

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

KATHLEEN MOLLER,
Plaintiff,

v.

MARTIAN SALES, INC.; JOPEN,
LLC; JOHNSON FOODS, LLC; LP
IND., LLC; CAG HOLDINGS, LLC;
RMH HOLDINGS, LLC; ABC
INSURANCE COMPANY and John
Does 1-4,
Defendants.

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CIVIL ACTION NO.
2:24-CV-228-WBV-DPC
THE HONORABLE WENDY B. VITTER
MAGISTRATE JUDGE DONNA PHILLIPS
CURRAULT

**DEFENDANT’S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE
PLAINTIFF’S EXPERT EVELYN CADMAN UNDER FED. RULE OF EVID. 702**

Defendant JOpen, LLC (“Defendant” or “JOpen, LLC”) hereby files this Motion to Exclude Plaintiff’s Expert Witness Evelyn Cadman under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and incorporated memorandum of law.

I. INTRODUCTION

Plaintiff’s expert Evelyn Cadman does not offer scientific, toxicological, or industry-based opinions that would assist the jury in resolving any fact in dispute. Instead, her report advances a series of legal conclusions—that kratom is a “New Dietary Ingredient,” that O.P.M.S. products are “adulterated” and “misbranded,” and that Defendant violated federal regulatory law. These opinions exceed the proper scope of expert testimony under Rule 702 and *Daubert* for three independent reasons.

First, Cadman lacks relevant expertise. She has no scientific, medical, or regulatory experience specific to kratom and admits she does not know which regulatory category kratom even falls into. Her opinions therefore rest on speculation outside her field of competence.

Second, Cadman repeatedly offers impermissible legal conclusions. She does not merely explain regulatory frameworks; she applies statutory terms of art such as “adulterated,” “misbranded,” “new drug,” and “new dietary ingredient” and declares that Defendant violated federal law. Courts uniformly prohibit experts from rendering such conclusions. Determining whether a product violates the FDCA is a legal question reserved for the Court.

Third, even if her legal conclusions were permissible (they are not), they are unreliable because they rest on erroneous and unsupported assumptions about the Federal Food Drug and Cosmetic Act (FDCA)’s regulatory scheme. Her analysis collapses distinct statutory categories, ignores how products are classified based on labeling and marketing, and disregards regulatory realities reflected in the record. An opinion founded on an incorrect legal premise is not reliable under Rule 702.

Because Cadman lacks relevant expertise, crosses the line into legal advocacy, and relies on faulty foundational assumptions, her testimony would confuse the jury rather than assist it. The Court should exclude her opinions in their entirety.

II. FACTUAL BACKGROUND

A. Plaintiff’s claims and allegations.

This is a products liability case in which Plaintiff alleges that O.P.M.S. Silver kratom caused Harmony Moller’s death on February 6, 2023. Specifically, Plaintiff claims that Defendant designed an inherently and unreasonably dangerous product, that Defendant failed to adequately warn of the dangers associated with O.P.M.S. Silver kratom, and that Defendant failed to provide adequate instructions on how to avoid such risks. *See* ECF No. 100, at ¶ 61; *see also* ECF No. 184 at 2 (Plaintiff brings a “products liability claims under Louisiana’s Products Liability Act, La. R.S.

9:2800.51, et seq., asserting that the kratom product consumed by Harmony [her daughter] was unreasonably dangerous due to a failure to warn and a design defect.”).

B. Evelyn Cadman.

Evelyn Cadman is a consultant at a firm called FDA Compliance Simplified, working with clients in food, dietary, supplement, cosmetic, and pharmaceutical industries. Ex. 1, Expert Report of Evelyn Cadman, at 2. In her Report, Cadman opines that (a) “Kratom is a New Dietary Ingredient (NDI) for purposes of the Dietary Supplement and Health Care Education Act of 1994”¹; (b) “Defendants did not file a premarket NDI Notification and OPMS kratom is therefore deemed adulterated”; and (c) “Defendants’ OPMS kratom branded products were misbranded, were sold for therapeutic purposes, and sold as unapproved new drugs.” *Id.* at 3. Cadman intends to testify that that the O.P.M.S. kratom labels do not comply with regulations regarding food, dietary ingredients, or drugs; that the labels are not appropriate for food, dietary ingredients, or drugs; and that the labels are incomplete, deceptive, and confusing. *See generally* Ex. 2, Excerpts from Evelyn Cadman Dep. Tr. at 68:10–69:14; 83:14–86:3; 135:12–139:16; 182:15–185:10.

III. ARGUMENT

A. Standard for admissibility.

The district court has considerable discretion to admit or exclude expert testimony under Fed. R. Evid. 702. *See, Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 138–39 (1997); *Seatrax, Inc. v. Sonbeck Int’l, Inc.*, 200 F.3d 358, 371 (5th Cir. 2000); *Tajonera v. Black Elk Energy Offshore Operations, LLC*, Civ. A. No. 13-0366, 2016 WL 3180776, at *8 (E.D. La. June 7, 2016) (Brown, J.) (citing authority). The burden rests with the party seeking to present the testimony to show that the requirements of Rule 702 are met. *Moore v. Ashland Chemical, Inc.* 151 F.3d 269, 276 (5th

¹ Defendant does not dispute that kratom is an NDI.

Cir. 1998). Rule 702 provides that an expert witness “qualified ... by knowledge, skill, experience, training or education may testify in the form of an opinion” when the following requirements are met:

- (a) The expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 codifies the Supreme Court’s opinion in *Daubert*, which charges district courts to act as “gatekeeper” when determining the admissibility of expert testimony. *Tajonera*, 2016 WL 3180776, at *8. The purpose of a *Daubert* motion is “to ensure that only reliable and relevant expert testimony is presented to the jury.” *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 506 (5th Cir. 1999) (superseded by rule on other grounds) (citing *Daubert*, 509 U.S. at 590–93).

On appeal, courts “review the admission or exclusion of expert testimony for an abuse of discretion.” *Braggs v. BP Expl. & Prod., Inc.*, No. 23-30297, 2024 WL 863356, at *2 (5th Cir. Feb. 29, 2024) (quoting *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009)). Courts “will not find error unless the ruling is *manifestly erroneous*.” *Guy v. Crown Equip. Corp.*, 394 F.3d 320, 325 (5th Cir. 2004). This provides courts with “wide latitude in determining the admissibility of expert testimony.” *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988 (5th Cir. 1997).

B. The Court should exclude Cadman because her opinions are so fundamentally unsupported that they offer no assistance to the jury.

Cadman fails to comply with the principles set forth in Rule 702 and relevant case law. A court may exclude an expert's testimony altogether if the opinions are substantially reliant on inappropriate legal opinions and lack factual support in the record, rendering the testimony fundamentally unreliable:

[W]hile *Daubert* instructed that the focus of the reliability inquiry “must be solely on principles and methodology, not on the conclusions that they generate,” 509 U.S. at 595, 113 S. Ct. 2786, the Supreme Court later clarified that “conclusions and methodology are not entirely distinct from one another,” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997). Thus, “a district court’s focus on principles and methodology need not completely pretermitt judicial consideration of an expert’s conclusions,” *Kuhn*, 686 F.3d at 625 (internal quotation marks omitted), and a district court may exclude expert testimony if it finds “that there is simply too great an analytical gap between the data and the opinion proffered,” *Joiner*, 522 U.S. at 146, 118 S.Ct. 512. Or, to put it in the language we have frequently used both before and after *Daubert* and *Joiner*, a district court may exclude an expert’s opinion if it is “so fundamentally unsupported” by its factual basis “that it can offer no assistance to the jury.” *E.g., Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988); *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011).

In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig., 9 F.4th 768, 777–78 (8th Cir. 2021). If the factual basis of an expert’s opinion is so fundamentally unsupported because the expert fully relies on legal conclusions, altered facts and speculation, or fails to consider relevant facts in reaching a conclusion, the expert’s opinion can offer no assistance to the trier of fact, and is not admissible. *E.g., Nebraska Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416–17 (8th Cir. 2005) (when opinion is “so fundamentally unsupported” in failure to consider relevant facts, it can offer no assistance to the trier of fact and must be excluded); *McGlinchy v. Shell Chem. Co.*, 845 F.2d 802, 807 (9th Cir. 1988) (expert study and future testimony properly excluded where it rested on speculation, unsupported assumptions, and ignored distinctions crucial to arriving at a valid conclusion); *Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1331 (5th Cir.

1996) (expert testimony properly excluded where it was not based upon facts in the record but on altered facts and speculation designed to bolster party's position).

1. Cadman is not qualified to testify as an expert regarding kratom.

The Court should exclude Cadman's testimony in this case because she has no regulatory, scientific, or medical expertise regarding kratom, and therefore lacks relevant expertise in the subject matter at hand. *See generally Collett v. Weyerhaeuser*, 512 F. Supp. 3d 665, 674 (E.D. La. 2021) (excluding proposed experts where "there is no evidence to even suggest that either doctor has had any experience with the chemical involved in this case").

Cadman describes herself as "an expert in product development and regulatory compliance for the food, dietary, supplement, cosmetic, and pharmaceutical industries"; however, her only experience with kratom was providing a cursory review of a label for a kratom product ten years ago. Ex. 1, at 2; Ex. 2, at 16:15–18:16. In fact, Cadman decided over ten years ago that she did not want to work with the kratom industry. Ex. 2, at 19:9–21.

Cadman's lack of familiarity with and expertise in kratom is undeniable as she repeatedly admitted in her deposition that she actually has no idea about the regulatory structure for kratom. *See id.* at 79:19–80:9 ("As I stated, ... it's difficult to figure out should [kratom] come under the dietary supplement regulations, the food regulations, or the drug regulations?"); *id.*, at 81:18–22 ("Q: What is your opinion: Is OPMS kratom a dietary ingredient, a drug or a food? A: Yes. All three potentially. Either, or, and."). This is reason enough for the Court to exercise its gatekeeper role and exclude Cadman from providing these unsubstantiated opinions that she lacks the expertise to give. Cadman's general experience in "regulatory consulting" is not sufficiently specialized to the subject matter at hand, and courts frequently exclude experts who lack the specialized experience relevant to the issues in the litigation. This is particularly true where she

admits she has no knowledge whatsoever about the regulatory system governing kratom. Cadman’s opinions and testimony will do nothing here other than confuse the jury, and this Court should exclude her testimony to prevent such confusion. *See, e.g., Rheinfrank v. Abbott Lab’s, Inc.*, 680 F. App’x 369, 381 (6th Cir. 2017) (affirming limitation on regulatory and medical expert’s testimony on antiepileptic drugs, which was outside the scope of her expertise); *Payne v. C.R. Bard, Inc.*, 606 F. App’x 940, 943 (11th Cir. 2015) (affirming exclusion of expert’s testimony on IVC filter, where expert has worked on one project involving an IVC filter more than twenty years ago, had never designed, tested, or manufactured an IVC filter, and had never taught seminars or published articles about IVC filters).

2. Cadman’s opinions rest on impermissible legal conclusions that are incorrect as a matter of law.

a. Cadman’s opinions impermissibly cross the line into legal conclusions.

Cadman’s report ultimately advances a single overarching conclusion: that Defendants’ products violated federal law. She opines that (1) kratom is a “New Dietary Ingredient” (“NDI”) under the Dietary Supplement Health and Education Act; (2) Defendants failed to submit a premarket NDI notification and the products are therefore “adulterated”; (3) the products were “misbranded”; (4) they were marketed as unapproved “new drugs”; and (5) the labels violated specific FDA regulatory provisions. *See generally* Ex. 1. In short, Cadman does not merely describe regulatory frameworks—she repeatedly concludes that Defendants violated them.

Federal Rule of Evidence 704 permits testimony embracing an ultimate issue of fact, but it does not authorize experts to render legal conclusions. Courts have consistently drawn a careful distinction between (1) permissible testimony explaining complex regulatory schemes and industry practices, and (2) impermissible testimony opining that a party violated the law. *See Snap-Drape, Inc. v. C.I.R.*, 98 F.3d 194, 198 (5th Cir. 1996) (Rule 704 “does not allow an expert to

render conclusions of law”); *Commodores Ent. Corp. v. McClary*, 879 F.3d 1114, 1128–29 (11th Cir. 2018) (“the court must be the jury’s only source of law”).

The governing line is well illustrated in *Robinson v. Ethicon, Inc.*, 588 F. Supp. 3d 726 (S.D. Tex. 2022). There, the court permitted a regulatory expert to testify “about what the regulations require and [the company’s] conduct with regard to the regulations,” but held that the expert “cannot take the final step of opining that the product was ‘misbranded’ or ‘adulterated,’ as these are impermissible legal conclusions.” *Id.* at 736. That distinction is critical. Experts may explain regulatory standards; they may not apply statutory terms of art to reach ultimate legal determinations. *See also In re Davol, Inc. Polypropylene Hernia Mesh Prods. Liab. Litig.*, 2021 WL 3286439, at *8 (S.D. Ohio Aug. 1, 2021) (prohibiting regulatory expert from offering opinion that product was “misbranded”).

Cadman’s opinions repeatedly invoke precisely those legal terms of art. “Adulterated,” “misbranded,” “new dietary ingredient,” and “new drug” are not vernacular descriptors; they are statutory classifications defined by the Federal Food, Drug, and Cosmetic Act and its implementing regulations. As the D.C. Circuit explained, when an expert “invok[es] a legal term of art,” the testimony “constitute[s] an impermissible legal conclusion.” *Burkhart v. Washington Metro. Area Transit Auth.*, 112 F.3d 1207, 1213 (D.C. Cir. 1997). The proper inquiry is whether the terms “have a separate, distinct and specialized meaning in the law different from that present in the vernacular. If they do, exclusion is appropriate.” *Id.* at 1212 (quoting *Torres v. County of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)). The FDCA classifications at issue here unquestionably meet that standard.

This is not a case where the expert simply describes regulatory background and leaves the ultimate question to the jury. Cadman goes further. She concludes that O.P.M.S. products “are

deemed adulterated,” “are misbranded,” “should not be sold as a drug,” and were marketed “in violation of [regulatory] standards.” Those statements are not technical explanations; they are legal determinations.

Permitting such testimony would invert the jury’s role and the Court’s function. Whether a product is legally “adulterated,” “misbranded,” or an unlawful “new drug” under federal law is a question of statutory interpretation and legal application reserved for the Court. Allowing Cadman to supply those answers would improperly substitute expert opinion for judicial instruction. As courts have cautioned, they “must remain vigilant against the admission of legal conclusions.” *Commodores*, 879 F.3d at 1128–29.

Cadman cannot opine that Defendant’s products violated those regulations or assign them statutory classifications that carry defined legal consequences. Her opinions that O.P.M.S. products were “adulterated,” “misbranded,” or unlawfully marketed therefore exceed the permissible scope of expert testimony and should be excluded.

b. Cadman’s legal opinions are wrong and unsubstantiated.

Cadman’s regulatory opinions all stem from her conclusions that (i) “Kratom is a New Dietary Ingredient (NDI) for purposes of the Dietary Supplement and Health Education Act of 1994” and (ii) “Defendants did not file a premarket NDI Notification and OPMS kratom is therefore deemed adulterated.” Ex. 1, at 3. Cadman’s conclusion is wrong.

Of course the FDA is aware that O.P.M.S. is sold over the counter as a food and permits this even though the FDA has not issued any NDIN for O.P.M.S. This is because under the FDCA, whether a product is a “conventional food” or a “dietary supplement” depends on how it is labeled, packaged, and marketed to consumers. The FDCA has provisions that clearly distinguish between

foods, drugs, dietary supplements, and food additives. *See* 21 U.S.C. § 321(f). If it is not labeled, packaged, or marketed as a food supplement, the FDA regards it as a food.

Cadman’s conclusions depend on a threshold legal assumption—that kratom must be treated as a “New Dietary Ingredient” requiring an NDI notification and that, absent such a notification, O.P.M.S. products are necessarily “adulterated.” That premise is simply wrong as a matter of federal law. Under the FDCA, whether a product is regulated as a conventional food, dietary supplement, drug, or food additive depends on how it is labeled, packaged, and marketed. *See* 21 U.S.C. § 321(f). A product not labeled or marketed as a dietary supplement is not automatically subject to the NDI framework. Cadman’s analysis collapses these distinct statutory categories and assumes that the absence of an NDIN renders the product unlawful—an assumption that does not reflect how the FDCA operates in practice.

An expert opinion that rests on a false or legally erroneous premise is inadmissible under Rule 702. The Fifth Circuit has made clear that “the Daubert reliability analysis applies to, among other things, ‘the facts underlying the expert’s opinion.’” *Jacked Up, LLC v. Sara Lee Corp.*, 291 F. Supp. 3d 795, 802 (N.D. Tex. 2018) (quoting *Moore v. Int’l Paint, L.L.C.*, 547 F. App’x 513, 515 (5th Cir. 2013)). “In particular, an opinion based on ‘insufficient, erroneous information,’ fails the reliability standard.” *Id.* (quoting *Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 389 (5th Cir. 2009)). Although *Daubert* is flexible, “the existence of sufficient facts ... is in all instances mandatory.” *Id.* (quoting *Hathaway v. Bazany*, 507 F.3d 312, 318 (5th Cir. 2007)).

Courts likewise recognize that while experts may incorporate legal assumptions into their analyses, “an expert’s reliance on incorrect legal assumptions would warrant exclusion.” *Villalpando v. Exel Direct Inc.*, 161 F. Supp. 3d 873, 895 (N.D. Cal. 2016). Where the governing statutory framework contradicts the expert’s foundational premise, the testimony is unreliable.

Here, Cadman’s opinions that O.P.M.S. products are “adulterated,” “misbranded,” or unlawfully marketed flow directly from her incorrect legal assumption about NDI requirements. Because her regulatory conclusions rest on a mistaken understanding of how the FDCA classifies foods versus dietary supplements, her testimony fails Rule 702’s reliability requirement and should be excluded in its entirety.

Cadman has not pointed to any evidence in the record that O.P.M.S. Silver is marketed as a dietary supplement, or that the FDA nevertheless identifies or regulates it as such.² Nor has Cadman identified any other advertisements, packaging, or other statements where Defendant has labeled O.P.M.S. Silver as a dietary supplement or made medical or health claims regarding this product. Furthermore, Cadman has not cited a statement or publication by the FDA wherein the agency refers to or designates O.P.M.S. Silver as a dietary supplement. Cadman’s failure to cite a single regulatory source or statement explicitly supporting her opinion is enough to exclude this testimony.

But Cadman has not only failed to provide any authority or concrete, reliable facts for this opinion, she also completely disregards the regulatory reality: FDA has not required an NDIN for kratom because it is not labeled, packaged, or marketed as a dietary supplement, and therefore the FDA regards it as a food. On its current website, FDA explains that while “kratom is not lawfully marketed in the U.S. as a drug product, a dietary supplement, or a food additive in conventional food,” it recognizes that “products prepared from kratom leaves are available in the U.S. online and in brick-and-mortar stores.” Ex. 3, FDA and Kratom. And while the FDA at one time recommended scheduling kratom as a controlled substance to the DEA in 2017, this effort was

² Cadman purports to rely on letters sent by the FDA to unrelated kratom manufacturers or distributors but does not dispute that none of the letters relied on related to the product at issue. *See* Ex. 2, at 61:14–62:15.

reversed and kratom was not listed because FDA actually rescinded that recommendation in 2018—an unprecedented event. More recently, the FDA commissioned a study on kratom in 2024, from which it concluded that “kratom leaves appear safe even at high doses when taken in capsule form.” Ex. 4, *Kratom Appears Safe in Early FDA Study That Excluded Popular Drinks*.

Cadman ignores this regulatory history and commentary in her report, including the obvious close attention that FDA has paid to kratom. Cadman cannot reconcile that position with the fact that FDA has carefully considered whether to continue its recommendation that DEA list kratom and then reversed that position in response to public comments and further study. She also ignores that FDA has inspected certain O.P.M.S. manufacturing facilities, issued warning letters for other kratom products making improper health claims, and confiscated certain mislabeled or adulterated products.

Hence, there can be no credible doubt that O.P.M.S. and other natural kratom products are well known to the FDA, and if the agency wished to ban or further regulate them, it would do so. Because Cadman’s opinions blatantly ignore kratom’s current status in the U.S. regulatory landscape, the Court should exclude her from testifying.

3. Cadman’s regulatory opinions have no factual support in the record.

In its gatekeeper role, the Court must also ensure that experts’ opinions are based not only on correct but also on sufficient facts and data. In addition to the reasons above that Cadman’s regulatory opinions are irrelevant, improper, and incorrect legal analysis, the Court should also exclude Cadman’s opinions and testimony because they are not supported by the factual record. *Bouelle v. Crown Equip. Corp.*, 220 F.3d 532, 539 (7th Cir. 2000) (“Many times we have emphasized that experts’ work is admissible only to the extent it is reasoned, uses the methods of

the discipline, and is founded on data. Talking off the cuff—deploying neither data nor analysis—is not acceptable methodology.”).

a. Cadman does not support her conclusory assertions that O.P.M.S. Silver was sold as a misbranded drug.

Cadman asserts that O.P.M.S. Silver kratom was sold as a “misbranded” drug, improperly for medical purposes, and as such did not include the proper warnings. Ex. 1, at 11–14. But in her deposition, Cadman repeatedly admitted that she knew of no marketing of O.P.M.S. Silver kratom as a drug but was simply basing it on the fact that it could be purchased in a capsule (among other forms). Ex. 2, at 75:9–76:1 (testifying that her opinion in terms of “labeling and marketing” was based on the “capsule format”). Simply put, there is no factual support for Cadman’s opinions and testimony regarding medical sales and marketing, and it should be excluded. *See Whyte v. Stanley Black & Decker, Inc.*, 514 F. Supp. 3d 684, 696 (W.D. Pa. 2021) (excluding expert who “testified that he believed a warning label must be provided whenever there’s a risk of significant injury—and he based this assertion simply on ‘common sense’”); *Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 479 (4th Cir. 2018) (“But Dr. Kasbekar’s inadequate warning opinion was not supported by studies, research, or other scientific basis of verification necessary to establish reliability for Daubert purposes.”); *Moore v. Nat’l Presto Indus., Inc.*, 603 F. Supp. 3d 676, 682 (W.D. Wis. 2022) (“King also does not explain how the cooker posed any foreseeable risks of harm or that any risks could have been reduced by providing reasonable instructions. And King does not provide any examples of reasonable alternative warnings.”).

b. Cadman does not support her opinion that the O.P.M.S. label was “misbranded” because it allegedly failed to correctly identify the responsible entity.

Cadman opines that the O.P.M.S. label at issue is “deemed misbranded because it does not correctly identify the actual name and place of business for the entity responsible for the product.”

Ex. 1, at 14. And then, in direct contradiction, she immediately states that the “O.P.M.S. label identifies Choice Organics and provides a phone number, address, and email.” *Id.*, at 15. Choice Organics is a trade name of the distributor, JOpen, but Cadman immediately jumps to an opinion that it is somehow “deceptive marketing” in its listing. *Id.* Cadman cites nothing for this opinion, and it should be rejected. *See Santoro ex rel. Santoro v. Donnelly*, 340 F. Supp. 2d 464, 475 (S.D.N.Y. 2004) (“Although experts may rely on existing data, nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. They must still explain how and why they could have extrapolated their opinions from the data.”).

c. Cadman does not support her claims that Defendant violated regulations for collecting, tracking, and reporting complaints and adverse events.

Cadman also opines that “the adverse events reporting system for OPMS kratom presents a disturbing lack of regard for the industry standards and human safety.” Ex. 1, at 16.

First, Defendant’s adverse events reporting procedures have no relevance to Plaintiff’s claims—particularly since Plaintiff did not report an adverse event. If there is marginal relevance, it is outweighed by the prejudice associated with introducing complicated and unnecessary regulatory procedures. Any testimony regarding Defendant’s adverse events reporting procedures should be excluded on that basis alone. *See generally Jones v. Ethicon, Inc.*, CV421-023, 2022 WL 22990442, at *12 (S.D. Ga. Dec. 6, 2022) (excluding adverse events reporting testimony where “[d]elving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors to erroneously conclude that regulatory compliance proved safety.”).

Cadman also lacks sufficient evidence to support her conclusions. She again states that there is insufficient contact information for adverse events reporting, despite having recognized

the existence of full contact information. Ex. 1, at 16. Moreover, David Gabbay, on behalf of JOpen, testified fully to the adverse events reporting procedures, making it clear that such procedures have been in place since at least 2015 or 2016, and continue to evolve in sophistication. *See generally* Ex. 5, Excerpts from JOpen, LLC Dep. at 35:4–37:3. Cadman’s unsubstantiated conclusions otherwise are simply unsupported by the record and should be excluded.

d. Cadman does not support her claim that O.P.M.S. was not properly tested.

Cadman opines that Defendant’s product testing is “wholly deficient.” Ex. 1, at 21–22. She appears to base this opinion on the fact that certain testing results differ from the original product specification sheet, and that “the test states that the alkaloid level results are simply reported to the manufacturer or party ordering the testing, and do not indicate a pass or fail.” *Id.* at 21. But the alkaloid levels are what indicate the pass or fail, and those working with the documents know that. There is no requirement that the documents state otherwise, and Cadman appears to rely on nothing in support of her argument that they do. Her opinion should be excluded.

CONCLUSION

For the foregoing reasons, the Court should exclude the testimony of Evelyn Cadman. Defendant requests a hearing for argument on this motion prior to trial in this case.

Dated this 2nd day of March, 2026.

Respectfully Submitted

By: /s/ Gwendolyn C. Payton

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CERTIFICATE OF SERVICE

This is to certify that on the 2nd day of March, 2026, a copy of the foregoing document was filed with the Clerk of Court and served on all counsel of record via the Court's ECF System.

/s/ Gwendolyn C. Payton

Gwendolyn C. Payton