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2014 WL 3764876

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United States District Court,
N.D. Texas,
Dallas Division.

UNITED STATES of America, Plaintiff,

v.

Barry BAYS (2), Defendant.

Criminal Action No. 3:13-CR-0357-B.

|

Signed July 31, 2014.

Attorneys and Law Firms

Brian Poe, US Attorney's Office, Dallas, TX, for Plaintiff.

MEMORANDUM OPINION AND ORDER

[JANE J. BOYLE](#), District Judge.

*1 Before the Court are Defendant Barry Bays's Motion to Exclude **Testimony** of Plaintiff's **Expert** Jordan Trecki, Ph.D. ("Dr.Trecki") and Motion to Exclude Plaintiff's Expert Michael L. Van Linn, Ph.D. ("Dr. Van Linn") (docs.177, 178), both filed on April 1, 2014. For the reasons described in this order, the Court **DENIES** these motions.

I.

FACTUAL BACKGROUND

This case arises out of an alleged conspiracy to manufacture and distribute synthetic cannabis products across the country. On August 23, 2013, a complaint was filed against Defendant Barry Bays alleging violations of [21 U.S.C. §§ 841](#) and [846](#). Doc. 1, Compl. A federal grand jury returned a one-count indictment against Defendants Barry Bays, Samuel Madeley, and David Muise on September 17, 2013, charging the defendants with violating [21 U.S.C. § 846](#) (Conspiracy to Distribute a Controlled Substance Analogue). Doc. 13, Indictment 1. On January 23, 2014,

Bays and five other defendants were named in a multi-count superseding indictment charging violations of [21 U.S.C. § 846](#) (Conspiracy to Distribute a Controlled Substance Analogue). Doc. 117, Second Sup. Indictment 1–2. The superseding indictment also separately charged Bays with violating [18 U.S.C. §§ 924\(c\)\(1\)\(A\)](#) and [\(c\)\(2\)](#) (Possession of a Firearm in Furtherance of a Drug Trafficking Crime) and [21 U.S.C. § 843\(b\)](#) (Using a Communication Facility to Facilitate a Drug Felony). *Id.*

On April 1, 2014, Defendant Bays filed both the Motion to Exclude Dr. Trecki (doc. 177), and the Motion to Exclude Dr. Van Linn (doc 178). Defendant Bays argues that under [Federal Rules of Evidence 104, 702, and 703](#) and [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), [509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 \(1993\)](#), the opinions of Dr. Van Linn and Dr. Trecki should be excluded to the extent that they opine on the substantial similarity of the four chemical substances identified in the Second Superseding Indictment to schedule I synthetic cannabinoids.¹ Second Sup. Indictment 1–2; Def.'s Mot. to Excl. Trecki 1; Def.'s Mot. to Excl. Van Linn 1.

II.

LEGAL STANDARD

[Rule 702 of the Federal Rules of Evidence](#) provides for the **testimony** at trial of an "**expert** by knowledge, skill, experience, training, or education," if such **testimony** "will assist the trier of fact to understand the evidence or to determine a fact in issue." [Fed.R.Evid. 702](#). Accordingly, the Court acts as a "gatekeeper" that "may admit proffered **expert testimony** only if the proponent, who bears the burden of proof, demonstrates that (1) the expert is qualified, (2) the evidence is relevant to the suit, and (3) the evidence is reliable." [Nunn v. State Farm Mut. Auto. Ins. Co.](#), No. 3:08-CV-1486-D, 2010 WL 2540754, at *2 (N.D. June 22, Tex.2010) (citing [Kumho Tire Co. v. Carmichael](#), [526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 \(1999\)](#)).

Whether an expert is qualified to testify is a question of law. [Mathis v. Exxon Corp.](#), [302 F.3d 448, 459 \(5th Cir.2002\)](#) (citing [Fed.R.Evid. 104\(a\)](#)). As such, "[b]efore a district court may allow a **witness** to testify as an **expert**, it must be assured that the proffered **witness** is qualified to testify by virtue of his knowledge, skill, experience, training, or education!" [Nunn](#), 2010 WL 2540754, at *2 (quoting [United](#)

States v. Cooks, 589 F.3d 173, 179 (5th Cir.2009) (internal quotation marks omitted). However, “Rule 702 does not mandate that an expert be highly qualified in order to testify about a given issue.” *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir.2009). Instead, “[d]ifferences in expertise bear chiefly on the weight to be assigned to the testimony by the trier of fact, not its admissibility.” *Id.*; see also *Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”).

*2 “Evidence is relevant if ‘it has any tendency to make any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.’” *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 882 (5th Cir.2013) (quoting Fed.R.Evid. 401(a)). Said differently, **expert testimony** is relevant when the **expert's** “reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 593. Conversely, “[e]xpert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Id.* at 591.

Evidence is reliable if “‘the reasoning or methodology underlying the testimony is scientifically valid.’” *Knight v. Kirby Inland Marine, Inc.*, 482 F.3d 347, 352 (5th Cir.2007) (quoting *Daubert*, 509 U.S. at 593). To determine whether the methodology employed by an expert is scientifically valid, the Court considers five non-exclusive factors: “1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; 2) whether the technique or theory has been subject to peer review and publication; 3) the known or potential rate of error of the technique or theory when applied; 4) the existence and maintenance of standards and controls; and 5) whether the technique or theory has been generally accepted in the scientific community.” *Florer v. Elec. Data Sys. Corp.*, No. 303CV1175H, 2004 WL 1562851, at *3 (N.D.Tex. July 13, 2004).

To be sure, the reliability test is a flexible one that grants district courts wide discretion, and *Daubert*'s dictates apply “not only to testimony based on ‘scientific’ knowledge, but also to testimony based on ‘technical’ and ‘other specialized’ knowledge.” *Kumho Tire*, 526 U.S. at 141. Reliability does not mean certainty, but more than speculation is required. *Nunn*, 2010 WL 2540754, at *2 (citing *Daubert*, 509 U.S.

at 590). Correspondingly, a court may consider one or more of the *Daubert* factors, as well as other factors “‘relevant to the case at hand,’” in determining the reliability of proffered testimony *Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (5th Cir.2009) (quoting *Black v. Food Lion Inc.*, 171 F.3d 308, 312 (5th Cir.1999)); see *Kumho Tire*, 526 U.S. at 138 (“A trial judge determining the admissibility of an ... **expert's testimony** may consider one or more of the specific *Daubert* factors.”).

III.

ANALYSIS

The Defendant's Motions to Exclude **Expert Testimony** are considered within the context of the Controlled Substance Analogue Enforcement Act of 1986 (“CSAEA”), which “Congress enacted ... to keep up with rapidly progressing drug technologies and to target the distribution of so-called ‘designer drugs.’” *United State v. Nasir*; No. 5:12-CR-102-JMH, 2013 WL5373619, at *1 (E.D.Ky. Sept. 25, 2013) (citing *United States v. Washam*, 312 F.3d 926, 933 (8th Cir.2002)); 21 U.S.C. § 813. DEA has concluded that each of the substances at issue-AM2201, 5F-PB-22, PB-22, and 5F-UR-244 (a .k.a.XLR11)-is a schedule I controlled substance or controlled substance analogue. 21 C.F.R. § 1308.11(g)-(h); Doc. 184, Pl.'s Resp. 2. A controlled substance analogue is a substance:

- *3 (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 or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
- (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

21 U.S.C. § 802(32)(A). In short, a chemical substance must be “substantially similar” to a controlled substance in schedule I or II. Defendant notes that “‘substantially similar’

is not a scientific concept,' " and that "the analogue act does not indicate that the term 'substantially similar' is to be defined in any scientific sense." Def.'s Mot. to Excl. Trecki 2–3 (quoting Anacker & Imwinkelried, *Controlled Substance Analogue Enforcement Act Criminal Defense*, 37 SW. U.L. REV. 267, 295 (2008) (internal quotation marks omitted).

The Court agrees. Indeed, "there is no indication that Congress intended the words 'substantially similar' to have a specialized or scientific meaning." *United States v. Reece*, No. 12-00146, 2013 WL 3865067, at *9 (W.D.La. July 24, 2013). "Therefore, these words should be given their ordinary meanings." *Id.*; see also *United States v. Brown*, 279 F.Supp.2d 1238, 1240–41 (S.D.Ala.2003), aff'd 415 F.3d 1257 (11th Cir.2005) ("Since the Analogue Act does not indicate that the term 'substantially similar' is to be defined as it is used scientifically, the court will interpret those words as they are used in everyday language."). Under this construct, "substantially similar" is read "as having 'essential elements in common.'" *Alemeda Mall, L.P. v. Shoe Show, Inc.*, 649 F.3d 389, 392 (5th Cir.2011) (citing Random House Webster's College Dictionary (2d ed.1999)) (defining "substantially similar" in a trade-name dispute). Accordingly, Defendant asserts that Dr. Van Linn and Dr. Trecki are unfit to testify as to whether AM2201, PB–22, and 5F–UR–144 (a.k.a.XLR11) have essential elements in common with JWH–018, and whether 5F–PB–22 has essential elements in common with AM2201. Def.'s Mot. to Excl. Trecki; Def.'s Mot. to Excl. Van Linn.

A. Van Linn

1. Qualifications

Defendant first complains that Dr. Van Linn, due to his embrace of flawed methodologies, is unqualified to offer **expert testimony**. Doc. 190, Def.'s Reply 2.

The Government, in contrast, offers an extensive list of accomplishments to showcase Dr. Van Linn's pedigree: employment as a forensic chemist in DEA's Office of Diversion Control (ODE), Drug and Chemical Evaluation Section, since September 2013; previous work as a forensic chemist with DEA's North Central Laboratory in Chicago, Illinois, and as a research scientist at Cambridge Major Laboratories in Germantown, Wisconsin; and numerous past positions in academia, including a post-doctoral fellowship. Pl.'s Resp. 4. In addition, Dr. Van Linn is the co-author almost twenty peer-reviewed articles and has received awards for outstanding work. *Id.*

*4 Defendant's contention that Dr. Van Linn's methods somehow render him unqualified to testify as an **expert** is misguided. As previously noted, an **expert witness** may be qualified based upon his "knowledge, skill, experience, training, or education." Fed.R.Evid. 702. Absent from the list of qualifying factors is subscription to any certain methodology or principle, which is instead considered by the reliability prong. Fed.R.Evid. 702(c); see also *Knight*, 482 F.3d at 352. While an expert's qualifications and the reliability of his methodology may be related, they are not dependent upon one another. *Engenium Solutions, Inc. v. Symphonic Technologies, Inc.*, 924 F.Supp.2d 757, 770–71 (S.D.Tex.2013) (finding **experts** qualified but subsequently excluding their **testimony** after considering their methodology under the reliability prong). Qualified experts sometimes employ unreliable methods and unqualified experts sometimes employ reliable methods.

Here, Dr. Van Linn's methodology does not diminish his qualification as an expert. Dr. Van Linn's advanced degree, work history as a forensic chemist, and previous experience in academia leave the Court little doubt that he has "specialized knowledge [that] will help the trier of fact to understand the evidence," and is therefore qualified under the factors set out by Rule 702 to testify as an **expert witness**. Fed.R.Evid. 702(a).

2. Relevance

Defendant next attacks the relevance of Dr. Van Linn's testimony under **Federal Rules of Evidence 702** and **402**. Def.'s Reply 2. Dr. Van Linn's opinion is irrelevant, Defendant contends, because the Government failed to provide any evidence of the sound chemistry required to determine substantial similarity. *Id.*

In response, the Government argues that Dr. Van Linn applied sound methods and principles to the facts of the case while analyzing the degree of similarity between: (1) AM2201, PB–22, and 5F–UR–144 (a.k.a.XLR11)and JWH–018; and (2) 5F–PB–22 and AM2201. Pl.'s Resp. 4. More specifically, Dr. Van Linn correctly relied on two-dimensional renderings and knowledge obtained from reviewing current scientific literature and chemistry information to compare the structural components of each substance, the chemical class of the substances by determining their core structure, and the differences between each substance. *Id.*

a. Federal Rule of Evidence 702

As stated above, **expert testimony** is relevant when the **expert's** “reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 593. Here, the facts in issue turn on the question of substantial similarity. See, e.g., *United States v. Bamberg*, 478 F.3d 934, 939 (8th Cir.2007); *Brown*, 415 F.3d at 1264; *Reece*, 2013 WL 3865067, at *5 n. 21. The Fifth Circuit has explained “that drugs which have been chemically designed to be similar to controlled substances, but which are not themselves listed on the controlled substances schedules, will nonetheless be considered as schedule I substances” if they meet the substantial similarity requirements set forth in § 802(32)(A). *United States v. Granberry*, 916 F.2d 1008, 1010 (5th Cir.1990). There is some question, however, as to what those requirements are.

*5 As the old adage instructs, the devil is in the details—the relevant detail here being the single word “or” between clauses (ii) and (iii) of the definition. There are two possible readings of the definition. Under a disjunctive reading, a substance that satisfies *any one* of the[] three criteria qualifies as a controlled substance analogue. Under a conjunctive reading, the provision requires two things: (1) [t]he substance in question must have a chemical structure substantially similar to a controlled substance (criterion one) *and* (2) it must *either* have a substantially similar [or greater] effect on the central nervous system (criterion two) *or* be purported or intended to have such an effect (criterion three).

United States v. Turcotte, 405 F.3d 515, 521 (7th Cir.2005). Defendant correctly notes that a majority of courts interpret the elements of § 802(32)(A) conjunctively, as opposed to disjunctively.² Def.'s Mot. to Excl. Van Linn 2 n. 3; *see also Reece*, 2013 WL 3865067, at *7 n. 31.³ The manner in which the Government presents its experts suggests that it, too, endorses a conjunctive interpretation. *See* Pl.'s Resp. 3–7. The Fifth Circuit also seems to favor a conjunctive reading and, although it “has not yet expressly weighed on which method of interpretation should be employed ..., [it has] paraphrased the definition in a way that is consistent with a conjunctive interpretation ... [and can be read] as implicitly adopting a conjunctive reading of the statute.” *Reece*, 2013 WL 3865067, at *7 (citing *Granberry*, 916 F.2d at 1010).

While the Court tends to agree that a conjunctive reading is preferable, such determination is unnecessary to reach a decision on relevancy. Here, it is quite clear that Dr. Van

Linn's reasoning and methodology can properly be applied to the facts in issue. Satisfaction of the chemical structure criterion of § 802(32)(A) is sufficient for substantial similarity under a disjunctive reading and necessary for substantial similarity under a conjunctive reading. *See Turcotte*, 405 F.3d at 521. In other words, an expert's opinion on chemistry directly relates to an integral issue on the case: whether the chemical structure of the compounds identified in the Second and Third Superseding Indictments is substantially similar to that of schedule I synthetic cannabinoids. Accordingly, Dr. Van Linn, a chemist, is anticipated to offer testimony that will “assist the trier of fact to understand the evidence or to determine a fact in issue.” *Daubert*, 509 U.S. at 589; Pl.'s Resp. 3–5. The Court therefore concludes that the expert opinion of Dr. Van Linn is relevant under the standards set forth by *Federal Rule of Evidence 702* and *Daubert*.

b. Federal Rule of Evidence 402

Defendant also asserts that the testimony of Dr. Van Linn should be excluded as irrelevant pursuant to *Federal Rule of Evidence Rule 402*. Def.'s Reply 2.

Rule 402 functions as a liberal, baseline standard of relevance for all **testimony**, not just that of **experts**, and is less rigorous than *Rule 702* and *Daubert*. 509 U.S. at 587. Under *Rule 402*, relevant evidence “is admissible unless otherwise provided by federal statutory or constitutional law, the Federal Rules of Evidence, or ‘other rules prescribed by the Supreme Court pursuant to statutory authority.’” *United States v. Perez-Solis*, 709 F.3d 453, 464 (5th Cir.2013) (citing *Fed.R.Evid. 402*). This standard grants district courts “broad discretion in ruling on questions of relevancy.” *United States v. Waldrip*, 981 F.2d 799, 806 (5th Cir.1993). “The burden is on the party opposed to admission of evidence to show a reason for its exclusion.” *United States v. D.K.G. Appaloosas, Inc.*, 630 F.Supp. 1540, 1562 (E.D.Tex.1986).

*6 As previously discussed, the expert opinion of Dr. Van Linn is relevant under the standard set forth in *Rule 702*. Testimony that is relevant under the high bar set by *Rule 702*'s expert standard is also relevant under the lower bar set by *Rule 402*'s baseline standard. *See Bocanegra v. Vicmar Servs., Inc.*, 320 F.3d 581, 584 (5th Cir.2003) (“The **expert testimony** must be relevant, not simply in the sense that all testimony must be relevant [under] *Fed.R.Evid. 402*, but also in the sense that the expert's proposed opinion would assist the trier of fact to understand or determine a fact in issue.”). Further, Defendant failed to identify any authority that might preclude Dr. Van Linn from offering testimony.

More precisely, Defendant cited to no authority whatsoever. Instead, Defendant offered only conclusory allegations of irrelevancy in support of his argument for exclusion. Def.'s Reply 2. The Court therefore determines that Defendant failed to satisfy his burden, and consequently concludes that Dr. Van Linn's testimony is relevant under Rule 402.

3. Reliability

Defendant next turns to the reliability of Dr. Van Linn's expected testimony, which is as follows:

1. In comparing the chemical structures for 5F-PB-22 and AM2201, the difference in chemical structures is minor and insignificant given that it consists of only a single atom substitution and an addition of a single atom. Therefore, 5F-PB-22 is substantially similar in chemical structure to AM2201, a schedule I controlled substance.⁴
 2. In comparing the chemical structures for AM2201 and JWH-018, the difference in chemical structure is minor and insignificant given that it consists of only a single atom substitution. Therefore, AM2201 is substantially similar in chemical structure to JWH-018, a schedule I controlled substance.
 3. In comparing the chemical structures for PB-22 and JWH-018, the difference in chemical structure is minor and insignificant given that it consists only of a single atom substitution and an addition of a single atom. Therefore, PB-22 is substantially similar in chemical structure to JWH-018, a schedule I controlled substance.
 4. In comparing the chemical structures for 5F-UR-144 (a.k.a.XLR11) and JWH-018, the difference in chemical structure is minor and insignificant given that it consists only of a change in the peripheral ring system and a single atom substitution. Therefore, 5F-UR-144 (a.k.a.XLR11) is substantially similar in chemical structure to JWH-018, a schedule I controlled substance.
- Def.'s Mot. to Excl. Van Linn, Exs. 1–4.

a. Idiosyncratic Comparison Under An Unscientific Standard

Defendant first contends that Dr. Van Linn's testimony, purportedly based on a review of current scientific literature and chemistry information, constitutes mere idiosyncratic comparison instead of scientific opinion. Def.'s Mot. to Excl. Van Linn 5–6. Dr. Van Linn's opinion is unreliable inconsistent, Defendant says, because he finds

different chemicals substantially similar for different reasons. Defendant goes on to posit that, even if Dr. Van Linn's opinion were consistent, it would still be nothing more than an idiosyncratic comparison of two chemicals because there is no scientific method to determine analogues. Def.'s Reply 6.

*7 In response, the Government argues that courts have accepted DEA, and specifically ODE, opinions on analogues and their underlying methodology for decades. Further, Defendant's reasoning is flawed because he attacks Dr. Van Linn's conclusions, whereas the Court's sole focus should be an expert's principles and methodologies. Pl.'s Resp. 11, 13.

The Court finds Defendant's argument that there is no acceptable method to determine substantial similarity wanting, and agrees with the Government that DEA opinions and methodology are widely accepted by courts. See *United States v. Makkar*, No. 13-CR-0205-CVE, 2014 WL 1385298, at *3 (N.D.Okla. Apr.9, 2014) (noting that the DEA "comparison of chemical substances are not novel scientific issues" and denying defendant's request to exclude Dr. Van Linn's **expert testimony** on substantial similarity between JWH-018 and XLR11). If there were no scientific or **expert** method to determine analogues, then **expert testimony** would be a moot point for both sides. Reality shows otherwise. See Doc. 108, Def.'s Mot. to Appoint Expert.

Defendant's attack on Dr. Van Linn's methodology by virtue of his conclusions and their underlying rationale is similarly unconvincing. Defendant maintains that Dr. Van Linn's methods are unreliable because a majority of scientists believe that UR-144 (a.k.a.XLR11) is not substantially similar in chemical structure to JWH-018, and that the addition of an atom precludes between two chemicals from being substantially similar. Def.'s Mot. to Excl. Van Linn 6–7; see also *The Smoke Shop, LLC v. United States*, 949 F.Supp.2d 877, 879 (E.D.Wisc.2013) "[T]he overwhelming weight of opinion in the scientific community is that the chemical structure of UR-144 and XLR-11 are not substantially similar to the chemical structure of JWH-018"). Defendant is correct that, in some cases, an **expert's** conclusions can affect the reliability of his **testimony**. See *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (explaining that methodology and conclusions are not entirely divorced, and that courts may exclude **expert testimony** where there is "too great an analytical gap between the data and the opinion proffered."); *Fed.R.Evid.* 702 advisory committee's note ("[W]hen an expert purports to apply principles and methods in accordance with professional

standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied.”) (citing *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir.1996)). Defendant's position that this is one of those cases, however, is unfounded.

First, the authority Defendant relies upon, *The Smoke Shop*, has been criticized by numerous courts. See, e.g., *United States v. Riley*, No. 2:12-CR-00478-JAD-UCF, 2014 WL 537013, at *5–6 (D.Nev. Feb.7, 2014) (explaining that the court was reluctant to give merit to any scientific opinions expressed in *The Smoke Shop* due to a lack of reasoning for its conclusion); *United States v. Carlson*, No. 12-CR-305 (DSD/LIB), 2013 WL 5125434, at *30 n. 33 (D.Minn. Sept.12, 2013) (“The Court [in *The Smoke Shop*] made no holding that UR-144 and XLR11 are not controlled substance analogues as a matter of law.”). Second, there is no one avenue that an expert must take to determine whether two chemical compounds are substantially similar. See *United States v. Ansaldi*, 372 F.3d 118, 123–24 (2d Cir.2004) (finding substantial similarity when there was a three atom difference); *Roberts*, 363 F.3d at 124–27 (finding substantial similarity when there was a two atom difference and the substance turned into the controlled substance when ingested); Pl.'s Resp., Ex. A Reinhold Depo. at 41:14–16 (“[O]ne atom switched out is the most specific definition of an analogue that I can find”). Finally, while trial courts *may* have cause to suspect expect testimony that arrives at an outlying conclusion, such conclusions are by no means automatically unreliable. See Fed.R.Evid. 702 advisory committee's note; see also *Riley*, 2014 WL 537013, at *5.

***8** After considering the standards accepted by other courts, it is hardly an analytical leap to find, in this context, that two chemical compounds are substantially similar based on the addition of one atom. As such, the Court concludes that Dr. Van Linn's conclusions are not per se unreasonable so as to render his opinion unreliable. If Defendant has evidence establishing that such changes substantially alter the chemical structure of the compounds in question, that evidence can be presented at trial to discredit Van Linn's conclusions. See *United States v. 14.38 Acres of Land, More or Less Situated in Leflore County*, 80 F.3d 1074, 1077 (5th Cir.1996).

b. Two-Dimensional Modeling

Defendant next attacks Dr. Van Linn's use of two-dimensional modeling to establish the substantial similarity of two chemical compounds. Def.'s Reply 3–4. This method is

unreliable, Defendant says, due to statements made by Lindsey Reinhold in an evidentiary exhibit submitted by the Government. In particular, Ms. Reinhold stated that “it is important to look at both two dimensional and three dimensional structures” in comparing chemical structure, and that every finding of substantial similarity is a matter of each chemist's opinion. Pl.'s Resp., Ex. A Reinhold Depo. at 34:12–23.

In reply, the Government asserts that two-dimensional structures are the primary manner in which chemists communicate, as reflected in many peer-related journals, and have been expressly approved by both the scientific community and courts. Pl.'s Resp. 11. Further, Ms. Reinhold agreed that, based on DEA's use of two-dimensional structures, she would concur that AM2201 was substantially similar to JWH-018.⁵ Id., Ex. A Reinhold Depo. at 41:5–19.

Here, too, the Court agrees with the Government that two-dimensional modeling is a reliable method of comparing the chemical structure of two compounds. Ms. Reinhold stated in her deposition that, when comparing two chemical compounds, two-dimensional models were useful for determining core structure and three-dimensional models were useful in identifying attached functional groups to see how they are similar. Pl.'s Resp., Ex. A Reinhold Depo. at 34:18–23. Ms. Reinhold continued to say that, based on these considerations, she felt comfortable identifying AM2201 as an analogue of JWH-018 “with the understanding that there are chemists out there that my disagree with [her].” Id. at 41:17–19.

Defendant misapprehends Ms. Reinhold's statement that other experts may disagree with her opinion to mean that two-dimensional modeling is an unreliable method. Def.'s Reply 3–4. As previously discussed, substantial similarity is not a scientific question and there is no requirement that experts agree on its exact definition. See *Carlson*, 2013 WL 5125434, at *26 (“[Defendant's] argument regarding a lack of consensus of a definition of ‘substantially similar’ in the chemistry community overlooks the fact ... that the question of whether a substance is substantially similar to another substance is not a scientific question and looks beyond the mere physical properties of a substance.”); *United States v. Fedida*, 942 F.Supp.2d 1270, 1279 (M.D.Fla.2013) (“[T]he Government need not overcome the critical eye of chemists and other experts ... [r]ather, it must merely show that ordinary people would be able to determine whether [the substances in question] are proscribed analogues of [a]

schedule I or II controlled substance].”). While Ms. Reinhold may determine that a three-dimensional model is appropriate, other experts, like Dr. Van Linn, may decide to rely solely on a two-dimensional model. In any event, determining which approach is best is not this Court's charge. *See Ruize-Troche v. Pepsi-Cola of P.R.*, 161 F.3d 77, 85 (1st Cir.1998) (“Daubert neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.”).

*9 Accordingly, the Court concludes that two-dimensional modeling is not an inherently unreliable method of comparing the chemical structure of two compounds. *See Brown*, 415 F.3d at 1267 (affirming trial court's admission of **expert testimony** on chemical structure in controlled substance analogue case based solely on visual assessment of a two-dimensional model even though it “only met one of the four *Daubert factors*.); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998) (“The proponent need not prove to the judge that the **expert's testimony** is correct, but [he] must prove by a preponderance of the evidence that the testimony is reliable.”).

c. Lack Of Peer Review and Reliance on Unpublished Studies

Finally, Defendant criticizes Dr. Van Linn's failure to cite to peer-reviewed studies and questions his reliance on unpublished studies, arguing that they give no insight into how he formed his conclusions or analyzed the chemicals to determine if they were substantially similar. Def.'s Mot. to Excl. Van Linn 6.; Def.'s Reply. 2. Defendant goes on to erroneously argue that the Fifth Circuit has altogether rejected the notion that expert opinions can be based on unpublished studies.⁶ In response, the Government states that, due to the changing nature of the “designer” drug market, often times there is little or no peer-reviewed literature specific to particular substances, and contends that publication is not an essential requirement of admissibility or reliability. Pl.'s Resp. 9.

Again, the Court agrees with the Government that Defendant's concerns regarding Dr. Van Linn's use of unpublished scientific studies go to the weight of the evidence rather than the admissibility of his opinions. *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir.1987). Peerreview, while helpful, is not itself determinative of reliability. *See Roman v. W. Mfg., Inc.*, 691 F.3d 686, 694 (5th Cir.2012) (“The absence of textual support or published studies is not dispositive

when reliable methods are used.”); *Knight*, 482 F.3d at 354–55 (explaining that there is no bright-line standard requiring publication or peer review, and that a lack of textual support goes to the weight of an **expert's testimony**, not its admissibility). Similarly, “[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published.” *Daubert*, 509 U.S. at 593 (internal citations omitted). Given the rapid developments and fluctuating landscape of the “designer” drug market, the Court concludes that Dr. Van Linn's use of unpublished scientific studies when evaluating the chemical structure of the substances in this case does not make his opinion intrinsically unreliable. As such, the exclusion of the whole of Dr. Van Linn's testimony is inappropriate at this time.

B. Trecki

1. Qualifications

*10 Defendant next attacks the admissibility of the Government's pharmacological expert, Dr. Trecki. Defendant argues that Dr. Trecki is unqualified to render **expert testimony** due to his embrace of flawed methodologies. Def.'s Reply 2.

In response, the Government contends that Dr. Trecki, a pharmacologist in DEA's ODE, Drug and Chemical Evaluation Section since 2012, regularly monitors, evaluates, and recommends emerging drugs for scheduling under the Controlled Substances Act, and lends his scientific opinion regarding drugs of abuse to local, state, and federal agencies. Pl.'s Resp. 5. Additionally, Dr. Trecki has previous work experience as neuropharmacologist and neurotoxicologist at the Environmental Protection Agency, has served as an adjunct professor and held a post-doctoral fellowship, coauthored peer-reviewed articles, and given presentations to scientific societies. *Id.* at 5–6.

The Government also states that Dr. Trecki has already been qualified as an **expert** and provided similar **testimony** in other federal courts.⁷ *Id.* Defendant counters by arguing that he lacks access to Dr. Trecki's previously admitted testimony. Def.'s Reply 5–6.

As previously discussed, “an **expert witness** may be qualified based upon his “knowledge, skill, experience, training, or education,” but not by his embrace of a certain method or principle. *See Fed.R.Evid. 702(a); Knight*, 482 F.3d at

352; *Engenium Solutions*, 924 F.Supp.2d at 770–71. Here, even if the court were to disregard Dr. Trecki's previous **testimony**, he would still qualify as an **expert** based on his current and previous work experience, history in academia, and expertise in scheduling under the Controlled Substance Act. See *McNamara v. Bre-X Minerals, Ltd.*, No. 5:97-CV-159, 2002 WL 32076175, at *4 (E.D.Tex. Sept.30, 2002) (finding the **witness's** education and experience qualified him as an **expert** even though he lacked trial experience in the area of testimony.) As such, the Court concludes that, under the factors set out by Rule 702, Dr. Trecki is qualified to testify as an **expert witness**. See Fed.R.Evid. 702(a).

2. Relevance

Defendant next challenges the relevance of Dr. Trecki's opinion under **Federal Rules of Evidence** 402 and 702, alleging that the Government failed to show the sound pharmacology necessary to determine substantial similarity. Def.'s Reply 2. In response, the Government argues that Dr. Trecki applied sound methods and principles to the facts of the case while analyzing: (1) the degree of similarity between AM2201, PB-22, and 5F-UR-144 (a.k.a.XLR11) and JWH-018; and (2) 5F-PB-22 and AM2201. Pl.'s Resp. 6. More specifically, Dr. Trecki correctly relied on data from *in vitro* receptor binding and functional studies, data from *in vivo* studies in animals, and scientific literature from National Institute on Drug Abuse (NIDA) studies. *Id.*

As discussed above, **expert testimony** is relevant when the **expert's** “reasoning or methodology properly can be applied to the facts in issue.” See *Daubert*, 509 U.S. at 593. The facts currently in issue turn on the question of substantial similarity. See *Reece*, 2013 WL 3865067, at *5 n. 21. Here, as with the testimony of Dr. Van Linn, there is little question that Dr. Trecki's reasoning and methodology apply directly to the issue at hand. See *supra* p. 9. Satisfaction of one of the two pharmacological criterion of § 802(32)(A) is sufficient for substantial similarity under a disjunctive reading and necessary for substantial similarity under a conjunctive reading. *Id.*; see also *Turcotte*, 405 F.3d at 521. Accordingly, Dr. Trecki, a pharmacologist, is anticipated to offer testimony that will “assist the trier of fact to understand the evidence or to determine a fact in issue.” *Daubert*, 509 U.S. at 589; Pl.'s Resp. 5–7. The Court therefore determines that the expert opinion of Dr. Trecki is relevant under the standards set forth by Rule 702 and *Daubert*. As the high bar is met, so too is the low. Correspondingly, the Court finds Dr. Trecki's testimony relevant under Rule 402 based on the logic set forth above. See *Bocanegra*, 320 F.3d at 584.

3. Reliability

*11 Defendant next turns to the reliability of Dr. Trecki's expected testimony, which is as follows:

1. AM2201 has a cannabinoid-like pharmacological effect on the central nervous system that is substantially similar to the cannabinoid-like pharmacological effects on the central nervous system as JWH-018, a schedule I controlled substance.
2. 5F-PB-22 has a cannabinoid-like pharmacological effect on the central nervous system that is substantially similar to the cannabinoid-like pharmacological effects on the central nervous system as AM2201, a schedule I controlled substance.
3. PB-22 has a cannabinoid-like pharmacological effect on the central nervous system that is substantially similar to the cannabinoid-like pharmacological effects on the central nervous system as JWH-018, a schedule I controlled substance.
4. XLR11 has a cannabinoid-like pharmacological effect on the central nervous system that is substantially similar to the cannabinoid-like pharmacological effects on the central nervous system as JWH-018, a schedule I controlled substance.

Def.'s Mot. to Excl. Trecki, Exs. 1–4.

a. Lack Of Peer Review and Reliance on Unpublished Studies

Defendant first complains that Dr. Trecki's opinion is unreliable because it is based, in part, on studies that are not publicly available, have not been provided to the defense, cannot be tested or empirically verified by the scientific community, and are not admissible under **Federal Rule of Evidence** 703. Def.'s Mot. to Excl. Trecki 5; Def.'s Reply 2–3. In particular, Defendant alleges that Dr. Trecki improperly relied on confidential NIDA reports.

The Government, meanwhile, contends that there is no legal requirement for an expert to cite only to published articles in formulating opinions, and points out that NIDA, a leader in the field of drug research for decades, relies upon well-founded scientific principles and methodologies. Pl.'s Resp. 12. Further, Dr. Trecki's opinion is based on studies conducted by qualified individuals in the scientific community whose

work has been internally peer-reviewed but has yet to be published publically. *Id.* at 10.

The Court agrees with the Government that this matter is appropriately dealt with by crossexamination than by exclusion. *See 14.38 Acres of Land*, 80 F.3d at 1077.

For starters, Defendant's assertion that the Government incorrectly relied upon confidential NIDA research is mistaken.⁸ Def.'s Mot. to Excl. Trecki 5. First, Defendant fails to provide the Court appropriate criteria with which to review his argument. A Request for Proposal ("RFP") is a requisite step to entering into a NIDA research contract. Because each NIDA contract is unique, different RFPs have different confidentiality requirements and statements of work. *See NIDA Requests for Contract Proposals (RFPs)*, National Institute on Drug Abuse, [http://www.drugabuse.gov/funding/funding-opportunities/nida-requests-contract -proposals-rfps](http://www.drugabuse.gov/funding/funding-opportunities/nida-requests-contract-proposals-rfps) (revised July 2014) (listing active RFPs with different confidentiality levels and requirements). Accordingly, it is incorrect to assume that the dictates of one flow uniformly to another. Here, the Court lacks an applicable standard because, even though Defendant based his argument on an RFP's confidentiality requirements, Dr. Trecki never used that RFP or its subsequent research contract in forming any of his submitted opinions. *See* Def.'s Mot. to Excl. Trecki, Exs. 1–5.

*12 Second, even if the confidentiality requirements in Defendant's proffered RFP were universal, Defendant fails to show that the research in question would be confidential or that he would otherwise be unable to access to it. Indeed, the main purpose of the confidentiality requirement is to protect private sources' proprietary information. Pl.'s Mot. to Excl. Trecki, Ex. 5 at 4. Consequently, "it is likely that NIDA will approve publication by the Contractor of data generated on ... non-proprietary compounds." *Id.* As there is no indication that Dr. Trecki relied upon proprietary information, Defendant should be able to gain access to any research which Dr. Trecki used in forming his opinions because "if the Government allows use of the data for any purpose other than direct contract performance, it will be made available for release to any interested party." *Id.* at 18.

Third, other courts have permitted experts to offer opinions based, in part, on NIDA research when testifying as to the substantial similarity of a chemical compound to a controlled substance. *See Makkar*, 2014 WL 1385298, at *3 (allowing DEA **expert witness** on pharmacology to review studies conducted by NIDA on synthetic cannabinoids during

controlled substance analogue proceeding). As such, the Court determines that Dr. Trecki's reliance on unpublished NIDA research is permissible and does not render his expert opinion unreliable.

In addition, Defendant offers nothing more than a conclusory statement to support his contention that Dr. Trecki's methods cannot be tested or empirically verified by the scientific community. Def.'s Mot. to Excl. Trecki 5. The Court's focus is on an expert's methods and principles, not the conclusions they generate. *See Joiner*, 522 U.S. at 146. While the studies referenced by Dr. Trecki may be unpublished, the Court agrees that the methodologies that he and NIDA employed are well known and can be cross-checked and examined by Defendant. *See Daubert*, 509 U.S. 593 (explaining that publication is not a *sine qua non* of admissibility or reliability); *Knight*, 482 F.3d at 354 (internal quotation marks omitted) ("Where an expert other reliably utilizes scientific method to reach a conclusion, lack of textual support may go to the weight, not the admissibility of the **expert's testimony**.").

Finally, Defendant has not sufficiently undermined the reliability of Dr. Trecki's reliance on unpublished studies so as to preclude admission of his opinion under **Federal Rule of Evidence 703**. Experts may rely on otherwise inadmissible facts or data "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." **Fed.R.Evid. 703**. The Court finds that the Government has sufficiently demonstrated that experts would rely on unpublished NIDA research or internally peer-reviewed given the quickly evolving and fluid nature of drug analogue cases. Pl.'s Resp. 9–10, 13–14. Therefore, the Court concludes that Dr. Trecki's opinion is admissible under Rule 703. *See Brown*, 415 F.3d at 1268 ("This means that **expert testimony** that does not meet all or most of the *Daubert* factors may sometimes be admissible."); *Makkar*, 2014 WL 1385298, at *3. If Defendant wishes to test or otherwise challenge Dr. Trecki's testimony or the underlying bases for his opinion, he may do so at trial with forceful crossexamination and the presentation of contrary evidence. *Viterbo*, 826 F.2d at 422 ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration.").

b. Studies Conducted Specifically In Anticipation of Litigation

*13 Defendant next complains that the studies Dr. Trecki relied upon were not conducted as part of his normal research, but specifically in anticipation of litigation. Def.'s Mot. to Excl. Trecki 6. Defendant points to the studies' short time-frame to support his position. *Id.* In response, the Government contends that Dr. Trecki did carry out the studies as part of his occupational duties, and that the cramped time-frame is due to dynamic landscape of the “designer” drug market. Pl.'s Resp. 11.

Once more, the Court agrees with the Government. See *Simpson v. Quarterman*, 593 F.Supp.2d 922, 937 (E.D.Tex.2009) (“Finders of fact are cautioned to consider the possible bias of an **expert witness** ‘including any bias you may infer from evidence that the **expert witness** has been or will be paid for reviewing the case and testifying, or from evidence that he testifies regularly as an **expert witness** and his income from such **testimony** represents a significant portion of his income.’”) (quoting Fifth Circuit Pattern Jury Instructions–Civil Cases, Pattern Instruction 2.19, pg. 23 (2006); *Daubert*, 43 F.3d 1311, 1317 (9th Cir.1995) (explaining that court should consider “whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.”). Although the time-frame in which Dr. Trecki carried out his research is brief, conducting studies on evolving drugs of abuse, is, by its nature, a fluid undertaking with unexpected developments and uncertain schedules. Pl.'s Resp. 5. Moreover, while testifying as an **expert witness** is not an infrequent occurrence for Dr. Trecki, he does so as a DEA agent, not a career **expert witness** searching for additional income. Consequently, the Court concludes that the time-line of Dr. Trecki's research is not indicative of his preparing expressly for the purpose of testifying, and does not weaken the reliability of his opinion.

c. Use Of In Vivo and In Vitro Studies

Finally, Defendant attacks Dr. Trecki's reliance on *in vivo* and *in vitro* studies. Def.'s Mot. to Excl. Trecki 7. These methods are unreliable, Defendant says, because they view the results of drug research carried out on animals as representative of those drugs' effects on humans. Defendant also contends that the Fifth Circuit has rejected *in vitro* and *in vivo* studies to establish causation in humans. *Id.* at 8; see also *Allen v. Pennsylvania En'g Corp.*, 102 F.3d 194 (5th Cir.1996).⁹ Defendant goes on to note that evidentiary rulings in criminal cases are subject heightened scrutiny. Def.'s Reply 7.

In response, the Government again argues that the special circumstances surrounding controlled substance analogues necessitate a different standard than the usual scientific methodology used for testing drugs. Pl.'s Resp. 12; see also *United States v. Klecker*, 228 F.Supp.2d 720, 729 (E.D.Va.2002) (“[T]he use of the term substantially similar in the Analogue Act creates an entirely different test than the scientific methodology required in the prescription drug approval process.”).

*14 The Court recognizes that “evidentiary rulings are subjected to heightened scrutiny in criminal cases.” *United States v. John*, 597 F.3d 263, 274 (5th Cir.2010). This, however, does not change the fact that “the rejection of **expert testimony** is the exception rather than the rule.” Fed.R.Evid. 702 advisory committee's note. Moreover, while the Fifth Circuit cautions that “‘studies of the effects of chemicals on animals must be carefully qualified in order to have explanatory potential for human beings,’ ” it does not hold them universally invalid as matter of law. *Johnson v. Arkema*, 685 F.3d 452, 463 (5th Cir.2012) (quoting *Allen*, 102 F.3d at 197).

The Court concludes that the research and study of controlled substance analogues is unique and satisfies the careful qualification requirement for animal studies. Additionally, the Court is disinclined to exclude testimony that other courts frequently admit in controlled substance analogue cases. See, e.g., *Nasir*, 2013 WL 5373619, at *3 (rejecting defendant's motion to exclude **expert testimony** on pharmacological effect of synthetic cannabinoids based on rodent drug discrimination tests in controlled substance analogue case); *United States v. McFadden*, No. 3:12CR00009, 2013 WL 8339005, at *5 (W.D.Va. May 10, 2013) (stating that **expert testimony** based on animal studies was properly admitted in a controlled substance analogue case and that any “shortcomings identified by the defendant went to the weight it should be given rather than its admissibility”), aff'd, 753 F.3d 432 (4th Cir.). As such, the Court concludes that Dr. Trecki's reliance on *in vivo* and *in vitro* studies was not so fundamentally unreasonable as to render his opinion unreliable. If Defendant has contrary evidence that casts doubt on the accuracy of Dr. Trecki's conclusions, that evidence can be presented at trial. *Mathis*, 302 F.3d at 461. Accordingly, the exclusion of the whole of Dr. Trecki's testimony at this time is unwarranted.

IV.**CONCLUSION**

For the reasons set forth above, Defendant's Motion to Exclude **Testimony** of Plaintiff's **Expert** Jordan Trecki, Ph.D., and Motion to Exclude Plaintiff's Expert Michael L. Van Linn, Ph.D. (Docs.177, 178), are **DENIED**. Should

it become evident during the trial of this matter that the testimony of either Dr. Van Linn or Dr. Trecki will not assist the trier of fact, Defendant may re-urge his objections to such testimony.

SO ORDERED.**All Citations**

Not Reported in F.Supp.3d, 2014 WL 3764876

Footnotes

- 1** On May 20, 2014, a federal grand jury re-alleged the charges in violation of [21 U.S.C. §§ 841](#) and [846](#) and, in addition, charged Bays and three other defendants with violating [18 U.S.C. §§ 1341](#) and [1349](#) (Conspiracy to Commit Mail Fraud). Doc. 222, Third Sup. Indictment 3. The conspiracy to commit mail fraud charge, issued after the Defendant filed this motion, identifies additional chemical substances not mentioned in the previous indictments. Those charges, however, are not at issue in the instant motion. The pertinent charges in the Third Superseding Indictment arising under [21 U.S.C. §§ 841](#) and [846](#) identify the same four chemical substances as the Second Superseding Indictment: AM2201, 5FPB–22, PB–22, and 5F–UR–144 (a.k.a.XLR11). Second Sup. Indictment 1–2; Third Sup. Indictment 4 at ¶ 12.
- 2** A conjunctive reading of [21 U.S.C. § 802\(32\)\(A\)](#) was adopted in the following cases: *Brown*, 415 F.3d at 1261; *Turcotte*, 405 F.3d at 523; *United States v. Roberts*, 363 F.3d 118, 121 (2d Cir.2004); *United States v. Hodge*, 321 F.3d 429, 433 (3d Cir.2003); *Washam*, 312 F.3d at 930; see *Reece*, 2013 WL 3865067, at *7 n. 31.
- 3** The Court notes that Defendant's footnote bears striking resemblance to the *Reece* court's footnote on the same topic. Curiously, there is no corresponding citation.
- 4** The Court notes that Defendant erroneously states that Dr. Van Linn found "the [difference between the] chemical structures for AM2201 and JWH–018 ... is minor and insignificant given that it consists of only a single atom substitution and an addition of a single atom," instead of relaying his actual finding that 5F–PB–22 was substantially similar to AM2201. Def.'s Mot. to Excl. Van Linn 4–5.
- 5** The Court notes Defendant's contention that Ms. Reinhold did not find AM2201 and JWH018 were substantially similar, but instead chemical analogues. Def.'s Reply 4. The Court also dismisses this stance as superfluous; two chemicals cannot be chemical analogues-under either the Federal definition or Pennsylvania state statute that controlled Ms. Reinhold's research during the occasion in question-without being substantially similar. See Pl.'s Resp, Ex. A Reinhold Depo. at 41:17–19; 45:10–13.
- 6** Defendant relies on *Moore*, 151 F.3d at 278, which, in pertinent part, states, "[i]n the absence of an established scientific connection between exposure and illness, or compelling circumstance such as those discussed in *Cavallo*, the temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation." The Fifth Circuit, in this case, was dealing with a toxic tort claim where the expert in question failed to produce any scientific support for his conclusion. Indeed, the phrase "unpublished scientific study" does not appear throughout the entirety of the opinion.
- 7** The Court notes that the Government lists *Carlson*, 12–cr–305; *Reece*, 6:12–cr–146; and *The Smoke Shop, LLC*, 2:12–cv–1186 as cases that Dr. Trecki has previously testified in, and provides their case numbers to Defendant so he might be able to search for available docket sheets.
- 8** Defendant paraphrases the requirement that "[n]one of these data may be used at any time for any purpose except to generate reports or other requirements specified in the Statement of Work, without prior written approval of the NIDA Contracting Officer." Def.'s Mot. to Excl. Trecki, Ex. 5 at 18, Art. H.8 (emphasis added); see [48 C.F.R. 352.224–70](#) (2010) (outlining confidentiality and privacy requirements applicable to NIDA RFP). Notably, the corresponding Statement of

Work goes on to say that “the resulting data are used by the DEA to support scheduling recommendations for new drugs of abuse.” *Id.* at

- 9 Defendant cites to other authority that it is neither applicable to the matter at hand nor binding on this Court. See *Wade-Greux v. Whitehall Labs., Inc.*, 874 F.Supp. 1441, 1453 (D.Vt.1994) aff'd, 46 F.3d 1120 (3d Cir.1994) (rejecting extrapolation by experts of animal experiments to determinations of human birth defects); *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706, 729 (1997) (stating that animal studies cannot act as stand alone conclusive evidence that a substance has a given biological effect on humans.).

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