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## **The Confusing World of the Controlled Substance Analogue Enforcement Act, 21 U.S.C. § 802(32)(A), Criminal Defense**

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*\* With revisions for inclusion in Chapter 23 of Professor Imwinkelried's  
2-volume treatise "Scientific Evidence" and with repagination.*

## **THE CONFUSING WORLD OF THE CONTROLLED SUBSTANCE ANALOGUE ENFORCEMENT ACT CRIMINAL DEFENSE**

**Paul Anacker\* & Edward Imwinkelried\*\***

### **Introduction**

Congress has identified certain substances as contraband. Those substances are listed as Schedule I Controlled Substances. By law, if not by science, they are declared to have no legitimate medical uses and to have high potential for addiction. It is illegal to possess, distribute, or even for doctors to prescribe these substances. The only people allowed to possess these substances are a dozen or so scientists who have DEA Class X (experimental) licenses. Closely related are Schedule II Controlled Substances. They are declared to have some medical use but a high potential for addiction. They can be prescribed by doctors but only with a triplicate script. There are stiff penalties for the unlawful possession or distribution of these substances.

Because those substances are expressly specified in schedules, some chemists have striven to avoid the statutes criminalizing the possession, distribution, and use of contraband substances.<sup>1</sup> Those chemists endeavor to slightly modify the chemical structure of prohibited substances to create a new substance that technically differs from the controlled substance. Those have been referred to as "designer drugs." One of the legislative drafts that pre- ceded the Controlled Substances Analogue Enforcement Act<sup>2</sup> ("CSAEA") was entitled the Designer Drug Enforcement Act.<sup>3</sup> If, despite the minor technical difference, the designer drug has a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system,<sup>4</sup> the chemist can market the substance while assuring his or her customers that they will not be prosecuted for possession or use of the substance. Perhaps the best example of this phenomenon occurred in the mid-1980s. Fentanyl is

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1 United States v. Turcotte, 405 F.3d 515, 523 (7<sup>th</sup> Cir. 2005).

2 21 U.S.C. 802(32)(A)

3 United States v. Forbes, 806 F.Supp. 232, 235 (D.Colo. 1992).

4 United States v. Turcotte, 405 F.3d 515, 523 (7<sup>th</sup> Cir. 2005); United States v. Forbes, 806 F.Supp. 232, 235-36 (D.Colo. 1992) ("underground chemists who tinker with the molecular structure of controlled substances to create new substances that are not scheduled").

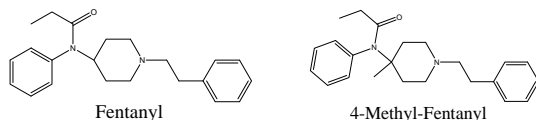
a synthetic pain reliever many times more powerful than morphine, a natural pain reliever. A chemist devised a way to produce 4-methyl-Fentanyl (Fentanyl with a methyl group at the “4” position). The new substance was 30 times more powerful than Fentanyl. It had a street name of “China White.”<sup>5</sup>

In an attempt to deal with this problem, Congress enacted the Controlled Substance Analogue Enforcement Act of 1986.<sup>6</sup> The Act sets out the following definition of a “controlled substance analogue.” A Controlled Substance Analogue is 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 or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
- (iii) with respect to a particular person, which such person represents to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that it is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.<sup>7</sup>

The initial interpretive question that arises is the relationship between clause (i) and clauses (ii) and (iii). There are two possibilities. One is a disjunctive interpretation of the provisions. Under that interpretation, a substance would qualify as a CSAEA analogue if it satisfies clause (i), (ii), or (iii). The other possibility is a conjunctive interpretation. According to a conjunctive interpretation, a substance constitutes an CSAEA analogue only if it satisfies (i) as well as either (ii) or (iii). “The vast majority” of the federal courts that have passed on this question have adopted a conjunctive interpretation.<sup>8</sup> The courts have reached that conclusion for several reasons.

5 The diagrams below depict Fentanyl and 4-Methyl-Fentanyl.



6 21 U.S.C. § 802(32)(A).

7 *Id.*

8 *United States v. Turcotte*, 405 F.3d 515, 522 (7th Cir. 2005) (the court cites eight cases embracing the conjunctive view; the courts add that “[t]he only arguable exceptions are *United States v. Fisher*, 289 F.3d 1329, 1338 (11th Cir. 2002), in which the Eleventh Circuit expressly declined to decide the issue, and *United States v. Granberry*, 916 F.2d 1008, 1010 (5th Cir. 1990), in which the Fifth Circuit recited the test in the disjunctive without discussion or elaboration); *United States v. Roberts*, 363 F.3d 118, 121 (2d Cir.

To begin with, although the connective “or” preceding (iii) suggests a disjunctive interpretation, both (ii) and (iii) effectively begin with “which”:

The operative segments of clauses (ii) and (iii) both begin with the word “which,” signalling the start of a dependent relative clause modifying a precedent noun. In each case, the precedent noun is “chemical structure” found in clause (i). Because both clauses (ii) and (iii) can be read to modify clause (i), the statutory language can be fairly read as requiring [a] two-pronged definition . . .<sup>9</sup>

In effect, the courts have treated (ii) and (iii) as modifying “chemical structure” in (i) rather than “substance.” Further, a disjunctive reading could lead to absurd consequences: Under a disjunctive interpretation, alcohol and caffeine could be criminalized as controlled substance analogues based solely on the fact that, in concentrated form, they might have depressant or stimulant effects similar to illegal substances.<sup>10</sup>

Under a disjunctive interpretation of the statute, it would not matter that alcohol and caffeine have radically different chemical structures than any controlled substances. Further, to a degree, molecular structure and effect on the central nervous system are interdependent.<sup>11</sup> Thus, the clear weight of federal authority is that to invoke the Act, the prosecution must demonstrate that the substance in question is “substantially similar” in chemical structure and has a “stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than” that of a controlled substance listed in schedule I or II.<sup>12</sup>

The problem is that the statute does not elaborate on the meaning of “substantially similar”, “chemical structure”, or “stimulant, depressant, or hallucinogenic effect on the central nervous system”. These omissions give rise to further interpretive issues and evidentiary problems. *United States v. Roberts*<sup>3</sup> is a case in point. In *Roberts*, the accused had distributed BD (1,4-butanediol) to body builders. BD is not a scheduled Controlled Substance. However, the government contended BD is a CSAEA analogue to a scheduled substance, namely, GHB (gamma-hydroxybutyric acid).

2004) (acknowledging *Fisher, supra*, and *Granberry, supra*); *United States v. Forbes*, 806 F.Supp. 232, 234-36 (D.Colo. 1992).

9 *Id.* at 235. But see *United States v. Turcotte*, 405 F.3d 515, 522 (7th Cir. 2005) (“The word ‘which’ in the beginning of clauses (ii) and (iii) could be construed to refer either to “substance” in the preface of the definition (favoring a disjunctive reading) or to “chemical structure” in clause (i) (favoring a conjunctive reading”).

10 *United States v. Forbes*, 806 F.Supp.2d 232, 235 (D. Colo. 1992)

11 *United States v. Forbes*, 806 F.Supp. 232, 236 (D.Colo. 1992). The court also cites legislative history, particularly in the House of Representatives. *Id.* at 235-36 (although the House report is incorrectly cited as H.R. 948; it is H.R. 848).

12 *United States v. Turcotte*, 405 F.3d 515, 533 (7th Cir. 2005).

13 2002 WL 31014834 (S.D.N.Y.).

In *Roberts*, the principal battleground was whether, under clause (i), BD has a substantially similar chemical structure to GHB<sup>14</sup>. For its part, the defense called two expert witnesses, Boyd Haley, Ph.D<sup>15</sup> and David Schuster, Ph.D.<sup>16</sup> The prosecution answered with its own expert, Tom DiBerardino, Ph.D.<sup>17</sup> The District Court judge detailed the state of the evidentiary record at trial:

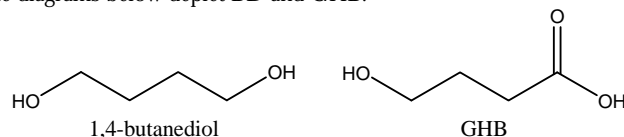
Each of the three experts agreed that the two substances in question contain a different “functional group”: 1,4-butanediol has an alcohol major functional group while GHB has a carboxylic acid major functional group. That is, one is commonly classified as an alcohol or diol, and one is an acid. Those functional groups impart physical properties to the chemicals, such as acidity levels, melting and boiling points, and odors. All three also agreed that the human body can convert 1,4-butanediol into GHB in a two-step enzymatic process after ingestion.

Both of the defendants’ experts concluded that 1,4-butanediol and GHB are not substantially similar in chemical structure . . . . Both based their conclusions upon a number of criteria, including the fact that GHB is an acid and [BD] is generally classified as an alcohol. They testified that the two substances would be classified in different parts of an organic chemistry book, which is [typically] organized by functional group . . . .

Dr. Haley related that GHB has a negative charge at one end of the molecule, and a positive charge at the other, so that the ends necessarily attract, thereby effectively rendering GHB an unstable molecule. In contrast, [BD] does not have such properties and would remain linear. Likewise, Dr. Shuster stated that when illustrated three dimensionally, GHB folded over upon itself, and would not appear static because of its instability.<sup>18</sup>

The defense testimony had substantial merit because function ordinarily follows chemical structure.<sup>19</sup> Nevertheless, the prosecution expert, Dr.

14 The diagrams below depict BD and GHB.



15 *Id.* at \*1 (“Chairman and Professor of the chemistry department at the University of Kentucky, with a joint appointment in the College of Pharmacy. Haley is the author of over 120 publications and 120 research papers. He is the holder of six patents, three as sole inventor”).

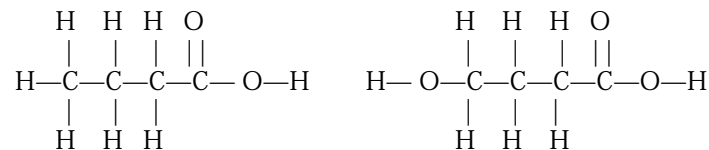
16 *Id.* (“Director of Graduate Studies in Chemistry at New York University and former visiting professor at Yale University. Schuster is the author of over 200 publications and holder of two patents”).

17 *Id.* (“an employee of the DEA’s Drug and Chemical Evaluation Section . . . with a PhD in polymer chemistry”).

18 *Id.* at \*2.

19 Marta Luksza, A System for Predicting Protein Function from Structure, Uppsala

Berardino, was highly critical of the defense experts’ testimony and asserted that they attached undue importance to the chemicals’ functional group.<sup>20</sup> He relied primarily on two-dimensional “stick and letter” diagrams of the chemicals’ structure.<sup>21</sup> The following are examples of stick and letter diagrams:



Butyric acid (3-4% in butter)

Gamma Hydroxybutyric acid (in all cells of the human body)

In such diagrams, the letter notations indicate the atoms present.<sup>22</sup> Thus, C designates carbon, O, oxygen, and H, hydrogen.<sup>23</sup> If a letter has a subscript such as H<sub>2</sub>, the number indicates the number of hydrogen atoms.<sup>24</sup> Subscripts are sometimes used in stick and letter diagrams, however, they are usually used only in chemical formulas, e.g., C<sub>4</sub>H<sub>8</sub>O<sub>3</sub>. The sticks or dashes in the diagrams are notations representing the bonds between the atoms.<sup>25</sup>

The history of the *Roberts* case illustrates the thorny nature of the problems in CSAE litigation. In 2002 in the District Court, Judge Sweet found that there is no generally recognized scientific method of determining whether the structure of two chemicals is “substantially similar.”<sup>26</sup> Given “the lack of consensus by experts,” he concluded that the Analogue Act was unconstitutional as applied because it did not give a reasonable person adequate notice that the sale of BD is prohibited conduct.<sup>27</sup>

However, in 2004, the Court of Appeals for the Second Circuit reversed.<sup>28</sup> The appellate court stated the following facts, *inter alia*: According to the court, there is “only a two-atom difference between” the chemi-

Master’s Thesis in Computer Science, Examensarbete DV3 (Sep. 25, 2005). *See also* Linus Pauling, Modern Structural Chemistry, Nobel Lecture (Dec. 11, 1954)..For a copy of the lecture, contact Mr. Anacker.

20 United States v. Roberts, 2002 WL 31014834 at \*4 (S.D.N.Y.)

21 *Id.* at \*4.

22 United States v. Brown, 279 F.Supp.2d 1238, 1245, 1246 n. 1 (S.D.Ala. 2003).

23 *Id.*

24 *Id.*

25 *Id.* *See* Linus Pauling, *The Nature of the Chemical Bond. Application of Results Obtained from the Quantum Mechanics and from a Theory of Paramagnetic Susceptibility of the Structure of Molecules*, 53 J.AMER.CHEM. SOCIETY 1367 (Apr. 1931).

26 United States v. Roberts, 2002 WL 31014834, at \*3-4.

27 *Id.* at \*4.

28 2004 U.S.App.LEXIS 6108 (2d Cir. Apr. 1, 2004).

cals<sup>29</sup>—“an oxygen atom in GHB is replaced by two hydrogen atoms” in BD.<sup>30</sup> Further, “once in the body, the suspect substance [BD] converts into [the] controlled substance,” GHB<sup>31</sup>—as do at least half a dozen other substances the DEA had chosen not to label as CSAEA analogues. The conversion occurs through the action of two enzymes naturally occurring in most people.<sup>32</sup> In another case,<sup>33</sup> a prosecution expert similarly argued the rapid<sup>34</sup> conversion of BD into GHB is evidence the two chemicals have a similar structure:

the common functional group and carbon chain in both molecules serve as a “handle” in BD, allowing enzymes to attach and convert the molecule into GHB. [T]he two molecules would have to be structurally similar because of the reaction of the body’s receptors to the identical “handle” found in both BD and GHB.<sup>35</sup>

Finally, on two-dimensional diagrams of the substances that chemists use as a sort of shorthand notation, the difference between the two diagrams would “appear[] minor”<sup>36</sup> to a layperson lacking intensive training in chemistry (including, of course, the knowledge of the appropriate uses and limitations of such diagrams).

29 *Id.* at [\*20].

30 *Id.* at [\*8]. In *United States v. Goodman*, U.S.D.C. W.D.Ky., Louisville, J. Simpson, 3:03CR-10-S, one of the authors, Mr. Anacker, cross-examined Dr. James DeFrancesco, a DEA chemist. Dr. DeFrancesco has appeared as a government witness in numerous CSAE cases. The cross-examination demonstrated that contrary to Dr. DeFrancesco’s testimony in that case and prior cases and the assertions of some appellate courts, there are other distinctions, including *inter alia*:

- both the OH groups of BD differ from one of the OH groups of GHB;
- there are single bonds between the atoms in all the positions in BD but a double bond in GHB;
- although the letters make the atoms appear similar in size, the atomic mass unit of hydrogen is one while the atomic mass unit of oxygen is 16; and
- the bond energies between two carbons of BD and of the same positioned two carbon atoms of GHB differ.

31 2004 U.S.App.LEXIS 6108 at [\*19] (2d Cir. Apr. 1, 2004).

32 *United States v. Brown*, 279 F.Supp.2d 1238, 1246-47 (S.D.Ala. 2003) (“First, after BD is ingested, it reacts with alcohol dehydrogenase (‘ADH’), an enzyme, in converting to gamma hydroxybutyraldehyde (‘GHBH’). Second, GHBH reacts with aldehyde dehydrogenase (‘ALDH’), another enzyme. It is GHBH that is converted to GHB”).

33 *Id.* at 1247.

34 There are several problems relying on the “rapid” conversion of BD into GHB. To begin with, the experiments which supposedly establish the rapid conversion involved intravenous injection of BD rather than oral consumption. The “first pass” through the stomach and liver has a greatly diminishing effect on substances and drugs. Moreover, “rapid” is a relative term without defined scientific criteria for assessing the speed of the conversion.

35 *United States v. Brown*, 279 F.Supp.2d 1238, 1247 (S.D.Ala. 2003). [However, see the comment by Mr. Anacker in Footnote 89, *supra*.]

36 *Id.*

The disagreement between the District Court and the Court of Appeal reflects the underlying evidentiary problem. On the one hand, prosecution experts consistently claim that a simple visual assessment of two-dimensional stick and letter diagrams is “the best method of forming an opinion on structural similarity and is generally accepted in the scientific community.”<sup>37</sup> On the other hand, defense experts are adamant that visual comparison of such diagrams is unscientific in the extreme because conclusions based on such comparisons are “not quantitative or testable by the scientific method.”<sup>38</sup> Indeed, defense critics point out that some prosecution witnesses have frankly conceded that their conclusion is “a ‘gut level thing’ . . . based on intuition . . . .”<sup>39</sup>—a troubling concession given the length of the sentences of imprisonment meted out for convictions based on such conclusions. This conclusion seems even more suspect than the opinion that the Supreme Court excluded in *Kumho Tire Co. v. Carmichael*.<sup>40</sup> In both cases, the conclusion rested on a visual inspection. However, in *Kumho Tire* the expert visually inspected the very tire in question in the case while in this context, the conclusion is farther removed from reality—it is a visual inspection of a diagram of the object in question.

The purpose of this section is to refine the analysis of this evidentiary issue. The first two subsections address the threshold question of whether it is even necessary to reach this evidentiary issue. The first subsection poses the possibility that rather than formally receiving testimony subject to evidentiary restrictions, the trial judge could resolve the question as a matter of statutory interpretation unconstrained by evidentiary rules. However, the subsection concludes that the mens rea requirement for Controlled Substance Abuse Analogue offenses mandates that the issue be resolved by the jury rather than the judge.<sup>41</sup>

The second subsection raises another potential method of circumventing formal evidentiary restrictions. This subsection discusses the question of whether, under the Controlled Substances Analogue Enforcement Act, the trial judge can withdraw the issue from the jury by judicially noticing the proposition that two molecules have a substantially similar chemical structure. As in the case of statutory construction, the subsection concludes that judicial notice does not afford an escape from the evidentiary rules.

Assuming that the evidentiary rules apply, the third subsection evaluates the admissibility of expert testimony on the question of substantial similarity.

37 *Id.* at 1244.

38 *United States v. Brown*, 415 F.3d 1257, 1267 (11th Cir. 2005).

39 *Id.*

40 526 U.S. 137 (1999).

41 Of course, the jury decision late in the criminal justice process accentuates the question of whether earlier the defendant had fair notice that his or conduct was prohibited.

As this subsection notes at the outset, one possible interpretation of the statutory language would render expert testimony logically irrelevant. The subsection explains why that interpretation is unsound. Positing an<sup>42</sup> alternative interpretation under which expert testimony is at least relevant, the subsection then assesses admissibility of such testimony under both the traditional general acceptance test and the reliability test prescribed in 1993 in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>43</sup> The subsection demonstrates that while expert opinions based on visual comparisons may pass muster under the former general acceptance test, its introduction is more problematic under *Daubert*. After critiquing the admissibility of opinions resting on visual assessment, the subsection discusses another suggested method of determining the degree of similarity between two chemicals, the use of the Tanimoto Similarity Algorithm.<sup>44</sup>

In the long term, the best solution may be either (1) a judicial interpretation of the definition of “controlled substance analogue” in the Controlled Substance Analogue Enforcement Act, 21 U.S.C. § 802(32)(A), as a definition of the criteria to be used in an Administrative Procedure Act hearing to determine if a substance is a CSAEA analogue with subsequent Federal Register publication to give the public notice or (2) an amendment of the CSAEA to prescribe that procedure.<sup>45</sup> However, in the meantime prior to such an interpretation or amendment, criminal practitioners must familiarize themselves with the interpretive and evidentiary issues highlighted in this section.

#### **I. One Potential Solution to the Evidentiary Problem: Allowing the Judge to Decide Whether the Two Molecules have Substantially Similar Chemical Structures as a Matter of Statutory Construction.**

As a matter of policy, it is debatable whether it is wise to assign judges the responsibility of making a decision that to a significant degree turns on sophisticated scientific issues. The typical judge lacks extensive training in chemistry and pharmacology. There is, though, a counter-argument that it is too late in the day to argue that standing alone, judges’ lack of formal scientific training is an adequate reason not to construe the CSAEA as assigning this decision to judges. Admittedly, the concern about the judges’ lack of training is a plausible one. However, it is the very concern that the late

42 That treatment of the subsection of the statute is arguably consistent with the overall title of 21 U.S.C. § 802, that is, “Definitions.”

43 509 U.S., 579 (1993).

44 *United States v. Brown*, 279 F.Supp.2d 1238, 1247-50 (S.D.Ala. 2003). The use of the algorithm produces a result referred to as a Tanimoto Coefficient.

45 *United States v. Roberts*, 2004 U.S.App.LEXIS 6108, [\*17] n. 3 (2d Cir. Apr. 1, 2004)(Calabresi, J.).

Chief Justice Rehnquist cited in his partial dissent in *Daubert* as a reason for rejecting the validation standard announced by the *Daubert* majority.<sup>46</sup> The majority clearly rejected the Chief Justice’s argument. In the final analysis, the question is one of statutory interpretation; and Congress may assign this decision to the trial judge unless there is a constitutional objection to the assignment.

In some cases, even trial courts perform essentially legislative tasks. A trial judge does so when he or she construes a statute or formulates a common-law or constitutional rule.<sup>47</sup> When the judge is engaged in a truly legislative function, the normal evidentiary rules are inapplicable.<sup>48</sup> The judge may receive and consider information that would be inadmissible under those formal rules. When a judge is formulating a constitutional rule, the judge is free to read any pertinent law review article or text. The judge enjoys the same freedom when he or she undertakes the task of construing a statute.

In CSAEA cases, although in the final analysis the basic question is scientific in nature, from another perspective the question can be characterized as an issue of statutory construction: Does the CSAEA apply to the substance alleged to be a CSAEA analogue? Or, to put the question slightly differently, should the CSAEA be construed as applying to that substance? The CSAEA could conceivably be construed as assigning that decision to the trial judge. To make that decision, the judge would have to make the scientific determination whether the chemical structure of an alleged CSAEA analogue is “substantially similar” to that of a schedule I or II controlled substance. Assuming that the judge made that scientific/legal determination, the jury would later decide as a matter of fact whether the substance in the defendant’s possession consisted of that molecule. In other words, while the judge would resolve the question of science/law whether the CSAEA applies to BD, the jury would decide the question of fact whether the substance in the accused’s possession was BD.

At first blush, treating the question of substantially similar chemical structure in this fashion seems plausible. After all, one could argue that there is a similar division of labor between the judge and jury in cases involving controlled substances. For example, the judge consults the relevant legislation to determine whether the legislation applies to the substance. For example, the judge reviews Schedules I and II to determine whether crack cocaine is a scheduled controlled substance. The judge then assigns the jury the task of determining whether, as a matter of historical fact, the substance found on

46 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 598, 600-01 (1993)(Rehnquist, C.J., concurring in part and dissenting in part).

47 Imwinkelried, *Expert Testimony by Ethicists: What Should Be the Norm?*, 76 TEMPLE L.REV. 91, 113-18 (2003).

48 Imwinkelried, *supra* note 46, at 113-118.

the defendant's person on the alleged occasion was crack cocaine.

However, CSAEA cases differ fundamentally from controlled substance cases. In controlled substance cases, the substances such as crack cocaine and marijuana are per se illegal substances.<sup>49</sup> In these cases, "knowledge [of the identity] of the specific substance involved will usually automatically imply knowledge that the substance is controlled."<sup>50</sup> It is so widely understood that such substances are contraband that the accused cannot defend on the ground that he or she was unaware of the legislation criminalizing possession of the substance: "ignorance of the law is no excuse" in the case of per se illegal substances.<sup>51</sup>

In contrast, in the case of a substance alleged to be a CSAEA analogue, "knowledge of the substance's identity does not automatically imply knowledge of its status as" an illegal substance.<sup>52</sup> It is fair to assume that any reasonably intelligent person realizes that it is illegal to possess crack cocaine, but that can hardly be said in the case of BD or even more clearly GBL.<sup>53</sup> Consequently, although there is contra authority,<sup>54</sup> as a matter of fairness most courts have imposed a special scienter or *mens rea* requirement in CSAEA cases.<sup>55</sup> Absent such a requirement, the CSAEA would "ensnare individuals engaged in apparently innocent conduct."<sup>56</sup> It is not enough for the prosecution to show that the accused knew that the substance in his or her possession was GBL. In the words of the Court of Appeals for the Seventh Circuit,

the defendant must know that the substance at issue meets the definition of a controlled substance analogue set forth in 21 U.S.C. § 802(32)(A): A defendant must know that the substance at issue has a chemical structure substantially similar to that of a controlled substance, and he or she must either know that it has similar physiological effects or intend or represent that it has such effects.<sup>57</sup>

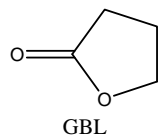
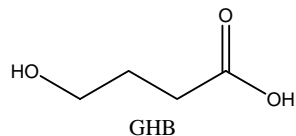
49 United States v. Turcotte, 405 F.3d 515, 525 (7th Cir. 2005).

50 *Id.*

51 *Id.*

52 *Id.* at 526.

53 The diagrams below depict GHB and GBL.



It seems evident that upon viewing these diagrams, most laypersons would say that these diagrams do not appear "substantially similar."

54 *Id.*, discussing United States v. Forbes, 806 F.Supp. 232, 238 (D.Colo. 1992).

55 405 F.3d at 526-27.

56 *Id.* at 527.

57 *Id.* The requirement for proof of scienter may not afford the defendant as much protection as might initially appear. It is true that in *Turcotte*, the court ruled that the

In short, those showings are essential elements of the charged offense.

In its recent line of decisions including *Apprendi v. New Jersey*,<sup>58</sup> *Blakeley v. Washington*,<sup>59</sup> and *United States v. Booker and Fanfan*,<sup>60</sup> the Supreme Court has powerfully affirmed that at jury trials, it is the jury's province to determine the existence of the essential elements of the charged crime.<sup>61</sup> As previously stated, most federal courts have interpreted the CSAEA as requiring proof that the accused knew that the substance in his or her possession had a chemical structure substantially similar to that of a controlled substance. Understandably, the uniform practice has been to submit that question to the jury.<sup>62</sup> By their terms, the Federal Rules of Evidence apply to testimony submitted to a criminal jury during the guilt phase.<sup>63</sup>

## II. Another Potential Solution to the Evidentiary Problem:

statute (1) had to be read conjunctively, mandating proof of both similar structure and physiological effects and (2) requires proof of scienter as to both. However, in another passage, the court held that proof of scienter as to the second element, substantially similar effects, gives rise to a permissive inference of scienter of the first element: "[I]f the scienter requirement is met with regard to the second part of the CSAEA 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.* at 527. There are constitutional limitations on even permissive inferences of elements of the charged offense in criminal cases. 2 E. IM-WINEKLRIED, P. GIANNELLI, F. GILLIGAN & F. LEDERER, COURTROOM CRIMINAL EVIDENCE § 2920 (4th ed. 2005). A chemist might dispute that the inference is as obvious as the court makes it out to be.

58 530 U.S. 466 (2000).

59 542 U.S. 296 (2004).

60 543 U.S. 220 (2005).

61 In *Holmes v. South Carolina*, 126 S.Ct. 1727, 164 L.Ed.2d 503 (2006), the Supreme Court struck down state evidentiary restrictions on the admissibility of evidence that a third party had committed the crime the defendant was charged with. The lower courts excluded the defense evidence on the ground that the prosecution evidence of guilt was so strong that the defense evidence could not raise a reasonable doubt as to the defendant's guilt. The prosecution evidence included forensic testimony, namely, DNA analysis and evidence of a palm print. However, the defense proffered expert testimony that the DNA samples were contaminated and that the palm print had been planted. In reversing, Justice Alito wrote:

Just because the prosecution's evidence, if credited, would provide strong support for a guilty verdict, it does not follow that the evidence of third-party guilt has only a weak logical connection to the central issues in the case. And where the credibility of the prosecution's witnesses or the reliability of its evidence is not conceded, the strength of the prosecution's case cannot be assessed without making the sort of factual findings that have traditionally been reserved for the trier of fact . . .

62 United States v. Brown, 415 F.3d 1257, 1260 (11th Cir. 2005); United States v. Turcotte, 405 F.3d 515, 536 (7th Cir. 2005); United States v. Brown, 279 F.Supp.2d 1238, 1242, 1245 (S.D.Ala. 2003); United States v. Forbes, 806 F.Supp.2d 232, 236, 238 (D.Colo. 1992).

63 FED.R.EVID. 1101(a)-(b), 28 U.S.C.A..

### Permitting the Judge to Take Judicial Notice of the Proposition that a Particular Substance has a Chemical Structure Substantially Similar to that of a Controlled Substance

The formal submission of evidence to the jury is not the only method of inputting scientific information to the judicial process. In many cases, the courts resort to judicial notice as an alternative method.<sup>64</sup> Federal Rule of Evidence 201(b)(2) provides that a judge may dispense with formal evidence and judicially notice a proposition that is “not subject to reasonable dispute in that it is . . . capable of accurate and ready resolution by resort to sources whose accuracy cannot reasonably be questioned.”<sup>65</sup> The courts have frequently invoked this provision to notice scientific propositions.<sup>66</sup> When a judge is deciding whether to judicially notice a proposition, the judge may consider information even if the data would not be admissible under the technical evidentiary rules.<sup>67</sup>

The question then arises: Can a trial judge circumvent the evidentiary problem in a CSAEA case by simply judicially noticing the proposition that BD has a chemical structure substantially similar to that of GHB?<sup>68</sup> In the words of Rule 201(b)(2), the crucial question is whether that proposition is “not subject to reasonable dispute . . . .”<sup>69</sup>

Truly scientific propositions often qualify for judicial notice.<sup>70</sup> Given the test announced in Rule 201(b), a judge might well properly judicially notice the propositions that BD has an alcohol major functional group or that upon ingestion, BD is converted into GB through the action of two naturally

64 Section 11-2 of this treatise.

65 Fed.R.Evid. 201, 28 U.S.C.A..

66 Section 1-2 of this treatise.

67 By way of example, California Evidence Code § 454(a) states:

In determining the propriety of taking judicial notice of a matter, or the tenor thereof:

- 1) Any source of pertinent information, including the advice of persons learned in the subject matter, may be consulted or used, whether or not furnished by a party.
- 2) Exclusionary rules of evidence do not apply except for Section 352 and the rules of privilege.

California Evidence Code § 352 corresponds to Federal Rule of Evidence 403, permitting the trial judge to exclude otherwise admissible evidence when incidental probative dangers substantially outweigh the probative worth of the item of evidence. Fed.R.Evid. 403, 28 U.S.C.A..

68 Even if the judge chose to do so, in a criminal case a federal judge may not instruct the jury that it must assume the truth of the noticed proposition. Federal Rule of Evidence 201(g) reads:

In a civil action or proceeding, the court shall instruct the jury to accept as conclusive any fact judicially noticed. In a criminal case, the court shall instruct the jury that it may, but is not required to, accept as conclusive any fact judicially noticed.

69 FED. R. EVID. 201.

70 GIANNELLI & IMWINKELRIED, *supra* note 63, at §§ 1-2

occurring enzymes. Those propositions fall within the domain of science. However, in a CSAEA case, the judge must go farther: The judge would have to notice the proposition that the chemical structure of a certain molecule is “substantially similar” to that of another molecule. Neither the proposition about BD’s alcohol functional group nor the proposition about its conversion into GB dictates that conclusion. One would not assert that the physical structure of a caterpillar is substantially similar to that of a butterfly simply because the caterpillar naturally transforms into a cocoon which, in turn, naturally becomes a butterfly.

Substantial similarity is a concept that chemists sometimes discuss,<sup>71</sup> but it has a different meaning from “substantially similar” in this context. “Substantially similar” is not a scientific concept,<sup>72</sup> and “the Analogue Act does not indicate that the term ‘substantially similar’ is to be defined” in any scientific sense.<sup>73</sup> Worse still, the trial records in cases such as *Roberts* demonstrate that scientists can dispute over such propositions.<sup>74</sup> At least when the record documents such a dispute, a judge will be hard pressed to justify judicially noticing the proposition under Rule 201(b). If so, like the statutory construction theory discussed in Part I, the judicial notice theory fails. At least when the proposition is disputable, judicial notice is inappropriate. When the judicial notice route is unavailable to establish the proposition, in order to do so the proponent will have to submit testimony subject to the normal evidentiary restrictions.

### III. The Evidentiary Problem

Assume *arguendo* that the trial judge decides that it is the jury’s province to decide on the merits during the guilt phase whether the chemical structure of the alleged analogue found in the accused’s possession is substantially similar to that of a scheduled controlled substance. On that assumption, the prosecution must present admissible evidence to establish that proposition.

#### A. The Logical Relevance of Expert Testimony

To be admissible, any item of evidence must be logically relevant to a fact of consequence in the case.<sup>75</sup> In a CSAEA prosecution, the relevance of any proffered testimony depends on the trial judge’s interpretation of the

71 November 18, 2001 Declaration of Rickey J. Williams, Ph.D. (on file with Mr. Anacker).

72 Alexander Shulgin, Letter to the Editor, 35 Journal of Forensic Sciences 8 (1990); October 30, 2002 Declaration of Alexander T. Schulgin, Ph.D. (on file with Mr. Anacker).

73 United States v. Brown, 279 F.Supp.2d 1238, 1240 (S.D.Ala. 2003).

74 United States v. Roberts, 2002 WL 31014834 (S.D.N.Y.)

75 Fed.R.Evid. 402, 28 U.S.C.A. (“Evidence which is not relevant is not admissible”).

language, “substantially similar to the chemical structure of a controlled substance,” in 21 U.S.C. § 802(32)(A)(i). The prosecution might argue that the statutory text prescribes the test whether, upon viewing two-dimensional diagrams of the two drugs, a reasonably intelligent layperson would find the two diagrams to be substantially similar. Some judicial opinions contain passages lending support to that argument.<sup>76</sup> If the trial judge adopted this narrow interpretation of the statutory text, that interpretation could render expert testimony logically irrelevant and therefore inadmissible.<sup>77</sup> It would not matter whether an expert disagreed with the hypothetical layperson’s comparison of the diagrams; under this interpretation, the layperson’s assessment is dispositive. The proponent of expert testimony could not even contend that expert testimony was relevant because it might influence the hypothetical layperson; according to this view, the layperson is to base his or her conclusion solely on a visual comparison of the two stick and letter diagrams.

However, this interpretation of the statute is flawed. To begin with, although there is favorable language in some judicial opinions, that language must be read in context. In those cases, the court does not purport to be announcing the proper interpretation of the statutory language. Rather, the court is ordinarily holding only that the record containing the two diagrams is legally sufficient to sustain the jury’s guilty verdict.<sup>78</sup> Moreover, some of those records of trial contain expert testimony.<sup>79</sup>

Even more importantly, the statutory text points to a broader, more expansive interpretation. A hypothetical layperson’s perspective may be dispositive when the question is whether the CSAEA violates due process by failing to give fair notice of the proscribed conduct.<sup>80</sup> However, that question differs from the present interpretive issue. As several CSAEA cases illustrate,<sup>81</sup> the question of fair notice would be resolved pretrial by a motion

76 *E.g.*, *United States v. McKinney*, 79 F.3d 105, 108 (8th Cir. 1996) (“In our case, a reasonable layperson could . . . have examined a chemical chart and intelligently decided for himself or herself, by comparing their chemical diagrams, whether the chemical structures of the two substances were substantially similar”), overruled on other grounds, 520 U.S. 1226 (1997).

77 This interpretation would have the virtue of largely mooted the question of whether the Act is void for vagueness. One of the key questions in vagueness analysis is whether the statute gives adequate notice to “the person of ordinary intelligence.” *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972).

78 *Id.*

79 *Id.*

80 *United States v. Brown*, 279 F.Supp.2d 1238, 1241 (S.D.Ala. 2003).

81 *United States v. Roberts*, 2002 WL 3104834 (S.D.N.Y. 2002) (a pretrial motion to dismiss); *United States v. Forbes*, 806 F.Supp.2d 232 (D.Colo. 1992) (a pretrial motion to dismiss).

to dismiss the indictment.<sup>82</sup> In contrast, the present issue arises at the trial on the merits when the proponent attempts to introduce expert testimony and the opponent interposes a relevance objection. On its face, the statute indicates that the controlling question on the merits is whether in fact “the chemical structure” of the alleged analogue “is substantially similar to the chemical structure of a controlled substance . . . .”<sup>83</sup> The statute does not contain any language indicating that that determination must be made solely on the basis of a comparison of the substances’ two-dimensional diagrams, much less only on the basis of a hypothetical layperson’s assessment of the degree of similarity between the two diagrams.

Finally, it is hard to believe that Congress intended the statutory language to be construed in that narrow manner. If the question is the degree of similarity between the chemical structure of two drugs, exhibits depicting stick and letter diagrams of the substances’ chemical structures are arguably<sup>84</sup> logically relevant; and the jury may therefore review those exhibits in making its decision on the merits. However, they are an inferior basis for the jury’s decision. The typical stick and letter diagram submitted to a jury in a CSAEA prosecution is a crude, very limited, two-dimensional depiction of some features of chemical structure in which each letter representing an atom is of the same size. The atomic mass units of atoms vary radically. For instance, while hydrogen atoms have an atomic mass unit of 1, the atomic mass unit of oxygen atoms is 16. Some stick and ball diagrams use the same size balls for all atoms. Proportional stick and ball diagrams, indicating the relative atomic weight of the atoms, are a more accurate depiction of chemical structure. Yet, as two-dimensional diagrams, both stick and letter and stick and ball diagrams are unrealistic. Objects such as atoms do not exist in only two dimensions; like human beings, they are three-dimensional. Just as a stick and ball diagram is more complete than a stick and letter diagram, in turn a three-dimensional model is more accurate than a stick and ball diagram.<sup>85</sup> Further, all of these

82 *E.g.*, *United States v. Roberts*, 2002 WL 3104834 (S.D.N.Y. Sep. 9, 2002).

83 21 U.S.C. § 802(32)(A).

84 *Fed.R.Evid.* 401-02, 28 U.S.C.A.. See *United States v. Leftenant*, 341 F.3d 338, 346 (4th Cir. 2003) (“to be admissible, evidence need only . . . have a ‘plus value’”); *United States v. Casares-Cardenas*, 14 F.3d 1283, 1287 (8th Cir. ) (“Relevance is established by any showing, however slight, that makes it more or less likely . . . .”), cert.denied, 513 U.S. 849 (1994); *United States v. Nason*, 9 F.3d 155, 162 (1st Cir. 1993) (“The threshold for relevance is very low under Federal Rules of Evidence 401”), cert.denied, 510 U.S. 1207 (1994); *People v. Romero*, 33 Cal.App.4th 1838, 1843, 40 Cal.Rptr.3d 85, 88 (1995) (the definition of relevant evidence “is manifestly broad”; evidence “is relevant when no matter how weak it tends to prove a disputed issue”). However, an item of evidence that passes muster under Rule 401 may be vulnerable to exclusion under Rule 403. *Fed.R.Evid.* 403, 28 U.S.C.A..

85 A three-dimensional model is especially helpful in cases such as *United States v. Roberts*, 2002 WL 3104834 (S.D.N.Y. Sep. 9, 2002), posing the question of whether BD is an



types of exhibits—two-dimensional stick and letter diagrams, stick and ball diagrams, and three-dimensional models—embody scientific conventions.<sup>86</sup> Most exhibits omit features, such as relative atomic weight and bonding. A chemist has a much better understanding of atomic weight than the typical layperson and certainly a superior knowledge of bonding rules. Given the ready availability of markedly superior potential evidence, it defies common sense to think that Congress wanted the jury's decision to rest solely on a lay assessment of stick and letter notations.

## B. The Admissibility of Testimony

Assuming that expert testimony can be logically relevant in a CSAEA prosecution, the next question that arises is whether it is admissible. What are the various types of expert testimony that might be offered, and will they satisfy the governing standard for the admissibility of expert testimony?

### 1. The Various Types of the Expert Testimony

A survey of the cases reveals that the litigants have typically relied on one or both of three types of expert testimony.

One type is a generalized testimony about a simplistic, subjective expert analysis of the degree of similarity between diagrams setting out stick and letter depictions of chemical structure. The prosecution often offers such evidence.<sup>87</sup> In assessing the degree of similarity, prosecution experts have considered such other factors as whether the alleged analogue “quickly”<sup>88</sup> metabolizes into the controlled substance upon ingestion<sup>89</sup> and whether the

alleged analogue produces the same pharmacological effects.<sup>90</sup> The government experts treat those factors as circumstantial evidence of similar chemical structure. The experts reason that if the alleged analogue rapidly converts into the controlled substance or produces the same effects as the scheduled substance, that factor is some evidence that the alleged analogue and the controlled substance share structural features.

The second type of expert testimony relates to Tanimoto Coefficients.<sup>91</sup> Tanimoto Coefficients are the results of a mathematical expression developed to do searches in hyperspace. A few companies use Tanimoto Coefficients to search for substances similar to patented drugs. Pharmaceutical companies search for alternate substances to develop into drugs that have a similar effect as that of a patented drug. The companies do so in order to avoid having to pay the licensing fee for the patented drug. The companies want to find

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experts have treated conversion as circumstantial evidence of similar chemical structure. In *Brown*, Dr. Irwin testified that the rapid conversion process factors into his opinion that the chemical structures of BD and GHB are substantially similar since the alcohol functional group and carbon chain of both molecules have to be similar in order to bind in the body. He noted that the common functional group and carbon chain in both molecules serves as a “handle” in BD, allowing enzymes to attach and convert the molecule into GHB. Although he explained that basic metabolism of one molecule into another does not generally mean that the two are structurally similar, in this case he opined that the rapid conversion emphasized the similarity in structure. He stated that the two molecules would have to be structurally similar because of the reaction of the body's receptors to the identical “handle” found in both BD and GHB. *Id.* at 1247.

The authors have been unable to locate any empirical studies which support Dr. Irwin's final conclusion. To the contrary, there is research indicating that BD does not bind to GHB receptor sites. November 15, 2001 declaration of Steven Wm. Fowkes (on file with Mr. Anacker).

In *United States v. Brown*, 415 F.3d 1257, 1271 (11th Cir. 2005), the court further quoted Dr. Irwin:

This structure has to be basically identical to this structure in order for the BD to be converted to GHB and for it to fit into the GHB receptor. And so in this context that influences—that basically requires that the structures be very similar.

Again, the extant research points to the conclusion that BD does not bind to GHB receptor sites. [See note at Fn 34]

90 This factor must be evaluated carefully to prevent the conflation of clause (i) and (ii) of the CSAEA. However, the argument is that the similarity in effect is circumstantial evidence of similar structure: “Because 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.” *United States v. Forbes*, 806 F.Supp. 232, 236 (D.Colo. 1992). However, this generalization is flawed. For example, both GHB and diphenhydramine HCL tend to put people to sleep, but their structures are quite different. See Pharmaceutical Information, NYTOL Extra Strength—Block Drug—Diphenhydramine HC1—Sleep Aid, <http://www.rxmed.com/b.main>.

91 See generally Patterson, Cramer, Ferguson, Clark & Weinburger, *Neighborhood Behavior: A Useful Concept for Validation of “Molecular Diversity” Descriptors*, 39 J. MED. CHEM. 3049 (1996).

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CSAEA analogue of GHB. BD has a linear structure while “when illustrated three dimensionally, GHB fold[s] over upon itself . . . .” *Id.* at \*2. In fact, the ends simply tend to attract each other. (September 27, 2006 personal communication between the witness, Professor Shuster, and Mr. Anacker.)

86 *United States v. Brown*, 279 F.Supp.2d 1238, 1246 nn. 1-2 (S.D.Ala. 2003).

87 *E.g.*, *United States v. Brown*, 415 F.3d 1257, 1262 (11th Cir. 2005); *United States v. Roberts*, 2004 U.S.App.LEXIS 6108, at [\*17]-[\*18] (2d Cir. Apr. 1, 2004); *United States v. Brown*, 279 F.Supp.2d 1238 (S.D.Ala. 2003); *United States v. Roberts*, 2002 WL 31014834, at \*4 (S.D.N.Y. Sep. 9, 2002).

88 Neither the courts nor the prosecution experts have specified an objective criterion to identify “rapid” conversion. *But see* *United States v. Turcotte*, 405 F.3d 515, 529 (7th Cir. 2005) (“In amending the Controlled Substances Act to include GHB, Congress declared that “[i]f taken for human consumption, common industrial chemicals such as gamma butyrolactone [GBL] and 1,4-butanediol [BD] are swiftly converted by the body into GHB”); *United States v. Roberts*, 2004 U.S.App.LEXIS 6108 at \*16 n. 2 (2d Cir. 2004). Although the *Turcotte* opinion pointed to passages in the legislative history, those passages are unilluminating. To begin with, the studies mentioned in the legislative history involved intravenous administration of the substances rather than oral consumption. Moreover, there is no indication what “swiftly” means in this context.

89 *United States v. Brown*, 279 F.Supp.2d 1238, 1243 (S.D.Ala. 2003). Some government

substances with at least a 90% or preferably a 95% coefficient compared to the target drug before they invest funds researching the development of the alternate drug.<sup>92</sup> This coefficient computation compares “fingerprints” for two molecules. In this context, a “fingerprint” is simply a bit string, each bit being an item of information about a feature of the molecule. Suppose, for example, that the researcher is interested in four different features of chemical structure including the presence of a particular atom. It turns out that molecule #1 has features A, C, and D while molecule #2 has features A, B, and D. To compute the Tanimoto Coefficient to determine how similar the two molecules are, the researcher uses the following formula:

$$\text{Tanimoto Coefficient} = N_{12} / (N_1 + N_2 - N_{12}).$$

In the formula,  $N_{12}$  is the number of bits or features shared by molecules #1 and #2.  $N_1$  is the number of features or bits in molecule #1 while  $N_2$  is the number of features present in molecule #2. In our hypothetical, the computation would be

$$0.50 = 2 / (3 + 3 - 2)$$

$$0.50 = 2 / (6 - 2)$$

$$0.50 = 2 / 4.$$

When the coefficient approaches the value 0, the result indicates that the compounds are dissimilar or diverse. When the coefficient nears the value 1, the result indicates that the compounds are very similar.

In the past, the Tanimoto Coefficient has been employed for such purposes as constructing databases or libraries of molecules.<sup>93</sup> If a researcher wants to use a database to screen an unknown drug, he or she wants the database to be as diverse as possible. The more diverse the molecules in the database library, the more informative the search will be; a search of a diverse database is more likely to yield potential candidates for a match. In contrast, if the molecules in the library are clustered together in chemical structure, the less likely the database will yield potential matches and be useful to the

92 Ginn, Ranade, Willett & Bradshaw, *The Application of Data Fusion to Similarity Searching in Chemical Databases*,

<http://www.daylight.com/meetings/mug98/Bradshaw/datafusions/datafusion/emrgconf.html>; Landes Bioscience, Similarity Searching, Eureka.com.

93 Patterson, Ferguson, Cramer, Garr, Underiner & Peterson, *Design of a Diverse Screening Library*, in HIGH THROUGHPUT SCREENING—THE DISCOVERY OF BIO-ACTIVE SUBSTANCES 243 (J.P.Devlin, ed. 1997); Brown & Martin, *Use of Structure-Activity Data to Compare Structure-Based Clustering Methods and Descriptors for Use in Compound Selection*, 36 J. CHEM. INF. COMPUT. SCI. 572 (1996). The original use of the coefficient was for the purpose of searching hyperspace.

researcher. Tripos is a company that constructs LeadQuest databases. While Tripos generally uses Tanimoto Coefficient computations to ensure that neighboring molecules in the database are relatively dissimilar—the inverse of similarity—it has done computations of relative similarity for one of the authors, Mr. Anacker. In some cases, defense experts have relied on Tanimoto Coefficient computations as a basis for arguing that the alleged analogue is dissimilar to the controlled substance in chemical structure.<sup>94</sup>

While the defense has sometimes offered testimony about Tanimoto Coefficients, the third type of testimony, like the second, is usually proffered by the prosecution. Here the prosecution expert is no longer content to merely describe stick and letter depictions of the chemical structures of the substances. Instead, the expert takes a further step; based on a visual inspection of the diagrams, the expert opines directly that the two substances have substantially similar chemical structures.<sup>95</sup> As previously stated, this sort of superficial inspection seems even less reliable than the visual inspection that the Supreme Court rejected as a basis for an expert opinion in *Kumho Tire*.<sup>96</sup>

## 2. The Admissibility of the Various Types of Expert Testimony Under the Controlling Standards

Which, if any, of these types of expert testimony qualify for admission into evidence? In part, the answer turns on which standard for admissibility the jurisdiction in question subscribes to. In the United States, there are two leading tests for the admissibility of purportedly scientific testimony.

### a. Admissibility under the Traditional General Acceptance Test

The traditional standard is traceable to the decision by the Court of Appeals

94 *United States v. Brown*, 415 F.3d 1257, 1263, 1269-70 (11th Cir. 2005); *United States v. Brown*, 279 F.Supp.2d 1238, 1247-50 (S.D.Ala. 2003). In *Brown*, the computation was originally prepared by Tripos scientists at Mr. Anacker's request. The computation compared GHB to six other 4-Carbon molecules – Email from Tripos, Inc. to Mr. Paul Anacker (on file with Mr. Anacker). At trial, without consulting Mr. Anacker, it was used during the testimony of a botanist. It would have been far better if Tanimoto Coefficients had been explained by a Mathematical or Computational Chemist. The latter type of expert could have demonstrated that BD ranks lower than many other substances that the F.D.A. and D.E.A. do not consider to be GHB analogues. Mr. Anacker points out that both pharmaceutical companies and the U.S. Dept. of Health and Human Services, the F.D.A.'s parent organization, endorse the use of Tanimoto Coefficients. See “Similarity Searching” at <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=eureka.section.3798>.

95 Federal Rule 702 permits the expert to testify “in the form of an opinion or otherwise . . . Fed.R.Evid. 702, 28 U.S.C.A..

96 *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

for the District of Columbia in *Frye v. United States*.<sup>97</sup> In that case, the defense proffered expert testimony based on the systolic blood pressure test. That test was a forerunner of the modern polygraph test. The underlying theory was that when an individual engages in conscious deception, his or her systolic blood pressure changes. According to the theory, if an investigator carefully monitored a suspect's systolic blood pressure during interrogation, the investigator could determine whether the suspect is being untruthful. In *Frye*, a defense expert was prepared to testify that the accused was being truthful when he denied committing the charged crime. The trial judge excluded the testimony, and the appellate court affirmed. The court did so for the stated reason that the defense had not shown that the systolic blood pressure had gained general acceptance in the relevant scientific fields, that is, psychology and physiology.<sup>98</sup> At one time, the general acceptance test was the controlling standard in all the federal circuits and 45 states. It remains the law in such populous, litigious jurisdictions as California, Florida, Illinois, New York, Pennsylvania, and Washington.<sup>99</sup> Hence, even today the general acceptance standard governs at most state trials. In short, if the accused is prosecuted under a state statute corresponding to the federal CSAE Act, the question becomes whether the theory or technique underlying the expert's testimony is generally accepted.

### Diagram Evidence

Can the technique of visual inspection of two-dimensional stick and letter diagrams satisfy the general acceptance test? In one case, a federal District Court concluded that "the scientific community cannot . . . agree on the proper methodology used to determine structural similarity."<sup>100</sup> The court added that there is "a lack of consensus [among] experts in the field as to the import of those diagrams . . ."<sup>101</sup> At the polar extreme, another District Court accepted testimony by prosecution witnesses that "a visual assessment was the best method of forming an opinion on structural similarity and is generally accepted in the scientific community."<sup>102</sup>

97 293 F. 1013 (D.C.Cir. 1923).

98 Section 1-5 of this treatise.

99 *Id.*

100 *United States v. Roberts*, 2002 WL 31014834, at \*4 (S.D.N.Y. Sep. 9, 2002).

101 *Id.*

102 *United States v. Brown*, 279 F.Supp.2d 1238, 1244 (S.D.Ala. 2003). There are varying notational conventions. In some systems, the diagram includes a letter representation for each atom; in other systems, hydrogen atoms are sometimes be omitted; and in still others, carbon atoms are omitted by substituting a vertex. Although the International Union of Pure and Applied Chemistry is currently working to develop a single, comprehensive set of guidelines for creating chemical structure diagrams, at present there is no universally accepted set of conventions. Graphical Representation for Chemical

It cannot be overemphasized how little information about chemical structure these diagrams convey, especially to the average person. Perhaps the best analogy is to an artist's drawing of a person. At the simplest level, an artist might draw a rudimentary stick figure—a circle for the head, one line for the body, two other lines for legs, and another two for arms. That type of drawing of a person roughly corresponds to a stick and letter diagram of a molecule. To make the drawing more realistic, the artist might crook the arm and leg lines to depict elbows and knees. The artist could then add a short and pants or a skirt to indicate whether the person is male or female. Further, the artist could make the stick lines for legs proportionally thicker than those for arms. The artist might then progress to a doll and on to a mannequin. Even the mannequin, though, would not depict internal features such as a weak heart or a bad back. Suppose that an artist prepared mannequins of two individuals. Standing alone, would a visual comparison of the mannequins be sufficient to support a judgment as to whether two persons were "substantially similar"? Quite frankly, it would make more sense to do that than to rest a judgment about the similarity of two molecules on a visual comparison of stick and letter diagrams. It is highly doubtful that a professional chemist would accept such a comparison, without more, as an adequate basis for a conclusion that the structure of the two molecules is "substantially similar."<sup>103</sup>

### Opinion Evidence

It is critical to distinguish between mere testimony about the diagram and an opinion, based on a visual inspection of such diagrams, that two substances have a substantially similar chemical structure. No serious chemist would rest such a conclusion based solely on such diagrams. Any chemically literate investigator would realize what an incomplete and crude tool a stick and letter diagram is. Moreover, he or she will appreciate that a thorough investigation would entail the use of more sophisticated tools such as nuclear magnetic resonance (NMR) instruments.<sup>104</sup> Crime laboratories employ NMR instru-

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Structure Diagrams, [www.iupac.org/projects/2003/2003-045-3-800.html](http://www.iupac.org/projects/2003/2003-045-3-800.html).

103 November 22, 2001 Declaration of Boyd E. Haley, Ph.D. (on file with Mr. Anacker)("To represent a house, a person could draw a square with a triangle on top of it. This would be a skeleton type diagram. They could add rectangles to represent windows, doors, steps, etc., representing a stick and letter type diagram. They could also draw a 3D representation of the frame of the house (the studs, joists, rafters, etc.) similar to a rods and balls type drawing. Finally, they could build a model with all the exterior walls—a space-filling type model. However, none of these would represent the actual structure of the house. To know that, one needs to see the blueprint and the specifications for the different materials used in the construction of of the house. For example, the thickness of the concrete with the amount and type of rebar used in the foundation.").

104 *See* the references to NMR in *United States v. Roberts*, 2004 U.S.App.LEXIS 6108 (2d Cir. Apr. 1, 2004) and *United States v. Roberts*, 2002 WL 31014834 (S.D.N.Y. Sep. 9,

ments to determine the identity of unknown substances in Controlled Substance prosecutions.<sup>105</sup> The fairest statement would probably be that while the relevant specialties may generally accept two-dimensional diagrams as a limited tool, they would not have a stick and letter diagram for an unknown and would never accept such diagrams as a sufficient basis for a conclusion as to chemical structure.

### *Tanimoto Coefficients Evidence*

How does the use of Tanimoto Coefficients fare? The use of coefficients for this purpose may be too novel to satisfy the *Frye* standard. In part, the use of coefficients has not yet gained widespread acceptance because of the proprietary nature of drug development;<sup>106</sup> one pharmaceutical company does not want another to easily find similar substances to avoid paying licensing fees on patented drugs. Several government experts have explicitly testified that their specialty does not yet embrace the use of coefficients to determine structural similarity.<sup>107</sup> Even the testimony of some defense experts on this topic has been equivocal.<sup>108</sup> As a consequence, a proponent of testimony based on the coefficients will likely face an uphill battle in a jurisdiction still adhering to the *Frye* test.

#### **b. Expert Testimony Under the Reliability Test**

In modern times, though, the general acceptance standard is not the only test governing the admissibility of purportedly scientific testimony. Indeed, although the *Frye* test originated in federal court, that test is no longer controlling in federal practice. As previously stated, at one point in time *Frye* had been approvingly cited in virtually every federal circuit. However, in 1975, the statutory Federal Rules of Evidence took effect. The question posed was whether the *Frye* decision was still good law. In 1993 in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>109</sup> the Supreme Court answered in the negative.

In *Daubert*, Justice Blackmun authored the lead, majority opinion. That opinion issued two holdings. First, Justice Blackmun announced that the

enactment of the Federal Rules had impliedly superseded *Frye*. Federal Rule of Evidence 402 states that all logically relevant evidence is admissible unless it can be excluded based on the Constitution, federal statute, other provisions of the Federal Rules of Evidence, or other rules adopted pursuant to statutory authority such as the Federal Rules of Civil and Criminal Procedure.<sup>110</sup> In his opinion, Justice Blackmun approvingly quoted a statement by the late Edward Cleary, the Reporter for the committee which drafted the Federal Rules: “In principle under the Federal Rules [of Evidence] no common law of evidence remains.”<sup>111</sup> Justice Blackmun construed Rule 402 as abolishing uncodified exclusionary rules of evidence. Although the general acceptance test enjoyed widespread support prior to the enactment of the Federal Rules, the test was a common-law rule. The general acceptance test was a creature of case law. Justice Blackmun canvassed the Federal Rules and professed that he could not find any statutory language which was subject to the interpretation that it codified the general acceptance test. Absent such statutory language, the test has been overturned when the Federal Rules went into effect in 1975.

Second, Justice Blackmun quickly added that the abolition of the *Frye* test did not signal that any purportedly scientific testimony is admissible willy nilly in federal court. Justice Blackmun turned to Federal Rule 702.<sup>112</sup> That rule provides that to qualify as an expert, a witness must possess “scientific, technical or other specialized knowledge.”<sup>113</sup> Justice Blackmun reasoned that if the possession of such knowledge qualifies the witness as an expert and the witness should confine his or her testimony to the limits of their expertise, the substance of the expert’s testimony must amount to “scientific . . . knowledge.” The problem then became defining that expression. Drawing on several amicus briefs filed by scientific organizations, the Justice adopted an essentially methodological definition of the expression.<sup>114</sup> Justice Blackmun described the methodology in classic Baconian terms: formulating an hypothesis and then engaging in systematic observation or experimentation to either falsify or validate the hypothesis.<sup>115</sup> When the proponent of expert testimony can show that the expert has validated the theory or technique by sound scientific methodology, the testimony is admissible even if the technique is novel or the theory controversial. The Justice then listed several factors which trial judges may consider in deciding whether the expert’s major premise rests on solid scientific validation: whether the hypothesis is testable,

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2002), judgment vacated, 363 F.3d 118 (2d Cir. 2004).

105 Section 23-3(B) of this treatise.

106 *United States v. Brown*, 279 F.Supp.2d 1238, 1249-50 (S.D.Ala. 2003) (“Dr. Steele conceded that he did not know the parameters of the relevant software beyond the guess that it probably used some variation of the Tanimoto coefficient along with other factors. He admitted that he did know what the other factors might be because the parameters of the software were ‘proprietary’ information”). The other factor was Unity 2D fingerprints.

107 *United States v. Brown*, 415 F.3d 1257, 1263 (11th Cir. 2005).

108 *United States v. Brown*, 279 F.Supp.2d 1238, 1250 (S.D.Ala. 2003).

109 509 U.S. 579 (1993).

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110 Fed.R.Evid. 402, 28 U.S.C.A..

111 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993).

112 Fed.R.Evid. 702, 28 U.S.C.A..

113 *Id.*

114 Imwinkelried, *The Daubert Decision: Frye Is Dead, Long Live the Federal Rules of Evidence*, 29 TRIAL 60, 62-63 (Sep. 1993).

115 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590, 593 (1993).

whether it has been tested, whether the technique has a known or ascertainable margin of error, whether there are recognized standards for applying the technique, whether the theory has been subjected to peer review and publication, and whether the theory has gained general acceptance.<sup>116</sup> While general acceptance is no longer a sine qua non for admissibility as it was under *Frye*, it survives as a relevant factor because it can be circumstantial evidence of the soundness of the underlying methodology. If a theory has been in circulation long enough to have garnered such widespread acceptance, presumably a number of other scientists have examined the supporting research and found it to be methodologically sound. If, after applying these factors, the trial judge finds the methodology sound, the testimony amounts to admissible, reliable “scientific . . . knowledge” within the meaning of that expression in Rule 702.

Can any of the three types of expert testimony proffered in CSAEA cases satisfy this admissibility standard? Here again it is vital to distinguish mere testimony describing stick and letter diagrams from an opinion, based solely or primarily on an analysis of such diagrams, that the two substances have a substantially similar chemical structure.

### *Diagram evidence*

Initially, consider the theory that a chemist could determine whether two molecules are substantially similar simply by comparing the stick and letter diagrams for the molecules. Under *Daubert*, the question is the empirical validity of stick and letter diagrams as depictions of some features of the chemical structure of molecules. Some diagrams might be valid while others might be found wanting. For example, suppose an expert proffered a diagram showing a molecule having a structure like a “C” indicating that the ends have a strong attraction to each other, but empirical research demonstrates that the molecule actually has ends that are only slightly attracted to each other, the diagram is obviously worthless as evidence. If a particular diagram for a certain molecule has been used as a convention in chemistry for decades, the odds are that it has some empirical validity as a partial representation of selected features of the molecule’s structure. However, there may be more recent gas chromatography/mass spectrometry (GC/MS)<sup>117</sup> and nuclear magnetic resonance (NMR)<sup>118</sup> experiments showing that various features of a molecule have been omitted in the extremely limited data represented by the conventional stick and letter notations.<sup>119</sup> If the opponent can show that such

116 *Id.* at 593-94.

117 Section 23-3(C) of this treatise.

118 *Id.* at § 23-3(B).

119 Of course, if a lay trier of fact is attempting to determine similarity based on a simplistic comparison of the diagrams, without additional expert testimony the lay juror will not

experimental verification shows the omission of those features in a particular two-dimensional diagram, the trial judge might altogether preclude the expert from relying on the diagram even though it is a long accepted convention in chemistry. And, again, as emphasized during the discussion of the general acceptance test for admissibility, these diagrams convey very little information about the chemical structure of the molecules depicted.

### *Opinion Evidence*

An opinion as to substantial similarity, based primarily on a review of stick and letter diagrams, is certainly problematic. To justify such an opinion, the proponent must validate that a chemist can determine if two molecules are substantially similar by comparing stick and letter diagrams for the molecules. Assume government experts, in the past, were correct in testifying “a visual assessment . . . is generally accepted in the scientific community.”<sup>120</sup> Even on that assumption, under *Daubert* it will be a challenge to rationalize admitting an expert’s testimony that the visual comparison technique is reliable enough to allow an expert to determine, on that basis alone, that two molecules are substantially similar.

To begin with, as previously stated, “substantial 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 Justice Blackmun’s threshold criterion for reliable “scientific . . . knowledge”: There is no way to test the proposition empirically.

Putting that problem aside, a showing of general acceptance may not be enough to guarantee the admission of the testimony under *Daubert*. To be sure, Justice Blackmun listed general acceptance as one of the pertinent factors in his opinion. Indeed, in the early lower court cases applying *Daubert*, the courts attached a good deal of importance to that factor.<sup>121</sup> However, that factor is no longer dispositive. In footnote 11 in his opinion, Justice Blackmun stated that one of the principal differences between the traditional *Frye* standard and the newly minted reliability test was that the former applies only to “novel” scientific theories and techniques.<sup>122</sup> The lower courts have read that statement as a pronouncement that even traditional scientific theories and

even know which features have been omitted.

120 *United States v. Brown*, 279 F.Supp.2d 1238, 1244 (S.D.Ala. 2003).

121 *Dixon & Gill, Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision*, 8 PSYCH., PUB. POLY & L. 251, 284-87 (2002).

122 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993).

techniques must run the gauntlet of the reliability standard.<sup>123</sup> For instance, in light of footnote 11, the courts have permitted defense counsel to relitigate the admissibility of such conventional forensic science techniques as questioned document examination.<sup>124</sup> One court even took the position that fingerprint analysis did not qualify as reliable “scientific . . . knowledge” and that a fingerprint examiner should not be permitted to opine on the ultimate question of whether a fingerprint impression could be attributed to a particular person.<sup>125</sup> That court ultimately relented and permitted the receipt of an opinion on the ultimate question, but the court made it clear that it was admitting the testimony only as non-scientific expertise.<sup>126</sup> Hence, even positing the accuracy of the government experts’ characterization of a visual comparison as generally accepted, the technique is not immune from attack under *Daubert*.

Further, even when there is such experimentation, the trial judge could well block the expert’s attempt to rest an opinion solely on the comparison of stick and letter diagrams. Under *Daubert*, The degree of allowable definiteness of the expert’s final opinion should vary with the reliability foundation laid by the expert’s proponent. Assume, for example, that an epidemiologist is prepared to testify only that a person’s exposure to a certain pesticide increases or enhances the person’s risk of contracting a particular illness. Some courts would allow the epidemiologist to testify to that opinion so long as the supporting epidemiological study found a relative risk (“RR”) exceeding 1.0. Alternatively, suppose that the expert wanted to express the more definite opinion that it is probable that exposure to the pesticide can cause the illness. In that event, many courts would rule the same foundation inadequate; they reason that only a study finding an RR greater than 2.0 justifies an opinion couched as a probability.<sup>127</sup>

Assume *arguendo* that in CSAE cases involving a stick and letter diagram, the court allows an expert to testify that in assessing the degree of similarity between the chemical structure of two molecules, an expert would at least consider such diagrams. It is quite another matter to permit the expert to take the next step and testify flatly that standing alone, such a comparison enables a chemist to determine whether two substances are substantially similar. As

123 Giannelli & Imwinkelried, *Scientific Evidence: The Fallout from Supreme Court’s Decision in Kumho Tires*, 14 CRIM.JUST. 12 (Wint. 2000).

124 *United States v. Starzecpyzel*, 880 F.Supp. 1027 (S.D.N.Y. 1995).

125 *United States v. Llera Plaza*, 179 F.Supp.2d 492 (E.D.Pa. 2002).

126 *United States v. Llera Plaza*, 188 F.Supp.2d 549 (E.D.Pa. 2002). The significance of classifying the testimony as non-scientific expertise is that the trial judge might give the jury a cautionary instruction, informing the jury of that classification and cautioning the jury against overvaluing the testimony. Judge McKenna stated that he would administer such an instruction in *United States v. Starzecpyzel*, 880 F.Supp. 1027 (S.D.N.Y. 1995).

127 Imwinkelried, *The Relativity of Reliability*, 34 SETON H. L.REV. 269, 277-78 (2003).

we have seen, stick and letter diagrams omit data indicating the relative atomic weight of the component atoms; and they are unrealistic in the sense that they furnish no information at all about the third dimension of reality or about atomic angles, resonance, spin, bond type, and bond strength. In short, even if the prosecution can lay a foundation permitting an expert to opine that an expert would consider a particular stick and letter diagram in making the determination, the degree of certitude of the opinion expressed ought to be severely circumscribed.

In particular, suppose that based exclusively or largely on an analysis of stick and letter diagrams, a prosecution expert were prepared to opine to a “reasonable degree of scientific probability” that two substances have substantially similar chemical structures. It is true that in *Daubert*, Justice Blackmun cautioned against confusing admissibility and legal sufficiency.<sup>128</sup> However, that distinction begins to blur when the expert opines directly on the ultimate issue. By way of example, in 1997 in *Joiner*,<sup>129</sup> the plaintiff’s experts tendered opinions on the ultimate issue of causation and couched their opinions as expressions of probability. The Supreme Court therefore inquired whether the foundational data cited by the experts were adequate to justify the specific opinions that the experts proffered.<sup>130</sup> The Court found the data to be insufficient. As amended in 2000, Federal Rule of Evidence 702 now expressly provides that the proponent must demonstrate that the expert’s opinion “is based upon sufficient facts or data . . . .” Stick and letter diagrams are such incomplete depictions of substances and the comparison of such diagrams is so subjective that there is a strong case that those opinion do not pass muster under *Daubert*.

### *Tanimoto Coefficients Evidence*

Alternatively, would testimony based on Tanimoto Coefficients satisfy *Daubert*? A judge might well find that Tanimoto Coefficient computations do not as yet enjoy the same degree of general acceptance as the use of stick and letter diagrams. However, general acceptance is only one consideration, not a litmus test, under *Daubert*. If such computations rest on sufficiently extensive, sound validation, they are admissible in a *Daubert* jurisdiction.<sup>131</sup>

How should the trial judge go about assessing the extent of the validation? For one thing, the judge should not generalize about all such computations.

128 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993).

129 *General Electric Co. v. Joiner*, 522 U.S. 137 (1997).

130 *Id.* at 144.

131 As previously stated, another factor mentioned in Justice Blackmun’s opinion is whether the literature describing the theory or technique has been peer reviewed. *E.g.*, Patterson, Cramer, Ferguson, Clark & Weinburger, *Neighborhood Behavior: A Useful Concept for Validation of “Molecular Diversity” Descriptors*, 39 J. MED.CHEM. 3049 (1996).

Each computation compares two fingerprints. As previously stated, each fingerprint is a string of bits or information as to whether the molecule possesses certain structural features. To persuade the trial judge, the proponent must establish the reliability of two propositions. First, the proponent must establish that the particular fingerprints being compared have been validated at least in the sense that there is hard data indicating that the molecule in question possess those features. The proponent can marshal testimony about GC/MS and NMR research to establish that proposition. Second, the proponent must convince the judge that the structural features selected are relevant in CSAE litigation. An imaginative chemist can go to great lengths in dissecting the structure of any molecule and choose many different structural features. The issue is whether ascertaining the presence of those features makes a meaningful contribution to the determination of whether one molecule is “substantially similar” in “chemical structure” to the other. Why were those specific structural features selected? To answer that question, the proponent might present foundational testimony as to why the chosen features play a role in determining chemical structure. If such testimony were available, the *Daubert* foundation would suffice to permit the expert to testify at least that the Tanimoto Coefficient computation should be considered in deciding whether the two molecules have substantially similar chemical structure.

#### IV. Conclusion.

The purpose of this article has been to critique the admissibility of evidence of “substantially similar” chemical structure in CSAE cases. It is important to delimit that topic.

To begin with, the article does not even touch upon the question of the admissibility of evidence of effects on the central nervous system. Under 21 U.S.C. § 802(32)(A)(ii), the second prong of the statutory definition of an analogue is a showing the substance has “a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or *greater than* the stimulant, depressant, or hallucinogenic effect on the central system of a controlled substance in schedule I or II.” There is a question whether there is a technique for measuring such effects that would pass muster under *Frye* or *Daubert*. There is a dearth of research on this subject. A Chicago company, Miicro, Inc., is endeavoring to devise a new methodology for attempting to quantify these effects.<sup>132</sup> However, it is far from clear that any available evidence on this issue would satisfy either of the major admissibility tests.

Likewise, this article focuses exclusively on the question of admissibility

<sup>132</sup> See [www.miicro.com](http://www.miicro.com).

and does not undertake a discussion of permissible methods of attacking prosecution evidence of similarity of chemical structure. Even after a trial judge rules prosecution evidence admissible, under the Sixth Amendment the accused has a constitutional right to challenge the weight of the testimony.<sup>133</sup> Suppose, for example, the prosecution relies heavily on the superficial similarity between stick and letter diagrams of features of a Controlled Substance and an alleged CSAEA analogue. The defense has a strong argument that it should be entitled to attack that evidence by introducing similar diagrams of clearly lawful substances such as dietary supplements and arguing that those diagrams are even more similar to that of the scheduled Controlled Substance. Likewise, the defense should be allowed to expose the subjectivity of an expert’s evaluation of the degree of similarity between such diagrams.<sup>134</sup>

Further, this article has confined its analysis to the statutory and common-law questions of admissibility of evidence. The article has not directly addressed the substantial constitutional question of the vagueness of the statute as applied. Admittedly, “[t]he circuit courts considering this issue have unanimously held that the CSAEA is not unconstitutionally vague.”<sup>135</sup> However, in well reasoned opinions, a number of District Courts have reached the contrary conclusion.<sup>136</sup> To an important degree, the constitutional question will turn on the final interpretation of the CSAEA. To the extent that the CSAEA is construed as making the determination of similar chemical structure dependent on factors that only experts can critically evaluate, it will be more difficult for average citizens to determine the legality of their conduct before a trial of charges against them. In the words of one federal District Court judge,

even if the diagrams . . . were made available to a layperson, the lack of consensus by experts in the field as to the import of those diagrams demonstrates that they could not provide such a person with the degree of notice sufficient to know whether their conduct would be prohibited by the Analogue Statute.<sup>137</sup>

A person of “common intelligence must necessarily guess at” the applicability

<sup>133</sup> *Crane v. Kentucky*, 476 U.S. 683 (1986). See also *Holmes v. South Carolina*, 126 S.Ct. 1727, 164 L.Ed.2d 503 (2006).

<sup>134</sup> E. IMWINKELRIED, *THE METHODS OF ATTACKING SCIENTIFIC EVIDENCE* § 13-11 (4th ed. 2004).

<sup>135</sup> *United States v. Turcotte*, 405 F.3d 515, 531 (7th Cir. 2005). See also *United States v. Roberts*, 2004 U.S.App.LEXIS 6108 (2d Cir. 2004).

<sup>136</sup> *E.g.*, *United States v. Roberts*, 2002 WL 31014834 (S.D.N.Y. 2002); *United States v. Forbes*, 806 F.Supp.2d 232 (D.Colo. 1992).

<sup>137</sup> *United States v. Roberts*, 2002 WL 31014834 (S.D.N.Y. 2002).

of the CSAEA.<sup>138</sup> The Supreme Court has yet to pass on a void-for-vagueness challenge to the CSAEA.

In the short term, it would be worthwhile for the courts to investigate the possibility of employing expert masters and court-appointed experts in CSAEA cases to help make the determination of whether a particular substance constitutes a CSAEA analogue to a scheduled substance. Acting as a master, a chemist (or neuropharmacologist for CNS effects) could evaluate the parties' submissions much more knowledgeably than the typical judge. Federal Rule of Evidence 706 governs the court appointment of experts, and by its terms it explicitly applies in criminal cases.<sup>139</sup> For its part, Federal Rule of Civil Procedure 53 controls the appointment of masters. On its face, it is limited to civil actions.<sup>140</sup> However, the courts could conceivably adapt the procedure by analogy in CSAEA prosecutions.

As the introduction to this article suggested, though, in the long-term the best solution would be either (1) a judicial interpretation of the CSAEA as requiring the Attorney General to list CSAEA analogues after following the same sort of procedures employed to add substances to Schedule I or II, although using only the criteria stated in the CSAEA, or (2) a Congressional amendment of the CSAEA to mandate that procedure. In either event, the CSAEA would be treated as establishing criteria that the Attorney General would utilize in a hearing governed by the Administrative Procedure Act; and the Attorney General's determination would be published in the Federal Register.<sup>141</sup> This would give notice to the public. Under well-settled interpretive doctrine of constitutional avoidance,<sup>142</sup> if a statute is subject to two interpretations—one which raises substantial doubts about its constitutionality and another which moots those doubts—the courts prefer the latter interpretation.<sup>143</sup>

138 *United States v. Forbes*, 806 F.Supp.2d 232, 236 (D.Colo. 1992), quoting *Connally v. General Const. Co.*, 269 U.S. 385, 391 (1926).

139 Fed.R.Evid. 706(b), 28 U.S.C.A..

140 Fed.R.Civ.P. 53, 28 U.S.C.A..

141 Indeed, 21 U.S.C. § 802(23) does not explicitly state it is to be used as a basis for criminal prosecution. Further, the provision is included under a section entitled "Definitions." As a definition, it could be used by experts in an administrative hearing to determine whether or not a substance is a CSAEA analogue.

142 *Clark v. Martinez*, 543 U.S. 371 (2005); *United States v. Johnson*, 437 F.3d 157 (1st Cir. 2006); *Artichoke Joe's Calif. Grand Casino v. Norton*, 353 F.3d 712, 730 (9th Cir. 2003).

143 *United States v. Rumely*, 345 U.S. 41, 45 (1953); *Crowell v. Benson*, 285 U.S. 22, 62 (1932)(a "cardinal principle"); *Hooper v. California*, 155 U.S. 648, 657 (1895)(an "elementary rule"); *United States v. Vargas-Amaya*, 389 F.3d 901 (9th Cir. 2004); *United States v. A.D.*, 28 F.3d 1353, 1359 (3d Cir. 1994); *United States v. Harvey*, 814 F.2d 905, 917 (4th Cir. 1987); *United States v. Arias*, 409 F.Supp.2d 281, 299 (S.D.N.Y. 2005); *State of Georgia v. Westlake*, 929 F.Supp. 1516 (M.D.Ga. 1996).

It remains to be seen whether the courts will adopt such an interpretation, in order to moot the constitutional issue. The courts certainly do not have license to disingenuously<sup>144</sup> rewrite<sup>145</sup> a statute under the guise of interpretation. If the courts conclude that they cannot legitimately interpret the CSAEA to require listing of CSAEA analogues by the Attorney General, Congress should intervene. Congress ought to revisit the CSAEA to better ensure the CSAEA makes scientific sense while simultaneously providing fair notice to innocent citizens subject to the CSAEA.

144 *Initiative and Referendum v. U.S. Postal Service*, 417 F.3d 1299 (D.C.Cir. 2005).

145 *National Abortion Federation v. Gonzales*, 437 F.3d 278, 289 (2d Cir. 2006); *Planned Parenthood Federation of America v. Gonzales*, 435 F.3d 1163 (9th Cir. 2006).



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