U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

MAY 07 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Neil Doherty, Deputy Assistant Administrator of the Office of Diversion Control for the Drug Enforcement Administration, before the House Committee on Energy and Commerce on October 25, 2017, at a hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives." We hope that this information is of assistance to the Committee.

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,

Prim Escalona

Prim F. Escalona
Principal Deputy Assistant Attorney General

Enclosure
cc: The Honorable Frank Pallone
Ranking Minority Member

QUESTIONS FOR THE RECORD

NEIL DOHERTY
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION
DEPARTMENT OF JUSTICE

HOUSE COMMITTEE ON ENERGY AND COMMERCE

HEARING ON
"FEDERAL EFFORTS TO COMBAT THE OPIOID CRISIS: A STATUS UPDATE ON CARA AND OTHER INITIATIVES"

OCTOBER 25, 2017

Questions Posed by Representative Adam Kinzinger

1. With respect to Prescription Drug Monitoring Programs, what issues should we be aware of regarding PDMP access by law enforcement personnel?

RESPONSE: As you know, prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and, where permitted, law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. The Drug Enforcement Administration (DEA) strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th state to have an operational PDMP, pursuant to the Governor's Executive Order in July 2017. As of January 2018, 40 of these 49 states with operational PDMPs require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[1] The DEA encourages all practitioners and pharmacists to use their state PDMPs.

PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion. Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information (PII) is vital. Access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data. These requirements can hinder DEA's investigations of those who are operating outside of the Controlled

[1] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf retrieved March 6, 2018.

Substances Act (CSA) and may affect DEA's ability to effectively protect the public health and safety.

Questions Posed by Representative Bill Flores

2. A serious problem in the opioid epidemic is synthetic drugs. The DEA released its 2017 National Drug Threat Assessment Monday. One of the findings was, and I quote, "Overdose deaths, already at high levels, continue to rise. The increased mixing of heroin with analogues of the highly-potent synthetic opioid fentanyl and other synthetic opioids has exacerbated this situation."

   Our colleague, Mr. Katko of New York, testified before this committee earlier this month about a bill he has that help protect our communities from synthetics and analogues. Now, there is still work to be done on his proposal – which has passed the Judiciary Committee, I should note.

   - Mr. Doherty, has the DEA focused any attention on providing technical comments on the Katko bill, titled the Stop the Importation and Trafficking of Synthetic Analogues Act – or SITSA for short?

   RESPONSE: Yes. The Department of Justice (the Department) and DEA have provided extensive technical assistance on SITSA to both the House and the Senate. The Department and DEA welcome any additional tools that Congress can provide to assist DEA in combating the opioid epidemic. In the interim, DEA will continue to utilize all available tools, including temporary scheduling of substances as authorized by 21 USC 811(h). In fact, on November 9, 2017, the Department and DEA announced that we intended to take immediate action against the flow of illicit fentanyl analogues into this country and the alarming increase in overdose deaths linked to synthetic opioids by scheduling all fentanyl-related substances on an emergency basis. The "notice of intent" was published in the Federal Register on December 29, 2017. The final order was published in the Federal Register on February 6, 2018, and made effective on that date. Pursuant to this final order, anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This critical scheduling action will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances.

3. Are there tools that the DEA has requested from Congress to help combat synthetics?

   RESPONSE: DEA and the Department have provided technical assistance to both the House and Senate regarding SITSA, which would be a useful tool to combat the proliferation of synthetic analougues. As mentioned in the response to the previous question, DEA continues to utilize its regulatory authority to place many synthetic substances into Schedule I of the CSA pursuant to the aforementioned temporary scheduling authority.

4. I understand law enforcement desires additional scheduling authorities, while researchers have concerns with how this may unintentionally impact the scientific community's ability to study compounds for groundbreaking medications.

    - Is there a way we can strike a balance of scheduling these rapidly-multiplying analogues in a timelier manner while also protecting the important work being done by scientific researchers?

RESPONSE: The introduction of new drugs of abuse is causing unprecedented harm to our communities and scheduling is an important tool DEA uses to protect the public from the trafficking and diversion of these harmful substances. It bears repeating that scheduling does not prevent DEA-registered researchers from conducting research on the substances. DEA agrees that it is important for the research community to have access to these novel psychoactive substances and DEA strongly supports research with controlled substances, including those in schedule I of the CSA. This research informs regulatory and policy decisions. Indeed, the process of drug scheduling requires the Department of Health and Human Services (HHS) to evaluate the research and provide DEA with a binding recommendation regarding the control of a substance. The scientific evidence remains critical to both the drug scheduling and the approval process. As a provider of this binding control recommendation and a primary source for funding, HHS should continue to maintain a robust role. The procedures that must be followed to apply for a DEA registration to conduct research with a schedule I controlled substance are set forth in 21 C.F.R. 1301.18.

DEA has taken steps to simplify the research application process, including the introduction of a new electronic system through which applications can be submitted, and will continue to work with the research community to ensure applications are processed in a timely manner. DEA has granted every application received for bona fide research with a schedule I controlled substance, and as of March 18, 2018 there are 601 DEA-registered schedule I researchers.

DEA worked with the Department to provide formal technical assistance on SITSA. During that time, DEA and HHS engaged extensively in order to understand its concerns related to permanent scheduling and research under SITSA.

<u>Questions Posed by Representative Chris Collins</u>

5. As PDMPs have evolved in recent years, incorporating PDMP data into a prescriber or pharmacist's clinical workflow seems to be the key to ensuring that the data is used effectively while also increasing efficiency and saving time for providers. What are the barriers currently preventing more states from incorporating PDMP data into clinical workflow?

RESPONSE: DEA agrees that integrating PDMP data into electronic health records to better inform the prescriber and pharmacist before a prescription

is dispensed is a best practice. However, DEA is not aware of barriers that are currently preventing states from incorporating PDMP data into clinical workflow and respecfully defers to HHS.

6. We know that the "moment of clarity" when a patient realizes they need to go into treatment can be short-lived, and having resources in place to immediately connect patients to treatment is critical to the chances of recovery. When a PDMP does indicate a patient has been "doctor shopping" and potentially has a substance use disorder, what policies are in place to direct them to treatment if they wish to go? If none exist, how could we help encourage them to access treatment at that time?

   RESPONSE: DEA is not aware of any policies aimed at directing patients to treatment and would respectfully defer to the Bureau of Justice Assistance (BJA) or HHS. Although there are no policies mandating referral to treatment, DEA is not aware of anything to prohibit health professionals who currently have access to PDMP information to engage in intervention and referral to treatment. DEA defers to the Substance Abuse and Mental Health Services Administration (SAMHSA) to explore the expanding practice of screening, brief intervention, and referral to treatment among health professionals. Additionally, DEA plays a role in supporting effective drug treatment of persons with opioid use disorders through providing waivers and certifications to physicians, physician assistants, and nurse practitioners to dispense/administer medications approved by the U.S. Food and Drug Administration (FDA) for addiction treatment – buprenorphine, naltrexone, and methadone in certain settings.

7. a. Some states such as Massachusetts have started using data as a weapon in the fight against opioids. They are combining data from prescription records, death records, medical examiners… even prisons. For example, they found that a person who is released from jail in Massachusetts has a 56 times greater chance of dying from an overdose than the average person. They are using that information to make better policy decisions, as well as to identify specific individuals who are in need of services. States are supposed to be the laboratories of democracy. What has the CDC learned from states in their use of data analytics?

   RESPONSE: DEA respectfully defers to the Centers for Disease Control and Prevention (CDC) for a response.

   b. Is there a plan to use data to fight the opioid crisis?

   RESPONSE: DEA uses data when pursuing actions against those who violate the CSA. For example, the Automation of Reports and Consolidated Orders System (ARCOS) is the electronic system in which manufacturers and distributors report the manufacture, sale, purchase, loss, or other disposition of certain controlled substances. ARCOS is an important tool in both DEA's law enforcement mission and its regulatory mission. DEA field elements use ARCOS to assist investigators with accountability audits during onsite regulatory investigations and also to review

and verify specific registrant's activities and reporting accuracy. A unit within the Diversion Control Division's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution created by the CSA. This unit performs quality control reviews of ARCOS data and then uses validated ARCOS data to detect anomalies and identify leads. This unit is now proactively preparing reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil, and regulatory investigations. DEA shares ARCOS data with its federal, state, local, and tribal law enforcement and regulatory counterparts who have a need to know and are operating in coordination with DEA for investigative purposes. In addition to ARCOS data, DEA registrants are required under current regulations to report the theft or significant loss of controlled substances. Each report is fully investigated and this data also informs DEA's decision making and resource prioritization.

In addition to data that is collected by DEA pursuant to the CSA, we are also engaging with both federal and state partners on data sharing agreements to enhance our efforts. DEA is currently working with a coalition of States Attorneys General (Coalition) to develop an information-sharing agreement in support of ongoing investigations that the Coalition has initiated. This information sharing agreement will include the sharing of ARCOS data with States and in return, those States who can, will share data from PDMPs in support of active DEA investigations. DEA has also been working with HHS on an information sharing agreement. HHS's Office of Inspector General (OIG) has been sharing with DEA information from HHS's OIG analytics for the Medicare Program. DEA has already received data from HHS regarding the Part D prescription program that is being utilized alongside additional data in support of ongoing matters.

Finally, in line with the Department's Opioid Fraud and Abuse Detection Unit (a Department pilot program announced in August, 2017), the Department, DEA, Federal Bureau of Investigation (FBI), and counterparts at HHS are utilizing advanced data-analytics to combat the opioid crisis. As part of this program, the Department has dedicated experienced prosecutors for a three-year term in twelve districts, who will focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense opioids for illegitimate purposes.

<u>Questions Posed by Representative Buddy Carter</u>

8. Under CARA, prescribers can write up to three 30-day prescriptions without any refills. You can look into how pharmacists could play a larger role and ways to address prescriber behavior.

   Additionally, you can ask questions about limiting prescriptions for acute pain needs, such as dental work or minor surgeries with the possibility for a limited refill.

   Mr. Doherty, under CARA, prescribers were allowed to write up to three 30-day

prescriptions for a patient but no refills. While CARA took some great steps forward, I think it's worth taking another look at its progress and ways to improve the program. One area I'd like to raise would be limiting prescriptions for acute pain procedures and needs. As a pharmacist, I've seen people come in with 30 day prescriptions for minor dental procedures. Have you looked in to that possibility and what would be the DEA's outlook on such a move?

RESPONSE: DEA has reviewed CARA and could not locate a provision authorizing prescribers to write up to three 30-day prescriptions for a patient with no refills. The question may be referring to a final rule on the "Issuance of Multiple Prescriptions for Schedule II Controlled Substances," which DEA published in the Federal Register on November 19, 2007. (72 FR 64929) This rule allowed prescribers to issue three sequential prescriptions at one time for a schedule II controlled substance, effectively allowing a patient to be issued prescriptions for a 90-day supply of controlled substances. 21 C.F.R. 1306(b). DEA does not dictate what quantities of controlled substances constitute a 30-day supply, as DEA does not regulate the practice of medicine.

With regard to limiting prescriptions for acute pain, DEA notes that the CDC published guidance to prescribers suggesting that three days or less of an opioid medication will often be sufficient for acute pain. DEA does not dictate the amount of a controlled substance that a prescriber should authorize as these clinical decisions are the direct result of the doctor's clinical training and the result of his/her evaluation of the patient's particular needs.

Finally, DEA provided technical assistance on the provision in CARA that authorized prescribers and patients to request a partial fill of a prescription for a schedule II controlled substances. This provision authorizes a patient or practitioner to request that the pharmacist only dispense a portion of the quantity prescribed, and he/she may request the remainder of the quantity prescribed to be dispensed within 30 days. This provision was intended to reduce the amount of unused and unwanted opioids outside of the drug supply chain, i.e., in people's homes.

9. Would the DEA be willing to look at reducing the number of prescriptions for opioids and allowing for one, limited refill of the prescription? I believe it could help to reduce the amount in circulation as well as address some of these accessibility needs we've brought up through take-back programs.

RESPONSE: It is not clear how authorizing one limited refill of a schedule II controlled substance would result in a reduction in the number of prescriptions written and the amount of controlled substances in circulation. The refilling of a prescription for a controlled substance listed in schedule II is prohibited under Federal law. 21 USC §829(a).

10. October 28th is the 14th National Drug Take-Back Day. During your tenure in the state legislature, you helped create the program that turned in 9,630 pounds of unwanted

medications during the April drive in Georgia.

- How would the DEA approach a national mail-in take-back program across the country? What sort of security concerns and guidelines would need to be addressed to make it effective?

RESPONSE: A mail in take-back program is one of several acceptable options authorized under current DEA regulations. 21 C.F.R. 1317.70. On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet. According to the 2016 National Survey on Drug Use and Health, approximately half of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or received it free from a friend or relative. These regulations provide a safe and legal method for the public to dispose of unused or expired controlled prescription drugs (CPDs). As of January 9, 2018, a total of 3,214 DEA registrants have become "authorized collectors."

11. On top of those concerns, would a nominal fee paid by the patient be able to cover the costs of such a program?

RESPONSE: Per 21 C.F.R. 1317.70(c), "collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free)" for the collection of controlled substances via mail. Collectors set their own fee should they choose to do so. It should be noted that 21 C.F.R. 1317.70(c)(4) states that "the cost of shipping the package shall be postage paid."

<u>Questions Posed by Representative Pete Olson</u>

12. Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)? Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?

RESPONSE: DEA does not have grant making authority and is therefore unaware of how much funding has been allocated to state prescription drug monitoring programs as a result of CARA.

Questions Posed by Representative Susan Brooks

13. I have heard you say that preventing drug use before it begins is the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

RESPONSE: It is true that preventing drug use before it starts is the most cost-effective way to reduce drug use and its related consequences. Interventions that prevent substance misuse and substance use disorders can yield a greater economic return than the services that treat them. For instance, a study of prevention programs estimated that every dollar spent on effective, school-based programs to delay onset of use of alcohol, tobacco, and illegal drugs may save an estimated $18 in costs related to problems later in life such as lost productivity and diminished quality of life.[2]

Effective research-based programs share the following core elements: structure—how each program is organized and constructed; content—how the information, skills, and strategies are presented; and delivery—how the program is selected or adapted and implemented, as well as how it is evaluated in a specific community. When adapting programs to match community needs, it is important to retain these core elements to ensure that the most effective parts of the program stay intact.[3]

While it is important to note that prevention strategies must be tailored to the individual setting, thereby avoiding a "cookie-cutter" approach, successful prevention approaches share a variety of characteristics. For instance, they are data-driven, in that data is compiled and used to guide all prevention-related decisions, from determining which drug abuse issues to address to choosing the most appropriate way to address those problems. Also, they focus on population-level change, which means implementing multiple strategies that address the identified risk and protective factors related to drug abuse in a given community. Furthermore, they are comprehensive, combining a variety of strategies rather than relying on a singular strategy. Lastly, they rely on a team approach. An effective prevention approach needs – and greatly benefits from – the participation of diverse partners. These individuals and institutions may change over time, but the need for prevention partners is constant.[4]

Besides a lack of resources, which continues to be a significant barrier to implementing prevention and intervention programs throughout the government, other barriers include insufficient training and technical assistance opportunities

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[2] Miller, T., & Hendrie, D. (2008). Substance abuse prevention dollars and cents: A cost-benefit analysis. (DHHS-Pub. No. (SMA) 07-4298). Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention.)

[3] www.drugabuse.gov/publications/preventing-drug-abuse-among-children-adolescents-in-brief/chapter-3-applying-prevention-principles-to-drug-abuse-prevention-programs/what-are

[4] www.samhsa.gov/capt/applying-strategic-prevention-framework

for community coalitions and others across the nation working to prevent drug abuse, workforce shortages in the drug abuse prevention field, a lack of conformity to implementing evidence-based programs as designed, and apathy about drug abuse prevention in general.

Questions Posed by Representative Markwayne Mullin

14. I introduced H.R.3528, the Every Prescription Conveyed Securely Act, with Katherine Clark (D-MA), to require e-prescribing of controlled substances (EPCS) under Medicare Part D. As you may know, the President's Commission on Opioids recommended that the use of e- prescribing of opioids should be encouraged. Since the DEA relaxed its prohibition of e-prescribing for controlled substances in 2010, e-prescribing has expanded for Medicare beneficiaries and six states have mandated its use specifically for controlled substances.

    Does the DEA have a position on this legislation? Please explain the DEA's position and any concerns it may have with EPCS.

    RESPONSE: Thank you for your work on this important issue. The Administration has not taken a position on this legislation. DEA supports the e-prescribing of controlled substances through its issuance of an interim final rule on EPCS, which was published in the Federal Register in March 2010. This rule clarifies the criteria by which DEA-registered practitioners may electronically issue controlled-substance prescriptions and by which DEA-registered pharmacies may receive and archive those prescriptions. It also creates an authentication procedure to ensure the prescriptions are not forgeries. The goal of this interim rule is to reduce the number of errors caused by illegible written prescriptions and help hospitals integrate prescription records into other medical files. As a result of this interim final rule, DEA received a number of comments and subsequently has met with stakeholders as it drafts a final rule. DEA will continue to work towards the publication of this final rule.

Questions Posed by Representative Ben Ray Lujan

15. In the U.S., we still have too few locations to drop off unwanted and expired medication – some of which can be dangerously addictive or fatally lethal in even small doses – like fentanyl. According to the 2017 National Drug Threat Assessment, in 2015, over half of people who misused prescription pain relievers, like opioids, got them from a friend or relative while roughly 34% got them from one doctor.

    - Administrator Doherty, what is the DEA doing to combat the misuse of pain relievers that are given by, bought from, or stolen from family friends?

    RESPONSE: On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies,

mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related SUDs, and promotes awareness that according to the 2016 National Survey on Drug Use and Health, one source of these drugs is often the home medicine cabinet, as approximately half of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free. These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of January 9, 2018, a total of 3,214 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on April 25, 2018. As a result of all fifteen National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of nearly 10 million pounds (4.98 tons) of medications from circulation. The sixteenth National Drug Take Back Day is scheduled for October 2018.

Education is a key piece of combatting the opioid epidemic, including the misuse of pain relievers that are given by, bought from, or stolen from family friends. DEA initiated and continues to expand upon its 360 Strategy. The strategy leverages existing Federal, state, local, and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and demand reduction. Our enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding the heroin and prescription drug epidemic in our communities. We are also enhancing our diversion control efforts and working with community partners for them to implement evidence-based programs and efforts designed to reduce demand and to prevent the same problems from resurfacing.

As part of the 360 Strategy, DEA has partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide development of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. The program has reached more than 1.1 million students to date, will run for at least three consecutive school years (through spring 2019), and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

Since launching the 360 Strategy in 2016, it has been implemented in eight cities: Louisville, Kentucky; St. Louis, Missouri; Pittsburgh, Pennsylvania; Milwaukee, Wisconsin; Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia; and Manchester, New Hampshire. DEA is expanding this program to additional locations including the announcement of the Salt Lake City, Utah location in September 2017. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

16. What is the DEA doing to make it harder to misuse of prescription drugs attained directly from doctors?

RESPONSE: DEA cannot control if ultimate users will misuse prescription drugs obtained directly from doctors. With that said, DEA works to prevent the diversion of controlled prescription drugs from doctors. DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and the present, DEA increased the number of operational TDSs from 37 to 77. In addition, we established two mobile TDSs that can deploy quickly to "hot spots" in furtherance of the Diversion Control Division's mission.

Additionally, please see the discussion of DEA's National "Take-Back" Initiative discussed above in response to question 1. This program, along with the authorized disposal methods in the Secure and Responsible Drug Disposal Act of 2010 and 21 C.F.R. 1317, is intended to reduce the amount of unwanted and unused controlled prescription drugs in peoples' homes such that they cannot be misused by the ultimate user or others.

17. I'm aware of private sector organizations such as CVS and Walgreens that are working diligently to provide more drop-off locations in their stores and local communities. What would it take to have drop-off locations for controlled substances in every community in the United States? What is the public sector doing to aid the private sector in these efforts?

RESPONSE: The DEA cannot mandate nor does it offer an incentive to a DEA-registered pharmacy, hospital or clinic to become an "authorized collector" pursuant to the September 2014 final order that establishes rules for this activity. DEA strongly encourages its approximately 90,000 registrants in these classes to consider becoming authorized collectors so that families have safe and convenient opportunities to dispose of unused and unwanted controlled prescription drugs 365 days per year.

The GAO recently studied this issue in its report entitled, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs* (GAO-18-25, published October 12, 2017).

18. Addressing the opioid epidemic is going to require a multi-faceted approach. We cannot cure opioid addiction through law enforcement or treatment alone. We must also work to address the problem at the start. This means we should also be adopting policies and practices to reduce the amount of opioids that are available in circulation, and educating health care providers on opioids, pain management, and non-opioid pain alternatives.

    Approximately 80 percent of the legal global opioid supply is consumed in the United States. Based on 2015 sales, the top five opioid products were made by Purdue Pharma, Johnson & Johnson, Insys Therapeutics, Mylan and Depomed, according to sales. A 2016 survey by the National Safety Council revealed that about 99 percent of physicians exceed the recommended three-day dosage limit, with a quarter of them writing prescriptions for a full month and thus overprescribing these types of medications.

    Members of this Committee have called for additional prescriber education and training to this effect and I want to learn more about what role FDA and DEA can play in this process.

    - Mr. Doherty, as you know, a number of stakeholders have called for mandatory prescriber training on opioids to be a requirement of DEA registration. What role do you see prescriber education playing in addressing the opioid crisis, and what role has, or can, DEA play in ensuring health care practitioners are properly informed about the benefits and risks of opioids and the role appropriate prescribing can play in addressing the opioid epidemic?

RESPONSE: DEA believes that all entities in the controlled prescription drug supply chain benefit from having the most information possible regarding the benefits and risks of opioids, as well as the role that appropriate prescribing can play in addressing the opioid epidemic. DEA supports the CDC's *Guideline for Prescribing Opioids for Chronic Pain.* DEA is encouraged to see that the total prescriptions dispensed for the opioid analgesic class has trended downward from a high of approximately 290 million prescriptions in 2014 to approximately 240 million prescriptions in 2017.[5]

Additionally, in 2018, DEA has initiated a nationwide program to offer training to individual practitioners on the important role they play in preventing diversion of these controlled substances. This program will be modeled after, and will follow upon, the success of the 97 Pharmacy Diversion Awareness Conferences that DEA held throughout the country, culminating in October 2017. DEA trained over 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled.

[5] Information obtained by DEA pursuant to its contract with Quintiles IMS Health's for statistical information from its National Prescription Audit database. Information obtained on 12/6/17.

19. In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. *The New York Times* reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The *Times* and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long- term investments in prevention, treatment, recovery, and monitoring.
The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a 95 percent hit.

    - Deputy Assistant Administrator Doherty, do you have all of the tools you need to stop the opioid epidemic?

RESPONSE: With four out of five new heroin initiates reporting that they previously misused prescription pain relievers,[6] the efforts of DEA's Diversion Control Division have never been more critical. The DEA has a wide array of tools to ensure its more than 1.7 million registrants are in compliance with the CSA. These include outreach to industry, medication disposal, regulatory oversight, administrative actions, civil penalties, and criminal charges, among others. DEA has and will continue to use all available tools to combat the opioid epidemic.

Outreach to Industry

Due to the complexity of DEA's regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its more than 1.7 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by: (1) hosting Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy (NABP), American Medical Association (AMA), and Federation of State Medical Boards (FSMB), and other groups to address diversion problems and educate the medical community on improving prescribing practices.[7] As of November 2017, DEA will have hosted 100 PDACs in all 50 states (as well as the District of Colombia and Puerto

[6] Substance Abuse and Mental Health Services Administration. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Department of Health and Human Services, August 2013. *available at:* https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

[7] In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

Rico) resulting in the training of more than 13,300 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In May 2018, DEA plans to initiate a nationwide program to offer similar training to individual practitioners.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail-back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related SUDs, and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free[8]. These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of November 30, 2017, 2,948 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on April 25, 2018, which collected another record-setting 949,046 pounds—474.5 tons—of potentially dangerous expired, unused, and unwanted prescription drugs for disposal at more than 5,800 collection sites. As a result of all 15 National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed nearly 10 million pounds (4,982 tons) of medications from circulation. The sixteenth National Drug Take Back Day is scheduled for October 2018.

Prescription Drug Monitoring Programs

PDMPs are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th state to have an operational PDMP, pursuant to the Governor's Executive Order in July 2017. As of August 2017, 24 of

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[8] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

these 49 states with operational PDMPs require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[9] DEA encourages all practitioners and pharmacists to use their state PDMPs.

Production Quotas for Schedule II Opioids

The Diversion Control Division is responsible for setting Aggregate Production Quotas (APQs) every year. These APQs are the "total quantity of each basic class of controlled substance listed in schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. The APQs are determined after consideration of certain statutory factors, described in 21 C.F.R. § 1303.11 (b), which include:

1. **Total net disposal (e.g. domestic sales, exports, waste) of the substance by all manufacturers during the current and two preceding years;**
2. **Trends in the national rate of net disposal of the substance; total actual (or estimated) inventories of the substance and of all substances manufactured from that substance, and trends in inventory accumulation;**
3. **Projected demand as indicated by procurement quotas requested in accordance with DEA regulations; and**
4. **Other factors affecting medical, scientific, research, and industrial needs in 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.**

Since 2014, DEA has observed a decline in prescriptions written for certain schedule II opioids. These declines have led to overall reductions in licit demand which, in turn, have directly impacted the factors DEA considers when establishing the APQs for schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous years' (2016) level. The 2018 APQs result in a nearly 20 percent reduction from the 2017 levels. These reductions include the aforementioned opioids, as well as oxymorphone, codeine, and meperidine. These decreases can be attributed to local, state, and federal agencies creating new partnerships, enforcing current regulations, and issuing updated guidance documents, including the Centers for Disease Control and Prevention's 2016 publication entitled, *CDC Guideline for Prescribing Opioids for Chronic Pain*. In addition, we are

[9] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20170824.pdf retrieved October 19, 2017.

encouraged that more states have enacted and enforced laws mandating the use of prescription drug monitoring programs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

DEA'S 360 Strategy and Operation Prevention

To counter the opioid crisis, DEA continues to expand its 360 Strategy, a comprehensive three-pronged approach tackling the cycle of violence and addiction generated by the link between drug cartels, violent gangs, and the rising problem of prescription opioid misuse and heroin use in U.S. cities. The 360 Strategy features: coordinated law enforcement actions against drug cartels and heroin traffickers in specific communities; diversion actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners; and community outreach through local partnerships that empower communities to take back affected neighborhoods after enforcement actions and prevent the same problems from cropping up again. In 2016, DEA implemented its strategy in: Louisville, Kentucky; Milwaukee, Wisconsin; St. Louis, Missouri and Pittsburgh, Pennsylvania. In 2017, DEA implemented its strategy in Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia and Manchester, New Hampshire. In 2018, DEA is implementing this program in Salt Lake City, Utah; Northern and Southern New Jersey; and Philadelphia, Pennsylvania.

As part of the 360 Strategy, DEA has partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide development of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. The program has reached more than 1.1 million students to date, will run for at least three consecutive school years (through spring 2019), and will be free for all law enforcement, prevention, treatment, and community groups to use and distribute.

Significant Enforcement Efforts

In addition to the actions of the Diversion Division, DEA continues to aggressively combat the opioid epidemic through a variety of enforcement and partnership efforts. The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Customs

Enforcement, Homeland Security Investigations (HSI) and Customs and Border Protection (CBP); supplemented by the FBI and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department's Criminal Division, the Department of Defense (DOD), the Intelligence Community (IC), and other government entities, and provides field offices from all agencies with valuable support in their respective investigations.

These relationships have led to several large enforcement actions, including two separate OCDETF investigations centered in North Dakota and Southern Mississippi that resulted in the first-ever indictments in September 2017 of two Chinese nationals responsible for the manufacturing, importation, and distribution of fentanyl in the United States. In addition, SOD played an integral role in the July 2017 seizure of the largest criminal marketplace on the Internet, AlphaBay, which operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. Multiple OCDETF interagency investigations into AlphaBay revealed that numerous vendors sold fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

Automated Reporting and Consolidated Orders System (ARCOS) Data

DEA's Diversion Control Division has also taken numerous steps to examine sales and monitoring processes. For example, Diversion Control utilizes various reports and records to monitor trends or determine anomalous transactions, which can then be developed into investigative leads. A unit within the Diversion Control's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit is now proactively preparing quarterly threat assessment reports for each of DEA's 22 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil and regulatory investigations. DEA is working collaboratively with a coalition of States Attorneys General to provide non-public, law enforcement sensitive ARCOS data to support their active investigations against certain manufacturers and distributors.

Diversion Enforcement Actions

DEA uses a wide array of diversion enforcement tools to ensure its more than 1.7 million registrants are in compliance with the CSA. These include administrative actions, civil penalties, and criminal charges. Within DEA's administrative authorities, there are multiple actions that may lead to an individual or entity having

a registration revoked, which include orders to show cause (OTSC), immediate suspension orders (ISO), and voluntary surrenders. Upon a registrant surrendering a registration for cause, or DEA obtaining a suspension/revocation of the registration, the registrant can no longer dispense, prescribe or administer controlled substances, which DEA deems to be a success. Since FY 2011, these combined actions result in an average of roughly 980 registration revocations per year. Of the total registration revocations, ISOs have historically made up a small portion, averaging less than three percent annually. Additionally, combined ISO and OTSC actions in 2017 more than doubled since 2014.

Working with the United States Attorneys' Offices, DEA has pursued civil actions against some of the nation's largest drug distributors. Over the last decade, opioid distributors nationwide have paid nearly $390 million in civil penalties and DEA has entered into Memoranda of Agreement (MOAs) with the distributors to ensure their future compliance. In Fiscal Year 2017, distributors paid more than $194 million in civil penalties, which is more than the previous seven years combined (close to $148 million).

Since 2010, DEA has re-prioritized its criminal investigators and embedded them with diversion investigators into enforcement groups called tactical diversion squads (TDS). TDSs investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and present, DEA increased the number of operational TDSs from 37 to 77. In addition, DEA established two mobile TDS groups that can deploy quickly to "hot spots" in furtherance of the Diversion Control Program's mission. For example, one mobile TDS team recently deployed to Charleston and Clarksburg, West Virginia. Each of these groups focuses primarily on criminal enforcement and the results of their work often lead DEA registrants to surrender their DEA registration for cause. Over the last seven years, these TDS groups have initiated an average of more than 1,500 cases per year and made an average of more than 2,000 arrests per year.

Supporting Effective Drug Treatment

Additionally, DEA plays a role in supporting effective drug treatment of persons with opioid use disorders through providing waivers and certifications to physicians, physician assistants, and nurse practitioners to dispense/administer medications approved by the FDA for addiction treatment – buprenorphine, naltrexone, and methadone in certain settings.

20. How will the DEA allocate its 3.7 percent boost in funding in the President's budget proposal to fight the opioid epidemic?

RESPONSE: DEA appreciates the U.S. House of Representatives mark of the FY 2018 budget, which is consistent with the President's budget request. DEA has developed proposals that identify priorities that focus on anticipated program needs and that will allow DEA to continue to target the most significant drug trafficking threats including CPOTs, PTOs, and other significant DTOs. The FY 2018 President's Budget request will provide DEA resources to build upon our success and to continue to address the scourge of heroin and controlled prescription drug abuse. Enhancement requests include the following:

1. **<u>Heroin Enforcement:</u> $8.5 million in support of coordinated Law Enforcement actions that aim to sever the ties between cartels and the violent gangs which supply deadly opioids to our communities.**

2. **<u>Transnational Organized Crime</u>: $6.5 million for investigative activities focusing on the TCOs responsible for large quantities of drugs arriving in U.S. cities. DEA will enhance overseas investigative capabilities and the Sensitive Investigative Units (SIU) Program.**

3. **<u>Violent and Gun-Related Crime Reduction Task Force:</u> $5.9 million to tackle the violence generated by drug cartels and street gangs. DEA appreciates the U.S. House of Representatives mark of the FY2018 budget, which is consistent with the President's budget request. This request includes $21 million to combat the opioid epidemic and violent crime (10 agents) in support of the disruption and dismantlement of the individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA.**

4. **<u>Opioid Training, Enforcement, and Drug Disposal:</u> $20 million in support of actions against individuals and organizations operating outside the law. Additionally, long-term education and training engagements with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners will be conducted.**

5. **<u>Diversion Investigators and Tactical Diversion Squads:</u> $9.4 million will provide 55 positions (to include 10 Special Agents and 28 Diversion Investigators) to create new and enhance current Diversion Groups while solidifying existing TDSs to conduct criminal enforcement activities involved in diversion schemes (i.e. pill mills, prescription forgery rings, and rogue internet pharmacies).**

21. Opioid addiction is not a new problem. Misuse of and addiction to pharmaceuticals has existed for centuries, ever since morphine was heralded in the 1850s as a solution to our opium addiction problem– until it, in turn, morphine became a larger problem, as did heroin, and then methadone. Today, we understand the importance of pain relieving agents, but as my constituents continue to perish at alarming rates due to these drugs, we need to be working together to address the crisis. The public and private sectors can and should work together to swiftly address the opioid epidemic. The Reagan-Udall

Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science that is necessary to helping the FDA accomplish its mission. The Foundation was created by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to address regulatory science challenges of the 21st century. The central focus of the Foundation is to assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the agency's ability to protect and promote the health of the American public.

- Understanding what we know now about this issue, what further information or support do you need from pharmaceutical manufacturers to more aggressively combat this crisis?

RESPONSE: As the U.S. Food and Drug Administration (FDA) is the agency with a regulatory obligation to ensure that only safe and effective drugs are approved for marketing in the United States, DEA respectfully defers to the FDA on what additional measures pharmaceutical manufacturers should take to address the opioid epidemic.

22. Stopping the flow of opioids into the U.S. will require a decrease in demand. People who are at highest risk of overdose use prescription opioids nonmedically for 200 or more days a year. These highest-risk users are approximately four times more likely than the average user to buy the drugs from a dealer or other stranger. From a supply perspective, the ways for illicit opioids and heroin to enter the U.S. are ever-changing and creative, driven by the rise of e-commerce and outpacing our current abilities to monitor what enters across our borders.

    Opioids and heroin illicitly enter the U.S. through the U.S. Postal Service and traditional drug smuggling channels. Illicit synthetics are largely manufactured in China and smuggled into the United States via traditional channels and through the U.S. Postal Service. Fentanyl is a synthetic opioid that Americans can order online through illicit drug marketplaces. Online ordering of counterfeit prescription drugs is possible via e-commerce websites and through dark web markets on the Tor network. Because fentanyl is potent, it is easy to hide in letters and small packages that are sent by post. Overseas labs in China are mass-producing fentanyl and fentanyl-related compounds and marketing them to drug trafficking groups in Mexico, Canada, and the United States. Mexico often serves as a transshipment point for fentanyls shipped from China. In 2017, fentanyl is being trafficked through Mexico into the U.S. alongside heroin and cocaine, though it is largely produced in Asia. Customs and Border Protection officers search packages entering the U.S. through the John F. Kennedy International Airport mail center for fentanyl and other synthetic opioids using an old X-ray machine, a borrowed handheld laser that can peek into packages, and a dog trained to detect fentanyl. In fiscal year 2016, the CBP team at JFK airport seized seven fentanyl packages. This year, they have seized 64 as of September 17, 2017.

    Not all illicit synthetics enter the U.S. from other countries. A DEA intelligence brief

published in July 2016 noted that people within the U.S. are also making and selling fentanyl pills. In January 2016, DEA agents seized 6,000 fentanyl pills made to look like oxycodone from a dealer who was manufacturing them in his New York residence. A similar pill pressing operation was discovered in Los Angeles in March 2016.

Heroin consumed in the U.S. comes mainly from Afghanistan and Mexico, according to the UN's International Narcotics Control Board (INCB). As much as 94 percent of the heroin entering America comes from Mexico, estimated William R. Brownfield, assistant secretary of the Bureau of International Narcotics and Law Enforcement Affairs.

- Why can't the U.S. stop and dramatically reduce trafficking of opioids and heroin into the U.S.?

RESPONSE: DEA is diligently working by taking a whole of government approach with our federal partners to reduce the trafficking of opioids and heroin into the United States. There are many current initiatives aimed at combatting this problem, some of which are listed below.

Significant Enforcement Efforts

The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from DEA, U.S. Immigration and Customs Enforcement Homeland Security Investigations (HSI) and Customs and Border Protection (CBP); supplemented by the FBI and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department's Criminal Division, the Department of Defense (DOD), the Intelligence Community (IC) and other government entities, and provides field offices from all agencies with valuable support in their respective investigations.

The HFTF mission aims to:

- **Identify, target, and dismantle command and control networks of national and international fentanyl and New Psychoactive Substances (NPS) trafficking organizations.**
- **Provide case coordination and de-confliction on all domestic and foreign investigations to ensure that multi-jurisdictional, multi-national, and multi-agency investigations and prosecutions have the greatest impact on targeted organizations.**
- **Provide direct and dynamic operational and investigative support for domestic and foreign field offices for all agencies.**
- **Identify new foreign and domestic trafficking, manufacturing, importation, production and financial trends utilized by criminal enterprises.**
- **Analyze raw intelligence and documented evidence from multiple resources**

to develop actionable leads on viable target(s) involved in possible illicit pill production and/or distribution networks.

- Educate overall awareness, handling, trafficking trends, investigative techniques and safety to domestic and foreign field offices for all law enforcement, DOD, IC and governmental agencies.
- Facilitate, coordinate and educate judicial districts during prosecutions of fentanyl and other NPS related cases.

AlphaBay "Dark Market" Shutdown

In July 2017, the Department announced the seizure of the largest criminal marketplace on the Internet, AlphaBay, which operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation and efforts by law enforcement authorities in Thailand, the Netherlands, Lithuania, Canada, the United Kingdom, and France, as well as the European law enforcement agency Europol. Multiple OCDETF interagency investigations into AlphaBay revealed that numerous vendors sold fentanyl and heroin, and there have been multiple overdose deaths across the country attributed to purchases on the site.

Mexico: Partnership to Reduce Supply of Illicit-Narcotics

DEA, through its partnership with the U.S. Department of State, helps Mexican government officials to improve capacity to interdict and seize illicit narcotics. DEA routinely engages with Mexico through the bilateral drug policy working group with the Office of the Attorney General (PGR) in Mexico City. These efforts were instrumental in constructive policy changes such as Mexico's decision to schedule the two primary fentanyl precursors, ANPP and NPP in mid-2017.

China: Government Action and Cooperation

DEA, through its leadership in the United States and its country office in Beijing, has maintained an ongoing relationship with government officials of the People's Republic of China for years, and has been able to leverage this relationship to combat the rising threat from NPSs and their precursors. Engagement has been occurring at the leadership level through interagency working groups that operate under the U.S.-China Joint Liaison Group (JLG) framework co-chaired by the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, DEA, and DHS, including the Counternarcotics Working Group led by the Department of Justice, and the Bilateral Drug Intelligence Working Group led by DEA.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls against four fentanyl-class substances: carfentanil;

furanyl fentanyl; valeryl fentanyl; and, acryl fentanyl. This announcement was the culmination of ongoing collaboration between DEA and the Government of China, and reaffirms an expanding collaborative commitment to countering illicit fentanyl.

Over the past year, DEA and Chinese officials have met regularly to discuss mutual interests and shared responsibilities in countering the threat from fentanyl class substances. Representatives from the China National Narcotics Laboratory, the Narcotics Control Bureau, and the Ministry of Public Security met with DEA (along with Department of Justice and Department of Homeland Security) officials to exchange information on emerging substances' scientific data, trafficking trends, and sample exchanges. This continued dialogue is anticipated to foster a bilateral information exchange related, but not limited to, the identification of new substances of abuse that may then be considered for national control. The meeting also deepened professional contacts between relevant technical and legal experts.

A key moment in enhanced cooperation on synthetic drugs came in October 2015, when, following similar discussions, China decided to implement domestic controls on 116 NPS, which included a number of fentanyl analogues, and streamlined its procedures to control additional substances with no known medicinal use. In total, China has scheduled 138 different NPS, including 128 since October 2015.

Finally, as this threat has increased, law enforcement cooperation at the street level has been very productive, particularly on fentanyl cases. DEA will continue to collaborate with the Government of the People's Republic of China as the threat from fentanyl continues to evolve.

Class Wide Scheduling of Fentanyls

As stated in previous responses, the Department of Justice and DEA announced on November 9, 2017, that DEA intended to take immediate action against the flow of illicit fentanyl analogues into this country and the alarming increase in overdose deaths linked to synthetic opioids by scheduling all fentanyl-related substances on an emergency basis. The "notice of intent" was published in the Federal Register on December 29, 2017. The final order was published in the Federal Register on February 6, 2018, and made effective on that date. Pursuant to this final order, anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. This scheduling action will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances.

23. If Congress was to allow for international drug importation writ large, does that have the potential to impact either positively or negatively the ability for nefarious actors to increase illegal opioid trafficking in the US?

RESPONSE: Any such authorization would require changes to the CSA and DEA

is not in a position to comment on a hypothetical issue without knowing how Congress might seek to make those statutory changes. DEA notes that its mission is to enforce the controlled substances laws and regulations of the United States, which would include preventing the importation and distribution of illegal drugs, as well as preventing the diversion of controlled prescription drugs from the legitimate drug supply chain. DEA is willing to review any draft legislation proposed by Congress on this matter.