

EXHIBIT 31

**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.

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

THE HONORABLE WENDY B. VITTER

**MAGISTRATE DONNA PHILLIPS
CURRAULT**

DECLARATION OF JACK HENNINGFIELD, PHD

I, Jack Henningfield, declare as follows:

1. My name is Jack Henningfield. I have personal knowledge about the facts set forth in this declaration.

2. A copy of my curriculum vitae is attached as Exhibit A. The information in my CV is true and correct. It includes a more detailed description of my education, training, appointments, publications, and awards. I have a PhD in experimental psychology with a pharmacology supporting program from the University of Minnesota; postdoctoral training in psychopharmacology at Johns Hopkins University School of Medicine and the University of Minnesota Medical School Department of Psychiatry; and a BA in psychology from the University of Minnesota.

3. Currently, I am Vice President for Research, Health Policy and Abuse Liability at Pinney Associates, and Adjunct Professor of Behavioral Biology, Part-time Department of Psychiatry and Behavioral Sciences, Behavioral Biology Division. I am a consultant to the American Kratom Association and previously provided pro bono support to the same group in its efforts to prevent the Drug Enforcement Administration (“DEA”) from banning kratom. I also

worked on dietary supplement notifications for kratom products in an effort to get the FDA to regulate kratom as a dietary supplement.

4. I have contributed to numerous comments to the FDA on drug regulation and policy and have published nearly 500 scientific articles, monographs, and books related to public health, pharmacology, and addiction. which most have been peer reviewed, as well as many reports and comments to Federal and International agencies. I have also given more than 600 presentations at scientific meetings including meetings convened by Federal and international agencies and organizations, many of which were invited.

5. In 2010, I was honored by the American Psychological Association's Psychopharmacology and Substance Abuse Division 28 with the MED Associates Brady/Schuster Award, for outstanding research underscoring the fundamental importance of behavioral science to psychopharmacology or substance use disorder. The College on Problems of Drug Dependence awarded me its Distinguished Service Award in 2010 for outstanding contributions to the field of drug abuse beyond scientific contributions. In 1997, Secretary of Health and Human Services Dr. Donna E. Shalala and FDA Commissioner Dr. David A. Kessler presented me with the U.S. Department of Health and Human Services Secretary's Award for Distinguished Service, for outstanding performance in the development of regulations to protect the nation's children from cigarette smoking.

6. I spent the first 16 years of my career with the Intramural Research Program of the NIH's National Institute on Drug Abuse ("NIDA"), where I led abuse potential assessments and developed drug scheduling recommendations in collaboration with FDA and DEA. My appointments at NIDA included service as Chiefs of the Biology of Dependence and Abuse Potential Section and the Clinical Pharmacology Branch. My responsibilities included conducting research to evaluate the safety and addictiveness of known and potentially addictive substances, as well as potential addiction treatment medicines. Beginning with my research and regulatory responsibilities at NIDA until the present, I have contributed to the development and/or regulatory

approval of most of the medicines presently approved by the FDA for treating opioid, tobacco and alcohol use disorders and withdrawal (“addictions”).

7. My work at NIDA included contributing to the regulation of potentially addictive drugs and substances, such as prescription medicines and tobacco products. This included work with the FDA and DEA on matters pertaining to addiction science, abuse potential assessment, and Controlled Substances Act drug scheduling. My NIDA position involved advising several Surgeons General, including Dr. C. Everett Koop, and several FDA commissioners, including Dr. David Kessler (from whom I received service awards for my addiction research and contributions to substance control and regulation). I also represented NIDA in various congressional hearings and FDA briefings. Additionally, I was detailed at times to serve on various FDA committees involved in drug and tobacco regulation and various U.S. Surgeon General’s reports on addiction-related issues, including the prevention and treatment of substance abuse and addiction.

8. Since leaving NIDA, I have served on various governmental committees and as a Special Government Employee at the FDA Center for Drug Evaluation and Research and separately for the FDA Center for Tobacco Products. I was invited by the World Health Organization to serve on its inaugural Scientific Advisory Committee and then its Tobacco Regulatory Study group based on my expertise in addiction, abuse potential assessment and substance regulation. I served from 2001 to 2014.

9. While at NIDA, with outside activities approval, and since leaving NIDA, I have served as an expert witness in matters related to addiction science, treatment and prevention. This included serving as the lead addiction witness for state attorneys general against the tobacco industry in the late 1990s and for the U.S. Department of Justice against the tobacco industry in the early 2000s.

10. My work at NIDA included a focus on addiction treatment development. These efforts began with buprenorphine for opioid use disorder and pain management at NIDA in 1980, nicotine gum for tobacco use disorder and withdrawal in 1982, and naltrexone for opioid use disorder in the mid-1980s (after the compound was essentially given to the Department of Health

and Human Services (“HHS”) by Dupont). Later, these efforts also included nicotine gum, patch, nasal spray, a nicotine vapor device, and other tobacco addiction treatments and substitutes. Through my research at NIDA and Johns Hopkins and consulting with Pinney Associates, I have been involved in the development and regulatory approval of most of the FDA-approved treatments for opioid, tobacco, and alcohol addiction. I have also given invited testimony to congressional hearings, the FDA, and the White House on the importance of providing less harmful alternatives for people who continue to use addictive substances.

11. My research and responsibilities at NIDA included consideration of the risk to benefit balancing that a wide array of public health institutions, such as the Centers for Disease Control and Prevention (CDC), the FDA, and international bodies, taking into account in their regulatory and other substance policy efforts to advance public health. As listed in my CV, I regularly publish state of the art reviews on these topics, often along with former FDA and DEA officials and at times along with working FDA staff.

12. My work on kratom product research, product assessment, and regulation began in 2014 working with then former FDA Office of Dietary Supplement staff and legal regulatory consultants on kratom product submissions to the FDA, labeling and other issues. I am a leading kratom scientist. I have co-authored 17 original research articles and reviews of kratom abuse and dependence potential, safety, toxicology and public health impact, and five joint scientific expert reports and comments to federal agencies and the White House. More than 30 of my presentations at scientific meetings addressed kratom science, safety, and policies to benefit public health. I was accepted by the World Health Organization (WHO) to provide testimony on kratom safety, real world therapeutic use, and addictiveness during its 2021 review of kratom to determine if it should be put under one of the international drug control conventions. After giving consideration to the types of factors summarized above, the WHO and the United Nations Bureau on Drugs and Crime determined that putting kratom under international drug control treaties (which would have banned legal kratom) was not warranted. Rather, they recommended that kratom should remain under surveillance.

13. Kratom (*Mitragyna speciosa*) is a tropical tree native to Southeast Asia, particularly Thailand, Indonesia, Malaysia, and Papua New Guinea. Its leaves contain compounds that can have psychoactive (mind-altering) effects.

14. Kratom can act as a stimulant or sedative depending on dosage. Low doses may produce increased energy, alertness, and sociability. Higher doses may produce pain relief, relaxation, and euphoria. Kratom is typically consumed as crushed leaves, powder, capsules, liquids, or brewed into tea. Kratom was traditionally used in Southeast Asia for fatigue and to improve stamina (by laborers), pain relief, and for opium withdrawal. In the U.S. and elsewhere, kratom is used (often self-prescribed) for chronic pain, anxiety or depression, and opioid withdrawal or substitution.

15. Kratom does not produce opioid-like respiratory depressant effects, nor carry opioid-like risks of death. These factual statements have been evaluated and verified as true by the 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.

16. Kratom is not an opioid or narcotic by nature of its botanical origin, by chemical structure, its known overall pharmacology, or by having 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.

17. Kratom does not carry a high risk of death. To the contrary, the risk of death by kratom alone is described by FDA and NIDA as rare and generally involving other drugs. There is no consensus on the basis by which kratom might cause death, in contrast to most substances that contribute to overdose deaths (*e.g.*, respiratory depression by opioids and sedatives, cardiovascular incidents by stimulants). While there are rare reports of kratom-caused deaths, virtually all of them appear to be polydrug overdoses. If a kratom user died from a kratom overdose

or kratom caused cardiac event, it would be a very rare and idiosyncratic event given how few deaths are reported among 10 to 20 million kratom users. There are no reported deaths in Southeast Asia. A recent FDA statement also states that while “in rare cases,” it has been reported that “deaths have been associated with kratom use,” “in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear.” Ex. 20.

18. Kratom is an overall public health asset that is regularly used by millions of people as a harm reduction approach to reduce or eliminate the use of opioids, sedatives, stimulants, and alcohol. 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.

19. The experience of Americans is the same as has been well-established over decades, if not centuries, in Southeast Asia, where there have been no reported deaths. This same product was brought to the United States, where kratom is consumed through tea, decoctions, and other approaches. If a kratom product is composed of natural products, meaning that it is not boosted artificially in alkaloids, there is no FDA or legal requirement to submit a new dietary ingredient application to sell kratom and as summarized by the Department of Justice, DEA, kratom sales are legal in the US except in jurisdictions where they are specially banned. Kratom was not banned for legal sale in the state of Louisiana prior to 2025.

20. The vast majority of the evidence upon which I base my opinions was generated by independent researchers primarily supported by the National Institutes of Health (“NIH”) and NIDA. Such studies have been published at an increasing rate year by year over the past decade in leading biomedical research institutions, including Johns Hopkins, the University of Florida, the NIDA intramural program itself, and many others. A small fraction (likely a few percent) of such publications were supported by commercial companies.

21. As a result of kratom’s known benefits to the public and the apparently low if not non-existent risk of kratom use, kratom is a legally marketed product in 43 states, and it is legal for people in those states to possess and consume kratom. Several of the states that placed kratom

as a Schedule I drug in their Controlled Substances Act frameworks on advice from the FDA from 2014 to 2016 are presently in the process of replacing those laws with laws to ensure legal access and appropriate regulatory oversight of kratom.

22. Kratom is legally sold in the United States, with the exception of six states and some other jurisdictions. On August 31, 2016, the DEA announced its intent to temporarily add kratom to Schedule I of the CSA “to avoid an imminent hazard to the public safety.”¹ In response, U.S. 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.² These comments explained that kratom is safer than prescription opioids and that, compared to opioids, deaths attributable to kratom overdose are essentially non-existent.

23. U.S. Representatives Mark Pocan (D-WI) and Matt Salmon (R-AZ) sent a letter to the DEA and the Office of Management and Budget—a letter that received bipartisan support and was signed by 50 members of Congress—against the ban. The letter noted that kratom is an internationally consumed herb and condemned the proposed ban as “hasty” because of known beneficial effects of kratom. 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.

24. 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

¹ Ex. A, 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.

² Ex. B, *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).

Schedule I ban.³ The co-sponsors are Orrin G. Hatch (R-UT), Michael F. Bennet (D-CO), Angus 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).

25. Less than two months later, on October 13, 2016, the DEA withdrew its intent to schedule kratom because of “numerous comments from the public.” 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.”⁴

26. The DEA “requested that the FDA expedite its scientific and medical evaluation and scheduling recommendation for this substance, which DEA previously requested” 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 kratom’s use.⁵

27. In response to the DEA request for comments, I led the development and submission of a Controlled Substances Act eight factor analysis following the same standards that my colleagues and I developed for FDA filings for new drug applications.⁶ It was submitted to DEA by the American Kratom Association and their legal Counsel, Hogan Lovells. In brief, it concluded that neither kratom in total nor the specific primary alkaloid mitragynine nor 7-hydroxymitragynine met statutory standards for CSA scheduling, and furthermore such scheduling was contrary to the public health interest as addressed in Factors 4, 5 and 6 of the eight factors.

³ Ex. C, 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>

⁴ See Ex. D, 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.”).

⁵ *Id.*

⁶ See Ex. P, J. Henningfield, et al., *The Abuse Potential of 7-Hydroxymitragynine to the 8 Factors of the Controlled Substances Act*, September 29, 2025.

28. On October 1, 2017, HHS officials wrote a letter to the DEA recommending scheduling kratom.⁷ 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. For example, Andrew Kruegel, a Columbia University Professor of Chemistry who has studied 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.”⁸ Researchers also expressed that scheduling kratom would make it more difficult to study kratom, because any clinical study would require DEA’s permission.

29. In 2018, I led a prestigious group of leaders in kratom science, opioids and drug regulation in a review of FDA’s analysis and letter. In brief, we concluded that FDA did not meet its own standard for what is expected in an FDA 8 factor analysis submission, nor the standards of the CSA as followed by DEA.

30. In August 2018 the Assistant Secretary of Health, Dr. Brett Giroir, who is 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.”⁹ As a result, the DEA ceased its scheduling efforts.

⁷ Ex. E, 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>.

⁸ Ex. F, *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.>

⁹ See Ex. G, 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-16-2->

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

32. In December 2021, the Expert Committee on Drug Dependence ("ECDD") at the World Health Organization, 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. "People report using kratom to self-medicate a variety of disorders and conditions, including pain, 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." "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."¹⁰

33. 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. 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."¹¹

34. 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

018.pdf?rlkey=hynbhtl46j903cewsr0w3m8rg&e=1&dl=0+%28last+accessed+on+August+28%2C+2024%29.

¹⁰ See Ex. H, 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). Ex. I, United Nations Commission on Narcotic Drugs Report at https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_64Reconvened/ECN72021_CRP12_V2108992.pdf.

¹¹ Ex. J, 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).

even at high doses when taken in capsule form.”¹² 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.”¹³ Over the course of the study, the FDA found no serious complications and stated that it “recognize[s] that further studies are needed to advance our understanding of kratom.” The FDA noted plans for additional peer-reviewed research in the near future.

35. In general, kratom products are legal and widely available for purchase in physical stores in most states, and through the Internet. 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 NIH, which is part of HHS. *Id.*

36. Regarding the risk of death related to kratom, the FDA’s latest statement on December 2, 2025 stated, “In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. However, in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear.”¹⁴

37. Acceptance by the FDA of a New Dietary Ingredient Notification (“NDIN”) is not a requirement for legal sale of kratom. The FDA only requires an NDIN for a drug product, a dietary supplement, or a food additive in conventional food. Because kratom is legally marketed as a food, the NDIN is optional.

38. 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 a single NDIN

¹² See Ex. K, Fiona Rutherford & Immanuel John Milton, *Kratom’s First FDA Study Suggests Capsules Safe at High Doses*, Bloomberg (Sept. 17, 2024).

¹³ Ex. L, 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->.

¹⁴ Ex. M, FDA and Kratom, <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>.

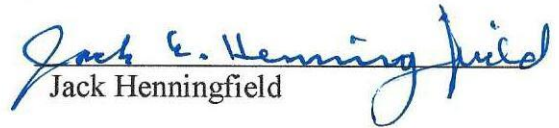
for any kratom product. I have assisted various companies in the kratom industry on NDINs, and in my opinion they have demonstrated that kratom is safe, but the FDA has not accepted them.

39. On July 29, 2025 the HHS Secretary and FDA Commissioner held a press conference in which they discussed their conclusions and presented documents supporting their conclusion that a metabolite of mitragynine, 7-hydroxymitragynine (7-OH) carries serious risks of addiction and possibly death and should be placed in Schedule I of the US Controlled Substances Act.¹⁵ In the media conference and materials they made clear that “kratom was not the focus of their concern” and discussed uses of kratom such as for pain.

40. I agree with the July 29 DHHS and FDA conclusions as discussed in detail in my 8-factor analysis of 7-OH which I submitted to DEA, FDA, and NIDA on September 29, 2025. An implication of this discussed in my 8-FA was that many reports of kratom associated harm may have actually been attributed to 7-OH products marketed as “kratom” and/or assumed by consumers to be “kratom”.

¹⁵ Ex. N, M. Makary, *Dear Colleague, Letter from Martin A. Makary to Colleagues*, July 29, 2025; Ex. O, Reissig et al., *7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat*; Ex. Q, FDA, *Preventing the Next Wave of the Opioid Epidemic: What You Need to Know About 7-OH*.

Executed this 2nd day of March, 2026, at Baltimore, City, Maryland


Jack Henningfield