

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

KATHLEEN MOLLER

CIVIL ACTION NO. 24-0228-WBV-DPC
ALL CASES

VERSUS

*** JUDGE WENDY B. VITTER**

MARTIAN SALES, INC; JOPEN, LLC, a Texas limited liability company; JOHNSON FOODS, LLC, a Wyoming limited liability company; LP IND., LLC, a Wyoming limited liability company; CAG HOLDINGS, LLC, a Wyoming limited liability company; RMH HOLDINGS, INC., a Wyoming corporation; ABC INSURANCE COMPANY and John Does 1-4.

* MAGISTRATE DONNA PHILLIPS
* CURRAULT

* * * * *

**PLAINTIFF’S STATEMENT OF MATERIAL FACTS IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT THAT OPMS SILVER KRATOM IS
UNREASONABLY DANGEROUS**

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, Plaintiff Kathleen Moller herein provides her statement of material facts in support of partial summary judgment for a determination that Defendant's OPMS Silver kratom products are unreasonably dangerous as a matter of law, for their failure to provide adequate warning or instruction regarding known risks, and for an unreasonably dangerous design. In the alternative, Plaintiff seeks a declaration that OPMS kratom products are "adulterated" and "misbranded" under the Food, Drug and Cosmetic Act, and an order pursuant to Rule 56(g) recognizing certain enumerated facts, such as the absence of warning as to a risk of a death and the existence of alternative designs, as established for purposes of this case.

I. STATEMENT OF MATERIAL FACTS

A) Harmony Moller's Death Was Caused by OPMS Kratom

- 1) This wrongful death action presents claims arising from the preventable death of Harmony Moller. Third Amended Complaint (“TAC”), Dkt. No. 100.
- 2) On February 6, 2023, Harmony Moller died suddenly and unexpectedly at the age of 36. *Id.* at ¶ 30. See also, Exhibit 7 (St. Tammany Parish Coroner's Office, autopsy report, NMS Labs toxicology report, and UCSF Toxicology report for Harmony Moller).
- 3) A postmortem exam determined the cause of death was “Abnormally high left coronary ostia takeoff exacerbated by mitragynine use.” TAC at ¶ 33. See also, Exhibit 7.
- 4) Mitragynine is the most abundant active alkaloid in the Southeast Asian plant *Mitragyna Speciosa*, commonly known as kratom.¹ TAC at ¶ 34.
- 5) The product leading to Harmony Moller's death was OPMS Silver Kratom, capsules and powder. *Id.* at ¶ 30; see also, Exhibit 1 & 2 (photos of packages found in Harmony's possession after death).²



¹ <https://www.merriam-webster.com/dictionary/mitragynine>

² The image above is one of the actual packages found with decedent, in her bedroom, where she passed.

B) OPMS was Created and Trademarked by Martian Sales

- 1) “OPMS kratom powder” is a known trademark for Martian Sales. See, Exhibit 3 (USPTO document for OPMS establishing Martian Sales as the party in possession of OPMS trademark).
- 2) Martian created the OPMS brand and began selling OPMS kratom in approximately 2012. See, Exhibit 4 (Excerpt of October 28, 2024, 30(b)(6) Deposition of Mark Reilly, Corporate Representative of Martian Sales, Inc., Vol. I) at 176:1-18.

C) Martian and JOpen Work Together on OPMS From the Start of the OPMS Brand

- 1) Martian began working with JOpen for distribution of OPMS kratom in 2012, after an introduction through Peyton Palaio. See, Exhibit 5 (Excerpt of March 14, 2025, 30(b)(6) Deposition of David Gabbay, Corporate Representative of JOPEN, LLC) at 269:13-270:10.
- 2) JOpen has been the only distributor of OPMS kratom since that time. *Id.* at 287:6-288:2; see also, Exhibit 4 at 56:5-9.

D) Martian Works with All Named Defendants for the Sourcing, Manufacture, and Distribution of OPMS Kratom

- 1) Martian has since sourced raw kratom for OPMS, processed OPMS kratom, encapsulated OPMS kratom, and ultimately shipped it across the country through entities managed by Mark Jennings, associated to Peyton Palaio, and named herein including Calibre and Nuza. See, Exhibit 4 at 100:7-10 & 100:21-101:14.
- 2) Prior to working with Calibre and Nuza, other Mark Jennings and Peyton Palaio managed entities assisted with sourcing, encapsulating, processing, and logistics, including Advanced Nutrition, LP Ind., and LIV Group, LLC. See Exhibit 4 at 101:22-102:10; 104:8-19; 266:3-267:22; & 275:12-277:3.

3) OPMS kratom is ultimately packaged, labeled, and distributed by JOpen through third party contracts. See e.g., Exhibit 6 (Distribution Agreement between Martian and JOpen).

4) JOpen works with Martian to manage its website. Exhibit 4 at 197:8-21.

E) JOpen Pays for Martian's Raw Kratom, Manufacture, Processing, Logistics, and Manages OPMS Packaging, Labeling, Web Presence, and Post Mark Surveillance

1) JOpen is the hub of the OPMS network insofar as it pays for raw kratom sourced by Nuza, pays manufacturing costs for Martian, and then manages packaging, distribution, and post market surveillance. See, Exhibit 5 at 295:22-296:9 & 281:15-284:25.

2) Martian owns OPMSkratom.com, however, the website is managed by JOpen and Martian has no access to it. See, Exhibit 5 at 98:5-99:6, 268:24-269:11, & 302:15-19, see also, Exhibit 4 at 197:8-21.

3) Incredibly, Martian has no knowledge of what happens to contact through the website's contact form. See, Exhibit 4 at 194:15-195:3.

F) OPMS Labels are Fraudulent. All Entities Within the Stream of Commerce for OPMS are Intentionally Structured to Avoid Detection and Liability for the Harms Caused by OPMS.

1) OPMS labels falsely identify the entity behind OPMS products. See, Exhibit 5 at 66:8-70:1, 79:19-81:7, 212:11-216:9, & 219:17-220:4.

2) The labels direct consumers, regulators, and the public to a non-exist entity named Choice Organics and provides a Los Angeles address that is a mailbox store P.O. box. See, Dkt. No. 132-44 (Decl. of Leodler) at ¶ 22.

3) The phone number provided did not function and has only recently come into alleged use for post market surveillance. *Id.*

G) OPMS Kratom is Labeled as Only for Use as a "botanical specimen," but Defendants Claim it is a Food. OPMS is Neither a Botanical Specimen, Nor a Food. OPMS Kratom is a Supplement and Unapproved New Drug.

- 1) OPMS Silver kratom labels states that the product is “Only for use a botanical specimen.” Exhibits 1 & 2.
- 2) A botanical specimen is plant material intended for scientific or research purposes and would consist of a whole partial plant sample, not a processed powder. Indeed, “A specimen is a single plant or animal which is an example of a particular species or type and is examined by scientists.” *See, e.g.*, “specimen,” Collins English Dictionary, 2019.
- 3) According to the National Institute of Health (NIH) Office of Dietary Supplements, “A botanical is a plant or plant part valued for its medicinal or therapeutic properties, flavor, and/or scent. Herbs are a subset of botanicals. Products made from botanicals that are used to maintain or improve health are sometimes called herbal products, botanical products, or phytomedicines.” See Exhibit 56.
- 4) Martian Sales agrees that a botanical specimen is “just a specimen of a botanical, like a piece of a leaf.” Exhibit 9 (Excerpt of October 8, 2025, 30(b)(6) Deposition of Mark Reilly Corporate Representative of Martian Sales) at 97:1-4; see also, Exhibit 10 (Excerpt of October 9, 2025 30(b)(6) Deposition of Mark Jennings Corporate Representative of LP IND, LLC) at 35:17-21 (Stating “It’s a plant or part of a plant.”).
- 5) Martian Sales also could not explain how a consumer would use OPMS kratom as a “botanical specimen.” Exhibit 9 at 97:7-17.
- 6) OPMS Silver kratom labels also state that “Mitragyna Speciosa is an unapproved dietary ingredient.” Exhibits 1 & 2. Martian Sales confirms that is the case. Exhibit 9 at 98:3-7.
- 7) Notwithstanding that claim that OPMS is only for use as a botanical specimen, Defendants attempt to argue that kratom is a food. Exhibit 10 at 51:18-20. Exhibit 11 (Excerpt of October 9, 2025 Deposition of Peyton Palaio) at 37:16-22; Exhibit 14 (Excerpt of October

16, 2025 30(b)(6) Deposition of David Gabbay, Corporate Representative of JOPEN, LLC) at 51:21-22. Compare with Exhibit 56 (NIH botanical dietary supplement discussion).

- 8) It is not. OPMS kratom is a dietary supplement.
- 9) The FDA has stated that Kratom, and OPMS kratom can be considered dietary supplements. See e.g. Exhibit 19 (FDA Import Alert 54-15 referring to kratom containing dietary supplements), Exhibit 38 (FDA Warns Consumers Not to Use Optimized Plant Mediated Solutions (OPMS) Black Liquid Kratom, July 26, 2024, accessible at: <https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-not-use-optimized-plant-mediated-solutions-opms-black-liquid-kratom> (last accessed February 26, 2026)) (referring to kratom products marketed as dietary supplements); see also, Exhibit 27 (Deposition of Defense Expert, Christopher McCurdy, Ph.D.) at 99:20-100:4 (stating, when asked the medical purpose that over the counter kratom can be safely used for, that “the only thing that it [kratom] can be sold as, as much dietary supplements are sold...for promoting well-being”).
- 10) Martian Sales has even filed trademarks for OPMS as a dietary supplement. Exhibit 3 (USPTO documents for OPMS trademark stating the mark is for “Nutritional and dietary supplements; herbal supplements.”)
- 11) Defendant, Nuza, LLC even marks OPMS products as a supplement when shipping to JOpen, LLC. See Exhibit 15 (Declaration of Evelyn Cadman), and Exhibit A-5 to Declaration of Evelyn Cadman at p. 21 (Bill of Lading listing shipment of OPMS kratom products at dietary supplements).
- 12) Calibre Manufacturing, LLC purposefully attempts to comply with supplement related regulations and good manufacturing practices. Exhibit 12 (Excerpt of October 10, 2025,

Deposition of Mark Jennings Corporate Representative of Calibre Manufacturing, LLC) at 43:15-46:16 & 46:25-47:11 & 74:22-75:9 & 76:25-77:20 & 80:24-81:8.

13) JOpen, agrees that Kratom can be considered a dietary supplement, even if Defendants consider it a food. Exhibit 14 (Excerpt of October 16, 2025, 30(b)(6) Deposition of David Gabbay Corporate Representative for JOpen, LLC) at 82:7-9.

14) LP acknowledges that dietary ingredient and dietary supplement can be used interchangeably. Exhibit 10 at 84:2-8.

15) Mr. Reilly states that an approved dietary ingredient is a dietary supplement. Exhibit 8 (Excerpt of October 8, 2025 Deposition of Mark Reilly) at 35:20-23.

H) Kratom, including OPMS kratom is dangerous, and its dangerous propensities were known to defendants prior to Harmony Moller's death.

1) OPMS Silver kratom labels states that “mitragyna speciosa can be dangerous,” but does not state how or in what manner mitragyna speciosa can be dangerous. Exhibits 1 & 2.

2) OPMS Silver Kratom labels also do not disclose that 7-hydroxymitragynine (7-OH) is dangerous and up to 40 times more powerful than morphine. Exhibits 1 & 2, and Exhibit 16 (February 17, 2026, Deposition of Defense Expert, Edward W. Boyer, M.D., Ph.D.) at 69:5-17; see also generally, Exhibit 17 (FDA, *7-Hydroxymitragynin (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat*, https://www.fda.gov/files/drugs/published/7-hydroxymitragynin_7-oh_an_assessment_of_the_scientific_data_and_toxicological_concerns_around_an_emerging_opioid_threat.pdf, last accessed Feb. 26, 2026).

3) Nonetheless the labels disclose that 7-OH is an ingredient of OPMS Silver kratom. Exhibits 1 & 2.

- 4) The FDA has been reporting of dangers associated to Kratom since at least August 18, 2015 when it issued an import alert stating in part: “In fact, the scientific literature disclosed serious concerns regarding the toxicity of kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms.” Exhibit 18 (FDA Import alert listing for human and animal drugs, indicating Import Alter 54-15 was published on August 18, 2015, accessible at: https://www.accessdata.fda.gov/cms_ia/industry_66.html?utm_source%201/6, last accessed February 26, 2026); Exhibit 19 (FDA Import Alert 54-15, accessible at: https://www.accessdata.fda.gov/cms_ia/importalert_1137.html, last accessed February 26, 2026); see also, Exhibit 21 (FDA and Kratom webpage warning of risks such a live toxicity, seizures, substance use disorder, and death, accessible at: <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>, last accessed February 26, 2026).
- 5) The DEA has listed kratom as a drug of concern since at least 2020. Exhibit 20 (DOJ/DEA, Drug Fact Sheet, Kratom, April 2020, accessible at: https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf, last accessed February 26, 2026).
- 6) Defendants were sued at least twice prior to Harmony Moller’s death putting them on notice of the risk of death associated directly to their products. See Exhibit 22 (Estate of Ethan Pope v OPMS et al., filed May 9, 2022) and Exhibit 23 (Estate of Daniel Scott Paul v OPMS et al., filed November 23, 2021).

7) Defendants’ own experts agree that kratom cannot be ruled out as a cause of death in this matter. Exhibit 24, (January 15, 2026 Deposition of Defense Expert Amber R. Wang, M.D.) at 132:24-133:7 (Stating she has listed kratom on cause of death factor in autopsies), 133:14-24 (Agreeing that kratom can interact with other drugs to cause an adverse event), 136:11-21, and 137:1-19 (Agreeing that “there is no indication” that kratom did not exacerbate Harmony Moller’s underlying cardiac condition); Exhibit 25 (February 13, 2026 Deposition of Defense Expert Winston H. Gandy, M.D., FACC, FASE) at 68:3-69:3 (Stating it is possible that kratom causes cardiac arrhythmia), 72:23-73:3 (Stating “all other drugs...including kratom, that had the potential to prolong the QT interval, in my opinion...made it easier for the arrhythmia to occur.”), and 162:21-163:4 (Stating in part, “More likely than not, I cannot say that [kratom] didn’t” contribute to the arrhythmia causing Harmony’s death); Exhibit 26 (January 20, 2026 Deposition of Defense Expert Marilyn A. Huestis, Ph.D.) at 186:3-19 (Admitting that kratom, along with the all the other substances present in the toxicology report may have contributed to Harmony’s death); Exhibit 27 (January 28, 2026, Deposition of Defense Expert Christopher McCurdy Ph.D.) at 107:7-108:13 (Stating that kratom cannot be ruled out as a contributing cause of death); and Exhibit 28 (Deposition of Allen L. Dollar, M.D., FACC, FACP) at 103:9-25 (Stating there is insufficient data in the medical literature to rule out kratom as a contributing factor), and 104:10-21 (Stating he cannot rule out that kratom, along with Phenergan and Benadryl, created an arrhythmia that caused Harmony’s death).

I) OPMS kratom is adulterated

1) OPMS Silver kratom is adulterated. See generally Exhibits 17, 19, 20, and 21; see also, Plaintiff’s Memorandum of Law in Support of Plaintiff’s Motion for Judicial Notice

incorporated herein by reference, and Exhibit 15 (Declaration of Evelyn Cadman) at Exhibit A-2 (FDA Inspection of JOpen, LLC stating in part “...a discussion was had regarding violative/adulterated products due to kratom. I explained to Mr. Gabbay that the FDA does not recognize kratom as an ingredient to be used in food items...”)

- 2) In fact, JOPEN has been directly informed by FDA investigators, investigating its facility in relation to a reported death caused by OPMS black liquid kratom, that OPMS kratom is adulterated. Exhibit 15 (Declaration of Evelyn Cadman) at Exhibit A-2.
- 3) Kratom can be addictive. Exhibit 29 (Interview of Defense Expert, Christopher McCurdy, Ph.D., stating that kratom can be addictive).
- 4) “Kratom may cause significant drug interactions, especially at high doses.” Exhibit 30 (Abstract of Dhoble et. al., *Evaluating the drug interactions in kratom usage: clinical application*, Expert Opinion on Drug Metabolism & Toxicology, June 2025 (Defense expert, Christopher McCurdy, Ph.D. is a co-author).

J) OPMS Kratom is misbranded

- 1) OPMS Silver kratom is misbranded. See generally, Exhibit 19 (FDA Import Alert 54-15, stating that the labeling, marketing, and/or promotion of kratom products may indicate that such products are unapproved or misbranded drugs) and Exhibit 31 (Expert Report of Evelyn Cadman, Section B, explaining OPMS is misbranded in part because it is sold for treatment of opiate use disorder).
- 2) A kratom product is “misbranded” when: (1) it is knowingly sold for use as a drug but fails to bear adequate directions for its intended uses; and/or (2) it is knowingly offered for conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. See, 21 USC § 352(f)(1); 352(a), (f), (i), (o) (identifying misbranded

drugs). Selling OPMS Silver kratom over the counter for opiate use disorder treatment without adequate directions renders OPMS Silver kratom misbranded.

- 3) The OPMS Defendants have testified to knowingly selling OPMS kratom products to people struggling with medical conditions, including opiate addiction, and testified to using kratom for this exact purpose as well. Exhibit 14 at 65:15-66:15; Exhibit 5 159:18-23 and pp.160:19-161:2; and Exhibit 4 at 206:23-207:10.
- 4) OPMS Silver kratom is also misbranded because the label does not correctly identify the actual name and place of business for the entity responsible for the product. See Exhibits 1 & 2, identifying Choice Organics; see also, 21 U.S.C. § 343(e).
- 5) The OPMS label identifies Choice Organics, and provides a phone number, address, and email. Exhibits 1 & 2.
- 6) Choice Organics is an entity made up out of whole cloth in response to a Utah state enforcement action. Further, the address, phone number, and email have had periods in which they have not functioned. Exhibit 5 at 66:8-68:24, 79:19-81:3, 212:15-213:5, 219:17-220:4, & 239:24-240:20; see also, Dkt. No. 132-44 (Decl. of Leodler) at ¶ 22.
- 7) The OPMS label is deemed misbranded because it does not specify a complete domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event. 21 U.S.C. § 343(y).

K) Despite having knowledge of kratom's dangers, Defendants did not warn of such dangers on OPMS kratom packaging.

- 1) OPMS Silver kratom does not state that OPMS Silver Kratom 7-OH can be dangerous, that 7-OH is 40 times more powerful than morphine, that kratom is addictive, or that kratom can cause adverse effects including. Exhibits 1 & 2.

- 2) Defendants have changed their warnings over time. Exhibit 33 (Excerpt of Martian Sales, Inc.'s Responses to Plaintiff's First Set of Interrogatories at Interrogatory No.4), compared with Exhibit 34 (Excerpt of Jopen, LLC's Supplemental Responses and Objections to Plaintiff's Fourth Set of Interrogatories at Interrogatories No.s 1, 3, 4, & 7), and Exhibit 35 (Excerpt of Martian Sales, Inc.'s Supplemental Responses and Objections to Plaintiff's Third set of Interrogatories at Interrogatories No.s 1, 3, 4, & 7).
- 3) Defendants have changed their website disclaimers over time. Exhibits 34 & 35; see also, Exhibit 36 (Copy of website disclaimer for 2021) and Exhibit 37 (Copy of website disclaimer from 2022).
- 4) Defendants have refused to explain the basis of these changes, claiming privilege. See Exhibits 34 & 35.
- 5) The package warning do not state known risks and differ from website disclaimers. Exhibits 1 & 2, compared with Exhibits 36 & 37.

L) Despite having knowledge of OPMS kratom's adulterated and misbranded status, Defendants did not inform consumers of this status.

- 1) OPMS Silver kratom does not state that OPMS Silver kratom is adulterated or misbranded. Exhibits 1 & 2.

M) Defendants knowingly sold OPMS kratom for human consumption and for treatment of opiate use disorder.

- 1) Defendants sold OPMS kratom for human consumption, in other words, they knew consumers would ingest their products. Exhibit 9 at 97:19-22; Exhibit 8 (October 8, 2025 Deposition of Mark Reilly in his Individual Capacity) at 37:2-12; and Exhibit 32 (JOpen, LLC's Responses and Objections to Plaintiff's Requests for Admission at No. 9 "Request

For Admission No. 9: Admit that JOPEN Marketed and sold kratom products for human consumption. Response: Admit.”).

- 2) Defendants sold OPMS kratom for the unlawful purpose of over-the-counter treatment for opiate use disorder.
- 3) Defendants have testified to knowingly selling OPMS kratom products to people struggling with medical conditions, including opiate addiction, and testified to using kratom for this exact purpose as well. Exhibit 14 at 65:15-66:15; Exhibit 5 159:18-23 and pp.160:19-161:2; and Exhibit 4 at 206:23-207:10.

N) OPMS Kratom can provide a more effective warning by clearly communicating the health risks associated to kratom, communicating how to minimize risks, and by complying by warning best practices.

- 1) JOpen has explained that updating product labels is a relatively easy endeavor. In fact, in response to enforcement actions in Utah, JOpen quickly printed updated stickers to be applied to labels while new labels were printed. Exhibit 5 at 67:1-17; 68:22-24;
- 2) Thus, it should be just as easy for JOpen to update the package warning label with changes such as clearly communicating the health risks associated to kratom (like cardiac adverse effects and risk of death), communicating how to minimize risks through clear guidance on dosage and timeframes for use, and by complying by warning best practices, such as use of clear familiar words, prominent placement of the warning, or use of icons or symbols to increase attention. See generally, Exhibit 39 (Expert Report of Sarah Kowitt, Ph.D.).

O) OPMS Silver kratom is made of dried and ground kratom leaves

- 1) OPMS Silver kratom is made from dried and ground kratom leaves. Exhibit 13 at 90:2-91:2; Exhibit 12 at 97:25-100:20; see also, Exhibits 51 & 52.

- 2) As soon as kratom leaves are picked from a tree they begin an oxidative process that increases content of 7-OH. Exhibit 27 at 154:21-156:5, 270:9-14, 276:5-24, 281:19-282:12.
- 3) 7-OH continues to increase as the leaves are dried and ground, and continues to increase as the dried leaf material is shipped, processed, packaged, and ultimately sold. *Id*; see also, Exhibit 40 (Transcript of Christopher McCurdy, Ph.D. regarding “Kratom Use in the United States” for NIH continuing education, accessible at: <https://www.nccih.nih.gov/training/videolectures/22/3>, last accessed February 26, 2026); see also, Kruegel, Andrew, et al., *7-Hydroxymitragynine Is An Active Metabolite of Mitragynine and a Key mediator of Its Analgesic Effects*, ACS Cent. Sci. 2019, 5, 992–1001(2019) (Discussing the metabolism of mitragynine into 7-OH in the body, and the risks and opioid impact of 7-OH); and Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022) (Christopher McCurdy listed a co-author, and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf).

P) Testing documents show that OPMS Silver kratom is subject to significant variability and includes alkaloids not identified on labeling, which are known and dangerous.

- 1) Defendants produced over ten (10) testing documents they claim are associated to the products at issue, an exemplar set of those documents is attached hereto. See generally, Exhibits 41-50.
- 2) Defendants could not identify with certainty which tests in fact correspond to the kratom in the packages found in Harmony’s possession. Exhibit 13 at 73:12-17 (Confirming tests produced correlate to product at issue and were allegedly within spec); 76:15-79:11

(discussing that tested product may later be blended together and uncertainty as to whether that would impact potency); 81:7-13 (inability to explain how five separate tests account or relate to two bags of product at issue); compare with Exhibit 14 at 154:4-17 (Stating JOpen cannot account for correlation of tests to products at issue, after Mr. Jennings stated JOpen would be able to.), 158:16-22, 159:1-6, 181:17-21, and 206:2-13 (failing to account for why counsel produced kratom extract tests with the representation they relate to the products at issue).

- 3) The testing documents produced show a wide variability of alkaloid content potency. See generally, Exhibits 41-50.
- 4) The test documents produced also show several alkaloids not identified on OPMS Silver kratom packaging, such as payantheine, speciogynine, speciociliatine, mitraphylline, and isoryhncophylline. Exhibits 41-50.

Q) OPMS Silver kratom is regularly produced and sold while out of spec

- 1) Defendants produced two product spec sheets. Exhibit 49 & 50.
- 2) The spec sheets are inconsistent insofar as Exhibit 51 provides no specification whatsoever for green powder kratom and only provides a specification dried leaf in a capsule. Further, the same document does not state any minimums or maximums on alkaloids content.
- 3) Meanwhile, Exhibit 52 references green material but provides different standards for microbials and heavy metals.
- 4) Neither spec sheet provides a spec for 7-hydroxymitragynine content. Exhibit 51 & 52.
- 5) Exhibits 52 simply states no 7-hydroxymitragynine is required, despite the known dangers associated to 7-OH.

R) There is no known safe dose of OPMS Silver kratom.

1) There is no known safe dose of OPMS Silver kratom. See Exhibit 16 (Deposition of Dr. Boyer) at 82:8-11 “Q: What is the maximum safe dose known for mitragynine? A: I don’t know that there are any publications that define a maximum safe dose...”), 83:14-19 (“Q: Do you know the maximum safe dose for 7-hydroxymitragynine? ...A: I know that no maximum safe dose has been defined...); see also, Exhibit 26 (Deposition of Marilyn Huestis) at 125:1-22 and 312:20-313:1 (Q: How is someone supposed to know how much OPMS kratom to take?...The Witness: That I don’t know because it says talk to your physician about it.”).

S) There are safer alternatives for OPMS kratom, such as whole fresh kratom leaves or a pre-market approved kratom product.

1) Whole fresh leaf kratom is safer than OPMS Silver kratom because it contains less 7-OH and is consumed in a manner that impacts the absorption and effect of kratom alkaloids on the body. Exhibit 27 at 154:21-156:5, 270:9-14, 276:5-24, 281:19-282:12; see also, Exhibit 40 (Transcript of Christopher McCurdy, Ph.D. regarding “Kratom Use in the United States” for NIH continuing education, accessible at: <https://www.nccih.nih.gov/training/videolectures/22/3>, last accessed February 26, 2026); see also, Kruegel, Andrew, et al., *7-Hydroxymitragynine Is An Active Metabolite of Mitragynine and a Key mediator of Its Analgesic Effects*, ACS Cent. Sci. 2019, 5, 992–1001(2019) (Discussing the metabolism of mitragynine into 7-OH in the body, and the risks and opioid impact of 7-OH); and Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022) (Christopher McCurdy listed a co-author, and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf).

- 2) Defendants can seek approval of OPMS Silver kratom as a pre-market approved drug, but have failed to do so, despite intending to sell OPMS Silver kratom for treatment of Opiate Use Disorder. See FDA, Development and Approval Process—Drugs, accessible at, <https://www.fda.gov/drugs/development-approval-process-drugs> (last accessed February 26, 2026) (providing an overview of FDA drug approval process).
- 3) Such a process would ensure FDA oversight and approval of product safety and product warnings after thorough vetting through studies, including clinical studies.

Dated: March 2, 2026.

Respectfully submitted,

By: s/ Michael Cowgill

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