Department of Justice

STATEMENT OF

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AT A HEARING ENTITLED

“RESPONDING TO AMERICA'S OVERDOSE CRISIS: AN EXAMINATION OF LEGISLATION TO BUILD UPON THE SUPPORT ACT”

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Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the committee: On behalf of the Department of Justice (Department), and in particular the nearly 10,000 employees working at the Drug Enforcement Administration (DEA), thank you for the opportunity to appear before you today to discuss DEA's work in implementing the 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.

Americans today are experiencing the most devastating drug crisis in our nation's history. This is because one drug—illicit fentanyl—has transformed the criminal landscape. Illicit fentanyl is exceptionally cheap to make, exceptionally easy to disguise, and exceptionally deadly to those who take it. It is the leading cause of death for Americans between the ages of 18 to 45, and it kills Americans from all walks of life, in every state and community in this country. Two Mexican drug cartels—the Sinaloa Cartel and Jalisco Cartel—are primarily responsible for driving the drug poisoning epidemic in the United States. They are modern, sophisticated, and extremely violent cartels that rely on a global supply chain to manufacture, transport, and sell illicit fentanyl, and on a global illicit financial network to pocket billions of dollars in revenue from those sales.

From February 2022 through January 2023, 110,000 people lost their lives to drug poisonings in the United States. Every day, 300 people die from drug poisonings. Countless more people are poisoned and survive. These drug poisonings are a national crisis.

DEA is committed to using every tool at our disposal to confront the deadly epidemic of drug poisonings. The drug poisoning epidemic requires a two-pronged approach that incorporates both the regulatory and enforcement sides of DEA. From an enforcement standpoint, DEA's top operational priority is to defeat the two Mexican drug cartels—the Sinaloa and Jalisco cartels—that are primarily responsible for driving the drug poisoning epidemic in the United States. DEA is

focusing its resources to counter this worldwide threat, and has launched a number of key initiatives to meet the moment.

DEA has acted with urgency to set a new vision, target the global criminal networks most responsible for the influx of illicit fentanyl into the United States, raise public awareness about how just one pill can kill, and ensure DEA's staffing levels are sufficient at all levels across the agency and across the nation. We have transformed our vision by focusing on illicit fentanyl—the drug killing the most Americans—and the criminal organizations most responsible for flooding illicit fentanyl into our communities—the Sinaloa and Jalisco cartels. And we are already starting to see results—as demonstrated with the April indictment of 28 members of the Chapitos network of the Sinaloa Cartel, as well as Operation Last Mile, an example of our network-based approach to apprehend cartel members and their associates in the United States.

On the regulatory side, DEA is diligently working to implement the SUPPORT Act and fulfill the intent of Congress. Further, as we continue to battle the drug poisoning epidemic, DEA has taken a number of actions to increase access to medication for opioid use disorder to help prevent drug poisonings from taking more American lives.

DEA collaborates with agencies across the federal government, including the Office of National Drug Control Policy in support of the President's National Drug Control Strategy.

By focusing on both the operational and regulatory sides of the drug poisoning epidemic, DEA is demonstrating its commitment to ending the epidemic and aiding those who have developed a substance use disorder caused by these substances.

The SUPPORT Act

On October 24, 2018, the SUPPORT Act was signed into law. This law 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 various provisions of the law and expanding existing programs to achieve this goal. Since its enactment, DEA has taken critical steps to implement key provisions to confront the drug poisoning epidemic.

<u>Implementing the SUPPORT Act: Data</u>

The SUPPORT Act established a number of requirements to bolster DEA's data on suspicious orders, provide manufacturers and distributors tools to better examine their customers, and require data sharing on controlled substances distribution from DEA to the states. However, DEA would also benefit from information on prescription drug monitoring programs from the states.

Suspicious Orders Database

The SUPPORT Act required DEA to establish a centralized database for collecting reports of suspicious orders. The purpose of the database is to improve the flow of information between registrants, DEA, and state and local law enforcement to prevent the diversion of controlled substances. Under the law, all DEA registrants that distribute controlled substances to other DEA registrants must report suspicious orders.

Per the SUPPORT Act, DEA is sharing information from the Suspicious Orders Report System (SORS) Online with states. 21 U.S.C. § 832(c). In order to maximize the use and effectiveness of SORS Online, DEA developed a portal for State Attorneys General (AGs) to review information concerning suspicious orders identified in their state. Point of contact (POC) information and authorization is required prior to providing portal access. Currently, 46 states have responded to DEA's request for POCs and those POCs now have access to the SORS Online portal. With this access, AGs are able to review individual pharmacy, practitioner, hospital, and Narcotic Treatment Plan (NTP) orders deemed suspicious by suppliers and the reason for the designation.

Enhanced Reporting to Prevent Opioid Diversion

In February 2018, DEA deployed a "Lookup Buyer Statistics" tool through its Automation of Reports and Consolidated Orders System (ARCOS). This function gives manufacturers and distributors the ability to see the aggregated orders that individual pharmacies or practitioner registrants have placed with multiple distributors. The SUPPORT Act required DEA to provide more detailed information and, in February 2019, DEA instituted enhancements to this tool to comply with these SUPPORT Act requirements and to be consistent with industry needs.

The information in the "Lookup Buyer Statistics" tool assists manufacturers and distributors with their obligation to "know their customer" and to identify/report suspicious activity. It is also a way for DEA to further assist drug manufacturers and distributors with their regulatory obligation under the Controlled Substances Act (CSA) to identify and report suspicious orders to DEA. This information sharing is just one of the many ways DEA is working collaboratively with its over 2 million registrants to combat the ongoing drug poisoning epidemic in the United States.

DEA continues to engage with industry, and remains open to making further enhancements based on comments it receives from registrants. The most recent enhancement allows bulk download capability containing expanded presentation of data, allowing better identification of products sold.

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, outliers, and trends of distributor and pharmacy registrants, for schedule II and schedule III narcotic controlled substances. All ARCOS reportable drugs are publicly available in standardized reports on DEA's website, current through 2022. The biannual reports are posted at: https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html. Additionally, to accomplish this information sharing requirement, DEA has developed a portal system where the POCs for each state can log on with a user name and password to view and download selected ARCOS reports with more detail in addition to the publicly available reports.

Implementing the SUPPORT Act: Regulations

DEA is actively working on a number of regulations to implement provisions of the SUPPORT Act.

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

The SUPPORT Act required the United States Attorney General or a designee to update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances. On April 21, 2020, DEA published an interim final rule which "reopened" the comment period to DEA's 2010 interim final rule, in order to obtain information from the public regarding this topic. DEA is currently reviewing comments it received.

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

The SUPPORT Act required the United States Attorney General or a designee to issue regulations that allow a pharmacy to deliver a controlled substance to a practitioner for administration in accordance with a prescription that meets the requirements of 21 U.S.C. § 829(a). DEA published an interim final rule in the Federal Register to implement this requirement on November 2, 2020.

Mobile Narcotic Treatment Programs

On June 28, 2021, DEA published a final rule in the Federal Register authorizing "narcotic treatment programs" to add a mobile component (mobile NTPs) to activities authorized under their registration. As a result, DEA is making progress in expanding access to treatment services, especially in healthcare deserts or rural areas where such access is limited.

Regulations Relating to Telemedicine

In 2008, Congress enacted the Ryan Haight Act, which generally prohibits prescribing of controlled medications when a practitioner has not conducted an in-person medical evaluation of a patient. In 2018, the SUPPORT Act directed the United States Attorney General or designee, in consultation with the Secretary of the Department of Health and Human Services (HHS), to promulgate final regulations specifying: (1) the limited circumstances in which a special registration for telemedicine may be issued that authorizes prescribing of controlled substances without an in-person evaluation; and (2) the procedure for obtaining a special registration.

On March 1, 2023, DEA, in concert with HHS, published in the Federal Register two proposed rules: "Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation" (the General Telemedicine NPRM) and "Expansion of induction of buprenorphine via telemedicine encounter" (the Buprenorphine NPRM), both of which proposed to expand patient access to prescriptions for controlled medications via telemedicine encounters relative to the pre-COVID-19 Public Health Emergency (PHE) landscape.[1] The General Telemedicine NPRM proposed rules which would allow telemedicine prescribing of non-narcotic schedule III, IV, and V medications. The Buprenorphine NPRM proposed rules which would allow telemedicine prescribing of buprenorphine as medication for opioid use disorder. The comment period for the two proposed telemedicine rules closed on March 31, 2023.

During the 30-day public comment period for the proposed rules, DEA received a record total of more than 38,000 comments. DEA takes these comments seriously and understands the

[1] The General Telemedicine NPRM explained in a footnote that DEA believes the proposed regulations therein are consistent with, and would fulfill, the Special Registration mandate of the SUPPORT Act.

importance of telemedicine for Americans across the country. Accordingly, DEA worked with HHS to temporarily extend the COVID-19 public health emergency telemedicine flexibilities while we work to find a way forward that will give Americans access to needed medications through telemedicine, with appropriate safeguards in place.

Under the extension, the public health emergency telemedicine flexibilities will remain in place for six months, through November 11, 2023. In addition, for any practitioner-patient telemedicine relationships established on or prior to November 11, 2023, those flexibilities will continue to apply for another year, until November 11, 2024.

Expanding Access to Medications for Opioid Use Disorder

At DEA, our goal is to make medications for opioid use disorder (MOUD) readily and safely available to patients who need them. Access to MOUD helps those fighting to overcome this disease, to sustain recovery, and—ultimately—to save lives.

One important way in which DEA has increased access to MOUD is by working with its federal partners in the Federal Bureau of Prisons (BOP), the Office of National Drug Control Policy (ONDCP) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to obtain the required SAMHSA certification and DEA registrations in 97 BOP complexes and correctional facilities. These facilities are now authorized to provide MOUD to those in custody. Access to MOUD will mitigate the increased risk of drug-related deaths of those individuals shortly after release from custody.

DEA is also increasing access to methadone and buprenorphine via its forthcoming exceptions to the "three-day rule." Congress passed a law in December 2020 directing DEA to amend the "three-day rule" "so that practitioners . . . are allowed to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both)." This will significantly expand immediate and emergency access to narcotic medications for individuals suffering from acute withdrawal symptoms while the individual awaits further, long-term treatment. This change in regulation will alleviate the burden on both the patient, specifically resulting from transportation, scheduling, and other issues, and on the practitioner from having to treat the same patient multiple days in a row.

Pending this rulemaking action, DEA has provided practitioners with a temporary "waiver" from the current regulation. Under this option, any DEA-registered practitioner working in a hospital, clinic, or emergency room, or any DEA-registered hospital/clinic that allows practitioners to operate under their registration number as per 21 CFR 1301.22(c), may request an exception to the one-day supply limitation currently imposed pursuant to 21 CFR 1306.07(b). DEA has issued 1,981 exception letters in 50 states and two territories.

Most recently, the Consolidated Appropriations Act of 2023 (the Act) eliminated the DATA-Waiver, dramatically increasing the number of medical professionals authorized to prescribe buprenorphine for the purpose of MOUD. The DATA-Waiver was established in 2000 and was later perceived as one of the primary barriers to increasing access to these potentially life-saving medications. DEA is committed to expanding access to MOUD to help those impacted by drug

trafficking and suffering from substance use disorder while maintaining effective controls against diversion. DEA has been working closely with its federal partners and associations representing DEA registrants to ensure they are aware of the elimination of the DATA-Waiver registration requirement to treat patients with buprenorphine for opioid use disorder as well as the elimination of patient caps or limits for prescribers who may treat for opioid use disorder with buprenorphine. DEA believes the elimination of the DATA-Waiver will increase access to buprenorphine for those in need.

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 drug poisoning epidemic.