



# Department of Justice

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**STATEMENT OF**

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**BEFORE THE**

**HOUSE JUDICIARY SUBCOMMITTEE  
CRIME, TERRORISM, HOMELAND SECURITY, AND INVESTIGATIONS  
U.S. HOUSE OF REPRESENTATIVES**

**FOR A HEARING ON**

**SYNTHETIC DRUGS**

**PRESENTED**

**MAY 17, 2016**

**Statement of Louis J. Milione  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration  
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**INTRODUCTION**

Chairman Sensenbrenner, Ranking Member Jackson Lee, and Members of the 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.

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.

DEA has become increasingly alarmed over the proliferation of illicit fentanyl and its derivatives, which have been added to heroin and also encountered as counterfeit tablets resembling controlled prescription drugs (CPDs). Fentanyl and fentanyl derivatives 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 11 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 by 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 derivatives represent the deadly convergence of the synthetic drug threat and current national opioid epidemic.

**SYNTHETIC DESIGNER DRUGS OVERVIEW**

NPS represent the most recent area of concern for DEA. NPS are dangerous chemical compounds with no known legitimate medical or industrial use, and are not approved by the Food and Drug Administration (FDA) for use in medicine. These compounds pose a great danger to the public, especially children and teenagers, because they are falsely perceived as “legal” alternatives to the illicit drugs they intend to mimic and because of their unpredictable health impacts.

## *Synthetic Cannabinoids and Synthetic Cathinones*

Synthetic cannabinoids and their products (sometimes sold under brand names such as K2 or Spice) continue to be a significant concern for public health and safety. These substances share biological activity with delta-9-tetrahydrocannabinol (THC), the primary psychoactive constituent in marijuana and 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 on-going challenge for DEA to schedule these substances in a timely manner to protect the public.

Synthetic cathinones, also commonly known as “bath salts,” can produce pharmacologic effects that are substantially similar to other controlled substances such as cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine. In short, these substances are abused for their stimulant effects. These substances have been known to be marketed to consumers as “bath salts” or “glass cleaner.” These substances are often labeled “not intended for human consumption” as a false means to defend against the Government’s utilization of the federal Controlled Substance Analogue Enforcement Act (Analogue Act). 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 the DEA National Forensic Laboratory Information System (NFLIS), substances identified as synthetic cannabinoids by federal, state, and local forensic laboratories increased from 23 reports in 2009 to 37,500 reports in 2014. Substances identified as synthetic cathinones increased from 29 reports in 2009 to 14,070 reports in 2014. This is the last full year for which data is available.

Synthetic cannabinoids and synthetic cathinones are almost entirely manufactured in China. They are then imported into the United States through mail services. Once in the United States, bulk powders are sprayed or otherwise applied on to plant matter and packaged into individual saleable units and then 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 are in Schedule I through legislative action or through administrative action to temporarily control the drug, initiated by DEA 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 traffic them frequently alter the chemical composition of the drugs they produce. These new substances, like the original substance, have an unpredictable impact on the body and pose a potentially severe public health threat.

NPS are typically used by younger individuals. Synthetic cannabinoids and synthetic cathinones are 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.

### *Synthetic Opioids*

Since 2014, DEA has encountered a dangerous new trend which represents the convergence of the synthetic drug threat and the epidemic of opioid abuse currently affecting our nation – clandestinely-manufactured fentanyl and fentanyl derivatives which are being added to heroin or replacing heroin altogether on the street. 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.

DEA is increasingly encountering counterfeit prescription drugs laced with fentanyl and fentanyl derivatives. The DEA NFLIS reported that there were 7,864 fentanyl exhibits tested by forensic laboratories across the country in 2014 (the latest year for which data is available); a 742 percent increase from the 934 fentanyl exhibits in 2013.<sup>1</sup> The products, purchased illicitly, bear markings consistent with authentic prescription pain relievers such as oxycodone and hydrocodone, which may lead an unsuspecting user to believe he or she is consuming a legitimate controlled prescription drug. These counterfeit products have been found to contain lethal doses of fentanyl or fentanyl derivatives and are responsible for some overdose death outbreaks. Determining if one of these fentanyl-laced counterfeit prescription pills contains fentanyl based on sight alone is impossible; the presence of fentanyl can only be detected upon laboratory testing.

Illicit fentanyl, fentanyl derivatives, 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 and the Caribbean. Once there, fentanyl or its derivatives 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 remains high. 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.

The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. 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, with 14 of those ultimately losing their lives.

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<sup>1</sup> (U) U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, Annual Reports 2004-2014.

In 2014, over 4.3 million Americans age 12 or older reported using prescription pain relievers non-medically within the past month. This makes nonmedical prescription opioid use more 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 derivative-laced counterfeit pills will cause more overdoses across the nation as they are more readily produced by drug trafficking organizations.

Law enforcement throughout the United States has been encountering fentanyl at historic levels. In 2014, the DEA NFLIS reported 7,864 instances where fentanyl was tested by forensic laboratories nationwide. This is five times as many fentanyl exhibits than what was submitted during the 2006 fentanyl crisis, and is a 742 percent increase from 2013. With fentanyl and its derivatives continuing to reach a greater share of this multimillion person illicit prescription drug market, there is the potential for a sharp increase in overdoses across the nation in the near term.

## **CURRENT CHALLENGES**

### *Traffickers Adapting to the Law*

Even though many NPS compounds have been controlled in Schedule I (the most highly controlled drugs, which for most purposes are equivalent to a ban) through temporary scheduling or by legislative or administrative scheduling (per 21 U.S.C. sections 811 and 812), entrepreneurs procure new synthetic cannabinoid compounds with relative ease. 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 any controlled substance.

Over the past several years, DEA has identified hundreds of designer drugs from at least eight different drug classes, the vast majority of which are manufactured in China. There are a seemingly infinite number of possible new chemical compounds that are on the horizon. 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.

There is also a large financial incentive that continues to drive the wholesale and retail distribution of these products. Information that DEA has obtained through the course of its investigations demonstrate that a \$1,500 purchase of a bulk synthetic cannabinoid can generate as much as \$250,000 of revenue at the retail level. It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for manufacturers, distributors, and retailers to seek and find substitute products that are not yet controlled or banned by federal or state action.

### *Prosecutions Pursuant to the Analogue Act*

A designer drug may be a “controlled substance analogue” pursuant to the Controlled Substances Act (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 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 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 is a new case even if the same substance is involved.

In addition, without establishment and inclusion of specific sentencing equivalencies in the U.S. Sentencing Guidelines, prosecutors are required to produce evidence addressing the factors identified in the relevant guidelines. This typically results in prosecutors calling 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. Different courts have reached very different results for the same substance which has resulted 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 aggressive contribution to the overall effort to combat the designer drug threat.<sup>2</sup> DEA will continue to identify ways to better combat the designer drug threat.

### *Lack of Scientific Evidence to Support Control*

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. This process is an interagency process and determinations about placement in the CSA are dictated by the following eight enumerated scientific factors:<sup>3</sup> 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

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<sup>2</sup> 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.

<sup>3</sup> The 8 factors are enumerated in 21 U.S.C. § 811(c).

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.

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,<sup>4</sup> during which time the interagency conducts the abovementioned scientific review for permanent placement under the CSA.<sup>5</sup>

DEA believes a coordinated response by public health and law enforcement and other stakeholders remains the most effective response to this problem. Earlier this year, scientific staffs from the FDA, the National Institute on Drug Abuse (NIDA), and DEA participated in discussions regarding a sampling of new psychoactive substances which were encountered on the illicit market and share similarity with controlled substances.<sup>6</sup> Often, the lack of scientific information for the new and rapidly emerging substances being encountered by law enforcement represents a significant challenge for DEA and other agencies as we seek to address this public health and safety threat. DEA continues to work with partners such as NIDA to collect pharmacological information critical to the evaluation of a number of synthetic designer drug substances for consideration for both temporary and permanent scheduling. Further, DEA will continue to share information and engage stakeholders to decrease the demand for NPS.

## **DEA RESPONSE TO THE THREAT OF SYNTHETIC DRUGS**

### *Scheduling by Administrative Rulemaking: Temporary Control*

DEA continues to utilize its regulatory authority to place many synthetic cannabinoids and synthetic stimulants 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 ten occasions to place 35 synthetic designer drugs into Schedule I, including two fentanyl analogues, butyryl fentanyl and beta-hydroxythiofentanyl. 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.

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<sup>4</sup> The temporary control of a substance is enumerated in 21 U.S.C. § 811(h).

<sup>5</sup> 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.

<sup>6</sup> This review was undertaken for the substances named in HR 3537, introduced by Representative Charles Dent.

### *Recent Major Enforcement Operations*

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 Drug Enforcement Task Forces (OCDETF) Operations throughout the United States, including those in 25 federal districts. This operation was coordinated by DEA in cooperation with U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI), the Federal Bureau of Investigations (FBI), U.S. 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 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.

The information and evidence obtained during Operation Log Jam led investigators to initiate Project Synergy, the second phase of a national cooperative effort in combating the synthetic designer drug distribution, which also resulted in multiple OCDETF operations in at least 13 federal districts. Project Synergy began in December 2012 and culminated in a nationwide take down on June 26, 2013 conducted by DEA, HSI, FBI, CBP, and the IRS, as well as domestic law enforcement departments in 45 states. This operation also included some of our international partners with joint operations being conducted with Australia, New Zealand, Canada, and Barbados.

As part of Project Synergy, DEA conducted an enforcement operation in June 2013 in the Houston, Texas, area on a synthetic cannabinoid wholesale distributor who was selling AM-2201 and XLR11. During this operation, law enforcement seized enough synthetic cannabinoid products to gross approximately \$21,000,000 in revenue at the retail level.

Project Synergy involved many investigations that culminated on June 26, 2013, and included 234 arrests, 416 search warrants, and 68 consent searches that led to the seizure of 305 kilograms of raw synthetic cathinones; 1,278 kilograms of raw synthetic cannabinoids; 10,263 packets of synthetic cathinones and cannabinoids; 959 kilograms of treated plant material ready to be packaged; and \$53,201,595 in currency and assets, 132 vehicles, and 141 weapons.

The second phase of Project Synergy culminated in May 2014 and involved law enforcement action in 29 states. More than 150 individuals were arrested and federal, state, and local law enforcement authorities seized hundreds of thousands of individually packaged, ready



to sell synthetic drugs as well as hundreds of kilograms of raw synthetic products to make thousands more. More than \$20 million in cash and assets were seized.

The third phase of Project Synergy which took place over 15 months and concluded in October 2015, was a collaborative effort between DEA, HSI, and CBP, along with other federal, state, and local law enforcement. This effort targeted the synthetic designer drug industry, including wholesalers, money launderers, and other criminal facilitators. It resulted in 151 arrests in 16 states and over \$15 million seized in cash and assets. 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.

Lastly, in September 2015, the DEA coordinated Operation Spice in partnership with the OCDETF New York Strike Force and multiple other law enforcement agencies in New York City in September. This massive takedown targeted the local sale of dangerous designer synthetic drugs manufactured in China. The scheme, which operated in all five boroughs of New York City, allegedly involved the unlawful importation of at least 100 kilograms of illegal synthetic compounds, an amount sufficient to produce approximately 1,300 kilograms of dried product, or approximately 260,000 retail packets. As part the operation, five processing facilities were searched, as well as warehouses used to process, store, and distribute the drugs. In addition, over 80 stores and bodegas around New York City were searched. Over two million packets of synthetic drugs were seized. These packets were ready for street distribution, concealed in over 100 laundry bags, and ready for delivery.

#### *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. Last October, China decided to implement domestic controls on 116 NPS, which included fentanyl derivatives. The United States, through DEA, is working with China to identify NPS as traffickers develop new ones, and China has streamlined its processes for scheduling additional NPS when identified. Finally, as this threat has increased, law enforcement cooperation at case 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 NPS continues to evolve.

## **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 formula for synthetic designer drugs, distributors are able to reap significant profits before legislation to control these specific psychoactive substances is

enacted. While synthetic drugs will remain prevalent as a whole, synthetic cannabinoid use will remain steady or increase, while synthetic cathinone use appears to be on the decline. The United States will continue to see overdoses and deaths as a result of synthetic drug use, primarily among the youth population.

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 numbers of people with active substance use disorders 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 or fentanyl derivatives, and Mexican-based TCOs who are pushing 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 Office of Diversion Control 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 synthetic drugs.