Model Controlled Substances Analogue Statute

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Policy Statement

The United States is experiencing a growing problem with novel psychoactive substances (i.e., synthetic drugs) and controlled substance analogues. Federal and state drug statutes control substances by listing them in their controlled substances act as a Schedule I, II, III, IV, or V substance. Each substance is listed according to its precise chemical structure. However, in today's world of the internet, no sooner is a substance made illegal than another appears to take its place. Novel psychoactive substances are cheap, easy to make, and return a high profit for manufacturers, distributors, and retailers. Novel psychoactive substances, particularly synthetic cannabinoids, substituted cathinones, and other synthetic substances, are sold as "legal" highs in convenience stores, gas stations, "head" shops, discount beer and tobacco shops, and on the internet. Typically, these substances are sold as "herbal incense," "bath salts," "plant food," "jewelry cleaner," and are labeled "not for human consumption."

In 2010, the American Association of Poison Control Centers ("AAPCC") received 2,906 calls relating to exposures to synthetic marijuana and 304 calls relating to exposures to bath salts (substituted cathinones). In 2011, the AAPCC received 6,959 calls relating to exposures to synthetic marijuana and 6,138 calls relating to exposures to bath salts. Those numbers dropped significantly in 2012 with the AAPCC receiving 5,202 calls relating to exposures to synthetic marijuana and 2,655 calls relating to exposures to bath salts. As of October 31, 2013, the AAPCC has received 2,222 calls relating to exposures to synthetic marijuana and 833 calls relating to exposures to bath salts.

Scheduling each of these substances as they appear can be a long process during which time more people may be injured through the use of a substance they believe to be harmless because they purchased it at their local gas station. Most current federal and state controlled substance analogue statutes are ineffective against these substances because there isn't enough scientific research to prove that the substance is substantially similar to a controlled substance or because it is difficult to prove that a substance labeled "not for human consumption" is intended to be ingested or otherwise consumed by humans.

The Model Law attempts to make it easier for judicial officials and law enforcement to take measures to address the problem of controlled substance analogues by clarifying what elements must be proven, setting parameters for determining that a substance is an analogue of a scheduled controlled substance, and setting out factors to be considered in determining whether a substance is an analogue.

Highlights of the Model Controlled Substances Analogue Statute

- Sets out parameters for what does not constitute a controlled substance analogue and provides language for dealing with substances labeled "not for human consumption."
- Lists factors to be considered to help determine whether a substance is a controlled substance analogue.
- Provides for a committee to temporarily schedule new analogues on an emergency or expedited basis as needed.
- Provides that an analogue shall be treated as a Schedule I substance and for emergency scheduling of such substance.
- Sample language 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* that is intended to have an effect on the body and provides guidance regarding what constitutes "substantially similar."

Section One. Controlled Substance Analogue Factors.

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

(i) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold;
(ii) Its diversion from legitimate channels, and its clandestine importation, manufacture, or distribution;
(iii) That the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means;
(iv) The defendant's prior convictions, if any, for a violation of any state or federal statute prohibiting controlled substances or controlled substance analogues; or
(v) Comparisons with accepted methods of marketing a legitimate nonprescription drug for medicinal purposes rather than for the purpose of drug abuse or any similar nonmedical use, 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.

COMMENT

THIS SECTION IS TAKEN IN PART FROM TENN. CODE ANN. § 39-17-454. SECTIONS ONE AND TWO LIST SEVERAL FACTORS TO BE CONSIDERED BY LAW ENFORCEMENT AND JUDICIAL OFFICIALS IN DETERMINING WHETHER A SUBSTANCE IS A CONTROLLED SUBSTANCE ANALOGUE. THESE FACTORS ARE BASED ON THE EXPERIENCES OF LAW ENFORCEMENT AND JUDICIAL OFFICIALS IN CONFRONTING THE PROBLEM OF NEW AND EMERGING SYNTHETIC DRUGS.

THESE TWO SECTIONS ARE INTENDED TO BE INCLUDED WITH THE DEFINITION OF "CONTROLLED SUBSTANCE ANALOGUE" TO PROVIDE GUIDANCE REGARDING WHAT MAY BE AN ANALOGUE OF A SCHEDULED SUBSTANCE.

Section Two. Scientific and Pharmacological Factors.

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:

(i) Its actual or relative potential for abuse;
(ii) Scientific evidence of its pharmacological effect, if known;
(iii) The state of current scientific knowledge regarding the substance;
(iv) The history of the substance and its current pattern of abuse;
(v) The scope, duration and significance of abuse;
(vi) What, if any, risk there is to the public health;

(vii) Its psychic or physiological dependence liability; or
(viii) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

COMMENT

THIS SECTION IS TAKEN IN PART FROM TENN. CODE ANN. § 39-17-454. SECTIONS ONE AND TWO LIST SEVERAL FACTORS TO BE CONSIDERED BY LAW ENFORCEMENT AND JUDICIAL OFFICIALS IN DETERMINING WHETHER A SUBSTANCE IS A CONTROLLED SUBSTANCE ANALOGUE. THESE FACTORS ARE BASED ON THE EXPERIENCES OF LAW ENFORCEMENT AND JUDICIAL OFFICIALS IN CONFRONTING THE PROBLEM OF NEW AND EMERGING SYNTHETIC DRUGS.

THESE TWO SECTIONS ARE INTENDED TO BE INCLUDED WITH THE DEFINITION OF "CONTROLLED SUBSTANCE ANALOGUE" TO PROVIDE GUIDANCE REGARDING WHAT MAY BE AN ANALOGUE OF A CONTROLLED SUBSTANCE.

Section Three. Evidence of Human Consumption.

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.

COMMENT

SECTION THREE IS TAKEN FROM CONGRESSIONAL S.B. 1323, 1ST SESSION OF THE 113TH CONGRESS. THIS SECTION IS INTENDED TO ALLOW A SUBSTANCE TO BE DECLARED AN ANALOGUE EVEN IF THERE IS NO EVIDENCE OF HUMAN CONSUMPTION.

Section Four. Controlled Substance Analogue Committee.

(A)(1) The [state scheduling authority], in consultation with [the Secretary of Health and Human Services and the Director of the Department of Public Safety], shall establish an interagency committee, to be known as the Controlled Substance Analogue Committee (referred to in this substance as the "Committee").

(2) The Committee shall be –

(A) headed by the [Administrator/Director] of the [state scheduling authority]
(B) comprised of scientific experts in the fields of chemistry and pharmacology designated by –
(i) [the Secretary of Health and Human Services];
(ii) [the Director of the Department of Public Safety];
(iii) the [state office of drug control policy or similar body];
(iv) the Board of Pharmacy;
(v) the Board of Medicine; and

(vi) any other agency determined by the [scheduling authority], in consultation with [the Secretary of Health and Human Services and the Director of the Department of Public Safety], to be appropriate.

(3)(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 rule-making, establish procedures of operation for the Committee.

(4)(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)(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).

(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.

COMMENT

SECTION FOUR IS TAKEN FROM CONGRESSIONAL S.B. 1323, 1ST SESSION OF THE 113TH CONGRESS. THIS SECTION CREATES A STANDING COMMITTEE WHOSE FUNCTION IS TO MEET AS NEEDED AND DESIGNATE EMERGING SUBSTANCES AS CONTROLLED SUBSTANCE ANALOGUES BY RULE.

Section Five. Controlled Substance Analogue Treated as Schedule I Substance.

A controlled substance analogue, must be treated, for the purposes of this [Act], as a substance included in Schedule I. Within [ ] days after the initiation of prosecution with respect to a controlled substance analogue by indictment or information, the [prosecuting attorney] shall notify the [appropriate person or agency] of information relevant to emergency scheduling. After 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.

COMMENT

THIS SECTION IS TAKEN FROM § 214 OF THE UNIFORM CONTROLLED SUBSTANCES ACT (1990). THIS SECTION PROVIDES THAT A CONTROLLED SUBSTANCE ANALOGUE BE TREATED AS A SCHEDULE I SUBSTANCE AND FURTHER PROVIDES FOR THE EMERGENCY SCHEDULING OF SUCH SUBSTANCE.

Section Six. Sample Definition Language.

THIS SECTION AND THE OPTIONS PROVIDED BELOW ARE ONLY SAMPLE LANGUAGE THAT A STATE MAY USE TO DEFINE "CONTROLLED SUBSTANCE ANALOGUE" AS THERE IS NO CURRENT CONSENSUS ON THE BEST LANGUAGE TO USE FOR THAT DEFINITION. NAMSDL IS AWAITING A REPORT FROM THE ADVISORY COMMITTEE FOR THE EVALUATION OF CONTROLLED SUBSTANCE ANALOGS (ACECSA) BEFORE MAKING A RECOMMENDATION ON MODEL LANGUAGE.

(A) Except as provided below, the term "controlled substance analogue" means a capsule, pill, powder, product, or other substance, however constituted –

(i) The chemical structure of which is derivative of, or substantially similar to, the chemical structure of a controlled substance; and
(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; or

(iii) 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

(iv) Which has been designated as a controlled substance analogue by the Controlled Substance Analogue Committee in accordance with section [section number].

COMMENT

THIS SECTION IS TAKEN IN PART FROM 21 USC § 802(32) AND TENN. CODE ANN. § 39-17-454. SUBSECTION (A) IS INTENDED TO CLARIFY THAT, IN ORDER TO MEET THE DEFINITION OF CONTROLLED SUBSTANCE ANALOGUE, SUBSTANCES MUST MEET THE REQUIREMENTS OF SUBSECTION (A)(I) *AND* EITHER (A)(II) *OR* (A)(III). BY INCLUDING THE WORD "OR" BETWEEN SUBSECTIONS (A)(II) AND (A)(III), THE DEBATE OVER HOW THE FEDERAL DEFINITION SHOULD BE INTERPRETED IS ENDED.

Subsection (B) - Option 1.

(B) As used in this section, the term "substantially similar to" means that the tested item 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.

COMMENT

THIS SECTION IS TAKEN IN PART FROM TENN. CODE ANN. § 39-17-454. SUBSECTION (B) IS INTENDED TO PROVIDE CLARIFICATION ON THE PHRASE "SUBSTANTIALLY SIMILAR" AND PROVIDE GUIDANCE TO PROSECUTORS, DEFENSE ATTORNEYS, AND JUDGES ON WHETHER A SUBSTANCE MEETS THAT STANDARD.

Subsection (B) - Option 2.

(B) As used in this section, the term "substantially similar to" means that the tested item 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 a substance that is an alkyl homolog of a controlled substance.

COMMENT

THIS SECTION IS TAKEN FROM SOUTH DAKOTA CODE § 34-20B-1. THIS OPTION PROVIDES ANOTHER OPTION FOR SETTING THE "SUBSTANTIALLY SIMILAR TO" STANDARD IN SUBSECTION (B).

Subsection (B) - Option 3.

(B) As used in this section, the term "substantially similar to" means that 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.

COMMENT

THIS SECTION IS TAKEN FROM THE UTAH BUREAU OF FORENSIC SERVICES CHEMISTRY PROCEDURE MANUAL. THIS OPTION PROVIDES A THIRD OPTION FOR SETTING THE "SUBSTANTIALLY SIMILAR TO" STANDARD IN SUBSECTION (B).

(C) "Controlled substance analogue" does not include:

(i) A controlled substance;
(ii) Any substance for which there is an approved new drug application;
(iii) With respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under 21 USCA § 355, to the extent conduct with respect to the substance is pursuant to such exemption; or
(iv) 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.

COMMENT

THIS SECTION IS TAKEN IN PART FROM 21 USC § 802(32) AND TENN. CODE ANN. § 39-17-454. SUBSECTION (C) SETS OUT THOSE SUBSTANCES WHICH ARE EXCLUDED FROM THE DEFINITION OF "CONTROLLED SUBSTANCE ANALOGUE." THE MOST SIGNIFICANT OF THOSE EXCLUSIONS IS SUBSECTION (C)(IV) WHICH IS INTENDED TO HELP ADDRESS THE CURRENT RELIANCE BY MANUFACTURERS AND DISTRIBUTORS OF SYNTHETIC DRUGS ON THE REQUIREMENT THAT THE SUBSTANCE NOT BE FOR HUMAN CONSUMPTION. THESE MANUFACTURERS AND DISTRIBUTORS PLACE THE PHRASE "NOT FOR HUMAN CONSUMPTION" ON THEIR PRODUCTS IN ORDER TO AVOID FALLING WITHIN THE CURRENT FEDERAL DEFINITION OF CONTROLLED SUBSTANCE ANALOGUE. SUBSECTION (C)(IV) ADDRESSES THIS POSSIBLE LOOPHOLE BY REQUIRING THAT, IN ORDER TO FALL WITHIN THIS EXCLUSION, THE SUBSTANCE MUST NOT PRESENT ANY SIGNIFICANT POTENTIAL FOR ABUSE.