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, the 112th Congress has demonstrated a renewed concern with the issue.

Synthetic drug abuse is reported to have dramatically increased between 2009 and 2011. Calls to poison control centers for incidents relating to harmful effects of synthetic cannabinoids and stimulants have increased at what some consider to be an alarming rate. The reported harmful effects of these 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 these drugs are unknown. Many states have responded to this issue by passing synthetic drug laws banning certain synthetic cannabinoids and stimulants.

In March 2011, the Attorney General—through the Drug Enforcement Administration (DEA)—used his temporary scheduling authority to place five synthetic cannabinoids on Schedule I of the Controlled Substances Act (CSA). In October 2011, the DEA used this temporary scheduling authority to add three synthetic stimulants to Schedule I. Concern over the reported increase in use of certain synthetic cannabinoids and stimulants has led some to call on Congress to legislatively schedule specific substances. This is, in part, because congressional action could permanently place certain substances onto Schedule I of the CSA more quickly than might occur through administrative scheduling actions authorized by the CSA.

Several bills have been introduced in the 112th Congress that confront the issue of synthetic drug use and abuse. These include the Combating Dangerous Synthetic Stimulants Act of 2011 (H.R. 1571, S. 409); the Synthetic Drug Control Act of 2011 (H.R. 1254) and its companion bill—the Dangerous Synthetic Drug Control Act of 2011 (also known as the David Mitchell Rozga Act, S. 605); and the Combating Designer Drugs Act of 2011 (S. 839). While these bills differ substantively from one another, they all aim to legislatively place various synthetic drugs on Schedule I of the CSA.

In considering permanent placement of specific 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 or not placing these synthetic drugs on Schedule I would hinder future medical research. In addition, Congress may consider whether it is more efficient to place these drugs on Schedule I of the CSA or to label them as analogue controlled substances under the Controlled Substances Analogue Enforcement Act.
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. 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. 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. 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 has led some to call on Congress to legislatively schedule specific substances. 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.

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 selected relevant legislation in the 112th Congress as well as issues for policymakers to consider.

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3 Synthetic cannabinoids are substances chemically produced to mimic tetrahydrocannabinol (THC), the active ingredient in marijuana.
5 For more information on the CSA and administrative scheduling actions, see “Scheduling of Synthetic Drugs: Controlled Substances Act.”
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). 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. 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. 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.

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

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7 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.
consumption) as a controlled substance under Schedule I. 10 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. 11

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. 12

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.” 13 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 one year. The Attorney General then has the authority to keep the substance on Schedule I for an additional six months before it must be removed or permanently scheduled.

Recent Temporary Drug Scheduling Actions

The two most recent temporary scheduling actions taken by the DEA were the October 2011 placement of three synthetic cathinones 14 and the March 2011 placement of five synthetic cannabinoids on the list of controlled substances under Schedule I of the CSA. Since 2002, the

14 Cathinones are central nervous system stimulants.
DEA has used this temporary scheduling authority on 10 substances, outlined in Table 1. Prior to 2002, the most recent time DEA exercised this authority was in 1995.\(^{15}\)

**Table 1. DEA Temporary Drug Scheduling Actions**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Natural/Synthetic</th>
<th>Temporary Scheduling Date</th>
<th>Temporary Scheduling Extension</th>
<th>Permanent Scheduling</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-methyl-N-methylcathinone (mephedrone)</td>
<td>Synthetic</td>
<td>10/21/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>3,4- methylenedioxy-N-methylcathinone (methylone)</td>
<td>Synthetic</td>
<td>10/21/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>3,4- methylenedioxypyrovalerone (MDPV)</td>
<td>Synthetic</td>
<td>10/21/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1-pentyl-3-(1-naphthoyl)indole (JWH-018)</td>
<td>Synthetic</td>
<td>3/1/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1-butyl-3-(1-naphthoyl)indole (JWH-073)</td>
<td>Synthetic</td>
<td>3/1/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)</td>
<td>Synthetic</td>
<td>3/1/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxyacyclohexyl]-phenol (CP-47,497)</td>
<td>Synthetic</td>
<td>3/1/2011</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxyacyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue)</td>
<td>Synthetic</td>
<td>3/1/2011</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>


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

Excluding the three substances that were temporarily scheduled on October 21, 2011, and the five substances that were temporarily scheduled on March 1, 2011, the other five substances were all

- initially placed on Schedule I through the DEA’s use of its temporary scheduling authority,
- given a six-month temporary extension on Schedule I, in accordance with the DEA’s temporary scheduling authority, and then
- permanently placed on Schedule I of the CSA.

Of note, the last 13 substances to have been temporarily (and, for five 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. Recently, 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.

**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. 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. 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 “Genie,” “Yucatan Fire,” “Sence,” “Smoke,” “Skunk,” and “Zohai,” among others.

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 psychological effects. We never intended them for human consumption.”

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 sleepiness, 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.

In at least one case, synthetic marijuana has been blamed for a fatality when an Iowa teen

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16 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.


committed suicide reportedly following a K2-induced panic attack. The American Association of Poison Control Centers (AAPCC) has noted that poison control centers around the country received 5,083 calls about synthetic cannabinoid substances in the first nine months of 2011. Poison control centers reported 2,915 calls about synthetic cannabinoid substances in 2010, up from a reported 14 calls in 2009.

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. The 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).

Pursuant to the temporary scheduling authority, these substances will remain on the list of Schedule I controlled substances for one year, and then may be given one six-month temporary extension. To remain on Schedule I thereafter, the substances would need to be permanently scheduled within the CSA. By mid-August 2011, at least 38 states had legislatively banned chemical substances contained in synthetic cannabinoids, and 11 states had legislation pending. The U.S. military has also banned personnel from possessing or using these substances.

### 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 the “most widely abused, domestically produced synthetic drug in the United States.”30 According to the 2010 National Survey on Drug Use and Health (NSDUH), there were approximately 353,000 current (in the past month) users of methamphetamine age 12 or older—similar to the number of current users annually from 2007 through 2009.31 Illicit methamphetamine manufacture and abuse have been long-standing problems in some states and regions of the country. The National Drug Intelligence Center (NDIC) predicts that domestic availability of methamphetamine may rise in the future because of increased availability of Mexican-produced methamphetamine.32

Another trend that may change 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.33 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 method. 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.34 Similarly, in the first two months of 2011, the Owensboro, KY, Police Department responded to 14 methamphetamine labs, most of which were also one-pot labs.35

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.36

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Other Stimulants

One current trend in synthetic stimulants is the appearance of synthetic cathinones, often labeled as “bath salts.”[37] 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,” “Scarf,” and “Hurricane Charlie,” among others.[38] 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.[39]

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.[40] Because MDPV and other amphetamine-like chemicals act as stimulants, they present a high risk for abuse and addiction.[41] There have also been reports of MDPV users craving the substance.[42] 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.[43] However, their actual effects are not yet known. Poison control centers across the United States received 303 calls about bath salts in 2010, and 5,226 such calls between January 1, 2011, and September 30, 2011.[44]

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.[45] The three substances are

- mephedrone,
- methylone, and
- MDPV.

[37] 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.
[40] MDPV, methylone, and mephedrone are not approved for medical use in the United States.
As provided through the DEA’s temporary scheduling authority, these three synthetic stimulants will remain on the list of Schedule I controlled substances for one year. As of mid-August 2011, at least 30 states had banned chemical substances contained in synthetic stimulants such as bath salts, and at least 9 states had legislation pending.

Selected Legislation in the 112th Congress

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. Several bills have been introduced in the 112th Congress that would confront the emerging issue of synthetic drug use and abuse. While these bills differ substantively from one another, they all aim to legislatively place various synthetic drugs on Schedule I of the CSA.

The Combating Dangerous Synthetic Stimulants Act of 2011 (H.R. 1571, S. 409) focuses on the issue of synthetic stimulants such as those marketed as “bath salts.” It would add 4-methylmethcathinone (mephedrone) and 3,4-methylenedioxypyrovalerone (MDPV) to the list of substances under Schedule I of the CSA. Neither the House nor the Senate version of this bill, however, would add 3,4-methylenedioxy-N-methylcathinone (methylone)—one of the drugs on which the DEA used its temporary scheduling authority. The Senate Committee on the Judiciary favorably reported S. 409 on July 28, 2011.

The Synthetic Drug Control Act of 2011 (H.R. 1254) and its companion bill, the Dangerous Synthetic Drug Control Act of 2011 (also known as the David Mitchell Rozga Act, S. 605) would add cannabimimetic substances—synthetic substances that mimic cannabis or marijuana—to the list of Schedule I substances under the CSA. Specifically, these bills would also add to Schedule I:

- 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).

In addition to the cannabimimetic substances, the Synthetic Drug Control Act of 2011 (H.R. 1254) would also place the following synthetic stimulants under Schedule I:

• 4-methylmethcathinone (mephedrone);
• 3,4-methylenedioxypyrovalerone (MDPV);
• 3,4-methylenedioxymethcathinone (methylone);
• Naphthylpyrovalerone (naphyrone);
• 4-fluoromethcathinone (flephedrone);
• 4-methoxymethcathinone (methedrone; Bk-PMMA);
• Ethcathinone;
• 3,4-methylenedioxyethcathinone (ethylone);
• Beta-keto-N-methyl-3,4-benzodioxoylybutanamine (butylone);
• N,N-dimethylcathinone (metamfepramone);
• Alpha-pyrrolidinopropiophenone (alpha-PPP);
• 4-methoxy-alpha-pyrrolidinopropiophenone (MOPPP);
• 3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (MDPPP);
• Alpha-pyrrolidinoveralophenone (alpha-PVP); and
• 6,7-dihydro-5H-indeno(5,6-d)-1,3-dioxal-6-amine) (MDAI).

Of note, the first three substances on this list are those that the DEA temporarily scheduled on October 21, 2011. Further, both H.R. 1254 and S. 605 would extend from one to two years the DEA’s (via the Attorney General) temporary scheduling authority and would expand the possible extension period from six months to one year. On July 21, 2011, the House Committee on Energy and Commerce, Subcommittee on Health, held a hearing on H.R. 1254. The subcommittee marked up the bill on July 26, 2011, and forwarded it to the full committee. It was then ordered reported on July 28, 2011. In addition, the House Committee on the Judiciary began consideration of H.R. 1254 on October 27, 2011. The Senate Committee on the Judiciary favorably reported S. 605 on July 29, 2011.

The Combating Designer Drugs Act of 2011 (S. 839) would add a number of hallucinogenic drugs to Schedule 1 of the CSA:

• 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 DEA has not used its temporary scheduling authority to temporarily schedule any of these substances. The Senate Committee on the Judiciary favorably reported S. 839 on July 28, 2011.

**Issues**

The 112th 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, if Congress chose to place MDPV onto Schedule I of the CSA, anyone convicted of simple possession of this substance would be subject to a minimum fine of $1,000 and could be imprisoned for up to one year. Of the inmates residing in federal prisons as of September 2011, and for whom offense data are known, more than half (101,929 or 50.4%) were serving sentences for federal drug offenses—including simple possession. And of the 24,366 federal drug offenders known to have been sentenced for drug-related offenses, 6,336 were sentenced for marijuana-related offenses and 4,309 were sentenced for methamphetamine-related offenses in 2010. It is unknown whether or how the relative number of drug-specific offenders would change if certain synthetic cannabinoids and stimulants were added to Schedule I.

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49 Federal Bureau of Prisons, *Quick Facts about the Bureau of Prisons*, September 24, 2011, http://www.bop.gov/news/quick.jsp. While there were 217,363 individuals in federal prisons, 180,725 of these inmates were in Bureau of Prisons facilities, 22,939 were in privately managed facilities, and 13,699 were in other contract facilities.
The growing federal prison population and prison crowding continue to be concerns for the Bureau of Prisons (BOP) as well as for policymakers. The number of inmates held in BOP facilities grew from 125,560 in FY2005\textsuperscript{51} to 180,725 as of September 2011. From FY2000–FY2010, prison crowding grew from 32\% over rated capacity to 37\% over rated capacity, despite the fact that the number of facilities operated by BOP increased from 97 to 116. 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.\textsuperscript{52} Given that a majority of the federal prison population is incarcerated for drug-related offenses, Congress may question the potential effect on the prison population and crowding should it move to schedule additional substances. It is unknown whether BOP, in the current fiscal environment, is able to accommodate increases in the number of inmates and the number of inmates requiring special services.

**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.\textsuperscript{53} 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.\textsuperscript{54} The Director of the Office of National Drug Control Policy (ONDCP), R. Gil Kerlikowske, issued a statement on bath salts in February 2011 in which he noted a lack of sufficient data regarding the prevalence of bath salt stimulant drugs.\textsuperscript{55} This lack of data may influence whether the Attorney General (through the DEA) permanently schedules such synthetic stimulants under the CSA.

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.”\textsuperscript{56}

Congress may debate whether to exercise its authority and pass legislation to permanently schedule synthetic drugs under the CSA. One related consideration is whether there is an

\textsuperscript{51} Data provided to CRS by the Bureau of Prisons. For more information, see CRS Report R41721, Commerce, Justice, Science, and Related Agencies: FY2012 Appropriations, coordinated by Nathan James, Jennifer D. Williams, and John F. Sargent Jr.


\textsuperscript{53} For more information on scheduling and the CSA, see archived CRS Report RL34635, The Controlled Substances Act: Regulatory Requirements, by James E. Nichols and Brian T. Yeh.

\textsuperscript{54} 21 U.S.C. §811.


\textsuperscript{56} P.L. 106-172.
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. The DEA has noted that “unilateral action by the Congress to place these dangerous substances [mephedrone and MDPV] 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.”\footnote{57} In other words, the DEA has recommended that Congress legislatively schedule these substances.

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 the future medical research involving synthetic drugs. There is shared concern among researchers that adding these substances to Schedule I could hinder medical research. As previously mentioned, Professor Huffman did not intend for K2 to be consumed by humans. He is, however, against adding synthetic cannabinoids to Schedule I, asserting that there is still much to learn about synthetic cannabinoids and that placing them on Schedule I would create too many hurdles for researchers who need to access these drugs.\footnote{58} Professor Huffman has created several synthetic cannabinoids that are seen as showing promise in treating skin cancers, pain, and inflammation.\footnote{59}

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.\footnote{60} 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.


\footnote{58} Email correspondence with Dr. John W. Huffman, Professor Emeritus of Chemistry at Clemson University, October 12, 2011.


\footnote{60} 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. 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.

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.

62 Ibid.
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