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Voiding the Federal Analogue Act

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ABSTRACT

Accordingly, [King Rex] announced to his subjects that he had written out a code and would henceforth be governed by it in deciding cases, but that for an indefinite future the contents of the code would remain an official state secret, known only to him and his scrivener. To Rex's surprise this sensible plan was deeply resented by his subjects. They declared it was very unpleasant to have one's case decided by rules when there was no way of knowing what those rules were.[1]

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1. LON L. FULLER, THE MORALITY OF LAW 35 (Yale Univ. Press rev. ed. 1969). In the chapter entitled "The Morality That Makes Law Possible," Fuller created an allegory about a monarch named Rex who discovered eight wrong ways to make law.

The Federal Analogue Act

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.[2]

> [T]he term "Controlled substance analogue" means a substance—
> (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 . . . 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 . . . a controlled substance in schedule I or II.[3]

2. 21 U.S.C. § 813(a).
3. 21 U.S.C. § 802(32)(A).

I. INTRODUCTION

If the Federal Analogue Act (Analog Act)[4] is to be applied evenly and consistently, regardless of race or class, against all defendants for possessing any analog substance, chocolate must be recognized as the legal equivalent of heroin. Selling brownies at a bake sale, drinking a mug of cocoa, or buying cookies from a Girl Scout can be punished as though the chocolate were an equivalent quantity of a methamphetamine mixture.[5] The Analog Act criminalizes substances that are "substantially similar" to scheduled narcotics in structure and effect and intended for human consumption. "Substantially similar" has no coherent or standardized definition, so it ultimately means whatever the jury or judge desires. In *United States v. Makkar*, Justice Neil Gorsuch, then a circuit judge for the Tenth Circuit Court of Appeals, questioned whether the courts should finally void the Analog Act based on the vagueness of the phrase "substantially similar."[6] This Article answers in the affirmative. Despite almost every federal court having deemed it constitutional, the Analog Act should be voided at the earliest opportunity.

The Analog Act violates the traditional void-for-vagueness doctrine because no one can realistically know in advance what the Analog Act outlaws or the punishment for violations; even scientists and drug experts—including the Drug Enforcement Administration (DEA)—routinely disagree on which substances qualify as analogs. All substances are neither legal nor illegal until a jury reaches its verdict, but because analog status is a fact found by the jury, prosecutions routinely reach opposing conclusions regarding the legality of the same substance. By criminalizing even mundane substances, the Act casts too wide of a net, making any enforcement arbitrary. As illustrated by the circuit splits both preceding and following the Supreme Court's only Analog Act decision, *McFadden v. United States*,[7] no scienter requirement has proven capable of effectively narrowing the Act's scope.

In addition to its unconstitutional vagueness, the Analog Act violates separation of powers principles. Only Congress has the power to criminalize substances. The Analog Act impermissibly delegates this power, effectively forcing the judicial branch to criminalize analogs

4. While "analogue" is the common spelling in British English, this Article employs the American English spelling "analog" to conform with the spelling used by most of the cited sources. *See Analogue*, OXFORD ENGLISH DICTIONARY, https://www.oed.com/viewdictionaryentry/Entry/7029 [https://perma.cc/47UT-88J5] (last visited Sept. 14, 2021).

5. More precisely, chocolate is illegal under the Analog Act for anyone knowing that chocolate is illegal, even if the underlying reasons for its illegality remain unknown. *See infra* Part V; U.S. SENT'G GUIDELINES MANUAL § 2D1.1 (U.S. SENT'G COMM'N 2004).

6. United States v. Makkar, 810 F.3d 1139, 1143 (10th Cir. 2015).

7. 576 U.S. 186 (2015).

temporarily on an inefficient and ad hoc basis. As a prosecutorial tool and deterrent, the Analog Act failed to stop the rise of synthetic cannabis, bath salts, and fentanyl analogs. By ignoring the rise of fentanyl analogs and other known drug threats, congressional inaction cost an untold number of lives.

Aligning American drug law with constitutional norms and protecting public health require voiding the Analog Act. The DEA and Congress have proven their ability to regulate dangerous psychoactive substances effectively without relying on the statute. Voiding the Act would remove a real threat to the emerging industries of legal cannabis and psychedelic therapy while also forcing law enforcement to focus on genuinely dangerous substances.

Part II of this Article presents three different scenarios encapsulating the Kafkaesque experiences of both Analog Act defendants and enforcers. Part III introduces the Analog Act, the Act's structure and history, and the traditional void-for-vagueness doctrine. Part IV explains why the substantial similarity requirement renders the statute unusable. Part V explores the circuit split over the Act's scienter requirement and the Supreme Court's failure to resolve this ambiguity in *McFadden*. Part VI examines the Act under the *Johnson* vagueness doctrine. Part VII analyzes the hazards created by the statute's continued existence. Part VIII first dispels the myth of rapid drug development originally used to justify the Analog Act and then surveys the existing alternate enforcement mechanisms.

II. ILLUSTRATIONS OF THE ANALOG ACT'S FAILURES

The following three scenarios best convey the failures of the Federal Analog Act.

A. First Scenario

Imagine that you are Iqbal Makkar.[8] You are an Indian-born naturalized citizen in your mid-thirties living with your family in the rural Midwest and working at your family's convenience store, the Gitter Done Store.[9] You pay your taxes, sponsor a local baseball team, and donate supplies to firefighters and police.

Your store sells the same legal psychotropic drugs—caffeinated beverages, alcohol, and nicotine products—as the local white-owned stores. Like other stores, yours also sells a product described as "in-

8. This first scenario is based on the facts of *United States v. Makkar*, No. 13-CR-0205, 2014 WL 1572394 (N.D. Okla. Apr. 18, 2014), *rev'd*, 810 F.3d 1139 (10th Cir. 2015).

9. *See* Defendants' Joint Trial Brief at 2, *Makkar*, 2014 WL 6068477 (No. 13-CR-0205).

cense" and prominently labeled "not for human consumption."[10] The incense manufacturer repeatedly assured you that the incense was legal, although it is understood that some purchasers are smoking the incense as a quasi-legal alternative to cannabis.[11]

You suspend sales of the incense when you learn that the state might soon outlaw the incense, and you ask the assistant district attorney to determine what substances the incense contains.[12] The local assistant district attorney declines, assuring you that any prosecution would target the incense distributors and not the retailers.[13] The assistant district attorney does not advise you to stop selling the incense.

One year later, law enforcement raids your store. At trial, evidence of your attempted compliance with the law is excluded.[14] Prosecutors argue that your knowledge of the incense's effects makes you guilty of drug distribution despite your ignorance of the actual chemical composition of the incense itself.

You are convicted. Your business, car, bank accounts, and property are forfeited.[15] Your sentencing report recommends punishing you as though you had distributed over 45,000 pounds of marijuana.[16] After a community letter-writing campaign, including a letter of support from the local mayor, you receive a relatively lenient sentence of ninety-seven months in prison.[17]

Numerous Oklahoma storeowners sold the same incense; some of these other storeowners even testified at your trial.[18] But the only two people federally indicted for selling the once-ubiquitous incense are you and your employee, who is also of East Indian descent.[19]

B. Second Scenario

Next, imagine that you are an employee of the Outer Edge, a company manufacturing and distributing a smokable herbal mixture.[20]

10. *See* Appellant Iqbal Makkar's Opening Brief at 28, *Makkar*, 810 F.3d 1139 (No. 13-CR-0205), 2015 WL 849413.
11. *See id.* at 4–8.
12. *See* Defendants' Joint Trial Brief, *supra* note 9, at 3.
13. *See id.* at 4.
14. *See* Appellant Iqbal Makkar's Opening Brief, *supra* note 10, at 9.
15. *See* Order for Entry of Forfeiture Money Judgment and Preliminary Order of Forfeiture of Property at 2–4, United States v. Makkar, No. 13-CR-0205 (N.D. Okla. Apr. 18, 2014).
16. *See* Response to Defendant Makkar's Objections to PSIR at 7, United States v. Makkar, No. 13-CR-0205 (N.D. Okla. Apr. 18, 2014), 2014 WL 6068535.
17. *See* Transcript of Sentencing Hearing at 21, *Makkar*, 2014 WL 6068501 (No. 13-CR-0205).
18. *See* Appellant Iqbal Makkar's Opening Brief, *supra* note 10, at 28.
19. *See id.* at 43–44.
20. This second scenario is based on the facts of *United States v. Picanso*, No. 14-40005 (D. Kan. 2014). *See* Branden A. Bell, *Not for Human Consumption: Vague*

Your employer appears legitimate: they pay taxes, maintain a staffed office, openly advertise their products, attend trade shows, and supply dozens of retailers across the county.[21] Your concerns about the legality of the company's product were allayed by assurances from your employer's lawyers that it complies with state and federal law and independent laboratory test results confirming that the product does not contain any federally scheduled narcotics.[22]

You and your coworkers—including "salespeople, office managers, and a delivery driver"—are indicted for distributing controlled substance analogs.[23] Facing the threat of twenty years in jail, eleven out of thirteen employees ultimately plead guilty to federal felonies and are sentenced to federal prison.[24] Only two employees go to trial. The jury acquits the pair once evidence emerges showing that even the DEA could not decide on the legality of the substances.[25]

C. Third Scenario

Finally, imagine being a federal prosecutor attempting to combat the national bath salts and Spice epidemics of the early 2010s. Openly sold in gas stations and head shops throughout the country, both substances go undetected by drug tests but replicate the effects of illicit drugs. The active chemicals in bath salts mimic the structures and effects of MDMA[26] or methamphetamine, while Spice contains synthetic cannabinoids mixed with smokable plant matter. Due to their chemical makeup, both products pose even graver dangers than their illegal counterparts.[27]

Both products likely contain chemicals outlawed by the little-used Analog Act, but the statute's opacity and demanding standards make for an exceedingly complicated and challenging prosecution. Worse, the Analog Act requires an analog's illegality to be proven anew in each prosecution. Due to law enforcement's inaction, the products are now a multi-billion-dollar industry, but cracking down would require a diversion of scarce resources from more routine drug prosecutions that promise a far better chance of conviction.

Laws, Uninformed Plea Bargains, and the Trial Penalty, 31 FED. SENT'G REP. 226, 229 (2019).

21. *See* Bell, *supra* note 20, at 229.
22. *See id.*
23. *Id.* at 230.
24. *See id.* at 230–31.
25. *See id.* at 231.
26. MDMA is "the technical name for the active ingredient in ecstasy." Hari K. Sathappan, Note, *Slaying the Synthetic Hydra: Drafting a Controlled Substances Act that Effectively Captures Synthetic Drugs*, 11 OHIO STATE J. CRIM. L. 827, 827 (2014).
27. *See id.* at 828 "In many cases, a controlled substance's analogue can be much more dangerous than the controlled substance itself.").

III. THE ANALOG ACT AND VOID FOR VAGUENESS

It is impossible to know the full range of substances criminalized by the Analog Act. Instead of regulating specific chemicals in the manner of more conventional drug laws, the tripartite Analog Act criminalizes every substance falling within its immensely wide scope. The Act's first part, § 802(32)(A), defines a "controlled substance analogue" as any substance:

> (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 . . . 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 . . . a controlled substance in schedule I or II.[28]

A small number of courts have read these subsections disjunctively, deeming a controlled substance analog to be any substance falling within one of the three subsections.[29] The majority of courts have instead adopted a conjunctive reading of § 802(32)(A). Under the conjunctive reading, a substance is a controlled substance analog when it satisfies subsection (i) and either subsection (ii) or subsection (iii).[30]

Section 802(32)(B) notes that the controlled substance precursors listed in paragraphs (34) and (35)—industrial chemicals like safrole, ephedrine, and ethyl ether—can still qualify as controlled substance analogs.[31] The Analog Act exempts only a narrow range of substances from controlled analog status: (1) a controlled substance; (2) "any substance for which there is an approved new drug application;" (3) a substance subject to an exemption for investigational use; and (4) "any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance."[32]

The Act's second part, § 813, provides that controlled substance analogs "shall, to the extent intended for human consumption, be

28. 21 U.S.C. § 802(32)(A).
29. *See, e.g.*, United States v. Greig, 144 F. Supp. 2d 386, 389–91 (D. V.I. 2001) (adopting a disjunctive reading of § 802(32)(A)), *aff'd in part, rev'd in part sub nom.* United States v. Hodge, 321 F.3d 429 (3d Cir. 2003).
30. *See, e.g.*, United States v. Forbes, 806 F. Supp. 232, 235–36 (D. Colo. 1992) ("The scientific interdependence of molecular structure and effect on the central nervous system is consonant with the legislative history evidencing congressional intent to establish a dependent, two-prong test."). In a *McFadden* footnote, Justice Thomas hinted at a willingness to consider the propriety of the conjunctive reading. McFadden v. United States, 576 U.S. 186, 194 n.2 (2015). Given the incredible breadth of the disjunctive reading, the conjunctive reading's near-uniform acceptance should not be disturbed.
31. 21 U.S.C. §§ 802(32), 802(34)(C), 802(34)(Q), 802(35)(D).
32. 21 U.S.C. § 802(32)(C).

treated, for the purposes of any Federal law as a controlled substance in schedule I."[33] Should the requirements of § 802 and § 813 be met, the now-illicit controlled substance analog can be prosecuted under any federal drug law, including the section prohibiting the knowing manufacture or distribution of a scheduled substance[34] and the section barring the possession of scheduled substances.[35]

The disjunctive interpretation of the Analog Act's plain language concludes that any chemical satisfying one of the three subsections in § 802(32)(A) may be treated as a controlled substance analog. The "or" connecting § 802(32)(A)(ii) and § 802(32)(A)(iii) indicates that satisfying any one of the three separate requirements—substantial structural similarity, substantially similar effects, or representation of substantially similar effects—makes a substance a controlled analog. If employed, this disjunctive reading of the statute would encompass even common legal psychotropics like coffee and alcohol.[36] The legislative history of the Act does not explain whether Congress intended this broad scope; the conjunction between the second and third subsections varied between different drafts of the bill, leaving congressional intent unclear.[37]

The statute does not require any formal or public listing of a chemical as a controlled substance analog before a prosecution can commence,[38] and courts have found that almost every prosecuted substance qualifies as a controlled substance analog.[39]

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33. 21 U.S.C. § 813(a). The human consumption requirement is why gas stations and smoke shops peddling bath salts (synthetic cathinones) or Spice (dangerous, smokable synthetic cannabinoids mixed with plant matter) label their wares as "not intended for human consumption." *See, e.g.*, Jennifer A. Gershman & Andrea D. Fass, *Synthetic Cathinones ('Bath Salts'): Legal and Health Care Challenges*, 37 PHARMACY & THERAPEUTICS 571, 571 (2012). To weaken the legal protection afforded by such labeling, a recent amendment to the Analog Act added a list of circumstantial factors permitting inferences of intended human consumption. *See* 21 U.S.C. § 813(b).

34. 21 U.S.C. § 841(a).

35. 21 U.S.C. § 844(a).

36. *See* United States v. Forbes, 806 F. Supp. 232, 235–36 (D. Colo. 1992).

37. *See* United States v. Fedida, 942 F. Supp. 2d 1270, 1274–76 (M.D. Fla. 2013) (citing 131 CONG. REC. 19114 (1985)).

38. *See, e.g.*, United States v. Cooper, No. 3:14-CR-014-J-20MCR, 2015 WL 13850123, at *7 (M.D. Fla. Jan. 14, 2015) ("There is no requirement that a controlled substance analogue be formally or expressly listed anywhere before a person may be prosecuted under the law for its manufacture, distribution, or possession.").

39. *See* Gregory Kau, Comment, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*, 156 U. PA. L. REV. 1077, 1104 (2008).

A. Void for Vagueness

Originating from the Fifth Amendment's Due Process Clause,[40] the void-for-vagueness doctrine acts as a constitutional safety valve for invalidating any criminal statute with "terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application."[41] Though the doctrine lacks precise boundaries,[42] defendants challenging the Analog Act have typically relied on *Kolender v. Lawson*'s two-part test. The test first looks to whether the statute provides actual notice by "defin[ing] the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited."[43] Second, the statute must be sufficiently definite such that it is not subject to "arbitrary and discriminatory enforcement," allowing "policemen, prosecutors, and juries to pursue their personal predilections."[44] Laws failing either requirement are deemed void.

Vague laws also violate the separation of powers. Only Congress possesses the ability to "make an act a crime."[45] Vague laws impermissibly transfer this ability to unelected judges and police officers, thereby "eroding the people's ability to oversee the creation of the laws they are expected to abide."[46] At its core, the Analog Act gives the judiciary the responsibility of creating new drug laws on a temporary and ad hoc basis.

Defendants have brought countless void-for-vagueness challenges attacking the substantial similarity requirement of the Analog Act,[47] arguing that the law's failure to define the term "substantially similar" falls short of the actual notice requirement described in *Kolender v. Lawson*.[48] Courts have almost universally rejected these challenges. But a closer look at the Analog Act's actual application reveals that it criminalizes an incredibly broad range of actions while also

40. *See generally* Cristina D. Lockwood, *Defining Indefiniteness: Suggested Revisions to the Void for Vagueness Doctrine*, 8 CARDOZO PUB. L. POL'Y & ETHICS J. 255, 266 (2010).

41. FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012) (quoting Connally v. Gen. Constr. Co., 269 U.S. 385, 391 (1926)).

42. *See generally* Lockwood, *supra* note 40, at 256 ("The void for vagueness doctrine is itself indefinite.").

43. Kolender v. Lawson, 461 U.S. 352, 357 (1983).

44. *Id.* at 357–58 (quoting Smith v. Goguen, 415 U.S. 566, 575 (1974)).

45. United States v. Davis, 139 S. Ct. 2319, 2325 (2019) (quoting United States v. Hudson, 11 U.S. 32, 34 (1812)).

46. *Id.*

47. *See, e.g.*, United States v. Brown, 279 F. Supp. 2d 1238, 1240–43 (S.D. Ala. 2003) (rejecting a void-for-vagueness challenge), *aff'd*, 415 F.3d 1257 (11th Cir. 2005). Void-for-vagueness challenges are almost as old as the Act itself. *See* United States v. Desurra, 865 F.2d 651, 653 (5th Cir. 1989).

48. *Kolender*, 461 U.S. 352.

making it effectively impossible to have advance notice of what the statute forbids.

B. The Controlled Substances Act

Understanding the Analog Act's incurable vagueness first requires understanding its history and role within federal drug law. The primary justification cited for implementing the Analog Act was that traditional drug laws like the Controlled Substances Act (CSA) could not effectively prosecute black market chemists who invent and sell new variations of existing narcotics.[49]

The CSA controls discrete substances by assigning them to one of five persistent schedules based on their perceived risk of abuse and medical utility.[50] Drugs that are considered extreme dangers to public health and have no medicinal value—including LSD, MDMA, heroin, cannabis, and mescaline—are assigned to schedule I.[51] Schedule II drugs, like fentanyl and oxycodone, are deemed very dangerous, but they also have some accepted medical uses.[52] Scheduling a substance requires either congressional action or, more commonly, formal rulemaking, through which the Attorney General must weigh numerous statutory factors, including a substance's risk of harm and its medicinal value.[53]

The Attorney General also possesses an emergency scheduling power invokable when a substance poses "an imminent hazard to the public safety."[54] Emergency scheduling places a substance on schedule I at least thirty days after the Attorney General announces the action in the *Federal Register* and notifies the Secretary of Health and Human Services.[55] The emergency scheduling remains in place for

49. *See, e.g.*, United States v. Washam, 312 F.3d 926, 933 (8th Cir. 2002) (asserting that a purpose of the Analog Act was "to prohibit innovative drugs that are not yet listed as controlled substances" (citing United States v. McKinney 79 F.3d 105, 107 (1996))); United States v. Fedida, 942 F. Supp. 2d 1270, 1276 (M.D. Fla. 2013) (discussing Congress's intent to close federal drug law loopholes); United States v. Forbes, 806 F. Supp. 232, 238 (D. Colo. 1992) ("Congress declared that the purpose of the statute is to attack underground chemists who tinker with the molecules of controlled substances to create new drugs that are not yet illegal.").

50. For an explanation of rule-based narcotics statutes, like the CSA, and standard-based narcotics statutes, like the Analog Act, see Kau, *supra* note 39, at 1087 (describing differences between rules and standards).

51. *See* 21 U.S.C. § 812(b)(1); *see also* U.S. DEP'T OF JUST., LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS (Aug. 2021) [hereinafter DEA ORANGE BOOK], https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf [https://perma.cc/3SZY-K7PD] (listing all scheduled chemicals).

52. *See* 21 U.S.C. § 812(b)(2); *see also* DEA ORANGE BOOK, *supra* note 51 (listing all scheduled chemicals).

53. *See* 21 U.S.C. §§ 811(a)–(c).

54. 21 U.S.C. § 811(h)(1).

55. *See id.*

two years with a possible one-year extension if the substance is in the process of joining a permanent schedule.[56] Once scheduled, a drug takes its place in the DEA's "Orange Book," a publicly accessible and regularly updated compilation listing all controlled chemicals under the CSA by their chemical and common names.[57]

C. History of the Analog Act

Congress passed the Analog Act in the wake of the first fentanyl analog outbreak.[58] In 1979 and 1980, a drug named China White contributed to the deaths of at least ten recreational drug users in California.[59] Law enforcement forensic analysts discovered that China White contained no illegal drugs but instead consisted of the opiate alpha-methylfentanyl, a fentanyl analog, mixed with lactose sugar.[60]

To the great frustration of law enforcement, the bulk of the lethal drugs fueling this first fentanyl crisis were, at the time, unregulated substances falling outside of the CSA. The drugs were produced by well-educated professional chemists moonlighting as recreational substance manufacturers. Drug-user deaths continued and stemmed from an ever-widening range of exotic fentanyl analogs: para-fluorofentanyl, 3-methyl-fentanyl, beta-hydroxyfentanyl, and others.[61]

Because the drugs were unscheduled, prosecutors had few options for criminal charges against these manufacturers. One DuPont chemist saw his sentence for selling 3-methyl-fentanyl vacated because 3-methyl-fentanyl was not then a prohibited substance. A California chemist and his co-conspirators were caught with sixty pounds of legal fentanyl analogs intended for black market distribution, yet prosecutors could only proceed under the feeble criminal provisions of the Food, Drug, and Cosmetic Act.[62]

At the time, the DEA dutifully scheduled new substances as it discovered them in illicit production,[63] but the temporal gap between the

56. *See* 21 U.S.C. § 811(h)(2).
57. DEA ORANGE BOOK, *supra* note 51.
58. *See generally* United States v. Tyhurst, 28 M.J. 671, 673 (A.F.C.M.R. 1989), *rev'd in part*, 29 M.J. 324 (C.A.A.F. 1989); Kau, *supra* note 39, at 1078.
59. *See* John J. Coleman, *Special Report: Fentanyl Analogs in Street Drugs*, PRESCRIPTION DRUG RSCH. CTR. 10 (Aug. 16, 2007).
60. *See id.* at 3, 11. The DEA added alpha-methylfentanyl to the list of schedule I drugs in 1981. *Id.* at 12.
61. *See* U.N. Off. on Drugs & Crime, Recommended Methods for the Identification and Analysis of Fentanyl and Its Analogues in Biological Specimens, U.N. Doc. ST/NAR/53 (Nov. 2017).
62. *See* Coleman, *supra* note 59, at 12.
63. Alpha-methylfentanyl was added to schedule I on September 22, 1981; beta-hydroxyfentanyl was emergency scheduled on November 29, 1985, and it was permanently added to schedule I in 1987. Fentanyl analogs continued to be scheduled after passage of the Analog Act. *See* DEA ORANGE BOOK, *supra* note 51

discovery of a drug on the black market and the drug's scheduling created a loophole for the drug manufacturers. To prevent more analog chemists from escaping prosecution, Congress drafted the Analog Act to temporarily criminalize newly discovered designer drugs until the DEA could complete all of the formal rulemaking procedures required to schedule them formally.[64] Once a drug completed the lengthy administrative process required for scheduling, it became subject to the CSA and exempt from the Analog Act.

D. The Analog Act as a Failed Prosecutorial Tool

As a threshold matter, it must be acknowledged that the Analog Act simply does not work as intended and has proven incapable of preventing or prosecuting the commercialization of designer drugs. During Senate Judiciary Committee hearings in 2019, thirty-four years after the statute's passage, the Department of Justice openly disparaged the statute's utility as a law enforcement tool, characterizing its prosecutions as "time-consuming, resource-intensive, and difficult for investigators, drug testing laboratories, prosecutors, courts, juries, and the entire criminal justice system" and filled with "technical and voluminous" filings addressing issues "simply not relevant to routine controlled substance prosecutions."[65]

The national bath salts and synthetic cannabis epidemics of the past decade illustrate the DEA's frustrations with the statute. Around 2008, packets of synthetic cannabis began appearing for sale in head shops, gas stations, and convenience stores across the United States. Often called Spice or K2, synthetic cannabis was a mixture of smokable plant material and a synthetic cannabinoid—such as JWH-018, UR-144, or XLR-11—capable of mimicking cannabis's psychoactive effects.[66] Although they were dangerous for consumers, synthetic cannabinoids had one chief advantage: they were not CSA scheduled. To

(listing the scheduling dates for para-fluorofentanyl, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, 3-methylthiofentanyl, and other fentanyl analogs).

64. *See, e.g.*, United States v. Way, No. 14-CR-00101, 2018 WL 2229272, at *7 (E.D. Cal. May 16, 2018) ("[T]he bill was meant to address 'the time lag between the production of these new designer drugs and their subsequent control under the Controlled Substances Act.'" (quoting 131 CONG. REC. 18938 (1985) (statement of Rep. Dan Lungren))), *aff'd*, No. 18-10427, 2020 U.S. App. LEXIS 5512 (9th Cir. Feb. 21, 2020).

65. *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 5 (2019) [hereinafter *The Countdown*] (statement of Amanda Liskamm, Director, Opioid Enforcement and Prevention Efforts, Office of the Deputy Att'y Gen. & Greg Cherundolo, Chief of Operations, Office of Global Enforcement, Drug Enforcement Administration).

66. *See* Asa Louis et al., *XLR-11 and UR-144 in Washington State and State of Alaska Driving Cases*, 38 J. ANALYTICAL TOXICOLOGY 563 (2014).

protect against § 813's human consumption requirement, sellers typically marketed synthetic cannabis as incense or potpourri in containers labeled "not for human consumption." Synthetic cannabis attracted consumers because of its availability, ability to evade drug tests, and modest cost (typically between twenty-five cents and ten dollars per gram).[67] By 2012, the synthetic cannabis industry was worth an estimated five billion dollars, with the drug trailing only real cannabis in popularity.[68]

Often sold in the same retail outlets as synthetic cannabis, bath salts gained widespread popularity in the United States as a "legal high" starting around 2009.[69] They were typically labeled as plant food or bath salts with a prominent warning that they were not for human consumption.[70] In reality, the package typically contained a few doses of synthetic cathinones or mephedrone, another chemical similar in structure and effects to MDMA or amphetamine.[71] Despite their similarities to schedule I substances, most synthetic cathinones were not then expressly illegal under the CSA and could be purchased legally for a few thousand dollars per kilogram. That kilogram of synthetic cathinones would then be packaged and sold at a nominal price, sometimes as little as five dollars per dose.[72] Bath salts reached an incredible level of international popularity. At the peak of their popularity, twenty percent of college and high school students in the United Kingdom had sampled mephedrone, and over half of all pills sold as MDMA were, in fact, mephedrone.[73] Bath salts also eclipsed more familiar narcotics in popularity among American high schoolers.[74]

Congress designed the Analog Act to prevent these kinds of controlled substance analogs from growing into nationally available products. It did not. The bath salts and synthetic cannabis outbreaks

67. *See, e.g.*, Tina Reed, *K2: Easily Accessible Substance that Mimics Marijuana—and Is Legal—Sold in Ann Arbor*, ANN ARBOR NEWS (Feb. 24, 2010, 6:02 AM), http://www.annarbor.com/news/easily-accessible-substance-that-mimics-marijuana—-and-is-legal—-sold-locally/ [https://perma.cc/U4LW-6HU3].
68. *See* Max Spaderna et al., *Spicing Things Up: Synthetic Cannabinoids*, 228 PSYCHOPHARMACOLOGY 525, 526 (2013).
69. *See* Jane M. Prosser & Lewis S. Nelson, *The Toxicology of Bath Salts: A Review of Synthetic Cathinones*, 8 J. MED. TOXICOLOGY 33, 33 (2012) (providing a brief history of bath salts).
70. *See id.*
71. *See* Anita Slomski, *A Trip on "Bath Salts" Is Cheaper than Meth or Cocaine but Much More Dangerous*, 308 JAMA 2445, 2446 (2012) (reporting that one package of bath salts was found to contain a synthetic cannabinoid and caffeine; another was entirely composed of lidocaine).
72. *See id.* at 2445.
73. *See* Prosser & Nelson, *supra* note 69, at 35.
74. *See generally* Joseph J. Palamar, *"Bath Salt" Use Among a Nationally Representative Sample of High School Seniors in the United States*, 24 AM. J. ADDICTIONS 488 (2015).

ended only after the scheduling of synthetic cathinones and cannabinoids. Despite the massive national consumption of the drugs and a large number of potential defendants, Analog Act prosecutions proved so difficult and time-consuming as to make them vanishingly rare: Westlaw reports that just over 200 federal cases have cited § 813 of the Analog Act since 2009.[75] While this is a sizable uptick in prosecutions—federal courts have cited § 813 only 280 times in total—by point of comparison, approximately 54,000 different federal decisions cited the CSA during the same time period.[76]

IV. SUBSTANTIALLY SIMILAR

No one can agree on the substances that the Analog Act controls. Under § 802(32) of the Analog Act, virtually every prosecution must prove that the alleged analog possesses substantially similar effects and structure to a schedule I substance.[77] Neither term has an objective scientific or technical meaning, so a jury may deem any substance a controlled substance analog.[78] Even DEA scientists routinely disagree over whether a substance bears the required structural similarity.

One of the earliest critics of the Analog Act, DEA consulting scientist Alexander Shulgin, publicly decried the substantial similarity requirement as "hopelessly vague" for having no scientific definition or meaning.[79] Shulgin spoke with special authority on controlled substance analogs: not only had he authored a popular law enforcement textbook on controlled substances and received multiple awards from

75. This information is current as of August 27, 2021. To find these cases in a legal research database, search cases for the citing reference "21 U.S.C. 813," filter for federal jurisdiction, and limit the results to those dated after January 1, 2009.

76. This information is current as of August 27, 2021. To find these cases in a legal research database, search cases for the citing reference "21 U.S.C. 841," filter for federal jurisdiction, and limit the results to those dated after January 1, 2009.

77. The exceptions are the relatively rare prosecutions under § 802(32)(iii), which only require proof that a defendant represented a substance as having effects that are substantially similar to those of a schedule I substance.

78. *See, e.g.*, Bell, *supra* note 20, at 227.

79. Alexander T. Shulgin, *How Similar Is Substantially Similar?*, 35 J. FORENSIC SCI. 8 (1990), http://www.thevespiary.org/rhodium/Rhodium/chemistry/shulgin.substantially.similar.html [https://perma.cc/7QP7-WPCG] ("There is no 'right' answer [to substantial similarity]. There can never be one."). Shulgin even describes the Act as a net which has a "completely variable mesh size" that permits law enforcement to "catch whatever fish one wishes to and let escape another fish that is not wanted." *Id.*

the DEA[80] but he had also personally discovered many of the analogs later prosecuted under the Act.[81]

Chemical structures possess many different features. Just as numerous qualities compose a person's appearance—height and weight; eye, hair, and skin color; and age, for example—chemicals similarly possess a vast number of distinct properties. These structural properties include chemical formula, atomic weight, shape (whether in two or three dimensions), "atomic angles, resonance, spin, bond type, and bond strength," functional groups, and many more.[82] Weighing substantially similar effects poses a comparably difficult problem. While the terms "stimulant, depressant, or hallucinogenic effect" are understandable, how to compare the effects of two substances remains unclear. No objective scale exists to judge the degree of similarity between, for example, hallucinations induced by ethanol alcohol withdrawal and those of LSD.[83]

Compounding the difficulty of these inquiries is the fact that schedules I and II contain hundreds of substances that induce all manners of psychological and physiological effects. Some substances are common—cannabis, quaaludes, fentanyls, cathinones, and tryptamines—while others are so exotic as to be virtually unknown: **propiram, Tilidine, drotebanol, CP-47, 1-[1-(2-**thienyl)cyclohexyl]pyrrolidine, and many more. The schedules have even included substances antithetical in effect to recreational drug use, such as naloxone, the opioid agonist now commonly administered as a fentanyl overdose antidote.[84]

A. No Coherent Test Exists for Determining Substantial Similarity

The majority of courts have consistently agreed that "substantially similar" lacks any coherent scientific meaning or concrete definition, with some judges going so far as to opine that Congress intended for the words to be given "their ordinary meanings."[85] Despite acknowl-

80. *See generally* Drake Bennett, *Dr. Ecstasy*, N.Y. TIMES MAG. (Jan. 30, 2005), https://www.nytimes.com/2005/01/30/magazine/dr-ecstasy.html [https://perma.cc/2STU-JJXH].

81. *See generally* ALEXANDER SHULGIN & ANN SHULGIN, TIHKAL: THE CONTINUATION (1997), https://erowid.org/library/books_online/tihkal/tihkal.shtml [https://perma.cc/3Z4R-GVYU].

82. Paul Anacker & Edward J. Imwinkelried, *The Confusing World of the Controlled Substance Analogue (CSA) Criminal Defense*, 42 CRIM. L. BULL. 744, 770 (2006).

83. *See* Bell, *supra* note 20, at 229.

84. *See* DEA ORANGE BOOK, *supra* note 51, at 11.

85. United States v. Lawton, 84 F. Supp. 3d 331, 337 (D. Vt. 2015) ("[T]here is no indication that Congress intended the words 'substantially similar' to have a specialized or scientific meaning. Therefore, these words should be given their ordinary meanings." (citation omitted) (quoting United States v. Reece, No. CRIM.

edging the lack of an agreed-upon scientific definition, almost all courts have found the statute permissibly definite to survive a void-for-vagueness challenge.

Parties rely chiefly upon expert witness testimony to define substantial similarity, and the jury is left to weigh the "relative strengths and merits of the methodologies supporting the experts' opinions."[86] But because no common scientific framework exists for analyzing substantially similar effects or structure, expert testimony often "amount[s] to little more than the deduction of a working hypothesis supported by a general knowledge of chemistry and biochemistry."[87] As one DEA expert witness very candidly explained, "'Substantial similarity' is a gut-level decision. . . . And all 'gut feelings' are legitimate."[88] Courts have agreed that "such a comparison defies quantification" and effectively hinges on an individual chemist's intuition.[89]

Federal Rule of Evidence 702 permits expert witness testimony when the expert's scientific knowledge will aid in determining a fact at issue, but Professor Edward Imwinkelried and Paul Anacker have voiced grave doubts regarding the propriety of allowing expert witness testimony to address the non-technical question of substantial similarity:

> "[S]ubstantial similarity" is not a scientific concept. To convert the notion into a scientific concept, a researcher would have to specify objective criteria for substantial similarity. Without the benefit of such criteria, the analyst must necessarily rely on subjective judgment, and his or her final conclusion as to similarity remains impressionistic. Until testable criteria are defined, the hypothesis fails [the] threshold criterion for reliable "scientific . . . knowledge": There is no way to test the proposition empirically.[90]

Despite the strength of this critique, defendants' challenges to the admissibility of expert witness testimony for the prosecution have proven unsuccessful, although the judicial justifications for denying these challenges fall short of persuasive.[91]

12-00146, 2013 WL 3865067, at *9 (W.D. La. July 24, 2013))); *see also* United States v. Brown, 279 F. Supp. 2d 1238, 1245 (S.D. Ala. 2003) ("[There is] no hard-line definition of the term . . . the definition of 'similar chemical structure' depends on the judgment of a chemist."), *aff'd*, 415 F.3d 1257 (11th Cir. 2005).

86. United States v. Cooper, No. 14-CR-014-J-20MCR, 2015 WL 13850123, at *5 (M.D. Fla. Jan. 14, 2015) (quoting United States v. Fedida, 942 F. Supp. 2d 1270, 1279 n.6 (M.D. Fla. 2013)).

87. *Fedida*, 942 F. Supp. 2d at 1281; *see also* Jeffrey C. Grass, McFadden v. United States*: Deconstructing Synthetic Drug Prosecutions*, CHAMPION, May 2015, at 34 (discussing expert witness issues related to the substantially similar standard).

88. *Brown*, 279 F. Supp. 2d at 1245. The expert witness's gut feelings were enough to support a conviction. *Id.*

89. *Id.*

90. Anacker & Imwinkelried, *supra* note 82, at 768.

91. *See, e.g.*, United States v. Brown, 415 F.3d 1257, 1266–69 (11th Cir. 2005); *Cooper*, 2015 WL 13850123, at *9.

No uniform legal tests guide the substantial similarity analysis. Scholarly literature describes structural similarity tests using phrases such as "core arrangement of atoms," "structure and effects," or "visual inspection."[92] Yet an examination of the cited appellate cases finds no judicially designed tests to guide future prosecutions; instead, there are only affirmations of a particular prosecution's means of proof. For example, *United States v. Klecker*[93] has been cited as the originating case for the "core arrangement of atoms" test.[94] In that case, the Fourth Circuit affirmed the district court's finding that 5-methoxy-N,N-diisopropyltryptamine (Foxy) was a controlled substance analog of the schedule I substance DET.[95] The district court based its finding on a number of facts, including that Foxy and DET share a "core arrangement of atoms" and both possess a "tryptamine core."[96] *Klecker* never referred to or adopted the "core arrangement of atoms" as a legal test.[97]

Similarly, the "structure and effect" test is described as a means of determining substantial similarity by examining a drug's chemical composition in tandem with its effects on users.[98] Left unexplained is how this test imposes different requirements than those imposed by a conjunctive reading of § 802(32)(A). Finally, the "visual inspection" test describes the same process discussed above in which the jury is presented with comparative visual representations of a controlled substance and its alleged analog.[99]

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92. Jeremy Mandell, Note, *Tripping Over Legal Highs: Why the Controlled Substances Analogue Enforcement Act Is Ineffective Against Designer Drugs*, 2017 U. ILL. L. REV. 1299, 1315; *see also* Brief of the National Association of Criminal Defense Lawyers as Amicus Curiae in Support of Petitioner at 4–5, McFadden v. United States, 576 U.S. 186 (2015) (No. 14–378) (explaining the different tests applied by the circuit courts of appeals).

93. 348 F.3d 69 (4th Cir. 2003).

94. *See* Mandell, *supra* note 92, at 1315.

95. *Klecker*, 348 F.3d at 72.

96. *Id.* at 73 (quoting United States v. Klecker, 228 F. Supp. 2d 720, 728 (E.D. Va. 2002)). LSD, psilocybin, and a host of other psychedelics all share a common tryptamine structure. *See* Bill Sanders et al., *"Research Chemicals": Tryptamine and Phenethylamine Use Among High-Risk Youth*, 43 SUBSTANCE USE & MISUSE 389, 392 (2008).

97. *See Klecker*, 348 F.3d at 73. A narrow reading of *Klecker*, in which the court's reasoning only encompasses drugs sharing a "tryptamine core," would yield unacceptable results by criminalizing common substances. Melatonin and 5-HTP, two over-the-counter sleep aids, also possess a tryptamine core. *See* Ricardo Letra-Vilela et al., *Distinct Roles of N-Acetyl and 5-Methoxy Groups in the Antiproliferative and Neuroprotective Effects of Melatonin*, 434 MOLECULAR & CELLULAR ENDOCRINOLOGY 238, 242 (2016) (noting melatonin's tryptamine core).

98. *See, e.g.*, Kathryn E. Brown, Comment, *Stranger Than Fiction: Modern Designer Drugs and the Federal Controlled Substances Analogue Act*, 47 ARIZ. STATE L.J. 449, 461–62 (2015).

99. *See* Mandell, *supra* note 92, at 1315.

Most questions of substantial structural similarity ultimately hinge upon a comparison of two-dimensional "stick and letter" diagrams.[100] These uninformative diagrams only illustrate a substance's atomic composition and location and omit all other relevant characteristics, leading the entire process to be dubbed "guilt by Rorschach test."[101] Bereft of any objective, scientific guideposts to control the structural similarity analysis, experts point to a seemingly endless number of chemical properties in support of their intuitions, a practice sanctioned by the courts.[102]

United States v. Roberts illustrates the sheer cacophony of contradictory scientific evidence that a judge or jury must weigh in a typical analog prosecution. In *Roberts*, the defendants had been indicted for selling 1,4-butanediol—an industrial solvent and alleged analog of the schedule I "date rape" drug GHB—to bodybuilders as a health supplement.[103] At a hearing challenging the Analog Act as unconstitutionally vague, three testifying experts compared the two chemicals based on the following criteria: (1) functional groups and the functional groups' properties; (2) whether the chemicals would be grouped together in an organic chemistry textbook; (3) two-dimensional charts, three-dimensional appearance, and the differences between the two; (4) results from a nuclear magnetic resonance spectrometer; (5) post-ingestion structure; (6) molecular linearity, stability, and charges; and (7) "atomic composition . . . as illustrated in their molecular chains."[104] The prosecution's expert, a DEA employee, concluded that the chemicals were substantially similar in structure.[105] The defendant's witnesses, both college professors, came to the opposite conclusion, going so far as to claim that "a student who stated on a college exam that GHB and 1,4-butanediol were similar in chemical structure would indeed fail such an exam."[106]

The district court ruled for the defendant, but the Second Circuit reversed on appeal. Judge Guido Calabresi found that 1,4-butanediol was substantially structurally similar to GHB because the chemicals differed by only two atoms and because 1,4-butanediol transformed into GHB upon ingestion.[107] Citing these two chemical features, the

100. *See, e.g.*, United States v. Fedida, 942 F. Supp. 2d 1270, 1279 (M.D. Fla. 2013).
101. Bell, *supra* note 20, at 228.
102. *See* Brief of the National Association of Criminal Defense Lawyers as Amicus Curiae in Support of Petitioner at 3–8, McFadden v. United States, 576 U.S. 186 (2015) (No. 14–378). One exception was the rejection of a plant pathologist's testimony using the Tanimoto coefficient to measure chemical similarities. *See* United States v. Brown, 415 F.3d 1257, 1263, 1269 (11th Cir. 2005).
103. United States v. Roberts, No. 01 CR 410, 2002 WL 31014834, at *1 (S.D.N.Y. Sept. 9, 2002), *vacated*, 363 F.3d 118 (2d Cir. 2004).
104. *Id.* at *1–2, *4.
105. *Id.* at *1.
106. *Id.* at *2.
107. *Roberts*, 363 F.3d at 125.

court disregarded the disagreement of the expert scientists, deciding that the Analog Act was sufficiently definite in regard to 1,4-butanediol.[108]

Recent Analog Act prosecutions have continued to acknowledge and dismiss the paradox of having expert scientific witnesses testify on a concept lacking any agreed-upon objective parameters. The typical justification for introducing conflicting or impenetrable expert testimony is to focus the inquiry only on whether a lay jury can use the evidence to reach a verdict.[109]

In *United States v. Fedida*, the court addressed whether the statutory definition of controlled substance analog permitted "ordinary people" to determine that synthetic cannabinoids UR-144 and XLR-11 were substantially similar in structure to the schedule I substance JWH-18.[110] The court surveyed the esoteric chemical evidence presented by the parties, including the "substitution of a tetramethylcyclopropyl moiety in place of the naphthyl moiety," the delocalized electrons in aromatic rings and their shapes, and most critical to the court's analysis, a "replacement found within the 3-position substituent."[111] While recognizing the legitimate disputes between experts, the court decided that "the Government need not overcome the critical eye of chemists and other experts. Rather, it must merely show that ordinary people would be able to determine whether UR-144 and XLR-11 are proscribed analogues of JWH-18."[112] The court ultimately found that the Analog Act was not unconstitutionally vague as applied because "[a] reasonable layperson who examines the two-dimensional drawings of the chemical structures . . . could plausibly conclude that such substances are substantially similar. This is all that is required."[113]

A lay jury can always reach a conclusion, no matter the volume of conflicting and arcane expert opinions. But this is not what the Due Process Clause requires. The Due Process Clause requires "that ordinary people can understand what conduct is prohibited"[114] *before* a jury's verdict. The Analog Act does not provide that notice.

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108. *Id.* at 127.

109. *See, e.g.*, United States v. Way, 804 F. App'x 504, 509 (9th Cir. 2020) ("The district court ruled that since the jury would decide what was a controlled substance analogue, any internal DEA disagreement as to whether 5-F-UR-144 was an analogue was irrelevant. We agree with the district court.").

110. United States v. Fedida, 942 F. Supp. 2d 1270, 1274 (M.D. Fla. 2013).

111. *Id.* at 1279.

112. *Id.* (footnote omitted) (citations omitted).

113. *Id.*

114. Kolender v. Lawson, 461 U.S. 352, 357 (1983).

B. No Coherent Test Exists for Determining Substantially Similar Effects

Like substantially similar structure, no definite criteria or test governs the question of whether a substance "has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to . . . a controlled substance in schedule I or II."[115]

Without an objective standard for determining the substantial similarity of effects, "it is far from clear that any available evidence on this issue would satisfy either of the major admissibility tests" for expert witness testimony.[116] Nonetheless, courts have been very permissive in allowing a wide range of evidence, including "anecdotal reports, affidavits and testimonials" from substance users as well as scientific studies.[117] Section 802(32)(A)(ii) states that the substance has an effect on the "central nervous system," but it does not specify that it must affect a *human's* central nervous system; experiments on animals (even toads, as one DEA expert opined[118]) are sufficient.[119]

Prosecutors have also employed studies measuring a substance's effect on particular nervous system receptor sites. However, these studies typically only report whether a substance acted on a given receptor site. In *United States v. Cooper*, the DEA concluded that 5F-PB-22 has substantially similar effects to the schedule I drug AM-2201 because both drugs act as agonists on the CB1 receptor, similar to marijuana.[120] Yet receptor site activity alone provides the illusion of scientific certainty with very little real information about a drug's effects. Other drugs affecting CB1 receptors include the antibiotic Minocycline[121] and the over-the-counter painkiller Tylenol.[122]

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115. 21 U.S.C. § 802(32)(A)(ii).
116. Anacker & Imwinkelried, *supra* note 82, at 772.
117. United States v. Klecker, 228 F. Supp. 2d 720, 729 (E.D. Va. 2002), *aff'd*, 348 F.3d 69 (4th Cir. 2003).
118. *See* Bell, *supra* note 20, at 232 n.27 (citing United States v. Picanso, No. 14-40005-DDC (D. Kan. Feb. 3, 2017)). An analog's effect on rats is also permissible evidence. *See* United States v. Nasir, No. 12-CR-102, 2013 WL 5373619, at *3 (E.D. Ky. Sept. 25, 2013).
119. *See generally* United States v. Way, No. 14-CR-00101-BAM, 2018 WL 5310773, at *4 (E.D. Cal. Oct. 25, 2018) ("[S]everal district courts have found that expert testimony based on animal studies is sufficiently reliable in Analogue Act prosecutions to demonstrate a substance's pharmacological effect on the human central nervous system." (citing United States v. Williams, No. 13-00236-01, 2017 WL 1856081, at *16 (W.D. Mo. Apr. 7, 2017))); United States v. Reulet, No. 14-40005, 2015 WL 7776876, at *11 (D. Kan. Dec. 2, 2015); United States v. Bays, No. 13-CR-0357-B, 2014 WL 3764876, at *14 (N.D. Tex. July 31, 2014).
120. *See* Motion to Dismiss Indictment and Memorandum of Law at 26, United States v. Cooper, No. 14-CR-014-J-20MCR (M.D. Fla. Jan. 14, 2015).
121. *See* Leonardo Guasti et al., *Minocycline Treatment Inhibits Microglial Activation and Alters Spinal Levels of Endocannabinoids in a Rat Model of Neuropathic Pain*, 5 MOLECULAR PAIN 35 (2009).

More confounding is the fact that courts have permitted prosecutions to proceed even if the government admits to having no concrete evidence regarding a substance's effect. In *Fedida*, after hearing the government's expert testimony on the effects of UR-144 and XLR-11, the court pointedly noted that the basis of this testimony had "not been subjected to peer review or publication. There was no evidence concerning the known or potential error rates of the experts' methodology."[123] And it remained unclear "whether the experts' opinions and methodologies were generally accepted in the scientific community."[124] One expert even "conceded that there is an insufficient basis for her to form an opinion about the pharmacologic effects" of the alleged analogs.[125] However, the court permitted the prosecution to proceed based on the government's assurances that "it is conducting tests which could support its experts' opinions."[126]

C. "Hybrid" Substantial Similarity

Further complicating the possibility of actual notice of analog illegality, the hybrid substantial similarity approach permits a substance to be considered a controlled analog if it is substantially structurally similar to one chemical yet similar in effects to an entirely different chemical.

In *United States v. Demott*, two defendants had been convicted of importing from China the unscheduled chemicals 4-methylmethcathinone (4-MMC or "mephedrone") and 4-methyl-n-ethylcathinone (4-MEC) and selling them as MDMA substitutes.[127] At trial, the government relied on expert testimony stating that both chemicals bore substantial structural similarities to methcathinone, which is listed on schedule I, and induced effects substantially similar to those of a different listed substance, MDMA.[128] The defendants contended that an analog must be substantially similar in effect and structure to the same scheduled narcotic. The court rejected the defendants' argument after finding no statutory requirement that an alleged analog be substantially similar in structure and effect to the same scheduled substance.[129]

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122. *See generally* Pascal P. Klinger-Gratz et al., *Acetaminophen Relieves Inflammatory Pain Through CB_1 Cannabinoid Receptors in the Rostral Ventromedial Medulla*, 38 J. NEUROSCIENCE 322 (2018).
123. United States v. Fedida, 942 F. Supp. 2d 1270, 1281 (M.D. Fla. 2013).
124. *Id.*
125. *Id.* at 1281 n.7.
126. *Id.* at 1282.
127. United States v. Demott, 906 F.3d 231, 235 (2d Cir. 2018).
128. *Id.* at 238.
129. *Id.* at 239 ("Nothing in the language of the Act suggests that the drug listed in Schedule I or II that is substantially similar in chemical structure to the ana-

D. Substantially Similar Punishment

Finally, no one knows what punishment an Analog Act conviction will merit. The federal sentencing guidelines dictate punishments based on the kind of substance involved in a conviction but do not list punishments for every conceivable analog. "In the case of a controlled substance that is not specifically referenced in [the] guideline," such as a controlled substance analog, judges must "determine the base offense level using the converted drug weight of the most closely related controlled substance referenced in [the] guideline."[130] Making this determination requires the judge to conduct yet another substantial similarity-in-structure-and-effects inquiry nearly identical to those performed at trial.

The judge's conclusion can be the difference between a few months or a few decades in prison.[131] In *United States v. Moreno*, the defendant, convicted for distributing alpha-PVP, contested the sentencing calculation, arguing that alpha-PVP should be considered an analog of a schedule V drug, pyrovalerone, instead of the schedule I methcathinone.[132] Using pyrovalerone as the reference drug would have yielded a sentence measured in months; however, the judge found methcathinone to be the closest correlating substance and sentenced the defendant to years in prison.[133]

This level of sentencing indeterminacy may satisfy due process for a typical CSA conviction in which a defendant knew the substance's legal status in advance. But the Analog Act's initial substantial similarity determination leaves defendants incapable of knowing whether a substance is illicit and, if it is, the sentencing guideline's substantial similarity inquiry makes it impossible to determine the severity of the punishment defendants may incur.

E. The Impossibility of Actual Notice

Courts have assumed that a defendant can conform their behavior to the law by seeking expert advice.[134] They cannot. The lack of an

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logue must be the same listed drug that is substantially similar to the analogue in pharmacological effect." (citation omitted)).

130. U.S. SENT'G GUIDELINES MANUAL § 2D1.1 cmt. 5 (U.S. SENT'G COMM'N 2021).

131. *See* Sarah Nishioka, Comment, *The "Grande Iced Nonfat Chai with a Shot of Espresso" Problem: Dealing with Designer Drugs in the Wake of* McFadden v. United States, 39 U. HAW. L. REV. 265, 287 (2016).

132. United States v. Moreno, 870 F.3d 643, 645 (7th Cir. 2017).

133. *Id.*

134. *See, e.g.*, *United States v. Niemoeller,* No. IP 02-09-CR-1, 2003 WL 1563863, at *4 (S.D. Ind. Jan. 24, 2003) ("[W]hen dealing with the distribution of organic chemical compounds for human consumption and with intended or hoped-for central nervous system effects, Congress could reasonably expect and require persons engaged in that activity to possess or obtain the specialized knowledge needed to conform their conduct to law.").

objective similarity standard renders expert advice meaningless. The government has secured Analog Act convictions against retailers who voluntarily submitted to preemptive DEA inspections[135] or who consulted law enforcement[136] or former DEA scientists.[137] Expert biochemists have even manufactured these substances, mistakenly believing them to be legal.[138] One defendant, Asim Malik, owned a gas station in central Kentucky and sold synthetic cannabis as a side business.[139] Conscious of a possible legal hazard, he "undertook extraordinary efforts to ensure that he was operating within the bounds of the law."[140] In 2010, Malik "took a sample of the materials to the Nicholasville Police Department's Drug Enforcement Division. He was told that at that time . . . the substances were legal."[141] In 2011, law enforcement seized some of his synthetic cannabis only to return it after deeming it legal.[142] Malik had each product tested at a laboratory to ensure that he did not sell any illegal substances. Even Malik's lawyer told him that his products were legal. Despite his efforts, Malik was ultimately convicted under the Analog Act and sentenced to fifty months in federal prison.[143]

As a practical matter, assessing an analog's legality would be extremely difficult. The first step would be to locate suitable experts on chemical structure and the pharmacology of exotic psychoactive substances. The experts would then sift through the structure and effects of hundreds of controlled schedule I and schedule II drugs in search of similar-seeming chemicals, looking at effects and structure separately.[144] Finally, the experts would analyze the candidate substance using all of the substantial similarity criteria employed in all prior Analog Act cases. Yet even these extreme precautions would afford a defendant no safety: ultimately, a controlled substance analog is

135. *See* Jordan S. Rubin, *Fear and Loathing—and Gorsuch!—in Synthetic Drug Fight*, BLOOMBERG L. (July 12, 2018, 11:32 AM), https://news.bloomberglaw.com/white-collar-and-criminal-law/fear-and-loathingand-gorsuch-in-synthetic-drug-fight [https://perma.cc/7WWR-UKX6].

136. *See* United States v. Makkar, 810 F.3d 1139, 1147 (10th Cir. 2015). At trial Makkar and his employee sought to introduce evidence "that they asked state law enforcement agents to test the incense to assure its legality under state law—and that they offered to stop selling the incense until the results came in." That evidence was excluded. *Id.*

137. *See* Rubin, *supra* note 135.

138. *See* Brown, *supra* note 98, at 457–58.

139. *See* United States v. Nasir, No. 12-CR-102, 2013 WL 5373625 (E.D. Ky. Sept. 25, 2013).

140. *Id.* at *4 (citation omitted).

141. *Id.* (citation omitted).

142. *See id.* (citation omitted).

143. United States v. Nasir, No. 12-CR-102, 2013 WL 6925061 (E.D. Ky. Dec. 17, 2013).

144. *See generally* United States v. Demott, 906 F.3d 231, 239 (2d Cir. 2018); Bell, *supra* note 20, at 228 n.31.

whatever a jury says it is, and there is no reliable avenue for gaining advance notice of what a jury might think.

F. Failed Attempts at Actual Notice

The Analog Act's animating purpose is to provide a flexible prosecutorial tool for combating novel substances of abuse, a goal that supposedly requires the DEA to withhold from the public a list of chemicals considered to be controlled substance analogs. Yet reporters recently discovered the existence of a DEA master list of controlled substance analogs.[145]

If the Analog Act was properly relied upon as merely a stopgap measure to criminalize dangerous substances until the completion of administrative scheduling, no secret DEA analog list would exist. Instead, the DEA would initiate formal rulemaking immediately or soon after an analog's discovery, thereby permitting citizens to learn whether a substance might be prosecuted as an analog by consulting the Code of Federal Regulations.

As of very recently, the DEA claims to issue advisory letters to "anyone who calls or inquires about a substance as [to] its potential status as an analogue," assuring that "one only needs to go on [the] DEA's website for that contact information."[146] The advisory letters themselves do not conclusively classify a substance but only offer an opinion on whether a substance "may" be treated as an analog.[147] Advice from the DEA would prove valuable for preventing certain good-faith Analog Act violations—people like Mr. Makkar and Mr. Malik could now consult federal authorities instead of relying on the limited expertise of local law enforcement. Yet this practice seems unlikely to save the statute from a vagueness challenge. The statute itself does not direct citizens to seek the DEA's advice, nor do traditional notions of due process require citizens to first seek out a clarifying opinion from law enforcement.

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145. *See* Jordan S. Rubin, *America's Secret Drug War Part One: The Psychedelic Shack*, BLOOMBERG L. (Aug. 1, 2019, 12:01 AM), https://news.bloomberglaw.com/featured/americas-secret-drug-war/part1 [https://perma.cc/2KY9-VSHZ].

146. Government's Opposition in Response to Defendant's Motion to Limit Testimony of Dr. Jordan Trecki at 13, United States v. Ritchie, No. 15-CR-00285 (D. Nev. Dec. 13, 2018), ECF No. 272; *see also* Jordan S. Rubin, *Calling the Designer Drug 'Hotline'—Is This Stuff Legal or Not?*, BLOOMBERG L. (Aug. 20, 2019, 11:23 AM), https://news.bloomberglaw.com/white-collar-and-criminal-law/calling-the-designer-drug-hotline-is-this-stuff-legal-or-not [https://perma.cc/6Z9P-BGAE] (explaining the process of contacting the DEA for information on compliance with the law).

147. *See* Letter from Terrence L. Boos, Chief, Drug & Chem. Evaluation Section, to Jordan Rubin, Bloomberg BNA (May 20, 2019), https://src.bna.com/KfF?_ga=2.123479115.1927138745.1574094489-802168933.1574094489 [https://perma.cc/ZTQ8-C23R].

Further devaluing these advisory letters' utility is the reality that the DEA's opinion on analog status can change rapidly and without warning. In *United States v. Cooper*, the defendant was indicted for selling 5F-PB-22.[148] At the time of the defendant's arrest, the DEA had not yet issued an internal declaration that 5F-PB-22 was a controlled substance analog of AM-2201.[149] In fact, "the DEA only issued an opinion as to the two substances' similarity after Cooper had been arrested."[150] The defendant challenged his prosecution under the Ex Post Facto Clause, arguing that he was being prosecuted for what had been legal behavior at the time. The court ruled in favor of the prosecution, finding that, under the statute, 5F-PB-22 had always been a controlled substance analog of AM-2201, even before the DEA added the chemical to its private list of controlled substance analogs.[151]

G. Schrödinger Legality

No one can have actual notice of what the Analog Act prohibits because the statute does not categorically criminalize substances. Instead, all substances exist in a state of legal superposition as neither legal nor illegal until a jury reaches its verdict. As recognized by the Seventh Circuit in *United States v. Turcotte*, "A substance's legal status as a controlled substance analogue is not a fact that a defendant can know conclusively *ex ante*; it is a fact that the jury must find at trial."[152] Thus, a substance's "analogue status exists for just the single instance" of any particular prosecution.[153] If a different defendant were to be tried again for the exact same substance, "the arguments all start over again," and a new jury must again perform the exact same inquiry.[154]

148. United States v. Cooper, No. 14-CR-014-J-20MCR, 2015 WL 13850123, at *1 (M.D. Fla. Jan. 14, 2015).

149. *Id.* at *4.

150. *Id.*

151. *Id.* at *7.

152. United States v. Turcotte, 405 F.3d 515, 526 (7th Cir. 2005); *see also* Kau, *supra* note 39, at 1105–06 (recognizing the impossibility of advance knowledge of analog status); *Dangerous Synthetic Drugs: Hearing Before the S. Caucus on Int'l Narcotics Control*, 113th Cong. 3 (2013) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA) ("Criminal liability depends upon a finding, in each particular prosecution, that the substance is a 'controlled substance analogue' and that the substance was intended for human consumption.").

153. ALEXANDER SHULGIN & ANN SHULGIN, *#11. a-ET*, *in* TIHKAL: THE CONTINUATION (1997), https://erowid.org/library/books_online/tihkal/tihkal11.shtml [https://perma.cc/UQ7D-6LR2].

154. *Id.* Res judicata does not prevent the government from indicting a third party for the possession or sale of a chemical previously found by a jury to *not* be a controlled substance analog. *See* Brown v. Felsen, 442 U.S. 127, 132 (1979).

In *McFadden*, the Supreme Court assumed that "past arrests" for a particular analog would "put a defendant on notice of the controlled status of a substance."[155] In practice, this assumption does not stand. As the Department of Justice acknowledged to the Senate, "Because a factual finding that a substance is an analogue of a controlled substance in a particular case has no precedential impact, each case can lead to disparate results."[156] This legal superposition poses grave complications for fair notice because a substance's temporary analog status means that, like the observer of Schrödinger's cat,[157] a defendant cannot know a substance's legal status in advance of a verdict.

A substance's legal superposition also poses a grave threat of arbitrary enforcement by permitting fact finders to reach opposite legal conclusions on the same substance. Criminal law typically treats identical acts differently depending on a defendant's state of mind.[158] For example, there is a clear difference between accidentally spilling rat poison in a tea kettle and intentionally poisoning a victim. Criminal law also distinguishes identical acts executed with identical states of mind that yield different outcomes. The tea kettle poisoner would receive a very different sentence if their victim died rather than merely fell ill.[159] But few, if any, statutes other than the Analog Act permit different legal outcomes for identical acts committed with identical states of mind that yield identical results.

Analog Act prosecutions concerning identical chemicals regularly reach different outcomes. For example, in *United States v. Washam*, a jury found that 1,4-butanediol was an analog of GHB.[160] Around the same time, the jury in *United States v. Turcotte* found that 1,4-butanediol—the exact same substance—was not an analog of GHB.[161]

155. United States v. Demott, 906 F.3d 231, 242 (2d Cir. 2018) (quoting McFadden v. United States, 576 U.S. 186, 192 n.1 (2015)).

156. *The Countdown*, *supra* note 65, at 5.

157. In physicist Erwin Schrödinger's famous "Schrödinger's cat" thought experiment, a cat is held for an hour in a closed chamber along with a bottle of poison. Attached to the bottle of poison is a mechanism that will either randomly shatter the vial, releasing the poison and killing the cat, or do nothing. To an outside observer, the cat exists in a superposition of states—it is either alive or dead—until the hour is up, the chamber opens, and the cat is observed. Until that moment, the observer cannot definitively know which state the cat occupies.

158. *See, e.g.*, Jeffrey S. Parker, *The Economics of Mens Rea*, 79 VA. L. REV. 741, 777 (1993) ("[A]s is observed in virtually all criminal law systems, externally identical events of the most serious nature, including killings and sexual assaults, are treated much differently depending upon the actor's state of mind.").

159. *See* Darryl K. Brown, *Federal Mens Rea Interpretation and the Limits of Culpability's Relevance*, 75 L. & CONTEMP. PROBS. 109, 129 (2012) ("These [criminal] offenses impose different degrees of liability on offenders whose conduct, intentions, and awareness are the same, depending on whether their identical actions caused a death, merely injured, or caused no injury at all." (footnote omitted)).

160. United States v. Washam, 312 F.3d 926 (8th Cir. 2002).

161. United States v. Turcotte, 405 F.3d 515 (7th Cir. 2005).

Similarly, two federal courts have reached opposite conclusions regarding the same synthetic cannabinoids. In *Smoke Shop, LLC v. United States*, a small Wisconsin store owner petitioned for the return of $100,000 in seized synthetic cannabis containing the chemicals UR-144 and XLR-11.[162] The store owner had initially agreed to the seizure, believing that the cannabis would be returned, but the DEA refused to return it, claiming that UR-144 and XLR-11 were controlled substance analogs of JWH-018.[163] After hearing expert testimony, the court agreed with the petitioner that "the overwhelming weight of opinion in the scientific community is that the chemical structures of UR–144 and XLR–11 are not substantially similar to the chemical structure of JWH–018."[164] The court did not ultimately order the return of the substances—the DEA had emergency scheduled both chemicals part way through the hearing—but noted that it had been "unfair for a federal agency to seize the property of a small business owner and then keep it until it is declared illegal."[165] But in *United States v. Fedida*, decided just a few weeks before *Smoke Shop*, a Florida district court had arrived at the exact opposite conclusion, finding that "the chemical structures of UR–144, XLR–11, and JWH–18 . . . are substantially similar."[166]

In one Analog Act case, the Second Circuit rebuffed legal superposition as a ground for voiding the statute by quoting *Smith v. United States*: "[T]he possibility that different juries might reach different conclusions as to the same material does not render the statute unconstitutional."[167] This reasoning falls flat. Conflicting legal conclusions on a substance's legality are the Analog Act's reality, not a mere possibility. There can be no enforcement more arbitrary than having two identical defendants receive different outcomes for the same behavior.

Legal superposition permits another kind of arbitrary enforcement: forcing defendants to plead guilty to distributing a legal substance. In *United States v. Picanso*,[168] federal prosecutors ultimately

162. Smoke Shop, LLC v. United States, 949 F. Supp. 2d 877, 878 (E.D. Wis. 2013).
163. *Id.*
164. *Id.* at 879.
165. *Id.*
166. United States v. Fedida, 942 F. Supp. 2d 1270, 1279 (M.D. Fla. 2013). *Compare* United States v. Way, No. 14-CR-00101-BAM-1, 2018 WL 5310773, at *2 (E.D. Cal. Oct. 25, 2018) ("The government charged defendant with violations of the Controlled Substances Act as to . . . AM-2201 . . . . [T]he jury at his trial did not convict defendant based on any conduct related to the use of AM-2201 . . . ."), *aff'd*, 804 F. App'x 504 (9th Cir. 2020), *with* United States v. Malone, 828 F.3d 331, 334 (5th Cir. 2016) (sentencing defendants to 117 months in prison for possession with intent to distribute AM-2201).
167. United States v. Ansaldi, 372 F.3d 118, 123 n.2 (2d Cir. 2004) (quoting *Smith v. United States,* 431 U.S. 291, 309 (1977)).
168. *See* Bell, *supra* note 20, at 229; *see also supra* text accompanying notes 20–25 (describing the *Picanso* case as a hypothetical scenario to illustrate the failures of

indicted thirteen company employees of the Outer Edge, a multi-state synthetic cannabis manufacturer and distributor, for conspiracy to manufacture and distribute controlled substance analogs. The Outer Edge had gone to great lengths to ensure compliance with federal and state law, employing researchers to keep abreast of new statutory developments and altering their product's chemical composition as required. Its legal staff had repeatedly assured employees and customers that all chemicals used were permitted by state and federal law.

Facing life-altering prison sentences, five employees accepted a "no look" plea bargain[169] without ever seeing the evidence against them. Two employees rejected all plea offers and proceeded to trial. They faced a maximum sentence of twenty years. The defendants' co-workers testified that the two defendants knew they were selling analogs intended for human consumption and had consumed the analogs themselves.[170] Yet discovery uncovered a surprising revelation: even the DEA's scientists disagreed as to whether the analogs were sufficiently similar to controlled substances. The jury ultimately acquitted both defendants.[171] Their coworkers who pled guilty went to prison.

V. THE MISSING SCIENTER REQUIREMENT

Even when the Analog Act has attracted judicial skepticism, courts have consistently rejected vagueness challenges by finding a scienter requirement and sufficiently narrowing the range of criminalized conduct to squeeze the statute into due process boundaries.[172]

It is well established that a scienter requirement can save an otherwise vague statute from being voided. In *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, the Supreme Court found that a scienter requirement immunized an ordinance from being voided for lack of notice.[173] At issue was an ordinance requiring a business to

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the Analog Act). Bell's article provides a detailed exploration of *Picanso* and the extreme injustices created by combining the Analog Act with modern plea-bargaining practices.

169. *See* United States v. Loeffler, No. 14-CR-40005 (D. Kan. Aug. 3, 2017) (judgment).

170. *See* Excerpt Transcript of Jury Trial (Testimony of Tracy Picanso) at 15–16, United States v. Adams, No. 14-CR-40005 (D. Kan. 2017).

171. *See* Verdict Form for Terrie Adams, United States v. Adams, No. 14-CR-40005 (D. Kan. 2017); Verdict Form for Craig Broombaugh, United States v. Broombaugh, No. 14-CR-40005 (D. Kan. 2017).

172. *See, e.g.*, United States. v. Roberts, 363 F.3d 118, 123 (2d Cir. 2004); United States v. Hofstatter, 8 F.3d 316, 322 (6th Cir. 1993); United States v. Carlson, 87 F.3d 440, 444 (11th Cir. 1996); *see also* United States v. Klecker, 348 F.3d 69, 71 (4th Cir. 2003) ("The intent requirement alone tends to defeat any vagueness challenge based on the potential for arbitrary enforcement."). A small number of courts have found no scienter requirement at all. *See Carlson*, 87 F.3d at 443 n.3.

173. Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc., 455 U.S. 489, 499 (1982) ("[A] scienter requirement [in a criminal statute] may mitigate a law's vagueness,

obtain a license before it sold "any items, effect, paraphernalia, accessory or thing which is designed or marketed for use with illegal cannabis or drugs."[174] The Court found a scienter requirement in the ordinance, reasoning that a violation required a store to "deliberately display[ ] its wares in a manner that appeals to or encourages illegal drug use" and that "a retailer could scarcely 'market' items 'for' a particular use without intending that use."[175]

Yet an elusive scienter requirement fails to provide meaningful restrictions on the range of behaviors that a vague statute criminalizes. And in judging a void-for-vagueness challenge, one factor weighing against a statute's continued existence is if it remains the subject of a deep and persistent circuit split even after numerous attempts at clarification.[176] Despite decades of attempted clarification, no court has successfully clarified the Analog Act's scienter requirement. To the extent the Supreme Court's decision in *McFadden* provided clarity, it did so by sanctioning the use of almost every conceivable form of scienter using any kind of evidence, including facts logically unconnected to a defendant's knowledge or intent. Such expansive scienter does not aid in narrowing an overly vague statute.

A. Pre-*McFadden* Scienter

Before *McFadden*, courts had reached a number of conflicting interpretations of the Analog Act's scienter requirement. In *United States v. Desurra*, the Fifth Circuit considered whether prosecutors needed to prove that the defendants knew that MDMA (then unscheduled) was an analog of the schedule I substance MDA.[177] The *Desurra* court located the intent requirement in § 841, reasoning that when "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."[178]

A few years later, in *United States v. Hofstatter*, the Sixth Circuit reached an entirely different conclusion.[179] In *Hofstatter*, two aspiring black-market chemists challenged their Analog Act convictions, attacking the substantial similarity requirement as unconstitutionally

especially with respect to the adequacy of notice to the complainant that his conduct is proscribed.").

174. *Id.* at 492.

175. *Id.* at 502.

176. *See, e.g.*, United States v. L. Cohen Grocery Co., 255 U.S. 81, 91 (1921) (observing that the failure of "persistent efforts" to establish a standard can provide evidence of vagueness); Johnson v. United States, 575 U.S. 591, 597 (2015).

177. United States v. Desurra, 865 F.2d 651, 652 (5th Cir. 1989).

178. *Id.* at 653.

179. United States v. Hofstatter, 8 F.3d 316 (6th Cir. 1993).

vague as applied to the intended manufacture of cathinones.[180] Citing *Hoffman Estates*, the Sixth Circuit rejected the challenge, finding that § 813's requirement that the substance be intended for human consumption sufficiently narrows the range of criminalized conduct, therefore preventing arbitrary or discriminatory enforcement.[181]

These differences in Analog Act application continued to grow for decades, with courts employing an increasing number and variety of overlapping or contradictory scienter requirements. Although the circuit split has been characterized as a two-way split and elsewhere as a three-way split,[182] either description understates the total lack of circuit uniformity. Closer examination reveals at least seven different pre-*McFadden* approaches to Analog Act scienter: (1) knowledge that an analog satisfies both substantial similarity requirements;[183] (2) knowledge of an analog's substantially similar effects, from which the court imputes the defendant's knowledge of substantially similar structure (called the *Turcotte* inference);[184] (3) knowledge that an analog is a controlled substance under § 841;[185] (4) knowledge that an analog is intended for human consumption;[186] (5) some combination or modification of the preceding standards,[187] such as knowing a drug's identity and "posess[ing] it with the statutorily defined bad purpose;"[188] (6) that there is no scienter requirement;[189] and (7) that

180. *Id.* at 319.

181. *Id.* at 322 (citing Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc., 455 U.S. 489, 498 (1982)).

182. *Compare* Grass, *supra* note 87, at 37 (dividing circuits into two main groups regarding scienter requirements) *and* Nishioka, *supra* note 131, at 287 (finding the circuits split into two major camps), *with* Brown, *supra* note 98, at 464 (describing a "three-way circuit split").

183. *See* United States v. Turcotte, 405 F.3d 515, 527 (7th Cir. 2005).

184. *See id.* The *Turcotte* inference permits that "if the scienter requirement is met with regard to the second part of the analogue definition (knowledge or representation of similar physiological effects), the jury is permitted—but not required—to infer that the defendant also had knowledge of the relevant chemical similarities." *Id.*

185. *See* United States v. Roberts, 363 F.3d 118, 123 n.1 (2d Cir. 2004) (establishing that the defendant must know that the drug in their possession is a controlled substance but does not need to know the identity of the drug).

186. *See* United States v. McFadden, 753 F.3d 432, 441 (4th Cir. 2014)*, vacated*, 576 U.S. 186 (2015); *Hofstatter*, 8 F.3d at 322 ("[T]he Act deals only with chemicals 'intended for human consumption.'" (quoting 21 U.S.C. § 813)); *see also* United States v. Klecker, 348 F.3d 69, 71 (4th Cir. 2003) (explaining that the Act treats controlled substance analogs "intended for human consumption" as schedule I substances).

187. *See* McKinney v. United States, 221 F.3d 1343, 1343 n.3 (8th Cir. 2000) (unpublished table decision). In *McKinney*, the district judge instructed the jury to find whether the defendant "knowingly and intentionally distributed the aminorex as described in the indictment; and . . . at the time of such distribution, the defendant knew that the substance distributed was aminorex." *Id.*

188. *See* United States v. Desurra, 865 F.2d 651, 653 (5th Cir. 1989).

189. *See* United States v. Forbes, 806 F. Supp. 232, 238 (D. Colo. 1992).

the statute lacks any vagueness,[190] obviating the need for a narrow scienter. Given the demonstrated lack of scienter uniformity, this list should not be taken as an exhaustive survey of pre-2015 Analog Act scienter requirements.

B. *McFadden*

The Supreme Court unsuccessfully sought to resolve this circuit-fracturing issue in its first and only Analog Act opinion, *McFadden v. United States*. In 2013, Stephen McFadden was convicted for selling methcathinone bath salts. On appeal to the Fourth Circuit, McFadden argued that the Analog Act's scienter requirement required proof that he knew the substantially similar structure and effects of the controlled substance analog that he distributed.[191] The government, citing § 841(a)(1)'s prohibition against the knowing or intentional manufacture or distribution of a "controlled substance," contended that a successful conviction only required proof that a defendant knew a controlled substance analog was a "controlled substance" under *any* law.[192] Adhering to precedent, the Fourth Circuit rejected both positions and ruled that the scienter requirement was § 813's "intended for human consumption" requirement.[193] McFadden appealed to the Supreme Court.

Writing for the majority, Justice Thomas ostensibly rejected all three positions and instead located the scienter requirement in § 841(a)(1), finding that the prosecution "must prove that a defendant knew that the substance with which he was dealing was 'a controlled substance,'" meaning "those drugs listed on the federal drug schedules or treated as such by operation of the Analogue Act."[194] This knowledge "can be established in two ways."[195] The first is if the defendant "knew that the substance with which he was dealing is some controlled substance—that is, one actually listed on the federal drug schedules or treated as such by operation of the Analogue Act—regardless of whether he knew the particular identity of the substance."[196] The second is if "the defendant knew the specific analogue he was dealing with, even if he did not know its legal status as an analogue."[197]

190. *See* United States v. Granberry, 916 F.2d 1008, 1010 (5th Cir. 1990) ("There is nothing vague about the statute.").

191. *McFadden*, 753 F.3d at 438–39.

192. McFadden v. United States, 576 U.S. 186, 196 (2015).

193. *See id.*

194. *Id.* at 195–96.

195. *Id.* at 196.

196. *Id.* at 194.

197. *Id.*

Yet the Court proceeded to note an apparent third means of proving knowledge: because "[t]he Analogue Act defines a controlled substance analogue by its features" (substantially similar structure and effects), a defendant knowing those features "knows all of the facts that make his conduct illegal, just as a defendant who knows he possesses heroin knows all of the facts that make his conduct illegal."[198] In a later passage, the Court reiterated that the knowledge requirement of § 841(a)(1) "can be established in the two ways previously discussed" but described these means as proving scienter "either by knowledge that a substance is listed or treated as listed by operation of the Analogue Act, §§ 802(6), 813, or by knowledge of the physical characteristics that give rise to that treatment."[199]

Finally turning to address directly the void-for-vagueness challenge, the Court abruptly dubbed the statute "unambiguous," and declared that the newly announced scienter requirement "alleviate[d] vagueness concerns" by limiting "prosecutorial discretion."[200]

In a footnote, the Court approved the use of direct or circumstantial evidence to prove knowledge. Direct evidence includes "past arrests that put a defendant on notice of the controlled status of a substance," while circumstantial evidence includes "a defendant's concealment of his activities, evasive behavior with respect to law enforcement, knowledge that a particular substance produces a 'high' similar to that produced by controlled substances, and knowledge that a particular substance is subject to seizure at customs."[201] Another footnote pointedly noted that the Court accepted the government's contention that the statute was to be read conjunctively, leaving open the possibility that a disjunctive reading could be upheld.[202]

In his concurrence, Justice Roberts rejected the notion that knowledge of a substance's identity would be sufficient, citing the rule that ignorance of the law is an excuse when a person lacks knowledge of a legal element.[203] Roberts observed that the majority's statements on knowledge of identity were unnecessary to resolve the controversy at issue and thus did not control future cases.[204]

198. *Id.*

199. *Id.* at 196.

200. *Id.* at 197 (quoting Gonzales v. Carhart, 550 U.S. 124, 149–50 (2007)).

201. *Id.* at 192 n.1.

202. *Id.* at 194 n.2 ("The Government has accepted for the purpose of this case that it must prove two elements to show that a substance is a controlled substance analogue under the definition in § 802(32)(A) . . . . Because we need not decide in this case whether that interpretation is correct, we assume for the sake of argument that it is.").

203. *Id.* at 198–99 (Roberts, J., concurring).

204. *Id.* at 199.

The Court in *McFadden* twice claimed to describe only two ways of satisfying § 841's scienter requirement, but it described these two ways in at least four distinct manners:

> (1) Knowledge of Illegality. "[The] defendant knew that the substance with which he was dealing is some controlled substance—that is, one actually listed on the federal drug schedules or treated as such by operation of the Analogue Act—regardless of whether he knew the particular identity of the substance."[205]
>
> (2) Knowledge of a Substance's Identity. "[T]he defendant knew the specific analogue he was dealing with, even if he did not know its legal status as an analogue."[206]
>
> (3) Knowledge of Features. The defendant knew that the analog's structure and effects are substantially similar to those of a scheduled controlled substance, so he therefore "[knew] all of the facts that make his conduct illegal."[207]
>
> (4) Knowledge of the Physical Characteristics. The defendant knew the "physical characteristics"[208] that make the substance a controlled analog.

Each of these means of proving scienter present major interpretive challenges.

Regarding the first manner, knowledge of a chemical as a "controlled substance" hurtles directly into the puzzle of Schrödinger legality described above. Because the Analog Act does not expressly or categorically outlaw any given substance in advance, one cannot know a substance's legal status until a jury reaches its verdict. This also means that certain kinds of evidence the *McFadden* Court lists as capable of proving knowledge are, in fact, nonsensical. If the Analog Act does not categorically criminalize any substances, "past arrests" cannot "put a defendant on notice of the controlled status of a substance."[209] Similarly, circumstantial evidence showing a defendant's "knowledge that a particular substance is subject to seizure at customs"[210] provides equally little probative value. Arrests and seizures are merely law enforcement predictions that a substance might be found illegal under a particular set of circumstances.

McFadden treats the final three manners of satisfying the scienter requirement as identical, yet they possess little actual overlap. Knowledge of identity is most easily construed as knowledge of a substance's chemical name, yet knowing a name does not imply knowledge of a substance's substantially similar structure or effects. For example, one can determine practically nothing about a substance's physical

205. *Id.* at 194 (majority opinion).

206. *Id.*

207. *Id.* at 194–95.

208. *Id.* at 196.

209. *Id.* at 192 n.1.

210. *Id.*

characteristics or substantial similarity to a schedule I or II substance just by knowing that the substance is called alpha-PVP or gravel.[211]

Similarly, a chemical's "physical characteristics" include only those properties that one can externally observe or measure without altering the chemical's composition or identity, such as chemical structure.[212] Physical characteristics do not include the chemical's effects upon ingestion. Even qualified experts are incapable of properly deducing a substance's effects from its physical characteristics alone.[213] A substance can be identical in molecular structure to a scheduled substance yet have no substantially similar effects,[214] or it can be substantially similar in structure and have opposite effects.[215]

C. *McFadden*'s Endlessly Broad Means of Proving Scienter

McFadden's amorphous list of acceptable approaches to satisfying the scienter requirement and equally nebulous assertion regarding circumstantial evidence have proven so endlessly malleable as to justify almost any pre-*McFadden* conviction. By addressing the Analog Act's scienter requirement, *McFadden* set off a cascade of appeals[216]: of the approximately 284 federal cases citing § 813,[217] approximately

211. Both are names for the same synthetic cathinone once commonly sold to consumers as bath salts.

212. *See Differences in Matter—Physical and Chemical Properties*, CHEMISTRY LIBRETEXTS, https://chem.libretexts.org/Bookshelves/Introductory_Chemistry/Map%3A_Introductory_Chemistry_(Tro)/03%3A_Matter_and_Energy/3.05%3A_Differences_in_Matter-_Physical_and_Chemical_Properties#:~:text=summary-,A%20physical%20property%20is%20a%20characteristic%20of%20a%20substance%20that,undergo%20a%20specific%20chemical%20change [https://perma.cc/487R-8WK5] (July 19, 2021).

213. *See* United States v. Fedida, 942 F. Supp. 2d 1270, 1281 n.7 (M.D. Fla. 2013).

214. Chemical "chirality" means that two substances can share an identical structure yet induce different effects. For example, r-methamphetamine is crystal meth, and its chiral mirror image, l-methamphetamine, has such mild psychoactive effects that it is sold over the counter in asthma inhalers. *See L-Methamphetamine (Illegal in the Mirror)*, SCIENCEBLOGS (Oct. 27, 2006), https://scienceblogs.com/moleculeoftheday/2006/10/27/lmethamphetamine-would-you-bel [https://perma.cc/8QUQ-LKBX].

215. *See* Andrew Payne Norwood, Note, *When Apples Taste Like Oranges, You Cannot Judge a Book by Its Cover: How To Fight Emerging Synthetic "Designer" Drugs of Abuse*, 39 U. ARK. LITTLE ROCK L. REV. 323, 337 (2017) (comparing the structures of heroin and naltrexone, which controls opiate withdrawals).

216. *See, e.g.*, United States v. Sharp, 879 F.3d 327, 333 (8th Cir. 2018); United States v. Smutek, 730 F. App'x 18, 21 (2d Cir. 2018); Aburokbeh v. United States, No. 17-3084, 2017 WL 3397435, at *1 (6th Cir. July 10, 2017); United States v. Newbold, 686 F. App'x 181, 183 (4th Cir. 2017); Jones v. United States, 650 F. App'x 974, 977 (11th Cir. 2016); Stallard v. United States, No. 14-CR-20, 2017 WL 3452356, at *2 (E.D. Tenn. Aug. 10, 2017); United States v. Singh-Sidhu, No. 13-CV-00032, 2017 WL 1364582, at *3 (D. Nev. Apr. 13, 2017).

217. This information is current as of January 28, 2022.

135 were decided prior to *McFadden*[218] and seventy-eight were decided in the three years after the decision.[219] Many circuits previously employed scienter requirements clearly incompatible with *McFadden*; for example, the Sixth and Fourth Circuits had previously only required proof of intended human consumption.[220] Despite the sizable shift in the legal landscape, very few appeals succeeded.[221] The Supreme Court had sanctioned almost every scienter created by the circuit courts. The only two means of satisfying the scienter requirement that *McFadden* did not overtly sanction are (1) knowledge that the substance is intended for human consumption and (2) knowledge of the substance's substantially similar effects, from which the jury can infer knowledge of substantially similar structure (the *Turcotte* inference). Moreover, the Court expressly permitted expansive use of circumstantial evidence logically unrelated to a defendant's intent.

D. Post-*McFadden*: Scienter and Notice

Though the circuit courts have attempted to dutifully honor the Court's insistence that there are only two ways of proving Analog Act scienter, a division has emerged over *which* two of the four means are correct. The Second, Fifth, and Seventh Circuits, plus a few district courts, have adopted the first and second means of proof: knowledge of illegality and knowledge of a substance's identity.[222] Others, including the First, Fourth, Eighth, Tenth, and Eleventh Circuits, have tacked toward Justice Robert's concurrence by adopting the first and

218. To find these cases in a legal research database, search cases for the citing reference "21 U.S.C. 813," filter for federal jurisdiction, and limit the results to those dated before June 18, 2015.

219. To find these cases in a legal research database, search cases for the citing reference "21 U.S.C. 813," filter for federal jurisdiction, and limit the results to those dated between June 18, 2015, and June 18, 2018.

220. *See* United States v. McFadden, 753 F.3d 432, 441 (4th Cir. 2014), *vacated*, 576 U.S. 186 (2015); United States v. Hofstatter, 8 F.3d 316, 322 (6th Cir. 1993).

221. *But see* United States v. Demott, 906 F.3d 231, 235 (2d Cir. 2018) (ordering a retrial for two defendants in light of the new *McFadden* ruling on scienter); United States v. Makkar, 810 F.3d 1139, 1148 (10th Cir. 2015) (overturning a pre-*McFadden* conviction that was based only on the defendant's knowledge of effects); United States v. Stanford, 823 F.3d 814, 838 (5th Cir. 2016).

222. *See, e.g.*, United States v. Hamdan, 910 F.3d 351, 356 (7th Cir. 2018); United States v. Moton, 951 F.3d 639, 643 (5th Cir. 2020); United States v. Al Haj, 731 F. App'x 377, 378 (5th Cir. 2018) (per curiam); United States v. Canfield, 758 F. App'x 51, 54 (2d Cir. 2018); United States v. Turks, No. 17CR444, 2018 WL 5292540, at *3 (N.D. Ohio Oct. 25, 2018); *Demott*, 906 F.3d at 240–44; United States v. Galecki, No. 15-CR-00285, 2016 WL 8732504, at *2 (D. Nev. Sept. 19, 2016) ("In *McFadden*, the Supreme Court recently held that in order to be convicted for a violation of the Analogue Act, the defendant must knowingly and intentionally distribute a mixture or substance that has substantially similar effects on the nervous system as a controlled substance . . . ."), *report and recommendation adopted*, No. 15-CR-00285, 2017 WL 1330193 (D. Nev. Apr. 5, 2017).

third means of proof: knowledge of illegality and knowledge of substantially similar features.[223]

This division in approaches is not a proper "circuit split" because *McFadden* clearly sanctioned all four means of proving scienter, leaving courts to choose *which* two ways are preferred for any given case. Cases within the Sixth Circuit have already employed conflicting scienter pairs. In *Aburokbeh v. United States*, the Sixth Circuit summarized *McFadden* as holding that the government must prove that a defendant knew "the substance was controlled under the Controlled Substances Act or Analogue Act or knew the specific features of the substance that made it a 'controlled substance analogue.'"[224] In a later case, *United States v. Stallard*, the Sixth Circuit restated *McFadden* as requiring proof that a defendant either knew a substance's identity or knew that it was a controlled substance.[225] Reading post-*McFadden* appeals reveals the case's bewildering effect on circuit court judges.

In *Demott,* one of the few opinions to openly wrestle with *McFadden*'s ambiguity, the Second Circuit noted that *McFadden* actually employs at least three definitions of what it means for a substance to be "controlled."[226] It ultimately adopted an unusual interpretation of what it means for a defendant to know a substance's identity.[227] Because there is no known list of illicit analogs, the court in *Demott* reasoned that knowledge of a substance's name cannot establish knowledge of identity. Instead, "the defendant must know the *characteristics* of the substance that qualify that substance as an analogue"—its substantially similar effects and structure.[228]

223. *See, e.g.*, United States v. McFadden, 823 F.3d 217, 223 (4th Cir. 2016); United States v. Ketchen, 877 F.3d 429, 431 (1st Cir. 2017); *Makkar*, 810 F.3d at 1143; Jones v. United States, 650 F. App'x 974, 977 (11th Cir. 2016); United States v. Newbold, 686 F. App'x 181, 186 (4th Cir. 2017); United States v. Ramos, 814 F.3d 910, 916 (8th Cir. 2016); United States v. Ritchie, No. 15-CR-00285, 2018 WL 6580570, at *3 (D. Nev. Dec. 13, 2018).

224. Aburokbeh v. United States, No. 17-3084, 2017 WL 3397435, at *1 (6th Cir. July 10, 2017).

225. Stallard v. United States, No. 17-6188, 2018 WL 1442984, at *2 (6th Cir. Mar. 15, 2018) ("The knowledge requirement for controlled substance analogue cases requires a showing that the defendant either (1) 'knew that the substance with which he was dealing is some controlled substance,' . . . or (2) 'knew the specific analogue he was dealing with, even if he did not know its legal status as an analogue.'" (quoting McFadden v. United States, 576 U.S. 186, 194 (2015))).

226. *Demott*, 906 F.3d at 242. The court noted that "controlled" could mean (1) "knowing that the substance was generally illegal;" (2) "knowing that the substance was illegal specifically under *federal law*;" or (3) "knowing that the substance was illegal under the *particular controlling statute*, such as the CSA or Analogue Act." *Id.*

227. *See id.*

228. *Id.*

In *United States v. Novak*, the Seventh Circuit reasoned that knowledge of a substance's identity necessarily implies knowledge of its substantially similar structure and effects,[229] and knowledge of a substance was soon to be added to the CSA's schedules qualified as knowledge of its present "status as a controlled substance analogue."[230] A seventy-one-year-old Army veteran with early-stage Alzheimer's[231] had received a four-year sentence for selling synthetic cannabis made with XLR-11.[232] XLR-11 was placed on the federal schedules sometime after the defendant had stopped his sales.[233] The defendant claimed ignorance of XLR-11's status as a controlled substance analog and proved that he had stopped selling it before it was scheduled.[234] In reviewing the circumstantial evidence supporting the guilty plea, the Seventh Circuit found that the defendant and his coconspirator knew XLR-11 was an illicit analog.[235] In drawing this conclusion, the court relied almost entirely on the pair's Facebook announcement that XLR-11 was soon to be outlawed.[236]

E. The Elasticity of Circumstantial Evidence

The most likely reason for the missing flood of reversals following *McFadden* was the Supreme Court's authorization of circumstantial scienter evidence. Not all of *McFadden*'s means of proving scienter readily lend themselves to circumstantial proof—it is difficult to conceive of how "a defendant's concealment of his activities"[237] could be circumstantial evidence that he knew a particular substance's chemical composition. Yet as noted in *Demott*, this was not a mistake: "[T]he Court explicitly approved examples of circumstantial evidence that would not support a logical inference that the defendant knew anything about the CSA or Analogue Act . . . ."[238] Permitting such broad use of circumstantial evidence has allowed courts to uphold almost any Analog Act conviction. As an example, the Eighth Circuit held that a defendant knew the chemical structure and effects of alpha-PVP based on the circumstantial evidence that she sold bath salts to an informant for cash late at night in a parking lot.[239]

229. United States v. Novak, 841 F.3d 721, 728–29 (7th Cir. 2016).
230. *Id.* at 729.
231. *Id.* at 727–28.
232. *Id.* at 726.
233. *Id.* at 724.
234. *Id.*
235. *Id.* at 729.
236. *Id.*
237. McFadden v. United States, 576 U.S. 186, 192 n.1 (2015).
238. United States v. Demott, 906 F.3d 231, 243 (2d Cir. 2018).
239. United States v. Ramos, 814 F.3d 910, 916–18 (8th Cir. 2016). Other circumstantial evidence of the defendant's chemical knowledge included the substance's high price, her knowledge that it made users feel good, her willingness to meet an

In *Stallard*, a petitioner appealed his pre-*McFadden* 180-month sentence for distribution of the controlled substance analog gravel, claiming that he never knew the actual identity of the substance nor did he know that it was a controlled substance analog.[240] The petitioner claimed ineffective assistance of counsel on the grounds that his attorney erroneously led him to believe that "his knowledge that state authorities were criminalizing the distribution of 'bath salts' and 'gravel' was enough to meet the knowledge element of 21 U.S.C. § 841."[241] Citing knowledge of illegality and knowledge of identity as *McFadden*'s two ways of establishing scienter,[242] the court denied his certificate of appealability. The court pointed to circumstantial evidence as proof of the petitioner's knowledge, including his evasiveness during a traffic stop and his knowledge of the substance's street name gravel, and its effects.[243]

At least one court has even used circumstantial evidence to resurrect the *Turcotte* inference, one of the two means of proving scienter not expressly sanctioned by *McFadden*.[244] In *United States v. Carlson*, defendant James Carlson and his family had sold synthetic cannabis at their head shop in Duluth, Minnesota. At trial, the judge gave a *Turcotte* instruction, permitting the jury to infer Carlson's knowledge of the synthetic cannabis's substantial structural similarity to a controlled substance based on his knowledge of its substantially similar effects.[245] Carlson received 210 months in prison but appealed under *McFadden*. In affirming Carlson's guilt, the Eighth Circuit adopted knowledge of illegality and knowledge of substantial similarity as *McFadden*'s two forms of scienter.[246] The *Carlson* court recognized that *McFadden*'s approval of circumstantial scienter evidence, including "knowledge that a particular substance produces a 'high' similar to that produced by controlled substances,"[247] tacitly permitted continued use of the *Turcotte* inference.[248]

Finally, some courts seem to have ignored *McFadden* entirely, going as far as adopting the Fourth Circuit's position rejected in *McFad-*

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informant at a gas station to sell him a product, her failure to charge the informant tax, and the product's logo, consisting of a woman and a disco ball. *See id.*

240. Stallard v. United States, No. 17-6188, 2018 WL 1442984, at *1–2 (6th Cir. Mar. 15, 2018).

241. *Id.* at *2.

242. *Id.*

243. *Id.*

244. *See* United States v. Carlson, 810 F.3d 544, 551–52 (8th Cir. 2016).

245. *Id.*

246. *Id.* at 550.

247. McFadden v. United States, 576 U.S. 186, 192 n.1 (2015) (citing United States v. Ali, 735 F.3d 176, 188–89 (4th Cir. 2013)).

248. *Carlson*, 810 F.3d at 552–53.

den and upholding indictments alleging only that the defendant knew of the intended human consumption.[249]

F. *McFadden* and Arbitrary Enforcement

By stretching the scope of permissible scienter, *McFadden* pushed the Analog Act past the limits of due process and into the realm of the impossible. Chocolate is illegal. After reading the previous sentence, a reader cannot possess chocolate intended for human consumption without violating federal criminal law, even if they do not know why chocolate violates the Analog Act. *McFadden* requires only "that a defendant knew that the substance . . . is controlled under the . . . Analogue Act, regardless of whether he knew the substance's identity."[250] Courts have treated the analog in chocolate as the legal equivalent of methamphetamine[251] and imposed lengthy prison sentences,[252] with the most recent indictment in 2018.[253] Damningly, the *McFadden* Court would consider these successful arrests and prosecutions as public notice of chocolate's controlled substance status.[254]

The identity of the controlled substance analog hiding in chocolate is phenethylamine (PEA), a molecule responsible for some of chocolate's pleasurable effects.[255] PEA causes stimulant effects successfully compared by prosecution expert witnesses to methamphetamine,[256] and it serves as the basic chemical scaffolding for a host of illicit substances: methamphetamine, MDMA, mescaline, and the cathinones active in bath salts. PEA and methamphetamine are apparently so structurally similar that one court believed the fact to be obvious to any "reasonable layperson" who "examined a chemical chart."[257] Although chocolate only contains some one percent PEA, as one prosecu-

249. *See, e.g.*, United States v. Way, No. 14-CR-00101, 2018 WL 2229272, at *7 (E.D. Cal. May 16, 2018), *aff'd*, 804 F. App'x 504 (9th Cir. 2020); United States v. Galecki, No. 15–CR–00285, 2016 WL 8732504, at *3 (D. Nev. Sept. 19, 2016).

250. *McFadden*, 576 U.S. at 187.

251. *See* McKinney v. United States, 221 F.3d 1343 (8th Cir. 2000) (unpublished table decision); United States v. McKinney, 79 F.3d 105, 107 (8th Cir. 1996), *vacated*, 520 U.S. 1226 (1997).

252. *See, e.g.*, United States v. Nunez, 57 F. App'x 776 (9th Cir. 2003).

253. *See* Indictment at 2, United States v. Thomas, No. 18-CR-00104 (S.D. Ala. Apr. 26, 2018) (issuing a phenethylamine indictment for .987 of a gram).

254. *See McFadden*, 576 U.S. at 192 n.1 ("Direct evidence [of scienter] could include, for example, past arrests that put a defendant on notice of the controlled status of a substance.").

255. *See* DALE PENDELL, PHARMAKODYNAMIS 76 (2002).

256. *See McKinney*, 79 F.3d at 108.

257. *Id. But see* 3 GEORGE A. BURDOCK, ENCYCLOPEDIA OF FOOD AND COLOR ADDITIVES 2155 (1997) (providing chemical information about phenethylamine). As a similar example of unintended criminalization, Florida's state analog act prohibits the amino acid tyramine, calling into question the legal status of high protein foods such as egg whites, yogurt, and cheese. *See* FLA. STAT. ANN. § 893.03(1)(c)(66) (West 2021).

tor correctly observed, the Analog Act "just requires . . . a substance that contains a controlled substance. There is no requirement or language with regards to a substantial amount."[258]

Despite its illicit status, PEA is widely available in health and grocery stores as an over-the-counter dietary supplement and energy enhancer; a seller on Amazon openly touts it for its energy increasing effects.[259] The product's recreational utility has not gone unnoticed: one reviewer compares the experience to MDMA,[260] and a potential buyer inquired as to whether the substance can be easily consumed by snorting.[261]

No legally cognizable difference exists between the synthetic cannabis sold by the Indian-born immigrant Mr. Makkar,[262] the PEA sold through Jeff Bezos's company, and the chocolate chip cookies served in the Supreme Court cafeteria.[263] But only one of these three parties has received the life-shattering impact of a federal prosecution. This is the kind of arbitrary enforcement that the Due Process Clause cannot tolerate—that people like Makkar are harshly punished while equally deserving defendants go free. The Analog Act has delegated "basic pol-

258. Transcript at 20–21, United States v. Chong, No. 13-CR-00570 (E.D.N.Y. Jan. 31, 2014). The prosecutor also opined that even a one in five million ratio of analog to filler substance would permit prosecution. *Id.*

259. *BulkSupplements.com Phenylethylamine HCL (Pea) Powder (100 grams)*, AMAZON, https://www.amazon.com/Bulksupplements-Pure-Phenylethylamine-Powder-grams/dp/B00ENRRBYO (last visited Sept. 23, 2021) (asserting that the product improves mood, brain health, and energy).

260. Zach, Customer Review for *BulkSupplements.com Phenylethylamine HCL (Pea) Powder (100 grams)*, AMAZON (May 16, 2017), https://www.amazon.com/gp/customerreviews/R352M5VX0P4DP0/ref=cm_cr_dp_d_rvw_ttl?ie=UTF8&ASIN%20%20=B00ENRRBYO [https://perma.cc/4B4Y-3BXA] ("Holy crap it's almost like you're on Molly if you take too high a dose.").

261. Customer Question for *BulkSupplements.com Phenylethylamine HCL (Pea) Powder (100 grams)*, AMAZON (Oct. 15, 2019), https://www.amazon.com/ask/questions/TxVOVEBI7UH66R/ref=ask_dp_dpmw_al_hza [https://perma.cc/9RLZ-UDBJ].

262. An alarming number of Analog Act defendants are Middle Eastern or South Asian immigrants. *See, e.g.*, United States v. Khan, No. 17-CR-40-SCJ, 2017 WL 9605112, at *3 (N.D. Ga. Sept. 5, 2017) ("[F]our people of Indian or Pakistani origin were indicted on the same day for similar charges based on investigations by the same Hindi-speaking DEA agent.").

263. The Justices' publicly acknowledged relationship with chocolate raises the possibility that they would be ethically incapable of ruling on the law. *See* Tom Porter, *'Hazing' Rituals Await Supreme Court's 'Junior Justice' Neil Gorsuch*, NEWSWEEK (Apr. 12, 2017, 11:44 AM), https://www.newsweek.com/hazing-rituals-await-supreme-courts-junior-justice-neil-gorsuch-583090 [https://perma.cc/W95W-TKPN] (explaining that the junior Justice must sit on the Court's cafeteria committee, "where literally the agenda is what happened to the good recipe for the chocolate chip cookies" (quoting Justice Elena Kagan)); *see also* Ellen Sherberg, *A Closer Look: Martin Ginsburg's Oatmeal Cookies*, BIZWOMEN (Jan. 14, 2019, 7:38 AM), https://www.bizjournals.com/bizwomen/news/out-of-the-office/2019/01/a-closer-look-martin-ginsburg-s-oatmeal-cookies.html?page=all [https://perma.cc/4RX2-PWXG] (providing the recipe for the Ginsburg family's chocolate chip cookies).

icy matters," such as determining which substances demand the severest possible restrictions and punishments, "to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis,"[264] leaving "judges to their intuitions and the people to their fate."[265]

VI. NEW VOID FOR VAGUENESS

In 2015, the Supreme Court voided a criminal statute in *Johnson v. United States* because the Court concluded that the statute violated the due process guarantee of the Constitution.[266] The statute at issue in *Johnson* was the residual clause of the Armed Career Criminal Act (ACCA), and the Court's voiding of the clause may provide sufficient grounds for voiding the Analog Act. In *Makkar*, Justice Gorsuch, then a circuit court judge, drew parallels between the ACCA's newly voided residual clause and the Analog Act, noting that it is an "open question, after all, what exactly it means for chemicals to have a 'substantially similar' chemical structure—or effect."[267]

The ACCA permits enhanced sentences for felons convicted of firearm possession who have three prior convictions for "violent felonies," which included, under the residual clause, crimes posing a "serious potential risk of physical injury to another."[268] "Serious potential risk of physical injury" lacked any statutory definition. As a remedy, the Court had developed the categorical approach to assess a crime's risk of physical injury.[269] Under the categorical approach, the sentencing judge would first engage in "the ordinary case" inquiry by imagining the facts underlying an ordinary instance of the crime of conviction, such as whether a garden-variety burglar poses a risk of confrontation between the burglar and the homeowner.[270]

Next, in a step dubbed the "hazy risk threshold" analysis, the sentencing judge would decide whether the risk of injury posed by this ordinary instance was so grave as to constitute a "serious potential risk of physical injury," thus qualifying it as a "violent felony." This categorical approach proved to be of little practical use in guiding sentencing courts, and the list of permissible residual clause considerations grew, eventually encompassing statistics, common sense assessments, and the hypothetical secondary effects of a crime (such as the possibility of a violent confrontation with a neighborhood watch member during an attempted burglary).[271]

264. *Grayned v. City of Rockford*, 408 U.S. 104, 108–09 (1972).
265. Sessions v. Dimaya, 138 S. Ct. 1204, 1224 (2018) (Gorsuch, J., concurring).
266. Johnson v. United States, 576 U.S. 591, 591 (2015).
267. United States v. Makkar, 810 F.3d 1139, 1143 (10th Cir. 2015).
268. Taylor v. United States, 495 U.S. 575, 578 (1990) (quoting 18 U.S.C. § 924(e)).
269. *See Johnson*, 576 U.S. at 596.
270. *See id.* at 597.
271. *See id.* at 597–98.

Despite numerous efforts over the course of decades, the Supreme Court failed to provide meaningful guidance clarifying the categorical approach. Thus, the *Johnson* majority deemed the residual clause offensive to due process for "combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony."[272] No defendant could reasonably know how a judge might imagine a crime or rate its risk, so the statute failed to provide the constitutionally required notice.

As later confirmed in *Sessions v. Dimaya*[273] and *United States v. Davis*,[274] two cases voiding other risk-of-harm inquiries, to be void under *Johnson* a statute must require both an "ordinary case inquiry" and a "hazy risk threshold" analysis.

The Analog Act's substantial similarity inquiry meets both requirements four times over. Like "serious potential risk of physical injury," "substantial similarity" lacks a statutory definition. Therefore, the fact finder must first engage in the equivalent to "the ordinary case" inquiry by deciding when two molecules are so alike as to be similar. Like the list of residual clause considerations, the number of facts considered is nearly endless: two-dimensional structure, core arrangement of atoms, structure and effects, and more. After establishing their preferred criteria for deeming molecules structurally similar, the fact finder must engage in a "hazy risk threshold" analysis by deciding whether the alleged analog and a scheduled substance are not only similar but are *substantially* similar.

Next, the fact finder must conduct a similar analysis of the analog's effects, first deciding when one might consider two narcotics to have similar effects and then analyzing whether the alleged analog produces effects *substantially* similar to those of some scheduled compound. Finally, if the fact finder decides to convict the defendant, the sentencing judge must repeat these same steps under the Sentencing Guidelines in order to arrive at an appropriate sentence.

In dicta, the *Johnson* Court noted that a statute does not generally offend due process simply because it applies "a qualitative standard such as 'substantial risk' to real-world conduct."[275] Post-*Johnson* Analog Act decisions have latched onto these statements to conclude that

272. *Id.* at 598.

273. 138 S. Ct. 1204 (2018). In *Dimaya*, the Supreme Court voided § 16(b) of the Immigration and Nationality Act on the grounds that its "crime of violence" inquiry violated the same tenets of the Due Process Clause as the ACCA's residual clause. *See id.* at 1211–12.

274. 139 S. Ct. 2319 (2019). In *Davis*, the Supreme Court voided 18 U.S.C. § 924(c)(3)(B), a residual clause permitting lengthier criminal sentences for using or carrying a firearm in furtherance of any federal "crime of violence or drug trafficking crime." *Id.* at 2321.

275. *Johnson*, 576 U.S. at 604.

juries may decide the question of substantial similarity because "'non-numeric,' 'qualitative standard[s]' abound in our law, and are not so inherently problematic as to independently render a statute void for vagueness."[276] This reasoning misses the point. The Analog Act is not vague because it contains a qualitative standard. It is vague because the phrase "substantially similar" prevents actual notice of the conduct prohibited and permits arbitrary enforcement.

A. The Separation of Powers and Prudential Limitations on the Analog Act

If the Analog Act is not voided entirely, courts should at least limit the statute to prosecuting drug chemists who create novel psychoactive chemicals designed to evade existing drug laws.[277] Courts should find the Analog Act vague as applied in prosecutions involving substances (including chocolate) that Congress opted not to criminalize despite ample opportunity to do so. This is the approach adopted by the only two successful as-applied vagueness challenges, *United States v. Forbes*[278] and *United States v. Roberts*.[279]

In 1990, the DEA investigated the *Forbes* defendants for legally buying alpha-ethyltryptamine (AET) from a chemical supply company and then selling it as a substitute for MDMA. Created by the Upjohn Company, AET is an antidepressant that was commercially abandoned due to dangerous side effects.[280] Determining that AET was not a controlled substance analog, prosecutors initially declined to charge the defendants.[281] Two years later, prosecutors reversed position and decided that AET *was* a controlled substance analog of schedule I substances dimethyltryptamine (DMT) and diethyltryptamine (DET).[282]

The defendants challenged the Analog Act as applied to AET. DEA chemists testified for both sides. The prosecution's chemist concluded that AET was substantially similar to DMT and DET because all three shared a tryptamine structure and exhibited some level of hallucinogenic activity, although he candidly admitted that scientists disagreed on the methodology for determining substantial structural similarity.[283] The defense's chemist disagreed, pointing out that DET

276. United States v. Demott, 906 F.3d 231, 237 (2d Cir. 2018) (quoting *Dimaya*, 138 S. Ct. at 1215).
277. *See* United States v. Makkar, 810 F.3d 1139, 1143 (10th Cir. 2015) (speculating that federal courts faced with the Analog Act might "wad[e] incrementally, in one as-applied challenge after another, deeper into an analytical swamp" rather than void the Act with one decision).
278. 806 F. Supp. 232 (D. Colo. 1992).
279. No. 01 CR 410, 2002 WL 31014834 (S.D.N.Y. Sept. 9, 2002).
280. *Forbes*, 806 F. Supp. at 233.
281. *Id.* at 234.
282. *Id.*
283. *Id.*

and DMT are tertiary amines while AET is a primary amine. Two neuropharmacologists also testified that AET was not substantially similar and lacked the hallucinogenic or stimulating properties of DET and DMT.[284]

After acknowledging the propriety of the conjunctive reading,[285] and that the Act possesses no limiting scienter requirement,[286] the court addressed vagueness. It first noted that while "the 'substantially similar' language may be generally susceptible to adequate definition," Congress's use of this technical term could only be clarified by referring to the corresponding fields of chemistry and pharmacology.[287] The court seized on the lack of scientific consensus on that key phrase's meaning, even within the DEA itself, and predicted that "where there is no scientific consensus, criminal culpability will turn solely on a 'battle of the experts' at trial."[288] The court ultimately found the Analog Act unconstitutionally vague as applied because a "defendant cannot determine in advance of his contemplated conduct whether AET is or is not substantially similar to a controlled substance."[289] Also cited in support of the court's conclusion were the government's prior decision to decline prosecution; that the defendants were not drug innovators, the Act's real target; that AET can be legally purchased through the mail; and that the government had never scheduled AET at any point in the drug's thirty years of existence.[290]

In *United States v. Roberts,* discussed above in section IV.A, the district court ultimately ruled the Act vague as applied to 1,4-butanediol.[291] First, the court found that the lack of agreement among experts made actual notice of prohibited behavior impossible.[292] Turning to *Kolender*'s arbitrary enforcement prong, the court found that the government's definition of a GHB analog cast so wide a net as to include common food additives, yet those food additives were not prosecuted.[293] The court found that the statute's only real limitation was Congress's intent to target designer drugs specifically designed to evade existing drug law.[294] However, 1,4-butanediol did not qualify as a designer drug because it had been used for decades as an industrial solvent. Therefore, any protection against arbitrary enforcement

284. *Id.* at 233.
285. *Id.* at 235 (gathering textual evidence supporting the conjunctive reading).
286. *Id.* at 238.
287. *Id.* at 237.
288. *Id.* at 238.
289. *Id.* at 237 (citing Gentle v. State Bar of Nev., 501 U.S. 1030, 1047 (1991)).
290. *Id.*
291. United States v. Roberts, No. 01 CR 410, 2002 WL 31014834, at *1 (S.D.N.Y. Sept. 9, 2002), *vacated*, 363 F.3d 118 (2d Cir. 2004); *see also supra* text accompanying notes 103–108 (explaining the *Roberts* case).
292. *Id.* at *3–4.
293. *Id.* at *5.
294. *Id.*

would result from "retroactive judicial decisionmaking" and not the statute's language.[295] The court in *Roberts* found this feature to be proof of "the failure of Congress to 'establish minimal guidelines to govern law enforcement.'"[296]

The *Roberts* court noted that "[n]othing has prevented Congress from either scheduling or listing 1,4–butanediol as a controlled substance" despite the substance having been in common use for decades as an industrial solvent and despite the scheduling of other, similar chemicals.[297] Ultimately, the court found enforcement of the Analog Act against 1,4-butanediol as proof "that Congress has 'impermissibly delegate[d] basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.'"[298]

The Supreme Court has clearly forbidden legislatures from "abdicat[ing] their responsibilities for setting the standards of the criminal law."[299] Congress violated the Court's command by creating the Analog Act and "set[ting] a net large enough to catch all possible offenders, and leav[ing] it to the courts to step inside and say who could be rightfully detained, and who should be set at large."[300] Putting the judiciary in charge of deciding which substances are illicit is a clear violation of the separation of powers. It is unlikely that any prudential limitations can save the statute. However, the most convincing limitation would be to align the law with Congress's original intent and only prosecute drug chemists who invent novel psychoactive substances for the purpose of evading existing laws. Congress has the power to prohibit substances as it sees fit, and it should not force that role onto the judiciary by the passage of ambiguous legislation.

VII. THE ANALOG ACT'S CONTINUING THREAT

A. The Analog Act as a Failed Deterrent

The Analog Act encourages the introduction of legally purchased analogs into the American black market by failing to provide notice to overseas distributors of the substances it prohibits.

Overseas chemical laboratories, particularly those in China and India, supplied many of the analogs that fueled the fentanyl and bath salts crises.[301] Without an official list of suspected controlled sub-

295. *Id.*
296. *Id.* (quoting Smith v. Goguen, 415 U.S. 566, 574 (1974)).
297. *Id.*
298. *Id.* at *6 (alteration in original) (quoting Grayned v. City of Rockford, 408 U.S. 104, 108–09 (1972)).
299. *Id.* at *5 (quoting *Smith,* 415 U.S. at 575).
300. *Id.* (quoting Kolender v. Lawson, 461 U.S. 352, 358 n.7 (1983)).
301. *See* Jake Schaller, Comment, *Not for Bathing: Bath Salts and the New Menace of Synthetic Drugs*, 16 J. HEALTH CARE L. & POL'Y 245, 248 (2013).

stance analogs, suppliers cannot readily ascertain whether they are trafficking in potentially illicit substances. And even if a substance seems to satisfy the criteria for being a controlled substance analog, suppliers cannot readily determine whether a purchaser intends the chemical for human consumption; many analogs have legitimate uses as industrial solvents[302] or animal tranquilizers,[303] and they are used for research and development. Without intended human consumption, a controlled substance analog remains effectively uncontrolled. Unless an analog purchaser actually admits to intended human consumption, even a supplier who suspected black market product diversion would likely escape prosecution.

Imagine that in 2014, a chemical supplier in Guangzhou, China, received an order from a Tennessee zoo offering a few thousand dollars for a kilogram of thiafentanil, a large game tranquilizer[304] close to one hundred times more potent than fentanyl.[305] The supplier's attorney approves the sale, reasoning that thiafentanil is not a controlled substance, has never been the subject of an Analog Act prosecution, and because the purchaser intends to use the drug as an animal tranquilizer, is not intended for human consumption. Even if the supposed zoo turned out to be a heroin dealer diverting thiafentanil into the black market, the chemical supplier did not violate any laws by making the sale.

Not surprisingly, prosecuting overseas analog distributors has proven to be so immensely difficult that as of 2017, the Department of Justice had indicted only one pair of overseas fentanyl analog distributors.[306] Until Congress replaces the Analog Act with a law that produces an actual deterrent effect, the open sale of analogs will continue unabated.

302. *See* World Health Org. [WHO], *Gamma-Butyrolactone (GBL) Critical Review Report*, at 7 (June 16–20, 2014), https://www.who.int/medicines/areas/quality_safety/4_3_Review.pdf [https://perma.cc/6WES-FCM2].

303. *See* Schedules of Controlled Substances: Placement of Thiafentanil into Schedule II, 81 Fed. Reg. 58,834, 58,840 (Aug. 6, 2016) (codified at 21 C.F.R. §§ 1301, 1305, 1308).

304. *See, e.g.*, Lisa L. Wolfe et al., *Immobilization of Mule Deer with Thiafentanil (A-3080) or Thiafentanil Plus Xylazine*, 40 J. WILDLIFE DISEASES 282 (2004).

305. Schedules of Controlled Substances: Placement of Thiafentanil into Schedule II, 81 Fed. Reg. at 58840.

306. Press Release, Dep't of Just., Justice Department Announces First Ever Indictments Against Designated Chinese Manufacturers of Deadly Fentanyl and Other Opiate Substances (Oct. 17, 2017), https://www.justice.gov/opa/pr/justice-department-announces-first-ever-indictments-against-designated-chinese-manufacturers [https://perma.cc/B5AS-YY5M].

B. The Analog Act's Continued Existence Threatens Emerging Psychedelic Medicine

The continued existence of the Analog Act impermissibly frustrates critical medical research into psychedelic medicine. After decades of relative inactivity due to legal complications, renewed interest in psychedelic research has led to breakthrough treatments for some of the most common and debilitating conditions: post-traumatic stress disorder, substance use disorder, cluster headaches, anxiety, and depression.[307] Due to its unusual nature, the Analog Act creates a level of legal ambiguity that discourages active development of these treatments.

The Analog Act hamstrings efforts to replicate in humans some of the more surprising—and even miraculous—experiments on animals. For example, tiny doses of DOI, one of Shulgin's super potent hallucinogens, totally halts asthma development in mice.[308] If voided, the Analog Act would no longer act as a barrier to these kinds of breakthroughs.

C. The Hemp Industry Is Subject to Analog Act Prosecution

The Analog Act could be employed to prosecute the sale and possession of hemp-derived cannabinoids intended for human consumption, potentially including the now ubiquitous cannabidiol (CBD). Cannabis contains over one hundred unique chemicals, known as cannabinoids,[309] the most famous being delta-9 tetrahydrocannabinol (THC), the molecule primarily responsible for cannabis's psychoactive properties.

Before 2018, the CSA's definition of marijuana encompassed "all parts of the plant Cannabis sativa L.,"[310] making cannabis a controlled substance and thus beyond the reach of the Analog Act. The Agriculture Improvement Act of 2018 (AIA) excluded hemp—cannabis sativa plants not exceeding .3% THC by weight—from the CSA's definition of marijuana.[311] The AIA's definition of hemp includes hemp "seeds . . . and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not."[312] The cannabis

307. *See generally* Albert Garcia-Romeu et al., *Clinical Applications of Hallucinogens: A Review*, 24 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 229 (2016).
308. Felix Nau Jr. et al., *Serotonin 5-HT$_2$ Receptor Activation Prevents Allergic Asthma in a Mouse Model*, 308 AM. J. PHYSIOLOGY L191 (2015).
309. *See generally* Eric W. Bow & John M. Rimoldi, *The Structure–Function Relationships of Classical Cannabinoids: CB1/CB2 Modulation*, 8 PERSPS. MED. CHEMISTRY 17 (2016).
310. 21 U.S.C. § 802(16)(A).
311. *See* 21 U.S.C. § 802(16)(B)(i). Section 812(c) now also exempts hemp-derived THC from schedule I.
312. 7 U.S.C. § 1639o(1).

industry interpreted the AIA as legalizing the sale of *all* hemp-derived cannabinoid substances or mixtures containing .3% or less THC, and sellers began distributing cannabinoid products across the country.[313] The most popular cannabinoid, CBD, which is marketed as an effective treatment for every ailment from anxiety to arthritis, quickly grew into a multi-billion-dollar national industry.[314]

Yet by removing hemp and its extracts from the CSA, the AIA also placed hemp and its derived cannabinoids outside of § 802(32)(C)'s Analog Act exemptions. The Act expressly omits four categories of substances. First, it excludes all controlled substances,[315] meaning "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV or V."[316] The other three exempt categories are the following:

> (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 section 355 of this title [section 505 of the Federal Food, Drug, and Cosmetic Act] . . . ; or
> (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.[317]

Hemp-derived cannabinoids do not seem to fit into any of these exempt categories. Although the FDA approved a prescription version of CBD, Epidiolex, the DEA considers Epidiolex and non-prescription CBD to be legally distinct, thus preventing CBD from enjoying Analog Act immunity based on Epidiolex's new drug application.[318]

Compared to prior prosecutions for other substances, CBD provides a fairly good target for prosecution as a controlled substance THC analog. CBD easily satisfies the structural similarity requirement, as the two chemicals are enantiomers sharing the same chemi-

313. Under the AIA, the same cannabinoid can be legal when derived from hemp but illegal when derived from marijuana despite being chemically identical.

314. *See generally Cannabidiol Market Growth Analysis Report, 2021–2028*, GRAND VIEW RSCH. (Feb. 2021), https://www.grandviewresearch.com/industry-analysis/cannabidiol-cbd-market#:~:text=report%20Overview,22.2%25%20from%202019%20to%202025 [https://perma.cc/MH2B-5U4H].

315. *See* 21 U.S.C. § 802(32)(C)(i).

316. 21 U.S.C. § 802(6).

317. 21 U.S.C. § 802(32)(C).

318. *See* Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48950, 48952 (Sept. 28, 2018) (codified at 21 C.F.R. §§ 1308, 1312) ("[A]ny material, compound, mixture, or preparation *other than Epidiolex* that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802(16), including any non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA."). At the time of this rule's issuance, the AIA had yet to come into effect. *See* United States v. Turcotte, 405 F.3d 515, 530 (7th Cir. 2005) (exploring a new drug application exception).

cal formula,[319] their precursor chemicals are created by the cannabis plant using nearly identical biosynthetic pathways,[320] and CBD can be converted into THC using commonly available acids.[321]

As for substantially similar effects, though CBD is primarily an anxiolytic lacking THC's immediate psychoactivity, both chemicals act as cannabinoid receptor agonists.[322] In *United States v. Cooper*, the court held that a substance acting as a cannabinoid receptor agonist sufficed to prove substantially similar effects.[323] Furthermore, under *Demott*'s hybrid substantial similarity,[324] CBD could be deemed an analog based on its structural similarity to THC and the similarity of its anxiolytic effects to quaaludes or some other schedule I anti-anxiety drug.[325]

Despite the strength of a case against CBD, the prominence of the national CBD market and federal agency cooperation with the cannabis industry make mass prosecutions seem very unlikely. However, as shown by the prosecution of the synthetic cannabis industry, size is no protection from the Analog Act, and as in *Cooper*, the Act's position toward an analog can change rapidly without impairing prosecutions.

Newer commercial cannabinoids like delta-8 THC are very vulnerable to Analog Act prosecution. Tiny amounts of delta-8 THC naturally occur in hemp, but manufacturers have learned how to synthetically derive commercially viable quantities from other hemp cannabinoids like CBD.[326] Manufacturers contend that this produc-

319. *Cf.* United States v. Fedida, 942 F. Supp. 2d 1270, 1279 (M.D. Fla. 2013) (comparing the structures of UR-144, XLR-11, and JWH-18).

320. *See* M. David Marks et al., *Identification of Candidate Genes Affecting* Δ^9*-Tetrahydrocannabinol Biosynthesis in Cannabis Sativa*, 60 J. EXPERIMENTAL BOTANY 3715, 3716 (2009).

321. *See* Josh Bloom, *CBD and THC: The Only Difference Is One Chemical Bond*, AM. COUNCIL ON SCI. & HEALTH (Apr. 8, 2019), https://www.acsh.org/news/2019/04/08/cbd-and-thc-only-difference-one-chemical-bond-13937 [https://perma.cc/VUB4-2KGA] (describing how to convert CBD into THC with simple acids); *cf.* United States v. Fisher, 289 F.3d 1329, 1339 (11th Cir. 2002) (finding that GBL converts into GHB when ingested).

322. *See* R.G. Pertwee, *The Diverse CB1 and CB2 Receptor Pharmacology of Three Plant Cannabinoids:* Δ^9*-Tetrahydrocannabinol, Cannabidiol and* Δ^9*-Tetrahydrocannabivarin*, 153 BRIT. J. PHARMACOLOGY 199, 199 (2008).

323. United States v. Cooper, No. 14-CR-014-J-20MCR, 2015 WL 13850123, at *6 (M.D. Fla. Jan. 14, 2015); *cf.* United States v. Stanford, 823 F.3d 814, 823 (5th Cir. 2016) ("JWH–018 and AM–2201 are naphthoylindoles that activate the cannabinoid receptors in the human body, producing a 'high.'").

324. *See supra* section IV.C.

325. *See generally* Harry Low & Tom Heyden, *The Rise and Fall of Quaaludes*, BBC NEWS MAG. (July 9, 2015), https://www.bbc.com/news/magazine-33428487 [https://perma.cc/MK8U-AMJ2].

326. *See* Andrea Steel & Lisa Pittman, *Did the DEA's New Rule Confirm Hemp-Derived Delta-8 THC Is Illegal?*, CANNABIS BUS. EXEC. (Sept. 1, 2020), https://www.cannabisbusinessexecutive.com/2020/09/did-the-deas-new-rule-confirm-hemp-derived-delta-8-thc-is-illegal/ [https://perma.cc/F5JW-2PJZ].

tion process places hemp-derived delta-8 THC under the protections of the AIA, and they openly sell the product online and in head shops.

Delta-8 THC is almost certainly a THC controlled substance analog. Studies indicate that delta-8 THC's effects and potency closely mimic those of THC[327] and that the molecules are nearly identical in structure.[328] The DEA has moved aggressively to halt the commercial spread of synthetically derived hemp cannabinoids. In August of 2020, the DEA struck its first blow by issuing an interim final rule specifying that synthetically derived cannabinoids like delta-8 THC fall outside of the AIA and are schedule I marijuana derivatives,[329] an act quickly met by legal challenges from the cannabis industry.[330] Should the DEA's administrative efforts fail, the agency's final recourse would be prosecuting delta-8 THC manufacturers under the Analog Act.

Similarly, THCA would almost certainly qualify as a controlled substance analog of THC. Most dried marijuana contains a large amount of THCA—sometimes as much as thirty-five percent—and a relatively low level of THC—typically under one percent and often low enough to qualify as industrial hemp.[331] THCA supplies the majority of THC responsible for cannabis's psychoactive effect because THCA converts into THC when heated or smoked.[332] By sanctioning the sale of hemp-derived THCA, the AIA unintentionally legalized recreational cannabis containing less than .3% THC by weight.

The United States Department of Agriculture attempted to close this loophole by issuing regulations stating that the hemp "testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC) and [that] test result[s] reflect the total available THC derived from the sum of the THC and THC-A content."[333] Left

327. *See, e.g.*, Leo E. Hollister & H.K. Gillespie, *Delta-8- and Delta-9-Tetrahydrocannabinol: Comparison in Man by Oral and Intravenous Administration*, 14 CLINICAL PHARMACOLOGY & THERAPEUTICS 353, 353–57 (1973).

328. *See generally* José Alexandre S. Crippa et al., *Oral Cannabidiol Does Not Convert to Δ^8-THC or Δ^9-THC in Humans: A Pharmacokinetic Study in Healthy Subjects*, 5 CANNABIS & CANNABINOID RESEARCH 89, 89 (2020).

329. Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020) (codified at 21 C.F.R. §§ 1308, 1312).

330. *See, e.g.*, Hemp Indus. Ass'n v. DEA, No. CV 20-2921, 2021 WL 1734920 (D.D.C. May 3, 2021), *appeal filed,* No. 21-5111 (D.C. Cir. May 21, 2021).

331. *See* Thomas A. Coogan, *Analysis of the Cannabinoid Content of Strains Available in the New Jersey Medicinal Marijuana Program*, J. CANNABIS RSCH. 2019, at 1, 5 fig.5; *see also Test Results: Blue Ox*, ANALYTICAL 360 (Dec. 11, 2016), http://archive.analytical360.com/m/flowers/631597 [https://perma.cc/A2MY-PEHL] (finding recreational cannabis to possess .3% delta-9 THC and 23.43% THCA).

332. *See* People v. Korkigian, 965 N.W.2d 222, 225 (Mich. Ct. App. 2020) (describing the conversion of THCA into THC), *appeal denied*, 960 N.W.2d 530 (Mich. 2021).

333. 7 C.F.R. § 990.25(b) (2021).

unexplained is how an administrative rule could extend a substance-specific statute to also regulate an entirely different substance. The rule's chances of surviving a legal challenge appear slim.[334]

With all other options foreclosed or unpromising, THCA prosecutions could still take place under the Analog Act. THCA is nearly identical in structure to the schedule I THC and its ready conversion into THC would weigh heavily in favor of finding it to be a controlled substance analog.[335] While it seems unlikely that federal authorities would ever prosecute the cannabis industry under the Analog Act, the possibility remains—synthetic cannabis was also once a billion-dollar national industry. Until the Act is void, the entire cannabis industry remains vulnerable.

VIII. THE ANALOG ACT AND SEPARATION OF POWERS

A. The Rapid Development Myth

The original rationale justifying the Analog Act's implementation was protecting the public from innovative drug manufacturers creating novel recreational chemicals faster than the DEA could schedule them.[336] Yet very few, if any, Analog Act defendants are prosecuted for manufacturing an entirely novel recreational compound. Designer drug dealers lack research budgets and thus find it more convenient to identify suitable candidate molecules already discovered by legitimate scientific research.[337]

The real challenge in stopping the spread of dangerous analogs is not the pace of innovation. Very rarely do analog drugs appear without warning. While the modern pace of analog drug capitalization exceeds that of prior decades, most emerging drugs of abuse are reported by users in response to government surveys or are rapidly detected by international law enforcement.[338] Therefore, the real challenge in

334. *See* Rod Kight, *What Is "Total THC" and Does It Matter?*, KIGHT ON CANNABIS (May 10, 2019), https://cannabusiness.law/what-is-total-thc-and-does-it-matter/ [https://perma.cc/EY6M-8Z68].

335. *Cf.* United States v. Roberts, 363 F.3d 118, 125 (2d Cir. 2004) (citing 1,4-butanediol's conversion into GHB as evidence that it is an analog of GHB).

336. *See* United States v. Turcotte, 405 F.3d 515, 518 (7th Cir. 2005) ("[The Act was] Congress's attempt to adapt the nation's controlled substances laws to the dizzying pace of innovations in drug technology.").

337. *See* Kau, *supra* note 39, at 1083–85, 1094–95. "Virtually all 'designer drugs' are either legitimate pharmaceutical products on the market or potential products that were synthesized in medical research and development but discarded because they didn't produce an intended effect." *Id.* at 1083 (footnote omitted).

338. *See* Salma M. Khaled et al., *The Prevalence of Novel Psychoactive Substances (NPS) Use in Non-Clinical Populations: A Systematic Review Protocol*, SYSTEMATIC REVS., 2016, at 1, 2.

stopping the spread of dangerous analogs is Congress's apparent lack of interest to do so.[339]

Almost all of the well-known analogs have existed for decades. Synthetic cannabinoids were described in academic literature long before they were marketed as Spice in head shops and gas stations. Pfizer invented a number of them as far back as the 1970s.[340] Professor John Huffman invented hundreds of synthetic cannabinoids and meticulously documented their properties in his academic articles.[341] Many of the drugs even bear his initials, such as JWH-018.[342] And a drug's black-market potential may not be immediately apparent. JWH-018 first appeared in commercially distributed synthetic cannabis in 2008.[343] European countries banned JWH-018 almost immediately, but three years passed before the DEA finally emergency scheduled the substance.[344]

DEA-consulting chemist Alexander Shulgin created scores of psychedelic analogs and self-published multiple encyclopedic guides describing their syntheses and effects.[345] Some of his creations are scheduled, but many nearly identical substances are not. For example, 2,5-dimethoxy-4-iodoamphetamine (DOI) and 4-chloro-2,5-dimethoxyamphetamine (DOC) are nearly identical super-potent hallucinogenic amphetamines that can cause day-long hallucinations from milligram

339. *Cf.* Timothy P. Stackhouse, Note, *Regulators in Wackyland: Capturing the Last of the Designer Drugs*, 54 ARIZ. L. REV. 1105, 1117–18 (2012) (acknowledging U.S. failure to promptly regulate bath salts and synthetic cannabis).

340. *See* EUR. MONITORING CTR. FOR DRUGS & DRUG ADDICTION, UNDERSTANDING THE 'SPICE' PHENOMENON 9 (Off. Publ'ns Eur. Cmties, 2009), https://www.emcdda.europa.eu/publications/thematic-papers/understanding-spice-phenomenon_en [https://perma.cc/E24Z-X7Y9].

341. *See generally* Terrence McCoy, *How This Chemist Unwittingly Helped Spawn the Synthetic Drug Industry*, WASH. POST (Aug. 9, 2015), https://www.washingtonpost.com/local/social-issues/how-a-chemist-unwittingly-helped-spawn-the-synthetic-drug-epidemic/2015/08/09/94454824-3633-11e5-9739-170df8af8eb9_story.html [https://perma.cc/YVN9-GBDA?type=image].

342. *See* Government's Opposition in Response to Defendant's Motion to Limit Testimony of Dr. Jordan Trecki, *supra* note 146, at 5; Jenny L. Wiley et al., *Hijacking of Basic Research: The Case of Synthetic Cannabinoids*, RTI PRESS, Nov. 2011, at 2, https://www.rti.org/sites/default/files/resources/op-0007-1111-wiley.pdf [https://perma.cc/N3HY-L2UA]; John W. Huffman et al., *3-Indolyl-1-Naphthylmethanes: New Cannabimimetic Indoles Provide Evidence for Aromatic Stacking Interactions with the CB1 Cannabinoid Receptor*, 11 BIOORGANIC & MED. CHEMISTRY 539 (2002); *see also* Jennifer M. Frost, *Indol-3-yl-Tetramethylcyclopropyl Ketones: Effects of Indole Ring Substitution on CB2 Cannabinoid Receptor Activity*, 51 J. MED. CHEMISTRY 1904 (2008) (finding indole ring substitutions on CB2 generally detrimental to agonist activity).

343. *See* EUR. MONITORING CTR. FOR DRUGS & DRUG ADDICTION, *supra* note 340, at 3.

344. *See* 21 C.F.R. § 1308.11(g)(3) (2020).

345. *See generally* SHULGIN & SHULGIN, *supra* note 81.

doses. DOC is a schedule I substance, yet DOI is only regulated by the Analog Act.[346]

The synthetic cathinone analogs in bath salts are also not new discoveries. *United States v. Hofstatter*, decided in 1993, upheld convictions for the attempted manufacture of synthetic cathinone analogs.[347] Yet these analogs were not properly scheduled until decades later and only after the emergence of the bath salts industry.[348] European law enforcement first seized mephedrone, one of the more popular cathinones found in bath salts, in November of 2007. Individual members of the European Union responded by criminalizing the substance, with the first prohibitions passed in 2008.[349] The United States delayed its response, finally emergency scheduling mephedrone in late 2011.[350]

B. Fatal Delay in Scheduling Fentanyl Analogs

Law enforcement's most costly mistake was the failure to respond swiftly to the threat posed by fentanyl analogs. The majority of the over 600 existing fentanyl analogs[351] were invented in the 1960s and 1970s by Belgian physician Paul Janssen.[352] In 1975, Shulgin predicted fentanyl's eventual domination of the opioid black market, citing its comparative ease of production and profit margins.[353] Producing a kilogram of heroin requires growing tens of thousands of opium poppies, collecting the raw opium from the mature poppy pods,

346. *See* 21 C.F.R. § 1308.11 (2020).

347. United States v. Hofstatter, 8 F.3d 316, 322 (6th Cir. 1993).

348. *See* Placement of Synthetic Cannabinoids on Controlled Substance Schedule, 76 Fed. Reg. 65371, 65371–74 (Oct. 21, 2011) (codified at 21 C.F.R. § 1308.11 (2021)).

349. *See Europol–EMCDDA Joint Report on a New Psychoactive Substance: 4-Methylmethcathinone (Mephedrone)*, EUR. MONITORING CTR. FOR DRUGS & DRUG ADDICTION 16 (2010), www.emcdda.europa.eu/system/files/publications/559/2010_Mephedrone_Joint_report_279863.pdf [https://perma.cc/UQ9B-V8C7].

350. *See* Press Release, Drug Enf't Admin., Chemicals Used in "Bath Salts" Now Under Federal Control and Regulation (Oct. 21, 2011), https://www.dea.gov/press-releases/2011/10/21/chemicals-used-bath-salts-now-under-federal-control-and-regulation [https://perma.cc/THH3-5SLB].

351. *See Fentanyl, Fentanyl Analogues, and Synthetic Cannabinoids: Public Hearing Before the U.S. Sent'g Comm'n*, 115th Cong. 3 (2017) (statement of Barry K. Logan, Chief Scientist, NMS Labs, Inc.).

352. *See generally* U.N. Off. on Drugs & Crime, *Recommended Methods for the Identification and Analysis of Fentanyl and Its Analogues in Biological Specimens*, 1, U.N. Doc. ST/NAR/53 (2017), https://www.unodc.org/documents/scientific/Recommended_methods_for_the_identification_and_analysis_of_Fentanyl.pdf [https://perma.cc/GAF5-66FN]. For a history of fentanyl development and use, see Theodore H. Stanley, *The Fentanyl Story*, 15 J. PAIN 1215 (2014).

353. *See* BRYCE PARDO ET AL., THE FUTURE OF FENTANYL AND OTHER SYNTHETIC OPIOIDS 45, 72 (2019), https://www.rand.org/content/dam/rand/pubs/research_reports/RR3100/RR3117/RAND_RR3117.pdf [https://perma.cc/39BP-9J8W].

and refining the opium into heroin in a laboratory. By contrast, a kilogram of fentanyl requires some precursor chemicals, a laboratory, and minimal chemical expertise, and it yields many times more doses than an equivalent amount of heroin.

Despite this risk, the majority of fentanyl analogs were never scheduled. A handful were scheduled after the first fentanyl crisis in the early 1980s. But between 1988 and 2014, the DEA and Congress abandoned efforts to control fentanyl, scheduling only two synthetic fentanyl analogs.[354] One of the many analogs to go unscheduled was acetylfentanyl, a drug that is five to fifteen times more potent than heroin. In 2013, acetylfentanyl ravaged the eastern United States, killing dozens of opiate users in Rhode Island, Pennsylvania, and New Orleans.[355] The drug was finally added to schedule I in 2015, more than two years after the first known fatal overdose.[356]

In 2013, there were 945 forensic cases in the United States involving fentanyl analogs. By 2017, that number had risen to 71,341. Despite the dramatic increase in cases, the United States waited until 2018 before emergency scheduling all fentanyl analogs.[357] By comparison, China had outlawed many fentanyl analogs in 2015.[358] Even black-market drug distributors moved quicker than the DEA in providing protections against dangerous fentanyl analogs. In 2016, the first dark web markets categorically banned the sale of fentanyl analogs "[d]ue to recent deaths and the threat to customers' well-being," a policy adopted by many other dark web markets.[359]

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354. *See* Patil Armenian et al., *Fentanyl, Fentanyl Analogs and Novel Synthetic Opioids: A Comprehensive Review*, NEUROPHARMACOLOGY, Oct. 2017, at 1, 4.

355. *See* Matthew J. Lozier et al., *Acetyl Fentanyl, a Novel Fentanyl Analog, Causes 14 Overdose Deaths in Rhode Island*, *March–May 2013*, 11 J. MED. TOXICOLOGY 208, 208 (2015).

356. *See* Armenian et al., *supra* note 354, at 4.

357. *See* 21 C.F.R. § 1308.11 (2020).

358. *See* Sara Ganim, *China's Fentanyl Ban a 'Game-Changer' for Opioid Epidemic, DEA Officials Say*, CNN HEALTH (Feb. 16, 2017, 4:52 PM), https://www.cnn.com/2017/02/16/health/fentanyl-china-ban-opioids/index.html [https://perma.cc/4ZJY-A8PC]. China implemented a blanket ban on fentanyl analogs in 2019. *See* Vanda Felbab-Brown, *Fentanyl and Geopolitics: Controlling Opioid Supply from China*, BROOKINGS INST., July 22, 2020, at 1, 9, https://www.brookings.edu/wp-content/uploads/2020/07/8_Felbab-Brown_China_final.pdf [https://perma.cc/A3VC-P7QT] (recounting the history of Chinese policy regarding fentanyl).

359. Joseph Cox, *Dark Web Market Bans Synthetic Opioid Fentanyl After Recent Deaths*, VICE (Aug. 31, 2016, 8:15 AM), https://www.vice.com/en_us/article/ezp5vj/dark-web-market-bans-synthetic-opioid-fentanyl-after-recent-deaths [https://perma.cc/JFS8-7ZMB]. Dark web markets are online marketplaces that use cryptography to shield transactions, thereby facilitating the anonymous sale of recreational chemicals and other illicit goods. *See* Ahmed Ghappour, *Searching Places Unknown: Law Enforcement Jurisdiction on the Dark Web*, 69 STAN. L. REV. 1075, 1077–90 (2017) (describing dark web markets).

The number of Americans who lost their lives due to the government's failure to schedule fentanyl analogs will never be known.[360] The CDC has repeatedly warned that "[m]ore timely and comprehensive surveillance data . . . are urgently needed to curb deaths involving prescription and illicit opioids, specifically [fentanyls]."[361] The unexplained deaths of opiate users provide the first real clue to the arrival of a novel fentanyl analog on the black market. However, in the United States, up to one quarter of all drug overdoses lack any identified drug on the death certificate.[362] Exotic fentanyls like acetylfentanyl typically escape postmortem detection because of their obscurity and because they are intermixed with more common and readily identifiable narcotics.[363]

It must also be noted that, as a public health protection, the Analog Act's limited scope renders it ineffective against chemicals structurally unrelated to schedule I or II substances. U-47700,[364] a synthetic opioid surpassing heroin's potency, bears no structural resemblance to morphine or other scheduled opioids, and it went unregulated until an emergency DEA scheduling in 2016. By then, U-47700 had already

360. *See, e.g.*, Armenian et al., *supra* note 354, at 4 ("It is believed that the magnitude of this outbreak is underappreciated since acetylfentanyl is not routinely monitored by clinical and forensic toxicology laboratories.").

361. Lawrence Scholl et al., Ctrs. for Disease Control & Prevention, *Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017,* 67 MORBIDITY & MORTALITY WKLY. REP. 1419, 1419 (Jan. 4, 2019), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm675152e1-H.pdf [https://perma.cc/HEJ8-DQUR]. While the DEA's National Forensic Laboratory Information System (NFLIS) aggregates some state and federal drug data, it does not collect the comprehensive post-mortem toxicology data required for early detection of novel psychoactive substances. *See NFLIS Frequently Asked Questions (FAQ)*, NAT'L FORENSIC LAB'Y INFO. SYS., https://www.nflis.deadiversion.usdoj.gov/faq.xhtml [https://perma.cc/3MGW-SBBL] (last visited Aug. 30, 2021).

362. *See* Svetla Slavova et al., *Drug Overdose Deaths: Let's Get Specific*, 130 PUB. HEALTH REP. 339, 339 (2015) ("Previous work has shown that about 25% of U.S. overdose deaths had no drugs specified on the death certificate . . . ."). This number has steadily fallen, reaching twelve percent in 2017. *See* Scholl et al., *supra* note 361, at 1426.

363. *See, e.g.*, Jane Mounteney et al., *Fentanyls: Are We Missing the Signs? Highly Potent and on the Rise in Europe*, 26 INT'L J. DRUG POL'Y 626, 628 (2015) ("The toxicity of these drugs mean that evidence of their use is often first documented through mortality data."); Michael H. Baughmann & Gavril W. Pasternak, *Novel Synthetic Opioids and Overdose Deaths: Tip of the Iceberg?*, 43 NEUROPSYCHOPHARMACOLOGY REVS. 216, 216 (2018) ("The role of NSOs in opioid overdose deaths is difficult to determine, because the substances are not detected by standard toxicology screens, which rely on immunoassays sensitive to heroin, its metabolites, and chemically related compounds."); Amanda L.A. Mohr et al., *Analysis of Novel Synthetic Opioids U-47700, U-50488 and Furanyl Fentanyl by LC–MS/MS in Postmortem Casework*, 40 J. ANALYTICAL TOXICOLOGY 709, 716 (2016).

364. *See generally* Saeed K. Alzghari et al., *U-47700: An Emerging Threat*, 9 CUREUS 1 (Oct. 22, 2017) (describing the rise of U-47700).

saturated the black market and contributed to the deaths of at least forty drug users that year,[365] including the singer Prince.[366] MT-45, another opioid structurally unrelated to fentanyl or other scheduled drugs, was first reported in 2013[367] but not banned until 2018.

C. Substances Requiring Emergency Scheduling

Congress still refuses to properly regulate dangerous, novel psychoactive substances despite the very real threats of death and addiction. Some of the most obvious candidates for scheduling include flualprazolam, norfludiazepam, and the numerous other unregulated benzodiazepines that are widely available from online merchants. The Analog Act does not encompass benzodiazepine analogs because all benzodiazepines are on schedule IV. Unscheduled benzodiazepine analogs have been circulating freely in the American and European recreational drug markets since at least the early 2010s.[368] One unscheduled benzodiazepine analog, etizolam, has recently eclipsed the more familiar drug ketamine, with the DEA reporting thousands of seizures in 2019.[369]

Another candidate for emergency scheduling, W-18, was discovered in the 1980s by a group of Canadian scientists searching for alternative analgesics. Early tests revealed W-18 to have 10,000 times the pain-killing effect of morphine.[370] The drug first appeared on the black market sometime after 2010 and has been found across Canada

365. *See* Mike A. Mojica et al., *Designing Traceable Opioid Material Kits To Improve Laboratory Testing During the U.S. Opioid Overdose Crisis*, 317 TOXICOLOGY LETTERS 53, 55 tbl.1 (2019).

366. *See* Mary Emily O'Hara, *U-47700: Everything You Need To Know About New Deadly Drug*, ROLLING STONE (Oct. 4, 2016, 7:46 PM), https://www.rollingstone.com/culture/culture-news/u-47700-everything-you-need-to-know-about-deadly-new-drug-187042/ [https://perma.cc/LLU3-7QT2].

367. *See Special Report: Opiates and Related Drugs Reported in NFLIS, 2009–2014*, NAT'L FORENSIC LAB'Y INFO. SYS. (2017).

368. *See A Review of the Evidence of Use and Harms of Novel Benzodiazepines*, ADVISORY COUNCIL ON THE MISUSE OF DRUGS 1, 8 (Apr. 2020), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/881969/ACMD_report_-_a_review_of_the_evidence_of_use_and_harms_of_novel_benzodiazepines.pdf [https://perma.cc/44J6-EV4S]; Adam Blumenberg et al., *Flualprazolam: Report of an Outbreak of a New Psychoactive Substance in Adolescents*, 146 PEDIATRICS 1 (2020).

369. NFLIS–DRUG 2019 ANNUAL REPORT, NAT'L FORENSIC LAB'Y INFO. SYS. 8 tbl.1.2, 15 tbl.2 (2020), https://www.nflis.deadiversion.usdoj.gov/nflisdata/docs/NFLIS-DRUG_2019_Annual_Report.pdf [https://perma.cc/8YN6-G8K5]. For more information about etizolam's history and effects, see World Health Org., CRITICAL REVIEW REPORT: ETIZOLAM (2019), https://www.who.int/medicines/access/controlled-substances/Final_Etizolam.pdf?ua=1 [https://perma.cc/XC64-YAQD].

370. *See* Xi-Ping Huang et al., *Fentanyl-Related Designer Drugs W-18 and W-15 Lack Appreciable Opioid Activity in Vitro and in Vivo*, JCI INSIGHT, Nov. 16, 2017, at 1, 4, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5752382/pdf/jciinsight-2-

and the United States,[371] sometimes in raw powder form and sometimes in the pill form of oxycodone or other pharmaceutical opiates.[372] Experts believe that W-18 caused a rash of naloxone-nonresponsive overdose deaths,[373] and it continues to appear in black market opiate preparations around the world.[374] While Canada outlawed the drug in 2016, the American federal government continues to ignore W-18.[375]

D. Congress and the DEA Have Already Abandoned the Analog Act

Congress and the DEA have already proven capable of remedying the Analog Act's failures by passing more drug prohibitions that target narrow categories of structurally related chemicals. Congress first employed a narrow categorical prohibition in the Synthetic Drug Abuse Prevention Act of 2012 (SDAPA), a CSA amendment adding the category "cannabimimetic agents" to schedule I.[376]

The SDAPA defines a cannabimimetic agent as "any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes."[377] The statute then provides five prohibited chemical structures, their chemical variations, and a list of fifteen chemicals illustrating the kind of chemicals prohibited.[378] This kind of precise statutory language remedies many of the practical notice issues plaguing the Analog Act. By providing scientific standards

97222.pdf [https://perma.cc/YRK2-DW9R]. Although it was once believed to be a super potent opioid, no one understands how W-18 works. *Id.*

371. *See* Bryan X. McCrone, *'Super Strong' Drug Called W-18 Has Area Cops on High Alert*, NBC PHILA. (May 6, 2016, 11:50 AM), https://www.nbcphiladelphia.com/news/local/Super-Strong-Drug-Opioid-W-18-Has-Philadelphia-Region-on-High-Alert-378286811.html [https://perma.cc/8BKE-MF67].

372. Canadian authorities seized W-18 that was being sold as fentanyl shaped like OxyContin. *See W-18*, STREETDRUGS, https://www.streetdrugs.org/w-18/ [https://perma.cc/N78K-L2EQ] (last visited Aug. 30, 2021).

373. *See* Sandy Scarmack, *Pa. Officials Warn of Dozens of Deaths from Carfentanil, W-18*, EMS WORLD (Aug. 6, 2016), https://www.hmpgloballearningnetwork.com/site/emsworld/news/12241694/pa-officials-warn-of-dozens-of-deaths-from-carfentanil-w-18 [https://perma.cc/NZ5Y-DDPD].

374. *See generally* Maarten Degreef et al., *Determination of Ocfentanil and W-18 in a Suspicious Heroin-Like Powder in Belgium*, 37 FORENSIC TOXICOLOGY 474 (2019).

375. *See* Regulations Amending the Food and Drug Regulations (Parts G and J – Lefetamine, AH-792-45 and W-18), SOR/2016-106 (Can.).

376. 21 U.S.C. § 812(c).

377. *Id.*

378. *Id.* Categorical substance restrictions based on receptor site activity may prove to be the preferred method of control. For example, the Modernizing Drug Enforcement Act of 2019 proposed adding all "mu opioid receptor agonists" to schedule I. *See* Modernizing Drug Enforcement Act of 2019, H.R. 2580, 116th Cong. § 2(b) (2019).

for measuring effects and substantial structural similarity, in addition to examples, the statute brings actual notice into reach.

In 2017, the DEA applied a similar narrow categorical prohibition when it employed its emergency scheduling power to move all fentanyl analogs to schedule I. Instead of prohibiting chemicals "substantially similar" to fentanyl, the DEA defined illicit fentanyl analogs by describing five chemical modifications to the basic fentanyl structure, such as "[r]eplacement of the *N*-propionyl group by another acyl group."[379] The notice outlaws all fentanyl analogs matching this description, even if the DEA cannot yet name those molecules. However, the rule also affirms that the DEA will update the *Federal Register* and the DEA website to list any new fentanyl analogs falling within these parameters.

The passage of the SDAPA and the categorical fentanyl ban tacitly admit the Analog Act's failure; all of the substances barred by both prohibitions were, in theory, already schedule I controlled substance analogs. Were the Analog Act an effective deterrent and prosecutorial tool, prohibiting a range of substances already ostensibly outlawed by the Act would be redundant and unnecessary.

The DEA has voiced concerns that it may be unable to provide the proof-of-abuse potential and lack of medical application required to permanently schedule fentanyl analogs.[380] The agency called upon Congress to permanently schedule fentanyl analogs via legislation, warning that it would be forced to resort to the Analog Act if the emergency scheduling expired. Congress declined, citing serious legal concerns about the legislation's scope and punishments, as well as the possibility that the Act will ban medically useful chemicals.[381] It did, however, extend the temporary ban until 2021.

E. Life Without the Analog Act

For nearly four decades, Congress has shirked its responsibility to enact criminal legislation by using the Analog Act to put judges in charge of criminalizing substances on an ad hoc basis. Congress, not

379. Schedules of Controlled Substances: Placement of Four Specific Fentanyl-Related Substances in Schedule I, 86 Fed. Reg. 14707, 14710 (Mar. 18, 2021) (codified at 21 C.F.R. § 1308.11 (2021)).

380. Scheduling an unknown range of substances that have yet to threaten public health seems to exceed the enabling statute's scope, which permits only emergency scheduling of "a substance," not multiple substances or a class of substances, "on a temporary basis [when] necessary to avoid an imminent hazard to the public safety." 21 U.S.C. § 811(h)(1).

381. *See* JOANNA R. LAMPE, CONG. RSCH. SERV., LSB10404, AN EXPIRATION DATE FOR TEMPORARY CONTROL OF FENTANYL ANALOGUES 3–4 (2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10404 (explaining the administrative and legislative scheduling processes and the difficulty of scheduling fentanyl analogs).

the judiciary, is the constitutionally appropriate body for regulating hazardous substances. Voiding the Analog Act would immediately restore the separation of powers by placing the burden of criminal legislation back onto Congress.

As a practical matter, voiding the Analog Act will have little effect on the spread of illicit substances. Analog Act prosecutions are already rare, and the statute's weak deterrent effect proved incapable of preventing the spread of bath salts, synthetic cannabis, and unscheduled fentanyl analogs. In the event of the Analog Act's repeal, the DEA already has a due process-compliant tool for prohibiting dangerous substances: emergency scheduling. Scheduling individual chemicals permits swift and nearly unilateral DEA action, requiring only minimal notice and a brief waiting period, all without the need or opportunity for judicial review.[382]

The DEA has recently proven willing to rely on rapid, single-substance emergency scheduling instead of the Analog Act. In 2019, researchers discovered that an unscheduled and highly potent benzimidazole opioid, isotonitazene, was being sold on the recreational drug market and killing opiate users.[383] The DEA employed emergency scheduling to ban the drug by July of 2020, a remarkably swift reaction time given the recency of the drug's emergence.

Emergency scheduling also avoids the overbreadth defects common to standards-based approaches while providing the constitutionally required actual notice of prohibition. Critically, emergency scheduling only imposes a temporary ban of up to three years. Opting for permanent prohibition requires the strategic devotion of agency resources to scientific research and the rigors of administrative rulemaking. Law enforcement must be incentivized to focus on substances posing an actual risk to public health and ignore harmless recreational drugs.

IX. CONCLUSION

Until Congress takes legislative action against emerging dangerous analogs, only liberal use of the DEA's emergency scheduling power can protect the public while comporting with the Constitution's due process requirement. However, if drug development outpaces the DEA's regulatory ability, decriminalization will provide the only effective and constitutional means of insulating drug users from dangerous, novel psychoactive substances. Cannabis, LSD, psilocybin, and many other schedule I substances have been used with relative safety for decades, and they are far safer than the gray market analog drugs

382. *See id.*

383. *See* Peter Blanckaert et al., *Report on a Novel Emerging Class of Highly Potent Benzimidazole NPS Opioids: Chemical and in Vitro Functional Characterization of Isotonitazene*, 12 DRUG TEST ANALYTICS 422, 422–23 (2020).

sold as substitutes. Compared to fentanyl analogs, even heroin presents a safer means of satisfying an opioid addiction.

Whether it employs the traditional void-for-vagueness doctrine, the *Johnson* trilogy, or the legal superposition rationale, the Supreme Court should void the Analog Act at the earliest opportunity. The Constitution places the responsibility of establishing criminal laws and penalties on Congress, not the judiciary. The Analog Act improperly tasks the judicial branch with scheduling analog drugs on an ad hoc basis, and it casts so wide a net as to reach practically every American. Temporarily scheduling substances through prosecution fails to provide actual notice of the prohibited behavior. Given the minuscule volume of overall prosecutions, the statute's tacit abandonment by Congress and the DEA, and the existence of more effective enforcement mechanisms, voiding the Act poses no meaningful threat to public safety. Congress should not be allowed to continue shirking its responsibility to enact constitutionally compliant drug laws.