



Department of Justice

STATEMENT OF

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BEFORE THE

**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

FOR A HEARING ENTITLED

“FENTANYL: THE NEXT WAVE OF THE OPIOID CRISIS”

PRESENTED

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**Statement of
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Before the
Subcommittee on Oversight and Investigations
Energy and Commerce Committee
United States House of Representatives
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INTRODUCTION

Chairman Murphy, Vice Chairman Griffith, Ranking Member DeGette, and Members of the Oversight and Investigations Subcommittee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the threat posed by dangerous synthetic drugs.

DEA has become increasingly alarmed over the proliferation of illicit fentanyl and its analogues, which have been added to heroin and other illicit substances and have also been encountered as counterfeit tablets resembling controlled prescription drugs (CPDs). Fentanyl and fentanyl analogues are potent synthetic opioids which present a serious risk of overdose and death by those who misuse these substances. The 2015 market for misused prescription pain relievers was 12.5 million people¹, and if illicit fentanyl is introduced into even a small portion of that overall market, there is a likelihood that overdoses will increase. In addition, this drug can be absorbed through the skin or inhaled, which makes it particularly dangerous for public safety personnel who encounter the substance during the course of their daily operations. Fentanyl and fentanyl analogues represent the deadly convergence of the synthetic drug threat and current national opioid epidemic.

On a broader scale, synthetic designer drugs, also known as New Psychoactive Substances (NPS), refer to man-made substances designed to mimic the effects of known licit and illicit controlled substances; these substances are oftentimes unscheduled and unregulated. There are a variety of synthetic designer drugs, which are categorized based on the types of controlled substances they are intended to mimic: cannabinoids, cathinones, and hallucinogens known as phenethylamines. The two most commonly used categories of synthetic designer drugs in the United States are synthetic cannabinoids and synthetic cathinones. NPS continue to pose a nationwide threat to the United States and related overdoses and deaths continue to occur.

¹ Center for Behavioral Health Statistics and Quality. (2016). *Results from the 2015 National Survey on Drug Use and Health*. Table 1.27A. Retrieved from <http://www.samhsa.gov/data/>

SYNTHETIC DESIGNER DRUGS OVERVIEW

Fentanyl and Its Analogues (Synthetic Opioids)

Fentanyl is a Schedule II controlled substance produced in the United States and used widely in medicine. It is an extremely potent analgesic widely used for anesthesia and also pain control in people with serious pain problems and, in that case, it is indicated only for use in people who are opioid tolerant.

According to DEA investigations, illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped through mail carriers directly to the United States or alternatively shipped directly to transnational criminal organizations (TCOs) in Mexico, Canada, and the Caribbean. Once there, fentanyl or its analogues are prepared to be mixed into the U.S. heroin supply domestically, or pressed into a pill form, and then moved to the illicit U.S. market where demand for prescription opioids and heroin remain at epidemic proportions. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this market. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for \$3,000 - \$5,000 can generate upwards of \$1.5 million in revenue on the illicit market.

According to the DEA National Forensic Laboratory Information System (NFLIS), from January 2013 through December 2016, a total of 50,440 fentanyl reports were identified by Federal, State and local forensic laboratories. During 2016, there were 28,751 fentanyl reports compared to 1,041 reports in 2013, a substantial increase over the past four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a December 2016 Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, from 2014 to 2015, the death rate from synthetic opioids other than methadone, which includes fentanyl, increased by 72.2%, from 5,544 (age adjusted rate 1.8 per 100,000) to 9,581 (3.1 per 100,000). Over a two week period in late March and early April 2016, DEA issued a public safety alert for the Sacramento, California region following an outbreak of overdoses related to counterfeit hydrocodone which had been laced with fentanyl. In all, there were 52 individuals who overdosed, 14 of whom ultimately lost their lives. Additionally, between January and March 2016, nine people died in Pinellas County, Florida from counterfeit Xanax® pills that contained fentanyl.

In 2015, about 3.8 million Americans age 12 or older reported misusing prescription pain relievers within the past month². This makes nonmedical prescription opioid misuse more

² Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from <http://www.samhsa.gov/data/>

common than use of any category of illicit drug in the United States except for marijuana. The illicit market for prescription drugs is considerable in size, which significantly increases the risk that fentanyl or fentanyl analogue-laced counterfeit pills will cause more overdoses across the nation as they are more readily produced by drug trafficking organizations.

CURRENT CHALLENGES

Traffickers Adapting to the Law

Even though many fentanyl-related and NPS compounds have been controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA), entrepreneurs procure new synthetic compounds with relative ease. Over the past several years, DEA has identified numerous fentanyl class substances and hundreds of designer drugs from at least eight different drug classes, the vast majority of which are manufactured in China.

In fact, when DEA takes an action to temporarily schedule a substance, retailers begin selling new versions of their products with new, unregulated compounds in them. Manufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new products that are not listed as such in any of the controlled substance schedules.

Fentanyl, Fentanyl Analogues and the Internet

The tools needed to manufacture counterfeit pills containing fentanyl or fentanyl analogues are available online and are relatively inexpensive compared to other forms of drug production, contributing to its unique level of threat. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. Illicit fentanyl and fentanyl analogues are available for purchase online from anonymous darknet markets and even overtly-operated websites. Industrial pill press machines are also widely available on the open Internet.

Use of Freight Forwarders

Traffickers often use freight forwarders to mail fentanyl and fentanyl analogues from China. Several DEA investigations have revealed that the original supplier will provide the package to a freight forwarding company or individual, who transfers it to another freight forwarder, who then takes custody and presents the package to customs for export. The combination of a chain of freight forwarders and multiple transfers of custody makes it difficult for law enforcement to track these packages. Often, the package will intentionally have missing, incomplete, and/or inaccurate information.

Prosecutions Pursuant to the Analogue Act

A designer drug, including fentanyl analogues, may be a “controlled substance analogue” pursuant to the CSA if it meets the criteria of substantial similarity of chemical structure and effect on the central nervous system. Even if a particular substance is widely regarded as a “controlled substance analogue” under the CSA, each criminal prosecution must establish that

fact anew. The primary challenge to preventing the distribution and use of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is treated as a Schedule I controlled substance only once proven to meet the definition of a controlled substance analogue; prosecutors must also prove that the substance was intended for human consumption. Accordingly, each prosecution requires expert testimony even if the same substance is involved.

In addition, without establishment and inclusion of specific sentencing equivalencies in the U.S. Sentencing Guidelines, prosecutors must produce evidence addressing the factors identified in the relevant guidelines. As a result, prosecutors typically call two expert witnesses to testify at every sentencing hearing to demonstrate that the substances in question fall within guideline definitions, a time consuming, resource intensive, and inefficient process. This in turn raises concern that different courts could reach different sentencing results for the same substance, potentially resulting in disparate sentences for similarly situated offenders.

The above considerations, along with the increasing volume and variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Analogue Act a cumbersome and resource-intensive tool to prevent manufacturing, trafficking, and abuse of designer drugs. That said, agents, chemists, and prosecutors have worked together tirelessly to make the Analogue Act work, with many successful prosecutions to show for it. The Synthetic Drug Abuse Prevention Act of 2012 (SDAPA) approach to control specific, known, synthetic substances in some instances by description of chemical characteristics, was a swift and effective contribution to the overall effort to combat the designer drug threat.³ DEA will continue to identify ways to better combat the designer drug threat.

The Drug Control Process under the CSA

The CSA provides the Attorney General (delegated to the DEA Administrator) with a mechanism to bring new drugs of abuse under CSA control and subject them to a regulatory scheme to protect the public. Through an interagency process, determinations about placement in the CSA are dictated by the following eight enumerated scientific factors:⁴ the state of current scientific knowledge about the substance; its pharmacological effect; its risk to the public health; its psychic or psychological dependence liability; whether the substance is an immediate precursor of a controlled substance; its actual or relative potential for abuse; its history or current pattern of abuse and its scope; and the scope, duration, and significance of abuse. In this process, the Secretary for the Department of Health and Human Services (HHS) is responsible for any scientific and medical considerations about a substance and a recommendation made by the Secretary is considered by the DEA Administrator along with other relevant facts to determine whether there is substantial evidence to warrant control. These scheduling evaluations by both HHS and DEA require extensive scientific, medical, law enforcement and other data. The acquisition of this data is often an arduous and time consuming process. The

³ P.L. 112-144 – Food and Drug Administration Safety and Innovation Act, Subtitle D, Section 1151, titled “Synthetic Drug Abuse and Prevention Act of 2012.

⁴ The eight factors are enumerated in 21 U.S.C. § 811(c).

public continues to be impacted adversely while these data are being obtained in support of control under the CSA.

In circumstances when the DEA Administrator concludes that control of a substance is necessary to avoid an “imminent hazard to public safety,” the DEA Administrator may initiate temporary control of that substance for a period of two years, subject to possible extension for up to one year,⁵ during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.⁶

DEA believes a coordinated response by public health and law enforcement and other stakeholders remains the most effective response to this problem. Further, DEA will continue to share information and engage stakeholders to decrease the demand for illicit fentanyl, fentanyl analogues, and other synthetic substances encountered on the illicit market.

DEA RESPONSE TO THE THREAT OF FENTANYL AND OTHER SYNTHETIC DRUGS

Scheduling by Administrative Rulemaking: Temporary Control

DEA continues to utilize its regulatory authority to place many synthetic substances into the CSA pursuant to the aforementioned temporary scheduling authority. Once a substance is temporarily placed in Schedule I, DEA moves towards permanent control by requesting a scientific and medical evaluation and scheduling recommendation from HHS and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, medical examiners, treatment professionals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since March 2011, DEA has utilized this authority on twelve occasions to place 37 synthetic designer drugs into Schedule I, including four fentanyl analogues, acetyl fentanyl, butyryl fentanyl beta-hydroxythiofentanyl, and furanylfentanyl. In comparison, over the first 25 years (1985-2010) after Congress created this authority, DEA utilized it a total of 13 times to control 25 substances.

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 and U.S. Customs and Border Protection ; supplemented by the Federal Bureau of Investigation and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the Organized Crime Drug Enforcement Task Forces (OCDETF) Fusion Center (OFC), the

⁵ The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).

⁶ Temporary control of a substance may be extended for a period of 1 year if DEA receives the Secretary’s scientific and medical evaluation and scheduling recommendation within the 2-year temporary control period.

Department of Defense (DOD), Intelligence Community (IC) and other government entities, and provides field offices (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 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.

China: Government Action and Cooperation

Through both DEA leadership and its country office in Beijing, DEA has maintained an ongoing relationship with People's Republic of China Government Officials for years, and has been able to leverage this relationship to combat the rising threat from NPS. Engagement has been occurring at the leadership level through interagency working groups that operate under the U.S.-China Joint Liaison Group framework, the Counternarcotics Working Group led by the Department of Justice, and the Bilateral Intelligence Working Group led by DEA.

Recently, China's National Narcotics Control Commission announced that scheduling controls against four fentanyl-class substances, carfentanil, furanyl fentanyl, valeryl fentanyl, and acryl fentanyl, would begin on March 1, 2017. This announcement was the culmination of ongoing collaboration between DEA and the Government of China, in large part through the U.S.-China Joint Liaison Group framework, and reaffirms the shared commitment to countering illicit fentanyl.

Over the past several months, DEA and Chinese officials 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 officials to exchange information on emerging substances' scientific data, trafficking trends, and sample exchanges. This dialogue resulted in improved methods for identifying and submitting deadly substances for government control.

Additionally, in October of 2015, following similar discussions through the 2015 U.S. Joint Liaison Group fall meetings, China decided to implement domestic controls on 116 NPS, which included multiple fentanyl analogues.

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 and NPS continues to evolve.

North American Dialogue on Drug Policy (NADD)

DEA is working with the Office of National Drug Control Policy (ONDCP) and the Department of State to enhance coordination with Canada and Mexico to combat the opioid crisis through the North American Dialogue on Drug Policy (NADD). Through the inaugural trilateral meeting in October 2016 and March 2017 technical workshops, DEA has shared best practices and methodology on identifying the sources of heroin and fentanyl in North America and combatting criminal distribution networks. DEA will continue to work with Canada and Mexico to convene experts in these fields so that our three countries can better prevent the production and movement of drugs in and through our countries.

DEA'S 360 STRATEGY

DEA is implementing its 360 Strategy to address the opioid, heroin, and violent crime crisis. The strategy leverages existing federal, state, local and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and community relations. The strategy is founded upon our continued enforcement activities directed at the violent street gangs responsible for feeding the heroin and prescription drug abuse epidemic in our communities.

While law enforcement plays a central role in the 360 Strategy, enforcement actions alone are not enough to make lasting changes in our communities. The 360 Strategy, therefore, also focuses on preventing diversion by providing education and training within the pharmaceutical community and pursuing those practitioners who are operating outside of the law. The final component of the strategy is a community effort designed to maximize all available resources to help communities turn around the recurring problems that have historically allowed the drug and violent crime problems to resurface after enforcement operations.

Following is a summary of the three key facets of the 360 Strategy.

Enforcement: A Commitment to Stopping Violence Associated with Drug Trafficking

The enforcement component of the strategy is built around Rolling Thunder, a DEA-led OCEETF-supported law enforcement initiative that targets the link between the cartels and violent gangs – these two elements have become the “New Face of Violent Crime.” To execute the enforcement, DEA continues to rely upon all of its resources, including its Task Force Officers from local and state partners in the area.

The 360 Strategy aims to address the increased violence and drug trafficking on American streets. In the past, DEA would put its emphasis on working toward the Mexico-based organizations pushing drugs into the United States. As part of Rolling Thunder, DEA Agents actively work to shut down the violent street gangs that regulate the drug trafficking business through the barrel of a gun.

Diversion: Enlisting DEA's Registrant Population in the Fight Against Opioid Abuse

As stated above, the nonmedical abuse of prescription opioids is a strong risk factor for heroin use. The 1.6 million registrants who represent manufacturers, wholesale distributors, dispensers, and prescribers are key partners in our efforts to reduce opioid abuse.

DEA continues to engage with industry, practitioners, and government health organizations to facilitate an honest and frank discussion about the CPD abuse contributing to the current heroin epidemic. Additionally, DEA is studying ways, in collaboration with public health partners, to improve access to information that will help identify the nature of the drug abuse problem plaguing a particular area.

Further, DEA will remain vigilant in identifying and pursuing prescribers and other registrants operating outside of the law. This process will be enhanced locally through the use of tactical diversion squads (TDS), which can mobilize to address regional or local issues, and additional diversion investigators.

Community: Leaving something lasting and positive in the communities we serve

After an enforcement operation targeting violent criminals, there is an opportunity for a prepared community to take advantage of the space and time created to better itself and prevent new traffickers from moving in.

This program enables communities to achieve long-term solutions by addressing not only the immediate drug trafficking problems, but also the underlying conditions that allow drug trafficking, drug use and related violence to flourish. DEA will not only work with federal, state and local agencies to bring greater enforcement resources to bear, but also marshal community groups and their resources to identify local drug abuse problems, barriers to dealing with those problems and treatment solutions. DEA will also partner with other federal agencies and sources of expertise and funding to broaden the resources available to the community.

The 360 Strategy has been implemented in the following cities –Pittsburgh, Pennsylvania; St. Louis, Missouri; Milwaukee, Wisconsin; Louisville, Kentucky; Manchester, New Hampshire; Charleston, West Virginia. Additionally, DEA plans to implement the 360 Strategy in Albuquerque, New Mexico and Dayton, Ohio.

CONCLUSION

Illicit fentanyl and fentanyl analogues will remain an extremely dangerous public safety threat while the current production of non-pharmaceutical fentanyl continues. Fentanyl poses not only a threat to users, but also to law enforcement personnel and postal service employees as minute amounts of the drug are lethal and can be inadvertently inhaled or absorbed through the skin. Although many drug users avoid fentanyl, still others actively seek it out for its strong and

intense high. In 2015 traffickers expanded the historical fentanyl markets as evidenced by a massive surge in the production of counterfeit tablets containing the drug, and by manipulating it to appear as black tar heroin. The illicit fentanyl market will continue to expand in the future as new fentanyl products attract additional users.

Illicit fentanyl and fentanyl analogues will continue to pose a nationwide threat to the United States and overdoses and deaths will continue to occur. These substances are inexpensive and widely available, making them accessible to anyone who wants to use the drugs. In addition, traffickers will continue pressing these substances into counterfeit prescription pills, to expand their market to an unsuspecting user base. These characteristics make illicit fentanyl and fentanyl analogues a valuable commodity to traffickers, since traffickers modify and disguise them as traditional drugs. Traffickers will continue to avoid scheduling actions by modifying the chemical formulas to create new, unregulated and unscheduled drugs. In addition, traffickers may continue to distribute popular substances regardless of their status under the Controlled Substances Act.

DEA will continue to address these threats by pursuing the Mexican-based TCOs that have caused tremendous harm to our communities. Additionally, DEA's Diversion Control Division will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. We look forward to continuing to work with Congress to find legislative solutions needed to address the threat posed by illicit fentanyl, fentanyl analogues, and other synthetic substances encountered on the illicit market. s.