl fentanyl, fentanyl carbamate, 4-methylfentanyl, 3',4'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-fluoro acrylfentanyl, *beta*-methylfentanyl, benzodioxole fentanyl, *ortho*-fluoroisobutyryl fentanyl, 4'-methyl acetyl fentanyl, 3-fluoroisobutyryl fentanyl, *meta*-fluorofentanyl, *para*-methoxyfuranyl fentanyl, *ortho*-fluorofuranyl fentanyl, *ortho*-methyl acetylfentanyl, 2'-fluoro *ortho*-fluorofentanyl, *beta'*-phenyl fentanyl, hexanoyl fentanyl, *para*-methylcyclopropyl fentanyl, *ortho*-methylmethoxyacetylfentanyl, 3-furanyl fentanyl, alpha'-methyl butyryl fentanyl, and 2',5'-dimethoxyfentanyl). Of the 27 substances, only 12 new substances have been encountered since

enactment of the temporary order and the remainder of FRS, 15 substances were present on the illicit market prior to the class control and were regulated as schedule I substances. It is important to note that most of the 12 fentanyl-related substances that were identified after the temporary control action in February 2018 were isolated incidents; only one substance (*para*-fluoro furanyl fentanyl) of the 12 was encountered in more than five law enforcement exhibits according to the National Forensic Laboratory Information System (NFLIS) (query date 30 April 2020). Additionally, since 2018, there has been a significant decline in law enforcement reports to NFLIS of fentanyl-related substances. In the 24 months preceding the temporary order (February 2016 through January 2018), there were over 17,500 reports of these substances to NFLIS, excluding those controlled prior to 2016. Since the temporary class control (February 2018 through December 2019), there were fewer than 8,800 reports to NFLIS for substances structurally related to fentanyl, a 50 percent reduction. This is evidence that the control of these substances is effective in keeping these deadly substances off the streets.

A review of the scientific literature notes none of the 27 FRS noted above that were encountered by law enforcement was the subject of a research program. The majority of researchers are investigating detection methodology of these substances, which highlights the concerns of fentanyl analogs on the public health and safety; these substances are both drugs of abuse and potential chemical weapons.

To provide some historical context to the class-wide scheduling action and why it was necessary, fentanyl was placed under the CSA in schedule II by Congress in 1970. Fentanyl is a substance with a high potential for abuse and approved medical use. Since the enactment of the CSA, a series of modifications has been made to the CSA in response to trafficking and abuse trends related to opioids. Some examples are the Comprehensive Crime Control Act of 1984 (temporary scheduling provision) and Controlled Substance Analogue Enforcement Act of 1986 (commonly known as, the analogue provision). As the current opioid epidemic increased in complexity, law enforcement and public health officials reported trafficking and abuse of fentanyl analogues. In response to the reporting, DEA issued a series of temporary (emergency) scheduling actions in the interest of the public safety. From July 2015 to the temporary fentanyl class control in February 2018, DEA responded with eight emergency scheduling actions to control 17 fentanyl analogues. In response to trafficking and documented harm, sadly oftentimes in the form of mortality information, DEA was initiating a new regulatory control every few months.

The DEA is committed to ensuring that substances that pose a threat to the public health and safety are appropriately controlled under the CSA. With that objective in mind, the DEA issued the February 2018 temporary order defining "fentanyl-related substances" and placing them under schedule I control. Prior to the class control, DEA observed a rapid and reliable emergence of new fentanyl-related substances in an attempt to evade controls. The action served as an effective deterrent and removed an incentive for clandestine manufacturers and traffickers to transition to new fentanyl-related substances in an attempt to circumvent regulatory controls.

The class control of fentanyl-related substances has proactively protected the public from those preying on vulnerable populations and ultimately saved lives. The action provided for the seizure of these substances at our ports of entry and subjected the substances to a closed system

of distribution for legitimate manufacturing, distribution, and research. At the same time, this action allowed lawful entities (registrants) to handle the entire class of fentanyl-related substances under a single controlled substance code number while providing additional tools for law enforcement and public health.

Temporary scheduling under the CSA controls a substance in schedule I for a period of two years. During this timeframe, DEA initiates a request for a scientific and medical evaluation and scheduling recommendation from HHS. On an ongoing basis, DEA also provides encounter and pharmacology data to inform HHS' decisions To further assist HHS, DEA has established a number of pharmacology contracts with researchers to elucidate drug effect. Traffickers are introducing drugs to users with unpredictable effects. Through investigation, DEA contract researchers are adding evidence to inform decisions and these researchers are a large proportion of the overall number of researchers registered to investigate FRS. Over the last 10 years, the rate of new psychoactive substances being trafficked in the United States has increased dramatically. DEA's efforts at protecting the public health and safety has led to many temporary scheduling actions. A response by Congress would remove incentives for illicit manufacturers and traffickers and protect researchers and the FDA drug approval process. The class of FRS needs to be categorically and permanently scheduled. A solution that prevents FRS from falling out of control is essential to continue tackling the opioid epidemic our country currently faces, and the Department and DEA firmly believe that a solution can be found that will achieve this goal while also accommodating interests in continued research on these substances.

With respect to the second concern in the question to ensure that "we are not arresting and prosecuting people for possession of substances that may not have any psychoactive effect," we are aware of no cases where class scheduling has led to that undesirable effect, and we deem it extremely unlikely that it would. First, the substances that meet the definition of FRS are not benign but are controlled based on scientific evaluation of their structure. Second, in a rare case where a trafficker would peddle a substance that meets the definition of FRS but is determined not to be psychoactive, and the trafficker knew it, we would expect that prosecutorial discretion would interpose a check. Our priority is to address those trafficking and preying on these individuals with no regard for their health and safety.

Questions from Senator Klobuchar

1. **I have heard from several people in my state about the increase in the sale and misuse of methamphetamines. According to the Minnesota Department of Public Safety, 161 people died from methamphetamine overdose in 2018 and a record 1,145 pounds of meth was seized in 2018, compared to just 143 pounds seized in 2013. What is the DEA doing to address the threat posed by the recent rise in the sale and distribution of methamphetamine, and what tools or specific resources would help the DEA in collaborating with state and local partners to address this public health crisis?**

RESPONSE: DEA is attacking methamphetamine at the source. By increasing the number of personnel in Mexico, and working with the Department and other international partners, DEA is pressuring the Mexican government to do more – such as increasing information sharing and taking action on the methamphetamine labs identified by DEA. Moreover, DEA is hitting the command and control of Mexican cartels that benefit from the methamphetamine trade. Cartel members/leaders have been identified by the DEA and have been indicted. DEA is working with its law enforcement counterparts in Mexico to bring these criminals to justice in U.S. courts. In addition to our continued work to stop drugs before they are smuggled across the border, DEA has initiated Operation Crystal Shield. This operation is providing enhanced enforcement at nine identified methamphetamine transportation hubs throughout the U.S. to prevent bulk methamphetamine from making its way to neighborhood streets. DEA will use its investigative expertise to find and shut down the financial networks used by cartels.

Questions from Senator Whitehouse

1. **A number of federal agencies collect data related to drug trafficking and drug abuse, including the DEA, U.S. Customs and Border Patrol, and the Centers for Disease Control**

    a. **What information is currently shared among these agencies? How is it shared?**

RESPONSE: On a daily basis, DEA shares drug related information regarding drug traffickers with U.S. Immigration and Customs Enforcement/Homeland Security Investigations () and U.S. Customs and Border Protection (CBP). This information includes but is not limited to sharing of phone numbers that cartel members/local drug dealers are utilizing, addresses of their residences, vehicle information and other important biographical information. Additionally, there are local de-confliction centers to ensure that all agencies are aware of which agency is investigating a certain "target" to prevent any overlap in investigation or "blue on blue," incidents. The sharing is mostly done through a system utilized by DEA called DARTS that is tied into the system utilized by HSI and CBP, and other state, local, federal, and tribal agencies called DICE. Another way information is shared and disseminated is through our Special Operations Division (SOD), which houses numerous federal agencies.

In addition to HIS and CBP, DEA's DC has a number of collaborations with HHS, which includes the monitoring, pharmacological testing, and analysis of new substances of abuse with NIDA and FDA and routinely provides law enforcement, seizure data to the CDC. Through State Department, HHS and DEA support a number of international bodies efforts related to drug and chemical control and monitoring. With the passage of the SUPPORT Act, combined with, DEA's published a final rule effective August 15, 2018, codifying the requirement for DEA to consider relevant additional information. Accordingly, DEA has further expanded its information sharing capabilities with the HHS, FDA, CDC, as well as the Centers for Medicare and Medicaid Services (CMS), and the state Attorneys General to better inform DEA for the purpose of quota setting.

    b. **What are the barriers to information sharing between federal agencies?**

RESPONSE: Fortunately, because of the use of DARTS and DICE, along with several information sharing centers, such as Special Operations Divisions and El Paso Intelligence Center (EPIC), along with local de-confliction centers, there are few barriers between federal agency information sharing.

    c. **What additional resources or authorities would facilitate better information sharing between federal agencies?**

RESPONSE: At this point DEA has not identified any additional resources that would improve information sharing between federal agencies.

2. **In an exchange with Sen. Kennedy, you discussed how having access to data from state prescription drug monitoring programs (PDMPs) would enhance the Drug Enforcement Administration's (DEA) efforts to disrupt drug trafficking. States vary widely in whether and how they permit the DEA to access their PDMP data: some allow access if there is an open law-enforcement investigation, while others require an administrative subpoena[1] or a warrant. Some have argued that the U.S. Supreme Court's recent decision in Carpenter v. United States[2] raises questions about whether PDMP records are protected by the Fourth Amendment. Recently, the state of New Hampshire refused to comply with an administrative subpoena for PDMP records, and the DEA sued to compel the records.[3] The trial court found that patients do not have a reasonable expectation of privacy in their prescription drug records, and New Hampshire appealed. The First Circuit will decide the case this year.**

   i. **What can Congress do to facilitate the DEA's access to state PDMP records?**

RESPONSE: At present, DEA's access to Prescription Drug Monitoring Programs (PDMP) data is limited to information relating to an ongoing investigative matter, as required by 27 states, and the means by which DEA obtains PDMP information vary from state to state, with 21 states requiring some kind of court or grand jury process. Access to state PDMP data consistently across all 50 states would assist DEA in carrying out its mission under the CSA. DEA stands at the ready to educate Congress on this current problem and find a solution to share data that is crucial to DEA's enforcement capability and its ability to protect the public from the drug overdose epidemics.

   ii. **Would regular access to anonymized PDMP records, which may not raise the same Fourth Amendment concerns, assist the DEA in its law enforcement efforts?**

RESPONSE: PDMP's are state-run data collection programs that help states, prescribers, and in some cases law enforcement prevent prescription drug diversion. Prescriptions contain important information pertaining to ensuring patient care, including the name, quantity and strength of the drug prescribed, information about the patient (name and DOB), and information about the doctor who wrote the prescription. Where PDMPs exist, pharmacists report this data along with the pharmacy, which filled the prescription to the state or local PDMP. Currently, 49 states have an operational PDMP; Missouri has several county PDMPs and proposed legislation to authorize a state-wide PDMP. Generally speaking, if a state's PDMP is operated by a Department of Health or a Single State Authority for Substance Use Services, then concerns over patient and provider confidentiality can impact law enforcement access. If a PDMP is operated

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[2] Carpenter v. United States, 138 S.Ct. 2206, 2219 (2018).
[3] Sarah Merken, *Medical Prescription Warrantless Searches Get New Challenge*, BLOOMBERG LAW, Dec. 16, 2019, https://news.bloomberglaw.com/privacy-and-data-security/medical-prescription-warrantless-searches-get-new-appeals-test.

by a Board of Pharmacy outside a health agency or by a law enforcement agency, then it is sometimes regarded as easier for law enforcement to obtain records pursuant to an ongoing investigation; however, there is concern in the public health community about unnecessary law enforcement intrusion into patient privacy and prescriber activity. Currently, 21 states require some kind of court or grand jury process in order for law enforcement to obtain information from PDMPs pursuant to an active investigation. This may include a court order, subpoena, search warrant, or grand jury order. No states have procedures in place for sharing their PDMP database with federal law enforcement, although DEA continues to explore whether existing Memorandums of Understanding with State Attorneys General can be the vehicle for that sharing.

Information sharing from state PDMPs to Federal Law Enforcement is greatly important for a number of reasons. PDMPs are an essential tool to help detect the overprescribing of controlled substances by practitioners and the pharmacies who may be indiscriminately filling controlled substance prescriptions. Data from PDMPs can be used to identify a number of risk factors that indicate the potential diversion of controlled substances due to prescribing practices or doctor shopping by people with addiction or for distribution on the black market. Currently 1.7 million practitioners, 71,000 pharmacies, and 18,000 hospitals are registered with the DEA. This means that 99.1% of the DEA registrant population consists of prescribers. Manufacturers and distributors – the only entities that must report transactions to ARCOS – constitute only 0.06% of DEA registrants. The vast majority of doctors and pharmacies nationwide comply with their obligations under federal and state law; however, some doctors and pharmacies operate outside the law, and, unfortunately, these actors can and do have a disproportionate impact on the opioid epidemic. To protect public health and safety, Congress has mandated that DEA be "proactive" in its efforts to control prescription drug diversion. DEA has made important strides to combat this epidemic. But without access to an encrypted comprehensive database of all prescribing records for controlled substances, DEA faces challenging knowledge gaps that hinder its ability to effectively fight prescription drug diversion. Since the SUPPORT Act requires DEA to "estimate" diversion and then reduce manufacturers' quotas based on those estimates, DEA needs new tools to assist it in calculating diversion. For this specific purpose, data from state and local PDMPs, are essential to estimate diversion. Sharing this data with DEA can be done in a manner that protects both the privacy and health of U.S. Citizens.

b. What other information, if any, do state and local governments share with the DEA?

RESPONSE: DEA can request and receive a variety of information from state and local governments pursuant to active criminal or civil investigations.

c. How many state and local governments currently share other types of information with the DEA?

RESPONSE: It is possible that other types of information are being shared with DEA by different state and local governments through MOUs set up between an individual DEA office and that particular state or local government. To determine what information sharing is taking

place at the state or local levels, DEA would need to query all of its offices and that would be very laborious and time intensive.

d. Are you aware of other state and local data sources that the DEA does not currently have access to that would help the DEA's efforts to disrupt drug trafficking? What are these sources?

RESPONSE: DEA has not identified any additional data sources that would assist in DEA's efforts to disrupt the diversion of controlled substances and drug trafficking but continues to develop and foster strong working relationships with state and local counterparts in order to facilitate and encourage any future data sharing that may be useful in the disruption and dismantlement of controlled prescription drug trafficking activities.

e. What are the barriers to information sharing between federal, state, and local governments?

RESPONSE: The barriers are differences in technology and operating systems used. SOD maintains the DICE system that is internet based and is used to share information between partner federal, state, local, tribal, and some international agencies, greatly reducing the barriers to information sharing. Also, as stated in previous answers, the lack of a federal law providing DEA access to state and local PDMP data is also a significant barrier. Additionally, the disclosure of substance abuse treatment records by the Department of Veterans Affairs to law enforcement entities are prohibited without a qualifying court order. *See* 38 U.S.C. § 7332.

f. What additional resources or authorities would facilitate better information sharing between federal, state, and local governments?

RESPONSE: Better information sharing could be facilitated by better PDMP information and consistent information from state medical boards of current actions being taken against prescribers in their area of responsibility. A statutory requirement mandating the use of the SOD across the federal drug law enforcement enterprise would facilitate better information sharing and operational efficiencies. This information sharing would assist greatly in the daily de-confliction that happens at SOD to limit the risk of blue-on-blue fatalities and case handling.

3. It is my understanding that pharmacies can transfer up to five percent of their inventory to another pharmacy without having to immediately report to DEA. Pursuant to the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, P.L. 114-145, the Department of Health and Human Services (HHS), in coordination with DEA, was required to issue a report evaluating the effect of the new law. The report was due in April 2017 but has still not yet been published.

a. Has DEA provided information to HHS in connect with this report? If so, please provide us with any information DEA provided to HHS?

RESPONSE: The report to Congress was provided in June 2020 to the Chairs and Ranking Members of the House Committees on the Judiciary and Energy and Commerce and the Senate Committees on Health, Education, Labor, and Pensions and the Judiciary, as required by the Act.

A copy of the report is available by contacting the HHS Office of the Assistant Secretary of Legislation or one of the Committees.

b. How many Immediate Suspension Orders has DEA issued since 2017?

RESPONSE: DEA has issued the following Immediate Suspension Orders (ISO) since 2017:

Fiscal Year	Number of ISOs Issued
2017	6
2018	20
2019	29
2020*	10

*Through May 7, 2020.

Questions from Senator Dianne Feinstein

1. **In 2018, the Using Data to Prevent Opioid Diversion Act of 2018, which I authored, was enacted as part of the SUPPORT Act. The law requires the DEA to share anonymized information from the ARCOS database with manufacturers and distributors about the quantity and type of opioids delivered to each pharmacy. If manufacturers and distributors fail to consider this information when determining whether an order is suspicious, they can be held civilly and criminally responsible.**

    a. **The October 2019 U.S. Department of Justice Office of the Inspector General (DOJ OIG) report noted two deficiencies with the ARCOS system: 1) not all registrants input data at the same intervals, making analysis more difficult; and 2) the system does not capture data for all controlled substances. Would a statutory change to require all registrants to input data on a monthly basis for all controlled substances be helpful?**

    b. **What independent steps is the DEA taking to improve its analysis of ARCOS data to generate actionable investigative leads?**

RESPONSE: DEA uses ARCOS data to support ongoing investigations and analyzes this data to identify investigative leads for its field division offices. Additionally, industry-reported data is analyzed by a business intelligence tool that accesses and summarizes large amounts of data, allowing identification of anomalies, outliers, and patterns based on the submitted request for data.

DEA also utilizes ARCOS data proactively and in concert with other data sets, including Drug Theft and Loss, and the SORS Online system, to detect the diversion of opioids and emerging drug trends in a timely manner to protect public health and safety. DEA strives to proactively target highly anomalous pharmacies, practitioners, manufacturers, distributors, drugs, and/or locations based on their collective sales and purchases.
DEA has been enhancing the algorithms used to automate the ARCOS quality control and validation process with the goal of improving ARCOS effectiveness. During this process, the data is reviewed and analyzed to ensure the information reported does not contain errors. The review process includes contacting registrants to validate abnormalities identified in their reports.

In April 2020, DEA began preparing and sharing detailed ARCOS reports for the State Attorneys General. These reports consist of nationwide ARCOS reported transactions, including all schedule II and schedule III narcotic drugs reported by distributors nationwide. These transactions are to retail, chain, and mail order pharmacies, HMOs and practitioners. The transactions are summarized and ranked by drug, state, and county every six months, and include information on state and U.S. averages. In addition, DEA began providing the data used to prepare these reports to the state Attorneys General for them to be used as a targeting tool.
It should be noted that although the data reported to ARCOS is very important, it only captures what is being sold from manufacturers and distributors to retail. The other piece of the picture is data that the states capture in their respective PDMPs. Currently 1.7 million practitioners,

71,000 pharmacies, and 18,000 hospitals are registered with the DEA. This means that 99.1% of the DEA registrant population consists of prescribers. Manufacturers and distributors – the only entities that must report transactions to ARCOS – constitute only 0.06% of DEA registrants. The vast majority of doctors and pharmacies nationwide comply with their obligations under federal and state law; however, some doctors and pharmacies operate outside the law, and unfortunately, these actors can and do have a disproportionate impact on the opioid epidemic. To protect public health and safety, Congress has mandated that DEA be "proactive" in its efforts to control prescription drug diversion. DEA has made important strides to combat this epidemic. But without a comprehensive database of all prescribing records for controlled substances, DEA faces challenging knowledge gaps that hinder its ability to effectively fight prescription drug diversion. Since the SUPPORT Act requires DEA to "estimate" diversion and then reduce manufacturers' quotas based on those estimates, DEA needs new tools to assist it in calculating diversion. For this specific purpose, data from PDMPs, encrypted in order to protect patient confidentiality, would be essential to estimate diversion.

Additionally, the SUPPORT Act requires the Attorney General to make the following information available through the existing ARCOS database to monitor controlled substances: (1) the total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant; and (2) the total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant. These enhancements to the ARCOS database were instituted and made available on February 26, 2019. These changes have greatly improved the quality and timeliness of ARCOS data with the goal of being able to identify prescription drug trends more quickly. Whereas data used to be more than a year old by the time it was available, with the enhancement, the data is now no more than 3 or 4 months old and is provided in an electronic format. DEA continues to engage with industry regarding their suggested enhancements.

As part of the ARCOS enhancement, the DEA is required to prepare and make available to state entities a standardized report containing descriptive and analytic information on the actual distribution patterns as gathered through ARCOS. The report must include detailed amounts, outliers, and trends of distributor and pharmacy registrants in such states for schedule II controlled substances. 2018 ARCOS standardized reports for all ARCOS reportable drugs are publicly available on DEA's website, and the 2019 data is also publicly available.
An updated, standardized list of ARCOS reports is maintained at
www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html.

2. **It is my understanding that pharmacies can transfer up to five percent of their inventory to another pharmacy without having to immediately report to DEA.**

   a. **Does this create a blind spot for diversion to occur?**

RESPONSE: Yes, this does create a blind spot for the diversion of controlled substances in schedules III-V to occur because Pharmacy A could request that several pharmacies within its chain or within its local area order a larger amount of Drug X and then ship 5% of that particular drug to Pharmacy A. It is conceivable that Pharmacy A would then receive a substantial amount

of Drug X, which could then be diverted. It is important to note that a DEA-222 form is required for any transfers of schedule II controlled substances, as it would be with any such distribution. 21 C.F.R. § 1307.11(a)(1)(iii). Although this DEA-222 requirement would document the transfer, it is still not an ARCOS-reportable transaction, since pharmacies are not required to report transactions to ARCOS; thus, DEA would not have these distributions captured in its ARCOS database. As a matter of clarification, it should be noted that transfers made under the five percent rule are not cross-checked against the current inventory of the transferring registrant; rather, they are calculated as a percentage of the transferring registrant's annual inventory. Entities that transfer more than five percent of their annual inventory must register as distributors.

b. Would requiring pharmacies to report these transfers, unless they are for a specific patient need, help close this blind spot?

RESPONSE: Yes, requiring pharmacies to report to ARCOS all transfers, regardless of amount or patient need, would help to efficiently close this blind spot in the closed system of distribution and prevent the diversion of controlled substances.

3. **Regulations Required - It is my understanding that DEA has not issued several regulations that could help address the opioid epidemic. Specifically, DEA has not issued:**

   - **Regulations regarding what constitutes a suspicious order, which were required by the SUPPORT Act, enacted in 2018;**

   - **Regulations necessary to implement the telemedicine provisions triggered by the Administration's declaration of a public health emergency as well as the special telemedicine registration regulations required in the SUPPORT Act, enacted in 2018; or**

   - **Regulations related to the partial fill of opioid medications by pharmacists that were authorized by the Comprehensive Addiction and Recovery Act, enacted in 2016.**

   Please explain why these regulations have not been issued, and when you anticipate they will be issued.

RESPONSE: A point of clarification, the SUPPORT Act did not require DEA to promulgate regulations to define suspicious orders, and the Administration's declaration of a public health emergency does not trigger the need for DEA to issue regulations. The SUPPORT Act required the Attorney General to establish a centralized database for collecting reports of suspicious orders. Specifically, this database was created to improve the flow of information among registrants, DEA, and state and local law enforcement in order to prevent the diversion of controlled substances. The major changes involved in the reporting of suspicious orders are that ALL DEA registrants that distribute controlled substances to other DEA registrants must report suspicious orders. Additionally, the registrant must now give a reason for the order to be flagged

as suspicious and stop the order from being completed if flagged. Law enforcement, in turn, must investigate each report to determine if civil or criminal actions should occur. DEA met its obligation by the SUPPORT Act deadline and developed the robust database that became available to law enforcement and DEA registrants on October 23, 2019.

The regulations relating to a special registration for telemedicine require the Attorney General, in consultation with the Secretary of HHS, to promulgate final regulations specifying: (1) the limited circumstances in which a special registration under this subsection may be issued; and (2) the procedure for obtaining a special registration under this subsection. This regulation is in draft form and is going through the internal as well as the interagency review processes, and DEA has been addressing any edits/concerns that have been raised throughout that process. We anticipate these regulations being published in the near future.

4. **Poly Drug Use - The Centers for Disease Control and Prevention (CDC) has warned that a fourth wave of the drug overdose epidemic is upon us, and that most of those suffering from addiction use more than just opioids. For instance, in 2018, cocaine, methamphetamine, and benzodiazepines were present in nearly 60 percent of all opioid-related overdose deaths. In light of this, do you believe it is shortsighted to implement strategies that focus solely on opioids?**

   a. **In light of this, do you believe it is shortsighted to implement strategies that focus solely on opioids?**

   b. **What is the DEA doing to address the increases in meth and cocaine production, trafficking, and abuse?**

   c. **How is the DEA addressing the trend of adding fentanyl and other synthetic opioids to cocaine, methamphetamine, benzodiazepines and other illicit substances?**

RESPONSE: Yes, this would be shortsighted. DEA focuses its investigations on Transnational Criminal Organizations (TCOs). TCO's are poly drug distributors. When DEA investigates TCOs, it investigates all drugs that threaten our nation. DEA is very concerned about the disturbing trend of some TCOs adding fentanyl to other synthetic opioids and drugs like cocaine, methamphetamine, and others. DEA is also concerned about the violence this leads to in many communities throughout the country.

DEA, along with federal, state, and local law enforcement partners, recently launched Project Safeguard. Working in collaboration with our federal, state, and local partners, including the ATF and the U.S. Marshals Service, DEA's Project Safeguard will comprise three focus areas to address the growing violent crime and drug trafficking threat in many cities across the United States:

- Disrupting, dismantling, and destroying the most significant violent drug trafficking organizations throughout the United States;
- Increasing collaboration with ATF to ensure effective federal prosecution of firearms traffickers associated with drug trafficking organizations; and

- Prioritizing the capture of DEA fugitives who employ violence as part of drug trafficking.

The traffickers that flood our communities with deadly drugs, including opioids, heroin, fentanyl, meth and cocaine, are often the same criminals responsible for the high rates of assault, murder, and gang activity in our cities. These criminals employ fear, violence, and intimidation to traffic drugs, and in doing so, exacerbate a drug crisis that claims more than 70,000 American lives every year. DEA is committed to treating these crimes as homicides, where appropriate. Since it began in August 2020, Project Safeguard has resulted in more than 700 investigations, over 1,500 arrests – including nearly 40 DEA fugitives, more than 2,130 seized firearms, nearly $24 million in seized assets, and more than 6,100 kilograms of illicit drugs.

5. **Change in Demand from Heroin to Synthetic Drugs - Fentanyl is cheaper to produce and more deadly than heroin. It is my understanding that, in San Diego, California, a fentanyl pill can cost as little as four dollars. One thousand pills cost between $3,000 and $10,000. Often times, counterfeit pills, heroin, or other drugs are cut with fentanyl, making it stretch even further. Transnational criminal organizations and others selling fentanyl make a significant profit, as a $5,000 investment could yield as much as $1.5 million in retail sales. Given the low cost of production, do you anticipate that drug trafficking organizations will shift to exclusively producing synthetic drugs?**

RESPONSE: DEA has seen a large increase in the production of synthetic drugs like fentanyl and methamphetamine; however, DEA does not believe that DTOs will turn exclusively to synthetics based on the fact that demand for heroin and cocaine remains high in the United States.

6. **Public Health Emergency Declaration - In October 2017, the Trump administration declared the opioid epidemic a public health emergency. This declaration has been renewed every 90 days since then. According to the Government Accountability Office, the administration has only used three of 17 authorities triggered by the public health emergency declaration. With this in mind, what direct effect has the public health emergency declaration had on DEA's efforts to combat the opioid epidemic?**

RESPONSE: The Department draws broadly upon available legal authorities to support the Executive Branch's whole-of-government approach to fighting the opioid epidemic. These include statutory and regulatory authorities.

As of October 2020, there are over 85,400 qualifying practitioners who may prescribe, dispense or administer controlled substances (e.g., buprenorphine) for maintenance or detoxification treatment in an office-based setting. These individuals are called "DATA-waived practitioners," pursuant to the Drug Addiction Treatment Act (DATA) of 2000, as amended. The number of DATA-waived practitioners has increased by almost 67 percent since the end of FY2017 (50,888 in September 2018 to 85,400 in October 2020).

On October 3, 2019, DEA completed technical changes to its registration database that established new "business categories" for those mid-level practitioners authorized to provide

Medication-Assisted Treatment (MAT) for up to 275 patients. The SUPPORT Act authorized physician assistants and nurse practitioners to treat up to 275 patients with opioid use disorder with buprenorphine or other FDA-approved drugs. Previously, they were authorized to treat up to 100 patients. This modification to DEA's registration database was a necessary step in order for these qualified practitioners to obtain a license from DEA indicating their authority to treat that number of patients. As of October 2020, DEA has 996 mid-level practitioners each authorized to treat up to 275 patients.

Questions from Senator Grassley

1. **One recommendation in the Inspector General's report urges DEA to require criminal background investigations of all new registrant applications.**

    a. **When a new registrant applies with the DEA to manufacture or distribute controlled substances, what information or data indicates suspicious behavior?**

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

Further, DEA has provided guidance directed to all of our Registration Program Specialists (RPS) as to their duties and responsibilities for uniformly requesting background checks on new applicants through several third party companies. Per this guidance, DEA RPS review various background databases to determine if there are any current violations against the applicant. If that review identifies anything of concern, DEA initiates a pre-registration inquiry to further explore the applicant's response.

    b. **How does DEA measure its success in preventing suspicious applicants from becoming registrants, and how successful has DEA been in this?**

RESPONSE: DEA has a robust pre-investigation process that includes a set of liability questions in the application that require the applicant to disclose, on pain of a material falsification charge, information including registration revocations/surrenders and state licensure actions. When an applicant answers any liability question in the affirmative, DEA initiates a pre-registration inquiry to further explore the applicant's response. DEA also reviews various background databases to determine if there are any current or previous violations that would demonstrate that need to further explore the applicant's background. DEA has a registrant population of more than 1.8 million registrants of which fewer than 1% that have been the subject of an investigation or had a criminal/civil/administrative action taken against them. With such a small percentage of the registrant population having violated the Controlled Substances Act, DEA feels confident that the existing pre-registration process is successful in preventing suspicious applicants from becoming registrants.

2. **An illicit drug that is of particular concern to me is methamphetamine. Domestic production of meth has decreased over the past decade; however, most of the meth available in the U.S. is produced in Mexico and smuggled across the Southwest Border. Meth use is increasing across the United States, which is particularly concerning when considering the advent and increase of polydrug use. Why is methamphetamine use on the rise?**

RESPONSE: Most of the methamphetamine available in the United States is produced clandestinely in Mexico and smuggled across the Southwest Border in massive bulk quantities.

Because of the massive bulk quantities being produced, the price of methamphetamine remains low. Additionally, methamphetamine purity and potency are very high compared to past levels.. In addition, throughout history, we have seen rises in stimulants following narcotic surges.

Like other synthetic drugs, methamphetamine has inherent advantages over plant-based drugs such as cocaine and heroin:

1. It is not subject to growing seasons and does not require the control of large areas.
2. It is relatively cheap and easy to make, although it requires a basic knowledge of chemistry and reliable access to precursor chemicals.
3. Unlike cocaine, Mexican cartels control the majority of the supply chain, which mitigates risk and increases profits.
4. It is highly addictive, but not as apt to cause overdose death as synthetic opioids like fentanyl, leading to the perception that it is less harmful which may lead to a steadier revenue stream for sellers and switching to methamphetamine by those who fear opioids.
5. It is often cheaper than other illicit drugs sold on the street.

3. What lessons from the opioid epidemic can help us prevent a deadly surge of methamphetamine?

RESPONSE: DEA has never stopped aggressively pursuing individuals responsible for distributing methamphetamine in the United States and abroad. As stated before, DEA is attacking methamphetamine at the source. By increasing the number of personnel in Mexico, and working with the DOJ and other international partners, DEA is pressuring the Mexican government to do more – such as increase information sharing and act on the methamphetamine labs identified by DEA. DEA is hitting the command and control of Mexican cartels that benefit from the methamphetamine trade. Cartel members/leaders have been identified by the DEA and have been indicted. DEA is working with its law enforcement counterparts in Mexico to bring these criminals to justice in an American court. In addition to our continued work to stop drugs before they are smuggled across the border. As was recently announced, Operation Crystal Shield will surge enforcement at nine identified methamphetamine transportation hubs throughout the United States to prevent bulk methamphetamine from making its way to neighborhood streets. DEA will use its investigative expertise to find and destroy the financial networks used by cartels.

Similar to the illicit production of the opioids fentanyl and fentanyl analogues, significant amounts of precursor chemicals are shipped from China to Central America for the production of methamphetamine. Unlike with opioids, it is not readily apparent whether prescription amphetamine use leads to methamphetamine use. The interagency is examining this. If this turns out to be true, approaches to minimize overprescribing, diversion, and injection of prescription stimulants may also be helpful.

Questions for the Record for
Amanda Liskamm
Director of Opioid Enforcement and Prevention Efforts
Office of the Deputy Attorney General
U.S. Department of Justice

From a Hearing Before the
United States Senate
Committee on the Judiciary
Entitled
"Tackling the Opioid Crisis: A Whole-of-Government Approach"
December 17, 2019
Part II

Questions from Senator Grassley

1. **At the hearing, I asked you what significant developments show the American people that we are winning the fight against Chinese fentanyl entering our country. You answered that there's been a decrease in the amount of fentanyl and fentanyl analogues coming from China into the United States through the U.S. Postal System, which shows a positive impact from China's class-wide scheduling action.**

    a. **Does the Department of Justice have updated data on how much of fentanyl in the United States comes from China via the mail? If so, please provide such data.**

RESPONSE: The People's Republic of China (PRC)'s enactment of classwide control of fentanyl-related substances in May 2019 directly resulted in the substantial decrease of direct shipments of fentanyl and fentanyl-related substances (FRS) via the mail from the PRC to the United States. According to the most current U.S. Customs and Border Protection (CBP) data available to the Department of Justice (the Department), nationwide fentanyl-related substances seizures and number of incidents in the air environment decreased from FY 2018 to FY 2019. According to CBP, there have been no seizures of fentanyl coming directly from the PRC to the United States since September 2019.

	FY 2018	FY 2019*
Amount Seized	119 kilograms	55 kilograms
Number of incidents	534 incidents	157 incidents

*(Partial year, October 2018 – July 2019)

    b. **What specific resources has the Department of Justice devoted to address the synthetics threat from China?**

RESPONSE: The Department, through the Drug Enforcement Administration (DEA), uses a multi-faceted approach to address the threat of synthetics from the PRC. The DEA Beijing

Country Office, in coordination with the U.S. Embassy-Beijing mission and DOJ personnel, used overt engagement with PRC law enforcement counterparts, specifically the Ministry of Public Security (MPS) and the National Narcotics Control Commission (NNCC), to encourage Chinese officials to schedule fentanyl and its analogues as a class. This effort contributed to the successful scheduling of fentanyl and analogues in PRC. DEA continues to conduct bi-lateral investigations with PRC MPS and the PRC Anti-Smuggling Bureau, specifically targeting Mexican cartels obtaining fentanyl precursor chemicals from the PRC. Through direct operational engagement, DEA facilitated surveillance operations by PRC MPS to monitor Mexican cartel associates who traveled to the PRC to organize shipments of precursor chemicals. Additionally, DEA domestic and foreign offices conducted multiple investigations specifically targeting synthetics entering the United States directly from the PRC. Investigative leads regarding potential sources of supply in the PRC were passed to the PRC MPS for exploitation and investigative action. DEA coordinated high-level engagement between senior U.S. Government and PRC Government officials, including former DEA Acting Administrator Dhillon's official visit to the PRC in January 2020. DEA also coordinates the annual Bilateral Drug Intelligence Working Group (BDIWG) and Counternarcotics Working Group (CNWG) meetings involving executive staff members from DEA, other Federal law enforcement partners, the Office of National Drug Control Policy, and the PRC MPS, during which the synthetics threat from the PRC is specifically addressed through operational briefings and intelligence sharing by DEA and MPS investigators. DEA also facilitated chemist exchange seminars between DEA and PRC MPS senior chemists to discuss synthetics analyses and trends, and to enhance cooperation between the United States and the PRC to address the threat of synthetics.

Currently, there are 109 active Organized Crime Drug Enforcement Task Forces (OCDETF) investigations reporting judicial and prosecutorial participation and coordination with the PRC. Twenty-eight of these investigations have validated Consolidated Priority Organization Target (CPOT) links and sixteen are linked to Regional Priority Organization Targets (RPOTs). These cases have produced charges against 896 defendants resulting in 594 convictions (over the course of these investigations). These investigations span all nine OCDETF Regions and 39 federal judicial districts. These successes illustrate important coordination with Chinese law enforcement to help stem the flow of illicit fentanyl to the United States.

c. What additional resources would you recommend to help combat fentanyl supply from China into the United States?

RESPONSE: Congressional support for the opening of DEA offices in Guangzhou and Shanghai will increase cooperation between DEA and MPS, and their collective abilities to target synthetics produced in the PRC. These offices will significantly enhance DEA's ability to identify sources of supply for not just fentanyl, but also fentanyl analogues, and fentanyl precursor chemicals in southern provinces of the PRC where the majority of manufacturing occurs. DEA personnel posted at the U.S. Consulate in Guangzhou will be able to work on a consistent basis with Chinese law enforcement counterparts in those southern provinces. Because Shanghai is the PRC's financial center, DEA personnel posted at the U.S. Consulate in Shanghai will be able to work directly with Chinese counterparts to target illicit proceeds (from the sale of precursor chemicals and synthetics) funneled through the PRC's

banking system. Continued high-level engagement between the U.S. Government and Government of the PRC will strengthen bi-lateral cooperation on synthetics investigations conducted by DEA and the PRC MPS.

Additionally, an important legislative priority for the Department and DEA is to pass permanent legislation scheduling FRS as a class substance. This will send an important message to the PRC, as China scheduled fentanyl as a class pursuant to significant diplomatic efforts and urging from the Department, DEA, and U.S. Mission Beijing. Furthermore, if the U.S. emergency scheduling order is allowed to expire, the PRC will be seen as being more proactive in restricting these substances than the U.S., further resulting in the U.S. losing leverage with the PRC in holding them accountable to enforcing their own class scheduling actions. The DEA worked with our partners at the ONDCP and the Department of Health and Human Services (HHS) on proposed legislation that would permanently schedule fentanyl-related substances while ensuring access for research purposes and expeditious de-scheduling of compounds subsequently determined not to be harmful. DEA and ONDCP shared the proposal with Committee staff. We would welcome further discussion with Congress about legislative solutions to appropriately address the harms posed by fentanyl-related substances.

2. **One recommendation in the Inspector General's report urges DEA to require criminal background investigations of all new registrant applications.**

    a. **How will a criminal background investigation increase DEA's ability to identify troubling behavior? Can you provide any examples of how criminal behavior in the past indicates suspicious behavior of registrants?**

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

Further, DEA has provided guidance directed to all of the Registration Program Specialists (RPSs) as to their duties and responsibilities for uniformly requesting background checks on new applicants through several third-party companies. Per this guidance, DEA RPSs review various background databases to determine if there are any current violations against the applicant. If that review identifies anything of concern, DEA initiates a pre-registration inquiry to explore further the applicant's response.

3. **An illicit drug that is of particular concern to me is methamphetamine. Domestic production of meth has decreased over the past decade; however, most of the meth available in the U.S. is produced in Mexico and smuggled across the Southwest Border. Meth use is increasing across the United States, which is particularly concerning when considering the advent and increase of polydrug use.**

    a. **Why is methamphetamine use on the rise?**

RESPONSE: Most of the methamphetamine available in the United States is produced clandestinely in Mexico and smuggled across the Southwest Border in massive bulk quantities. Because of the massive bulk quantities being produced, the price of methamphetamine remains low. Additionally, methamphetamine purity and potency are very high compared to past levels. Also, throughout history, there have been rises in stimulants following narcotic surges.

Like other synthetic drugs, methamphetamine has inherent advantages over plant-based drugs such as cocaine and heroin:

1. It is not subject to growing seasons, and does not require the control of large areas.
2. Although it requires a basic knowledge of chemistry and reliable access to precursor chemicals, it is relatively cheap and easy to make.
3. It is conducive to counterfeit pill manufacturing.
4. Unlike cocaine, Mexican cartels control the majority of the supply chain, which mitigates risk and increases profits.
5. It is highly addictive, which leads to a steady revenue stream. However, polysubstance use is on the rise. Methamphetamine is being mixed with fentanyl causing an increase in methamphetamine-related overdose deaths. At this time, it is difficult to determine when individuals are using these drugs separately to offset the effect of the other, mixing opioids with the stimulants intentionally, or taking them in combination unknowingly.

b. What lessons from the opioid epidemic can help us prevent a deadly surge of methamphetamine?

RESPONSE: Multiple agency partners, including DEA, FBI, Homeland Security Investigations (HSI), and the Organized Crime and Drug Enforcement Task Forces (OCDETF) have never stopped aggressively pursuing individuals responsible for distributing methamphetamine in the United States and abroad. DEA continues to attack methamphetamine at the source. By increasing the number of personnel in Mexico, and working with the Department and our international partners, DEA is pressuring the Mexican government to do more – such as increase information sharing and act on the methamphetamine labs identified by DEA. DEA is targeting the command and control of Mexican cartels that benefit from the methamphetamine trade. Cartel members and leaders have been identified by the DEA and have been indicted. DEA is working with its law enforcement counterparts in Mexico to bring these criminals to justice in a U.S. court, in addition to its continued work to stop drugs before they are smuggled across the border. As was recently announced, Operation Crystal Shield will significantly increase enforcement at nine identified methamphetamine transportation hubs throughout the U.S. to prevent bulk methamphetamine from making its way to neighborhood streets. DEA will use its investigative expertise to find, disrupt, and dismantle the illicit financial networks used by cartels.

Questions from Senator Feinstein

1. **Foreign Narcotics Kingpin Designation Act- In 1999, I was the lead Democratic cosponsor of the Foreign Narcotics Kingpin Designation Act, often referred to as "the Kingpin Act," which was enacted as an amendment to the Intelligence Appropriations Act.**

   This law enables the United States to block and seize assets of narcotics traffickers who threaten our country's national security.

   Recent examples of those whose assets have been blocked as a result of this law include 63 individuals and entities in Mexico tied to the Jalisco New Generation Cartel, as you pointed out in your written statement.

   a. **Given the proliferation of drug trafficking organizations and cartels involved in facilitating the manufacture, trafficking and sale of fentanyl and other illicit drugs, which are responsible for record numbers of drug overdose deaths in the United States, are there any ways in which the Kingpin Act could be strengthened?**

RESPONSE: The Kingpin Act is a powerful tool in the United States' fight against drug traffickers and money launderers around the world. It blocks the assets of designated narcotics traffickers and drug money launderers that are within the jurisdiction of the United States, and generally prohibits U.S. persons from dealing with them. The Kingpin Act also allows the U.S. Government to target high-level narcotics traffickers and senior members of their organizations by disrupting their financial networks. Identifying and disrupting illicit financial networks not only assist in the prosecution of criminal activity of all kinds, but also allows law enforcement to halt and dismantle criminal organizations and other bad actors and thereby prevent harm to our citizens and our financial system

The Department and the Department of the Treasury (Treasury) work in close partnership on money laundering-related regulatory and enforcement matters generally. Previously, however, the Department has discussed and proposed adding violations of the Foreign Narcotics Kingpin Designation Act to the list of specific unlawful activities (SUAs) in 18 U.S.C. 1956(c)(7). The earlier proposal amends Section 1956 of Title 18, United States Code, in subsection (c)(7)(D) by inserting after the phrase "Trading with the Enemy Act," "section 807 (relating to penalties) of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. section 1906)."

2. **Online Sale of Illicit Opioids- Online marketplaces, including those on the surface web and the dark web, are often used to facilitate the sale of illicit narcotics. Transactions typically involve online payment services and cryptocurrencies. To combat these operations, the Federal Bureau of Investigations shifted special agents, intelligence analysts, and professional staff to establish the Joint Criminal Opioid Darknet Enforcement team (J-CODE).**

a. How is J-CODE interfacing with other law enforcement entities conducting dark web investigations?

RESPONSE: The Joint Criminal Opioid and Darknet Enforcement program (JCODE) works with all levels of law enforcement to target traditional drug traffickers and illicit online platforms. JCODE was created in January 2018 by then-Attorney General Jeff Sessions, and it consists of a dedicated team of agents, analysts, and professional staff from the FBI, DEA, United States Postal Inspection Service (USPIS), CBP, HSI, Department of Defense (DoD), Defense Intelligence Agency (DIA), Financial Crimes Enforcement Network (FinCEN), ATF, and Department. The team uses a strategic, multi-agency approach that relies on expertise in drugs, cyber technologies, money laundering, health care fraud, and more to focus on disrupting the sale of drugs via the darknet and dismantling criminal enterprises that facilitate this trafficking. JCODE has been successful in merging domestic efforts and executive branches within the greater U.S. Government along with dozens of law enforcement agencies worldwide.

The JCODE team is co-located at FBI Headquarters and serves as an intelligence hub for all agencies working Dark Net investigations aligned with our mission. In a threat environment that poses significant de-confliction and collaboration issues due to the anonymous nature of the actors and infrastructure, JCODE has paved the way for enhanced identification and de-confliction, and established mechanisms to ensure agencies work together. JCODE has worked collaboratively with the Department and DEA's Special Operations Division to triage, support and coordinate ongoing Dark Net operations targeting drug traffickers throughout the world. JCODE serves as a resource center to nearly every federal law enforcement agency in the United States by providing expertise in drugs, virtual currency, mail interdictions, and the interworkings of the international supply chains.

JCODE recognized the need for a collaborative whole-of-government strategy to bring these criminals from the virtual world into the real world, merging both cyber and organized crime expertise. This strategy included initiating proactive technical undercover operations and placing orders of fentanyl, which are shipped through the U.S. mail system. Recognizing the safety concerns involving USPIS employees, the FBI worked alongside the Department and USPIS to develop a mitigation strategy that not only ensure the safety of the postal workers but also allow agencies to conduct these proactive undercover purchases. This was the first interagency mitigation strategy allowing the shipment of fentanyl through the mail that was approved by the Department; it is now the standard for all domestic law enforcement agencies.

JCODE is often called upon by the ONDCP, Congressional oversight committees, and our partners in the U.S. Intelligence Community to weigh in on policy questions and concerns, help develop strategic goals, and identify how to leverage and share data more effectively and develop better de-confliction standards. JCODE has provided Dark Net and virtual currency training to over 1,000 domestic and international law enforcement agents and analysts. Offices across the country are replicating JCODE's framework and building JCODE operational teams. These teams are comprised of multi-agency partners and support investigations developed by the JCODE headquarters team. As a direct result of JCODE efforts, the FBI alone has opened hundreds of new investigations, stood up 17 undercover operations, and analyzed hundreds of

thousands of intelligence data points that were incorporated into targeted leads sent to JCODE agencies across the country and throughout the world.

b. What are the most significant challenges that the J-CODE program faces?

RESPONSE: The dark web consists of websites and other network services that leverage overlay networks providing anonymity. These overlay networks use the internet but require specific software and configurations to access. The overlay networks use multiple encrypted traffic relays, where an individual relay computer knows its source of information and where it is sending the information, but is never the original source, or ultimate destination, of the traffic simultaneously. This anonymity has provided criminals with the ability to host illicit material in a way that circumvents the ability of law enforcement to serve legal process to remove or effectively investigate sites offering illegal content, goods, and services for purchase or sharing.

Dark Net marketplaces are dark web-based e-commerce websites where individuals can use fiat or virtual currency to engage in transactions to purchase drugs, weapons, malware, counterfeit currency, stolen credit cards, personal identifying information, forged documents, unapproved pharmaceuticals, and other illicit goods.

Transnational Criminal Organizations (TCOs) increasingly leverage technology to obfuscate their identity and activity, expand their transnational reach to increase criminal proceeds, diversify their criminal activity, and exploit limitations on law enforcement.

In particular, TCOs are expanding their use of sophisticated communications platforms and encrypted hardened technology, from simple messaging applications such as Telegram and Wickr, to highly complex hardware/software combinations, which impedes law enforcement's ability to intercept communications regarding their criminal activity. TCOs use anonymizing platforms, such as encrypted communication applications and encrypted email services, in order to buy and sell drugs, weapons, malware, counterfeit currency, stolen credit cards, personal identifying information, forged documents, unapproved pharmaceuticals, and other illicit goods. The technological and legal impediments to accessing encrypted communications likely will continue to hamper criminal investigations for the foreseeable future as TCOs shift away from traditional means of communications.

The use of dark web, Clearnet, and other anonymizing platforms to distribute illegal drugs has contributed, and continues to contribute, to the substance misuse crisis that is devastating communities across the United States in large part because they have made access to illicit goods easier to obtain anonymously. Law enforcement agencies at all levels of government continue to investigate drug trafficking and the sale of other illegal goods and services via the Dark Net, Clearnet, and other anonymizing platforms. The anonymity the internet provides has made it more difficult to identify and prosecute the individuals and organizations who administer or otherwise operate Dark Net, Clearnet, or other anonymizing platforms that facilitate the distribution of illegal drugs, goods, or services or buy and sell illegal drugs, goods, or services through illicit marketplaces hosted on these anonymized platforms.

Although law enforcement agencies have succeeded in investigating the distribution and sale of

illegal drugs, goods, and services that occurs as a result of interactions on the Dark Net, Clearnet, and other anonymous platforms, investigative and prosecutorial collaboration, innovation, and advancement are critical to increasing the capacity to combat this threat and enhancing collaboration and coordination between federal, international, and other law enforcement partners as appropriate.

c. In your view, would it be helpful to authorize the J-CODE program in law?

RESPONSE: Yes. Authorizing the JCODE program into law would enhance JCODE's ability to detect, disrupt, and dismantle major criminal enterprises that rely on the Dark Net, Clearnet, or other anonymizing platforms to facilitate the distribution and trafficking of fentanyl and other narcotics, along with weapons and illicit services such as the sale of fraudulent products and documents.

JCODE's strategic vision and mission success relies heavily on its ability to stay on the cutting edge of technology and online, illicit trends across multiple platforms. This strategy requires collaboration and partnerships with subject matter experts, private sector companies and entities specializing in the online drug threat arena. Authorization would provide a means and pathway for JCODE to execute a long-term, strategic plan focused on mitigating illicit activity across Dark Net and online platforms with the development and implementation of technical tools and cyber infrastructure. Currently, JCODE is reliant upon yearly Department funding enhancements, which limit JCODE's ability to develop and maintain technical tools used to identify and target the most egregious drug traffickers on the Dark Net, Clearnet, or other anonymizing platform. JCODE has delayed and/or cancelled technical projects due to enhancement cuts. Delays and cancellations of upgrades and/or development of technical tools will greatly hinder JCODE's targeting capabilities. Technical tools incur recurring costs and cyber enabled threats require sophisticated technology to accurately target the criminal organizations rising to the federal prosecution level. Authorization would provide program stability and consistent targeting capabilities that would increase the impact of JCODE efforts.

By having a long-term authorization, JCODE would be able to expand its ability to engage in proactive and reactive investigations; build forensic examinations and effective prosecutions; and provide forensic, technical, and investigative training and assistance to prosecutors and law enforcement agencies. Additionally JCODE could develop multijurisdictional and multiagency responses and partnerships with federal, international, and other law enforcement agencies as appropriate by establishing procedures for information sharing and establishing lists of recommended specialized equipment and tools to investigate and prosecute the distribution of illicit drugs, goods, and services on the Dark Net, Clearnet, and other anonymizing platforms.

With authorization, JCODE would be better positioned to continue creating and implementing novel investigative approaches to target emerging technologies that facilitate the distribution of illegal drugs, goods, and services through the Dark Net, Clearnet, and other anonymous platforms and build forensic capacity and expertise to meet the challenges posed by new technologies. It would also be better positioned to enhance collaboration and coordination with international partners.

Moreover, JCODE has proven to be a leading force in training and statutory authorization would enhance JCODE's ability to develop a more comprehensive training program that reaches more local, state, federal, and international law enforcement partners, as appropriate, regarding techniques and procedures to recognize evidence or potential evidence related to the Dark Net, Clearnet, and other anonymous platforms; and to identify and recognize patterns and practices related to the distribution of illegal drugs, goods, and services through Dark Net, Clearnet, and such platforms.

3. **Change in Demand from Heroin to Synthetic Drugs- Fentanyl is cheaper to produce and more deadly than heroin. According to the Drug Enforcement Administration (DEA), in San Diego, California, a fentanyl pill can cost as little as four dollars. One thousand pills cost between $3,000 and $10,000. Often times, counterfeit pills, heroin, or other drugs are cut with fentanyl, making it stretch even further.**

   Transnational criminal organizations and others selling fentanyl make a significant profit, as a $5,000 investment could yield as much as $1.5 million in retail sales.

   a. **Given the low cost of production, do you anticipate that drug trafficking organizations will shift to exclusively producing synthetic drugs?**

RESPONSE: DEA has seen a large increase in the production of synthetic drugs like fentanyl and methamphetamine; however, DEA does not believe that Drug Trafficking Organizations (DTOs) will turn exclusively to synthetics, as heroin and cocaine continue to be very profitable substances for DTOs to distribute in the U.S. market.

4. **Poly Drug Use- The Centers for Disease Control and Prevention (CDC) has warned that a fourth wave of the drug overdose epidemic is upon us, and that most of those suffering from addiction use more than just opioids.**

   For instance, in 2018, cocaine, methamphetamine, and benzodiazepines were present in nearly 60 percent of all opioid-related overdose deaths.

   a. **In light of this, do you believe it is shortsighted to implement strategies that focus solely on opioids?**

RESPONSE: DEA focuses its investigations on TCOs, which distribute many types of drugs. However, when a drug emerges that kills people at alarmingly high rates, it is appropriate to focus quickly and strategically on that problem. DEA has always been an adaptable agency with the flexibility and skill set to pivot and address emerging threats. By focusing on investigating and prosecuting TCOs and other groups that sell all kinds of drugs, we target all drugs that threaten our nation.

b. What is the Justice Department doing to address the increases in meth and cocaine production, trafficking, and abuse?

RESPONSE: DEA is attacking methamphetamine at the source. By increasing the number of personnel in Mexico, and working with the Department and other international partners, DEA is pressuring the Mexican government to do more – such as increase information sharing and act on the methamphetamine labs identified by DEA. DEA is hitting the command and control of Mexican cartels that benefit from the methamphetamine trade. Cartel members and leaders have been identified by the DEA and have been indicted. DEA is working with its law enforcement counterparts in Mexico to bring these criminals to justice in American courts. In addition to our continued work to stop drugs before they are smuggled across the border, DEA will significantly increase enforcement at nine identified methamphetamine transportation hubs throughout the United States to prevent bulk methamphetamine from making its way to neighborhood streets. This surge is part of Operation Crystal Shield. DEA will use its investigative expertise to find and disrupt the financial networks used by cartels. DEA just completed phase one of Project Python, a nationwide surge targeting the Jalisco New Generation Cartel (CJNG), which is a key producer, smuggler, and distributor of methamphetamine and cocaine. Project Python netted more than 700 arrests, and intelligence gleaned from phase one will be used to refine targeting and continue to pursue CJNG. The Department has recently assembled a Methamphetamine Working Group to ensure a robust response to the surge in methamphetamine trafficking and use. The Working Group draws from a variety of components within Department to ensure a multifaceted approach, including the Office of Attorney General, the Office of the Deputy Attorney General, the Criminal Division, the Drug Enforcement Administration, U.S. Attorneys' Offices, and the Office of Justice Programs, among others. The Working Group is particularly focused on four key areas: (1) domestic operations, (2) international operations, (3) prosecutions, and (4) prevention, research, training, and policy. The Department is also engaged with the ONDCP and the HHS to coordinate the Administration's effort to reduce methamphetamine availability and use.

c. How is the Justice Department addressing the trend of adding fentanyl and other synthetic opioids to cocaine, methamphetamine, benzodiazepines and other illicit substances?

RESPONSE: The Department is working with our international partners to reduce illicit manufacture and distribution through strengthening their domestic controls and interdiction efforts. The precursors for illicit fentanyl, fentanyl analogues, and other new psychoactive substances (NPS) are often produced in the PRC and shipped directly to TCO in Mexico and the rest of Latin America. Once in the Western Hemisphere, TCOs use the precursors to manufacture fentanyl or its analogues, which is then prepared for mixing into the heroin supply and other non-opioid drugs, or pressed into a tablet form, and then smuggled into the illicit U.S. market across the Southwest Border (SWB) and stored at stash houses, often with other drugs. Specifically, these deadly substances are often smuggled via concealed, hard to detect spaces in spare tires, gas tanks, and hidden compartments. Seizure data from DEA's National Forensic Laboratory Information Systems (NFLIS) and the National Seizure System (NSS) indicate the California border with Mexico is an essential transit zone with regards for fentanyl and FRS.

While the volume of fentanyl and FRS submitted to DEA laboratories has dramatically increased nationally since 2014, nearly half the volume submitted to DEA laboratories was acquired in southern California. DEA reporting indicates that production and trafficking of fentanyl and fentanyl-related substances through this corridor is primarily controlled by the Sinaloa Cartel and CJNG. Additionally, one of the most alarming trends developing is the willingness of these TCOs to press fentanyl and FRS into tablets resembling prescription versions of oxycodone products. The long-range approach by these TCOs to use fentanyl and FRS as a more profitable alternative to authentic but diverted pharmaceutical products, will inevitably increase the reach of the opioid epidemic. TCOs are actively incorporating a variety of technologies and continuously evaluate and respond to law enforcement action and techniques to protect and facilitate the concealment of their illicit product and activities from law enforcement intervention.

DEA continues to focus on dismantling and disrupting TCOs. These criminal organizations are involved in the transportation of all the above-mentioned drugs. Thus, when DEA dismantles or disrupts a criminal organization, DEA in effect is stopping the trafficking of all illicit drugs trafficked by that TCOs.

5. **Public Health Emergency Declaration- In October of 2017, the Trump administration declared the opioid epidemic a public health emergency. This declaration has been renewed every 90 days since then.**

   According to the Government Accountability Office, the administration has only used three of 17 authorities triggered by the public health emergency declaration.

   a. **With this in mind, what direct effect has the public health emergency declaration had on the Justice Department's efforts to combat the opioid epidemic?**

RESPONSE: The Department draws broadly upon available legal authorities to support the Executive Branch's whole-of-government approach to fighting the opioid epidemic. These include statutory and regulatory authorities.

As of October 2020, there are over 85,400 qualifying practitioners who may prescribe, dispense or administer controlled substances (e.g., buprenorphine) for maintenance or detoxification treatment in an office-based setting. These individuals are called "DATA-waived practitioners," pursuant to the Drug Addiction Treatment Act (DATA) of 2000, as amended. The number of DATA-waived practitioners has increased by almost 67 percent since the end of FY2017 (50,888 in September 2018 to 85,400 in October 2020).

On October 3, 2019, DEA completed technical changes to its registration database that established new "business categories" for those mid-level practitioners authorized to provide Medication-Assisted Treatment (MAT) for up to 275 patients. The SUPPORT Act authorized physician assistants and nurse practitioners to treat up to 275 patients with opioid use disorder with buprenorphine or other FDA-approved drugs. Previously, they were authorized to treat up to 100 patients. This modification to DEA's registration database was a necessary step in order

for these qualified practitioners to obtain a license from DEA indicating their authority to treat that number of patients. As of October 2020, DEA has 996 mid-level practitioners each authorized to treat up to 275 patients.

Questions from Senator Whitehouse

6. **You testified about the Department of Justice (DOJ) and Federal Bureau of Investigation's (FBI) efforts to disrupt trafficking in synthetic opioids, including counterfeit pills containing fentanyl, on the dark web. Are there additional legal authorities or resources you need to effectively investigate and prosecute these cases?**

RESPONSE: The Department's efforts in combatting the opioid crisis include the dismantling of darknet websites that allow some of the most prolific drug suppliers to peddle their poison. In 2018, the FBI established the Joint Criminal Opioid and Darknet Enforcement team, also known as JCODE. Since JCODE's launch, there have been successful operations that have taken hundreds of kilograms of drugs off the streets and dozens of Dark Net accounts offline. For more information on JCODE, please see the answer to Feinstein Question 2, beginning on page 5.

7. **In October, the DOJ Office of the Inspector General (OIG) found that the DEA was slow to respond to the significant increase in the use and diversion of opioids since 2000; did not use its available resources, including its data systems and immediate suspension orders, to detect and regulate diversion effectively; and that its policies and regulations did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids. One of the OIG's recommendations was that the DOJ expand the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increase the number of federal prosecutors dedicated to prosecuting opioid-related cases. The DOJ concurred in that recommendation. What steps has the DOJ taken to implement this recommendation?**

RESPONSE: The Office of Inspector General recommended that the Department consider expanding the Opioid Fraud and Abuse Detection (OFAD) program, a pilot project that dedicated eleven Assistant U.S. Attorneys (AUSAs) to investigating opioid diversion with a healthcare fraud nexus. The Department concurred in the recommendation to consider an expansion and undertook a thorough assessment of the pilot program. After an analysis of the productivity of the program and recognizing that fewer prosecutorial resources were required to adjust and adapt to rapidly evolving and changing opioid threats, the Department determined the most effective way to maximize prosecutorial effectiveness would be to continue funding the eleven OFAD AUSA positions for an additional two years. Expanding the number of positions is unnecessary at this time.

8. **Pursuant to the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, P.L. 114-145, the Department of Health and Human Services (HHS), in coordination with DEA, was required to issue a report evaluating the effect of the new law. The report was due in April 2017 but has still not yet been published.**

    a. **Has the DOJ worked with DEA to provide information to HHS in connect with this report? If so, please provide us with any information DOJ has provided to HHS.**

RESPONSE: The report to Congress was provided in June 2020 to the Chairs and Ranking Members of the House Committees on the Judiciary and Energy and Commerce and the Senate Committees on Health, Education, Labor, and Pensions and the Judiciary, as required by the Act. A copy of the report is available by contacting the HHS Office of the Assistant Secretary of Legislation or one of the Committees.

9. **The DOJ is currently participating in the National Prescription Opiate Multi-District Litigation, which consolidates the 2,400 federal opioid lawsuits by local governments and other plaintiffs, as a friend of the court. Negotiations for a global settlement of those suits are ongoing.**

   Separately, thousands of municipal governments and nearly two dozen states have reached a tentative settlement with Purdue Pharma and its owners, which will be subject to approval through that company's bankruptcy proceedings. Four state attorneys general, who have brought suit in state court, have also announced an alternative global settlement framework.

   a. **What is the DOJ's position on the proposed settlement agreements? Have other federal agencies, such as the U.S. Centers for Medicare and Medicaid Services, have provided any input to the DOJ on those proposals?**

   b. **In its Motion to Participate in Settlement Discussions and as Friend of the Court, the DOJ stated that it hoped to provide "information to the Court and the parties to facilitate effective non-monetary remedies to address problems arising from the national opioid crisis."[1]**

      i. **What "non-monetary remedies" is the DOJ is suggesting as part of any settlement agreement? Would legislation be needed to implement those remedies?**

      ii. **Technology available today enables patients to wear a device that can be worn to monitor oxygen saturation, pulse rate, and respiratory rate, and transmit that data to a smart phone or remote view station where clinicians can monitor it and alarms and alerts can be sent to individuals, their caregivers, healthcare providers and first responders. This technology can provide earlier identification of the deteriorating patient condition which will increase the chance of a positive outcome. Would you support using some of the funds from the opioid litigation, or other funds allocated to addressing the opioid epidemic, for opioid users that wish to monitor themselves with this technology?**

[1] United States' Motion to Participate in Settlement Discussions and as Friend of the Court, *In re: National Prescription Opiate Litigation,* Doc. No. 1:17-MD-02804, at 2 (N.D. Ohio Apr. 2, 2018), available at https://www.justice.gov/opa/press-release/file/1048036/download.

RESPONSE: The United States is not a party to the National Prescription Opiate Multi-District Litigation. However, the Department remains willing to engage with the court or the parties should the Department's assistance be necessary or helpful in effectuating a settlement. If requested, the Department will seek input from the relevant federal agency stakeholders, including the U.S. Department of HHS and ONDCP.

With respect to any proposed settlement framework in connection with the Purdue bankruptcy proceeding, the Department is analyzing the potential settlement options with the assistance of HHS, among other federal agency stakeholders, but has not yet taken a position on any particular proposal.

The Department does not currently have a position on the advisability of the technology described in Question 12.b.ii, or whether it would be appropriate to allocate settlement funds for this purpose.

10. **Many state attorneys general are pursuing civil claims against opioid manufacturers and distributors in state courts. This year, after the state of Oklahoma settled its claims against Purdue Pharmaceuticals shortly before trial, the U.S. Centers for Medicare and Medicaid Services sent a letter to an Oklahoma Medicaid official stating that the federal government is entitled to a portion of the settlement because it may involve a Medicaid overpayment.**

    Under what circumstances will the federal government seek a portion of settlement funds in claims settled by the states?

RESPONSE: Under Section 1903(d) of the Social Security Act, codified at 42 U.S.C. § 1396b(d), CMS is required to seek recovery of various Medicaid overpayments from states . CMS' approach to Oklahoma's settlement with Purdue, reflects its general approach to the application of this mandate. CMS has sought information from the Oklahoma Health Care Authority (OHCA) to determine the basis for the State of Oklahoma's claims against Purdue Pharma, settled for $270 million, and the extent to which Section 1903(d) requires Oklahoma to reimburse CMS for a portion of the settlement. CMS is reviewing the information Oklahoma provided and considering the proper method for calculating an amount to which the federal government is entitled.

Questions from Senator Booker

1. **To date, fentanyl trafficking prosecutions have disproportionately targeted low-level cases and communities of color. According to the United States Sentencing Commission, about 50 percent of those sentenced for fentanyl trafficking in 2016 were defendants involved at the bottom of the distribution chain, couriers/mules (25.5 percent) and street-level sellers (23.5 percent). In 2018, nearly half of individuals prosecuted for fentanyl cases were convicted of offenses carrying mandatory-minimum penalties, and people of color constituted more than 77 percent of those prosecuted.**

   It is concerning that the Department of Justice's approach to the opioid crisis seeks to continue the same problematic and heavy-handed approach it began decades ago. Bills like the Stopping Overdoses of Fentanyl Analogues Act would expand the cohort of substances- fentanyl analogues- subject to these sentences, in contrast with this Committee's move to refocus federal prosecutions away from low-level drug cases. Given Justice Department's record of pursuing low-level drug prosecutions, how can Congress help the Department shift its focus to prosecuting cases involving high-level operators responsible for importing dangerous substances into the country and orchestrating sophisticated drug operations?

RESPONSE: In your question, you write that in "2018, nearly half of individuals prosecuted for fentanyl cases were convicted of offenses carrying mandatory-minimum penalties, and people of color constituted more than 77 percent of those prosecuted." The Sentencing Commission reported that among defendants sentenced during the 2018 Fiscal Year, "39.1% of fentanyl trafficking offenders were Black."[2] The same report also notes that "44.6% were convicted of an offense carrying a mandatory minimum penalty," but also notes, importantly, that "46.0% of those offenders were relieved of that penalty". *Id.* In other words, about one in five defendants in fact received a mandatory minimum penalty. Defendants are relieved mandatory minimum sentences as a result of substantial assistance, the drug safety valve (section 3553(f) of Title 18), or both. The report further explains why nearly half of fentanyl defendants were subject to a mandatory minimum penalty in the first place: the median drug weight was many times the weight necessary for a mandatory minimum: between 160 and 280 grams of fentanyl, which is an amount containing up to 140,000 lethal doses of fentanyl. The report does not mention the number of defendants "prosecuted."

In your question, you also write that "about 50 percent of those sentenced for fentanyl trafficking in 2016 were defendants involved at the bottom of the distribution chain, couriers/mules (25.5 percent) and street-level sellers (23.5 percent)." Because the role of a courier or mule may vary from organization to organization, a defendant's culpability and entitlement to a guideline reduction due to role depends on the facts of the specific case at hand. While courts have uniformly rejected defendants' arguments that they are automatically entitled to a mitigating role adjustment based solely on their status as couriers or mules, couriers and mules "may receive" an adjustment under USSG § 3B1.2, even if they are held accountable only for the quantity of drugs they personally transported. In contrast, the drug safety valve at section 3553(f) of Title 18

[2] U.S. Sentencing Commission, "Quick Facts— Fentanyl Trafficking Offenses, FY 2018, p.1.

addresses this very issue, and reserves the right to be relieved of a mandatory minimum penalty for a drug trafficking offense to a defendant who, among other things, was not "an organizer, leader, manager, or supervisor of others in the offense." *Id.* (Other disqualifiers include the use violence or threats or a firearm, or causing death or a serious bodily injury. *Id.*) And, regarding the 51 defendants sentenced for fentanyl trafficking in 2016, the Commission reported the same median base offense level for these defendants, 26 (*id.* at slide 26), which, as the Commission noted in its 2018 publication, a base offense level of 26 corresponds to "between 160 and 280 grams of fentanyl" ("Quick Facts— Fentanyl Trafficking Offenses, FY 2018, p.1.), again, an amount containing up to 140,000 lethal doses of fentanyl. And for trafficking up to 140,000 lethal doses of truly toxic substance, these 51 defendants received an average sentence of 66 months. Id. at 27.

The Department's response has been appropriate and commensurate to the public dangers posed by the deadly opioid crisis. The Department's opioid enforcement efforts are carefully calculated to generate effective results in decreasing the availability of illegal opioids and prosecuting dealers. Prosecutors are guided by the Principles of Federal Prosecution, set forth in the Department of Justice's Justice Manual. The Justice Manual provides:

> The attorney for the government should commence or recommend federal prosecution if he/she believes that the person's conduct constitutes a federal offense, and that the admissible evidence will probably be sufficient to obtain and sustain a conviction, unless (1) the prosecution would serve no substantial federal interest; (2) the person is subject to effective prosecution in another jurisdiction; or (3) there exists an adequate non-criminal alternative to prosecution

Justice Manual, § 9-27.220, Grounds for Commencing or Declining Prosecution (Feb. 2018), https://www.justice.gov/jm/jm-9-27000-principles-federal-prosecution.

Prosecutors follow these guidelines when choosing to bring any federal prosecutions, including for drug offenders. In doing so, the Department focuses heavily on investigating and prosecuting senior members of DTOs, including through the investment of personnel and funds devoted to that end. One such example is the OCDETF, and the principal mission of the OCDETF program is to identify, disrupt, and dismantle the most serious drug trafficking and money laundering organizations, including transnational criminal organizations, that are primarily responsible for the nation's drug supply.

In targeted areas where opioid overdose deaths have reached particularly alarming levels, the Department has intensified efforts to remove all dealers from affected counties by coordinating with state and local authorities to bring prosecutions in appropriate courts. This approach has dramatically curtailed opioid trafficking and substantially reduced opioid-induced overdose deaths in areas where it has been deployed. One example of this intensified, collaborative approach was Operation Hot Batch in Manatee County, Florida.
See https://www.justice.gov/usao-mdfl/pr/more-30-opioid-drug-traffickers-charged-part-operation-hot-batch

One area in which Congress could assist the Department in its ongoing focus on prosecuting high-level members of DTOs is the passage of permanent class wide scheduling of fentanyl-related substances as a class will help the Department more effectively prosecute the most prolific dealers of fentanyl analogues that are as deadly – and often more deadly – than fentanyl itself. The DEA worked with our partners at the ONDCP and the HHS on proposed legislation that would permanently schedule fentanyl-related substances while ensuring access for research purposes and expeditious de-scheduling of a compound subsequently determined not harmful. The involved agencies shared the proposal with committee staff. We would welcome further discussion with Congress about legislative solutions to appropriately address the harms posed by fentanyl-related substances.

2. **In your testimony, you stated there have been two successful large-scale takedowns since the Joint Criminal Opioid Darknet Enforcement (J-CODE) was launched. You also mentioned two other initiatives: Operation Synthetic Opioid Surge (SOS), which has led to the prosecution of more than 300 cases in 10 of the districts with some of the highest overdose death rates in the country, and Appalachian Regional Prescription Opioid Strike Force, which resulted in charges against 70 individuals responsible for distributing more than 40 million pills.**

    a. **Please provide data on how many people have been federally prosecuted for synthetic drugs, including fentanyl, since the temporary scheduling order on February 6, 2018. Please include a breakdown of their role (according to the United States Sentencing Commission guidelines), demographics, age, and average sentence.**

    b. **What percentage of these drug cases were decided by a jury versus part of a plea deal?**

RESPONSE: The Executive Office for United States Attorneys does not track case data in the manner you have requested. We believe that the United States Sentencing Commission (USSC) may have data in the format you are seeking. You may also find these USSC data analysis reports useful. Please see attached.

3. **Please list in detail any efforts completed to ensure the Drug Enforcement Administration can meet the benchmarks of the SUPPORT Act.**

RESPONSE: Under the SUPPORT Act, DEA is one of the many entities charged with implementing new statutory requirements and expanding existing programs to obtain the goal of reducing the national opioid crisis. We remain committed to implementation, as it is a top priority for both the Department and DEA. Although work remains to be completed for DEA to fully implement the requirements of this law, DEA has implemented many key provisions since enactment, as noted below.

Establishment of Suspicious Order Database

The SUPPORT Act requires the Attorney General to establish a centralized database for collecting reports of suspicious orders. The purpose of the database is to create a better flow of information among registrants, DEA, and state and local law enforcement to prevent the diversion of controlled substances. The major changes involved in the reporting of suspicious orders are that all DEA registrants that distribute controlled substances to other DEA registrants must now report suspicious orders DEA also developed and deployed the centralized database on October 23, 2019, meeting its SUPPORT Act deadline. DEA has developed a portal system where the points of contact for each state can log on with a user name and password to view and download suspicious orders reported in their state for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances.

Published Proposed Regulations to Controlled Substance Quotas

On October 23, 2019, the DEA published a Notice of Proposed Rulemaking in the Federal Register to change regulations to improve DEA's ability to oversee the production of controlled substances. The goal of these changes is to limit further excess quantities of medications that might be vulnerable to diversion for illicit distribution and use. The proposal also codifies DEA's utilization of several subcategories of quotas that DEA grants to certain DEA-registered manufacturers. These use-specific quotas include quantities of controlled substances for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These use-specific quotas will greatly improve the timeliness of DEA's responses to applications filed by manufacturers while simultaneously improving DEA's ability to respond quickly to drug shortages.

DEA is analyzing how current data-sharing agreements with the U.S. Food and Drug Administration (FDA) can be expanded and modified to include the Centers for Disease Control and Prevention (CDC) and the CMS. These expanded information-sharing efforts will concentrate on changes in accepted medical use and medical prescribing practice data. On February 6, 2020, DEA held the Interagency Data Sharing Working Group kick-off meeting. The working group is a collaboration of DEA, HHS, CMS, CDC, and FDA. It is focused on finding data sharing solutions to support DEA's new statutory obligations for establishing quotas for covered substances in accordance with the Controlled Substances Act, as amended by the SUPPORT Act, and evaluating all available and relevant information about changes in accepted medical use and public health impacts, such as death and abuse rates for covered controlled substances. DEA is committed to working with its interagency partners to leverage their unique data sources in order to comply with this statutory requirement. We plan to reconvene periodically in support of our efforts to propose the 2021 aggregate production quota (APQ), which was published in the Federal Register on September 1, 2020.

Automation of Reports and Consolidated Orders System Database Enhancement to Further Prevent Opioid Diversion

The SUPPORT Act also requires the Attorney General, not less frequently than quarterly, to make the following information available to manufacturer and distributor registrants, through the

Automation of Reports and Consolidated Orders System (ARCOS) database, to monitor selected controlled substances: (1) the total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant; and (2) the total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant. These changes will continue the process of improving the quality and timeliness of ARCOS data with the goal of being able to identify prescription drug trends more quickly. Registrants are also required to submit their data in an electronic format, which will improve timeliness and quality of data. These enhancements to the ARCOS database were instituted and made available on February 26, 2019. DEA continues to engage with industry, and remains open to making further enhancements based on comments it receives from the regulated industry.

ARCOS Report to States

As part of the ARCOS enhancement, once every 6 months, DEA is required to prepare and make available to state entities a standardized report containing descriptive and analytic information on the actual distribution patterns as gathered through ARCOS. The report must include detailed amounts, outliers, and trends of distributor and pharmacy registrants in such states for those schedule II controlled substances determined to have the highest abuse. All ARCOS reportable drugs are publicly available in a standardized report for 2018 and 2019 on DEA's website. Biannual reports will be posted at: https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html.

Additionally, to accomplish this information-sharing requirement, DEA is developing a portal system where the points of contact for each state can log on with a user name and password to view and download selected, more detailed, ARCOS reports in addition to the publically available reports.

Medication-Assisted Treatment for Opioid Use Disorders

As of October 2020, there were more than 85,400 qualifying practitioners who may dispense narcotic drugs in schedules III, IV, or V approved for use in maintenance or detoxification treatment (*e.g.*, buprenorphine) in an office-based setting. These individuals are called "DATA-waived practitioners," pursuant to the Drug Addiction Treatment Act (DATA) of 2000, as amended. The number of DATA-waived practitioners has increased by more than 47 percent since the end of FY 2017.

On October 3, 2019, DEA completed technical changes to its registration database that established new "business categories" for those mid-level practitioners authorized to provide medication-assisted treatment (MAT) for up to 275 patients. The SUPPORT Act authorized physician assistants and nurse practitioners, among others, to treat up to 275 patients with opioid use disorder with buprenorphine or other FDA-approved substances. Previously, physician assistants and nurse practitioners were authorized to treat up to 100 patients. This modification to DEA's registration database was a necessary step in order for these qualified practitioners to obtain a license from DEA indicating their authority to treat that number of patients.

Questions from Senator Durbin

1. **Please provide case citations for each criminal prosecution to date that has relied on the class-wide fentanyl-related scheduling authority.**

RESPONSE: The Department does not track data in the manner that you have requested. After the class-wide fentanyl analogue scheduling authority went into effect, the Executive Office for U.S. Attorneys began asking offices to identify cases charging a fentanyl analogue in their data system. However, that system does not further differentiate between individually scheduled analogues and class scheduled analogues. The Department has undertaken a number of measures to identify the information you have requested including reviewing information from the United States Sentencing Commission, conducting a data call to the U.S. Attorneys' offices and the DEA, and a manual review of charging documents. As of May 31, 2020, DEA was aware of the following four prosecutions with charges involving fentanyl-related substances scheduled under class-wide scheduling authority:

US v. Kristofer Rucinsky, 18-CR-2 (WDVA)
US v. Thomas Watkins, 18-CR-127 (EDNY)
US v. Westley Siggers, 19-CR-147 (NDOH)
US v. Joseph Turner, 19-CR-539 (NDOH)

2. **In 2013, a powerful and deadly fentanyl analogue, Acetyl Fentanyl, began to emerge. The DEA responded in June 2015 by temporarily placing Acetyl Fentanyl on Schedule 1, and on June 7, 2017, the DEA made that classification permanent. In 2018, despite this classification, DEA Emerging Threat Reports indicated that encounters with Acetyl Fentanyl more than doubled.**

    a. **Was this scheduling action successful in reducing importation of Acetyl Fentanyl?**

RESPONSE: Scheduling substances continues to be an effective and critical tool in decreasing the encounters of a substance. Acetyl fentanyl is a unique situation; although the encounters with acetyl fentanyl have increased since permanent scheduling, this is a direct byproduct of increased illicit fentanyl production by TCOs. Acetyl fentanyl is a common impurity in fentanyl synthesis. Therefore, the analysis of illicit fentanyl also results in co-identification of acetyl fentanyl. However, the encounters with high purity acetyl fentanyl exhibits (high purity would suggest acetyl fentanyl was the intended substance) continues to decrease since the permanent scheduling of acetyl fentanyl.

    b. **Is it time to consider new approaches to stopping the importation of synthetic drugs into the United States?**

RESPONSE: In conjunction with our foreign partners, DEA strives to interdict synthetic drugs well before TCOs and others attempt to be entered, introduced, or otherwise smuggled them into the United States. DEA also continually works with our federal law enforcement partners to ensure that controlled substances are seized, forfeited, and not released for public abuse and

consumption. This includes the sharing of intelligence, use of joint operations, and the utilization of Title 21 and the customs laws of the United States to the greatest extent possible under existing law. As for new approaches, that is what makes the proactive class-wide scheduling of FRS so critical. This approach allowed the Department, DEA, and our nation to move away from a reactive whack-a-mole approach to thwart clandestine chemists who, with relative ease, created new deadly synthetic compounds by merely altering the chemical composition of the substances, creating uncontrolled new synthetics. These fentanyl-related substances are specifically engineered to evade U.S. law. Although the Department and DEA appreciate the temporary, 15-month, class-wide control of FRS implemented by Congress in January of this year, it is crucial that this scheduling be made permanent in order for DEA and our partners to most effectively disrupt and dismantle narcotics trafficking and to ensure that no potential legal loopholes exist. The DEA worked with our partners at the ONDCP and the HHS on proposed legislation that would permanently schedule fentanyl-related substances while ensuring access for research purposes and expeditious de-scheduling of a compound subsequently determined not harmful. DEA and ONDCP shared the proposal with Committee staff. We would welcome further discussion with Congress about legislative solutions to appropriately address the harms posed by fentanyl-related substances.

Table 1
Primary Drug Type for Drug Cases
(February 6, 2018 through September 30, 2019)

Primary Drug Type	N	Percent
TOTAL	**32,505**	**100.0**
Powder Cocaine	6,042	18.6
Crack Cocaine	2,566	7.9
Heroin	4,184	12.9
Marijuana	3,153	9.7
Methamphetamine	13,377	41.2
Fentanyl	1,220	3.8
Fent Analogue	172	0.5
Synthetic Cannab	195	0.6
Synth Cathinone	62	0.2
MDMA/Ecstasy	128	0.4
Hydrocodone	130	0.4
Oxycodone	763	2.4
Other Drug	513	1.6

This table is limited to offenders who were sentenced from February 6, 2018 through September 30, 2019 whose primary sentencing guideline was determined under Chapter 2, Part D (Drugs) in the Guidelines Manual. Cases sentenced under 2D1.11 were excluded. There were three cases missing information on drug type.

SOURCE: United States Sentencing Commission's FY2018 and Preliminary FY2019 Datafiles, USSCFY18 and PRELIMFY2019.

Table 2
Demographic Information by Primary Drug Type for Drug Cases
(February 6, 2018 through September 30, 2019)

		GENDER		RACE/ETHNICITY				CITIZENSHIP		AGE	
Primary Drug Type	N	Male %	Female %	White %	Black %	Hispanic %	Other %	U.S. Citizen %	Non-U.S. %	Average	Median
Powder Cocaine	6,042	89.2	10.8	6.2	27.1	66.0	0.8	62.9	37.1	37	36
Crack Cocaine	2,566	91.8	8.2	5.9	81.0	12.2	0.8	98.1	1.9	36	34
Heroin	4,184	84.8	15.2	15.9	41.7	41.1	1.2	82.0	18.0	36	34
Marijuana	3,153	86.0	14.0	13.0	14.0	68.3	4.7	56.4	43.6	33	30
Methamphetamine	13,377	77.9	22.1	40.0	12.6	43.1	4.4	81.7	18.3	36	35
Fentanyl	1,220	84.8	15.2	23.9	40.5	34.5	1.2	84.3	15.7	34	33
Fent Analogue	172	89.0	11.1	34.5	53.2	9.9	2.3	96.5	3.5	32	30
Synthetic Cannabinoid	195	88.2	11.8	47.4	21.1	15.0	16.5	86.7	13.3	40	39
Synthetic Cathinone	62	88.7	11.3	51.6	35.5	6.5	6.5	95.2	4.8	36	34
MDMA/Ecstasy	128	91.4	8.6	52.3	21.9	19.5	6.3	87.5	12.5	32	30
Hydrocodone	130	67.7	32.3	48.8	41.1	7.8	2.3	100.0	0.0	42	42
Oxycodone	763	68.9	31.1	48.8	33.4	11.2	6.6	96.2	3.8	41	39
Other Drug	513	77.8	22.2	50.4	32.4	12.9	4.3	94.2	5.9	39	37

This table is limited to offenders who were sentenced from February 6, 2018 through September 30, 2019 whose primary sentencing guideline was determined under Chapter 2, Part D (Drugs) in the Guidelines Manual. Cases sentenced under 2D1.11 were excluded. There were three cases missing on drug type. Cases missing information on gender, race, or citizenship that were excluded from those portions of the table.

SOURCE: United States Sentencing Commission's FY2018 and Preliminary FY2019 Datafiles, USSCFY18 and PRELIMFY2019.

Table 3

Sentencing Information by Primary Drug Type for Drug Cases

(February 6, 2018 through September 30, 2019)

Primary Drug Type	N	MODE OF CONVICTION		SENTENCE	
		Plea %	Trial %	Average	Median
Powder Cocaine	6,042	97.2	2.8	71	60
Crack Cocaine	2,566	95.8	4.3	77	60
Heroin	4,184	97.5	2.5	69	57
Marijuana	3,153	98.4	1.6	29	18
Methamphetamine	13,377	98.0	2.0	95	78
Fentanyl	1,220	98.0	2.0	69	54
Fent Analogue	172	94.2	5.8	89	72
Synthetic Cannabinoid	195	96.9	3.1	45	27
Synthetic Cathinone	62	91.9	8.1	40	24
MDMA/Ecstasy	128	99.2	0.8	37	26
Hydrocodone	130	94.6	5.4	39	13
Oxycodone	763	95.8	4.2	42	24
Other Drug	513	95.5	4.5	36	13

This table is limited to offenders who were sentenced from February 6, 2018 through September 30, 2019 whose primary sentencing guideline was determined under Chapter 2, Part D (Drugs) in the Guidelines Manual. Cases sentenced under 2D1.11 were excluded. There were three cases missing on drug type. Cases missing information on mode of conviction or sentence were excluded from those portions of the table.

SOURCE: United States Sentencing Commission's FY2018 and Preliminary FY2019 Datafiles, USSCFY18 and PRELIMFY2019.

Table 4
Role in the Offense by Primary Drug Type for Drug Cases
(February 6, 2018 through September 30, 2019)

Primary Drug Type	N	ROLE IN THE OFFENSE		
		No Role %	Aggravating Role %	Mitigating Role %
Powder Cocaine	5,931	72.8	9.1	18.1
Crack Cocaine	2,537	90.2	5.9	4.0
Heroin	4,120	75.9	9.1	15.1
Marijuana	3,090	55.2	5.0	39.7
Methamphetamine	13,123	72.1	5.6	22.3
Fentanyl	1,207	82.2	4.7	13.1
Fent Analogue	170	80.0	9.4	10.6
Synthetic Cannabinoid	194	60.8	27.8	11.3
Synthetic Cathinone	62	72.6	9.7	17.7
MDMA/Ecstasy	124	80.7	7.3	12.1
Hydrocodone	126	82.5	15.1	2.4
Oxycodone	756	79.8	13.1	7.1
Other Drug	505	85.7	6.7	7.5

This table is limited to offenders who were sentenced from February 6, 2018 through September 30, 2019 whose primary sentencing guideline was determined under Chapter 2, Part D (Drugs) in the Guidelines Manual. Cases sentenced under 2D1.11 were excluded. There were three cases missing on drug type. Cases missing either complete guideline application information or information about role in the offense were excluded from the table.

SOURCE: United States Sentencing Commission's FY2018 and Preliminary FY2019 Datafiles, USSCFY18 and PRELIMFY2019.