U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

AUG 24 2018

The Honorable Michael C. Burgess, M.D.
Chairman
Subcommittee on Health
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 Susan A. Gibson, Deputy Assistant Administrator for the Office of Diversion Control Regulatory, Diversion Control Division, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Health on February 28, 2018, at a hearing entitled "Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety." We hope that this information is of assistance to the Committee.

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. Please do not hesitate to contact this office if we can be of additional assistance regarding this or any other matter.

Sincerely,

Prim Escalona

Prim F. Escalona
Principal Deputy Assistant Attorney General

Enclosure

cc: The Honorable Gene Green
Ranking Member

Questions for the Record
Drug Enforcement Administration
Before the Subcommittee on Health
Energy and Commerce Committee
U.S. House of Representatives
For a Hearing Entitled
"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"
February 28, 2018

The Honorable Michael C. Burgess, M.D.

1. **Ms. Gibson, in your testimony, you state that manufacturers and distributors will keep one step ahead of government action by introducing and repackaging new synthetic products that are not listed as controlled substances. The distribution and use of these synthetic opioids have wreaked havoc on our nation's public health, and we have convened this hearing to analyze and develop legislation that will prevent further spread of the opioid epidemic.**

    - **In what ways can the Special Operations Division Heroin/Fentanyl Task Force Working Group bridge the gaps between agencies so that there's a united enforcement effort to prohibit crafty manufacturers and distributors from exploiting the cracks in our system?**

RESPONSE: The shared goal of neutralizing criminal networks that threaten our national security as well as our partner nations is what bridges the gaps between agencies. The Drug Enforcement Administration's (DEA) Special Operations Division (SOD) Heroin/Fentanyl Task Force Working Group works in a complementary and comprehensive manner in our approach. This focus, in effect, is about the quality and nature of our relationships that make SOD successful as part of the whole-of-government approach to combat these persistent threats.

Through a "top-down/bottom-up approach," SOD analyzes field inputs and applies its specialized capabilities to identify connections between domestic and foreign networks. This unique approach enables SOD to leverage the authorities, capabilities, and resources of its partners to energize joint operations and satisfy intelligence requirements in support of national coordination strategies. This approach allows SOD to work across Department lines as a powerful resource that coordinates national and international efforts to combat fentanyl, fentanyl related compounds, precursor chemicals, money laundering, and synthetic opioid networks.

HEROIN/FENTANYL TASK FORCE: In 2014, the SOD prioritized operations that targeted major international and domestic heroin/fentanyl distributors and threat streams, and created the SOD Heroin/Fentanyl Task Force (HFTF). The HFTF improved information sharing between U.S. law enforcement agencies, to include DEA, Homeland Security Investigations (HSI), the Federal Bureau of Investigation (FBI), the U.S. Customs and Border Protection (CBP), the U.S. Postal Inspection Service (USPIS), as well as the DEA Special Testing and Research Laboratory (STRL). These agencies collaborate closely by refined information sharing mechanisms established at SOD with the Department of Defense Narcotics and Transnational Crime Support Center, the National Targeting Center, and the Joint Interagency Task Force West to develop actionable lead packages on potential fentanyl/synthetics distributors, which are actioned domestically and internationally in various field offices.

The HFTF collaborates with the STRL regarding large seizures that test positive for fentanyl. The HFTF utilizes the information from the STRL as a pointer system to connect fentanyl networks, regionally and internationally.

EXAMPLE OF SOD-HFTF COORDINATION SUCCESS: Since May 2013, law enforcement agencies, working together under the Attorney General's Organized Crime Drug Enforcement Task Forces (OCDETF) Program, have been investigating the drug trafficking activities of Chinese national Jian Zhang and his criminal organization based in Shandong Province, China. OCDETF used various techniques during the investigation of Zhang, which included judicial wire intercepts of electronic communications by the United States and China, undercover transactions by federal agents, collaboration with the private sector, and debriefing of confidential sources and cooperating defendants. Zhang's criminal organization utilizes the internet to advertise the sale of his controlled substances distributed by various manufacturing laboratories in mainland China. Zhang was responsible in recruiting, teaching and organizing U.S. and Canada based regional distributors to purchase and manufacture his synthetic opioids into counterfeit pills such as 30 mg oxycodone.

SOD-HFTF SUPPORT TO COMBAT CHINESE TCOs: Under these SOD-supported operations, HFTF was able to identify, interdict, and successfully indict Zhang, who was purchasing raw materials from China chemical suppliers for the purpose of synthesizing, producing, and distributing dangerous narcotics through the United States and Canada. The illicit drugs Zhang trafficked into Canada and the United States were linked and directly responsible for multiple overdose deaths and serious injuries across the nation.

RESULTS AND IMPACT: On September 21, 2017, Zhang was indicted in North Dakota on five separate counts to include conspiracy to possess with the intent to distribute the fentanyl resulting in serious bodily injury and death. In addition to the investigation clearly establishing that Zhang was the source of supply for the fentanyl and fentanyl analogues that supplied a Canadian re-distributor, Zhang was also found to be the source of narcotics for eight other federal investigations across the United States. As a result of SOD and OCDETF coordinated enforcement operations, U.S. law enforcement agencies arrested 56 drug traffickers, seized in excess of 1,000 kilograms of drugs of various types, $1 million in currency, and other assets totaling over $450,000 in U.S currency. Each were connected to investigations under SOD Operation Deadly Merchant, Operation Denial, and Operation

Slippery Pete. These actions represent a significant milestone in denying the illicit trafficking of fentanyl in the United States and international markets, as well as sending a clear message of future unified efforts to combat these threats from SOD and its partners. These examples of SOD supported operations are representative of increasing multi-jurisdictional success stories that arise from cooperation and superbly coordinated interagency efforts from dozens of federal, state, and local agencies spanning both regional and international borders.

2. **You also state in your testimony that there was an exponential increase in the number of fentanyl reports from 2013 to 2016. This statistic suggests that fentanyl has become more accessible, which implies that trafficking of illegal fentanyl, and other synthetic opioids, has increased.**

    - **Mr. Katko's bill aims to modernize scheduling guidelines so that your agency can keep up with the rapidly changing nature of synthetic drugs. Can you comment on the importance of working with the Food and Drug Administration in your efforts to discover and schedule these new drugs in a timely manner?**

RESPONSE: The Department of Justice (Department) and DEA have worked with the Department of Health and Human Services, and its appropriate components, including the Food and Drug Administration (FDA), to provide extensive technical assistance to both the House and the Senate on H.R. 2851 and S. 1327, the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017," or the SITSA Act. The rapidity and ease with which dangerous synthetic drugs are manufactured and introduced into the illicit market make control through law enforcement responses extremely challenging. Additional tools are needed to reduce the threat these substances pose, including a more expeditious pathway to schedule such substances under the Controlled Substances Act (CSA). DEA has engaged extensively with FDA and the National Institute on Drug Abuse on ways to streamline the current scheduling framework, without impeding bona fide scientific and medical research.

DEA agrees that it is important for the research community to have access to psychoactive substances for licit research and DEA strongly supports research on controlled substances, including those in Schedule I of the CSA. Recognizing that the process of obtaining a DEA registration may result in significant delays, DEA has taken steps to improve the process. One example is the new electronic system through which applications can be submitted. DEA also understands the significant role FDA plays in both the scheduling and registration process for controlled substances. SITSA would: provide DEA with a critical tool enabling it to be proactive in combating the influx of synthetic drugs that are causing great harm to the public; preserve an appropriate role for the FDA in the scheduling process; and ensure adequate access to analogues of controlled substances for licit research.

3. **Ms. Gibson, in your testimony, you talk about fentanyl and fentanyl analogues coming into the United States from China to be mixed with heroin and cocaine, or pressed into a pill form. You say, and I quote, "In some cases,**

traffickers have industrial pill presses shipped into the United States directly from China and operate illegal fentanyl pill press mills domestically."

- **What is the DEA doing to stop pill presses from being used for criminal activity?**

Response: All regulated persons are required to submit in advance the notification of an import or export of a tableting or an encapsulating machine. The advance notification must contain the information described in 21 CFR 1310.06 (e)(1) and (e)(2). DEA would pursue enforcement action as it receives information from CBP about illegal imports of tableting or encapsulating machines.

4. **I agree that the current pill press proposal – in discussion draft form – needs to be more narrowly tailored. This concept was raised in the President's Commission made this recommendation – it's number 25. The intent of this legislation is to capture criminal practices of pill presses being used to produce counterfeit drugs and not create a burden on legitimate industries.**

    - **Do you have any creative ways we could do this without causing unnecessary harm on legitimate industries, like over-the-counter products or dietary supplements?**

Response: DEA is willing to work with the Committee by providing technical assistance on any legislation that will address the criminal practices of pill presses being imported and used to produce counterfeit drugs, while also allowing legitimate industries to continue to operate within the confines of the law.

The Honorable Susan W. Brooks

5. **One commonly referenced method of reducing opioid overdoses is to reduce opioid prescriptions. As you know, a DEA registration is required for practitioners to be able to prescribe controlled substances. I would like to focus my questions today on the importance of prescriber education in reducing the number of prescriptions. I am working on a bill that will require prescribers to complete continuing medical education (CME) prior to receiving a DEA registration.**

    - **In what ways does DEA monitor prescribing practices? Have there been any changes related to prescribers that DEA has implemented in response to the current opioid epidemic?**

Response: DEA does not have the statutory authority to monitor the prescribing practices of DEA-registered prescribers. 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. Federal law enforcement access to a state's PDMP is limited and access varies according to state law. It is usually only granted when a prescriber is under a federal investigation. 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. If funded, Missouri would become the 50th, pursuant to the Governor's Executive Order in July 2017.[1] 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.[2] 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 ability to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects patient privacy 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 for law enforcement to obtain data. Some requirements can hinder DEA's investigations of those who are operating outside of the CSA and impact DEA's ability to effectively protect the public health and safety.

In May 2018, DEA initiated a nationwide program to offer training to all DEA-registered prescribers. This program is designed to train DEA-registered prescribers on how to detect and guard against diversion activities in response to the current opioid

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[1] The Missouri statewide PDMP has not been funded and is not operational. Please note that the county of St. Louis, Missouri, instituted its own operational PDMP in April 2017. This PDMP is open to participation from additional jurisdictions outside of St. Louis County. As of February 2018, there are 58 jurisdictions participating in the PDMP. These 58 jurisdictions cover 79% of the state population and 92% of healthcare providers.

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

epidemic. In addition to the training opportunities offered to registrants, DEA has also begun a program to proactively send targeted email messages to various segments of its registrant population on matters of mutual interest. For example, in February 2018, DEA sent correspondence to 1.3 million doctors nationwide alerting them of the Centers for Disease Control and Prevention's (CDC) recommendations for the prescribing of opioids for acute pain and advising practitioners of a free training webinar available from CDC. In the coming months, DEA will send targeted messages to certain practitioners on how they may utilize telemedicine to treat opioid use disorder.

Much like the recommendations of the President's Commission on Combating Drug Addiction and the Opioid Crisis, DEA recognizes the importance of fostering training amongst prescribers about the risks and benefits of opioid therapy. DEA supports the recommendation made by the Commission to require new and existing practitioners to demonstrate that they have received continuing medical education when applying for or renewing their DEA license. In order to better inform the Department on how many prescribers are taking training in this area, on February 7, 2018, DEA began to ask each individual practitioner, at the time of their application or renewal, whether they have received training regarding the prescribing or dispensing of opioids. Since deployment, 83 percent of the respondents have affirmatively stated that they have taken such training.