Slaying the Synthetic Hydra: Drafting a Controlled Substances Act that Effectively Captures Synthetic Drugs

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In 1985, the Drug Enforcement Agency [DEA] scrambled to schedule a new designer drug called ecstasy.1 Scheduling the drug would make it illegal under the Controlled Substances Act [CSA]. The DEA had to jump the hurdles of the long and cumbersome scheduling process.2 While trying to schedule MDMA (the technical name for the active ingredient in ecstasy), the DEA failed to comply with the requirements, which resulted in an invalid scheduling and having to start the long process over again.3 Despite knowing just how dangerous MDMA was, the DEA was forced to sit back and watch the drug run rampant, its hands tied by a scheduling process that ultimately took four years.4 Discontent with the spread of ecstasy and desperate to unshackle the DEA, Congress hastily birthed the Controlled Substances Analogue Enforcement Act [Analogue Act].

The Analogue Act defines “analogue” as any substance that is structurally and pharmacologically substantially similar to a controlled substance.5 Analogues are to be treated as controlled substances as long as they are intended for human consumption.6 Because MDMA is structurally similar to MDA (a controlled substance analogue), the DEA was forced to reschedule it in 2001.7

1 See Grinspoon v. Drug Enforcement Admin., 828 F.2d 881 (1st Cir. 1987).
3 Grinspoon, 828 F.2d 881 (vacating the rule initially banning MDMA).
4 All told, there were almost four years between the DEA’s announcement that it planned to schedule MDMA and the substance’s classification as a controlled substance. Amanda Kay, The Agony of Ecstasy: Reconsidering the Punitive Approach to United States Drug Policy, 29 FORDHAM URB. L.J. 2133, 2163–66 (2002).
substance) and because it produces pharmacological effects similar to MDA, MDMA is an analogue and illegal under the Analogue Act.

Eventually ecstasy was scheduled, brought under the purview of the CSA, and the Analogue Act was rendered unnecessary. When synthetic drugs reemerged around the turn of the millennium, many prosecutors and narcotics agents believed that these new drugs were legal. The Analogue Act had been forgotten.

The Analogue Act has recently been dusted off and used to successfully prosecute distributors of some of the most dangerous new synthetic drugs. The Analogue Act provides an invaluable service in widening the reach of the CSA by including dangerous substances not otherwise scheduled. However, prosecution under the Analogue Act is more expensive, time consuming, and cumbersome than prosecution under the CSA. First, it must be shown that the substance in question is an “analogue.” This raises the difficult question of what makes two substances “substantially similar” in chemical structure and pharmacological effects. Proving substantial similarity involves the use of experts, which in turn raises costs to all parties involved: the prosecution, the court, and even the defense. Further, analogues are only illegal if they are “intended for human consumption.” Synthetic drug distributors will often provide their products with innocuous names, such as “bath salts” or “plant food,” and label them “Not For Human Consumption” in order to insulate themselves from investigation and prosecution. In many cases, a controlled substance’s analogue can be much more dangerous than the controlled substance itself. This makes the additional investigatory and procedural hurdles found in the Analogue Act counterintuitive and, as to some of these hurdles, unnecessary.

Part I lays out the historical context in which the Analogue Act was enacted and outlines how the Analogue Act has been construed and interpreted. Part II discusses the two primary differences between the CSA and the Analogue Act and how these differences create investigatory and procedural hurdles for those seeking to enforce the Analogue Act. Part III details two significant approaches that the federal and state governments have taken towards addressing the problem of synthetic drugs. Finally, Part IV analyzes these two approaches and recommends a third approach to the synthetic drug problem.

I. THE CONTROLLED SUBSTANCES ANALOGUE ENFORCEMENT ACT

The late 1960s and the early ‘70s marked the beginning of the United States’ war on drugs. Congress passed the Controlled Substances Act to commence what President Richard Nixon called an “all-out global war on the drug menace.” The

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7 United States v. Sullivan, 714 F.3d 1104 (8th Cir. 2013) (finding guilty, under the Analogue Act, a distributor of 4-methylmethcathinone (“mephedrone”), an active component of “bath salts”).
CSA made it illegal to distribute, manufacture, or dispense "controlled substances." In 1973, through executive order, Nixon created the Drug Enforcement Agency. Through enforcement of the CSA, the DEA effectively clamped down on the international distribution of controlled substances, such as marijuana, cocaine, and heroin. However, the CSA did not contemplate the emergence of "new" drugs.

Underground chemists quickly identified the weaknesses of the CSA. In order for a substance to be illegal under the CSA, its specific molecular structure had to be "scheduled" by the DEA. If a substance's molecular structure was not specifically scheduled, it was not illegal. This meant that the CSA could be circumvented by synthetically altering a controlled substance's chemical structure, transforming it from an illegal controlled substance to a completely legal uncontrolled substance. What was, and still is, problematic is that the circumvention of the CSA can be accomplished through modifications so slight that the new "designer drug" can retain all of the old controlled substance's dangerous pharmacological effects.

At first, the process of molecular modification was difficult for underground chemists, with their limited resources and lack of expertise. Instead, underground chemists relied on the work of academic and industrial chemists, eagerly hijacking their legitimate counterparts' work. For example, the drug MDMA was first synthesized by Merck in 1912. Merck had no intention of creating a psychedelic drug. Their goal was a product that stopped abnormal bleeding; MDMA was merely an intermediate compound synthesized as part of that process. MDMA itself had no value to Merck chemists. It took over sixty years for a report of MDMA's psychotropic effects to be published. MDMA became popular in nightclubs and at raves. The drug became commonly known as ecstasy and, like the designer drugs that would follow it, ecstasy was synthetically designed to avoid the stringent requirements of the CSA.

In response to the threat that designer drugs like ecstasy posed, Congress drafted the Analogue Act. The purpose of the Act was to prohibit the manufacture

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9 See Controlled Substances Act of 1970, 21 U.S.C. § 841 (2006) (making it unlawful for any person "to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance").


11 The list of scheduled controlled substances can be found in the DEA regulations at 21 C.F.R. §§ 1308.11-15 (1974).

12 S. Bernscheider-Reif et al., The Origin of MDMA ("Ecstasy")—Separating the Facts from the Myths, 61(11) PHARMAZIE 966-72 (2006).

13 Id.

14 Id.

and distribution of substances similar to the most dangerous controlled substances. The Senate Judiciary committee reported that law enforcement agencies found themselves one step behind underground chemists who could slightly alter the molecular structure of controlled substances, creating new drugs and avoiding the CSA. The Analogue Act made it possible for law enforcement and prosecutors to bring charges against distributors of these substances, despite the fact that the substances were not specifically scheduled.

A. Statutory Construction

In order to be deemed an analogue, 21 U.S.C. § 802(32)(A) requires that a substance (i) be structurally similar; (ii) have similar pharmacological effects; or (iii) be represented as having or intending to have those similar effects. Void for vagueness claims directed at the definition provided in § 802(32)(A) were common and usually focused on the proper construction of the three subparagraphs. The primary question was whether the subparagraphs should be read to be conjunctive or disjunctive. The first court to address the issue was the District Court of Colorado, in United States v. Forbes. The defendants in Forbes argued that the definition should be read to require subparagraphs (i) and either (ii) or (iii), whereas the government argued that it was enough to show either (i), or (ii), or (iii). Under the defendants' interpretation, § 802(32)(A) sets out a two-part test: the first part requires a substantially similar chemical structure and the second part requires either a substantially similar pharmacological effect or an intent to have


(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.”

20 Id.
21 See generally id.
22 Id. at 234.
such an effect. The government’s position was that the definition merely required any one of the subparagraphs—chemical structure, or pharmacological effects, or intent to produce such effect—to be true.

The Forbes court sided with the defendants in order to avoid unintended and absurd results. The court provided two hypotheticals. First, reading § 802(32)(A) disjunctively, alcohol and caffeine would be analogues because they meet the subparagraph (ii) requirement: substantially similar pharmacological effects. Second, powdered sugar would be an analogue if the defendant represented it to be cocaine because it would fulfill the subparagraph (iii) requirement.

The conjunctive reading of § 802(32)(A) has been adopted by a majority of the Federal Circuit Courts of Appeal. Combining the conjunctive reading of § 802(32)(A) with § 813 results in the accepted analogue test: a substance is an analogue when it has (1) substantially similar chemical structure, (2) has, is intended to have, or is represented as having substantially similar physiological effects, and (3) is intended for human consumption.

II. COMPARING THE ACTS

Upon first blush, the CSA and the Analogue Act seem to prohibit similar conduct and their differences seem minor and trivial. There are two key differences between the two Acts: 1) the intent requirement as to “human consumption” and 2) the legal definition of the substance in question:

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23 Id.
24 Id.
25 Id. at 234–35.
26 Id. at 235.
27 Id.
28 Id.
29 See United States v. Roberts, 363 F.3d 118, 121 (2d Cir. 2004); United States v. Hodge, 321 F.3d 429, 436 (3d Cir. 2003); United States v. Klecker, 348 F.3d 69, 71 (4th Cir. 2003); United States v. Turcotte, 405 F.3d 515, 523 (7th Cir. 2005); United States v. Washam, 312 F.3d 926, 930 n.2 (8th Cir. 2002); United States v. Brown, 415 F.3d 1257, 1261 (11th Cir. 2005). While the First and Tenth Circuits have not decided the issue, district courts under their jurisdiction have held that the act should be read in the conjunctive. United States v. Sole, No. CRIM.04-10221-RWZ, 2005 WL 1668384, at *1 (D. Mass. July 15, 2005) (First Circuit); Forbes, 806 F. Supp. at 235–36. No decisions have accepted the disjunctive interpretation of the act and been left undisturbed on appeal.
30 See, e.g., Klecker, 348 F.3d at 71.
Intent requirement as to "human consumption" | Legal definition of the substance in question
---|---
The Controlled Substances Act | None. The CSA merely states: It is unlawful for anyone to knowingly distribute a controlled substance.\(^{31}\) A controlled substance is any substance with a chemical structure specifically listed in the DEA regulations.\(^{32}\)
The Analogue Act | The Analogue Act states that analogues should be treated, for purposes of federal law, as a controlled substance in schedule I, to the extent that they are intended for human consumption.\(^{33}\) An analogue is any substance with a chemical structure substantially similar to a controlled substance that produces pharmacological effects substantially similar to a controlled substance.\(^{34}\)

As this note will show, these differences are hardly trivial. They create investigatory and procedural hurdles in the Analogue Act that are not present in the CSA. These additional hurdles are unjustified and, in some instances, unnecessary.

A. Human Consumption

The intent requirement as to human consumption is a glaring weakness in the Analogue Act and one that distributors easily exploit. A clever distributor can cloak his product with an innocuous name. Perhaps the most infamous of these monikers is the term “bath salts,” the name given to the drug that caused a user in Miami to attack and cannibalize a homeless man.\(^{35}\) The term “bath salts” has


\(^{32}\) The list of scheduled controlled substances was originally found at 21 U.S.C. § 812 (1990), but has since been superseded by DEA regulations at 21 C.F.R. §§ 1308.11–15 (1974). See United States v. Macedo, 406 F.3d 778, 784–85 (7th Cir. 2005); United States v. Gori, 324 F.3d 234, 240 (3d Cir. 2003); United States v. Segler, 37 F.3d 1131, 1133 (5th Cir. 1994); United States v. Kendall, 887 F.2d 240, 241 (9th Cir. 1989).


\(^{35}\) On May 26, 2012, Rudy Eugene, the “Causeway Cannibal,” ripped off his clothes on the side of a Miami causeway and attacked a sixty-five-year-old homeless man. In a prolonged and barbaric assault, Eugene chewed chunks of flesh off the homeless man's face. Police officers could not pull Eugene off his victim and were forced to resort to deadly force. Scott Hiaasen & Nadge Green, No bath salts detected: Causeway attacker Rudy Eugene had only pot in his system, medical examiner reports, MIAMI HERALD (June 27, 2012), http://www.miamiherald.com/2012/06/27/2871098/mes-report-eugene-had-no-drugs.html. Although toxicology reports did not show signs of bath salts, experts stated that this was because even the most
spawned the misconception that the aromatherapy bath salts you would buy at Bed, Bath, and Beyond can somehow make a person high upon ingestion. This is simply not true. These so-called bath salts are synthetic cocktails, analogues of the schedule I controlled substance “cathinone.” Synthetic cathinones are given their innocuous moniker by distributors. The term “bath salts” is a shibboleth that grants the distributor deniability under the “human consumption” loophole in the Analogue Act. If intent as to human consumption is an essential element, then the clever distributor can point to the name of his product in his defense: “These are bath salts. When I sold them, I thought my customer was going to put them in his bath. I never intended for them to be used to get high.” As terms like “bath salts” become more widely known, distributors can simply change their product’s name to another innocuous moniker. Distributors further insulate themselves by marking packages: “Not For Human Consumption.”

While such tricks obviously cannot stop investigations cold, they provide the analogue distributor with a layer of security not available to the controlled substances distributor. If a distributor is selling cocaine, simply calling the substance something else is of little use. For example, assume a certain distributor was selling “baking powder,” which was actually cocaine. The distributor could perhaps argue—under the knowledge requirement—that he thought he was selling baking powder, but it would not matter what he intended his customers to do with the “baking powder.” Even if the distributor genuinely believed that his customers were going to use the substance to bake cakes, the prosecution could still go forward if it could be shown that the distributor knew the substance was cocaine.

Change just one fact from the hypothetical above: instead of cocaine, “baking powder” is a cocaine analogue. In this tweaked hypothetical, inexplicably, the distributor’s genuine belief that his customers were going to use the cocaine

sophisticated labs could only test for a fraction of the synthetic drugs in circulation and that Eugene’s behavior was consistent with bath salts usage. See Nicole Watson, Toxicology reports questioned in case of Rudy Eugene, shot during face eating zombie attack, ABC ACTION NEWS (July 9, 2012), http://www.abcactionnews.com/dpp/news/state/report-toxicology-reports-questioned-in-case-of-rudy-eugene-shot-during-face-eating-zombie-attack.

In the Book of Judges, when fugitive Ephraimites tried to return home guised as Gileadites, the Gileadite guards would ask them to say the word “shibboleth.” If they replied “sibboleth,” then the guards would know that these were actually Ephraimites because “sibboleth” was the Ephraimite pronunciation of “shibboleth.” Judges 12:5-6. Shibboleths are useful because they are phrases, sounds, or words that only a certain group of people know and can be used as passwords. In the arena of synthetic drugs, the metaphor from Judges is reversed: the outlaws know the shibboleth, and the guards must deal with the consequences.

As prosecutors and law enforcement have learned to say “shibboleth” instead of “sibboleth.” Cf. id.

See United States v. Sullivan, 714 F.3d 1104, 1106 (8th Cir. 2013).

The Eighth Circuit, in Sullivan, stated that a “label indicating a substance is not for human consumption is not dispositive evidence of the distributor’s [innocent] intent.” Id. at 1107.
analogue to bake cakes is now an affirmative defense.\textsuperscript{40} Even if the distributor affirmatively stated that “baking powder” was a cocaine analogue, there would be no crime if he genuinely believed it was not going to be consumed.\textsuperscript{41} For a more practical, real world application, assume the belief is not genuine, but rather feigned; the distributor knows he is caught, but simply alleges—falsely—that he did not intend the product to be used for human consumption. Under the Analogue Act, such a simple lie gives the distributor the opportunity to slow down investigation and prosecution. The government must expend time and resources showing that the drugs being sold were being sold as drugs. A similar lie, under the CSA, would be irrelevant: it is simply understood that the drugs being sold are being sold as drugs.

How can law enforcement show the analogue distributor’s intent as to human consumption? Direct evidence may be available. Sometimes the defendant will affirmatively state, to an undercover officer or a cooperating informant, that he intends his customer to consume his product.\textsuperscript{42} This is the best-case scenario for an analogue investigation, but it is still a step not required in the investigation of a controlled substance. Usually, undercover officers and confidential informants need to coax these statements out of the distributor by asking leading questions: “Do you have any other flavors?” “How long is the high?” The clever distributor will not answer these questions and, instead, point to the “Not For Human Consumption” label on the package.

Alternatively, the Sixth Circuit, in \textit{United States v. Hofstatter}, has allowed circumstantial evidence to show that the analogue was intended for human consumption.\textsuperscript{43} In \textit{Hofstatter}, evidence was obtained during the execution of a search warrant.\textsuperscript{44} The DEA found a notebook in the defendants’ laboratory, one entry read: “let some sit for 3 days (less smell) closer to amphetamine.”\textsuperscript{45} Another entry gave a 1–10 rating on particular attributes of the product including its euphoria,

\textsuperscript{40}“Tweaking” the hypothetical results in a hypothetical affirmative defense. Ironically, controlled substance distributors can find a very real affirmative defense by similarly “tweaking” their product.

\textsuperscript{41}The Eighth Circuit, in \textit{Sullivan}, stated that the Analogue Act “expressly excludes substances to the extent the substances are not intended for human consumption . . . . Accordingly, had Sullivan not intended the mephedrone powder to be for human consumption, it would not have been illegal under any law in effect at the time.” 714 F.3d at 1108. Mephedrone was eventually scheduled and the court mentions “any law in effect at the time” because, now, after mephedrone’s scheduling, Sullivan’s intent as to human consumption would be irrelevant. \textit{Id.}

\textsuperscript{42}United States v. Washam, 312 F.3d 926, 928 (8th Cir. 2002) (defendant stated that he was aware the substance was to be used for human consumption). \textit{See also Sullivan}, 714 F.3d at 1107 (stating that a reasonable juror could infer the human consumption prong because, when he was pulled over and asked if there were any illegal substances in the car, defendant responded affirmatively).

\textsuperscript{43}8 F.3d 316, 321–22 (6th Cir. 1993).

\textsuperscript{44}\textit{Id.} at 319–20.

\textsuperscript{45}\textit{Id.} at 320.
smell, taste, and jones. All of this, the court found, "provide[d] ample support for the conclusion that the defendants were attempting to manufacture substances designed for human consumption."  

B. Legal Definition of the Substance  

Under the CSA, it must be proven that the substance the defendant was distributing was a "controlled substance" and that the defendant knew the substance was a controlled substance. The Analogue Act, however, is slightly, yet significantly, different. Under the Analogue Act, it must be proven that the substance was "substantially similar" to a controlled substance.  

What does "substantially similar" mean? Is it so vague that a person might not actually know whether he is breaking the law? Even more interestingly, when must the substance be substantially similar? Before it is consumed? While it is being metabolized? Answering these questions—or perhaps more to the point: the fact that these questions even exist—is a second major hurdle in the prosecution of analogue distributors.  

1. Showing that the substance is in fact an analogue  

In controlled substances cases, the government has the burden of showing that the substance in question is a controlled substance. This means that it must be proven that the substance has the chemical structure specifically listed in the DEA regulations. Lab tests make this a simple enough task: the government calls the analyst who ran the test to the stand, and he testifies as to the results. However, in an analogue case, the government has the burden of proving that the substance in question has a chemical structure that is substantially similar to a controlled substance. Additionally, if the evidence is not sufficient to support a finding that

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46 Id.  
47 Id. at 321–22.  
49 United States v. Turcotte, 405 F.3d 515, 521 (7th Cir. 2005).  
51 Forensic analysis allows the government to accurately identify substances. At trial however, the report alone may not be submitted as evidence that a substance is a controlled substance; under the Sixth Amendment, the defendant also has the right to confront the particular analyst who performed the analysis. Melendez-Diaz v. Massachusetts, 557 U.S. 305, 311 (2009).  
52 United States v. Klecker, 228 F. Supp. 2d 720, 727 (E.D. Va. 2002) aff'd, 348 F.3d 69 (4th Cir. 2003). One thing is clear: that "substantially similar" does not mean "exactly the same." A substance with a structure "exactly the same" as a scheduled controlled substance would not be an analogue, it would be a controlled substance. United States v. Washam, 312 F.3d 926, 930–31 (8th Cir. 2002).
the defendant intended or represented the substance as having pharmacological
effects similar to a controlled substance, then the government has the burden of
proving that the substance in fact has those effects.\textsuperscript{53}

Both sides must call expert witnesses who can testify as to substantial
similarity. Trials are inevitably longer. This entails additional costs to the
prosecution, the court, and even the defense. Further, some defendants do not have
the resources to pay for their own experts and have to rely solely on cross-
examination of government witnesses. The necessity of experts was contemplated
by Congress and intentionally put into place.\textsuperscript{54} However, none of this is necessary
in the prosecution of a controlled substances distributor; all that is necessary is the
analyst that performed the lab test.

i. Substantially similar chemical structure

While it seems “substantially similar” is meant to be a scientific term of art
with a specific definition, consensus as to the degree of similarity required is
something neither the courts nor the scientific community have found.\textsuperscript{55} Courts
have allowed experts to use various methods in showing substantial similarity
while rejecting other methods. One oft-used method that courts have struck down
is the “Tanimoto coefficient” method. Accepted methods include the “core
arrangement” of atoms method, the “visual inspection” method, and the “structure
and effect” method.

The Eleventh Circuit rejected the “Tanimoto coefficient” method in \textit{United States
v. Brown}.\textsuperscript{56} This is a quantitative method that involves counting the substructures
in each of the substances to be compared, then dividing this number by the total
number of substructures, which produces a number between zero and one hundred
percent similarity.\textsuperscript{57} The Eleventh Circuit agreed with the district court that the
test should be rejected because it produced skewed and bizarre results when
assessing simple linear molecules.\textsuperscript{58} Using the Tanimoto coefficient method, the
defense’s expert found that 4-Phenylbutylamine was 51.40\% similar to BD, but

\textsuperscript{53} \textit{See Washam}, 312 F.3d at 930–31. Of course, the burden of showing that defendant
intended or represented the substance as having pharmacological effects substantially similar to or
greater than a controlled substance is also on the government. \textit{See id.}

\textsuperscript{54} “In determining whether a substance does have a chemical structure ‘substantially similar’
to that of a Schedule I or II controlled substance, the trier of fact will presumably consider the

\textsuperscript{55} \textit{See, e.g.}, \textit{United States v. Forbes}, 806 F. Supp. 232, 237 (D. Colo. 1992); \textit{see also} \textit{United
States v. Turcotte}, 405 F.3d 515, 522 (7th Cir. 2005) (noting that the Analogue Act is not a model
of statutory clarity).

\textsuperscript{56} 415 F.3d 1257, 1269 (11th Cir. 2005).

\textsuperscript{57} \textit{Id.} at 1263.

\textsuperscript{58} \textit{Id.} at 1269. The district court described the expert’s use of the Tanimoto coefficient as “a
move that would make Las Vegas odds-makers and Enron accountants proud.” \textit{United States v.
that GHB was only 46.7% similar.⁵⁹ These are the molecular structures for those three chemicals:

![Molecular structures](image)

4-Phenylbutylamine

GHB

The government’s expert stated that he would be “stunned” if someone claimed that BD was more similar to 4-Phenylbutylamine than GHB.⁶⁰ Yet, the Tanimoto coefficient method leads to that bizarre result.

The “core arrangement” of atoms method examines the core atoms in a chemical structure. The Fourth Circuit has accepted this method.⁶¹ In *United States v. Klecker*, the Eastern District of Virginia addressed the issue of whether a hallucinogenic substance branded “Foxy” was substantially similar to DET, a hallucinogenic controlled substance.⁶² Even though there were a number of molecular substitutions between Foxy and DET, the court found that they shared the same “core arrangement” of atoms and were therefore substantially similar.⁶³ It was persuasive that Foxy and DET share a tryptamine core, which the court noted is present in a number of hallucinogenic drugs.⁶⁴

The “visual inspection” method involves comparison of the substances’ two-dimensional models to determine structural similarity.⁶⁵ The Eleventh Circuit relied on this method in *United States v. Brown*.⁶⁶ In *Brown*, the government’s experts testified that 1-4-butanediol was structurally substantially similar to GHB

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⁶⁰ *Id.* at 1249.
⁶² *Id.*
⁶³ *Id.*
⁶⁴ *Id.*
⁶⁶ *Id.* at 1271.
by referring to two-dimensional representations of the two substances’ chemical structures. Based on visual inspection of the models, the experts stated that the two molecules only differed in their functional groups and then concluded that the substances were substantially similar.

The final method accepted by the courts is the “structure and effect” method. This method conflates the “pharmacological effects” and “chemical structure” parts of an analogue’s definition. While the federal courts now largely accept this method, the blurring of the effects and structure parts of the analogue definition was controversial. For instance, the District Court for the Southern District of New York rejected the government’s application of the structure and effect method in United States v. Roberts [Roberts I]. The court held that the chemical BD was not substantially similar to the controlled substance GHB and thus not an analogue. The court found that, notwithstanding the fact that only two atoms were different between the molecules, it was persuasive that the two changed atoms significantly altered GHB’s chemical properties. The two changed atoms were located in GHB’s functional groups. GHB is generally considered an acid, whereas BD is an alcohol. The defense pointed out that the molecules would be found in different sections of a chemistry textbook. Further, GHB is negatively charged on one end and positively charged on the other, making it unstable and causing the molecule to fold; BD, conversely, is stable.

The court was not persuaded by the government’s argument that, after consumption, BD is metabolized into GHB. The court stated that this sort of analysis conflates the “chemical structure” and “pharmacological effects” parts of the test. As one commentator put it, a caterpillar undergoes metamorphosis and turns into a butterfly, but no one would suggest that the two are structurally

67 Id. at 1262.
68 Id.
69 United States v. Forbes, 806 F. Supp. 232, 236 (D. Colo. 1992) (stating “[b]ecause structurally similar substances have similar pharmacological effects . . . a finding of such similar effects is some indication that the molecular structures should be classified as substantially similar”); see also United States v. Fisher, 289 F.3d 1329, 1339 (11th Cir. 2002); United States v. Roberts, 363 F.3d 118, 125 (2d Cir. 2004); United States v. Niemoeller, No. IP 02-09-CR-1 H/F, 2003 WL 1563863, at *6 (S.D. Ind. Jan. 24, 2003).
72 Id. at *3.
73 Id.
74 Id. at *2.
75 Id.
76 Id.
77 Id. at *4.
78 Id.
substantially similar. The court wanted a showing of substantially similar chemical structure and then a showing of substantially similar effects: not a mixing of the two.

On appeal, the Second Circuit was persuaded by the government’s position. For the same reasons as the district court, the court of appeals did not think that the two-atom difference or the metabolism argument alone was sufficient. However, it found that, together, the chemical structure part was satisfied. Many federal courts have gone one step further and criticized Roberts I outright. Most federal courts believe that the analysis begins “upon ingestion and not on a blackboard.” The District Court for the Southern District of Alabama has stated that the most sensible approach to the Analogue Act—and substantial structural similarity—is one that recognizes its concern with “human consumption.”

ii. Substantially similar pharmacological effects

The courts are less stringent as to the “pharmacological effects” element of the definition. Courts have held that “anecdotal reports, affidavits and testimonials,” while perhaps insufficient to gain FDA approval for prescription drugs, are “persuasive evidence of hallucinogenic effects” in an analogue case. In United States v. Klecker, the District Court for the Eastern District of Virginia was persuaded of different substances’ substantial pharmacological similarity based on expert testimony stating that the substances were “known to have similar hallucinogenic effects” and by anecdotal reports of users. The court asserted that the substances “produce[] hallucinogenic effects lasting from five to ten hours” and that they produced an “initial Ecstasy feeling followed by substantial hallucinogenic effects similar to those of LSD.” The court finally concluded that the “studies and anecdotal evidence presented by the Government [were] unrebutted,” and found substantial pharmacological similarity.

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80 Roberts I, 2002 WL 3104834, at *3.
81 United States v. Roberts, 363 F.3d 118, 125–26 (2d Cir. 2004).
82 Id. at 125.
83 Id.
84 United States v. Washam, 312 F.3d 926, 932–33 (8th Cir. 2002).
86 Id.
88 Id.
89 Id. at 729–30.
2. Showing that the defendant had knowledge that the substance was an analogue

Usually, a defendant must have knowledge that the substance he was distributing meets the definition of an "analogue" under 21 U.S.C. 802(32)(A).\(^9\) This means that the government must show that the defendant knew that the substance was structurally similar to a controlled substance and that it produced substantially similar or greater effects. This is a steep hill for the prosecution to climb and, fortunately for prosecutors, some courts have been lenient. For example, the Seventh Circuit has created a "provisional remedy," which permits a jury—but does not require it—to infer knowledge of a substantially similar structure when it finds either "knowledge or representation of similar physiological effects."\(^9\) Some courts have gone even further and said that the definition of "controlled substance analogue" does not require any scienter at all.\(^9\) Of course, the government still must show that the substance in fact meets the definition of an analogue, regardless of the defendant's knowledge; otherwise, absurd results would occur.\(^8\)

III. CURRENT ATTEMPTED SOLUTIONS TO THE SYNTHETIC DRUG PROBLEM

In the 1970s, underground chemists had to rely on well-funded academic and industrial research to provide them with new synthetic procedures. That time is gone. Now, new synthetic drugs flood the market, the only limiting factor being an underground chemists' creativity. Clamping down on the flow of these dangerous substances is a duty that the criminal justice system cannot take lightly.

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\(^9\) "A defendant must know that the substance at issue has a chemical structure substantially similar to that of a controlled substance, and he or she must either know that it has similar physiological effects or intend or represent that it has such effects." United States v. Turcotte, 405 F.3d 515, 527 (7th Cir. 2005). \(^9\) See also United States v. Bamberg, 478 F.3d 934, 939 (8th Cir. 2007); United States v. Roberts, 363 F.3d 118, 123 n.1 (2d Cir. 2004) (stating, without discussion, that the government must prove that the defendant knew he was in possession of an analogue).

\(^9\) Turcotte, 405 F.3d at 527.

\(^9\) "[A] defendant does not have to 'know' that a substance has a substantially similar chemical structure to an illegal drug." United States v. Forbes, 806 F. Supp. 232, 238 (D. Colo. 1992); see also United States v. Carlson, 87 F.3d 440, 443 n.3 (11th Cir. 1996) (citing Forbes in coming to the conclusion that the Analogue Act lacks a scienter requirement). "If a defendant possesses an analogue, with intent to distribute or import, the defendant need not know that the drug he possesses is an analogue. It suffices that he know what drug he possesses, and that he possess it with the statutorily defined bad purpose." United States v. Desurra, 865 F.2d 651, 653 (5th Cir. 1989).

\(^8\) For example, defendants who scheme to defraud their customers by representing that a substance has the same effects of a controlled substance when it is actually neither a controlled substance nor substantially similar in chemical structure do not violate the Analogue Act. See United States v. Clifford, 197 F. Supp. 2d 516, 518, 522 (E.D. Va. 2002) (stating that it was "undisputed that defendants represented that the pills they sold were MDMA, thus clearly satisfying" the effects part of the definition, but failing the structure part because the pills were actually ginseng and vitamin B).
Two approaches currently address the synthetic drug problem. The first approach, followed by the federal government and an overwhelming majority of the states, is scheduling new drugs as they appear. The second approach is to schedule specific molecular structures, as other jurisdictions do, but also schedule general structural classes. Currently, Rhode Island is the only state following this approach. The Rhode Island legislation enacting this approach was signed into law in July 2013.

A. Scheduling Substances as They Appear

On July 16, 2012, President Obama signed the Synthetic Drug Abuse Prevention Act of 2012 [SDAPA] into law. The new law added twenty-six chemicals—including many of the active components of bath salts—to the schedule I list of controlled substances. The Act reclassified substances that were once analogues as schedule I controlled substances, freeing them of the procedural hurdles associated with the Analogue Act.

Since 1971, 21 U.S.C. § 812 has mandated that the schedule list “shall be updated and republished on an annual basis.” The road from substance to officially scheduled controlled substance is long. The Attorney General makes the threshold inquiry as to whether a particular substance has a “potential for abuse.” The Attorney General then asks the Secretary of Health and Human Services for a recommendation. The Secretary’s recommendation is based on several factors: the drug’s actual or relative potential for abuse; the scientific evidence of its pharmacological effect; the state of current scientific knowledge regarding the drug; its history and current pattern of abuse; the risk to the public health; its psychic or physiological dependence liability; and whether the substance is an immediate precursor of a substance already controlled. The Secretary also recommends on which schedule the substance should be placed. This recommendation is based on the substance’s potential for abuse, its psychological or physical dependence, and whether it has any accepted medical use in treatment in the United States. Section 812(b) sets the requirements for a substance to be

94 For example, one of these twenty-six drugs is the synthetic cathinone 3,4-methylenedioxy-N-methylcathinone, also known as “methylone” or “bk-MDMA.” See 21 C.F.R. § 1308.11(h)(1) (2013).
100 See 21 U.S.C. § 812(b).
placed on a certain schedule.\textsuperscript{101} This process takes years, not months, and it is only after this long process that a dangerous substance can be prosecuted under the CSA as opposed to the encumbered Analogue Act.

B. The Rhode Island Approach

The Rhode Island Synthetic Drug Ban [RISDB] was a response to what Rhode Island Attorney General Peter Kilmartin called the alarming and deadly growing availability and use of synthetic drugs.\textsuperscript{102} The RISDB does more than simply schedule a specific chemical compound; instead, the RISDB schedules entire structural classes.\textsuperscript{103} For example, the federal law discussed in the previous section scheduled bk-MDMA (a substance sometimes found in bath salts) specifically as “3,4-methylenedioxy-N-methylcathinone.”\textsuperscript{104} The RISDB, however, takes a broader approach. In addition to scheduling specific substances, the RISDB also broadly schedules “Synthetic cathinones[, that is] . . . any chemical compound . . . structurally derived from 2-aminopropan-1-one.= . . .”\textsuperscript{105}

2-aminopropan-1-one is the core structure of all cathinones. The RISDB lists the positions on the core structure that can receive substitutions, banning any substance that has certain molecular groups substituted at these positions.\textsuperscript{106} Finally, there is a catch-all provision that further bans “[a]ny other synthetic cathinone.”\textsuperscript{107}

\begin{table}
\centering
\begin{tabular}{|c|c|c|}
\hline
Schedule & Potential for Abuse & Currently accepted medical use in treatment & Psychological or physical dependence \\
\hline
Schedule I & High & No & \\
Schedule II & High & Yes, with severe restrictions & Severe \\
Schedule III & Less than substances in schedule I or II & Yes & Moderate or low \\
Schedule IV & Low relative to schedule III & Yes & Limited relative to schedule III \\
Schedule V & Low relative to schedule IV & Yes & Limited relative to schedule IV \\
\hline
\end{tabular}
\end{table}

\textsuperscript{101} Id. Summary of § 812(b) requirements for a substance to be placed on a certain schedule:


\textsuperscript{103} See R.I. GEN. LAWS § 21-28-2.08(h)–(i)(4) (2013).

\textsuperscript{104} 21 C.F.R. § 1308.11(h)(1) (2013).

\textsuperscript{105} See R.I. GEN. LAWS § 21-28-2.08(i) (2013).

\textsuperscript{106} See R.I. GEN. LAWS § 21-28-2.08(i)(1)–(3) (2013).

\textsuperscript{107} See R.I. GEN. LAWS § 21-28-2.08(i)(4) (2013).
What does this mean? What are the differences between the new federal ban and the RISDB? Visual diagrams are instructive. The federal law bans this one specific substance:

![Diagram 1](image1.png)

The RISDB, on the other hand, bans any substance containing this core structure:

![Diagram 2](image2.png)

In this second diagram, R₁, R₂, R₃, and R₄ represent positions on the core structure where substitutions can be made. While the federal law only bans the molecule shown in diagram 1, the RISDB bans the molecule in diagram 1 as well as any other substance with the core structure shown in diagram 2. It includes everything in the federal ban while casting a wider net as well.

IV. ANALYSIS AND RECOMMENDED SOLUTION

Scheduling new synthetic drugs as they appear is an unviable solution. The analogue market is a Hydra and scheduling analogues as they appear has been as frustrating to the DEA as lopping off the monster's head—only to have two new heads take its place—was to Hercules. By the time the DEA can schedule an analogue, two new analogues have taken its place. Take mephedrone, for example, the synthetic cathinone the Eleventh Circuit, in Sullivan, confirmed as an analogue. At the time of the Sullivan defendant's initial arrest—October,

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108 The core structure in diagram 2 can be substituted to become the molecule in diagram 1 by substitution of a CH₂O₂ group at R₁, no substitution at R₂, a hydrogen atom at R₃, and a methyl (CH₃) group at R₄.

—prosecution of mephedrone could only occur under the Analogue Act, if at all. By July 2012, mephedrone was scheduled as one of the substances included in the SDAPA. Mephedrone could now be prosecuted, quickly and efficiently, under the CSA. Problem solved, right? Unfortunately not. In June 2013, the U.S. Attorney’s Office for the Southern District of Ohio found itself having to prosecute a defendant under the Analogue Act for pentedrone, a synthetic cathinone nearly identical to mephedrone. The DEA had cut off the Hydra’s mephedrone head by scheduling it, only to have the pentedrone head grow in its place a year later.

In order to effectively address the problem of synthetic drugs, this Note recommends that both state and federal governments take two steps. First, state and federal governments must strengthen their analogue laws; specifically, they should drop the “human consumption” requirement currently associated with them. The second step is abandoning the schedule-the-drugs-as-they-appear approach and replacing it with Rhode Island’s new system of scheduling both specific substances and general structural classes. This second step strengthens the regulation of controlled substances by expanding the definition of what a controlled substance is. However, it does nothing to strengthen the regulation of substances that still manage to elude controlled substances laws. This is why the step one strengthening of analogue laws is also necessary.

A. Strengthening the Analogue Act by Removing the “Human Consumption” Requirement

Evading the CSA is certainly one of the benefits a manufacturer seeks when he synthetically alters a controlled substance. However, the manufacturer is also interested in making his product more potent. In fact, many designer drugs are more dangerous than their controlled substance counterpart. For example, “Foxy” is an analogue of the schedule I controlled substance DET. “Foxy” is designed to metabolize slower, due to additional methoxy and diisopropyl groups. The result is greater duration and a more intense effect.112 Yet, analogue prosecution is encumbered by the “human consumption” requirement. Imposing this extra hurdle is counterintuitive. It provides loopholes for underground chemists, creates unnecessary investigatory burdens for law enforcement, and adds to the cost of trials. Removing the “human consumption” requirement would have practical benefits—it would bolster the Analogue Act’s ability to combat the evil Congress intended it to, while preserving a defendant’s rights.

An implicit assumption in the language of the Analogue Act is that analogues are less dangerous than controlled substances. A controlled substance is dangerous

111 Transcript of Motion Hearing at 3–4, United States v. Aburokbeh, No. 2:13-CR-020 (S.D. Ohio June 27, 2013) [on file with author].
when intended for human consumption. Because there is no intent requirement as to human consumption in the CSA, it can further be assumed that a controlled substance is dangerous even when it is not intended for human consumption. Similarly, an analogue is dangerous when it is intended for human consumption. However—and here is the difference—the Analogue Act declares that analogues are not dangerous when not intended for human consumption. How can this be? What distinguishes an analogue from a controlled substance?

One difference is that analogues have a slightly altered chemical structure and different pharmacological effects. This cannot be the basis of treating the analogue differently; again, many analogues are more dangerous than their controlled substance counterpart. A second difference is the process behind scheduling. Controlled substances are rigorously researched before being scheduled. However, the “human consumption” intent requirement is hardly justified by this, admittedly significant, difference. The assumption must be that because analogues have not been researched as thoroughly, they are only dangerous if they are intended for human consumption. This cannot be right; adding the “human consumption” intent requirement does not compensate for a relative lack of research. The solution is not tailored to the problem. Needing to prove “substantial similarity,” however, does address the problem. The assumption here is that because the analogue has not been thoroughly researched, it follows that experts should testify as to the substance’s dangerousness at trial. This makes sense and is why this Note does not argue a relaxing of the “substantially similar” standards.

Another argument in favor of the “human consumption” intent requirement is that, without it, otherwise lawful behavior might fall into the Analogue Act’s ambit. It is certainly conceivable that a chemical manufacturer might have a product that meets both “substantially similar” requirements of the Analogue Act, but genuinely does not intend its chemical to be used to intoxicate. The “human consumption” intent requirement does protect the legitimate chemical manufacturer, but it also protects the illegitimate analogue peddler. Perhaps this would be a worthwhile trade-off if it were impossible to devise a statutory scheme that exclusively protected the legitimate manufacturer; however, this statutory scheme is no fantasy and, in fact, already exists in the CSA. The CSA includes a number of exemptions and exceptions. Controlled substance distributors and manufacturers can register with the Attorney General as legitimate.

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115 Though they are, by definition, not “substantially” different. In fact, they must be “substantially similar.” 21 U.S.C. § 802(32)(A)(ii). Some of the pharmacological effects might even be “greater than” the corresponding controlled substance. Id.
categories of persons are exempt and lawfully allowed to possess controlled substances even without registering.118

An analogue is already supposed to be treated "as a controlled substance."119 Removing the "to the extent intended for human consumption" provision from the Analogue Act would injure legitimate analogue manufacturers and distributors only insofar as they would have to register with the Attorney General. The trade-off is well worth it: stripping illegitimate distributors of an unjustified statutory protection.

A final argument against removal of the "human consumption" requirement is that the "human consumption" requirement necessitates a finding of scienter that curtails the potential for arbitrary enforcement. In defeating an arbitrary enforcement claim, the Fourth Circuit stated that the "intent requirement [in the 'intended for human consumption' part] alone tends to defeat any vagueness challenge based on the potential for arbitrary enforcement."120 The court, however, did not hold that the "human consumption" intent requirement is necessary to satisfy scienter. Certainly, the requirement that distributors know that a substance is structurally and pharmacologically substantially similar to a controlled substance is enough of a mens rea requirement to prevent arbitrary enforcement. Removal of the "human consumption" requirement would not unfairly tread on defendants' rights.

B. Adopting the Rhode Island Approach to Controlled Substances

The SDAPA scheduled twenty-six analogues, allowing them to be prosecuted under the CSA. While this is certainly a victory, it is a short-term one. By the time the proposed list made it through the House and Senate and was signed by the President, it was already outdated. The Seventh Circuit noted that the sluggish scheduling processes cannot keep up with the "dizzying pace of innovation[]" displayed by underground chemists.121 Despite this reality, the schedule-the-drugs-as-they-appear approach is still the prevailing approach to synthetic drugs. Why is this?

One persuasive argument is legitimacy. The scheduling process's extensive nature, while criticized in this Note, does tend to legitimize a substance's classification as "dangerous." Because of the extensive process, once a substance has been scheduled and survives judicial challenge, there can be little doubt as to its illegality. When judges and juries are shown a lab report, they can comfortably be assured that a controlled substance, such as cocaine, is dangerous and its distribution is worthy of punishment.

118 21 U.S.C. § 822(c).
121 United States v. Turcotte, 405 F.3d 515, 518 (7th Cir. 2005).
However, the Rhode Island approach equally addresses the issue of legitimacy. Under an approach that schedules general structural classes, those structural classes must still be rigorously researched and must still go through an extensive scheduling process. A lab report confirming that a substance has a specific core arrangement of atoms lends just as much legitimacy to the conclusion that the substance is dangerous as a lab report confirming that a substance has a specific molecular structure. The benefit of putting the structural class, as opposed to a specific structure, though the scheduling process is that the DEA will not have to research one specific substance at a time. By allowing the DEA to research structural classes, its efforts can result in the banning of many dangerous substances, both in existence and likely to come into existence, in one stroke. Even if chemists make substitutions or alterations, their new product will still be under the purview of the broad controlled substances statute.

A further flaw in the schedule-the-drugs-as-they-appear approach is that the DEA has higher standards than underground chemists. In a recent evidentiary hearing regarding pentedrone’s substantial similarity to methcathinone, defense counsel asked the government’s expert how many scientific studies were done on pentedrone. The answer was only one, completed a month before the hearing, in preparation for that hearing. The crux of the synthetic drug problem is the answer to the next question: Why was there only one study? Answer: because pentedrone was a brand new drug. An underground chemist looked through the list of scheduled chemicals and made a single substitution to methcathinone’s α-carbon and the new drug, pentedrone, had to be prosecuted under the Analogue Act. Under the schedule-the-drugs-as-they-appear approach, while the DEA begins the long and tedious process of scheduling pentedrone, an underground chemist can synthesize another methyl group onto pentedrone’s α-carbon and be on his way. When the next distributor gets caught selling this even newer drug, another set of experts will have to be brought in to argue the new drug’s similarity to methcathinone (not its similarity to pentedrone, because pentedrone will still not be scheduled).

In the 70s, scheduling the drugs as they appeared made sense. There were only a handful of dangerous substances. The DEA knew about them, identified them, and scheduled them. A new drug was an event, and the DEA had the luxury of time in the scheduling process and notice. If drug manufacturers wanted to create a new drug, they needed resources and money. That was the 70s. Now,

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122 "Q. Okay. So, it’s all been in the test tube?
A. I wouldn’t even say ‘all.’ There’s been one. DEA contracted this one study. This is all the information that’s available on pentedrone.
Q. That’s it? One study. And that was done how long ago?
A. We received the results in May of 2013.

Transcript of Motion Hearing at 77–78, United States v. Aburokbeh, No. 2:13-CR-020 (S.D. Ohio June 27, 2013) [on file with author].
synthesizing a new drug is not nearly as difficult. Scheduling new drugs as they appear is not a viable option because the CSA was designed in an era where the emergence of new drugs was not a common occurrence.

The true problem with the CSA is its obsolescence. The current Analogue Act attempts to address the CSA's antiquity, but falls short. It recognizes that new drugs can emerge and that, if they are substantially similar and intended for human consumption, they should be illegal. However, even though analogues are illegal, procedural hurdles encumber their prosecution. The RISDB attempts to address the CSA's antiquity in a more comprehensive manner.

While the RISDB does not remove any procedural hurdles from Rhode Island's analogue law, it expands that state's controlled substances law to include general structural classes, essentially expanding the controlled substances law to include substances substantially similar to current controlled substances. It expands Rhode Island's schedule list to include all currently known dangerous substances and most of the currently imaginable substances that would be structurally and pharmacologically similar to them. This means that, as to those substances, law enforcement would not need to worry about "human consumption," and prosecutors would not need to worry about proving "substantial similarity."

The broad scope of the statute accounts for advances in technology and more precisely targets the problem Congress wished to address: the danger of abusive drugs. In the 70s, the CSA was enough. It addressed the technology that underground chemists had: the technology to create controlled substances. It also addressed all of the abusive drugs on the market. The RISDB acknowledges and accounts for the fact that specific substances are no longer the issue; the issue is structural classes that can be modified with relative ease.

Mere adoption of the RISDB does have one problem: it leaves the government on the defensive. A broad scheduling of a structural class will help with the prosecution of substances in that structural class; however, it does nothing to prevent entirely new drugs, with entirely new structural classes. What happens when underground chemists begin finding ways to make dangerous substances whose precursors are nowhere to be found on the schedule lists? The RISDB admirably strengthens our first line of defense but does nothing to strengthen the safety net. If underground chemists find a way around the Rhode Island law, they will find the Analogue Act just as weak and just as encumbered as it has always been. That is why this Note suggests both adopting the Rhode Island approach to controlled substances and strengthening the Analogue Act.

V. CONCLUSION

Analogues are the most dangerous substances currently in the drug market. They are designed to be more potent and addictive than ordinary controlled substances. Because they do not have the exact chemical structure listed in DEA regulations, they cannot be prosecuted under the Controlled Substances Act. This
means that if prosecution is to go forward at all, it must be done under the Controlled Substances Analogue Enforcement Act. However, despite the fact that synthetic drugs are potentially more dangerous than controlled substances, the Analogue Act is encumbered with procedural hurdles not found in the Controlled Substances Act. Trials are longer and cost more, and defendants unfairly enjoy more protection and are able to exploit loopholes.

The current prevailing approach to addressing synthetic drugs is to schedule them as they appear. Once a synthetic drug is scheduled, law enforcement and prosecution can abandon the Analogue Act and work more efficiently under the Controlled Substances Act. However, the scheduling process is long and cumbersome and cannot keep up with the dizzying pace of innovation in the designer drug world.

The solution to this problem is two-fold. First, the scope of controlled substances statutes must be expanded. This can be accomplished through a mimicking of the Rhode Island Synthetic Drug Ban, which schedules entire structural classes as opposed to individual and specific molecular structures. The second step is to strengthen the analogue statutes so that any modified substances that still manage to get past expanded controlled substances statutes are not met by an encumbered analogue statute. This can be accomplished by removing the intent requirement as to “human consumption” currently associated with analogue statutes. This requirement protects only illegal activity and is therefore unnecessary and unjustified.