STATEMENT OF

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BEFORE THE

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FOR A PUBLIC HEARING ON SYNTHETIC CATHINONES

PRESENTED

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INTRODUCTION

Judge Pryor and members of the Sentencing Commission, 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 synthetic cathinones.

DEA's primary mission is to protect the public. That task becomes even more challenging when battling foreign manufacturers who often operate with impunity and exploit the United States' laws and regulations as well as laws in foreign countries. Synthetic drugs, such as, synthetic cathinones are dangerous substances that are marketed as a "legal high" and have adverse effects that are unpredictable in both their psychological and physical impact on each individual. Synthetic cathinones are synthetic (i.e., human-made) drugs chemically related to cathinone, a Schedule I controlled substance with stimulant properties that is found naturally occurring in the khat plant. Khat is a shrub grown in East Africa as well as southern parts of the Arabian Peninsula. People sometimes chew its leaves for their stimulant effects. High doses or chronic exposure of synthetic variants of cathinones often leads to dangerous medical consequences, including psychosis, violent behaviors, tachycardia, hyperthermia, and even death.[1]

Synthetic cathinones are included in a group of drugs that concern public health officials called "new psychoactive substances" (NPS). NPS are unregulated mind-altering substances that have become available on the market, and are intended to mimic the effects of controlled substances. Law enforcement cases, hospital emergency department encounters and media reports reflect that users of synthetic cathinones may suffer from a host of severe psychological symptoms. For example, one practitioner described a user response to the synthetic cathinone known as alpha-PVP (known on the street as "Flakka") as "severe anxiety, paranoia, and delusions, leading to a psychotic state, characterized by a surge of violence, associated increased strength and loss of awareness of reality and surroundings."[2] Some of these substances have been around for years, but have re-entered the market in altered chemical forms or due to renewed popularity. These substances are abused for their stimulant effects and can produce pharmacologic effects that are substantially similar to methcathinone, MDMA, amphetamine, methamphetamine, and cocaine. These substances are marketed to consumers as "glass cleaner"

[1] Michael H. Baumann et al., *Bath Salts, Spice, and Related Designer Drugs: The Science Behind the Headlines*, 34 The Journal of Neuroscience, issue 46, Nov. 12, 2014, at 15150 – 15158.
[2] Robert Glatter, MD, Flakka: The New Designer Drug You Need to Know About, FORBES (April 4, 2015), http://www.forbes.com/sites/robertglatter/2015/04/04/flakka-the-new-drug-you-need-to-know-about/#3c6cefdb20bf.

or "bath salts" and are often labeled as "not intended for human consumption" as an attempt to defend against the Government's utilization of the federal Controlled Substance Analogue Enforcement Act (Analogue Act).[3]

PRODUCTION AND DISTRIBUTION

Synthetic cathinones are generally manufactured in East Asia, predominantly in China, and have been distributed throughout Europe, North America, Australia, and other parts of the world. Synthetic cathinones are created in laboratories and do not require any plant-based material. Each variety of these substances requires different chemical precursors and different synthetic production routes, which means that laboratory operators require relatively sophisticated scientific equipment along with a relatively high degree of knowledge in chemistry for their production.

Due to their wide availability in China, synthetic cathinones are usually purchased in bulk, through mail order, online order, or in-person, through chemical brokers from China. The bulk white powders are then transported directly to the United States via package delivery services (international mail, UPS, FedEx, etc.). Of particular concern is the manner in which traffickers use freight forwarders to mail NPS from China. DEA investigations reveal 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 which exacerbate these challenges.

Once in the United States, these white powders require minimal processing. Domestic drug traffickers typically mix or "cut" the powders with adulterating agents and bag the product into saleable forms. Synthetic cathinones are distributed throughout the United States in gas stations, convenience stores, adult stores, smoke shops and on Internet sites. They are sold as seemingly innocuous products (i.e., "bath salts") and labeled as "not for human consumption." DEA cases demonstrate that the distribution of synthetic cathinones is also taking place on the streets like traditional drug sales, under names such as "Molly" or "Flakka." Synthetic cathinone dealing can be a lucrative business. One kilogram of a synthetic cathinone can be purchased from China for $2,000-$5,000 per kilogram. Once the substance is cut and broken down into 1 to 2 gram packages (each selling for approximately $20 each), a trafficker stands to profit approximately $250,000 per kilogram.

The National Forensic Laboratory Information System (NFLIS) is a program of the DEA's Diversion Control Division which systematically collects drug identification results and associated information from drug cases submitted to, and analyzed by, Federal, State and local

[3] *See generally* 21 U.S.C. § 813 (stating that a controlled substance analogue "to the extent intended for human consumption" shall be treated as a Schedule I controlled substance).

forensic laboratories nationwide. In a 2016 NFLIS Special Report,[4] synthetic cathinone cases were identified in 48 of 50 states nationwide. The number of different synthetic cathinones identified by NFLIS grew from five in 2009 to thirty-five in 2015. Between 2013 and 2015, forensic laboratories identified a total of 51,824 reports for the twenty most frequently encountered synthetic cathinones in the United States. Methylone, alpha-PVP (i.e. Flakka), and ethylone were identified in over 90 percent of those reports: 17,282, 14,995, and 14,679 reports in 2013, 2014, and 2015, respectively.

LAW ENFORCEMENT CHALLENGES

Traffickers Adapting to the Law

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

Clandestine chemists can easily continue to provide retailers with "legal" products by developing/synthesizing new synthetic 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 by the manufacturers with chemical analyses that purport to document that the new product line does not contain any controlled substance. Manufacturers and distributors continue to stay one-step ahead of federal drug-specific banning or control action by introducing and repackaging new synthetic cathinone products that are not listed in any of the controlled substance schedules.

Prosecutions Pursuant to the Analogue Act

Many synthetic cathinones may be a "controlled substance analogue" pursuant to the CSA, if the substance 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, and is intended for human consumption.[5] 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

[4] DRUG ENFORCEMENT ADMINISTRATION, DIVERSION CONTROL DIVISION, SYNTHETIC CANNABINOIDS AND SYNTHETIC CATHINONES REPORTED IN NFLIS 2013-2015, NATIONAL FORENSIC LABORATORY INFORMATION SYSTEM (2016) https://www.deadiversion.usdoj.gov/nflis/SR-SynthCannabinoidCathinone.pdf.
[5] 21 U.S.C. § 802(32) (defining a "controlled substance analogue").

controlled substance analogue; prosecutors must also prove that the substance was intended for human consumption.

Accordingly, to obtain a conviction, each prosecution requires expert testimony – often of a highly scientific and often complex nature – even if the same substance was determined by another jury to meet the criteria of the analogue definition in a prior case. Moreover, the prosecution's expert testimony is often countered with that of a defense expert, resulting in a "battle of the experts" that may confuse a jury, despite strong evidence that the defendant trafficked a controlled substance analogue. This process is workable, but resource-intensive for DEA, federal prosecutors, the defense bar, and the court system. The issue is compounded when a defendant convicted under the Controlled Substance Analogue Enforcement Act receives his/her sentence. Due to the current structure of Application Note 6 to the U.S. Sentencing Guidelines, the sentencing hearing turns into lengthy chemistry and pharmacology lectures by scientific experts. 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 and Application Note 6 a cumbersome and resource-intensive process. That said, agents, chemists, and prosecutors have worked together tirelessly to make the Analogue Act and Application Note 6 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.[6] DEA will continue to identify ways to better combat the designer drug threat. And, the DEA greatly appreciates the Sentencing Commission's willingness to consider possible changes to the cumbersome process currently required by Application Note 6.

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:[7] 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

[6] Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, Synthetic Drug Abuse and Prevention Act of 2012, Subtitle D, § 1151.
[7] The eight factors are enumerated in 21 U.S.C. § 811(c).

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,[8] during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.[9]

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.

DEA RESPONSE TO THE THREAT

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 January, 2011, DEA has utilized this authority on 15 occasions to place 45 synthetic designer drugs temporarily (emergency control) into Schedule I. Thirteen of those substances are synthetic cathinones. Recently DEA published two Notice of Intents to initiate the temporary control of 4 additional synthetic drugs for possible control. In comparison, over the first 25 years (1985-2010) after Congress created this authority, DEA utilized this authority a total of 13 times to control 25 substances.

Temporary and permanent scheduling of synthetic drugs, including cathinones, directly impact availability on the illicit market. Take for example alpha-PVP (i.e., Flakka). In 2014, alpha-PVP represented 25 percent of all synthetic cathinones identified by forensic laboratories nationwide[10]. By 2016, more than one and a half years after its temporary control[11], alpha-PVP was identified in 12.6 percent of exhibits submitted to DEA's forensic laboratories.[12] In the second quarter of 2017, the quarter in which DEA permanently placed alpha-PVP in Schedule

[8] The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).
[9] 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.
[10] 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. Available at: https://www.deadiversion.usdoj.gov/nflis/SR-SynthCannabinoidCathinone.pdf.
[11] On March 7, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place alpha-PVP and 9 other synthetic cathinones into Schedule I of the CSA. 79 FR 12938.
[12] DRUG ENFORCEMENT ADMINISTRATION, EMERGING THREAT REPORT, ANN. (2016).

I[13], DEA's forensic laboratories identified the substance in 3 percent of its analyses.[14] Unfortunately however, alpha-PVP has been replaced by other synthetic cathinones on the illicit market such as N-ethylpentylone and butylone, amongst others.

China: Government Action and Cooperation on Synthetic Drugs

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. This relationship has assisted DEA in its efforts, 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.

Over the past year, DEA and Chinese officials have met regularly to discuss mutual interests and shared responsibilities in countering the threat from NPS. 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.

Finally, as this threat has increased, law enforcement cooperation at the street level has been very productive. DEA will continue to collaborate with the Government of the People's Republic of China as the threat from 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. Those two national efforts are 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 Organized Crime and Drug Enforcement Task Force (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, Customs and Border Protection (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

[13] On March 1, 2017, the DEA published a final order to permanently place alpha-PVP and 9 other synthetic cathinones into Schedule I of the CSA. 82 FR 12171, March 1, 2017.
[14] DRUG ENFORCEMENT ADMINISTRATION, EMERGING THREAT REPORT, 2nd Quarter (2017).

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 (the 2015 take down) continued to reveal the flow of millions of dollars in U.S. synthetic drug proceeds to countries in the Middle East.

More recently, in 2016, six individuals were indicted by a federal grand jury stemming from their participation in manufacturing and distributing synthetic cannabinoids and cathinones in and around Phoenix, Arizona. All individuals were also charged with misbranding violations and money laundering. Real estate properties forfeited as part of this investigation had a value of $800,000. Also in 2016, in California, DEA and CBP officials intercepted an inbound shipment from China to an individual suspected of manufacturing and distributing products containing synthetic cathinones. The 1.3 kg shipment was determined to be dibutylone (bk-DMBDB), a positional isomer of pentylone, a Schedule I substance.

CONCLUSION:

Synthetic cathinones are dangerous drugs that continue to pose a nationwide 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 DEA will continue to use all administrative tools to identify and control new and emerging synthetic cathinones that find their way onto our streets. DEA understands the unique challenges posed by this constantly changing threat and remains hopeful that the Commission will adopt a class approach that would treat a new synthetic cathinone the same as other

substances in the same drug class. This would result in sentences that are fair and consistent. It would also promote judicial economy by eliminating the time-consuming process that is currently required by Application Note 6. The DEA greatly appreciates the Commission's interest in this important issue and remains ready and willing to assist the Commission in the future.