



Department of Justice

STATEMENT OF

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BEFORE THE

**SUBCOMMITTEE ON HEALTH
HOUSE COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES**

AT A HEARING ENTITLED

**“COMBATTING AN EPIDEMIC: LEGISLATION TO HELP PATIENTS
WITH SUBSTANCE USE DISORDERS”**

PRESENTED

MARCH 3, 2020

**Statement of
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**Before the
Subcommittee on Health
House Committee on Energy and Commerce
U.S. House of Representatives**

**At a Hearing Entitled
“Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders”**

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Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee, as the Deputy Assistant Administrator of the Diversion Control Division, Drug Enforcement Administration (DEA), within the Department of Justice (Department), I am integrally involved in the Department’s efforts to implement the provisions of Pub. L. 115-271, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. The Diversion Control Division is tasked with the responsibility to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources, while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. I appreciate the opportunity to share with you an update on the actions that DEA has taken as well as those actions that DEA intends to take in the near future, with the goal of combatting the opioid epidemic, while supporting public health and safety.

According to the Centers for Disease Control and Prevention (CDC), more than 67,000 Americans lost their lives to drug overdoses in 2018. Well over half of those deaths involved opioids. While overdose deaths are one of the most devastating effects of the opioid crisis, prescription opioid misuse and other illicit drug misuse has also led to millions of property crimes and violent crimes. The opioid crisis’ ripple effects on families, communities, and the nation, are far reaching. This is why, in October 2017, the President’s Administration directed that the opioid crisis be declared a nationwide public health emergency. The Department and DEA have been committed and continue to attack this epidemic with every tool they have at their disposal.

Implementation of the SUPPORT Act

On October 24, 2018, President Trump signed the SUPPORT Act into law. This legislation is designed to be a comprehensive approach across the government with the goal of positively impacting and reducing the nationwide opioid crisis. DEA was one of the many

entities charged with implementing new policies and expanding existing programs to obtain this goal. Although much work remains to be completed for DEA to fully implement the requirements of this law, DEA has implemented some key provisions since enactment.

Establishment of Suspicious Order Database

The SUPPORT Act requires the Attorney General (AG) to establish a centralized database for collecting reports of suspicious orders. The purpose of the database is to make a better flow of information between 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 report suspicious orders. DEA met its obligation by the SUPPORT Act deadline. DEA also developed and deployed the robust database on October 23, 2019. 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 suspicious orders reported in their state.

Published Proposed Regulations to Controlled Substance Quotas

On October 24, 2019, the DEA published a Notice of Proposed Rulemaking in the Federal Register to change regulations that improve DEA's ability to oversee the production of controlled substances. The goal of these changes are to further limit 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.

This proposed regulation builds on important regulatory changes finalized in 2018, that require DEA to consider information presented by State Attorneys General and certain federal partners – including the CDC, the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS) (all components of the Department of Health and Human Services (HHS)) – in setting the Aggregate Production Quotas (APQs) for Schedule I and II controlled substances. DEA received 258 comments by the December 23, 2019, deadline for submitting comments to its proposal. DEA is currently reviewing those comments and will work with the Department and the Office of Management and Budget (OMB) to finalize the rule after full consideration of the comments received.

As a general matter, when establishing the APQs, DEA relies on the expertise and guidance of HHS regarding the scientific and medical evaluation research needs of all schedule I and schedule II controlled substances. DEA has entered into an information sharing agreement with FDA to help support data sharing efforts between the two agencies. The DEA annually solicits information from the FDA for use in determining APQs for each basic class of controlled substances in schedules I and II, and the list I chemicals- ephedrine, pseudoephedrine, and phenylpropanolamine. In return, DEA receives from the FDA, estimates of legitimate medical

need for two calendar years, as required by the statutes of both agencies.¹ The FDA information contains observed and estimated trends in net disposals, newly approved products, discontinued products, and other relevant information that FDA has determined to be useful to the DEA in setting the APQs, including estimates for the covered controlled substances. In addition to quota setting, DEA and FDA's active information sharing agreement supports data sharing efforts regarding accepted medical use to support many DEA decisions to include drug scheduling actions and drug shortage determinations.

DEA is analyzing how current data sharing agreements with FDA can be grown and modified to include the CDC as well as the CMS. These expanded information sharing efforts, will concentrate on changes in accepted medical use and practice data. On February 6, 2020, DEA held the Interagency Data Sharing Working Group kick-off meeting. This working group is a collaboration of DEA and HHS (including CMS, CDC, and FDA), and is focused on finding data sharing solutions to support DEA's new statutory obligations for establishing quota for covered substances in accordance with the Controlled Substances Act (CSA), as amended by the SUPPORT Act, to evaluate all available and relevant information about changes in accepted medical use. 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 APQ, which we expect to be published in the Federal Register later this summer.

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

The SUPPORT Act also requires the AG, 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. The data is also to be provided in an electronic format. 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, 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,

¹ 21 U.S.C. § 826 and 42 U.S.C. § 242.

outliers, and trends of distributor and pharmacy registrants, in such states for schedule II controlled substances. All ARCOS reportable drugs are publically available in a standardized report for 2018 on DEA's website. In December 2019, DEA released its first biannual reports covering January-June 2019. By the end of March 2020, DEA plans to release its second biannual report, covering July 2019 – December 2019. 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

There are a total of 75,650 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 Abuse Treatment Act (DATA) of 2000, as amended. The number of DATA-waived practitioners has increased by more than 47 percent since the end of FY2017 (50,888 in September 2018 to 75,650 February 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 February 18, 2020, DEA has 512 mid-level practitioners each authorized to treat up to 275 patients.

Regulations Required by the SUPPORT Act

Regulations Relating to a Special Registration for Telemedicine

The AG, in consultation with the Secretary of HHS, shall 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 on the unified agenda. DEA has drafted this proposed rule and submitted it to the Department for review.

On February 26, 2020, during the pendency of the telemedicine rule, DEA published a notice on the Federal Register of proposed rulemaking authorizing “narcotic treatment programs” to add a mobile component to activities authorized under their registration. As a result, DEA is making progress in doing its part to expand access to treatment services, especially in rural areas where such access is limited.

Update of Biometric Component of Multifactor Authentication for Electronic Prescription of Controlled Substances

The AG shall update the requirements for the biometric component of multifactor-authentication with respect to electronic prescriptions of controlled substances. This regulation is on the unified agenda. On February 6, 2020, OMB approved DEA's rule that seeks to "reopen" the comment period to DEA's 2010 interim final rule, in order to obtain information from the public regarding multi-factor authentication for the electronic prescribing of controlled substances. We expect that this rule will be published on the Federal Register during the first week of March.

Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation

The AG is required to issue regulations that will allow a pharmacy to deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of 21 U.S.C. §829(a). This regulation is in draft form and under internal review.

Prescription Drug Monitoring Programs

According to HHS, as many as 10 million Americans have misused a controlled prescription opioid in the past year. Whereas the vast majority will not go on to use heroin or illicit fentanyl, roughly 80% of those who do go on to misuse those substances, report starting their cycle of addiction with a prescription pain reliever. Accordingly, there has been tremendous congressional and public interest in DEA's response to addressing the diversion and misuse of controlled prescription opioids. One focus has been on the manner in which DEA is leveraging data and specifically sales information reported by DEA-registered manufacturers and distributors through ARCOS. ARCOS is helpful in understanding how much retailers are purchasing controlled substances (*e.g.*, pharmacies and hospitals), but there is a significant knowledge gap of what is going to the patient through prescriptions dispensed.

State Monitoring and Data Collection

Prescription Drug Monitoring Programs (PDMP) are state-run data collection programs that help states, prescribers, and 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 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 confidentiality can impact law enforcement access.² If a PDMP is operated by a Board of Pharmacy or law enforcement, then it is generally regarded as easier for

² 22 states are operated by a health department or Single State Authority for Substance Use Services.

law enforcement to obtain records pursuant to an ongoing investigation;³ however, there is concern in the public health community about unnecessary law enforcement intrusion into patient privacy. 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, though DEA continues to explore whether existing Memorandums of Understanding with State Attorneys General can be the vehicle for that sharing.

Importance of Information Sharing with Federal Law Enforcement

PDMPs are an essential tool to help detect the overprescribing of controlled substances by doctors 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. 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 which 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.

Stopping the Flow of Illicit Opioids

Temporary Schedule I Status for Fentanyl-Related Substances

The potency of substances structurally related to fentanyl, commonly called “fentanyl analogues” or “fentanyl-related substances” is one of the chief drivers of the opioid crisis. Fentanyl is approximately 100 times more potent than morphine, and the substances structurally related to fentanyl tend to be even more potent than fentanyl itself. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for \$3,000-\$5,000 can generate upwards of \$1.5 million in revenue on the illicit market—and contains hundreds of thousands of potentially lethal doses. The lethality of fentanyl is virtually unmatched.

³ 24 states are operated by a pharmacy board or by law enforcement.

In recognition of the unprecedented and continuing escalation in opioid-related overdoses, on February 6, 2018, DEA used its authority under Section 201 of the CSA⁴ to place all non-scheduled fentanyl-related substances, as defined in the order, into schedule I *temporarily*, on an emergency basis, for two years to combat these dangerous substances.⁵ Congress passed and the President has signed into law an extension of this temporary order for an additional 15 months beginning on February 6, 2020.⁶ As a result, anyone who possesses, imports, distributes, or manufactures any illicit, newly scheduled fentanyl-related substance, as defined in the regulation now extended by the law, is subject to criminal prosecution in the same manner as any other schedule I controlled substance. This makes it easier for federal agents to seize and investigate traffickers of fentanyl-related substances, and for prosecutors to prosecute such traffickers.

The positive impacts since implementation are significant. The class control has substantially slowed the rate at which new fentanyl related substances are introduced to, and being encountered in, the illicit market. Prior to this action, DEA observed a rapid and continuous emergence of new illicit fentanyl-related substances each time it scheduled a fentanyl-related substance. Under the temporary emergency scheduling order, there is little incentive for drug trafficking organizations to invent new substances in the fentanyl family for the purpose of evading DEA's control. As a consequence, DEA has encountered fewer new fentanyl analogue substances. DEA's experience under the relatively short temporary scheduling regime is a proof of concept that class-wide scheduling of fentanyl-related substances produces solid law enforcement results, without jeopardizing legitimate research with the scheduled compounds.

Legislative Action to Aid the Department

Permanent Scheduling of Fentanyl- Related Substances

DEA's emergency temporary scheduling action controlling fentanyl-related substances is set to expire on May 6, 2021.⁷ If action is not taken to provide for permanent class scheduling before May 6, 2021, these fentanyl-related substances will become non-controlled. As a result, DEA will enter into relatively unknown territory. Temporary class control has been shown to be incredibly effective in substantially reducing the number of fentanyl analogue encounters in the United States.

DEA is grateful that members of Congress, especially members of this subcommittee, have taken strong actions to ensure that the temporary emergency order on fentanyl-related substances did not expire; however, the class of fentanyl-related substances needs to be

⁴ 21 U.S.C. § 811(h)(1).

⁵ Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188 (Feb. 6, 2018), <https://www.federalregister.gov/documents/2018/02/06/2018-02319/schedules-of-controlled-substances-temporary-placement-of-fentanyl-related-substances-in-schedule-i>.

⁶ P.L. 116-114.

⁷ This date is based on P.L. 116-114, which granted a 15-month extension of DEA's temporary emergency scheduling order of fentanyl-related substances.

statutorily and permanently scheduled. A Legislative solution to permanently schedule fentanyl-related substances as a class by codifying DEA's temporary emergency scheduling order is absolutely essential to tackle the opioid epidemic this country currently faces. DEA strongly supports a proactive approach to permanent scheduling of fentanyl-related substances in Schedule I, that include measures to mitigate the potential negative impacts of such scheduling on research with these substances, as agreed to by interagency partners. A lapse in control would result in a step backwards in the fight against the opioid epidemic and those preying on our vulnerable populations.

Thank you for the opportunity to testify today and we look forward to continuing to work with Congress to find solutions necessary to address the threats posed by the opioid epidemic.