

STRANGER THAN FICTION: Modern Designer Drugs and the Federal Controlled Substances Analogue Act

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I. INTRODUCTION

Dylan McNabb was 19 years old when he murdered his grandmother.¹ On the day of the murder, Dylan smoked a drug commonly known as “bath salts” and returned home to 78-year-old Imogene McNabb.² Believing that she was possessed, Dylan picked up a shotgun and shot Imogene in the head, killing her.³ In an interview after the incident, Dylan reported that he believed she was the Antichrist and she intended to kill him.⁴ As of the time of this writing, he is in jail, awaiting trial for one count of first-degree murder.⁵

The stories stemming from bath salts use are truly stranger than fiction. After using bath salts, a 24-year-old Tennessee man jumped out of a third floor window to prove he was a god, and then got up and jumped off the second floor balcony on which he had landed.⁶ A Mississippi man attempted to skin himself alive,⁷ and a 19-year-old West Virginia man stabbed his neighbor’s pygmy goat while wearing women’s underwear.⁸ As

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1. Jonathan Gonzalez, *Police: Grandmother Killer Possibly High on Bath Salts*, BAKERSFIELDNOW.COM (Oct. 8, 2013, 5:53 PM), <http://www.bakersfieldnow.com/news/local/Police-Grandmother-killer-possibly-high-on-bath-salts-226992661.html>.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. Sebastian Murdock, *Self-Described ‘God’ Jumps from Balcony, Bleeds Just like Anyone Else Would*, HUFFINGTON POST (Oct. 7, 2013, 1:36 PM), http://www.huffingtonpost.com/2013/10/07/god-jumps-from-balcony_n_4058260.html.

7. Natasha Vargas-Cooper, *Bath Salts: Deep in the Heart of America’s New Drug Nightmare*, SPIN (June 14, 2012), <http://www.spin.com/articles/bathlands-deep-heart-americas-new-drug-nightmare/>.

8. *Id.*

Dr. Mark Ryan, director of the Louisiana Poison Control explained, “[w]ith LSD, you might see pink elephants, but with [bath salts], you see demons, aliens, [or experience] extreme paranoia, heart attacks, and superhuman strength like Superman . . . [i]f you had a reaction, it was a bad reaction.”⁹

Bath salts are just the latest in a series of designer drugs that have experienced popularity in the United States. Both bath salts, composed of synthetic cathinones, and synthetic marijuana, made up of synthetic cannabinoids, have generated a significant amount of media attention and subsequent state bans due to the public health risks that they pose.¹⁰ However, these bans have failed to curb designer drug manufacture and distribution because manufacturers can simply tweak designer drug formulas slightly to make the drugs legal once again.¹¹ To combat this problem, Congress enacted the Federal Controlled Substances Analogue Enforcement Act of 1986 (“CSAEA”) to provide law enforcement and prosecutors with tools to combat those who seek to profit by altering illegal drugs ever so slightly to try to make them legal.¹²

This Comment argues that the CSAEA is unsuited to meet the needs of federal prosecutors when proving their cases against the producers and distributors of today’s designer drugs. This Comment focuses on the first prong of the CSAEA, which defines the key requirement for classifying a designer drug as an analog of a controlled substance, and therefore an illegal substance. After providing an overview of the definition of a designer drug and the history of legislation regulating them, Part II introduces the CSAEA. Part III explores the existing case law on the CSAEA and discusses the current circuit splits on two crucial points of the law. Lastly, Part IV considers possible legislative modifications to the existing law in order to craft a more practical solution to an ever-evolving problem.

9. *Id.*

10. See *Substituted Cathinones (A.K.A. “Bath Salts”) Enactments*, NAT’L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/civil-and-criminal-justice/substituted-cathinones-enactments.aspx> (last visited Apr. 15, 2015); *Synthetic Cannabinoids (A.K.A. “K2”/“Spice”) Enactments*, NAT’L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/civil-and-criminal-justice/synthetic-cannabinoids-enactments.aspx> (last visited Apr. 15, 2015).

11. Gary L. Henderson, *Designer Drugs: Past History and Future Prospects*, 33 J. FORENSIC SCI. 569, 570 (1988).

12. See, e.g., *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.”).

II. THE RISE OF THE DESIGNER DRUG PROBLEM

A. Definition of a “Designer Drug”: The Misnomer’s Practical and Legal Meaning

It is virtually impossible to understand where the designer drug epidemic came from without understanding what exactly a designer drug is. The misnomer originated in the 1980s to describe synthetic drugs that individuals abused.¹³ In essence, a designer drug has three characteristics: 1) it is synthesized from common chemicals; 2) it is uncontrolled by the Drug Enforcement Administration due to the drug’s unique chemical structure; and 3) it is usually marketed under exotic-sounding names,¹⁴ such as acid, ecstasy, white china, or spice.¹⁵ The majority of designer drugs are either legitimate products sold in the open market for pharmacological purposes, or are potential products synthesized in medical research and development, but then abandoned because they did not accomplish the end-goal of the research.¹⁶

The problems that designer drugs pose to public safety and the difficulties that arise from attempts to regulate them can best be understood by looking to the history of designer drugs in the United States. The 1960s heralded in a new culture that accepted and even promoted designer drug use in the form of lysergic acid diethylamide, commonly known as “LSD.”¹⁷ A large swath of drug users utilized LSD for its hallucinogenic properties, as the drug provides a heightened sensory awareness and an enhanced sense

13. Henderson, *supra* note 11, at 569.

14. *Id.*

15. It is important to note that although acid (LSD) and ecstasy (MDMA) are typically included in the heading of “designer drugs,” they were both scheduled in Schedule I of the Controlled Substances Act (“CSA”), LSD (lysergic acid diethylamide) in 1970 at the inception of the CSA, and MDMA (3,4-methylenedioxy-N-methylamphetamine) in 1988 after the original scheduling was vacated in 1986, so these drugs *are* currently controlled by the Drug Enforcement Administration. *See* Controlled Substances Act, Pub. L. No. 91-513, § 202, 84 Stat. 1236, 1249 (1970); Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act; Remand, 53 Fed. Reg. 5156, 5156 (Feb. 22, 1988) (codified at 21 C.F.R. pt. 1308).

16. Gregory Kau, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*, 156 U. PA. L. REV. 1077, 1083 (2008). For an example of drug users consuming drugs abandoned by researchers, see the history of desomorphine, also known as “Krokodil,” in Maximilian Gahr et al., *Desomorphine Goes “Crocodile”*, 31 J. ADDICTIVE DISEASES 407, 408–09 (2012).

17. *See generally* Martin A. Lee & Bruce Shlain, *ACID DREAMS: THE COMPLETE SOCIAL HISTORY OF LSD: THE CIA, THE SIXTIES, AND BEYOND* (1985).

of clarity.¹⁸ LSD's widespread use triggered panic among many American families and thus eventually in lawmakers as well.¹⁹ In response to this perceived drug problem, Congress passed the Comprehensive Drug Abuse Prevention and Control Act ("CSA") in 1970.²⁰ The CSA replaced over fifty pieces of piecemeal legislation that previously governed drug enforcement, establishing a single system of control for narcotic and psychotropic drugs in the United States.²¹ Additionally, the CSA created five schedules to organize controlled substances based on their danger level, potential for addiction and abuse, and whether the drug possesses some legitimate medical value or purpose.²² Schedule I drugs have no accepted medical use, a lack of accepted safety for use under medical supervision, and a high potential for abuse.²³ Schedule II drugs have a high potential for abuse.²⁴ Schedule III, IV and V drugs decline in potential for abuse, with each category less likely to be abused than the preceding category.²⁵ The CSA also scheduled numerous designer drugs considered to be dangerous and problematic at the time—including LSD, which was scheduled as a Schedule I drug.²⁶

Following the CSA's enactment, President Nixon declared an "all-out, global war on the drug menace."²⁷ He merged the Office for Drug Abuse Law Enforcement and the Office of National Narcotics Intelligence, establishing the Drug Enforcement Administration ("DEA").²⁸ Nixon charged the DEA with enforcing the CSA.²⁹ In turn, the CSA empowered the DEA to schedule drugs through administrative procedures without

18. *D-Lysergic Acid Diethylamide*, DRUG ENFORCEMENT ADMIN. (Jan. 2013), http://www.deadiversion.usdoj.gov/drug_chem_info/lsd.pdf.

19. See, e.g., Jean M. White, *Leary Proposes a Ban on LSD Except in 'Psychedelic Centers': Regret Expressed*, WASH. POST, May 27, 1966, at A2.

20. Controlled Substances Act, 21 U.S.C. § 801 (2012); *DEA History in Depth: 1970–1975*, DRUG ENFORCEMENT ADMIN. 9, <http://www.dea.gov/about/history/1970-1975.pdf> (last visited May 28, 2015).

21. *DEA History in Depth: 1970–1975*, *supra* note 20, at 9.

22. *Id.*

23. *Controlled Substance Schedules*, DRUG ENFORCEMENT ADMIN., <http://www.deadiversion.usdoj.gov/schedules/> (last visited May 28, 2015).

24. *Id.*

25. *Id.*

26. Controlled Substances Act, Pub. L. No. 91-513, § 202, 84 Stat. 1236, 1249 (1970) (listing LSD at subsection (c)(9) under "Schedule I").

27. The President's Message to the Congress Transmitting Reorganization Plan No. 2 of 1973 to Establish the Drug Enforcement Administration, 9 WEEKLY COMP. PRES. DOC. 306 (Mar. 28, 1973).

28. Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 6, 1973).

29. *Id.*

Congressional approval once the agency had evidence that the drug was dangerous.³⁰ Since the CSA's inception, the statute has undergone some changes, but the process currently in force requires the DEA to gather data on the drug, and then to request an assessment of the drug from the Department of Health and Human Services ("HHS").³¹ HHS subsequently confers with two other agencies, the Food and Drug Administration ("FDA") and the National Institute of Drug Abuse ("NIDA"), and recommends whether the drug should be scheduled.³² The DEA Administrator can then schedule the drug if he or she believes scheduling is necessary.³³ Until 1986, the federal government presumed that any unscheduled drug was legal.³⁴

Despite these efforts, in the early 1980s the United States once again found itself facing new and dangerous designer drugs.³⁵ In 1984, Congress passed the Comprehensive Crime Control Act, giving the Attorney General the ability to schedule uncontrolled substances in Schedule I of the CSA on an emergency basis if necessary to avoid an "imminent hazard to the public safety."³⁶ Still, a year later, a flurry of media reports revealed that clandestine chemists in California manufactured legal drugs by altering the chemical composition of illegal drugs, making them legal once again.³⁷ Because the federal government banned drugs by their exact molecular structure, manufacturers could tweak one component of the molecular structure and the resulting drug no longer fit the definition of the scheduled illegal drug.³⁸ After nearly 100 drug-related deaths, the DEA found that chemists were manufacturing variations of fentanyl, a legal drug used in medicine.³⁹ Fentanyl is similar to morphine, but approximately 150 times more potent.⁴⁰ The chemists managed to alter fentanyl's chemical

30. See 21 U.S.C. § 812(b) (2012) (establishing the criteria and procedures utilized by the department to place a drug on a controlled substances schedule).

31. *Id.*

32. *Id.*

33. *Id.*

34. See, e.g., David A. Jerrard, "Designer Drugs"—A Current Perspective, 8 J. EMERGENCY MED. 733, 733 (1990).

35. *Id.*

36. Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 1976, 2071–72 (codified at 21 U.S.C. § 811 (2012)).

37. See, e.g., *Legal Drive Urged Against Designer Drugs*, S.F. CHRON., Sept. 10, 1985, at 7; Bill Wallace, *An Overdose of 'China White' in S.F.*, S.F. CHRON., Oct. 30, 1985, at 9; *'Designer Drugs' Investigated*, WASH. POST, Feb. 16, 1985, at A7.

38. Boyce Rensberger, *'Designer Drugs' Skirt the Law*, WASH. POST, Mar. 14, 1985, at A1.

39. Jerrard, *supra* note 34, at 735–36.

40. *Id.* at 735.

composition, thereby creating a drug that was 6,000 times more potent than morphine.⁴¹

In response to the rash of drug-related deaths, the Justice Department announced its intention to seek legislation that would close the designer drug loophole.⁴² During legislative debate over potential measures in Congressional hearings, numerous witnesses testified regarding how easy it was for manufacturers to make profitable designer drugs. One Congressman testified that approximately \$500 worth of chemicals and equipment could produce enough of one designer drug to net \$2 million on the street.⁴³ Another expert testified that a \$1,000 to \$2,000 investment in chemicals and equipment could produce enough of a designer drug to potentially gross millions of dollars.⁴⁴ These statements elucidated two main points. First, they demonstrated that because the cost of entering the designer drug market was low, virtually anyone with a desire to create designer drugs could do so with limited financial risk. Second, they made clear how easy it was to turn a few thousand dollars into a few million, thus highlighting individuals' financial incentives to create designer drugs.⁴⁵

Congress eventually responded to the perceived designer drug epidemic by enacting the Controlled Substances Analogue Enforcement Act of 1986 ("CSAEA").⁴⁶ By passing the CSAEA, Congress sought to prevent designer drug manufacturers from modifying drugs scheduled under the CSA to produce legal drugs.⁴⁷ Prior to the CSAEA, the federal government scheduled drugs by their chemical composition, unintentionally creating a

41. *Id.* In a bizarre case of "everything old is new again," fentanyl recently killed at least three drug users in Vermont. *Police Investigating Source of Vermont Fentanyl Deaths*, BRATTLEBORO REFORMER (Feb. 7, 2014, 2:15 PM), http://www.reformer.com/morelocalnews/ci_25085579/police-investigating-source-vermont-fentanyl-deaths. Investigators found that the drug was misrepresented as heroin. *Id.*

42. See Mary Thornton, 'Designer Drug' Ban Urged, WASH. POST, July 11, 1985, at A5.

43. *Designer Drugs: Hearing Before the S. Comm. on the Budget*, 99th Cong. 10 (1985) (statement of Hon. Charles Rangel, Chairman, Select Comm. on Narcotics Abuse and Control).

44. *Id.* at 10, 17 (statement of Gary Henderson, Associate Professor of Pharmacology and Toxicology, University of California).

45. For an example of the type of individuals who turn to designer drug manufacturing, see Peg Tyre, *Serial Killers Made Drug 1,000 Times Stronger than Heroin*, GAZETTE (Montreal), Mar. 10, 1993, at A1 (discussing a partnership between a "Pittsburgh business owner, an eccentric scientist and a mob associate"). See also *infra* text accompanying notes 67–78.

46. Controlled Substance Analogue Enforcement Act of 1986, Pub. L. No. 99-570, § 1203, 100 Stat. 3207, 3213–14.

47. See *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.").

huge legal loophole that manufacturers exploited by changing the chemical composition of the drug to make it legal.⁴⁸ In an attempt to close the designer drug loophole, the CSAEA casts these drugs in different terms. The CSAEA refers to a designer drug as a “controlled substance analogue” in order to reflect the drug’s relationship to a substance that the government previously banned. Under the CSAEA, a drug is a controlled substance analog if it meets three requirements.⁴⁹ First, the chemical structure of the drug in question must be “substantially similar” to the chemical structure of a controlled substance listed in Schedule I or II.⁵⁰ Second, the drug must have an effect on the central nervous system that is substantially similar to, or greater, than the effect of a controlled substance in Schedule I or II, or a particular individual involved in producing, marketing, or distributing the drug must represent or intend the drug to have such an effect.⁵¹ Third, the drug must be intended for human consumption.⁵²

B. *The Evolution of “Bath Salts”*

The regulatory difficulty of banning designer drugs is easily understood through the current public health problem of bath salts. The drugs that collectively form bath salts are known as synthetic cathinones and were discovered by chemist and researcher Richard Glennon.⁵³ Glennon’s research focused on how stimulants and hallucinogens work on the brain.⁵⁴ He was in the process of studying the conversion of stimulant drugs to hallucinogens when he added an oxygen atom to the side chain of amphetamine, creating a beta-keto amphetamine now known as a cathinone.⁵⁵ While cathinones were added to the CSA’s Schedule I in 1993 and therefore do not qualify as a designer drug,⁵⁶ Glennon did not stop his research and experimentation at cathinones. He added an additional methyl group—a carbon atom bound to three hydrogen atoms—to make

48. Jerrard, *supra* note 34, at 735.

49. Controlled Substance Analogue Enforcement Act, 21 U.S.C. §§ 802, 813 (2012).

50. *Id.* § 802(32)(A)(i).

51. *Id.*

52. *Id.* § 813.

53. Jane M. Prosser & Lewis S. Nelson, *The Toxicology of Bath Salts: A Review of Synthetic Cathinones*, 8 J. MED. TOXICOLOGY 33, 33 (2012); Jenny Marder, *The Drug That Never Lets Go*, PBS NEWSHOUR (Sept. 20, 2012), <http://www.pbs.org/newshour/multimedia/bath-salts/>.

54. Marder, *supra* note 53.

55. *Id.*

56. Placement of Cathinone and 2,5-Dimethoxy-4-ethylamphetamine Into Schedule I, 58 Fed. Reg. 4316, 4316 (Jan. 14, 1993); *see also* 21 C.F.R. § 1308.11(f)(3) (2015).

methcathinone, a more potent stimulant than cathinone.⁵⁷ By adding a methyl group, Glennon created a “designer drug,” because by changing the drug’s structure, it no longer fit under the “cathinone” umbrella in the CSA.⁵⁸ For decades Glennon’s synthetic cathinone was relegated to the lab, posing more of a “theoretical, scientific problem” than a public health problem⁵⁹—that is, until bath salts hit store shelves in 2010.⁶⁰

In 2010, bath salts were marketed as glass cleaner, ladybug attractant, and other items not intended for human consumption, but were predominantly sold in smoke shops and liquor stores.⁶¹ The drugs gained notoriety as a public health problem because they pose unique risks to drug users. As one physician explained, “[bath salts] have been described as possessing the worst characteristics of [LSD, PCP, ecstasy,] cocaine, and methamphetamine.”⁶² Bath salt consumption can cause a user to experience severe panic attacks, paranoia, hallucinations, violent behavior (including self-mutilation, suicide attempts, and homicidal activity), and death.⁶³ After bath salts hit store shelves in 2010, bath salt users began turning up at emergency rooms across the country, presenting with the aforementioned alarming symptoms.⁶⁴ Because the government knew very little about the drugs, in 2011 the Drug and Chemical Evaluation Section of the DEA Office of Diversion Control issued a public request for information, calling on law enforcement and scientists to report any information collected about bath salts.⁶⁵ After testing, scientists determined that the active ingredient in bath salts was in fact a synthetic cathinone.⁶⁶

57. Richard A. Glennon et al., *Methcathinone: A New and Potent Amphetamine-Like Agent*, 26 PHARMACOLOGY BIOCHEMISTRY & BEHAV. 547, 547 (1987).

58. *Id.*

59. Marder, *supra* note 53.

60. Henry A. Spiller et al., *Clinical Experience with and Analytical Confirmation of “Bath Salts” and “Legal Highs” (Synthetic Cathinones) in the United States*, 49 CLINICAL TOXICOLOGY 499, 500 (2011).

61. *Id.*

62. Edward A. Ross et al. “*Bath Salts*” Intoxication, 365 NEW ENG. J. MED. 967, 967 (2011).

63. *Id.*

64. See, e.g., Abby Goodnough & Katie Zezima, *An Alarming New Stimulant, Legal in Many States*, N.Y. TIMES (July 16, 2011), http://www.nytimes.com/2011/07/17/us/17salts.html?_r=1.

65. NAT’L DRUG INTELLIGENCE CTR., U.S. DEP’T OF JUSTICE, SYNTHETIC CATHINONES (BATH SALTS): AN EMERGING DOMESTIC THREAT 7 (2011).

66. Krasnodara N. Cameron et al., *Bath Salts: A Synthetic Cathinone Whose Two Major Components Act Similar to Methamphetamine and Cocaine on the Human Dopamine Transporter*, 102 BIOPHYSICAL J. 215a, 215a (2012); M. Coppola & R. Mondola, *Synthetic*

Although Congress attempted to stave off the flow of designer drugs into the American public through the CSAEA, a review of the synthetic cathinone epidemic demonstrates that the law has failed. Indeed, one report on synthetic cathinones issued in 2012 noted that although a dozen analogs had been scheduled by the DEA—rendering them illegal—it is still theoretically possible to create hundreds of legal synthetic cathinones with one small tweak in the chemical composition.⁶⁷

Further evidence of the CSAEA's shortcomings can be found in the synthetic cannabinoid (also called synthetic marijuana) epidemic. In 2009, the Advisory Council on the Misuse of Drugs ("ACMD") identified 171 existing synthetic cannabinoids, only five of which had been scheduled as banned substances.⁶⁸ Four years after the ACMD reported its findings, no additional synthetic cannabinoids have been scheduled. Thus, as of this writing, the remaining 166 are legal and can be openly sold to consumers. To make matters worse, anyone with a rudimentary understanding of chemistry can manufacture these drugs with very little equipment and low start-up costs, yet profit immensely in the process. A recent CSAEA case from Arizona, *United States v. Lane*,⁶⁹ is illustrative of this point.

C. *A Modern Story of Designer Drug Manufacturing*

In 2010, Colin Stratford graduated from Arizona State University with a degree in Biochemistry.⁷⁰ Stratford sought a position in the biochemistry field, but could not obtain one due to a previous conviction for marijuana possession.⁷¹ A friend put him in contact with Michael Lane, a manufacturer and distributor of bath salts, who needed a biochemist to manufacture his products.⁷² Stratford accepted the position, working as a manufacturer out of Lane's garage in Cave Creek.⁷³ While employed by Lane, Stratford turned

Cathinones: Chemistry, Pharmacology and Toxicology of a New Class of Designer Drugs of Abuse Marketed as "Bath Salts" or "Plant Food," 211 TOXICOLOGY LETTERS 144, 145 (2012).

67. Cameron et al., *supra* note 66, at 215a.

68. ADVISORY COUNCIL ON THE MISUSE OF DRUGS, CONSIDERATION OF THE MAJOR CANNABINOID AGONISTS 15–25 (2009), available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/119149/acmd-report-agonists.pdf.

69. 2:12-cr-01419 (D. Ariz. 2013).

70. Transcript of Record at 6, *United States v. Lane* (D. Ariz. 2013) (No. 2:12-cr-01419).

71. *Id.* at 8.

72. *Id.* at 32.

73. *Id.*; see also JJ Hensley, *Case Reveals Feds' Fight vs. Synthetic-Drug Makers*, AZ CENTRAL.COM (June 28, 2013),

chemicals ordered from China into bath salts that were eventually sold across the country.⁷⁴ During the operation, Stratford manufactured bath salts under the impression that he was acting legally.⁷⁵ The “lab” he used lacked even basic chemistry equipment, such as a melting point apparatus, yet Stratford and Lane were able to grow the business into a multimillion-dollar company.⁷⁶ At the peak of their success, the business brought in \$8,000 a day in online sales revenue.⁷⁷

Stratford left the company after lab tests he conducted on the bath salts indicated the presence of a banned substance, and Lane refused to purchase equipment that Stratford needed to verify that their product did not contain any other banned substances.⁷⁸ At trial, Stratford testified about methods Lane used to intentionally evade governmental attempts to prevent the manufacture of bath salts.⁷⁹ Stratford told the court that Lane watched the DEA closely to determine which drugs the DEA scheduled under its emergency powers.⁸⁰ Stratford indicated that Lane would have Stratford select chemicals that had not yet been banned, even though they were similar to banned chemicals.⁸¹ Most tellingly, Stratford told the court that he and Lane had discussed the CSAEA.⁸² When asked about their discussion of the CSAEA, Stratford told the court: “The reason that we were able to sell these products was based off the federal analogue act. Basically the stipulations in the federal analogue act, if you adhere to them in a certain way, you might be able to skirt the law.”⁸³ Unfortunately for Lane, the jury did not agree with his sentiments. In 2013, Michael Lane and others became the first persons in Arizona to be convicted under the CSAEA.

<http://www.azcentral.com/community/phoenix/articles/20130628case-reveals-feds-fight-vs-synthetic-drug-makers.html>.

74. Hensley, *supra* note 73.

75. Transcript of Record, *supra* note 70, at 20–21.

76. *Id.*

77. Matthew Hendley, “Eight Ballz Bath Salts” Maker Found Guilty by a Federal Jury, PHOENIX NEW TIMES (July 22, 2013, 12:46 PM), http://blogs.phoenixnewtimes.com/valleyfever/2013/07/eight_ballz_bath_salts_maker_f.php?page=2.

78. Transcript of Record, *supra* note 70, at 19–20; Hensley, *supra* note 73.

79. Transcript of Record, *supra* note 70, at 42.

80. *Id.* at 41–44.

81. *Id.* at 42.

82. *Id.* at 44.

83. *Id.*

III. THE INADEQUACIES OF THE CSAEA: DEFINING A DESIGNER DRUG UNDER THE ACT

While the jury ultimately found Lane guilty under the CSAEA, some courts have upheld his understanding of the statute.⁸⁴ Because of the ambiguous language of the CSAEA, the statute as it exists today is ineffective. The most problematic portion of the CSAEA arguably is its requirement that the drug in question be “substantially similar” in chemical composition to a drug controlled in Schedule I or II of the CSA.⁸⁵ This seemingly straightforward requirement is problematic for two reasons. First, because the statute provides little guidance, the courts are split on which test to apply when determining whether a drug qualifies as an analog for purposes of the CSAEA. Second, the circuits are split on whether the law imposes a scienter, or knowledge, requirement. In other words, the statute is silent on whether prosecutors have to prove that the defendant knew the manufactured drug was similar in chemical composition to a scheduled drug, so courts have had to address this issue individually and develop circuit-by-circuit interpretation of the law.

A. *When is a Designer Drug an Analog under the CSAEA?*

Under the CSAEA, a substance is an analog when its chemical structure is “substantially similar to the chemical structure of a controlled substance in Schedule I or II,” among other requirements.⁸⁶ Congress intended to draft this requirement in a way that would require expert testimony on the drug’s chemical composition. As the Senate Judiciary Committee report explained:

In determining whether a substance does have a chemical structure “substantially similar” to that of a Schedule I or II controlled substance, the trier of fact will presumably consider the testimony of expert chemists who have performed laboratory analyses of the drug’s molecular makeup. The Committee concurs with the

84. See, e.g., *United States v. Ansaldi*, 372 F.3d 118 (2d Cir. 2004); *United States v. Forbes*, 806 F. Supp. 232 (D.C. Colo. 1992).

85. Although this Paper only addresses the requirement set forth in 21 U.S.C. § 802(32)(A)(i), other portions of the CSAEA are problematic as well. The requirement set forth in 21 U.S.C. § 813 that the drug be “intended for human consumption” has also proved to be problematic, because bath salts are almost always marketed as products that are not consumed by people, e.g., ladybug attractant and glass cleaner. For a comprehensive discussion of the CSAEA’s other shortcomings, see Timothy P. Stackhouse, *Regulators in Wackyland: Capturing the Last of the Designer Drugs*, 54 ARIZ. L. REV. 1105, 1116–18 (2013).

86. 21 U.S.C. § 802(32)(A)(i) (2012).

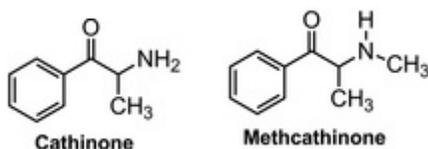
appraisal of the American Chemical Society that the term “substantially similar” chemical structure is meaningful to scientists and capable of reasoned interpretation by the trier of fact. If a drug has been patterned after a controlled substance, its strong chemical similarities to the parent substance can be demonstrated.⁸⁷

In reality, however, the courts grapple with the degree of similarity required to find that a new substance shares a substantially similar structure with a scheduled substance.⁸⁸ In *United States v. Washam*,⁸⁹ the Eighth Circuit noted that, “[t]he term ‘substantially similar’ as used in the statute, does not mean ‘exactly the same.’ There obviously will be differences in chemical structures between an ‘analogue’ chemical and a [S]chedule I or II chemical.”⁹⁰ The court went on to hold that testifying experts do not have to unanimously agree that the structures are substantially similar to satisfy the requirement.⁹¹ The question then becomes: how similar is similar enough to satisfy the statute?

As noted above, the CSAEA does not provide any guidance regarding how the courts should determine “substantial similarity.” In deciding this question, the courts have developed two tests: the “same core arrangement of atoms” test⁹² and the “structure and effect” test.⁹³ The same core arrangement of atoms test only considers the drugs’ chemical makeup. For instance, in *United States v. Klecker*,⁹⁴ the district court utilized the “same

87. S. Rep. No. 99-196, at 5 (1985).

88. Revisiting the problem of bath salts, this diagram shows the 2-D chemical composition of cathinones (illegal) and methcathinones (altered enough to be considered “legal”). These side-by-side comparisons are often used in litigation to determine whether the drugs are “substantially similar.” See, e.g., *United States v. Brown*, 415 F.3d 1257 (11th Cir. 2005).



89. 312 F.3d 926 (8th Cir. 2002).

90. *Id.* at 930–31.

91. *Id.*

92. See *United States v. Klecker*, 228 F. Supp. 2d 720 (E.D. Va. 2002), *aff'd* 348 F.3d 69, 73 (4th Cir. 2003); *United States v. Niemoeller*, No. IP02-0009-CR-01-H/F, 2003 U.S. Dist. LEXIS 4584 (S.D. Ind. Jan. 24, 2003).

93. See *United States v. Forbes*, 806 F. Supp. 232 (D. Colo. 1992); *United States v. Fisher*, 289 F.3d 1329 (11th Cir. 2002).

94. 228 F. Supp. 2d 720 (E.D. Va. 2002), *aff'd*, 348 F.3d 69 (4th Cir. 2003).

core arrangement of atoms” test.⁹⁵ The substances in question, AMT and “Foxy,” were compared to the scheduled substances AET and DET.⁹⁶ After comparing AMT and AET, the court noted that the only difference in chemical composition between the two was the addition of one methyl group in AMT.⁹⁷ Thus, the court concluded that AMT and AET were substantially similar for the purposes of the CSAEA because they contained the same core arrangement of atoms.⁹⁸ Next, the court looked to “Foxy” and DET. The court found that the two drugs shared the same core, known as tryptamine, but that “Foxy” had a number of different additions to the core.⁹⁹ The court nevertheless determined that the “Foxy” and DET were *also* substantially similar in chemical structure, even though their differences were far greater than the differences between AMT and AET.¹⁰⁰ On appeal, the Fourth Circuit affirmed the district court’s findings, as well as the “same core arrangement of atoms” test that the district court had applied.¹⁰¹ The Fourth Circuit subsequently took up another challenge to the CSAEA’s “substantial similarity” prong in *United States v. McFadden*.¹⁰² Relying on *Klecker*, the court found that the government’s expert satisfied the core arrangement of atoms test when he presented evidence that changes in the drugs’ chemical makeup were simply “peripheral and inconsequential.”¹⁰³

In contrast to the “same core arrangement of atoms” test, the “structure and effect” test looks to the chemical composition of the drug *in conjunction with* its effects on users.¹⁰⁴ Essentially, the test is composition plus effect, rather than simply composition considered in the core arrangement test. As previously discussed, the first prong of CSAEA requires that the chemical structure of the drug in question must be “substantially similar” to the chemical structure of a controlled substance listed in Schedule I or II.¹⁰⁵ The second prong requires that the drug in

95. *Klecker*, 228 F. Supp. 2d at 728. It should be noted that in *Klecker*, the issue of “substantial similarity” was submitted to the judge, not the jury, because the finding was made in regard to a motion filed. *Id.* at 726–27. The defendant ultimately pleaded out. 348 F.3d at 70. In a jury trial, the judge would not be the ultimate fact-finder regarding “substantial similarity.”

96. *Klecker*, 228 F. Supp. 2d at 728.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *United States v. Klecker*, 348 F.3d 69, 73 (4th Cir. 2003).

102. 753 F.3d 432, 436 (4th Cir. 2014).

103. *Id.* at 439–40.

104. *See, e.g., United States v. Forbes*, 806 F. Supp. 232, 236 (D. Colo. 1992).

105. Controlled Substance Analogue Enforcement Act, 21 U.S.C. § 802 (2012).

question have an effect on the user's central nervous system that is substantially similar to, or greater, than the effect of a controlled substance in Schedule I or II; or, in the alternative, a particular individual involved in producing, marketing, or distributing the drug must represent or intend the drug to have such an effect.¹⁰⁶ The "structure and effect" test looks to both prongs in order to make a determination under the first prong alone, essentially combining the two prongs into one. For example, in *United States v. Forbes*,¹⁰⁷ experts testified that a drug's structure and its effects are related.¹⁰⁸ The court noted that "[b]ecause structurally similar substances have similar pharmacological effects on the central nervous system, a finding of such similar effects is some indication that the molecular structures should be classified as substantially similar."¹⁰⁹ Similarly, in *United States v. Fisher*,¹¹⁰ the Eleventh Circuit considered the body's reaction to the drug in question, GBL, once it was ingested by the user.¹¹¹ The court concluded that because the body metabolizes GBL into GHB, a controlled substance, upon ingestion, GBL must have a substantially similar structure and effects.¹¹² In essence, the court in *Fisher* found that GBL's metabolism into GHB, standing alone and without regard to its chemical composition before ingestion, was enough to demonstrate that the drugs were substantially similar.¹¹³

To add more confusion to the conversation, some courts have applied the "structure and effect" test differently from others. In *United States v. Brown*,¹¹⁴ the Eleventh Circuit applied the "structure and effect" test while also affirming a method of showing similarities in chemical composition. In *Brown*, a DEA forensic chemist and a National Institute of Environmental Health Sciences biochemist both applied a "visual assessment method" to

106. *Id.* To further complicate matters, courts are split over whether the test is disjunctive, i.e., requiring the government to prove just one of the statutory elements; or conjunctive, requiring the government to prove both statutory elements. The majority of federal courts adopted the conjunctive reading. *See* *United States v. Turcotte*, 405 F.3d 515, 523 (7th Cir. 2005); *United States v. Hodge*, 321 F.3d 429, 433 (3d Cir. 2003); *United States v. Klecker*, 348 F.3d 69, 71 (4th Cir. 2003); *United States v. Washam*, 312 F.3d 926, 930 n.2 (8th Cir. 2002); *United States v. Forbes*, 806 F. Supp. 232, 235 (D. Colo. 1992). *But see* *United States v. Fisher*, 289 F.3d 1329, 1338 (11th Cir. 2002) (refusing to decide the issue); *United States v. Granberry*, 916 F.2d 1008, 1010 (5th Cir. 1990) (reciting the statute in the disjunctive without discussion).

107. 806 F. Supp. 232 (D. Colo. 1992).

108. *Id.* at 236.

109. *Id.*

110. 289 F.3d 1329 (11th Cir. 2002).

111. *Id.* at 1339.

112. *Id.*

113. *Id.*

114. 415 F.3d 1257 (11th Cir. 2005).

determine whether the drug in question, 1,4-butanediol, was substantially similar in chemical composition to GHB.¹¹⁵ The court determined that the drugs were substantially similar, despite the fact that the drugs had different functional groups attached to the end of the molecules.¹¹⁶ In doing so, the court relied on the experts' visual inspection comparisons and testimony, which demonstrated that the body metabolized the drug in question into GHB once ingested.¹¹⁷

Still other courts require that both tests be met before making a finding of substantial similarity. In *United States v. Roberts*,¹¹⁸ for instance, the Second Circuit looked at both the two-dimensional diagram and the body's metabolism of the drug to determine whether 1,4-butanediol was substantially similar to GHB.¹¹⁹ The court found that GHB and 1,4-butanediol differed by only two atoms on a two-dimensional diagram, and that 1,4-butanediol was readily converted to GHB upon ingestion.¹²⁰ In its holding, the court emphasized that both determinations were needed to discern whether the drugs were substantially similar:

Where there is only a two-atom difference between the relatively complex molecules of a suspect substance and of a controlled substance *and* where, upon ingestion, the suspect substance is metabolized into the controlled substance, we believe that the chemical structure of the suspect substance is manifestly "substantially similar to the chemical structure of [the] controlled substance," as that phrase is used in the definition of "controlled substance analogue."¹²¹

The resulting circuit split leaves many questions for parties on both sides of the CSAEA. Numerous circuits have not addressed the CSAEA's "substantially similar" language at all. The lack of uniformity in the test to be applied provides obstacles in litigation for both prosecution and defense, particularly in the circuits without a controlling circuit court opinion. As the law stands now, parties in states without controlling circuit court opinions are unable to determine which test their case has to meet, or their defense

115. *Id.* at 1262, 1267.

116. *Id.* at 1271.

117. *Id.* at 1271–72.

118. 363 F.3d 118 (2d Cir. 2004).

119. *Id.* at 121–22.

120. *Id.* at 125.

121. *Id.* (emphasis added) (quoting 21 U.S.C. § 802(32)(A)(i) (2000)); *see also* *United States v. Ansaldi*, 372 F.3d 118 (2d Cir. 2004).

has to disprove. Further obscuring things is the question of whether or not the CSAEA imposes a scienter requirement.

B. Scienter Requirement? Maybe, Maybe Not

Once a drug is deemed an analog, should the age-old maxim, “ignorance of the law is no excuse,” play a role in prosecuting manufacturers and distributors of designer drugs? Currently, the answer depends upon the circuit in which the case is brought. Indeed, whether a scienter requirement is built into the chemical composition standard has been the subject of much debate in the courts. The resulting decisions have formed a three-way circuit split.

The Second Circuit has perhaps the most stringent scienter requirement. In *United States v. Roberts*,¹²² the court imposed the same scienter requirement contained in the CSA¹²³ for controlled substances on the CSAEA.¹²⁴ The court asserted that defendants “need not know the exact nature of the drug; it is sufficient that they be aware they possessed ‘some controlled substance.’”¹²⁵

The Seventh and Eighth Circuits both impose a scienter requirement that is somewhat less stringent than the Second Circuit’s requirement. In *United States v. Turcotte*,¹²⁶ the Seventh Circuit held that the government must prove that a defendant knew the drug in question had a chemical structure that was substantially similar to a controlled substance.¹²⁷ The court asserted that because the CSAEA amended the CSA and imposes criminal liability through the CSA, its provisions were subject to the “well-established scienter requirement” of the CSA.¹²⁸ However, the court recognized that under the CSA, knowledge of a drug’s identity automatically translates to knowledge of its illegality.¹²⁹ Under the CSAEA, the same assertion was not necessarily true, specifically because designer drugs are often manufactured due to their presumed legality.¹³⁰ Recognizing the challenges that a scienter requirement imposes on prosecutors, the court built in a “provisional

122. 363 F.3d at 123.

123. See 21 U.S.C. § 841(a) (2012).

124. *Roberts*, 363 F.3d at 123.

125. *Id.* at n.1 (quoting *United States v. Morales*, 577 F.2d 769, 776 (2d Cir. 1978)).

126. 405 F.3d 515 (7th Cir. 2005).

127. *Id.* at 527.

128. *Id.* at 525.

129. *Id.*

130. *Id.* at 526.

remedy.”¹³¹ If the jury finds that the scienter requirement for the “similar physiological effects” prong is satisfied, the jury can infer that the defendant had knowledge of the chemical similarities as well.¹³² In *United States v. Bamberg*,¹³³ the Eighth Circuit implicitly adopted the reasoning in *Turcotte*, finding that a scienter requirement was built into the law.¹³⁴

The remaining courts that have addressed the issue have found no scienter requirement at all in the CSAEA. In *United States v. Desurra*,¹³⁵ the Fifth Circuit held that a defendant need only to know the identity of the drug he possesses and must possess it “with the statutorily defined bad purpose” in order to be convicted.¹³⁶ Similarly, in *United States v. Forbes*,¹³⁷ the district court found that “the definition of controlled substance analogue does not require any scienter—a defendant does not have to ‘know’ that a substance has a substantially similar chemical structure to an illegal drug.”¹³⁸ While the *Forbes* opinion was not controlling circuit law, as it came out of the district court level, the court’s reasoning found sway in the Eleventh Circuit in *United States v. Carlson*.¹³⁹ In *Carlson*, the court cited the *Forbes* reasoning in its analysis of the chemical composition requirement, noting the “absence of a scienter requirement” in the CSAEA.¹⁴⁰

In sum, the CSAEA as written is inadequate in many respects. The dual tri-circuit splits that currently exist on the “chemical composition” prong of the CSAEA and the knowledge requirement imposed by the prong leave many questions for parties on both sides of the CSAEA. Prosecutors in circuits that have not yet adopted standards are required to prove their case at the district court level, not at the appellate level. Yet as the circuit law currently stands, they have three different standards they may have to meet at the trial level. Otherwise, they face losing at the appellate level.

131. *Id.* at 527.

132. *Id.*

133. 478 F.3d 934 (8th Cir. 2007).

134. *Id.* at 939–40.

135. 865 F.2d 651 (5th Cir. 1989).

136. *Id.* at 653.

137. 806 F. Supp. 232 (D. Colo. 1992).

138. *Id.* at 238.

139. 87 F.3d 440 (11th Cir. 1996).

140. *Id.* at 443 n.3.

IV. CORRECTING THE CSAEA'S INADEQUACY: A LEGISLATIVE SOLUTION

As the circuit splits on two key requirements of the CSAEA's chemical composition prong demonstrate, the law as written is not sufficiently clear. A few major issues arise in the context of the CSAEA. Because the statute carries criminal penalties, in order to satisfy due process, the statute must be sufficiently definite so that an ordinary person could understand precisely what the statute is prohibiting.¹⁴¹ However, because the statute contains essentially a scientific standard, the law necessarily becomes more complicated for judges, attorneys, and defendants, not to mention the average individual who is supposed to be able to understand it.¹⁴²

Criminal statutes that define a crime's elements are unique in that they are susceptible to due process challenges, particularly "void for vagueness" challenges. Notwithstanding the Senate Judiciary Committee's assurance that the trier of fact can reasonably interpret the CSAEA's "substantially similar" language, in virtually every CSAEA case, the courts struggle to understand the science behind designer drugs, and in turn what that science means to the defendant and the government. For example, under the "structure and effect" test propagated by some circuits, a designer drug is substantially similar to a banned substance when it has a similar chemical structure *and* a similar effect on the user.¹⁴³ However, many circuits have allowed the question of effectual similarity to turn on what the drug does in the body after it is consumed, i.e. what it is metabolized into by the body. Anyone lacking a scientific background would not be able to predict whether GBL metabolizes into GHB, as was held to be sufficient to hold the defendant criminally liable in *United States v. Roberts*.¹⁴⁴ Indeed, some manufacturers are likely unaware of their designer drug's metabolic processes.

Because of the "sufficiently definite" constitutional requirement, the CSAEA cannot incorporate helpful scientific standards found in other areas of law. For example, the FDA is tasked with regulating any drug intended

141. *Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (citations omitted); *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926).

142. Indeed, just this year the Indiana Court of Appeals overturned Indiana's law prohibiting possession of synthetic drugs, finding that the law could not be understood by an ordinary person. *Tiplick v. Indiana*, 25 N.E.3d 190, 193–94 (Ind. Ct. App. 2015). The court's holding rested on the fact that the drugs were defined in agency regulations rather than in statute. *Id.* at 194–95. However, the court's decision is emblematic of the problems facing these designer drug statutes.

143. *See supra* text accompanying notes 103–13.

144. 363 F.3d 118, 125–26 (2d Cir. 2004).

for human consumption. In the course of its duties, the FDA promulgated a rule requiring that generic pharmaceutical drugs¹⁴⁵ be “bioequivalent” to name-brand pharmaceutical drugs.¹⁴⁶ Essentially, the standard allows the generic drug to differ from the name-brand drug in color, shape, taste, inactive ingredients, preservatives, and packaging,¹⁴⁷ as long as the drugs are similar in other ways. First, the drugs must have similar pharmacokinetics, meaning that the body does similar things to the drugs.¹⁴⁸ The key indicators of pharmacokinetics are absorption, metabolism, and the excretion of the drug.¹⁴⁹ Second, the drugs must have similar pharmacodynamics, meaning that the drugs do similar things to the body.¹⁵⁰ This inquiry considers the drug’s mechanism and the site of action.¹⁵¹

In many ways, this analysis is similar to the CSAEA’s requirements, yet the FDA standard is much more specific and informative. As such, the FDA standard, at first glance, would act as a much stronger standard than the current standard of “substantially similar,” if incorporated into the CSAEA. The FDA standard’s value shows through in litigation, as the standard provides experts with specific considerations for each FDA requirement. While the FDA’s bioequivalence standard is stronger than the CSAEA’s current standard for litigation purposes, it is arguably much weaker than the CSAEA in the area of due process definiteness. Namely, the FDA standard would very likely fail any due process challenge for vagueness if applied in the criminal law context. Specifically, the due process requirement that a statute be sufficiently definite, enabling an ordinary person to understand what acts are prohibited, is not satisfied by the FDA standard. Under the FDA standard, even a person with a strong scientific background would have a difficult time discerning a designer drug’s pharmacokinetics and pharmacodynamics on their own. Therefore, the FDA standard would

145. Generic pharmaceutical drugs encompass those drugs that an individual can acquire at a pharmacy for a lower price than name-brand drugs. *What’s the Difference Between Brand-Name and Generic Prescription Drugs?*, SCI. AM. (Dec. 13, 2004), <http://www.scientificamerican.com/article.cfm?id=whats-the-difference-betw-2004-12-13>.

146. 21 C.F.R. § 320.1(e) (2014).

147. *What’s the Difference Between Brand-Name and Generic Prescription Drugs?*, *supra* note 145.

148. 21 C.F.R. § 320.1(e); U.S. DEP’T OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS—GENERAL CONSIDERATIONS 4 (2003); *What’s the Difference Between Brand-Name and Generic Prescription Drugs?*, *supra* note 145.

149. *What’s the Difference Between Brand-name and Generic Prescription Drugs?*, *supra* note 145.

150. *Id.*

151. *Id.*

require that lawyers and judges conduct extensive research regarding pharmacokinetics and pharmacodynamics. As such, it would be quite a stretch to argue that the average individual would know precisely what the statute criminalized.

Comparing the FDA “bioequivalence” standard and the current standard in the CSAEA demonstrates problems endemic of criminalizing behavior based on science. Science’s complex standards are naturally at odds with the criminal law’s due process clarity requirements. This clash of law and science is just one of the many problems that the CSAEA faces, but represents a much larger issue as our society increasingly turns to science in the criminal court. Finding a solution for the CSAEA’s logistical issues could shed some light on how to solve the greater issue of regulating science through criminal law.

C. Amend the Language of the CSAEA to Include Objective Standards

The circuit split on two key requirements of the CSAEA’s “chemical composition” prong demonstrate that the law, as written, is not sufficiently clear. While the circuit split could be left for the Supreme Court to resolve, another more viable and certain option is to amend the law to reflect objective standards, such as appropriate methods of proving substantial similarity. Objective standards would provide prosecutors guidance in proving their cases; defendants knowledge of what constitutes illegal conduct under the CSAEA; and judges clarity when ruling on evidentiary matters related to chemical composition.

Another prong of the CSAEA could shed some light on a potential solution for the “chemical composition” prong. The “human consumption” prong has posed similar evidentiary issues as the chemical composition prong in court.¹⁵² At the time of writing, a Senate bill is pending that would amend the human consumption requirement of the CSAEA by adding specific factors that can be considered when determining whether a defendant intended the drugs for human consumption.¹⁵³ A similar

152. For a more complete discussion of the “human consumption” prong’s flaws, see Stackhouse, *supra* note 85.

153. S. 1327, 114th Cong. (2015). For instance, the bill provides that the “human consumption” prong of the CSAEA can be proven using “(1) [t]he marketing, advertising, and labeling of the substance. (2) The known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose. (3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold. (4) The diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance. (5) Whether the defendant knew or

amendment to the chemical composition prong of the CSAEA would greatly assist prosecutors, defendants, and judges in understanding the statute's requirements.

1. Proving a Substance is an Analog Under the CSAEA

One component of the amendment should be a standard by which substantial similarity in chemical composition can be judged. As previously addressed, the circuits are split between the “core arrangement of atoms” test, the “structure and effect” test, and requiring that both tests be met. For the following reasons, this Comment concludes that the “core arrangement of atoms” test is best, and as such should be included in the CSAEA.

To understand why the “core arrangement of atoms” test is preferable, one must understand the issues at play with the “structure and effect” test. As previously discussed, the Eleventh Circuit applied the structure and effect test and, after examining how the drug in question metabolized, determined that the structure and effect of the drug was similar to a banned substance.¹⁵⁴ This heavy reliance on metabolism is unwise. Metabolism is “the mechanism of elimination of foreign and undesirable compounds from the body and the control of levels of desirable compounds”¹⁵⁵ When dealing with synthetic drugs, particularly drugs such as bath salts that have a chemical composition that is constantly being tweaked to keep the drug legal, determining the metabolism of the drug is far from straightforward.¹⁵⁶ These calculations usually require an analytical chemist, and few manufacturers possess such a title or skill set.

This reliance on metabolism contributes to the structure and effect test's risk of being found unconstitutional, as it could be void for vagueness. The issue with codifying the structure and effect test is that the test is likely not sufficiently definite to an ordinary person. A manufacturer or distributor of a drug, such as the defendant Lane in *United States v. Lane*,¹⁵⁷ would likely know what the drug looks like on paper, and perhaps which aspects of the

should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.” *Id.* § 2(b)(1–5). The bill also provides that any other relevant factors not listed can be considered. *Id.* § 2(b).

154. See *supra* text accompanying notes 96–115.

155. Chandrani Gunaratna, *Drug Metabolism & Pharmacokinetics in Drug Discovery: A Primer for Bioanalytical Chemists, Part I*, 19 CURRENT SEPARATIONS 1, 18 (2000).

156. See, e.g., Jiunn H. Lin & Anthony Y.H. Lu, *Role of Pharmacokinetics and Metabolism in Drug Discovery and Development*, 49 PHARMACOLOGICAL REV. 403, 413 (1997) (discussing the challenges of testing a drug's metabolism and the process used).

157. No. 2:12-cr-01419 (D. Ariz. 2013).

drug differ from illegal substances through a two-dimensional rendering. However, the same manufacturer or distributor would likely not know that a body metabolizes the new substance into a banned substance once it is ingested. Even if a manufacturer knew that the new drug acted like a banned substance in its effects on a person, such knowledge does not necessarily translate to the manufacturer's understanding of the new drug's metabolism. As previously discussed, many of the labs used to manufacture designer drugs lack basic chemistry equipment. Thus, it is unlikely that many, if any, labs have the tools to determine the metabolic process of the drug manufactured. As such, the structure and effect test does very little to put defendants on notice.

While the structure and effect test is vulnerable to vagueness challenges, the core arrangement of atoms test is not. An individual with knowledge of basic chemistry can easily construct a side-by-side comparison of two-dimensional diagrams, a skill that any manufacturer—or chemist employed by a manufacturer—necessarily must possess. Additionally, two-dimensional diagrams can demonstrate the core arrangement clearly to an ordinary person, even one who lacks scientific knowledge.¹⁵⁸ In fact, courts that have considered the CSAEA have found that the core arrangement test is clear to the average individual. For example, in *United States v. McKinney*,¹⁵⁹ the court found that a “reasonable layperson could, for example, have examined a chemical chart and intelligently decided for himself or herself, by comparing their chemical diagrams, whether the chemical structure of two substances were substantially similar.”¹⁶⁰ By codifying this test, Congress would put all current and future manufacturers on notice that if their new substances are compared side-by-side to the banned drug they represent the new substance to be similar to, the new substance will fall under the CSAEA. Such a codification is much clearer to all parties than the law as it is currently written.

Of course, some experts believe that a two-dimensional diagram does not adequately encapsulate whether a drug is substantially similar in chemical composition to another, as a two-dimensional diagram is too simplistic.¹⁶¹ Indeed, that has been one of the primary evidentiary issues in CSAEA litigation. For example, at the district court level in *United States v. Roberts*,

158. See *supra* note 88, for an example of such a rendering.

159. 79 F.3d 105 (8th Cir. 1996), *rev'd in part on other grounds*, 520 U.S. 1226 (1997).

160. *Id.* at 108.

161. For a more complete discussion of this issue, see Paul Anacker & Edward Imwinkelried, *Controlled Substance Analogue Enforcement Act Criminal Defense*, 37 SW. U. L. REV. 267, 271–74 (2008).

the defense experts testified that GHB and 1,4-butanediol were not substantially similar, because one drug would remain linear in three-dimensional form, while the other would fold upon itself.¹⁶² Defense attorneys argue that allowing two-dimensional diagrams invites error, as there are other ways to compare whether the drugs are substantially similar in more precise terms.¹⁶³ While two-dimensional diagrams may be simplistic in the context of the study of chemistry, their reliability has been litigated in the context of the CSAEA and has consistently been upheld.¹⁶⁴ Moreover, the ease in which two-dimensional diagrams are understood by juries further reinforces their value in CSAEA litigation.

2. Scierter Requirement

Another component of the amendment should be a clarification of whether the CSAEA imposes a scierter requirement. As previously addressed, the circuit courts have imposed everything from no scierter requirement to the same stringent scierter requirement as the CSA. For the reasons set forth below, this Comment concludes that the provisional remedy crafted by the Seventh and Eighth Circuits is the best interpretation of the law.

Like the substantial similarity tests, the tri-circuit split on whether or not the CSAEA imposes a scierter requirement also hinges on the science behind the designer drug. Because Congress drafted the CSAEA to address the widespread problem of designer drug abuse, it is difficult to imagine that Congress would want to limit the law's scope to only manufacturers and distributors who knew they possessed controlled substances, as the Second Circuit asserted. The very purpose of manufacturing designer drugs is to skirt the laws governing controlled substances. Therefore, limiting the CSAEA in such a fashion is an illogical interpretation of the CSAEA's intended goal. The purpose of the CSAEA is to hold manufacturers and distributors criminally liable for manufacturing drugs that were not controlled, but nevertheless posed the same public health problems as the drugs that were controlled. To require the government to prove that a

162. No. 01-CR-410, 2002 WL 31014834, at *2 (S.D.N.Y. Sept. 9, 2002), *vacated*, United States v. Roberts, 363 F.3d 118 (2nd Cir. 2004).

163. Anacker & Imwinkelried, *supra* note 161, at 281–84.

164. *See, e.g.*, United States v. Brown, 415 F.3d 1257, 1266–70 (11th Cir. 2005).

defendant knew they possessed a controlled substance would defeat the very purpose of the law.¹⁶⁵

On the other hand, imposing no scienter requirement at all is a bridge too far. If there were no scienter requirement present in the statute, the law would ensnare those who purposefully manufactured or distributed a designer drug, knowing that the drug was similar to a banned substance (the intended effect of the law), but would also ensnare those who did so unwittingly (like Richard Glennon or other legitimate researchers). Some might argue that the activity of manufacturing or distributing any kind of drug is dubious at best, so the absence of a scienter requirement and the resulting ensnarement of unknowing participants is warranted. However, often these drugs are sold in smoke shops by high school and college students, who are unaware of the composition of the drug or its legality. Without a scienter requirement, these low level participants could be held accountable under the same felony charges as the individuals who ran the manufacture and distribution process. Such a system may deter the primary actors, but it would also serve to impair a perfectly legal commercial industry. It may also impede legitimate drug research and development, as any researcher who created a new synthetic drug similar to a banned substance would potentially face criminal charges and jail time.

For this reason, the best policy decision would be to impose a scienter requirement, but allow the government to prove that a defendant knew that the drug was substantially similar in chemical composition to a banned substance, *or* that the drug had an effect on the user that was substantially similar to a banned substance. Such a requirement would allow the law to have a deterrent effect both on individuals who know the science behind the drug (such as manufacturers), or those who sell the drug as a legal high similar to any one of the many banned drugs. In essence, this scienter requirement would serve as a catch-all provision, ensnaring any person who knew the designer drug was somehow similar to a banned substance.

165. Congress may add a scienter requirement to the “human consumption” prong of the CSAEA as a possible factor in proving the prong, however. A bill pending before the Senate would allow the government to introduce evidence that the defendant “knew or should have known” that the designer drug was to be consumed by injection, inhalation, ingestion, or any other means to demonstrate that the drug was in fact intended for human consumption. S. 1327, 114th Cong. (2015).

V. CONCLUSION

The CSAEA, while problematic as written, could be amended to close the designer drug loophole further by enhancing the government's ability to prosecute offenders. If legislatively altered to codify the "core arrangement of atoms" test and a scienter requirement, the CSAEA could serve as a successful model for other laws that will surely emerge as entrepreneurial individuals increasingly turn to criminality through science.