

**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, INC.; ABC
INSURANCE COMPANY and John
Does 1-4,**

Defendants.

*
*
*
*
*
*
*
*
*
*
*

CIVIL ACTION NO. 2:24-cv-228-WBV-DPC

THE HONORABLE WENDY B. VITTER

**MAGISTRATE DONNA PHILLIPS
CURRAULT**

DEFENDANTS’ RULE 56.1 STATEMENT OF MATERIAL FACTS

Pursuant to Eastern District of Louisiana Local Rule 56.1, Defendants LP Ind., LLC, CAG Holdings, LLC, RMH Holdings, Inc., Martian Sales, Inc., Johnson Foods, LLC, JOpen, LLC, Nuza, LLC, Calibre Manufacturing, LLC, FMK Group, Inc., PNW Holdings, LLC, CC US Holdings, LLC, Peyton Palaio, Mark Jennings, David Gabbay, and Mark Reilly (“Defendants”) respectfully submit this Statement of Material Facts in support of their Motion for Summary Judgment.

I. HARMONY MOLLER

1. Harmony Moller died on February 6, 2023. ECF No. 100 at ¶ 30.
2. The Third Amended Complaint alleges that Ms. Moller, a 36-year-old female, died as the result of the ingestion of O.P.M.S. brand Kratom. *Id.* at ¶¶ 30, 33.
3. Plaintiff alleges that Harmony Moller consumed O.P.M.S. Silver Kratom ground leaf material sold as a loose powder or with the powder placed in a capsule. Ex. 1, MOLLER_000023; Ex. 2, MOLLER_000025.

4. Harmony was not feeling well and thought she had food poisoning immediately prior to her death. Ex. 3, STPSO000001 (the St. Tammany Parish Sheriff's Office "Incident Report"), at 000001; Ex. 4, Excerpts from Deposition of Kathleen Moller ("Moller Dep.") at 220:10, 225:4–10, Dec. 14, 2025; Ex. 5, ST.TAMMANYFD_MOLLER00001 (the St. Tammany Parish Fire Department EMS Records), at 00002.

5. Both O.P.M.S. Silver kratom powder products contained identical "directions" and "disclaimer" and "warning" labels. *See* Exs. 1, 2.

6. "A postmortem examination determined the cause of death was 'Abnormally high left coronary ostia takeoff exacerbated by Mitragynine use' secondary to the ingestion of Kratom." ECF No. 100 at ¶ 33.

7. Ms. Moller's autopsy disclosed that she suffered from a coronary anomaly – specifically, her "left coronary artery arises 5 mm above the sinotubular ridge with an acute angle of origin[]" and "an inferior aortic wall flap[.]" Ex. 6, ST.TAMMANYCORONER_MOLLER00001 (St. Tammany Parish Coroner's Office "STPCO" Records), at 00009, 00020–22.

8. All medical experts in this matter agree that Ms. Moller died of a ventricular arrhythmia. Ex. 7, Excerpts from Deposition of Dr. Allen Dollar ("Dollar Dep.") at 87, Feb. 6, 2026; Ex. 8, Excerpts from Deposition of Dr. Winston Gandy ("Gandy Dep."), at 71, Feb. 13, 2026; Ex. 9, Excerpts from Deposition of Dr. Josef Thundiyil ("Thundiyil Dep."), at 151–52, Jan. 16, 2026; Ex. 10, Excerpts from Deposition of Dr. Amber Wang ("Wang Dep."), at 98–99, Jan. 15, 2026; Ex. 11, Excerpts from Deposition of Dr. Ronald Wharton ("Wharton Dep."), at 214:18–215:16, Feb. 23, 2026; Ex. 12, Defendant's Expert Report of Dr. Edward Boyer ("Boyer Rpt."), at ¶ 79.

9. Limited postmortem toxicology testing was performed by NMS Labs, and testing was performed on femoral blood and vitreous blood (the “NMS Labs Test”).¹ Ex. 13, Excerpts from NMS Labs Production, at NMS_MOLLER00004–40; Ex. 6 STPCO, at 00014–18; Ex. 14, Excerpts from Deposition of Dr. Michael DeFatta (“DeFatta Dep.”), at 144:4–11.

10. The NMS Labs Test did not quantify the amount of caffeine – it was only a presumptive positive. *Id.*; Ex. 14, DeFatta Dep. at 127:9–129:3, 144:4–11, 146:23–21; 188:10–24, 202:13–19, Feb. 25, 2026; Ex. 15, Excerpts from Deposition of Dr. Boyer Dep. (“Boyer Dep.”), at 253:2–7, Feb. 17, 2026.

11. The NMS Labs Test did not include testing to screen for food poisoning. Ex. 14, DeFatta Dep., at 117:24–118:11.

12. Mitragynine was detected at a concentration of 150 ng/mL. Ex. 6, STPCO, at 00014.

13. Other positive findings included diphenhydramine (64 ng/mL), promethazine (18 ng/mL), caffeine, and marijuana (delta-9 THC and delta-9 Carboxy THC). *Id.*

14. Diphenhydramine and promethazine have been scientifically proven to cause QT prolongation that can lead to a ventricular arrhythmia. Ex. 7, Dollar Dep. at 55:14–16, 69:1–5, 102:20–103:1.

15. Harmony Moller did not have a prescription for either Diphenhydramine or promethazine. Ex. 4, Moller Dep. at 226–228.

¹ Of the possible lab tests, “it starts out with a basic panel, an expanded panel, and an expert panel overall,” with “expert” being the most comprehensive, “and then you can add on dozens of different types of things if you’re looking for it.” Ex. 14, DeFatta Dep., at 70:5–9.

16. There is no evidence that Harmony Moller consumed O.P.M.S. kratom products before her death, as Plaintiff admitted she was unaware that Harmony Moller had ever consumed kratom before her death. *Id.* at 197–198.

17. The unopened O.P.M.S. Silver kratom products were found in the hallway of Plaintiff’s house, Ex. 16, K. Moller Dep. Ex. 29. Other items located in or around Harmony’s bedroom included several marijuana products, vaping devices, drug paraphernalia (a grinder and glass pipe), prescription medications (most belonging to other individuals), over-the-counter drugs, alcohol bottles, caffeine and weight-loss pills, dietary and herbal supplements and unidentified or unlabeled ground substances. Ex. 4, at 263:19–277; Exs. 17–20, K. Moller Dep. Exs. 14, 17, 18, 27 (photos of items from Harmony’s dresser in her bedroom); Exs. 21–23, K. Moller Dep. Exs. 19, 21, 22 (photos of items from Harmony’s dresser in her bedroom); Ex. 16, K. Moller Dep. Ex. 29; Ex. 24, K. Moller Dep. Ex. 28 (photos of the O.P.M.S. kratom packages and items found in a bag in the room near Harmony’s bedroom).

18. Plaintiff claims she threw away all of these items on the day of Harmony Moller’s death except for one supplement and the two O.P.M.S. Silver kratom packages. Ex. 4, at 188:12–190:13; 277:4–5; 280:5–6; *see also id.* at 190:23–24; 265:19–20; 266:10–11.

19. Among Harmony Moller’s possessions found by investigators was a cannabis product with a warning that the product “may not be transported outside the State of Illinois” and that “[p]ossession or use of this product may carry significant legal penalties in some jurisdictions and under federal law.” Exs. 25, 26, K. Moller. Dep. Exs. 23 and 24.

II. DEFENDANTS

A. JOpen.

20. Formed in 2012, JOpen is a Texas-based distributor of a variety of products to the convenience store market. One of the many thousands of products it distributes is O.P.M.S.

kratom. ECF No. 122-2, Declaration of David Gabbay ¶¶ 3–6; ECF No. 122-3, JOpen Cert. of Formation; ECF No. 122-4, JOpen Operating Agreement; *id.*, JOpen Company Agreement.

21. JOpen distributes O.P.M.S. kratom pursuant a contract with Defendant Martian Sales, which owns the O.P.M.S. trademarks. *Id.*, Distribution Agreements. JOpen oversees packaging and distributes products, including the O.P.M.S. Silver product at issue, using O.P.M.S. trademarks owned by Martian Sales.

B. Martian Sales.

22. Martian Sales is a Wyoming Company formed in 2012. ECF No. 122-5, Articles of Incorporation.

23. It was founded and fully-owned by Defendant Mark Reilly, who serves as its president and is the sole employee. ECF No. 122-6, Excerpts from Martian Sales Dep. at 16:12–23, 61:19–24.

24. Martian Sales is not affiliated with, owned by, or under common control with any other corporate Defendant, whether through subsidiaries, parent companies, or otherwise. ECF No. 122-7, Declaration of Mark Reilly ¶ 10.

25. Martian Sales owns the trademarks for O.P.M.S. kratom. ECF No. 122-6 at 18:2–5; ECF No. 122-8, Trademarks.

26. Martian Sales contracts with manufacturers located outside of Louisiana to manufacture kratom products, *see, e.g.*, ECF No. 122-9, Processing Agreement, and contracts with JOpen, also located outside of Louisiana, to distribute the products to wholesalers and retailers. ECF No. 122-4.

27. Martian Sales is paid a flat fee by JOpen for use of the O.P.M.S. trademark. ECF No. 122-7 at ¶¶ 7–9.

28. Martian Sales is adequately capitalized and observes all corporate formalities as a Wyoming company. Martian Sales does not have common offices, common property, common accounting systems, common directors and officers, or common employees with any other Defendant. Martian Sales does not finance any other Defendant; does not pay the salaries, expenses or losses of any other Defendant; and does not utilize the services of any employee of any other Defendant. Martian Sales exerts no authority over the internal business operations or daily operations of any other Defendant.

C. LP.

29. LP is a Wyoming company formed in 2012 with operations in Colorado. ECF No. 122-10, Articles of Org; ECF No. 122-11, Decl. of Mark Jennings ¶ 13.

30. LP is a manufacturer of bulk kratom. ECF No. 122-11, Decl. of Mark Jennings at ¶ 4.

31. LP did not and has never manufactured the O.P.M.S. kratom allegedly consumed by decedent. ECF No. 122-13, Excerpts from LP Dep. at 121:14–16; ECF No. 122-14, Plaintiff's Initial Disclosures at 2 (stating that decedent consumed Maeng Da Kratom Silver capsules).

D. CAG.

32. CAG is a Wyoming company formed in 2019. ECF No. 122-15, Articles of Org.

33. It is no longer in operation, but formerly operated a manufacturing facility that processed industrial hemp, and had no involvement with kratom. ECF No. 122-16, Decl. of Mark Jennings ¶¶ 4.

34. CAG has never marketed, distributed, or sold any kratom-containing products (or any other products) to consumers. ECF No. 122-17, CAG Resp. to Pl.'s First Req. for Produc. No. 1.

E. RMH.

35. RMH is a Wyoming company formed in 2015. ECF No. 122-18, Articles of Incorporation. It is no longer in operation. Ex. 27, Excerpts from RMH Holdings, LLC Dep. 12:16–18, Dec. 4, 2024.

36. It formerly operated a manufacturing facility that processed industrial hemp, and has no involvement in kratom. ECF No. 122-19, Declaration of Mark Jennings ¶ 4.

37. RMH has never marketed, distributed, or sold any kratom-containing products (or any other products) to consumers. ECF No. 122-20, Def. RMH's Resp. to Pl.'s First Interrog. No. 1.

F. CC US Holdings.

38. CC US Holdings is a Wyoming company which provides management and accounting services for LP, CMG, RMH and a number of other companies. ECF No. 122-27, Decl. of Mark Jennings ¶ 3.

39. CC US Holdings has never been involved in the distribution, sale, design, manufacture or marketing of kratom, in Louisiana or anywhere. *Id.* at ¶¶ 4–5.

G. PNW.

40. PNW is a Wyoming holding company. ECF No. 122-26, Declaration of Mark Jennings ¶ 3.

41. It has never been involved in the distribution, sale, design, manufacture or marketing of kratom, in Louisiana or anywhere. *Id.* at ¶¶ 4–5.

H. FMK.

42. FMK is a Wyoming holding company, and the sole member of Defendants CAG, LP, PNW, and CC US Holdings. ECF No. 122-25, Decl. of Mark Jennings ¶ 3.

43. It has never been involved in the distribution, sale, design, manufacture or marketing of kratom. *Id.* at ¶¶ 4–5.

I. Johnson Foods.

44. Johnson Foods is a Wyoming company formed in 2021. ECF No. 122-21, Articles of Org.

45. It has had no common ownership or control with any other Defendant at any relevant time. ECF No. 122-22, Declaration of Mark Jennings ¶ 4.

46. Johnson Foods has never marketed, distributed, or sold any kratom-containing products (or any other products) in Louisiana. *Id.*

J. Nuza.

47. Nuza is a Wyoming logistics company that assists in sourcing and transporting kratom from the manufacturer to the distributor. ECF No. 122-23, Decl. of Mark Jennings, ¶¶ 3–4.

48. Nuza does not distribute, sell, design, manufacture, or market kratom products in Louisiana. It has never done business in Louisiana. *Id.* at ¶¶ 5–6.

K. Calibre.

49. Calibre is a Wyoming kratom manufacturer that puts kratom powder into capsules and liquids. ECF No. 122-24, Decl. of Mark Jennings ¶¶ 3–4.

50. Calibre then sends the bulk kratom product to JOpen in Texas for packaging and distribution. *Id.* at ¶ 5.

51. Calibre does not distribute, sell, design, manufacture, or market kratom products in Louisiana. *Id.* at ¶¶ 6–7.

L. The Individual Defendants.

52. Peyton Palaio was formerly the manager of Defendants LP, CAG, RMH, CC US Holdings, and FMK.

53. Mark Jennings is the manager of Defendants LP, CAG, RMH, Johnson Foods, Nuza, Calibre, FMK, PNW, and CC US Holdings. ECF No. 122-11, Decl. of Mark Jennings ¶ 2; ECF No. 122-16, Decl. of Mark Jennings ¶ 2; ECF No. 122-19, Decl. of Mark Jennings ¶ 2; ECF No. 122-22, Decl. of Mark Jennings ¶ 2; ECF No. 122-23, Decl. of Mark Jennings ¶ 2; ECF No. 122-24, Decl. of Mark Jennings ¶ 2; ECF No. 122-25, Decl. of Mark Jennings ¶ 2; ECF No. 122-26, Decl. of Mark Jennings ¶ 2; ECF No. 122-27, Decl. of Mark Jennings ¶ 2.

54. Mark Reilly is the manager and sole employee of Martian Sales. ECF No. 122-6, Excerpts from Martian Sales Dep. at 17:12–14.

55. David Gabbay is the manager of JOpen. ECF No. 122-2, Decl. of David Gabbay at ¶ 2.

56. The raw kratom for the OPMS products at issue would have been sourced by Nuza and then sent to Calibre to be manufactured and encapsulated and then distributed by Defendant JOpen. ECF No. 122-6, Mark Reilly Dep. at 101:1–3; Ex. 28, Excerpts from Martian Sales, Inc. Dep. 34:9–22, Oct. 8, 2025; Ex. 29, Excerpts from Peyton Palaio Dep. 30:19–31:2, Oct. 9, 2025.

III. KRATOM

57. Kratom (*Mitragyna speciosa*) is a tropical tree native to Southeast Asia. Two alkaloids in kratom are mitragynine and 7-hydroxymitragynine, which interact with receptors in the brain. Ex. 12, Boyer Rpt., ¶¶ 20–21; Ex. 30, Expert Report of Marilyn Huestis, Ph.D., (“Huestis Rpt.”), ¶ 12; Ex. 31, Declaration of Jack E. Henningfield, Ph.D. (“Henningfield Decl.”), ¶ 13.

58. Kratom has been consumed for thousands of years in southeast Asia. Kratom was traditionally used in Southeast Asia for fatigue and to improve stamina (by laborers), pain relief, and for opium withdrawal. Ex. 33, Expert Report of Dennis Paustenbach, Ph.D., DABT, CIH

(“Paustenbach Rpt.”), ¶¶ 48, 114; Ex. 31, Henningfield Decl., ¶ 14. Kratom is typically consumed as crushed leaves, powder, extracts, capsules, liquids, or brewed into tea. Ex. 33, Paustenbach Rpt., ¶¶ 64, 95, 97, 112, 119.

59. In the U.S. and elsewhere, kratom is used to help with chronic pain, anxiety or depression, and opioid withdrawal or substitution. *Id.*, ¶¶ 48, 68; Ex. 31, Henningfield Decl., ¶ 14.

60. Unlike opioids, Kratom does not produce respiratory depressant effects, nor carry opioid-like risks of death. Ex. 34, Expert Report of Jack Henningfield (“Henningfield Rpt.”), ¶ 49; Ex. 30, Huestis Rpt., ¶¶ 8–18; Ex. 31, Henningfield Decl. ¶ 15.

61. The product at issue here consists only of ground leaves from the tree – there is no other ingredient. Ex. 56, Excerpts from Nuza Dep. 34:5–7, Oct. 10, 2025.

62. These factual statements have been evaluated and verified as true by the Drug Enforcement Administration (“DEA”), the U.S. Assistant Secretary of Health, and the World Health Organization’s Expert Committee on Drug Dependence which conducted an initial review to determine if kratom warranted a full review as a potential path to international scheduling and determined that the evidence did not warrant such. Ex. 31, Henningfield Decl. ¶ 15; Ex. 34, Henningfield Rpt., ¶¶ 49–59, 78, 101–102.

63. Kratom is not an opioid or narcotic due to the nature of its botanical origin, its chemical structure, its known overall pharmacology, and the fact that it does not have the high abuse potential and national drug threat assessment necessary to meet statutory requirements for U.S. Controlled Substances Act (“CSA”) Scheduling or requirements for inclusion in the United Nations International Drug Control Treaties. Ex. 31, Henningfield Decl. ¶ 16.

64. Most people use kratom for health and well-being, including as a supplement to, or replacement for, caffeinated beverages and to self-manage depression, anxiety, pain, opioid and

other drug withdrawal. Ex. 34, Henningfield Rpt., ¶ 102; Ex. 31, Henningfield Decl. ¶ 18. The vast majority of the evidence from which the foregoing facts were obtained was generated by independent researchers primarily supported by the National Institutes of Health (“NIH”) and NIDA. Ex. 34, Henningfield Rpt., ¶¶ 102, 116–120; Ex. 31, Henningfield Decl. ¶ 20. These studies have been published at an increasing rate year by year over the past decade in leading biomedical research institutions, including Johns Hopkins, University of Florida, the NIDA intramural program itself, and many others. Ex. 34, Henningfield Rpt., ¶¶ 116–120; Ex. 31, Henningfield Decl. ¶ 20.

65. Kratom is a legally marketed and sold product in 43 states. Ex. 34, Henningfield Rpt., ¶¶ 109–113; Ex. 31, Henningfield Decl. ¶ 21. Several of the states that placed kratom as a Schedule I drug in their Controlled Substances Act between 2014 to 2016 are presently in the process of replacing those laws with laws to ensure legal access. Ex. 34, Henningfield Rpt., ¶ 112; Ex. 31, Henningfield Decl. ¶ 21.

66. Kratom is legally sold in the United States after Congress, the DEA, and the Department of Health and Human Services (“HHS”)—the agency under which the FDA is organized—intensively investigated and deliberated about how to classify it. Ex. 34, Henningfield Rpt., ¶¶ 109–113; Ex. 31, Henningfield Decl. ¶ 22. The Secretary of HHS and Commissioner of the FDA have both testified before Congress that it is in the public health interest to keep kratom available for purchase over the counter. Ex. 31, Henningfield Decl. ¶ 22. They concluded that thousands of people would die from opioid overdoses if kratom was not made available as a substitute to opioids to the millions of people in the country who regularly purchase kratom. *Id.*

67. On August 21, 2014, the DEA requested that HHS conduct a medical and scientific evaluation of kratom to determine whether it should be recommended for scheduling as a controlled substance pursuant to the CSA. *Id.* ¶ 23. While HHS’s evaluation was ongoing, on

August 31, 2016, the DEA announced its intent to temporarily add kratom to Schedule I of the CSA.² *Id.* In response, thousands of citizens submitted numerous formal comments providing compelling evidence and testimony that kratom is not harmful, but rather critical to healing, managing pain, and combating opiate and alcohol addiction.³ *Id.* These comments explained that kratom is safer than prescription opioids and that, compared to opioids, deaths attributable to kratom overdose are essentially non-existent. *Id.*

68. U.S. Representatives Mark Pocan (D-WI) and Matt Salmon (R-AZ) sent a letter to DEA and the Office of Management and Budget—a letter that received bipartisan support and was signed by 50 members of Congress—against any ban. *Id.* ¶ 24. The letter noted that kratom is an internationally consumed herb and condemned the proposed ban as “hasty” because of known beneficial effects of kratom. *Id.* The letter said that a ban would adversely affect consumer access to kratom’s known benefits and undermine innovative products that could be used to treat individuals suffering from addiction. *Id.*

69. A bipartisan group of U.S. Senators sent a generally similar letter to the DEA as the Representatives letter, making similar arguments about the adverse public health benefits of a Schedule I ban.⁴ The co-sponsors were Orrin G. Hatch (R-UT), Michael F. Bennet (D-CO), Angus

² Ex. 47, DEA, Schedules of controlled substances: temporary placement of mitragynine and 7-hydroxymitragynine into Schedule I, 81 Fed. Reg. 59929 (Aug. 31, 2016) (to be codified 21 C.F.R. pt. 1308), www.gpo.gov/fdsys/pkg/FR-2016-08-31/pdf/2016-20803.pdf. “Schedule I drugs” are substances or chemicals with no currently accepted medical use and a high potential for abuse. Examples of Schedule I drugs include heroin, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (ecstasy), and peyote.

³ Ex. 48, *Harven M. Herbal drug kratom faces uncertain legal future, despite public outpouring*, PBS Newshour, www.pbs.org/newshour/updates/whats-next-kratom/ (Dec. 12, 2016, 4:22 PM EDT).

⁴ Ex. 49, U.S. Senate. (2016, November 30). *Letter to the U.S. Drug Enforcement Administration regarding the scheduling of kratom.* <https://i2.cdn.turner.com/cnn/2016/images/11/30/senate.kratom.letter.pdf>.

S. King, Jr. (I-ME), Mark Kirk (R-IL), Mike Lee (R-UT), Bernard Sanders (I-VT), Thom Tillis (R-NC), Mark R. Warner (D-VA), and Ron Wyden (D-OR). *Id.*

70. Less than two months later, on October 13, 2016, the DEA withdrew its intent to schedule kratom because of “numerous comments from the public.” *Id.* ¶ 26. The DEA stated that it was persuaded to take the highly unusual action of reversing itself because of the need to consider “comments offering their opinions regarding the pharmacological effects of these substances.”⁵ *Id.*

71. The DEA “requested that the FDA expedite its scientific and medical evaluation and scheduling recommendation for this substance, which DEA previously requested” *Id.* ¶ 27. The agency also set a December 1, 2016 deadline for additional comments and in fact received more than 23,000 comments during the 6-week comment period—most of which supported access to kratom. *Id.*

72. On October 1, 2017, HHS officials wrote a letter to the DEA recommending scheduling kratom.⁶ *Id.* ¶ 29. Once again, many individuals—both scientists and members of the public—submitted comments echoing the sentiment of the thousands of citizens who similarly opposed the ban when attempted in 2016. *Id.* For example, Dr. Andrew Kruegel, a Columbia University Professor of Chemistry studying kratom, stated: “I have major concerns about just pulling the rug out from under tens of thousands of people who are using this to support their health, especially in the case of people who are using it to stay off of more dangerous opioids.”

⁵ See Ex. 50, Hayden Griffen, Megan E. Webb, *The Scheduling of Kratom and Selective Use of Data*, 50 J. Psychoactive Drugs 2, 114-20 (2018) (“What is most unique about the case of kratom is that the DEA took action and then backed off.”).

⁶ Ex. 51, Letter from the Office of the Assistant Secretary for Health to The Honorable Robert W. Patterson, Acting Administrator for Drug Enforcement Administration, U.S. Department of Justice (Oct. 17, 2017), <https://www.documentcloud.org/documents/5031552-HHS-kratom-letter.html>.

*Id.*⁷ Researchers also expressed that scheduling kratom would make it more difficult to study kratom, because any clinical study would require the DEA's permission. *Id.*

73. In August 2018 the Assistant Secretary of Health, Dr. Brett Giroir charged with FDA scheduling recommendations to DEA, withdrew FDA's 2017 scheduling recommendation to the DEA. In the formal scheduling rescission letter, he stated that the "rescission is based on many factors, in part on new data, and in part on the relative lack of evidence, combined with an unknown and potentially substantial risk to public health if these chemicals were scheduled at this time." *Id.* ¶ 31.⁸ As a result, the DEA ceased its scheduling efforts. *Id.* This is the only time in United States' history that the DEA has withdrawn a proposed scheduling. *Id.*

74. Since Dr. Giroir's withdrawal letter, there have been several hundred new published research reports that further strengthen the case for kratom not being appropriate for scheduling. *Id.* ¶ 32. The DEA has not taken further action with respect to kratom. *Id.*

75. In December 2021, the Expert Committee on Drug Dependence ("ECDD") at the World Health Organization and the U.S. Commission of Narcotic Drugs, comprised of 12 international experts on substance safety and addiction, unanimously concluded that there was insufficient evidence to recommend a critical international scheduling review of kratom. *Id.* ¶ 33. "People report using kratom to self-medicate a variety of disorders and conditions, including pain,

⁷ Ex. 52, *HHS recommended that the DEA make kratom a Schedule I drug, like LSD or heroin*, PBS Newshour (Nov. 10, 2018, 12:40 PM EDT), <https://www.pbs.org/newshour/nation/hhs-recommended-that-the-dea-make-kratom-a-schedule-i-drug-like-lsd-or-heroin#:~:text=In%20the%20letter%20letter%20dated,in%20kratom%20on%20Schedule%201.>

⁸ Ex. 53, *See Letter from the Office of the Assistant Secretary for Health to The Honorable Uttam Dhillon, Acting Administrator for Drug Enforcement Administration, U.S. Department of Justice* (Aug. 16, 2018), <https://www.dropbox.com/scl/fi/vgclv41cv0xr6xne6x68z/HHS-Rescission-Letter-Dr.-Giroir-Aug-16-2018.pdf?rlkey=hynbhtl46j903cewsr0w3m8rg&e=1&dl=0+%28last+accessed+on+August+28%2C+2024%29.>

opioid withdrawal, opioid use disorder, anxiety and depression,” the ECDD said in its report. “Kratom is being used as a part of traditional medicine in some countries.” *Id.* “The Committee considered information regarding the traditional use and investigation into possible medical applications of kratom” and “concluded that there is insufficient evidence to recommend a critical review of kratom.” *Id.*⁹

76. The FDA has not begun to promulgate or issue a proposed or final rule specific to the regulation of kratom and has only recently begun to conduct formal scientific studies of kratom. *Id.* ¶ 34. In January 2024, the FDA posted a new grant opportunity to fund the first clinical trial “to characterize the abuse potential and subjective effects of botanical Kratom.” *Id.*¹⁰

77. Recently, on September 19, 2024, the FDA issued preliminary results of its first study on kratom products, which showed clearly, as the agency put it, that “[k]ratom leaves appear safe even at high doses when taken in capsule form.” *Id.*¹¹ ¶ 35. The study further noted: “The data suggest that at the doses tested, using the specific botanical kratom sourced for the study, and under carefully controlled clinical conditions . . . kratom was well tolerated.” *Id.*¹² Over the course of the study, the FDA found no serious complications and stated that it “recognize[s] that further

⁹ Ex. 54, See Patrick Beardsley et al., *WHO Expert Committee on Drug Dependence: forty-fourth report*, World Health Organization [WHO] (2022), <https://www.who.int/europe/publications/i/item/9789240042834> (last accessed on October 10, 2024).

¹⁰ Ex. 55, Dep’t of Health & Human Servs., *Cooperative Agreement to Support a Human Abuse Potential Study of Botanical Kratom*, <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-24-025.html> (last visited Oct. 18, 2024).

¹¹ See Ex. 44, Fiona Rutherford & Immanuel John Milton, *Kratom’s First FDA Study Suggests Capsules Safe at High Doses*, Bloomberg (Sept. 17, 2024).

¹² Ex. 35, Kelly Teal, *FDA pilot study on kratom leaf concludes botanica ‘is well tolerated,’* SupplySide (Sept. 24, 2024), <https://www.supplysidesj.com/herbs-botanicals/fda-pilot-study-on-kratom-leaf-concludes-botanical-is-well-tolerated->.

studies are needed to advance our understanding of kratom.” *Id.* The FDA noted plans for additional peer-reviewed research in the near future. *Id.*

78. Kratom products are legal and widely available for purchase in physical stores in most states and through the Internet. *Id.* ¶ 36.

79. The National Institute on Drug Abuse (“NIDA”) is studying and funding studies to investigate beneficial uses of kratom, including to help treat opioid addiction, and potential adverse effects. *Id.* NIDA is one of 27 Institutes and Centers that comprise the National Institutes of Health, which is part of the U.S. Department of Health and Human Services. *Id.*

80. A New Dietary Ingredient Notification (NDIN) is the premarket notification that must be submitted to FDA at least 75 days before a dietary supplement that contains a new dietary ingredient is marketed (one not marketed in the U.S. before Oct. 15, 1994). *See* 21 U.S.C. § 350b.

81. The FDA is aware that there is no NDIN on file for kratom and allows kratom including O.P.M.S. Silver to be sold in stores all over the country. *See* Ex. 31, Henningfield Decl. ¶¶ 34, 38–39.

82. The “required premarket notice and verification of safety under 21 U.S.C. § 350b(d)” refers to what is commonly called a New Dietary Ingredient Notification (“NDIN”). *Id.* at 38. Kratom is legally sold as a food. No Defendant markets kratom as a drug, dietary supplement, or a food additive. If a seller were to want to sell a product as a drug, dietary supplement, or a food additive, it would need to obtain additional regulatory approval, including possibly an NDIN. *Id.* Kratom has not received that additional regulatory approval to be sold drug, dietary supplement, or a food additive. *Id.* at 34–39.

83. For example, the FDA recognizes that kratom must be sold as a food, and cannot be market as a drug, drug, dietary supplement, or a food additive, having stated that: “FDA has not

approved any prescription or over-the-counter drug products containing kratom or its two main chemical components, mitragynine and 7-OH-mitragynine. There are no drug products containing kratom or its two main chemical components that are legally on the market in the U.S., and FDA has warned against the use of unapproved kratom products for medical treatment.” *Id.*; Ex. 36, FDA and Kratom.

84. The HHS Secretary and FDA Commissioner have determined that ongoing legal over the counter sale of kratom is in the public interest, but they have not accepted any NDIN for any kratom product. Ex. 31, Henningfield Decl., ¶ 39.

85. Acceptance by the FDA of an NDIN is not a requirement for legal sale of kratom as a food. *Id.* ¶ 38. The FDA only requires an NDIN for a drug product, a dietary supplement, or a food additive in conventional food. *Id.*

86. Kratom was legal in Louisiana until August 1, 2025. Ex. 34, Henningfield Rpt., ¶ 113.

IV. THE PRODUCT AND ITS WARNINGS

87. Plaintiff alleges that her daughter, Harmony Moller, consumed O.P.M.S. Silver kratom before her death. ECF No. 122-14, Plaintiff’s Initial Disclosures at 2 (stating that decedent consumed Maeng Da Kratom Silver capsules).

88. The product label for O.P.M.S. Silver contained warnings, including that the botanical Kratom leaf powder was “[o]nly for use as a botanical specimen” and “[i]ngesting *Mitragyna Speciosa* can be dangerous.” Exs. 1, 2.

89. The label included directives to “[c]onsult your healthcare professional to determine if this product is right for you, and if so, how to use it safely,” to “[c]onsult your physician about potential interactions, other possible complications, and precautionary measures

before considering this product,” and to “[i]nform your physician of the alkaloid content, labeled on the package.” *Id.* Plaintiff testified that, “[The label] says it is unapproved for dietary ingredients . . . so you shouldn’t consume it.” Ex. 4, at 316:22–25. She further testified about the label that “The only thing they’re going to tell you is don’t take or do take.” *Id.* at 315:17–25.

90. There is no evidence in the record that Ms. Moller ever discussed her kratom use with a physician. Plaintiff testified that Ms. Moller was not seeing a physician, apart from her dentist, and had not since moving back from Asia in approximately 2021. *Id.* at 246:7–14; 168:5–7.

V. SCIENTIFIC KNOWLEDGE AS OF FEBRUARY 2023

91. Kratom has not been shown to increase the risk of adverse cardiovascular effects in humans, nor pose significant cardiovascular risks from chronic use at any dose evaluated. Ex. 33, Paustenbach Rpt., ¶ 340; Ex. 37, Expert Report of Allen L. Dollar, MD, FACC, FACP, (“Dollar Rpt.”), ¶¶ 11, 22.

92. The concentration of mitragynine in Ms. Harmony Moller’s postmortem femoral blood (150 ng/mL) was within the range of mitragynine concentrations measured in healthy normal mitragynine users after a single 53.2 mg mitragynine dose—one not associated with toxicity. Ex. 30, Huestis Rpt., ¶ 28.

93. Scientific literature demonstrates that the postmortem concentration of mitragynine is approximately triple that of premortem measurements. Ex. 12, Boyer Rpt., ¶ 75.

94. At the time of Harmony Moller’s death in February 2023, published studies had assessed regular kratom users for evidence of cardiovascular toxicity through the performance of

electrocardiograms and echocardiograms. Ex. 37, Dollar Rpt., ¶ 11.¹³ For example, Leong Bin Abdullah and Singh (2021) reported that in a population of regular kratom users, serum levels of mitragynine ranged from 2,500 ng/mL to 22,400 ng/mL, with the only cardiac effect observed being a slight prolongation of the QT interval on the electrocardiogram that only appeared in subjects at the higher ranges of mitragynine levels. *Id.* Ms. Moller’s postmortem level of 150 ng/mL was less than a tenth of the *lowest* level found in that study. *Id.*

95. By February 2023, published literature had also established that mitragynine blood concentrations up to 191 ng/mL after kratom consumption were well tolerated and associated with no adverse effects. *See* Ex. 38, Papsun D, Schroeder W, Brower J, Logan B. *Forensic Implications of Kratom: Kratom Toxicity, Correlation with Mitragynine Concentrations, and Polypharmacy*. Current addiction reports. 2023;10(2):272-281. doi:10.1007/s40429-023-00477-4, (“Papsun 2023”) at 6 (“One such study documented mitragynine blood concentrations up to 191 ng/mL after consumption of kratom tea prepared with mitragynine concentrations of 104, 166, and 192 g/mL, with no adverse effects noted by chronic users.”).

96. Papsun 2023 was authored by NMS Laboratories and published in May 2023. Ex. 38. Papsun 2023 reported that in instances where “mitragynine toxicity” had been “listed as the cause of death,” the “blood concentrations ranged from 730 to 5900 ng/mL with a median concentration of 2000 ng/mL.” *Id.* at 6. Papsun 2023 reported that “[c]oncentrations of >1000 ng/mL are well above documented concentrations from the pharmacokinetic studies after drinking kratom tea.” *Id.* at 7.

¹³ Citing Ex. 32, Leong Bin Abdullah MFI, Singh D. *Assessment of Cardiovascular Functioning Among Regular Kratom (Mitragyna speciosa Korth) Users: A Case Series*. Front Pharmacol 2021; 12:723567.

97. The Papsun 2023 manuscript suggests that blood mitragynine concentrations alone up to 1000 ng/mL are unlikely to cause death. Ex. 30, Huestis Rpt., ¶ 16.

98. Plaintiffs' expert, Dr. Wharton, cites Krantz, M.J. et. al. Ventricular Arrhythmias Associated With Over-the-Counter and Recreational Opioids. *J Am Coll Cardiol* 2023;81:2258–2268 (“Krantz”) as a comprehensive review of opioid-associated arrhythmia in North America. Ex. 39, Expert Report of Dr. Ron Wharton, at 2.

99. Krantz published June 13, 2023, months after Ms. Moller's death. Ex. 40 (Krantz).

100. Krantz explained that even months after Ms. Moller's death “no regulatory agency has issued warnings regarding proarrhythmic properties of kratom.” *Id.* at 2259. Krantz also concluded that “causal determinations cannot be made” from it, and that “a convincing mechanistic link between mitragynine and ventricular arrhythmia is lacking.” *Id.* at 2266. Notably, Krantz explained that “[a]dditional risky behaviors, including unmeasured illicit drug ingestion, may have played a role in case fatalities but not captured in voluntary reporting” and that “[t]his confounding may be particularly relevant for mitragynine, given discordance in lines of evidence.”

101. Plaintiff's expert, Dr. Cadman, points to a March 20, 2023 publication by Xiaotong Li as identifying the “risks” posed by kratom. Ex. 41, Expert Report of Evelyn Cadman (“Cadman Rpt.”) at 13–14 (citing Ex. 42, Xiaotong Li, et al, *An evaluation of adverse drug reactions and outcomes attributed to kratom in the US FDAERS system 2004 to 2021* (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10264943/>) (“Xiaotong Li study”)).

102. The Xiaotong Li study post-dates Harmony Moller's death. Ex. 42. It describes itself as the *first* study to “summarize the characteristics of kratom-related adverse reactions” and posits that the “[s]ignals detected in this study can serve as valuable hypotheses for future studies.”

Id. at 1009. However, the Xiaotong Li study does not provide *any* analysis of mitragynine blood concentration levels. *See generally, id.*

103. Plaintiff’s expert, Dr. Thundiyl, asserts—without analysis or citation—that Harmony Moller’s 150 ng/mL blood concentration of mitragynine was “a level sufficient to cause adverse events.” Ex. 43, Expert Report of Dr. Josef Thundiyl, M.D., at 10. He similarly testified that “we don’t know the exact level [of kratom] that causes toxicity” and it is “nearly impossible . . . with the existing science, to have a dose that we know causes harm.” Ex. 9, Excerpts from Thundiyl Dep. 146:8–9, 147:3–5, Jan. 16, 2026. Dr. Thundiyl does not identify what kind of adverse events, offers no support for his conclusion, and crucially, provides no opinion or evidence that it was known in 2023 that a 150 ng/mL mitragynine concentration could cause death in any person, much less someone with Ms. Moller’s unique congenital heart defect.

104. Plaintiff’s expert Dr. Sarah Kowitt opines only that “studies published before February 2023 (when the Decedent’s death occurred)” merely “show associations between kratom use and health risks.” Ex. 45, Expert Report of Sarah D. Kowitt, PhD, at 2. Dr. Kowitt offers no opinion on causation or foreseeability. *See generally, id.*

105. Plaintiff has not identified any published scientific evidence pre-dating February 2023 that would have put a manufacturer on notice that 150 ng/mL mitragynine could cause death, or that such levels posed a foreseeable risk of fatal cardiac events in a person with a congenital heart defect.

106. A later 2024 study by Defendants’ expert, Dr. Marilyn Huestis, confirmed doses up to 753 ng/mL were “well tolerated” with “no serious adverse events.” Ex. 30, Huestis Rpt., ¶ 17.

107. Additional studies by the FDA in 2025 and Heustis *et al.* in 2026 further confirmed the safety of low mitragynine levels like the one at issue in this litigation. Ex. 46, Wharton Dep. Ex. 11.

Dated this 2nd day of March, 2026.

Respectfully Submitted

By: /s/ Gwendolyn C. Payton

Gwendolyn C. Payton (*pro hac vice*)

Hayley R. Ambler

Louisiana State Bar No. 25848

KILPATRICK TOWNSEND & STOCKTON LLP

1420 Fifth Ave., Suite 3700

Seattle, Washington 98101

Telephone: (206) 497-9600

Facsimile: (206) 299-0414

Email: hambler@ktslaw.com

Email: gpayton@ktslaw.com

Maeghan E. Whitehead (*admitted pro hac vice*)

KILPATRICK TOWNSEND & STOCKTON LLP

2001 Ross Avenue, Suite 4400

Dallas, Texas 75201

(214) 922-7138

(214) 279-4456

mewwhitehead@ktslaw.com

COUNSEL FOR DEFENDANTS

CERTIFICATE OF SERVICE

I, Gwendolyn Payton, hereby certify that on March 2, 2026, a copy of the foregoing document was filed with the Clerk of Court via CM/ECF, which sent an electronic copy to all counsel of record.

/s/ Gwendolyn C. Payton
Gwendolyn C. Payton