Department of Justice

STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, HOMELAND SECURITY, AND INVESTIGATIONS
COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

"STOP THE IMPORTATION AND TRAFFICKING OF SYNTHETIC ANALOGUES ACT OF 2017"

PRESENTED

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Statement of
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Before the
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Committee on the Judiciary
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For a Hearing Entitled
"Stop the Importation and Trafficking of Synthetic Analogues Act of 2017"

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INTRODUCTION

Chairman Gowdy, Ranking Member Jackson-Lee, and Members of the Committee: 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 yearly market for illegal non-medical prescription pain relievers is over 12.5 million people, and if 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; while fentanyl and some of its analogues are scheduled, 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: opioids, cannabinoids, cathinones, and hallucinogens known as phenethylamines. Other than synthetic opioids, 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 tragically, overdoses and deaths continue to occur.

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.

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.[1] During 2016, there were 28,751 fentanyl reports compared to 1,041 reports in 2013,[2] an exponential 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 Morbidity and Mortality Weekly Report, from 2014 to 2015, the death rate from synthetic opioids other than methadone, which include fentanyl, increased by 72.2%, from 5,544 (age adjusted rate 1.8) to 9,581(3.1). 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. Certain parts of the country have been particularly affected: for example, the Kaiser Family Foundation reported 2,698 deaths in Ohio from opioid overdoses during 2015 alone. It is assessed that the number of overdose fatalities resulting from fentanyl and fentanyl analogues remains under-reported and will increase as postmortem drug testing expands.

[1] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on March 22, 2017.
[2] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on March 22, 2017

In 2015, about 3.8 million Americans age 12 or older reported using prescription pain relievers non-medically within the past month[3]. This makes nonmedical prescription opioid use more prevalent than use of any category of illicit drug in the United States other than 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.

Synthetic Cannabinoids and Synthetic Cathinones

Synthetic cannabinoids and their byproducts (sometimes sold under brand names such as K2 or Spice) continue to be a significant concern for public health and safety. These substances have a similar mechanism of action to that of delta-9-tetrahydrocannabinol ("THC"), the primary psychoactive constituent in marijuana, but they are much more powerful. They are sourced from chemical manufacturers and suppliers primarily in China. Synthetic cannabinoid substances are typically prepared for packaging in the United States and marketed over the Internet or supplied to retail distributors before being sold to the public at retail stores (*e.g.*, "head shops," convenience stores, gas stations, and liquor stores). Laws governing the legality of the substances vary widely between states and the chemical components are frequently altered, making it an ongoing challenge for DEA to schedule these substances in a timely manner to protect the public.

Synthetic cathinones, often marketed to consumers as "bath salts" or "glass cleaner", can produce pharmacological effects that are substantially similar to cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine. In short, these substances are abused for their stimulant effects. These substances are often labeled "not intended for human consumption" in an attempt to skirt the Government's utilization of the federal Controlled Substance Analogue Enforcement Act ("Analogue Act"). While the Department of Justice has had successful prosecutions in these instances, thousands, if not millions of these substances are sold to unsuspecting consumers in the meantime. Synthetic cathinones are widely available and have been encountered as a replacement for MDMA, a Schedule I controlled substance that is often referred to as "Molly."

NPS are a significant area of concern for DEA. According to NFLIS, from January 2013 through December 2015, the 25 most frequently identified synthetic cannabinoids were identified in a total of 95,143 state and local forensic laboratory reports submitted to NFLIS. During the

[3] 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/

same period, state and local forensic laboratories reported finding the 20 most frequently identified synthetic cathinones a total of 51,824 times through the data submitted to NFLIS.[4]

NPS are typically used by younger individuals and by homeless persons. Synthetic cannabinoids and synthetic cathinones are inexpensive and widely available, being sold in packages adorned with bright colors and cartoons to attract younger users. These drugs are often marketed under varieties such as blueberry, strawberry, mango, and bubblegum to entice consumption.

As with illicit fentanyl, synthetic cannabinoids and synthetic cathinones are almost exclusively manufactured in China. They are then shipped to the United States through mail services. Once in the United States, bulk powders are sprayed or otherwise applied to plant matter, packaged into individual saleable units, and distributed for sale at gas stations, convenience stores, and head shops, or sold directly to individuals via the Internet. Synthetic cathinones are usually snorted or swallowed in their powder or crystal forms. Side effects of synthetic cathinone use may include heart attack, kidney and liver failure, paranoia, panic attacks, and hyperthermia. Many drugs in this class have been placed in Schedule I either through legislative action or through DEA-initiated administrative action to temporarily control the drug when the Administrator concludes that such action is necessary to avoid an imminent hazard to public safety. Unfortunately, when DEA initiates temporary control of a synthetic designer drug, those who produce and traffic the drug frequently alter the chemical composition of those drug. These new substances, like the original substance, have an unpredictable impact on the body and pose a severe public health threat.

CURRENT CHALLENGES

Traffickers Adapting to the Law

Even though many fentanyl 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.

Regarding NPS more broadly, clandestine chemists can easily continue to provide retailers with "legal" products by developing/synthesizing new synthetic cannabinoid products that do not appear on any schedule of controlled substances. 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. In addition, these same retailers are provided with spurious chemical analyses that purport to document that the new product line did not contain

[4] U.S. Drug Enforcement Administration, Diversion Control Division. (2016). *Synthetic Cannabinoids and Synthetic Cathinones Reported in NFLIS, 2013–2015.* Springfield, VA: U.S. Drug Enforcement Administration, accessed on March 8, 2017 at https://www.nflis.deadiversion.usdoj.gov/

any controlled substance. 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 synthetic cannabinoid 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. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. 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 is found to have a substantially similar chemical structure and substantially similar or greater depressant, stimulant or hallucinogenic effect on the central nervous system as a Schedule I or II controlled substance, or is represented to have such an effect. 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 abuse 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 in a given case 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 to obtain a conviction, even if the same substance was determined by a jury to meet the criteria of the analogue definition in a prior case. This process is workable, but resource-intensive for DEA, federal prosecutors serving in United States Attorney's Offices, the defense bar, and the court system.

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.[5] 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:[6] 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 use. In this process, the Secretary of Health and Human Services ("HHS") is responsible for any scientific and medical considerations about a substance and the DEA Administrator considers a recommendation made by the Secretary 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 collection and evaluation of scientific, medical, law enforcement and other data. The acquisition of this data is often an arduous and time-consuming process. The public continues to be impacted adversely while this data is being obtained in support of control under the CSA.

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,[7] during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.[8]

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 NPS.

[5] 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.

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

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

[8] 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.

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 fourteen occasions to place 44 synthetic designer drugs temporarily (emergency control) into Schedule I, including five fentanyl analogues, acetyl fentanyl, butyryl fentanyl, beta-hydroxythiofentanyl, furanyl fentanyl, and 4-fluoroisobutyryl fentanyl. Recently DEA published a Notice of Intent to initiate the temporary control of acryl fentanyl and is collecting and evaluating information on additional fentanyl analogues for possible control. 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 Custom Enforcement Homeland Security Investigations ("HSI") and Customs and Border Protection ("CBP"); supplemented by the Federal Bureau of Investigation ("FBI") and the U.S. Postal Inspection Service. HFTF utilizes every resource available, including support from the Department of Justice, Criminal Division's Organized Crime Drug Enforcement Task Forces ("OCDETF"), Fusion Center ("OFC"), the Department of Defense ("DOD"), Intelligence Community ("IC") and other government entities, and provides field offices (all agencies) with valuable support in their respective investigations.

<u>The HFTF mission aims to:</u>

- 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 officials of the People's Republic of China Government for years, and has been able to leverage this relationship to combat the rising threat from NPS 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 framework, the Counternarcotics Working Group led by the Department of Justice, and the Bilateral 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 the shared commitment to countering illicit fentanyl. In another move to demonstrate our shared commitment, on June 19, China announced that it will control U-47700.

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.

Additionally, in October of 2015, following similar discussions, China decided to implement domestic controls on 116 NPS, which included a number of 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.

Recent Major Synthetic Cannabinoid and Cathinone Enforcement Operations

Over the past six years, DEA has had two primary, national efforts (Operation Log Jam and Project Synergy) related to countering the threat from synthetic cannabinoid and cathinone operations, in addition to all other synthetic investigations executed by DEA field offices.

DEA's Operation Log Jam was initiated in 2011 and culminated in a nationwide takedown on July 25, 2012. This DEA Special Operations Division Operation resulted in multiple OCDETF Operations throughout the United States, including those in 25 federal districts. This operation was coordinated by DEA in cooperation with Homeland Security Investigations ("HSI"), FBI, CBP, and the Internal Revenue Service ("IRS"). The goals of this operation included the targeting of manufacturers, wholesale distributors, and retail distributors of designer drug products, the development of information on foreign based sources of supply, raising public awareness of the dangers associated with the use of these drugs, and the development of leads for a Phase II initiative (Project Synergy).

Operation Log Jam resulted in 100 arrests, the execution of 300 search warrants and 80 consent searches, and the identification of 38 manufacturing sites. Law enforcement seized 196 kilograms of raw synthetic cathinones, 722 kilograms of raw synthetic cannabinoids, 167,187 packets of synthetic cathinones ready for distribution, 4,852,099 packets of synthetic cannabinoids ready for distribution, 4,766 kilograms of plant material treated with synthetic cannabinoids ready to be packaged, 21,933 kilograms of untreated plant material, over $45,000,000 in U.S. currency and bank accounts, 88 vehicles, 77 firearms, additional assets valued at $5,688,500, and 1,096 gallons of acetone.

Project Synergy, the second phase of a national cooperative effort in combating synthetic designer drug distribution, has resulted in multiple OCDETF operations in at least 13 federal districts. Project Synergy has resulted in nationwide take downs in 2013, 2014, and 2015 by DEA, HSI, FBI, CBP, IRS, and domestic law enforcement departments in 45 states, and international partners in Australia, New Zealand, Canada, and Barbados. Over 400 individuals were arrested and authorities seized assets valued at nearly $75 million. In addition to curbing the flow of synthetic drugs into the country, Project Synergy III continued to reveal the flow of millions of dollars in U.S. synthetic drug proceeds to countries in the Middle East.

Outreach to First Responder Community

On June 6, 2017, DEA released an updated video message to law enforcement nationwide about the dangers of handling fentanyl and its deadly consequences. Acting Administrator Chuck Rosenberg and two local police detectives from New Jersey appear on the video to urge law enforcement personnel who come in contact with fentanyl or fentanyl compounds to take the drugs directly to a lab.

Previously, in March 2015, DEA issued an initial nationwide alert on fentanyl as a threat to health and public safety.

In all, DEA has posted six publications, and various multi-media links on its website, for use by first responders and the broader public.

CONCLUSION

Synthetic cannabinoids, cathinones, opioids, and phenethylamines will continue to pose a nation-wide threat. Synthetic drug producers modify and experiment with chemical formulas in search of new psychoactive substances. Once a new drug is formulated, the Internet and social media are used to market its arrival on the scene, allowing for its fast adoption and use. Due to the changing nature of the chemical formulas for synthetic designer drugs, distributors are able to reap significant profits before legislative and regulatory controls of these specific psychoactive substances are implemented. The United States will continue to see overdoses and deaths as a result of synthetic drug use.

Additionally, the United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of nonmedical prescription opioid use and the large number of people with active substance addictions who are not currently in treatment. It is likely that this demand will continue to be met in part by counterfeit prescription opioids which are being laced with fentanyl, fentanyl analogues, and other synthetic opioids (*e.g.*, U-47700), and that Mexican-based TCOs will push to expand their profits. DEA will continue to address this threat by pursuing the Mexican-based TCOs which have brought 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. Working with DOJ and interagency partners, DEA will continue to engage our international counterparts, especially China, both multilaterally and bilaterally. We look forward to continuing to work with Congress to find legislative solutions needed to address the threat posed by synthetic drugs.