



Synthetic Drugs: Overview and Issues for Congress

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Summary

Synthetic drugs, as opposed to natural drugs, are chemically produced in a laboratory. Their chemical structure can be either identical to or different from naturally occurring drugs, and their effects are designed to mimic or even enhance those of natural drugs. When produced clandestinely, they are not typically controlled pharmaceutical substances intended for legitimate medical use. Designer drugs are a form of synthetic drugs. They contain slightly modified molecular structures of illegal or controlled substances, and they are modified in order to circumvent existing drug laws. While the issue of synthetic drugs and their abuse is not new, Congress has demonstrated a renewed concern with the issue.

From 2009-2011, synthetic drug abuse was reported to have dramatically increased. During this time period, calls to poison control centers for incidents relating to harmful effects of synthetic cannabinoids (such as “K2” and “Spice”) and stimulants (such as “bath salts”) increased at what some considered to be an alarming rate. The number of hospital emergency department visits involving synthetic cannabinoids more than doubled from 2010 to 2011. In 2012, however, the number of calls to poison control centers for incidents relating to harmful effects of synthetic cannabinoids and synthetic stimulants decreased. The *Monitoring the Future* (MTF) survey results from 2012 indicate that annual prevalence rates for use of “bath salts” among college students and adults ages 18-50 was “very low.” In contrast, MTF reports that, among 12th graders, synthetic marijuana is the “second most widely used class of illicit drug after marijuana.” Media reports indicate that a synthetic substance known as “molly,” a psychoactive drug that may be similar or identical to MDMA (3,4-Methylenedioxymethamphetamine), appears to be gaining popularity among youth. In the summer of 2013, several deaths and drug overdoses have been attributed to molly.

The reported harmful effects of synthetic substances range from nausea to drug-induced psychosis. Due to the unpredictable nature of synthetic drugs and of human consumption of these drugs, the true effects of many of these drugs are unknown. Many states have responded to the synthetic drug abuse issue by passing synthetic drug laws banning certain synthetic cannabinoids and stimulants.

In 2011, the Attorney General—through the Drug Enforcement Administration (DEA)—used his temporary scheduling authority to place five synthetic cannabinoids and three synthetic stimulants on Schedule I of the Controlled Substances Act (CSA). Concern over the reported increase in use of certain synthetic cannabinoids and stimulants resulted in legislative action to schedule specific substances. The Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144)—added five structural classes of substances in synthetic cannabinoids (and their analogues) as well as 11 synthetic stimulants and hallucinogens to Schedule I of the CSA. In addition, the act extended the DEA’s authority to temporarily schedule substances. In April 2013, Attorney General Holder—through the DEA and in consultation with the Department of Health and Human Services (HHS)—took administrative action to permanently place methylene on Schedule I of the CSA. Most recently in May 2013, Attorney General Holder—again through the DEA—used his temporary scheduling authority to place three additional synthetic cannabinoids on Schedule I of the CSA.

In considering permanent placement of synthetic substances on Schedule I of the CSA, there are several issues on which Congress may deliberate. Policymakers may consider the implications on

the federal criminal justice system of scheduling certain synthetic substances. Another issue up for debate is whether Congress should schedule certain synthetic substances or whether these substances merit Attorney General (in consultation with the Secretary of HHS) scheduling based on qualifications specified in the CSA. Congress may also consider whether placing additional synthetic drugs on Schedule I may hinder future medical research. In addition, policymakers may consider whether it is more efficient to place these drugs on Schedule I of the CSA or to treat them as analogue controlled substances under the Controlled Substances Analogue Enforcement Act. In considering enforcement challenges identified by the DEA, Congress may consider whether to amend the CSA to better facilitate enforcement action against the illicit synthetic drug market.

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Background on Synthetic and Designer Drugs

Synthetic drugs, as opposed to natural drugs, are chemically produced in a laboratory. Their chemical structure can be either identical to or different from naturally occurring drugs, and their effects are designed to mimic or even enhance those of natural drugs.¹ When produced clandestinely, they are not typically controlled pharmaceutical substances intended for legitimate medical use. Designer drugs are a form of synthetic drugs. They slightly modify the molecular structures of illegal or controlled substances to circumvent existing drug laws.

For over three decades, there has been national-level attention on the use and abuse of synthetic drugs. Congress became concerned about the abuse of designer drugs in the early 1980s when policymakers were examining the diversion of controlled substances—intended for medical use—to the black market.² There was concern about the health and safety effects of using and abusing pharmaceutically created drugs as well as other modified synthetics. While a bulk of this focus has been on methamphetamine, the spotlight has recently shifted to other synthetic stimulants as well as synthetic cannabinoids.³ Due to the lack of research on many of these synthetics and their various analogues, the full scope of their effects and potential dangers is still not well known.

Concern over the reported increase in use of certain synthetic cannabinoids and stimulants led some to call on Congress to legislatively schedule specific substances.⁴ This is, in part, because congressional action could place certain substances onto Schedule I of the Controlled Substances Act (CSA) more quickly than might occur through administrative scheduling actions by the Attorney General and Secretary of the Department of Health and Human Services (HHS), as authorized by the CSA.⁵ In June 2012, Congress passed the Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).⁶ to, among other things, permanently schedule selected synthetic stimulants and other synthetic substances.

This report discusses the federal scheduling of controlled substances, including the temporary scheduling of substances. It also provides an overview of current trends in selected synthetic cannabinoids and stimulants. It concludes with a review of relevant legislation as well as possible issues policymakers might consider.

¹ United Nations Office on Drugs and Crime, *Synthetic Drugs*, http://www.apaic.org/index.php?option=com_content&view=article&id=91&Itemid=63.

² U.S. Congress, House Committee on the Judiciary, Subcommittee on Crime, *Designer Drugs*, 99th Cong., 1st sess., May 1, 1986, p. 1.

³ Synthetic cannabinoids are substances chemically produced to mimic tetrahydrocannabinol (THC), the active ingredient in marijuana.

⁴ Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, Senate United States Senate Caucus on International Narcotics Control, *The Dangers of Synthetic Cannabinoids and Stimulants*, 112th Cong., 1st sess., April 6, 2011, http://drugcaucus.senate.gov/hearing-4-6-11/DEA%20_Rannazzisi_%20testimony.pdf.

⁵ For more information on the CSA and administrative scheduling actions, see “Scheduling of Synthetic Drugs: Controlled Substances Act.”

⁶ It was offered as an amendment (S.Amdt. 2146) to S. 3187.

Scheduling of Synthetic Drugs: Controlled Substances Act

The Controlled Substances Act (CSA) was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513).⁷ It regulates the manufacture, possession, use, importation, and distribution of certain drugs, substances, and precursor chemicals. Under the CSA, there are five schedules under which substances may be classified—Schedule I being the most restrictive.⁸ Substances placed onto one of the five schedules are evaluated on

- actual or relative potential for abuse;
- known scientific evidence of pharmacological effects;
- current scientific knowledge of the substance;
- history and current pattern of abuse;
- scope, duration, and significance of abuse;
- risk to public health;
- psychic or physiological dependence liability; and
- whether the substance is an immediate precursor of an already-scheduled substance.

There are designated procedures under which the scheduling of substances normally occurs.⁹ Specifically, the Attorney General—through the Drug Enforcement Administration (DEA), and in consultation with the Secretary of HHS—may place a drug or substance on Schedule I if it meets all of the following criteria:

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.¹⁰

Controlled Substances Analogue Enforcement Act of 1986

The Controlled Substances Analogue Enforcement Act of 1986 (Analogue Enforcement Act) was enacted as Subtitle E of the Anti-Drug Abuse Act of 1986 (P.L. 99-570). This law amended the Controlled Substances Act to treat a controlled substance analogue (intended for human

⁷ 21 U.S.C. §801 et. seq.

⁸ The Attorney General (through the DEA) and the Secretary of Health and Human Services (through the Food and Drug Administration) may schedule substances, as may Congress through legislation.

⁹ 21 U.S.C. §811.

¹⁰ 21 U.S.C. §812(b)(1).

consumption) as a controlled substance under Schedule I.¹¹ Under this law, a controlled substance analogue is defined as a substance if

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.¹²

Of note, many of the synthetic cathinones marketed under household names such as “bath salts” or “plant food” are stamped with “not intended for human consumption.” This action is intended to circumvent the Analogue Enforcement Act under the CSA.¹³

Temporary Scheduling

Because policymakers were concerned about the effects of pharmaceutically created and other modified drugs, Congress gave the Attorney General the authority to temporarily place a substance onto Schedule I of the CSA to “avoid imminent hazards to public safety.”¹⁴ When determining whether there is an imminent hazard, the Attorney General (through the DEA) must consider the drug’s history and current pattern of abuse; scope, duration, and significance of abuse; and risk to public health.

Once scheduled through this temporary scheduling process, a substance may remain on Schedule I for two years. The Attorney General then has the authority to keep the substance on Schedule I for an additional one year before it must be removed or permanently scheduled. The Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144)—extended the DEA’s temporary scheduling authority. Prior to enactment of this act on July 9, 2012, the DEA was able to temporarily place a substance on Schedule I of the CSA for one year, with a potential extension of six months.

¹¹ 21 U.S.C. §813.

¹² 21 U.S.C. §802(32)(A). For more information on which drugs or substances may be placed on Schedule II, see 21 U.S.C. §812(b)(2).

¹³ Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *The Dangers of Synthetic Cannabinoids and Stimulants*, 112th Cong., 1st sess., April 6, 2011, http://drugcaucus.senate.gov/hearing-4-6-11/DEA%20_Rannazzisi_%20testimony.pdf.

¹⁴ 21 U.S.C. §811(h). The Attorney General was given this authority in the Comprehensive Crime Control Act of 1984 (Title II of P.L. 98-473).

Recent Temporary Drug Scheduling Actions

Over the past several years, the DEA has taken several temporary scheduling actions. In October 2011, the DEA placed three synthetic cathinones¹⁵ on the list of controlled substances under Schedule I of the CSA. In March 2011, the DEA placed five synthetic cannabinoids on Schedule I.¹⁶ In May 2013, the DEA placed three additional synthetic cannabinoids on Schedule I. Since 2002, the DEA has used this temporary scheduling authority on 16 synthetic substances, outlined in **Table 1**. Prior to 2002, the most recent time DEA exercised this authority was in 1995.¹⁷

Table 1. DEA Temporary Drug Scheduling Actions
2002–2013

Drug Name	Natural/ Synthetic	Temporary Scheduling Date	Temporary Scheduling Extension	Permanent Scheduling
1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone (UR-144)	Synthetic	5/16/2013	—	—
1-(5-fluoro-pentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11)	Synthetic	5/16/2013	—	—
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48)	Synthetic	5/16/2013	—	—
3,4-methylenedioxy-N-methylcathinone (methylone)	Synthetic	10/21/2011	10/17/2012	4/12/2013
4-methyl-N-methylcathinone (mephedrone)	Synthetic	10/21/2011	—	— ^a
3,4-methylenedioxypyrovalerone (MDPV)	Synthetic	10/21/2011	—	— ^a
1-pentyl-3-(1-naphthoyl)indole (JWH-018)	Synthetic	3/1/2011	2/29/2012	— ^a
1-butyl-3-(1-naphthoyl)indole (JWH-073)	Synthetic	3/1/2011	2/29/2012	— ^a
1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	Synthetic	3/1/2011	2/29/2012	— ^a
5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)	Synthetic	3/1/2011	2/29/2012	— ^a
5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue)	Synthetic	3/1/2011	2/29/2012	— ^a
Alpha-methyltryptamine (AMT)	Synthetic	4/4/2003	4/1/2004	9/29/2004
5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT)	Synthetic	4/4/2003	4/1/2004	9/29/2004
3-Trifluoromethylphenylpiperazine (TFMPP)	Synthetic	9/20/2002	9/20/2003	3/19/2004
N-Benzylpiperazine (BZP)	Synthetic	9/20/2002	9/20/2003	3/18/2004
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)	Synthetic	9/20/2002	9/20/2003	3/18/2004

¹⁵ Cathinones are central nervous system stimulants.

¹⁶ In February 2012, a temporary scheduling extension maintained the Schedule I placement of these substances.

¹⁷ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Lists of: Scheduling Actions, Controlled Substances, Regulated Chemicals*, May 2013, <http://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.

Source: U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Lists of Scheduling Actions, Controlled Substances, Regulated Chemicals*, May 2013, <http://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.

Notes: Dates are effective dates. Scheduling actions are listed in reverse chronological order.

- a. This substance was permanently scheduled, although not by the DEA. It was legislatively scheduled in P.L. 112-144.

Of note, the last 16 substances to have been temporarily (and, for six of them, subsequently permanently) placed on Schedule I of the CSA are synthetic substances.

Current Trends in Selected Synthetics

Synthetic compounds have been created across the various classes of drugs.¹⁸ Law enforcement and policymakers—at both the state and federal levels—have taken an interest in and responded to the increasing use of certain synthetic cannabinoids and stimulants. The United Nations Office on Drugs and Crime reports the global emergence of certain synthetic cathinones and cannabinoids from 2009-2011.¹⁹

Synthetic Cannabinoids

Synthetic cannabinoids are substances chemically produced to mimic tetrahydrocannabinol (THC), the active ingredient in marijuana. When these substances are sprayed onto dried herbs and then consumed through smoking or oral ingestion, they can produce psychoactive effects similar to those of marijuana.²⁰ Synthetic cannabinoids were first produced for research purposes to study the effects of cannabinoids on brain functioning and their efficacy in treating pain.

The DEA has indicated that the primary users of these synthetic substances are youth who purchase the substances online or in gas stations, convenience stores, smoke shops, and head shops.²¹ The substances are often sold as herbal incense, and common brand names under which synthetic cannabinoids are marketed are “Spice” and “K2.” Other names include “Blaze,” “Red X Dawn,” “Genie,” and “Zohai,” among others.²²

Clemson University Professor John Huffman is credited with first synthesizing some of the cannabinoids, such as JWH-018, now used in “fake pot” substances such as K2. The effects of JWH-018 can be 10 times stronger than those of THC. Dr. Huffman is quoted as saying, “These things are dangerous—anybody who uses them is playing Russian roulette. They have profound

¹⁸ The Controlled Substances Act regulates drugs in five major classes: narcotics (including marijuana), depressants, stimulants, hallucinogens, and anabolic steroids. For more information on these classes, see the U.S. Drug Enforcement Administration, *Drug Classes*, http://www.justice.gov/dea/concern/drug_classes.html.

¹⁹ United Nations Office on Drugs and Crime, *World Drug Report 2013*, Vienna, May 2013, pp. 67-70, <http://www.unodc.org>.

²⁰ National Conference of State Legislatures, *Synthetic Cannabinoids (K2)*, January 18, 2011, <http://www.ncsl.org/?tabid=21398>.

²¹ U.S. Department of Justice, Drug Enforcement Administration, *Nationwide Synthetic Drug Takedown*, DEA News, July 26, 2012, <http://www.justice.gov/dea/pubs/pressrel/pr072612.html>.

²² *Ibid*; U.S. Department of Justice, Drug Enforcement Administration, *Drugs of Abuse*, 2011 Edition, <http://www.dea.gov>.

psychological effects. We never intended them for human consumption.”²³ While synthetic cannabinoids may be used with the intention of getting a marijuana-like high, their actual effects are not yet known. Some reported effects of synthetic cannabinoids, such as relaxation and reduced blood pressure, are consistent with effects of marijuana. Other reported effects, such as nausea, increased agitation, elevated blood pressure, and racing heart rates, are not.²⁴ The Centers for Disease Control and Prevention (CDC) has noted epidemiological links between synthetic cannabinoid use and acute kidney injury.²⁵ In at least one case, synthetic marijuana has been blamed for a fatality when an Iowa teen committed suicide reportedly following a K2-induced panic attack.²⁶

According to the American Association of Poison Control Centers (AAPCC), poison control centers around the country received 2,906 calls about synthetic cannabinoid substances in 2010, up from a reported 14 calls in 2009. In 2011, these calls increased to 6,959 and in 2012, calls declined to 5,205. From January through August 2013, there were 1,821 reported calls regarding human exposure to synthetic cannabinoids.²⁷ It is unclear if this recent decline can be linked to the enactment of the Synthetic Drug Abuse Prevention Act of 2012, which, among other things, added certain synthetic cannabinoids to Schedule I of the CSA.

As mentioned, youth are the primary users of these substances. The Monitoring the Future (MTF)²⁸ survey first reported on the rise in synthetic cannabinoid use in its 2011 survey. MTF asked 12th graders about use in the prior 12 months, and 11.4 % indicated use during this time period. According to the 2012 MTF survey, use among 12th graders remained relatively unchanged at 11.3%. MTF reports that, among 12th graders, synthetic marijuana is the “second most widely used class of illicit drug after marijuana.”²⁹

On March 1, 2011, the DEA used its temporary scheduling authority and issued a final rule to place five synthetic cannabinoids on the list of controlled substances under Schedule I of the CSA.³⁰ The five substances are

²³ David Zucchino, “Scientist’s Research Produces a Dangerous High,” *Los Angeles Times*, September 28, 2011, <http://www.latimes.com/news/nationworld/nation/la-na-killer-weed-20110928,0,2646834.story?page=1>.

²⁴ National Institutes of Health, National Institute on Drug Abuse, *Drug Facts: Spice (Synthetic Marijuana)*, December 2012, <http://www.drugabuse.gov/publications/drugfacts/spice-synthetic-marijuana>.

²⁵ Centers for Disease Control and Prevention, *Acute Kidney Injury Associated with Synthetic Cannabinoid Use—Multiple States, 2012*, Morbidity and Mortality Weekly Report, February 15, 2013, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6206a1.htm>.

²⁶ See, for example, Malcolm Gay, “Synthetic Marijuana Spurs State Bans,” *The New York Times*, July 10, 2010, <http://www.nytimes.com/2010/07/11/us/11k2.html>.

²⁷ American Association of Poison Control Centers, *Synthetic Marijuana Data*, (As of August 31, 2013), <http://www.aapcc.org/alerts/synthetic-marijuana/>; and National Conference of State Legislatures, *Synthetic Cannabinoids (K2)*, January 18, 2011, <http://www.ncsl.org/>.

²⁸ The Monitoring the Future project is a long-term study of American adolescents, college students, and adults through age 50. It has been conducted annually by the University of Michigan’s Institute for Social Research since its inception in 1975 and has been supported by research grants from the National Institute on Drug Abuse. For more information, see <http://www.monitoringthefuture.org>.

²⁹ Lloyd D. Johnston, Patrick O’Malley, and Jerald G. Bachman, et al., *Monitoring the Future, National Results on Drug Use: 2012 Overview, Key Findings on Adolescent Drug Use*, The University of Michigan, Institute for Social Research, Research Grant No. 3 R01 DA 01411 from the National Institute on Drug Abuse, Ann Arbor, MI, February 2013, pp. 5 and 14, <http://www.monitoringthefuture.org>. Hereinafter, *Monitoring the Future, National Results on Drug Use: 2012 Overview, Key Findings on Adolescent Drug Use*.

³⁰ Department of Justice, Drug Enforcement Administration, “Schedules of Controlled Substances: Temporary (continued...)”

- 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).

Pursuant to the temporary scheduling authority, these substances remained on the list of Schedule I controlled substances for one year and on February 29, 2012, they were each given a six-month temporary extension.

In June 2012, Congress passed legislation to permanently schedule these five synthetic cannabinoids (and other synthetic substances). The Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144, signed by the President on July 9, 2012)—permanently added “cannabimimetic agents” to Schedule I of the CSA. Under this act, a cannabimimetic agent is defined as one of five structural classes of synthetic cannabinoids (and their analogues). The act also provided 15 examples of cannabimimetic substances, including the five substances that the DEA had temporarily scheduled in March 2011.

On May 16, 2013, the DEA again used its temporary scheduling authority and issued a final rule to place three synthetic cannabinoids on the list of controlled substances under Schedule I of the CSA.³¹ The three substances are

- 1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)
- [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11); and
- N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48).

Pursuant to the temporary scheduling authority, as expanded under the Synthetic Drug Abuse Prevention Act of 2012 (P.L. 112-144), these substances will remain on the list of Schedule I controlled substances for two years.

As of November 2012, at least 41 states and Puerto Rico had legislatively banned chemical substances contained in synthetic cannabinoids.³² Of note, the Maryland General Assembly passed a bill that bans “cannabimimetic agents” and specific compounds; this bill will take effect

(...continued)

Placement of Five Synthetic Cannabinoids Into Schedule I,” 76 (40) *Federal Register* 11075-11078, March 1, 2011.

³¹ Department of Justice, Drug Enforcement Administration, “Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids Into Schedule I,” 78 (95) *Federal Register* 28735-28739, May 16, 2013.

³² National Conference of State Legislatures, *Synthetic Drug Threats*, November 28, 2012, <http://www.ncsl.org/?tabid=21398>.

on October 1, 2013.³³ The U.S. military has also banned personnel from possessing or using these substances.³⁴

Synthetic Stimulants

Synthetic stimulants are chemically produced substances that affect the central nervous system. Stimulants include drugs such as amphetamine (including methamphetamine), cocaine, and Ecstasy (MDMA, or 3,4-Methylenedioxymethamphetamine). The synthetic forms of stimulants can be administered through oral ingestion, inhalation, or injection.

Methamphetamine

The DEA indicates that methamphetamine is “a continuing problem in the United States.”³⁵ According to the 2012 National Survey on Drug Use and Health (NSDUH),³⁶ there were approximately 440,000 current (past month) users of methamphetamine age 12 or older. The number of past month methamphetamine users decreased between 2006 and 2012, from 731,000 (0.3%) to 440,000 (0.2 %).³⁷ The illicit manufacture and abuse of methamphetamine have been long-standing problems in some states and regions of the country. In 2011, the National Drug Intelligence Center (NDIC) stated that domestic availability of methamphetamine was increasing because of increased production of methamphetamine in Mexico and increased illicit domestic production.³⁸

Another trend that appears to have changed the landscape of methamphetamine production is the emergence of small-scale, one-pot methamphetamine labs. The “one-pot” or “shake and bake” method uses a single vessel, such as a 2-liter plastic bottle, to combine all needed chemicals to create the anhydrous ammonia required for methamphetamine production.³⁹ Through this method, methamphetamine can be created in about 30 minutes in almost any location. Law enforcement agencies throughout the country have seen increases in the one-pot methamphetamine production

³³ State of Maryland, General Assembly, Chapter 442 (Senate Bill 109), Approved by the Governor, May 16, 2013, <http://mgaleg.maryland.gov>.

³⁴ U.S. Department of Defense, “2008 Federal Sentencing Guidelines Manual,” Chapter 2 – Part D – Offenses Involving Drugs and Narco-Terrorism, p. 23.

³⁵ U.S. Department of Justice, *Drug Enforcement Administration, FY2014 Performance Budget, Congressional Submission*, p. DEA-63, <http://www.justice.gov/jmd/2014justification/pdf/dea-justification.pdf>.

³⁶ The National Survey on Drug Use and Health (NSDUH) is an annual survey sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). NSDUH presents data on the use of illicit drugs, alcohol, and tobacco in the civilian, non-institutionalized population of the United States aged 12 years old or older. Approximately 67,500 persons are interviewed in NSDUH each year. For more information, see <http://www.samhsa.gov/data/NSDUH.aspx>.

³⁷ The previous numbers were 439,000 in 2011, 353,000 in 2010, 502,000 in 2009, 314,000 in 2008, 530,000 in 2007, 731,000 in 2006, 628,000 in 2005, 706,000 in 2004, 726,000 in 2003, and 683,000 in 2002. See U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, September 2013, <http://www.samhsa.gov/data/data/NSDUH.aspx>.

³⁸ U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, Product No. 2011-Q0317-001, August 2011, p. 32, <http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf>. (Hereinafter, NDTA, 2011.) On June 15, 2012, the National Drug Intelligence Center closed.

³⁹ National Drug Intelligence Center, *2009 National Methamphetamine Threat Assessment*, Product No. 2008-Q0317-006, December 2008, p. 13; NDTA, 2011, p. 35.

method.⁴⁰ For instance, the Tulsa, OK, Police Department responded to 327 methamphetamine labs in the first 10 months of 2011, up from 323 lab busts in all of 2010. This may be, in part, because one-pot methamphetamine can be easier to make than that produced on a larger scale.⁴¹

Congress continues to be concerned about the abuse and illicit manufacture of methamphetamine in clandestine labs as well as the illegal trafficking of this substance. Over the past 30 years, Congress has enacted legislation designed to address these problems. These measures have included more stringent federal regulation of methamphetamine precursor chemicals such as pseudoephedrine, enhanced criminal penalties for trafficking in the drug, and authorization of additional funding for grants providing methamphetamine-specific law enforcement assistance.⁴²

MDMA

MDMA (3,4-methylenedioxy-methamphetamine), also known as ecstasy, is a psychoactive substance capable of producing “feelings of increased energy, euphoria, emotional warmth and empathy toward others, and distortions in sensory and time perception.”⁴³ Users may also experience increased heart rate and blood pressure, muscle tension, involuntary teeth clenching, nausea, and in high doses, MDMA can interfere with the body’s ability to regulate temperature.⁴⁴ It first gained popularity in the early 1980s, after which it was permanently placed on Schedule I of the CSA by the DEA. It later resurfaced as a popular drug among youth in the nightclub scene and at raves in the 1990s.⁴⁵

In 2003, the Illicit Drug Anti-Proliferation Act of 2003⁴⁶ amended the CSA⁴⁷ to more directly target the producers of raves where synthetic drugs such as MDMA were often used. It shifted emphasis from punishing those who *establish* places where drugs are made, distributed, and consumed to those who *knowingly maintain* such places. It also established a civil penalty and equitable relief for “maintaining drug-involved premises.” This act also authorized appropriations for the DEA to educate youth, parents, and other interested adults about club drugs.

Most recently, in 2013, synthetic substances known as “molly” have gained popularity among youth at concerts, raves, and in nightclubs.⁴⁸ While the term “molly” is a street name that has been used for MDMA and substances similar to MDMA, such as methyone and 1-(3-

⁴⁰ U.S. Congress, United States Senate Caucus on International Narcotics Control, Written Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, “Status of Meth: Oregon’s Experience Making Pseudoephedrine Prescription Only,” 112th Cong., 1st sess., April 13, 2010.

⁴¹ Abbie Alford, “Tulsa Breaks Meth Lab Record,” *Fox23.com*, October 4, 2011.

⁴² For more information, see archived CRS Report RL32824, *Federal Crime Control: Background, Legislation, and Issues*, by Kristin Finklea and Lisa Seghetti.

⁴³ National Institute on Drug Abuse, *Drug Facts: MDMA (Ecstasy)*, December 2012, <http://www.drugabuse.gov/publications/drugfacts/mdma-ecstasy>.

⁴⁴ *Ibid.*

⁴⁵ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Lists of: Scheduling Actions, Controlled Substances, Regulated Chemicals*, May 2013, <http://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>; Charles F. Levinthal, *Drugs, Society and Criminal Justice*, 3rd ed. (New York: Prentice Hall, 2012), pp. 207-208; Associated Press, “U.S. Will Ban ‘Ecstasy,’ a Hallucinogenic Drug,” *New York Times*, June 1, 1985.

⁴⁶ Section 608 of the PROTECT Act (P.L. 108-21).

⁴⁷ Specifically, it amended Section 416 of the CSA, also known as the “crack house statute.”

⁴⁸ Marina Csomor, “There’s Something (Potentially Dangerous) About Molly,” *CNN*, September 3, 2013.

Trifluoromethylphenyl) piperazine (TFMPP),⁴⁹ recent media reports indicate that molly seizures in 2013 have involved the powder or crystal form of MDMA with some news articles referring to this version of molly as a purer version of MDMA.⁵⁰ In 2013, several deaths and multiple hospitalizations of young adults in the Northeast and the District of Columbia have been attributed to molly overdoses.⁵¹ The precise chemical makeup of the synthetic substance in question in these cases remains unclear.

Other Stimulants

One current trend in synthetic stimulants is the appearance of synthetic cathinones, often labeled as “bath salts.”⁵² These drugs are sold in powder form and are often marketed under brand names including “Ivory Wave,” “Purple Wave,” “Red Dove,” “Blue Silk,” “Zoom,” “Bloom,” “Cloud Nine,” “Ocean Snow,” “Lunar Wave,” “Vanilla Sky,” “White Lightning,” “Scarface,” and “Hurricane Charlie,” among others.⁵³ Bath salts are sold both online and in retail stores, and the DEA has indicated that, while user population information is limited, reports show that youth may be the primary consumers.⁵⁴

Bath salts often contain amphetamine-like chemicals such as 4-methyl-N-methylcathinone (mephedrone), 3,4-methylenedioxy-N-methylcathinone (methylone), and 3,4-methylenedioxypyrovalerone (MDPV), but the other contents of this substance are largely unknown.⁵⁵ Because MDPV and other amphetamine-like chemicals act as stimulants, they present a high risk for abuse and addiction.⁵⁶ There have also been reports of MDPV users craving the substance.⁵⁷ Reported side effects of these synthetic stimulants include chest pains, elevated blood pressure, increased heart rate, agitation, hallucinations, panic attacks, extreme paranoia, delusions, and even sleep deprivation-induced psychosis; however, their actual effects are not yet known.⁵⁸ Poison control centers across the United States received 304 calls about bath salts in

⁴⁹ U.S. Drug Enforcement Administration, *Safety Advisory Regarding New Club Drug “Molly”*, News Release, March 21, 2003, <http://www.justice.gov/dea/pubs/states/newsrel/2003/detroit032103.html>; U.S. Drug Enforcement Administration, *Wasilla Man Pleads Guilty in Synthetic Drug Case Which Resulted in Overdose Death*, Seattle News, August 9, 2013, <http://www.justice.gov/dea/divisions/sea/2013/sea080913.shtml>.

⁵⁰ Marina Csomor, “There’s Something (Potentially Dangerous) About Molly,” *CNN*, September 3, 2013; Jack Encarnacao, “DEA Warning: There’s No ‘Good Batch’ of Molly,” *Boston Herald*, September 2, 2013; Maia Szalavitz, “Concert Deaths: Four Myths About the Drug Molly,” *TIME*, September 3, 2013; Peter Hermann and Jenna Johnson, “Clubgoer Who Died in D.C. Might Have Used Drug Linked to Deaths in Boston, New York,” *The Washington Post*, September 5, 2013.

⁵¹ *Ibid.*

⁵² This stimulant drug is entirely different from the water-soluble substances actually designed to enhance the cleansing and bathing experience—also known as bath salts.

⁵³ National Institutes of Health, National Institute on Drug Abuse, *Message from the Director on “Bath Salts”—Emerging and Dangerous Products*, 2011, <http://www.nida.nih.gov/about/welcome/MessageBathSalts211.html>.

⁵⁴ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Methylenedioxypropylvalerone (MDPV)*, (“bath salts,” “Ivory Wave,” “plant fertilizer,” “Vanilla Sky,” “Energy-1”)[sic.], May 2013, http://www.deadiversion.usdoj.gov/drug_chem_info/mdpv.pdf.

⁵⁵ MDPV, methylone, and mephedrone are not approved for medical use in the United States.

⁵⁶ National Institutes of Health, National Institute on Drug Abuse, *Message from the Director on “Bath Salts”—Emerging and Dangerous Products*, 2011, <http://www.nida.nih.gov/about/welcome/MessageBathSalts211.html>.

⁵⁷ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Methylenedioxypropylvalerone (MDPV)*, (“bath salts,” “Ivory Wave,” “plant fertilizer,” “Vanilla Sky,” “Energy-1”)[sic.], May 2013, http://www.deadiversion.usdoj.gov/drug_chem_info/mdpv.pdf.

⁵⁸ *Ibid.* See also National Institutes of Health, National Institute on Drug Abuse, *Message from the Director on “Bath (continued...)”*

2010. This number climbed to 6,138 calls in 2011. Similar to the trend in poison control center calls regarding synthetic cannabinoids, calls regarding bath salts also declined in 2012 compared to 2011; in 2012, there were 2,657 reported calls to poison control centers about exposure to bath salts. From January through August 2013, there were 690 reported calls regarding human exposure to bath salts.⁵⁹ It is unclear if this recent decline can be related to the enactment of the Synthetic Drug Abuse Prevention Act of 2012. In 2012, MTF survey began collecting data on use of bath salts, and reported annual prevalence rates for 8th, 10th, and 12th graders to be 0.8%, 0.6%, and 1.3% respectively. MTF described these rates as very low.⁶⁰

On October 21, 2011, the DEA used its temporary scheduling authority and issued a final rule to place three synthetic stimulants (cathinones, in this instance) on the list of controlled substances under Schedule I of the CSA.⁶¹ The three substances are

- mephedrone,
- methylone, and
- MDPV.

In June 2012, Congress passed legislation to permanently schedule selected synthetic stimulants and other synthetic substances. The Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144, signed by the President on July 9, 2012)—permanently added mephedrone and MDPV, along with nine other synthetic stimulants and hallucinogens, to Schedule I of the CSA. This act did not, however, schedule methylone; as provided through the DEA’s temporary scheduling authority. Methylone was given a six month extension and remained on Schedule I for an additional six months until April 2013 when Attorney General Holder—through the DEA and in consultation with the Secretary of HHS—took administrative action to permanently place methylone on Schedule I of the CSA.⁶²

As of November 2012, at least 43 states and Puerto Rico had banned chemical substances contained in synthetic stimulants such as bath salts.⁶³ Of note, the Maryland General Assembly recently passed a bill that would ban certain cathinones among other substances; this bill will take effect on October 1, 2013.⁶⁴

(...continued)

Salts” – *Emerging and Dangerous Products*, 2011, <http://www.nida.nih.gov/about/welcome/MessageBathSalts211.html>.

⁵⁹ American Association of Poison Control Centers, “Bath Salts Data,” August 31, 2013, <http://www.aapcc.org/alerts/bath-salts/>.

⁶⁰ *Monitoring the Future, National Results on Drug Use: 2012 Overview, Key Findings on Adolescent Drug Use*, p. 5.

⁶¹ Department of Justice, Drug Enforcement Administration, “Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cathinones Into Schedule I,” 76 (204) *Federal Register* 65371-65375, October 21, 2011.

⁶² U.S. Drug Enforcement Administration, “Schedules of Controlled Substances: Placement of Methylone Into Schedule I,” 78 *Federal Register* 21818-21825, April 12, 2013.

⁶³ National Conference of State Legislatures, *Synthetic Drug Threats*, November 28, 2012, <http://www.ncsl.org/?tabid=21398>.

⁶⁴ State of Maryland, General Assembly, Chapter 442 (Senate Bill 109), Approved by the Governor, May 16, 2013, <http://mgaleg.maryland.gov>.

Synthetic Drug Abuse Prevention Act of 2012

While drugs and substances can be scheduled administratively by the Attorney General and the Secretary of HHS, through processes outlined in the CSA, they can also be scheduled directly through congressional legislation. On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).⁶⁵ The act added “cannabimimetic agents” to Schedule I of the CSA. Under this act, a cannabimimetic agent is defined as one of five structural classes of synthetic cannabinoids (and their analogues). The act also provided 15 specific examples of cannabimimetic substances:

- 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);
- 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);
- 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);
- 1-butyl-3-(1-naphthoyl)indole (JWH-073);
- 1-hexyl-3-(1-naphthoyl)indole (JWH-019);
- 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
- 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);
- 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);
- 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
- 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
- 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);
- 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);
- 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);
- 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and
- 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

Of note, five of these substances⁶⁶ were temporarily placed onto Schedule I of the CSA by the DEA on March 1, 2011. On February 29, 2012, the DEA extended this temporary scheduling by six months. These five substances would have been removed from Schedule I of the CSA at the end of August 2012 if Congress had not legislatively scheduled these and other substances.

The Synthetic Drug Abuse Prevention Act of 2012 also added 11 synthetic stimulants and hallucinogens to Schedule I of the CSA:

- 4-methylmethcathinone (Mephedrone);

⁶⁵ It was offered as an amendment (S.Amdt. 2146) to S. 3187.

⁶⁶ 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 or CP-47,497 C8-homolog).

- 3,4-methylenedioxypropylamphetamine (MDPV);
- 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E);
- 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D);
- 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C);
- 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I);
- 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2);
- 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4);
- 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);
- 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N); and
- 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

The Synthetic Drug Abuse Prevention Act of 2012 also extended the Attorney General's temporary scheduling authority. Prior to enactment of this act, the Attorney General (through the DEA) was able to temporarily place a substance on Schedule I of the CSA for one year, with a potential extension of six months. Now, once a substance is scheduled through this temporary scheduling process, it may remain on Schedule I for two years. The Attorney General then has the authority to keep the substance on Schedule I for an additional one year before it must be removed or permanently scheduled.

Issues

Congress may confront several issues when considering whether to schedule certain synthetic substances. These issues include potential implications on the federal criminal justice system, the influence of research on scheduling, possible effects of scheduling on future medical research, and the ability to use the Analogue Enforcement Act to enforce drug laws for synthetic substances of concern.

Implications of Scheduling

The scheduling of controlled substances has implications for the would-be violators of the CSA, as well as for the federal criminal justice system as a whole. Penalties for trafficking, manufacturing, and possession of Schedule I controlled substances range from fines to life in prison, depending on a number of factors pursuant to the crime. Factors considered in federal sentencing include, but are not limited to, the amount of drugs that is involved in the crime, the number of offenders, the type of drug, the number of prior offenses, and aggravating factors (e.g., death, weapons involved in the crime). For example, now that Congress has legislatively placed MDPV onto Schedule I of the CSA, anyone convicted of simple possession of this substance is subject to a minimum fine of \$1,000 and could be imprisoned for up to one year.⁶⁷ Of the inmates residing in federal prisons as of July 2013, and for whom offense data are known, nearly half

⁶⁷ 21 U.S.C. §844(a).

(89,669 or 46.8%) are serving sentences for federal drug offenses.⁶⁸ And of the 25,367 federal drug offenders known to have been sentenced for drug-related offenses, 6,134 were sentenced for marijuana-related offenses and 4,936 were sentenced for methamphetamine-related offenses in FY2012.⁶⁹ It is unknown whether or how the relative number of drug-specific offenders may change with the most recent addition of certain synthetic cannabinoids and stimulants to Schedule I.

The growing federal prison population and prison crowding continue to concern the Bureau of Prisons (BOP) and policymakers. The number of inmates under BOP jurisdiction facilities grew from 25,000 in FY1980 to 218,952 as of July 2013.⁷⁰ From FY2000 to FY2012, prison crowding grew from 32% over rated capacity to 38% over rated capacity, despite the fact that the number of facilities operated by BOP increased from 97 to 119. The growing federal prison population has not only resulted in more crowded prisons, but it has also strained BOP's ability to properly manage and care for federal inmates.⁷¹ Given that nearly half of the federal prison population is incarcerated for drug-related offenses, Congress may question the potential effect on the prison population and crowding now that it has scheduled additional substances. It is unknown whether BOP, in the current fiscal environment, is able to accommodate increases in the number of inmates.

Use of Research in Scheduling

There is consideration of drug research and data when the DEA and HHS seek to add a substance to Schedules I-V of the CSA.⁷² As required by the CSA, a drug must be evaluated on its history and current pattern of abuse; scope, duration, and significance of abuse; and risk to public health factors in order to be eligible for temporary or permanent scheduling by the Attorney General.⁷³ In the 2013 National Drug Strategy, the Office of National Drug Control Policy (ONDCP), notes that synthetic cathinones and cannabinoids are understudied substances, and there is limited research on these drugs.⁷⁴ This lack of research may influence whether the Attorney General (through the DEA) permanently schedules certain synthetic stimulants under the CSA. Of note, while Congress has scheduled several substances commonly marketed as “bath salts,” (including mephedrone and MDPV) Congress did not schedule the full array of substances that have been and may be marketed as such (e.g., methylone). The DEA permanently scheduled methylone on

⁶⁸ Federal Bureau of Prisons, *Quick Facts about the Bureau of Prisons*, July 27, 2013, <http://www.bop.gov/about/facts.jsp>. While there were 218,952 individuals in federal prisons, 176,423 of these inmates were in Bureau of Prisons facilities, 29,427 were in privately managed facilities, and 13,102 were in other contract facilities.

⁶⁹ U.S. Sentencing Commission, *2012 Sourcebook of Federal Sentencing Statistics*, Table 33, <http://www.ussc.gov>.

⁷⁰ For more information regarding the growing federal prison population, see CRS Report R42937, *The Federal Prison Population Buildup: Overview, Policy Changes, Issues, and Options*, by Nathan James; Federal Bureau of Prisons, *Quick Facts about the Bureau of Prisons*, July 27, 2013, <http://www.bop.gov/about/facts.jsp>.

⁷¹ U.S. Department of Justice, Bureau of Prisons, *FY2012 Performance Budget, Congressional Submission, Salaries and Expenses*, <http://www.justice.gov/jmd/2012justification/pdf/fy12-bop-se-justification.pdf>; *FY2013 Performance Budget, Congressional Submission, Salaries and Expenses*, <http://www.justice.gov/jmd/2013justification/pdf/fy13-bop-se-justification.pdf>; and *FY2014 Performance Budget, Congressional Submission, Federal Prison System, Salaries and Expenses*.

⁷² For more information on scheduling and the CSA, see archived CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*, by Brian T. Yeh.

⁷³ 21 U.S.C. §811.

⁷⁴ Office of National Drug Control Policy, *National Drug Control Strategy 2013*, p. 10, <http://www.whitehouse.gov/ondcp>.

Schedule I in April 2013, and may still consider temporary and permanent scheduling of not-yet-scheduled substances.

In contrast to what is required of HHS and the DEA, Congress is not statutorily required to consider research and data in its decision to schedule a drug under the CSA. In the past, Congress has exercised its scheduling authority by passing legislation to add drugs to the list of controlled substances, and Congress has cited public safety interests as the reason for taking legislative action. In 2000, for example, Congress passed legislation that provided for emergency scheduling of gamma hydroxybutyric acid (GHB), a synthetic stimulant also known as “liquid ecstasy.” In doing so, Congress cited GHB as “an imminent hazard to public safety that requires immediate regulatory action.”⁷⁵

Congress may debate whether to exercise its authority and pass legislation to permanently schedule certain synthetic drugs under the CSA. One related consideration is whether there is an imminent threat such that immediate scheduling through legislation may be more effective than the DEA and HHS carrying out the scheduling process laid out under the CSA. In doing so, policymakers may also consider how to best evaluate whether a particular substance is an imminent hazard or threat and whether Congress has reliable and valid standards for evaluating the potential threats posed by each substance of concern.

In addition to considering legislative actions surrounding synthetic substances, Congress may choose to exercise its oversight role in this area. Policymakers may evaluate whether the DEA and HHS are effectively and efficiently evaluating each identified synthetic drug of concern and subsequently taking appropriate action.

Future Medical Research

Another issue for consideration is future medical research involving synthetic drugs. There is shared concern among researchers that adding certain synthetic substances to Schedule I could hinder medical research. The CSA does not prohibit research with Schedule I controlled substances, but it requires that researchers go through a registration process that involves approval from their associated institutions, an external review board, the U.S. Food and Drug Administration (under HHS), and the DEA.⁷⁶ Congress may consider whether or not placing certain synthetic drugs on Schedule I will hinder future research on these substances.

Controlled vs. Analogue Substances

As mentioned, the Controlled Substances Analogue Enforcement Act of 1986 treats controlled substance analogues as Schedule I controlled substances under the CSA; however, this only applies to analogues that are intended for human consumption. One possible barrier to prosecuting individuals for violations relating to synthetic substances such as “bath salts” that are marketed as “not intended for human consumption” may be proving that despite this labeling, these substances are indeed intended for consumption.

⁷⁵ P.L. 106-172.

⁷⁶ 21 CFR §1301.18.

In addition, the Analogue Enforcement Act requires that a substance must be chemically similar to a controlled substance in order to be considered an analogue. The DEA has noted that the chemical structure of a substance can be manipulated such that it is not chemically similar to a controlled substance but still produces effects that are pharmacologically similar to a Schedule I or Schedule II controlled substance.⁷⁷ These manipulations can continuously occur to stay ahead of researchers and law enforcement.

The DEA has also pointed out several prosecutorial challenges for using the Analogue Enforcement Act to prevent drug use and abuse. These challenges include the following:

- Each case requires additional investigation to determine whether the substance in question was “intended for human consumption” and can therefore be considered an analogue.
- A forensic chemist can testify to laboratory analysis that would identify a controlled substance in a case; however, to establish that a substance is an analogue, additional testimony from experts in other disciplines is needed.
- In cases involving potential analogue substances, experts must establish that the substance has a substantially similar chemical structure (and pharmacological effect) to a Schedule I controlled substance. The threshold for “substantially similar” is subjective and may differ from expert to expert.
- Establishing a substance as an analogue in one case does not carry over to other cases. Each case involving the potential analogue substance must separately establish that the substance is indeed an analogue.⁷⁸

While some may argue that the Analogue Enforcement Act is insufficient or too cumbersome to investigate and prosecute cases involving the wide range of potential analogues, others may disagree. On the one hand, scheduling each analogue substance under the CSA could allow more efficient prosecution of cases involving that particular substance. On the other hand, as the DEA and others have noted, the chemical structure of substances can be continuously manipulated, thus constantly creating new analogue substances that are not scheduled under the CSA. Policymakers may deliberate whether the pace of scientific research, drug scheduling by the Attorney General in consultation with the Secretary of HHS, and legislative scheduling by Congress is sufficient in response to the current synthetic drug problem. Congress may also consider whether the rapid creation of new analogues could outpace such scheduling, leaving the Analogue Enforcement Act as a more efficient method of prosecution.

The DEA has led major enforcement efforts against the synthetic drug industry in 2012 and 2013.⁷⁹ In July 2012, “Operation Log Jam” yielded the arrests of more than 90 individuals and the

⁷⁷ Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *The Dangers of Synthetic Cannabinoids and Stimulants*, 112th Cong., 1st sess., April 6, 2011, http://drugcaucus.senate.gov/hearing-4-6-11/DEA%20_Rannazzisi_%20testimony.pdf; Statement of the Honorable Michele Leonhart, Administrator, Drug Enforcement Administration before the United States House of Representatives Committee on Appropriations, Subcommittee on Commerce, Justice, Science, and Related Agencies, 113th Cong., 1st sess., April 12, 2013, <http://appropriations.house.gov/uploadedfiles/hhrg-113-ap19-wstate-leonhartm-20130412.pdf>.

⁷⁸ Ibid.

⁷⁹ Enforcement efforts were conducted jointly with U.S. Immigration and Customs Enforcement, with assistance from the Internal Revenue Service Criminal Investigations, U.S. Postal Inspection Service, U.S. Customs and Border (continued...)

seizure of more than five million packets of finished synthetic designer drugs and the ingredients to produce 13.6 million more packets.⁸⁰ In June 2013, the DEA announced enforcement actions in 35 states “targeting the upper echelon of dangerous designer synthetic drug trafficking organizations” as part of the cooperative operation, “Project Synergy.” According to the DEA, these enforcement actions involved retailers, wholesalers, and manufacturers, and exposed “the massive flow of drug-related proceeds back to countries in the Middle East and elsewhere.”⁸¹ Of note, the DEA stated that a number of “Project Synergy” cases will be prosecuted under the Analogue Enforcement Act.⁸²

In considering enforcement challenges identified by the DEA, Congress may consider whether to amend the CSA to better facilitate enforcement action against the illicit synthetic drug industry. Two bills have been introduced in the 113th Congress⁸³ that would address the enforcement and prosecution challenges identified by the DEA:

- The Synthetic Abuse and Labeling of Toxic Substances Act of 2013 (S. 1322; the SALTSA Act) would amend the CSA so that additional factors may be considered in determining whether a controlled substance analogue was intended for human consumption.
- The Protecting Our Youth from Dangerous Synthetic Drugs Act of 2013 (S. 1323) would, among other things, redefine “controlled substance analogue” to include “the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II,” and would make it illegal to import a controlled substance analogue “unless the controlled substance analogue is imported pursuant to such notification or declaration as the Attorney General may by regulation prescribe.”

(...continued)

Protection, Federal Bureau of Investigation, Food and Drug Administration’s Office of Criminal Investigations, and state and local law enforcement agencies.

⁸⁰ For more information, see U.S. Drug Enforcement Administration, *Nationwide Synthetic Drug Takedown*, DEA News, July 26, 2012, <http://www.justice.gov/dea/pubs/pressrel/pr072612.html>.

⁸¹ U.S. Drug Enforcement Administration, *Updated Results from DEA’s Largest-Ever Global Synthetic Drug Takedown Yesterday*, Headquarters News, June 26, 2013, <http://www.justice.gov/dea/divisions/hq/2013/hq062613.shtml>.

⁸² Ibid.

⁸³ In the 113th Congress, two other bills have been introduced that would address the synthetic drug issue. The Synthetic Cathinones Control Act of 2013 (H.R. 315; introduced in January 2013) would, among other things, direct the Attorney General to add certain synthetic drugs, including 3,4-methylenedioxymethcathinone (methylone), to Schedule I of the CSA. As mentioned, in April 2013, the Attorney General took administrative action to permanently place 3,4-methylenedioxy-N-methylcathinone (methylone) on Schedule I of the CSA.

The Synthetics are Dangerous Act of 2013 (H.R. 2148; introduced in May 2013) would, among other things, amend the purposes of the national youth anti-drug media campaign (as authorized under the Office of National Drug Control Policy Reauthorization Act of 1998) to include encouraging parents and other interested adults to discuss with young people the dangers of synthetic drug use.

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