



Model Controlled Substance Analogue Act

September 2018 (original version published in 2014).

This project was supported by Grant No. G1799ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

Model Controlled Substance Analogue Act

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Model Controlled Substance Analogue Act

Policy Statement and Background

The emergence and proliferation over the past 10 years of manufactured drugs designed to mimic the effects of controlled substances is a significant public health threat facing the United States and other countries today. With unfortunate regularity, communities are experiencing outbreaks of localized overdoses or bad reactions due to the ingestion of one or more of these substances.¹ Colloquially referred to as “synthetic drugs” or “designer drugs,” the United Nations Office on Drugs and Crime (“UNODC”) uses the terms “new psychoactive substances” or “novel psychoactive substances” (“NPS”) to describe them. UNODC’s definition of NPS is “substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat.”²

NPS fall into several structural categories that include synthetic cannabinoids (also known as “synthetic marijuana,” “spice,” or “K2”), substituted cathinones (also known as “bath salts”), phenethylamines, opioids, tryptamines, benzodiazepines, and several others. According to UNODC’s World Drug Report 2018, in the nine years between 2009 and 2017, over 100 different countries report encountering more than 800 different NPS. The 800+ substances reported to UNODC during those years include more than 250 different synthetic cannabinoids, and approximately 150 different substances in each of the cathinone, phenethylamine, and “other” (which include fentanyl analogues and benzodiazepines) categories.³

The concerns about NPS stem from several factors. First, ingesting NPS can cause a number of serious health problems, including increased heart rate, increased blood pressure, agitation, anxiety, nausea, vomiting, tachycardia, tremors, seizures, hallucinations, paranoid behavior, non-responsiveness, and death. Second, products containing NPS are readily available to buyers, including at convenience stores, gas stations, and via online sellers, sometimes in packaging that appears designed to attract teenagers and young adults. Third, the clandestine chemists developing NPS often reconfigure the chemical structures of their products to create unregulated

¹ As one in a sea of examples, within the span of two days in July 2018, reports in Philadelphia and Washington, D.C. described recent overdose spikes caused in whole or in part by synthetic drugs. Marisa Penaloza, *D.C. Has Had More Than 300 Synthetic Marijuana Overdoses in 2 Weeks*, NPS (July 28, 2018), <https://www.npr.org/2018/07/27/632261920/d-c-has-had-more-than-300-suspected-k2-overdoses-in-2-weeks>; Joel Wolfram, *Synthetic marijuana detected in drug sample from Philly overdose spike*, WHYY (July 27, 2018), <https://whyy.org/articles/synthetic-marijuana-detected-in-drug-sample-from-philly-overdose-spike/>.

² UNODC *Early Warning Advisory on New Psychoactive Substances*, UNODC.org, <https://www.unodc.org/LSS/Page/NPS> (last visited Aug. 3, 2018)

³ UNODC, *World Drug Report 2018* 60 (June 2008), http://www.unodc.org/wdr2018/prelaunch/WDR18_Booklet_3_DRUG_MARKETS.pdf.

versions of drugs in an effort to circumvent controlled substance laws. Indeed, in some countries, people refer to certain NPS as “legal highs,” because of the belief (whether accurate or mistaken) that local drug prohibitions do not apply.

Ideally, any comprehensive approach to reducing NPS misuse should address at least: (1) prevention including education about the dangers of use; (2) ensuring adequate resources devoted to intervention, treatment, recovery supports; and (3) supply reduction primarily through law enforcement action. Supply reductions include decreasing the amount of NPS as well as strengthening deterrence by increasing the likelihood that an NPS manufacturer/distributor/seller faces consequences for his or her conduct, via criminal penalties, economic losses, or both.

One available avenue for reducing NPS supply is classifying each substance that presents a threat to public health as a controlled substance. By doing so, state and federal restrictions on the manufacture and sale of controlled substances can be applied to NPS. The ever-changing chemical structure of emerging substances makes this task difficult. By the time that policymakers can move from the initial discovery of a new substance to permanent scheduling as controlled (which can take over a year in some jurisdictions), a different substance replaces the old one and the process must restart. Accordingly, the National Alliance for Model State Drug Laws (“NAMSDL”) recommends a multi-faceted approach to controlled substance scheduling containing each of these aspects: (1) a robust set of regularly updated controlled substance schedules covering as many NPS as possible; (2) a method to schedule emerging NPS on an expedited (yet temporary) basis, while authorities decide whether, and work through the more timing consuming process, to schedule on a permanent basis; and (3) a means by which a yet-to-be-scheduled analogue can be treated as a controlled substance even before the temporary scheduling period begins.

NAMSDL’s Model Controlled Substance Analogue Act addresses aspect (3) above. The term “controlled substance analogue” (also spelled “analog”) is a legal term of art defined by applicable federal or state law. In general, the term refers to a yet-to-be-scheduled substance with a chemical structure and effect on humans that is similar enough to a controlled substance that the law treats it as one. The purpose of an analogue law is to allow law enforcement to prosecute the manufacture, distribution, or sale of a substance with harmful health effects as early as the first encounter, rather than waiting until the substance is scheduled. However, successfully prosecuting such an action is resource intensive. In these cases, law enforcement must prove to a judge or jury both the similarity between the substance in question and a controlled substance and that the defendant had knowledge of this similarity. As such proof is not required once a substance is scheduled, states should strive to limit the time in which an emerging harmful substance falls only under analogue provisions.

Both U.S. federal law, and the Uniform Controlled Substances Act (“UCSA”), define “controlled substance analogue,” albeit with a slight grammatical difference between the two definitions.⁴ As

⁴ 21 U.S.C. § 802 (32); Uniform Controlled Substances Act § 101(3) (1995).

of 2017, the laws of 38 states and the District of Columbia define “analogue” or a term akin to it. Unfortunately, there is some ambiguity in the proper construction of the federal definition and considerable variation in state law definitions, with only 22 jurisdictions having a definition that tracks closely with federal law/UCSA.⁵ A common requirement of “analogue” definitions is that the substance being considered have a chemical structure that is “substantially similar to” a controlled substance. Complicating this determination is the fact that there is no scientific standard for substantial similarity in chemical structure, leaving this as an issue for litigation in individual cases. Moreover, under federal and many states’ laws (and UCSA), an analogue must be “intended for human consumption” in order for controlled substance treatment to apply. As a result, products containing harmful NPS are intentionally mislabeled as “not for human consumption” in an effort to avoid this provision.

The purpose of this Model Act is to address the deficiencies present in state analogue laws derived from federal law or the UCSA by clarifying the definition of an analogue and setting out factors for consideration in determining whether an emerging substance is one. In particular, Section III provides several objective definitions of the phrase “substantially similar to,” each based upon a currently-in-force state law, that could be used to make the analogue determination easier. Additionally, the Act removes the requirement that an analogue be “intended for human consumption” in order for treatment as a controlled substance to apply. Finally, the Act proposes creating an interagency committee to make analogue determinations, thereby eliminating in many cases the need to make that determination at trial.

⁵ Jonathan Woodruff, *Current State Laws Addressing Novel Psychoactive Substances and Controlled Substance Analogues*, NAMSDL News – Subject Matter Analysis (May 25, 2017), <http://namsdl.dynamicwebware.com/News%20Tab/NAMSDL%20News/NAMSDL%20News%20May%2025%202017.pdf> (last visited Aug. 3, 2018).

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Highlights

- Clarifies that to be a controlled substance analogue, a substance must be substantially similar to a controlled substance *and* must either have a substantially similar effect on the body or is intended to have such an effect.
- Provides three options for an objective definition of “substantially similar to.”
- Sets out required and recommended factors for consideration when determining whether a substance is a controlled substance analogue.
- Provides that an analogue shall be treated as a Schedule I substance regardless of any evidence of actual human consumption.
- Requires notification of the controlled substance scheduling authority of a prosecution involving an analogue.
- Establishes an interagency advisory committee to designate substances as analogues.

SECTION I. SHORT TITLE.

This Act is known and may be cited as the “Model Controlled Substance Analogue Act” (the “Act”).

SECTION II. PURPOSE

The purpose of this Act is to amend existing state controlled substances acts by providing a framework to legally treat an emerging substance with potentially harmful health effects that is similar in chemical structure to a controlled substance—an analogue—as a controlled substance prior to the substance being scheduled.. The Act improves upon analogue laws derived from federal law or the Uniformed Controlled Substances Act (“UCSA”) by clarifying the definition of an analogue, setting out required and recommended factors for consideration during the determination, and creating an interagency committee tasked with making such determinations.

SECTION III. DEFINITION OF ANALOGUE.⁶

- 1) Except as provided below, the term “controlled substance analogue” means a capsule, pill, powder, product, or other substance, however constituted:
 - a) The chemical structure of which is derivative of, or substantially similar to, the chemical structure of a controlled substance; and
 - b) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system

⁶ Section III, Subsections (1) and (3) are based on the definitions of “analogue” contained in 21 U.S.C. § 802(32) and Tenn. Code. Ann. § 39-17-454. The use of “and” and “or” in Subsection (1) clarifies that in order to meet the definition of an “analogue,” a substance must meet the requirement of Subsection (1)(a) and either (1)(b) or (1)(c), thereby avoiding the debate over how the federal definition should be interpreted. This same change to the federal definition of “analogue” is proposed in current Congressional legislation (e.g. H.R. 2851, 115th Cong. § 8 (2018)).

In addition, there is no consensus in methodology for determining whether the chemical structure of a substance is “substantially similar to” another substance. Indeed, the Scientific Working Group for the Analysis of Seized Drugs (“SWGDRUG”), in its June 2016 recommendations concerning analogues, notes that evaluations of similarity should be made “using a variety of techniques and approaches depending on the specific question being addressed.” SWGDRUG, Recommendations: Version 7.1 (June 2016), <http://www.swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%207-1.pdf>. Accordingly, in what is perhaps an effort to promote consistency among such subjective determinations, several states have added objective elements to state law definitions of “controlled substance analogue.” In Subsection III(2), this Act provides three objective elements as definitions of “substantially similar to.” Subsection (2)(a) is based on Tenn. Code Ann. § 39-17-454. Subsection (2)(b) is based on South Dakota Code § 34-20b-1. Subsection (2)(c) is based on the Utah Bureau of Forensic Services Chemistry Procedure Manual.

- that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance; or
- c) With respect to a particular person, which such person represents or intends to have the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance; or
 - d) Which has been designated as a controlled substance analogue by the Controlled Substance Analogue Committee pursuant to the Section VIII of this Act.
- 2) As used in this section, the term “substantially similar to” means any of the following:
- a) the capsule, pill, powder, product, or other substance differs in no more than two (2) atoms, one (1) functional group, or any combination thereof, from the structure of a controlled substance. A functional group being that of an alkyl, alkene, alkyne, arene, haloalkane, haloalkyne, haloalkene, aromatic halide, alcohol, ether, amine, aldehyde, ketone, carboxylic acid, ester, or amide group;
 - b) the capsule, pill, powder, product, or other substance: (1) differs in its chemical structure to a controlled substance only by substituting one or more hydrogens with halogens or by substituting one halogen with a different halogen; or (2) is an alkyl homolog of a controlled substance; or
 - c) the substance in question shares a common core structure (the central portion of the molecule is the same) with a controlled substance in schedules I or II and has only one point of divergence from the controlled substance.
- 3) “Controlled substance analogue” does not include:
- a) a controlled substance;
 - b) any substance for which there is an approved new drug application;
 - c) any substance, for which an exemption is in effect for investigational use under 21 U.S.C.A § 355, to the extent conduct with respect to the substance is pursuant to such exemption; or
 - d) Any compound, mixture, or preparation that contains any controlled substance or controlled substance analogue that is not for administration to a human being or animal,

and that is packaged in such a form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

SECTION IV. TREATMENT OF ANALOGUES.⁷

- 1) A controlled substance analogue shall be treated, for the purposes of the [state Controlled Substances Act or equivalent act addressing controlled substances], as a substance included in Schedule I.
- 2) Within [] days after the initiation of a prosecution with respect to a controlled substance analogue by indictment or information, the [prosecuting attorney] shall notify [the controlled substance scheduling authority] of information relevant to expedited scheduling of the substance. Upon a final determination that the controlled substance analogue should not be scheduled, no prosecution relating to that substance as a controlled substance analogue may be commenced or continued.

SECTION V. DETERMINATION OF ANALOGUE – SCIENTIFIC OR PHARMACOLOGICAL FACTORS.⁸

In determining whether a substance is a controlled substance analogue, the following scientific or pharmacological factors may be considered, along with any other relevant factors:

- 1) Its actual or relative potential for abuse;
- 2) Scientific evidence of its pharmacological effect, if known;
- 3) The state of current scientific knowledge regarding the substance;
- 4) The history of the substance and its current pattern of abuse;

⁷ Section IV is based on Uniform Controlled Substances Act § 214 (1995), except that the requirement that an analogue be “intended for human consumption” is removed. This section provides that a controlled substance analogue be treated as a schedule I substance. In addition, Subsection (2) requires that law enforcement must notify the state’s controlled substance scheduling authority of the intention to prosecute a case under the Act so that the analogue can be considered for expedited scheduling.

⁸ Section V is based on Tenn. Code Ann. § 39-17-454. This section lists several scientific factors that may be considered by law enforcement and judicial officials in determining whether a substance is a controlled substance analogue. These factors stem from the experiences of the courts in confronting the problem of NPS and analogues.

- 5) The scope, duration and significance of abuse;
- 6) What, if any, risk there is to the public health;
- 7) Its psychological or physiological dependence liability; or
- 8) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

SECTION VI. EVIDENCE OF HUMAN CONSUMPTION.⁹

Evidence of human consumption by an individual or the public at large is not necessary before a substance may be found to be a controlled substance analogue. In addition, the fact that a substance was marketed, advertised, or labeled as “not for human consumption” does not preclude a finding, based on all the evidence, that the substance is a controlled substance analogue.

SECTION VII. DETERMINING KNOWLEDGE.¹⁰

In determining whether a defendant has knowledge that a substance is a controlled substance analogue, the following factors, viewed alone or in totality, shall be considered, along with any other relevant factors:

- 1) the difference between the substance’s selling price and the typical sales price of the product the substance is purported to be;
- 2) the substance’s diversion from legitimate channels, and its clandestine importation, manufacture, or distribution;
- 3) whether the defendant reasonably knew the substance was intended to be consumed by the

⁹ Section VI is based on S.1323, 113th Cong. (2013) and S.207, 115th Cong. (2017). This section allows classification of a substance as an analogue even if there is no evidence of human consumption. It also makes clear that in the absence of evidence of human consumption, the fact that a substance is marked as “not for human consumption” does not prevent classifying it as an analogue.

¹⁰ Section VII is based on Tenn. Code Ann. § 39-17-454. This section lists several factors pertaining to the defendant’s knowledge that must be considered by law enforcement and judicial officials in determining whether a substance is a controlled substance analogue. These factors stem from the experiences of the courts in confronting the problem of NPS and analogues.

final purchaser; or

- 4) comparisons between the circumstances of the sale of the substance at issue and accepted methods of marketing a legitimate nonprescription drug for medicinal purposes, including:
 - a) the packaging of the substance and its appearance in overall finished dosage form;
 - b) oral or written statements or representations concerning the substance;
 - c) the methods by which the substance is distributed; and
 - d) the manner in which the substance is sold to the public.

SECTION VIII. CONTROLLED SUBSTANCE ANALOGUE COMMITTEE.¹¹

- 1) The [state controlled substance scheduling authority], in consultation with [the state Secretary/Director of Health and Human Services and the Secretary/Director of the state Department of Public Safety], shall establish an interagency committee, to be known as the Controlled Substance Analogue Committee (the “Committee”).
- 2) The Committee shall be headed by the [Administrator/Director] of the [state scheduling authority] and shall be comprised of:
 - a) scientific experts in the fields of chemistry and pharmacology, as designated by:
 - i) the [state] Department of Health and Human Services;
 - ii) the [state] Department of Public Safety;
 - iii) the [state] office of drug control policy [or similar body];
 - iv) the [state] Board of Pharmacy;
 - v) the [state] Board of Medicine;
 - vi) the [state] Department of Forensic Science;
 - vii) the [state] Police Department;
 - viii) the [state] single state authority on drugs and alcohol; and
 - ix) any other agency determined by the [state scheduling authority], in consultation with [the state Secretary of Health and Human Services and the Director of the state Department of Public Safety], to be appropriate;

¹¹ The genesis of Section VIII is S.1323, 113th Cong. (2013). This section creates a standing committee whose function is to meet as needed to designate emerging substances as analogues by rule.

- b) local law enforcement experts, including but not limited to one designee of the [state police chiefs association], one designee of the [state association of narcotics law enforcement officers], and one designee of the [state district attorneys association]; and
 - c) addiction treatment and recovery experts, including but not limited to a person designated by the [statewide recovery organization].
- 3) Committee procedure
- a) The Committee shall convene, on an as needed basis, to establish and maintain a list of controlled substance analogues.
 - b) A substance may be designated as a controlled substance analogue by the Committee under this subsection if the substance is determined by the Committee to be similar to a Schedule I or II controlled substance in either its chemical structure or its predictive effect on the body, in such a manner as to make it likely that the substance will, or can be reasonably expected to have, a potential for abuse.
 - c) The [scheduling authority] shall, through rulemaking, establish procedures of operation for the Committee.
- 4) Notice of meetings
- a) Not later than [a minimum of 30 days] before each meeting of the Committee, the [scheduling authority] shall submit to [the Secretary of Health and Human Services] a notice of the meeting of the Committee, which shall include:
 - i) a list of the substances to be considered by the Committee during the meeting for designation as a controlled substance analogue; and
 - ii) a request for [the Secretary of Health and Human Services] to make a determination of whether an exemption or approval for each substance listed under clause (i) is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).
 - b) Not later than [30 days] after the date on which [the Secretary of Health and Human Services] receives notice under subparagraph (A), the [Secretary] shall submit to the [scheduling authority] a written response to the request described under subparagraph

(A)(ii). The Committee shall consider the response submitted by [the Secretary of Health and Human Services] in determining whether to designate a substance considered by the Committee at the meeting as a controlled substance analogue.

5) Publishing of designation

- a) The [scheduling authority] shall publish in the [State Register or equivalent public notice] any designation made by the Committee under this subsection.
- b) The [Administrator/Director] of the [state scheduling authority] shall publish, on the website of the [state scheduling authority], a designation made by the Committee under this subsection, which shall include –
 - i) the chemical and common name of the controlled substance analogue;
 - ii) the effective date of the determination, as described in paragraph (6); and
 - iii) any Schedule I or II controlled substance that the Committee has determined a substance is the analogue of.

6) A designation made by the Committee under this subsection shall take effect on the date that is [30 days] after the date on which the designation is published in the [State Register or equivalent public notice] under paragraph (5)(A). Such designation shall not provide a defense to a prosecution brought under either Section II(1)(a), (b) or Section II(1)(a), (c) prior to the designation's effective date.

7) If a substance designated as a controlled substance analogue by the Committee under this section is subsequently scheduled through a legislative or rulemaking proceeding, the substance shall be automatically removed from the controlled substance analogue list.

8) If a defendant challenges the designation of a controlled substance analogue made by the Committee under this subsection, the issue shall be considered a question of law.

SECTION IX. RULES AND REGULATIONS.

State agencies and officials shall promulgate rules and regulations necessary to implement their responsibilities under this Act.

SECTION X. SEVERABILITY.

If any provision of this Act or application thereof to any individual or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provisions or applications, and to this end, the provisions of this Act are severable.

SECTION XI. EFFECTIVE DATE.

This Act shall be effective on [specific date or reference to normal state method of determination of the effect.]