Department of Justice

STATEMENT

OF

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BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

AT A HEARING ENTITLED

"LEGISLATIVE HEARING TO ADDRESS BIOTERRORISM, CONTROLLED SUBSTANCES AND PUBLIC HEALTH ISSUES"

JULY 21, 2011

Statement for the Record of
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U.S. House Committee on Energy and Commerce, Subcommittee on Health
"Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues"

July 21, 2011

Chairman Pitts, Ranking Member Pallone and distinguished members of the Committee on Energy and Commerce, Subcommittee on Health, on behalf of Administrator Leonhart and the Drug Enforcement Administration (DEA), I appreciate your invitation to submit written testimony today regarding the growing threat of synthetic drugs in the United States and DEA's efforts to combat the emerging challenges presented by synthetic cannabinoids and stimulants.

Introduction

Over the past couple of years, "herbal incense" products marketed in the U.S. as being "legal" and providing a marijuana-like high when smoked have become increasingly popular, particularly among teens and young adults. These products consist of plant material that has been laced with substances (synthetic cannabinoids) that claim to mimic Δ9-tetrahydrocannabinol (THC), the primary psychoactive active ingredient in marijuana. These substances have not been approved by the FDA for any indication, and there is no regulatory oversight of the manufacturing process for the substances or the associated products. Brands such as "Spice," "K2," "Blaze," and "Red X Dawn" are labeled as herbal incense to mask their intended purpose.

There is also a growing abuse of a variety of synthetic compounds that produce stimulant effects when ingested, snorted and intravenously injected. These synthetic stimulants, which are based on a variety of known compounds, such as "MDPV" (3, 4-methylenedioxypyrovalerone), mephedrone (4-methylmethcathinone), and methylone (3,4-methylenedioxymethcathinone) are sold under the guise of "bath salts" or "plant food," in retail outlets and over the Internet. They are marketed under names such as "Ivory Wave," "Purple Wave," "Vanilla Sky," and "Bliss." In addition to their psychoactive effects, they also have potentially harmful side effects when ingested, snorted and intravenously injected. These products are not approved by the FDA for any indication and are not currently in any schedule under the Controlled Substances Act (CSA).

Both synthetic cannabinoids and synthetic stimulants are "designer drugs" that are manufactured and distributed in an attempt to circumvent the CSA. They are marketed in a manner so as to mask their intended purpose and are labeled with a statement that the package contents are "not for human consumption," or are "for novelty use only." The purpose of this statement is to circumvent the Controlled Substance Analogue Enforcement Act of 1986 (as

amended), which states that controlled substance analogues shall, "*to the extent intended for human consumption*," be treated as a controlled substance in Schedule I. 21 U.S.C. § 813 (emphasis added). The manufacturers and retailers who make and sell these products do not fully disclose all of the product ingredients and never disclose the active and potentially harmful ingredient(s). These products are sold at a variety of retail outlets, in head shops, and over the Internet from both domestic and international sources.

The manufacture and sale of "designer drugs" that are synthesized for the sole purpose of achieving the pharmacologic effects of some controlled substances is not a new phenomenon. History is replete with examples of substances that were synthesized to mimic the effects of a specific controlled substance in order to circumvent the provisions of the CSA. Historically, the introduction of "designer drugs" into the marketplace was generally similar to that of illicit controlled substances: covert meetings and sales on street corners, back alleys, and in dark clubs. In many instances, the ingestion of these drugs led to tragedy. Today, the marketing of such "designer drugs" has ushered in a new era of drug distribution. No longer are these substances sold in a covert manner to thwart law enforcement efforts. Instead, the substances are sold at retail outlets in plain view with the instructions, "not for human consumption" in products labeled as incense, bath salts, and plant food. Substances that are just as dangerous as their controlled substance counterparts are marketed as harmless sundry items in an attempt to protect the manufacturers, distributors and retail sellers from criminal prosecution. But these particular incense, bath salts, and plant food items are really nothing more than a means to make psychoactive substances available to the consumer.

Situational Overview

Incense-Herbal Products (Synthetic Cannabinoids)

Background

Since 2009, DEA has received an increasing number of reports from poison control centers, hospitals, and law enforcement agencies concerning products containing synthetic cannabinoids. Emergency room physicians report that individuals who use these types of products experience dangerous side effects, including: convulsions, anxiety attacks, dangerously elevated heart rates, increased blood pressure, vomiting, and disorientation. Because these substances pose a threat to the public health and safety, at least 38 states have taken action to control one or more of these chemicals. The Comprehensive Crime Control Act of 1984 amends the CSA to allow the Attorney General to place a substance temporarily in Schedule I when it is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. § 811(h).

In February 2011, the DEA Administrator used her authority to issue a final order which was published in the Federal Register on March 1, 2011 (76 Fed. Reg. 11075) temporarily placing five synthetic cannabinoids into the CSA pursuant to the temporary scheduling provision of the CSA. These five substances are:

1-pentyl-3-(1-naphthoyl)indole **(JWH-018);**
1-butyl-3-(1-naphthoyl) indole **(JWH-073);**

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole **(JWH-200);**
5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol **(CP-47,497); and**
5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (**cannabicyclohexanol**; CP-47,497 C8 homologue).

As a result of this order, the full effect of the CSA and its implementing regulations, including criminal, civil, and administrative penalties, sanctions, and regulatory controls of Schedule I substances will apply to the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids. In response to both Federal and State controls, the designer drug market has transitioned to new structurally similar substances.

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. § 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year, without regard for the requirements of 21 U.S.C. § 811(b), if he finds that such action is necessary to avoid imminent hazard to the public safety. The Attorney General may extend the temporary scheduling for up to six months during pendency of proceedings under 21 U.S.C. § 811(a)(1). A substance may be temporarily scheduled under the emergency provisions of the CSA if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. § 812), and if there is no exemption or approval in effect under 21 U.S.C. § 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. § 811 to the DEA Administrator. 28 CFR § 0.100.

In a letter dated October 6, 2010, the DEA Deputy Administrator, now Administrator, transmitted notice to the Assistant Secretary for Health of the Department of Health and Human Services (HHS) of her intention, as per section 201(h)(4) of the CSA (21 U.S.C. § 811(h)(4)), to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA. In response to this notification, the HHS Assistant Secretary for Health communicated in a letter dated November 22, 2010, to the then-Acting Administrator of DEA that there are no exemptions or approvals in effect for JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol under Section 505 of the Federal Food, Drug and Cosmetic Act (21U.S.C. § 355). The substances are not listed in any other schedule in 21 U.S.C. § 812.

A Notice of Intent to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA was published in the Federal Register on November 24, 2010. 75 Fed. Reg. 71635. Before making a finding that temporary placement of a substance into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors (factors 4, 5, and 6) set forth in section 201(c) of the CSA. 21 U.S.C. § 811(c). These factors are: the history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution . 21 U.S.C. § 811(h)(3).

As explained in the March 1, 2011 Final Order, the temporary placement of these five synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. First, these substances are not intended for human consumption, yet there has

been a rapid and significant increase in abuse of these substances in the United States. As a result of this abuse, several synthetic cannabinoids are banned/controlled in at least 38 states in the United States as well as in several countries, and all branches of the U.S. military prohibit military personnel from possessing or using synthetic cannabinoids. Second, before these substances were temporarily controlled as Schedule I substances, law enforcement agencies seized them in conjunction with controlled substances; and based on self-reports to law enforcement agencies and health care professionals, synthetic cannabinoids were being abused for their psychoactive properties. Third, numerous state and local public health departments and poison control centers have issued health warnings describing the adverse health effects associated with synthetic cannabinoids. These five substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

According to a recent press release from the American Association of Poison Control Centers, poison control centers received 2,915 calls relating to these products in 2010 and as of May 31, 2011, poison centers had received 3,094 calls for 2011. Many of these calls originated from or en-route to a healthcare facility. Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes observed in marijuana
abuse.

History and Current Pattern of Abuse

"Synthetic cannabinoids" are a large family of compounds that are functionally (biologically) similar to THC, the main psychoactive ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory.

Two of the five synthetic cannabinoids (CP-47,497 and cannabicyclohexanol) were first synthesized in the early 1980's for research purposes in the investigation of the cannabinoid system. JWH-018, JWH-073, and JWH-200 were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids. Furthermore, these five synthetic cannabinoids are not approved by the FDA forany indication.

The emergence of synthetic cannabinoids is relatively new to the U.S. "designer drug" market. Since the initial identification of JWH-018 by U.S. forensic laboratories, many additional synthetic cannabinoids including JWH-073, JWH-200, CP-47,497, cannabicyclohexanol, and many others have been identified in related herbal incense products. These synthetic cannabinoids have purported psychotropic effects when smoked or ingested. These chemicals are typically found in powder form or are dissolved in solvents, such as acetone, before being sprayed on the plant material comprising the "herbal incense" products.

The popularity of these THC-like synthetic cannabinoids has significantly increased throughout the United States, and they are being abused for their psychoactive properties as reported by law enforcement agencies, the medical community, and in

scientific literature. They are marketed as a "legal" alternative to marijuana or other drugs. They are also popular among those individuals who are subject to urinalysis testing, such as those individuals who are under the supervision of a drug court and those on probation or parole.

Some of the product names include, but are not limited to, "Spice," "K2," Zohai," "Dream," "Genie," "Sence," "Smoke," "Skunk," "Serenity," "Yucatan", "Fire," and many more. These products are labeled "Not for Human Consumption" and are typically advertised as herbal incense by Internet retailers, tobacco shops, head shops, liquor stores, and other domestic brick and mortar retail venues. These marketing techniques result in the perception that products that contain THC-like synthetic cannabinoids are "legal" alternatives to marijuana. No evidence exists that these synthetic cannabinoids add value to genuine incense products—there is no scent or odor associated with these substances.

According to Internet discussion boards and law enforcement encounters reported directly to DEA, synthetic cannabinoids are sprayed on plant material which provides a vehicle for the most common route of administration - smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). These materials are then packaged in small pouches or packets sold over the Internet, in tobacco and smoke shops, drug paraphernalia shops, gas stations, and convenience stores as herbal incense products. The retail sale of these products gave customers of all ages direct access to synthetic cannabinoids and the corresponding THC-like effects of these products. Research articles propose that the packaging is professional and conspicuous and targets young people, possibly eager to use cannabis, but who are afraid of the legal consequences and/or association with illicit drugs.

Scope, Duration, and Significance of Abuse

According to forensic laboratory reports, the initial appearance of these synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection first encountered products such as "Spice." Prior to arriving in the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents such as elevated heart rates, psychosis, and paranoia.Many countries in the European Union, plus Japan and Russia have banned these products/chemicals.

In addition to increasing concerns by members of the medical community, the increasing abuse of synthetic cannabinoids is also demonstrated by the
increase in federal, state, and local law enforcement activity associated with these substances. The National Forensic Laboratory Information System (NFLIS), a national repository for drug evidence analyses from forensic laboratories across the United States, has reported in excess of 6,000 reports regarding synthetic cannabinoids. These exhibits came from 40 states to include Alabama, Arkansas, California, Florida, Hawaii, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Nevada, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Virginia.

Even though there is no evidence of legitimate non-research related uses for these

synthetic cannabinoids, multiple shipments of JWH-018 and JWH-073 were encountered by U.S. Customs and Border Protection in 2010, and recent reports detail new synthetic cannabinoids being encountered in multi-kilogram shipments even though there is no known legitimate use for these new substances. One enforcement operation encountered five shipments of JWH-018 totaling over 50 kilograms (110.2 pounds) of powder. In addition, bulk quantities of JWH-018 and JWH-200 were encountered by law enforcement in 2010. For example, in Casper, Wyoming, DEA agents encountered large quantities of herbal incense products laced with the synthetic cannabinoid JWH-018, in conjunction with the seizure of methamphetamine and other illegal drugs, while executing search and arrest warrants.

Risk to the Public Health

Health warnings have been issued by numerous state and local public health departments and poison control centers describing the adverse health effects associated with the use of these synthetic cannabinoids and their related products, including agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness.

Smoking synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects has been identified as a reason for emergency room visits and calls to poison control centers. In a fact sheet issued by the National Drug Court Institute, the problem of synthetic cannabinoid abuse is described as "significant and disturbing." This is supported by information that was communicated to DEA from one of the major private toxicology laboratories. Specifically, laboratory findings from drug screens for the period July 2010 through November 2010, showed over 3,700 specimens tested positive for either JWH-018 or JWH-073. They also indicated that they were finding 30-35% positivity for specimens submitted by juvenile probation departments.

Based on law enforcement encounters reported directly to DEA, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals have suffered from intense hallucinations. Emergency department physicians and toxicologists have also reported the adverse health effects associated with smoking herbal incense products laced with these substances. Law enforcement agencies have recently reported examples of suspected *Driving under the Influence of Drug* incidents that were attributed to the smoking of synthetic cannabinoids. For example, in September 2010, police in Nebraska responded to an incident involving a teenager who had careened his truck into the side of a residence. After striking the residence and several more items, the teen continued several more yards before coming to a complete stop. Prior to crashing the truck, the individual had driven past a junior high school and nearly struck a child. Upon further investigation, the driver of the vehicle admitted to smoking "Wicked X," a product marketed as "herbal incense" and known to contain synthetic cannabinoids, prior to the accident. Preliminary toxicology reports at the hospital indicated that the individual did not have any alcohol or other illegal substances in his system and further analysis of biological specimens identified metabolites of JWH-018.

Detailed chemical analyses by DEA and other agencies have found these synthetic cannabinoids spiked on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material. As proposed in scientific literature, the risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids spiked on the plant material.

Self-reported abuse of these THC-like synthetic cannabinoids either alone (*e.g.*, in pills or with the substance in powder form) or spiked on plant material appear extensively on Internet discussion boards, and abuse has been reported to public health officials and law enforcement agencies. The abuse of these substances in the smoked form (sprayed on plant material) has been corroborated by forensic laboratory analysis of products encountered by law enforcement agencies.

According to U.S. Customs and Border Protection, a number of the products and synthetic cannabinoids appear to originate from foreign sources. Product manufacturing operations encountered by law enforcement personnel establish that the herbal incense products are manufactured in the absence of quality controls and devoid of governmental regulatory oversight. Law enforcement personnel have encountered the manufacture of herbal incense products in such places as residential neighborhoods. These products and associated synthetic cannabinoids are readily accessible via the Internet.

In May 2011, law enforcement encountered a warehouse in Maryland that was used to process large quantities of bulk material into retail level products which contained the synthetic cannabinoid JWH-018. Investigators determined that this was a large-scale operation.

Even though several of these compounds have been controlled/banned in some states, and temporarily scheduled by DEA, unscrupulous scientists are able to continue to provide retailers with "legal" products by developing/synthesizing new synthetic cannabinoid products that are not covered under state/Federal regulatory, administrative or statutory actions. Retail entrepreneurs are able to procure new synthetic cannabinoid products, which have comparative psychoactive properties, with relative ease. In fact, after DEA took action to temporarily schedule the five (5) initial cannabinoids, retailers began selling new versions of the products that do not contain the banned cannabinoids, but instead contain new versions of the JWH compounds. Retailers also began labeling their products as being devoid of temporarily scheduled substances--in some cases later found to be untrue. Additionally, some retailers are provided with a "chemical analysis" purporting that the new product line does not contain any of the banned cannabinoids, yet failing to identify what is actually in the product.

In Kansas, a major manufacturer/distributor of synthetic cannabinoid products told a law enforcement officer, "...if the compound that he is using, JWH-250, is banned, he would just switch and treat his dried plant material with another legal compound."[1] There may be in excess of 100's of cannabinoids that have yet to be introduced into the marketplace. Manufacturers and

[1] Testimony of Police Chief James D. Hill, City of Salina, Kansas Association of Chiefs of Police Representative before the Kansas Senate Committee on Public Health and Welfare, March 3, 2011.

distributors will continue to stay one step ahead of any state or Federal drug-specific banning or control action by introducing/repackaging new cannabinoid products that are not controlled.

There are also financial incentives that drive the wholesale and retail distribution of these products. Affidavits were filed by Plaintiffs in the United States District Court, District of Minnesota, in support of a motion for preliminary injunction and restraining order that attempted to enjoin the government from proceeding with the temporary scheduling of JWH-018, JWH-073, JWH-200, CP-47,497 and cannabicyclohexanol.[2] Each of the Plaintiffs, in a sworn affidavit, claimed that "outlawing" synthetic cannabinoids would have detrimental effects on their respective businesses. In total, these four Plaintiffs estimated their gross profit from the sale of these products to be in excess of $3.5 million annually. They stated that the sale of cannabinoid products represented more than 50% of total sales of L.P.O.E., Inc., a Minnesota corporation; more than 70% of total sales of Hideaway, Inc; approximately 41.27% of gross profits (from April 2010 to September 2010) of Down in the Valley, Inc; and approximately 57% of Disc and Tape, Inc sales (affiant estimated that he would lose over $6000 per day in sales if he had to stop selling the product).

It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for retailers to seek/find substitute products that are not yet controlled or banned by Federal or state action. This is reminiscent of the typical illicit drug dealer cost-benefit analysis, in which the potential for financial gain far outweighs the potential for legal consequences. The large profits and the fact that these chemicals can be easily synthesized to stay one step ahead of control, indicate there is no incentive to discontinue retail distribution of synthetic cannabinoid products under the current statutory and regulatory scheme. Although many good corporate citizen retailers will discontinue the sale of these products in support of public health and safety, many will not, instead opting for the profits realized to help their financial "bottom line."

Synthetic Stimulants

Background

Another serious drug threat that has recently emerged is the growing distribution and abuse of a class of synthetic substances that have stimulant/psychoactive properties when ingested and that are sold as "bath salts" or "plant food." On February 1, 2011, Director of the Office of National Drug Control Policy Gil Kerlikowske issued a press release concerning the emerging threat of synthetic stimulants. In his statement, Director Kerlikowske stated, "I am deeply concerned about the distribution, sale and use of synthetic stimulants-especially those that are marketed as legal substances. Although we lack sufficient data to understand exactly how prevalent the use of these stimulants is, we know they pose a serious threat to the health and well being of young people and anyone who may use them."

These products are sold under a variety of brand names including "Ivory Wave", "Vanilla Sky", "Energy-1" (NRG-1), "Ocean Snow", "Hurricane Charlie", "White Lightening", "Red Dove", "Cloud-9", "White Dove", "White Girl" and many others. They are indirectly marketed

[2] L.P.O.E, Inc v. U.S. Drug Enforcement Administration Civil Case No. 10-VC-4944.

as "legal" alternatives to the controlled substances cocaine, amphetamine, Ecstasy (MDMA or 3,4-methylenedioxymethamphetamine) and methcathinone. The most prevalent synthetic substances encountered within these products include MDPV (3,4-methylenedioxypyrovalerone), mephedrone (4-methylmethcathinone) and methylone (3,4-methylenedioxymethcathinone). These drugs have been distributed and abused in Europe, particularly Great Britain and Germany, for several years. Mephedrone was first detected as a drug of abuse in Europe in November 2007.

These synthetic substances are suspected to be manufactured in bulk quantities in countries such as China, Pakistan, and India, and some of the actual products may be packaged for wholesale distribution in intermediate locations such as Eastern Europe.

The appearance of these designer drugs in products being sold in the United States has proliferated because of the Internet. These substances are marketed as "research chemicals," "plant food," or "bath salts," not for human consumption, to circumvent the CSA. Products are sold in powder or pill form that can be easily ingested. Marketing in this manner attempts to hide the true reason for the products' existence -- the distribution of a psychoactive/stimulant substance for abuse. As with the synthetic cannabinoids, these synthetic stimulants are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, in addition to over the Internet. Retailers that sell these products post a disclaimer on their websites that their products are "not intended for human consumption," in an attempt to circumvent statutory and regulatory controls. Websites often list products containing these synthetic stimulants as "plant food;" however, the powdered form is encapsulated in gelatin capsules, and dealers offer "discreet delivery" to the potential customer. Additionally, these products retail at prices that are considerably higher than legitimately marketed plant food or bath salt products. They are even known on the street by nicknames such as "Meow Meow," "drone," or "Molly."

To date, twenty-nine states have enacted controls in response to the "bath salt" phenomenon. Additionally, the trend in the development, distribution, and consumption of this class of substances in Europe has resulted in the United Kingdom and Germany banning products containing these substances.

Scope, Duration, and Significance of Abuse

The substances sold as "bath salts" and "plant food" products are based on the schedule I controlled substance cathinone, which is a potent central nervous system stimulant. Cathinone is an active ingredient in the leaves of the khat plant. Synthesized cathinone-like compounds have been reported as substances of abuse in some European countries since the early 2000s. These substances currently have no known medical use.

Effects have been described as being similar to those caused by other stimulants such as methamphetamine, MDMA, and cocaine. These synthetic substances are abused for their desired effects, such as euphoria, alertness, talkativeness, and sexual arousal. They are increasing in popularity as substances of abuse because they are marketed as "legal highs."

NFLIS has received over 1,000 reports from analyzed seizures related to these substances. To date, poison control centers in the United States have received hundreds of calls from at least 45 states and the District of Columbia related to the side effects of and overdoses from the use of these products. According to a recent press release from the American Association of Poison Control Centers, poison control centers received 303 calls relating to these products in 2010 and as of June 30th, 2011, poison centers have received 3,740 calls for 2011. There is very limited information regarding the biological effects of these substances, and it is unknown what may be the potential acute and long-term effects on humans.

What is known about these substances is disconcerting. There have been reports in the media of overdoses from ingestion of "bath salt" products which resulted in emergency room visits, hospitalizations, and severe psychotic episodes, some of which have led to violent outbursts, self-inflicted wounds, and, in at least one instance, suicide. Abusers of "bath salt" products have reported that they experienced many adverse effects such as chest pain, increased blood pressure, increased heart rate, agitation, panic attacks, hallucinations, extreme paranoia, and delusions.

Some users have reported anecdotally that they have "crashed" or "comedown" from mephedrone with effects similar to those they experienced from "coming down" from ecstasy and cocaine. Users of "bath salt" products self-administer the drugs by snorting the powder, smoking it, or injecting themselves intravenously.

Current Efforts and Challenges - Temporary Scheduling and Prosecution under the Analogue Statute

As previously mentioned, the DEA Administrator published a final order on March 1, 2011, placing five synthetic cannabinoids into Schedule I of the CSA pursuant to the temporary scheduling provisions of the CSA. During the temporary scheduling period, DEA will continue to gather and analyze scientific data and other information collected from all sources, including poison control centers, hospitals, and law enforcement agencies, in order to demonstrate that these substances should be permanently scheduled.

DEA is gathering scientific data and other information about synthetic stimulants as well as evaluating their psychoactive effects to support administrative action to schedule these substances under the CSA. Once data have been gathered to meet the statutory criteria to immediately schedule these stimulants, DEA will publish a notice of intent to temporarily place them into Schedule I. 21 U.S.C. § 811(h).

The challenge with synthetic stimulants is that, as stated above, there are a number of other stimulants that could easily be substituted into new "bath salt" products should mephedrone and MDPV be placed in Schedule I.

Currently, there may be in excess of one hundred other chemical substances that are suspected synthetic cannabinoids or synthetic stimulants. In order to establish controls over these substances, DEA must first establish that each chemical is an "analogue." 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 not automatically subject to control.

Under 21 U.S.C. § 802(32), as interpreted by the weight of court decisions, the government can prove that a substance is an analogue if: (1) the chemical structure of the substance is substantially similar to the chemical structure of a schedule I or II controlled substance; AND (2) the substance is pharmacologically similar to or greater than a schedule I or II controlled substance, *i.e.,* has a similar or greater pharmacological effect on the central nervous system; OR (3) with respect to a particular person, that such person represents or intends the substance to have a pharmacological effect substantially similar to or greater than a schedule I or II controlled substance.

These statutory criteria require extensive investigation and analyses, as well as a qualified expert's opinion regarding the chemical and pharmacological characteristics of the substance.

The major differences between a substance specifically controlled under the CSA and a substance treated as an analogue in terms of preventing diversion and abuse include:

- Additional investigation is necessary on each and every potential analogue case to ascertain whether the substance was "intended for human consumption."

- It is acceptable for a forensic chemist to present testimony regarding laboratory analysis results in order to identify a controlled substance, while additional testimony is necessary from experts in different scientific disciplines to establish that a particular substance is an analogue.

- In criminal prosecutions involving analogue substances, an additional burden is on the government to establish, through experts in the field of chemistry, that the substance is substantially similar in chemical structure to a schedule I controlled substance. This is by its nature an "opinion" and therefore subject to opposing views from other expert chemists.

- In criminal prosecutions involving analogue substances, an additional burden is on the government to establish, through experts in the field of pharmacology, that the substance is substantially similar in pharmacological activity to a schedule I controlled substance. Such expert testimony can be based on pharmacological models that are subject to opposing views from other expert pharmacologists.

- A single successful prosecution under the analogue provision of the CSA does not render the substance an analogue in subsequent prosecutions. Each prosecution must establish that the particular substance is an analogue under the statutory definition, as set out above.

Because of these considerations, the current availability of the "analogue" process to prevent diversion and abuse of synthetic cannabinoids and stimulants is not adequate to address the problem, necessitating more assertive action through direct scheduling of these substances.

The problems posed by synthetic cannabinoids raise international concerns as well. The synthetic cannabinoid issue has been addressed in regional and international fora, such as the Organization of American States Inter-American Drug Abuse Commission (CICAD) and the United Nations Commission on Narcotic Drugs (CND). At the 2010 meeting of the CND, a resolution was adopted on synthetic cannabinoids. The resolution highlighted the growing abuse and trafficking in these substances--which are not controlled under the international drug control treaties. The resolution called upon countries to, *inter alia*, pay particular attention to the emerging trends in the widespread distribution of products containing synthetic cannabinoids and to consider adopting national legislation to control the use of synthetic cannabinoids.

Controlling the distribution and abuse of newly synthesized analogues is challenging because, as DEA investigates, researches, and develops evidence pertinent to potential analogue substances in support of administrative control, illicit drug makers abandon these substances and create *new* analogue substances. Such a circular pursuit requires the expenditure of substantial scientific and investigative resources and continually leaves government scientists, regulators, and investigators one step behind the traffickers.

Conclusion

The increasing manufacture, distribution, and abuse of synthetic cannabinoids and synthetic stimulant compounds continue to pose a significant challenge. Although not specifically the focus of this hearing, there are other drugs of concern that also pose significant challenges, including the 2C family of drugs (dimethoxyphenethylamines) that are synthetic psychedelic/hallucinogens. Recently, a 19-year-old male in Minnesota died of cardiac arrest after allegedly ingesting 2C-E, one of the substances within this class. Nevertheless, the DEA is committed to using all of the civil, administrative, and criminal authorities at its disposal to fight this growing problem on all fronts.

In fact, DEA's New York Field Division Bath Salts Task Force (BSTF), in conjunction with the U.S. Marshalls, recently arrested a major distributor of synthetic stimulants that were masked as "bath salts," as well as employees of the retailers that sold the drugs. During the investigation, some of the retail employees discussed how to ingest the "bath salts," and one employee advised that the drugs would not appear in a urinalysis. Over the course of the investigation, the BSTF purchased more than a kilogram of "bath salts." The BSTF also seized approximately 40 kilograms of the drug, valued at approximately $2 million on the street.

As noted, these purportedly legitimate, "legal" products that are marketed as "bath salts," "plant food," and "incense," are clearly a pretense for unlawful activity. This is particularly evident when one compares the cost of these products to similar, legitimate bath salts, plant food, and incense that are purchased at retail outlets or via the internet. For example, a 1.5 pound (681 grams) container of legitimate plant food for sale by a local retailer sells between $5 and $12. On the other hand, a 250 milligram (0.250 grams) package containing mephedrone and marketed

as “plant food” sells for $25. The same is true for the bath salt products containing MDPV, which cost the consumer $100 for a 3.5 gram package, compared to legitimate bath salts, which sell for approximately $15 per pound (454 grams). These types of retail sales also beg the question: Why would a retailer need to “discreetly” package and ship legitimate products, unless the products are subversive?

The challenge to controlling these substances individually through administrative actions pursuant to the CSA is that the manufacturers of these substances circumvent the statutory criteria by manipulating the chemical structure of the compound. They can create substances that are pharmacologically similar to a schedule I or II controlled substance, that may or may not be chemically (structurally) similar to a schedule I or II controlled substance. The statute requires both pharmacological and chemical similarity in order to be an analogue. Even more alarming is that the structure of a chemical substance can be manipulated in *endless variations* while the pharmacological activity of the substance may increase or remain substantially unchanged. As a result, it is almost impossible outside of a controlled laboratory environment to determine the chemical composition, and the quantity, potency, and type of synthetic ingredients in these substances. It is equally challenging to determine what the potential harmful effects may be due to human consumption.

The Department of Justice is supportive of working with the Congress to protect the public health and safety and to ensure that the Attorney General has the necessary tools to administratively control emerging drug threats in a timely manner. Challenges will persist in controlling new emerging drugs of abuse, particularly in addressing analogues of identified schedule I substances; however, unilateral action by the Congress to place these dangerous substances directly into the schedule and affording the DEA additional time to complete administrative scheduling actions pursuant to the CSA’s temporary scheduling provision is beneficial to the public’s health and safety.

In closing, DEA will continue to work with its local, state and federal counterparts to protect the public against the dangers of these ever-changing synthetic cannabinoids, stimulant compounds and “designer” drugs.