

EXHIBIT 14

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

KATHLEEN MOLLER

Plaintiff,

vs.

**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, LLC, A WYOMING LIMITED
LIABILITY COMPANY; OLISTICA, AN
UNINCORPORATED ASSOCIATION; ABC
INSURANCE COMPANY AND JOHN DOES
1-4.**

Defendants.

CIVIL ACTION NO. 24-0228-WBV-DPC

**DENNIS J. PAUSTENBACH, Ph.D.,
DABT, CIH EXPERT REPORT**

TABLE OF CONTENTS

EXPERT REPORT OF DENNIS J. PAUSTENBACH, Ph.D., DABT, CIH.....	1
EXPERIENCE	1
MATERIALS REVIEWED IN FORMULATING OPINIONS.....	4
CASE-SPECIFIC INFORMATION	4
OVERVIEW OF MY OPINIONS	13
BASES FOR OPINIONS.....	15
CLOSING COMMENTS.....	162

EXPERT REPORT OF DENNIS J. PAUSTENBACH, Ph.D., DABT, CIH

1. I have been asked by Defendants to review materials pertaining to, and to formulate opinions, regarding Ms. Moller's kratom use.

2. My time spent in the preparation of this opinion letter and reviewing documents to formulate my opinions, as well as for any deposition or trial testimony I may be called upon to give, will be billed at a rate of \$725 per hour. My opinions in this matter are expressed to a reasonable degree of scientific certainty and are based on information available to me on the date of this report. I have provided a list of documents that were reviewed in forming my opinions. This report may be supplemented if new information becomes available.

3. My opinions below are based on my background, education, training, experience, and the information available to me as of the date of this report. I reserve the right to amend or supplement my opinions to the extent that new information becomes available.

4. My opinions are also based on information that is related to this case, which includes a review of case materials provided to me by counsel, documents in the open scientific literature, and the opinions of some other experts.

5. A copy of my current curriculum vitae is attached as Appendix A. My list of References and Documents Considered is attached as Appendix B. My list of prior testimony for the last four years is set out in Appendix C.

EXPERIENCE

6. I am a board-certified toxicologist and certified industrial hygienist with nearly 40 years of experience in occupational health, risk assessment, toxicology, and environmental engineering. My experience includes investigating the health effects of exposure to, as well as the remediation of, carcinogenic and noncarcinogenic chemicals, including dioxins, furans, benzenes, polychlorinated biphenyls (PCBs), petroleum products, methyl tertiary-butyl ether (MTBE), chlorinated hydrocarbons, glycol ethers, beryllium, lead, 1,3-butadiene, methylene chloride, tetrachloroethylene (PCE), perfluorooctanoic acid (PFOA), chromium, MCHM, airborne biologic agents, kratom and kava, nicotine and asbestos, to name a few. I have published about 300 peer-

reviewed articles and written more than 50 book chapters in these fields. I have also given many lectures at universities on these issues and have conducted or supervised the conduct of more than 700 risk assessments related to persons exposed to various chemicals and radionuclides, occupational exposure to industrial chemicals, contaminated foods and pharmaceuticals, as well as contaminated soils, sediment, air, water and consumer products.

7. I have been the editor for three editions of the most popular textbook in the field of health risk assessment which is entitled “Human and Ecological Risk Assessment: Theory and Practice” (2024).

8. I have specialized in the areas of industrial and environmental toxicology, occupational health, historical state-of-knowledge regarding environmental issues, as well as ecological and human risk assessment. I am board certified in industrial hygiene (American Board of Industrial Hygiene [ABIH]), in toxicology (Diplomate of the American Board of Toxicology [DABT] and Fellow of the Academy of Toxicological Sciences [FACTS]), and in safety (Certified Safety Professional [CSP]). I have served as a graduate instructor/adjunct professor in industrial hygiene in the School of Pharmacy at Purdue University for four years; teaching all the courses in the curriculum. In that role, I taught more than 300 students about the theory and practice of this profession. This program in industrial hygiene, which I am credited for having founded, quickly became the largest program of its kind in the country.

9. I have also passed the theory portion of the professional engineering exam. I have served on many scientific advisory boards to government agencies in the U.S. and elsewhere; including being an advisor to the Administrator of the EPA and the head of the Centers for Disease Control (CDC). I have been an adjunct professor at five or more different universities. My professional education, training, and background are consistent with the topics and areas of scientific study about which I will testify.

10. I have studied issues associated with the hazards of ingested and inhaled consumer products and pharmaceuticals for many years. Specifically, in 2009, my team and I conducted a state-of-the-art evaluation of worldwide regulatory initiatives that evaluated possible health hazard

posed by trace levels of various trace chemicals in personal care products and drinking water. More recently, between 2018 and 2022 several products were identified by FDA as being contaminated with various forms of nitrosamines; we conducted health risk assessments on several of them, most notably n-nitrosodimethylamine (NDMA) and n-nitrosodiethylamine (NDEA). In March 2022, I presented a paper entitled “Current Thoughts on Risk Assessment Methodologies Used to Assess the Carcinogenic Risk of N-Nitrosodimethylamine (NDMA) and N- Nitrosodiethylamine (NDEA)” at the Society of Toxicology Annual Meeting in San Diego, California. In 2024, I published “Risk characterization of N-nitrosodimethylamine in pharmaceuticals” in the journal Food and Chemical Toxicology (2024).

11. I have conducted risk assessments of herbal, food, and vitamin supplements. In 2021, I conducted an evaluation of the toxicology of each component of an over-the-counter herbal supplement to determine the risk of acute liver failure. I have also evaluated risks associated with contamination of vitamin and food supplements with lead, arsenic, and vitamin A. Additionally, from 2021 to present, my team and I have examined potential risks associated with the contamination of a beverage with an agent that allegedly caused acute viral hepatitis in some consumers. Over the years, I have conducted risk assessments for an array of contaminated food products, with examples including frozen processed meats, kale, spices, candies and baked goods.

12. My colleagues and I recently published a review of the literature on kratom, mitragynine, and 7-hydroxymitragynine (Heywood et al. 2024). This included a comprehensive analysis of *in vitro*, *in vivo*, and kratom product chemistry data, along with human clinical data, case study/series, and epidemiological evidence.

13. We also presented two papers at the 2025 national College of Problems of Drug Dependence (CPDD) conference in New Orleans entitled “A Systematic Evaluation of the Literature Related to Alleged Kratom-Induced Seizures” and “What Are the Acute Adverse Health Effects of Kratom, if Any: An Analysis of Case Reports.”

14. Given the above, the study of the ingestion and inhalation risks of kratom and its alkaloids is a logical extension of my previous training and experience.

MATERIALS REVIEWED IN FORMULATING OPINIONS

15. My opinions are provided in Sections IV and V of this report. My opinions are based on my professional qualifications, work experience, and knowledge of industrial hygiene, toxicology, risk assessment, and related fields. My opinions also are based on information that is related to this case. In the process of preparing this report, my colleagues or I have reviewed and relied upon the references and case-specific documents listed in Appendix B.

16. In addition to these materials, I have reviewed published papers and textbooks on the toxicology and epidemiology of kratom, mitragynine, and other indole alkaloids available in the open literature and facts or data reasonably relied upon by persons in my field.

CASE-SPECIFIC INFORMATION

General Case Summary

17. Ms. Harmony Anne Moller (Ms. H. Moller) was born on February 18, 1986, and passed away on February 6, 2023, at the age of 36 (Obituary: pg. 1; Coroner's Report: pg. 2, 6). It was reported that Ms. H. Moller's cause of death was "[a]bnormally high left coronary ostia takeoff exacerbated by mitragynine use" (Coroner's Report: pg. 12; Death Certificate). According to a Patient Care Record, the primary impression for Ms. H. Moller's death was cardiac arrest (St. Tammany FD EMS Records: pg. 1). According to the Third Amended Complaint, "... ingestion of Kratom" was allegedly secondary to the cause of death (Third Amended Complaint, paragraph 33).

18. According to the Third Amended Complaint, Ms. H. Moller "... died as the result of the ingestion of OPMS brand Kratom which she purchased in Mandeville Louisiana" (Third Amended Complaint paragraph 30).

Timeline of the Incident on February 6, 2023

- **1:15 p.m.:** Ms. Kathleen Moller (Ms. K. Moller), the decedent's mother, saw Ms. H. Moller conscious (Incident Report: pg. 6). She reported that Ms. H. Moller previously told her that she "... was not feeling well and throwing up" (Incident Report: pg. 9).

- **1:30 p.m.:** Ms. K. Moller discovered Ms. H. Moller laying on her side on the floor of her bedroom. Ms. K. Moller reported that she started CPR until paramedics were on the scene (Incident Report: pg. 6). Ms. K. Moller noted that Ms. H. Moller's skin "... showed blueish discoloration" and that her eyes "... weren't pinpoint," and that Ms. H. Moller did not have a pulse (Incident Report: pg. 13). Ms. K. Moller reported that she "... heard gurgling from Harmony while she conducted chest compressions" (Incident Report: pg. 13).
- **2:11 p.m.:** Deputies dispatched to an unresponsive female (Incident Report: pg. 5).
- **2:58 p.m.:** Ms. H. Moller was pronounced deceased.

Ms. Harmony Anne Moller's Relevant Medical & Records

19. According to the answers to the interrogatories, Ms. H. Moller "... lived for many years abroad and her medical providers [were] unknown to Plaintiff at th[e] time" (Int. #4). According to the answers to the interrogatories, Ms. H. Moller "... occasionally drank alcohol and/or used marijuana" (Int. #8). According to the answers to the interrogatories, Ms. H. Moller "... did not share much [medication or medical] information ..." and she "... picked up a prescription for Depo-Provera injection on May 16, 2022" (Int. #9).

20. According to the answers to the interrogatories, Ms. K. Moller had "[g]rief, depression, anxiety, loss of enjoyment of life, [and] loss of consortium" (Int. #12). According to the answers to the interrogatories, Ms. H. Moller "... died from ingestion of OPMS brand Kratom, which she purchased at the Ra Shop in Mandeville, Louisiana" (Int. #21).

Autopsy and Toxicology Screening

21. According to the postmortem forensic medical examination report, Ms. H. Moller had pulmonary edema and congestion, chronic passive congestion of the liver, and mild nephrosclerosis (Coroner's Report: pg. 12). However, according to organ donor records, Ms. H. Moller's cause of death was due to "[c]hronic [c]ongestion of [l]iver ...[p]ending [t]ox ..." (Coroner's Report: pg. 30). It was reported that Ms. H. Moller also had cardiomegaly with mild biventricular hypertrophy (Coroner's Report: pg. 12).

22. According to the toxicology report, Ms. H. Moller's femoral blood was qualitatively positive for caffeine and naloxone (Coroner's Report: pg. 16). According to the toxicology report, quantitative values for pharmaceuticals were provided including Delta 9-Carboxy THC (10 ng/mL), Delta-9 THC (8.6 ng/mL), Diphenhydramine (64 ng/mL), Promethazine (18 ng/mL), and Mitragynine (150 ng/mL) (Coroner's Report: pg. 16). According to the toxicology report, quantitative values for endogenous and dietary compounds were provided including creatine (0.864 mg/dL), sodium (142 mmol/L), potassium (7.47 mmol/L), chloride (118 mmol/L), glucose (18.2 mmol/L), and urea nitrogen (17.2 mmol/L) (Coroner's Report: pg. 16).

23. According to a Comprehensive Drug Analysis conducted by UCSF Clinical Toxicology and Environmental Biomonitoring Laboratory, confirmed drugs included mitragynine (158 ng/mL), 7-OH mitragynine (0.8 ng/mL), diphenhydramine, Naloxone, and Promethazine (Coroner's Report: pg. 21). It was reported that the value for 7-OH mitragynine "... was below the lower limit of quantification of 3 ng/mL and equal to the limit of detection for the analysis" (Coroner's Report: pg. 21).

Scene Description

24. It was reported that on top of the bedroom dresser was "... drug paraphernalia, one red lighter, one suspected marijuana grinder, one nuEra cannabis container containing suspected marijuana residue, and four empty prescription bottles" (Incident Report: pg. 14). It was noted that the empty prescription bottles included Acyclovir 400 mg (filled 9/26/2022), Methylphenidate HCL ER 27 mg (filled 4/12/2022), Hydrocod/Acetam-5-325 mg (filled 12/1/2015), and Gabapentin 300 mg (filled 12/8/2021) (Incident Report: pg. 14). It was indicated that Acyclovir and Hydrocod/Acetam-5-325 were prescribed to Ms. K. Moller; however, the bottle containing Methylphenidate HCL ER was prescribed to Trenton A. McNab and the bottle containing Gabapentin had its prescription label torn (Incident Report: pg. 14).

25. It was reported that the first bedroom drawer contained "... an empty liquor bottle, one additional empty prescription bottle [for] Amoxicillin 500 mg: prescribed to Harmony Moller (filled 2/10/22), one black case containing suspected marijuana residue, and one suspected item of

drug paraphernalia. The second drawer contained multiple articles of clothing and five empty bottles of Jameson Irish Whiskey. The third drawer contained multiple additional articles of clothing” (Incident Report: pg. 14).

26. It was reported that “[a]fter relocating to the hallway, an open door was observed left of the stairwell. The opened door led to what appeared to be a storage room. Two twin doors were located across the room, which led to a balcony. On the right side of the storage room shared a connected bathroom with the decedent’s bedroom. Inside the bathroom, a Rouse’s bag was located. A search of the bag was conducted, which contained over-the-counter drugs and other items” (Incident Report: pg. 14) which included: one full bottle of CVS brand Daytime Cold & Flu Relief, one bottle of Apetropics chewable CBD, Lion’s Mane, and Cordyceps gummies, one bottle of DG Health immediate release Mucus Relief 400 mg, one bottle of DG Health Naproxen Sodium 220 mg, one bottle of Natrol High Caffeine Energy support tablets 200 mg, one opened sealed bag of Maeng Da brand Kratom of 30 capsules (18 g), one opened sealed bag of Maeng Da brand Kratom 4 oz powder, and one unopened bottle of Knob Creek Whiskey (Incident Report: pg. 14).

27. According to the photos provided of the kratom products found in Ms. H. Moller’s bag, she had one bag containing 30 capsules (18 grams) of Green Vein Maeng Da O.P.M.S Silver Kratom (MOLLER_000023). According to the packaging, the product contained 600 mg mitragyna speciosa, 7.8 mg mitragynine (1.3% mitragynine content), and less than 0.27 mg 7-OH-mitragynine (<0.045% 7-OH-mitragynine content) per capsule (MOLLER000024). It was noted that the whole package contained a total of 234 mg mitragynine and less than 8.1 mg 7-OH-mitragynine (MOLLER000024).

28. The directions on the packaging stated to “[c]onsult your healthcare professional to determine if this product is right for you, and if so, how to use it properly” (MOLLER000024). The package included a disclaimer that stated “By using this product you accept full responsibility for any adverse events of health complications that may arise from its use. Manufacturers/Re-sellers assume no responsibility or liability for the use or misuse of this product”

(MOLLER000024). In addition, the package included a warning that stated “This product contains botanical kratom leaf capsules. Only for use as a botanical specimen. Mitragyna Speciosa is an unapproved dietary ingredient. The manufacturers/re-sellers of this product, therefore, cannot advise on its use. Ingesting Mitragyna Speciosa can be dangerous. Consult your physician about potential interactions, other possible complications, and precautionary measures before considering this product. By opening this package you accept full responsibility for the use of the product including but not limited to any adverse events or health complications. Inform your physician of the alkaloid content, labeled on the package. Manufacturers/Re-sellers assume no responsibility for the use or misuse of this product” (MOLLER000024)

29. In addition, a photo of one bag of Green Vein Maeng Da Silver O.P.M.S. Kratom 4 oz powder found in Ms. H. Moller’s bag was provided (MOLLER_000025). According to the packaging, the product contained 13 mg mitragynine (1.3% mitragynine content) and less than 0.45 mg 7-OH-mitragynine (<0.045% 7-OH-mitragynine content) per gram of powder (MOLLER000026). It was noted that the whole package contained a total of 1474.2 mg mitragynine and less than 51 mg 7-OH-mitragynine (MOLLER000026).

30. The directions on the packaging stated to “[c]onsult your healthcare professional to determine if this product is right for you, and if so, how to use it properly” (MOLLER000026). The package included a disclaimer that stated “By using this product you accept full responsibility for any adverse events of health complications that may arise from its use. Manufacturers/Re-sellers assume no responsibility or liability for the use or misuse of this product” (MOLLER000026). In addition, the package included a warning that stated “This product contains botanical kratom leaf powder. Only for use as a botanical specimen. Mitragyna Speciosa is an unapproved dietary ingredient. The manufacturers/re-sellers of this product, therefore, cannot advise on its use. Ingesting Mitragyna Speciosa can be dangerous. Consult your physician about potential interactions, other possible complications, and precautionary measures before considering this product. By opening this package you accept full responsibility for the use of the product including but not limited to any adverse events or health complications. Inform your

physician of the alkaloid content, labeled on the package. Manufacturers/Re-sellers assume no responsibility for the use or misuse of this product” (MOLLER000026).

Expert Reports

Expert Report of Christopher Williams, PhD (dated November 17, 2025)

31. Dr. Williams stated that Ms. H. Moller’s “... cause of death was officially documented as ‘abnormally high left coronary ostia takeoff exacerbated by mitragynine use’. It [was] [his] opinion that the mechanisms of Kratom alkaloid activity support this conclusion” (Williams: pg. 2).

32. Dr. Williams reported that “... Kratom contains alkaloids which rival the potency of clinically available opioids like morphine in experimental models” (Williams: pg. 2). He added that:

“... cardiotoxicity has been clearly linked to opioid usage including Kratom, which includes QT prolongation. Experimental models have shown that MG inhibits delayed rectifying K⁺ currents, similar to methadone, potentially leading to cardiac arrhythmias. It is important to note that blockade of K⁺ signaling has been implicated in sudden cardiac death related to toxic opioid exposure” (Williams: pg. 3).

33. Dr. Williams stated that, according to a 2023 FAERS study:

“... MG was associated with a greater incidence of ventricular arrhythmia/cardiac arrest than any other drug tested... In 39% of those cases, MG exposure was indicated in the absence of concurrent QTc prolonging drugs, thereby suggesting that MG was the primary driver of cardiotoxicity” (Williams: pg. 2-3).

34. Dr. Williams opined that kratom derived products:

“... can lead to unintentional cases of polypharmacy, where drugs with overlapping off-target effects can result in significant toxicity. In the case of Harmony Moller, Kratom may well impact K⁺ currents in the heart and exacerbate the typically moderate effects of antihistamines like diphenhydramine or promethazine. Of note, the level of the diphenhydramine (64 ng/ml) and promethazine (18 ng/ml) are in accordance with

expected levels in therapeutic drug usage, suggesting that these drugs alone were not used at a level that should precipitate cardiorespiratory toxicity” (Williams: pg. 4).

Expert Report of Josef Thundiyil, M.D. (dated November 13, 2025)

35. Dr. Thundiyil stated that he agreed that “... mitragynine use contributed to and caused Harmony Moller’s death” and that “... Harmony Moller’s death was an adverse cardiorespiratory event caused by kratom” (Thundiyil: pg. 2-3). He added that “[t]he substances present in Harmony Moller’s system at time of death are insufficient to cause [her] death in the absence of mitragynine” (Thundiyil: pg. 3).

36. Dr. Thundiyil reported that cardiac arrhythmias were a documented symptom of kratom use and that kratom related deaths involve clinical findings consistent with cardiorespiratory arrest (Thundiyil: pg. 9). He added that:

“[k]ratom also acts as a stimulant. Stimulants like kratom have the potential to cause enlargement of the heart. An enlarged heart is a heart that is electrically susceptible to arrhythmias. The stimulant effects of kratom increase the likelihood of electrical instability and sudden cardiac death. The stimulant effect of kratom has been associated to occur at lower doses” (Thundiyil: pg. 9-10).

37. Dr. Thundiyil stated that Ms. H. Moller’s conditions, including pulmonary edema and congestion, chronic passive congestion of the liver, mild nephrosclerosis, high origin of left coronary artery, and cardiomegaly, “... may have been co-morbidities for [her] but were not the primary cause of death. The primary cause of death was a cardiorespiratory event caused by kratom” (Thundiyil: pg. 10). He stated that “the concentration of mitragynine (150 ng/ml) found in Ms. H. Moller’s blood was sufficient to cause adverse events” (Thundiyil: pg. 10).

38. Dr. Thundiyil stated that “... those selling the kratom frequently do not provide warnings or safe instructions for use and dosing” (Thundiyil: pg. 9).

Expert Report of Ronald H. Wharton, MD, FACC, FASE (dated November 4, 2025)

39. Dr. Wharton reported that:

“[t]here are multiple reports in the medical literature that associate the use of kratom products with the development of ventricular tachycardia and ventricular fibrillation (VT/VF), which cause the heart to stop beating. This leads to the immediate cessation of circulation and death within a few minutes unless treated with defibrillation. [His] opinion [was] based on exclusion, as a cardiorespiratory death, such as cardiac arrhythmia, cannot be confirmed by autopsy or postmortem toxicology” (Wharton: pg. 2).

40. Dr. Wharton explained that adverse cardiac events such as VT/VF can be caused by exogenous substances and stated that a review of opioid-associated arrhythmia in North America published in 2023 “... demonstrated a ‘disproportionate’ association of ‘life threatening arrhythmias in North America’ with mitragynine” (Wharton: pg. 2). He noted that the “... literature discussing kratom consumption and its effects suggests a significant linkage between the main alkaloid in *Mitragyna speciosa* (kratom) use, ventricular arrhythmias (ventricular tachycardia, ventricular fibrillation) and cardiorespiratory adverse events” (Wharton: pg. 2-3).

41. Dr. Wharton reported that the “... high ostia take-off of the left coronary artery is a benign finding which was not a cause of [Ms. H. Moller’s] sudden death” (Wharton: pg. 3). He stated that “... more likely than not, Harmony Moller died from a cardiorespiratory adverse event induced by consumption of kratom” (Wharton: pg. 3).

Expert Report of Evelyn Cadman (dated November 17, 2025)

42. Ms. Cadman stated that the “... supply, marketing, distribution, and sale of OPMS Kratom fails to comply with basic industry and regulatory standards of care for supplements, and in particular New Dietary Ingredients” (Cadman: pg. 6). She added that the kratom in this case was misbranded and that “[d]efendants violated the standards that prohibit the marketing, distribution, and sale of unapproved and new drugs” (Cadman: pg. 6-7).

43. Ms. Cadman stated that “... none of the named defendants ever verified that the OPMS kratom products manufactured and sold by them were reasonably safe for human consumption” (Cadman: pg. 8). She reported that “... OPMS kratom consumers, including Harmony Moller, were not properly warned of the serious risks from Kratom, including the risks

of seizures, cardiorespiratory adverse effects, death, dependence and addiction, and drug-drug interactions (Cadman: pg. 13).

Expert Report of Ryan J. Clark (dated November 18, 2025)

44. Mr. Clark stated that:

“1. Defendants’ failure to produce internal financial information and income tax returns is unusual and provides no basis for verifying their financial representations.

2. Mr. Gabbay’s and Jopen’s financial control and alleged payments on behalf of Martian Sales lack appropriate accounting and documentation and indicate commingling between the two entities.

3. Jopen’s financial contributions to the American Kratom Association further illustrate and irregular business practice and irregular accounting practices.

4. Mr. Gabbay and/or Jopen exercises significant control over Martian Sales and other various aspects of the kratom business, despite having no equity ownership in Martian Sales, which is highly unusual.

5. The financial practices and intercompany conduct between Jopen and Martian Sales are consistent with factors commonly identified in forensic accounting investigations as indicators of a lack of corporate separateness” (Clark: pg. 6).

Expert Report of Sarah D. Kowitt, PhD (dated November 12, 2025)

45. Dr. Kowitt stated that the “... warnings on the kratom packages discovered near Ms. Moller were not adequate” (Kowitt: pg. 2). She reported that the “... Defendant’s warnings did not warn about risks associated with product use,” “... did not provide clear instructions on how to avoid risks associated with product use,” “... did not use language that was clear or understandable,” and “... did not optimally capture or hold attention” (Kowitt: pg. 2-4).

46. Dr. Kowitt stated that “... the manufacturers in this case knew or should have known that users could be exposed to a risk of significant injury or death under normal conditions of use. The warnings provided did not reasonably inform an ordinary user of the nature and extent of the risk of death or serious health risks” (Kowitt: pg. 5).

OVERVIEW OF MY OPINIONS

Opinion 1 - People in numerous countries have used kratom (*Mitragyna speciosa*) safely for hundreds (if not thousands) of years. The body of scientific literature on kratom and its alkaloids continues to evolve, but historic and recent data indicate that beneficial effects associated with kratom use have a robust pharmacologic basis. It is my opinion that few to no adverse effects are expected in typical users when kratom is used alone and that adverse outcomes in dual- and polysubstance users can be attributed to other compounds, not kratom or its alkaloids.

Opinion 2 - The risk assessment process is a methodology that is widely accepted and used by many scientific bodies and governmental agencies around the world. It is my opinion that it is an appropriate method to use for characterizing the health risks potentially associated with use of kratom products (especially when comparing potential health risks associated with kratom use to those associated with use of opioids to yield similar effects).

Opinion 3 - The health effects of kratom can be attributed to more than 50 indole alkaloids present in the plant. Of these, mitragynine and 7-hydroxymitragynine are the most biologically significant. It is my opinion that alkaloid concentrations vary across kratom product types, but data from the peer-reviewed literature indicates that these typical concentrations contained in teas or capsules, taken in a reasonable manner, would not increase the risk of acute or chronic adverse health effects among typical users.

Opinion 4 - Animal studies and studies of humans are defined as *in vivo* analyses. Kratom, mitragynine, 7-hydroxymitragynine, and other associated alkaloids have been studied *in vivo* for over 100 years. It is my opinion that these studies provide support for two primary conclusions. First, kratom and its alkaloids can yield dose-dependent stimulant or pain relief effects under typical human use and may aid with opioid withdrawal. Second, kratom alkaloids can be classified as very low to moderately toxic in animals. It is my opinion that since these alkaloids are only a small percentage of kratom products by weight, few to no adverse health effects are expected in kratom users, even among higher volume consumers. No chronic adverse

effects have been reported *in vivo* following repeated kratom administration at relatively high doses to test animals or humans.

Opinion 5 - Studies of isolated cells, termed *in vitro* analyses, help provide information on potential organ-specific effects and the toxicological mechanisms driving health outcomes following exposure to a given compound. *In vitro* data indicate that kratom alkaloids are primarily metabolized by Cytochrome P450 (CYP) isoforms CYP3A4 and CYP2D6 and that physiological effects are driven by alkaloid activity at opioid, adrenergic, serotonergic, and dopaminergic receptors. Kratom's pain relief (analgesic) and euphoric effects can be explained by kratom alkaloid binding at opioid receptors (ORs). However, it is my opinion that the activity of mitragynine, 7-hydroxymitragynine, and other kratom alkaloids at ORs is weak relative to that of numerous drugs (e.g., morphine, fentanyl) and endogenous endorphins (e.g., β -endorphin, enkephalins, dynorphins). However, depending on the dose, 7-hydroxymitragynine can cause morphine like effects if ingested in a relatively pure state (i.e., as a synthetic isolate).

Opinion 6 - Data on the effects of kratom use in humans includes epidemiological evidence, as well as information from case reports and case series. It is my opinion that human studies, although limited, indicate that kratom use is associated with potential benefits including stimulant effects, pain relief, and as a substitute or withdrawal aid for opioids at doses yielding few to no adverse behavioral or physiological effects. Case data indicate that kratom's alkaloids produce few to no acute adverse health effects when kratom is used alone, but that mitragynine and 7-hydroxymitragynine have been reported along with other compounds in the post-mortem blood and tissues of dual- and polysubstance users.

Opinion 7 - Based on the records regarding Ms. Moller's passing, it is likely that she experienced an adverse cardiovascular event, which led to her death. Kratom has not been found to increase the risk of heart attacks in humans. It is my opinion that, should it be determined that Ms. Moller experienced a heart attack or comparable cardiovascular event which resulted in her death, kratom would not have been the cause.

Opinion 8 – It is possible to assess the health risks of using specific kratom products by considering various exposure scenarios and by combining multiple lines of evidence from available scientific literature. Based on this information, it is my opinion that estimated whole-body and compartment-specific alkaloid doses for typical kratom users are 3-fold to 50,000-fold below those expected to increase the risk of adverse health effects in animals, depending on the types of products used. This is a conservative estimate, as animals are often more sensitive to potentially adverse effects of chemical exposures than humans. It is my opinion that, given the available literature, typical doses of kratom, such as the ones that Ms. Moller potentially ingested, would not increase her risk of death. Additionally, her postmortem blood concentration of mitragynine of 150 ng/mL is comparable to blood concentrations observed in human volunteers following kratom doses that are documented to be well-tolerated in humans with no adverse effects.

BASES FOR OPINIONS

Basis of Opinion 1

M. Speciosa Traditional Use

47. *Mitragyna speciosa*, commonly known as kratom, is a tree native to Southeast Asia, specifically, Thailand, Indonesia, Malaysia, Borneo, Myanmar, and Vietnam. *M. speciosa* can reach up to 25 meters tall at maturity and is noted for having dark green leaves with green, white, or red veins (Cinosi et al. 2015). It conventionally grows in swampy areas, in areas inundated by water, and alongside riverbanks (Grundmann 2017; Ahmad et al. 2022). Depending on the country, kratom is referred to by its local name: ketum or biak (Malaysia), keton or kadamba (Indonesia), benisa (Myanmar), mambog or lugub (Philippines), ithang, thom, kratom (Thailand), or giam (Vietnam) (Gong et al. 2012; Cinosi et al. 2015; Grundmann 2017; Eastlack et al. 2020).

48. Kratom leaves were historically used in rural communities by farmers, laborers, or fishermen in Southeast Asia as a stimulant to reduce or prevent fatigue stemming from hard labor by chewing the leaves raw or drying them for later consumption (Cinosi et al. 2015; Grundmann 2017; Singh et al. 2017). Although less common in Southeast Asia, it is reported that the dried