STATEMENT TO THE RHODE ISLAND HOUSE COMMITTEE ON CORPORATIONS

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H7518 (Rep. McGaw, et al.)
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Clarifying Claims Regarding "Kratom Deaths," Federal Public Health Findings, State Actions on Kratom, and Kratom Harm Reduction

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to respond to the claims made during the House Committee on Corporations hearing convened on March 12, 2026, that included claims kratom is responsible for increasing numbers of deaths in the United States. Statements made during the hearing — including references to data from Utah, Rhode Island, and other states — risk giving the Committee an incomplete or misleading picture of what federal public-health authorities and state officials have concluded about kratom-related fatalities.

FDA HUMAN KRATOM DOSE FINDING STUDY ON THE SAFETY OF KRATOM

The FDA published its findings in the past week on its "Pilot, Dose-Finding, Pharmacokinetic Study of Orally Administered Botanical Kratom" in the Journal of Clinical Psychopharmacology that reported on the results of a human dose-finding study on the safety of natural kratom leaf products. This study had 40 human participants and were divided proportionately between kratom and placebo cohorts and were measured at each dose for the effects in a 5-minute period after dosing.

> Results: No deaths or serious adverse events (SAEs) occurred. Somnolence, vomiting, and nausea were the most common AEs reported. Kratom alkaloid concentration showed generally orderly, dose-related effects. At doses $\geq$ 3 g. kratom produced pupillary constriction. Few dose-related effects were observed, although the 12 g. dose of kratom produced increases on several subjective measures including ratings of "drug liking." [SEE THE ATTACHED REPORT]

FEDERAL PUBLIC HEALTH AUTHORITIES HAVE CONSISTENTLY FOUND THAT KRATOM DEATHS ARE RARE

The most authoritative assessments of kratom safety come from the federal public-health agencies responsible for monitoring drug safety and mortality trends: the National Institutes of Health (NIH), the National Institute on Drug Abuse (NIDA), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

Those agencies consistently report three key findings:

1. Deaths attributed solely to kratom are extremely rare.

2. When deaths are reported as "kratom-involved," multiple substances are almost always present.
3. Many of the cases involve adulterated products or other drugs.

The National Institute on Drug Abuse (NIDA) explains:

> "Compared to deaths from other drugs, a very small number of deaths have been linked to kratom products and nearly all cases involved other drugs or contaminants."

Similarly, the Food and Drug Administration (FDA) notes:

> "In rare cases, deaths have been associated with kratom use… however, in these cases kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear."

The Centers for Disease Control and Prevention (CDC), reviewing national mortality data, found:

- Multiple substances were detected in nearly all kratom-positive deaths, and
- Approximately 80% of the decedents had a documented history of substance misuse.

On March 16, 2022, in a letter from HHS Secretary Becerra,[1] the Secretary acknowledged "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

These findings demonstrate an essential point: the presence of kratom on a toxicology screen is not proof that kratom caused the death.

FDA has the legal authority to take regulatory action against a manufacturer, distributor, or vendor of a food product that is adulterated under the standards set forth in the Food, Drug and Cosmetic Act. It may do so if a food product "bears or contains any poisonous or deleterious substance which may render it injurious to health, or the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling."[2]

If FDA finds a food product adulterated, the Agency may take enforcement action against a kratom company through issuing Warning Letters, Untitled Letters, 483 Inspection Observations, and Recalls.[3]

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[1] https://kratomanswers.org/wp-content/uploads/2022/07/TAB-14-HHS-Becerra-Letter-Lee-and-Pocan.pdf
[2] This list is not an exhaustive list. 21 U.S.C. § 342; *Questions and Answers Regarding Mandatory Food Recalls*, FDA Guidance, November 2018, available at https://www.fda.gov/media/117429/download.
[3] *See generally Compliance & Enforcement (Food)*, FDA.gov, available at https://www.fda.gov/food/compliance-enforcement-food.

MISINTERPRETATION OF "KRATOM-INVOLVED" DEATH DATA

The confusion often arises from the way mortality databases categorize deaths. A death may be listed as "kratom-involved" simply because kratom was detected in a toxicology screen.

But toxicology screens commonly detect multiple substances—including opioids, benzodiazepines, alcohol, antidepressants, and other drugs.

Medical examiners must determine the actual cause of death, not simply the presence of substances.

During the Rhode Island hearing itself, it was acknowledged that the Rhode Island Department of Health data cited by Representative McGaw did not identify whether the deaths involved natural kratom leaf products, adulterated products, or polydrug use.

Without that forensic detail, citing those numbers risks misleading policymakers.

MISCHARACTERIZED STATE ACTIONS AND POLICY DECISIONS

Several state actions cited during the hearing were described in ways that do not accurately reflect what those states have actually done.

Utah

Representative McGaw cited Utah as evidence that states are reversing kratom policy because of deaths attributed to kratom. In fact, Representative McGaw told the Committee that the Utah Office of the Medical Examiner reported an increase of 43% of kratom-related overdoses between 2021 – 2025 since the KCPA passed in 2019.

However, testimony from the Utah Office of the Medical Examiner clarified that the deaths referenced in the Utah data were polydrug cases in which kratom was detected along with other substances, not deaths where kratom alone was determined to be the cause.

In other words, the Utah data show kratom presence, not kratom causation.

Utah has also not required kratom products to be placed behind lock and key. The Utah Kratom Consumer Protection Act continues to allow retail sales of regulated kratom products.

What Utah did address legislatively were chemically manipulated products, including high-concentration 7-hydroxymitragynine products, which present very different pharmacological risks than natural kratom leaf.

This distinction is particularly important when evaluating the Utah data cited during this hearing. Testimony from the Utah Office of the Medical Examiner clarified that the majority of

the reported fatalities involved polydrug use, meaning several substances were present simultaneously.

Dr. Amaro, the Utah State Medical Examiner, testified at the Utah Health and Human Services Interim Committee on November 19, 2025, as follows:

> "The vast majority of overdoses are the result of multi substances. This is true for all drug overdoses, but again a little bit more pronounced for kratom. So 94% of overdoses involved another substance. **I think a notable trend though is that we saw more Kratom only deaths in the most recent 12-month period than we've seen.**" (emphasis added)

Of course, it is the market introduction of 7-OH products that occurred in September 2025 that has led to this spike in so-called "kratom only" deaths which the FDA has identified as 7-OH being the reason for the spike in these death reports.

Ohio

Representative McGaw also cited Ohio as moving toward banning kratom products.

That description is inaccurate.

The Ohio Board of Pharmacy issued an emergency scheduling order targeting chemically manipulated and synthetic compounds, specifically 7-hydroxymitragynine and related derivatives that are being marketed as kratom products.

At the same time, the Ohio Board of Pharmacy has opened a regular rulemaking process to review the regulatory status of natural kratom leaf products, meaning the state is evaluating the science on kratom — and the state has not implemented a blanket ban on natural leaf kratom products.

Rhode Island Data

The Rhode Island Department of Health epidemiology office reported that kratom was "involved" in 10 deaths between 2020 and 2024.

However, the term "involved" in epidemiological reporting means that the substance was present in the toxicology screen, not that it was determined by a medical examiner to be the cause of death.

During the hearing, when asked whether those Rhode Island deaths involved natural kratom products or adulterated substances, Representative McGaw acknowledged that this level of forensic detail was not provided by the Department of Health.

Without a full medical examiner review, citing those cases as “kratom deaths” is therefore not supported by the available evidence.

Louisiana Ban

Misunderstandings about kratom chemistry have also appeared in legislative debates in other states.

During the Louisiana House floor debate on kratom legislation, Representative Villio, the sponsor of the kratom ban, stated that there was “no such thing as synthetic kratom.”

Louisiana House of Representatives Floor Debate on Kratom Ban, May 27, 2025	
Rep. Jordan: - “Thank you, Mr. Speaker. Rep Villio, you know, I've had people talk to me about this and frankly, Kratom is one of those things that I know very little about, but I have done some reading. **So my question is, what is the difference, or is there a difference between the leaf, the tea and the synthetic version.” (emphasis added)**	**Rep. Villio** – “**There is no synthetic version**, Rep Jordan, and thank you for the question. You might see an amendment that talks about synthetic Kratom. It's an insult to all of us. When I saw an amendment like that, another member was gonna bring it, and I said, **"Tell the lobbyists who gave you that "I may have been born at night, "but I wasn't born last night." Because in effect, what we would be banning is a product that doesn't exist.“ (emphasis added)**

That statement is demonstrably incorrect.

Scientists and federal regulators recognize that many products currently marketed as kratom are in fact chemically manipulated derivatives, including:

- High-concentration 7-hydroxymitragynine products, and
- Synthetic or semi-synthetic compounds such as mitragynine pseudoindoxyl and MGM 15/16.

These substances are not present in meaningful concentrations in the natural kratom plant and are produced through chemical conversion processes.

Statement by FDA Commissioner Makary, July 29, 2025
“**The enhanced amount of 7-OH in these products is likely synthetically derived through oxidate chemical conversion of mitragynine isolates or kratom extracts**. Given the trace

amounts of 7-OH that are naturally present in kratom, direct extraction of 7-OH from plant material would simply be unfeasible economically."[4] **(emphasis added)**

STATUS OF KRATOM PRODUCTS IN WISCONSIN

Representative McGaw failed to provide the Committee with the report from the Wisconsin Controlled Substances Board to the Wisconsin Legislature as follows:

> The Wisconsin Controlled Substances Board ("CSB") received a report from Dr. Chris Cunningham, Associate Professor of Pharmaceutical Sciences at Concordia University Wisconsin, with the following conclusion:
>
> "Based on our review of the available literature, we conclude that regulation of M. speciosa in Wisconsin as a schedule-I substance is not justified at this time. We base this conclusion, in part, on the scientific evidence demonstrating that M. speciosa and its chemical constituents have lower potential for overdose and abuse relative to other agents that are not scheduled in this way. We believe that controlling M. speciosa and its chemical constituents under schedule-I harms public health and stifles much-needed research into its therapeutic and toxic properties."
>
> In response, members of the Wisconsin Legislature asked the CSB for an assessment of whether kratom's constituents meet the statutory requirements for scheduling under the 8-factor analysis. On March 10, 2023, the CSB approved a motion to affirm natural kratom leaf does not meet the required 8-factors for scheduling under Wisconsin law.

STATUS OF KRATOM PRODUCTS IN VERMONT

Vermont followed the FDA's recommendation to schedule kratom in 2016. Pursuant to a petition filed with the Vermont Department of Health to remove mitragynine and 7-hydroxymitragynine from the Regulated Drug Rule, the Department granted the petition submitted by the AKA on March 1, 2023, and will commence rulemaking to complete that process, stating as follows: "This email it to apprise you that the Department is granting your petition to remove mitragynine and 7-hydroxymitragynine form the Regulated Drug Rule." That review by the department and legislature is currently ongoing.

NIDA DIRECTOR NORA VOLKOW ON KRATOM AND HARM REDUCTION

Another important perspective comes from Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA).

[4] https://www.fda.gov/media/187899/download?attachment

Dr. Volkow has emphasized that stigma can discourage individuals suffering from opioid addiction from seeking safer alternatives or treatment. Research supported by NIDA has documented that many individuals report using kratom as a harm-reduction tool to reduce or discontinue opioid use.

NIDA Director Nora Volkow has offered two public statements on kratom's potential value in the battle against drug overdose deaths. The first was published in NIDA Director Dr. Nora Volkow' blog and offered the following assessment of kratom on January 24, 2020:[5]

> "Research published in June in ACS Central Science provided new insights while raising new questions about the drug kratom. Its active ingredient mitragynine acts as a weak partial agonist at the mu-opioid receptor (MOR), but new findings by a team that included researchers at Columbia and Memorial Sloan-Kettering found that the drug's analgesic properties are significantly mediated by a metabolite produced when mitragynine is consumed orally, called 7-hydroxymitragynine. In mice, at least, this compound seems to provide analgesia but with fewer respiratory-depressing and reward-associated side effects than other opioids such as morphine. These findings point toward the potential of this drug in pain research as well as the need for further research on the pharmacology of kratom's constituents, their toxicity and potential value in the treatment of opioid use disorder (OUD)."

Then, Director Volkow testified before the US House of Representatives Appropriations Committee on May 25, 2022, and stated the following:

> "Kratom, most notably mitragynine, has many interesting properties that could be of value potentially as a medication for pain. Also, interestingly, they could hold value as a treatment for addiction [...] it is important to actually do research on this substance."[6]

Researchers at Johns Hopkins University concluded that 87% of adult consumers using kratom to treat opioid dependence reported relief from withdrawal symptoms, and 35% replaced the opioid with kratom within a year. The researchers concluded that serious adverse events are uncommon even at high consumption rates.[7]

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[5] https://www.drugabuse.gov/about-nida/noras-blog/2020/01/reviewing-nidas-2019-achievements-looking-to-future

[6] https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health

[7] https://www.dropbox.com/s/bob9xr5jp2bwcg1/Garcia%20Drug%20and%20Alcohol%20Dependence%20kratom%20study%20Feb%203%202020%20.pdf?dl=0

The NIDA message is that kratom is a harm reduction tool that should be available to consumers. The science on kratom speaks equally powerfully on its value for consumers, and the FDA's own research proves pure and unadulterated kratom is not dangerous to consumers.

Within the broader public health discussion on harm reduction, federal researchers have noted that policies that stigmatize lower-risk alternatives may discourage individuals from moving away from far more dangerous substances such as fentanyl and prescription opioids.

Ensuring reasonable access to products that some individuals use as harm-reduction tools — while regulating dangerous adulterated products — is therefore consistent with modern public health strategies aimed at reducing opioid-related harm.

To that end, on December 29, 2022, President Biden signed the FY23 Omnibus bill with kratom report language commending NIDA for funding studies on kratom that "may provide help for some Americans struggling with addictions, given its analgesic and less addictive properties as compared to opioids." [8]

IF MU-OPIOID RECEPTOR ACTIVITY IS THE STANDARD, IT SHOULD BE APPLIED CONSISTENTLY

Representative McGaw, in responding to a question regarding her professional experience as a pharmacist, specifically stated that any products interacting with mu-opioid receptors should be placed behind the counter and in a cabinet that can only be opened with a key secured by the clerk.

If that pharmacological standard is adopted, it should logically apply to all products that affect the same receptor systems, not selectively to kratom, the one botanical ingredient that Representative McGaw has acknowledged she has targeted. Several consumer products currently sold legally in the United States interact with opioid receptors, including:

- Loperamide (Imodium) — an over-the-counter anti-diarrheal that acts as a mu-opioid receptor agonist.
- Nutmeg — a culinary spice whose compounds can interact with opioid receptor pathways at high doses.
- Corydalis supplements — herbal products containing alkaloids that affect opioid receptor systems.
- Akuamma seed — botanical products containing alkaloids that bind to opioid receptors.
- Certain kava extracts — supplements with compounds that influence opioid receptor pathways.
- Cheese and dairy-derived peptides — digestion of milk proteins produces casomorphins, peptides that bind to mu-opioid receptors.

[8] https://www.whitehouse.gov/briefing-room/legislation/2022/12/29/bill-signed-h-r-2617/

None of these products are restricted to behind the counter or locked behind glass cabinets in retail stores.

This illustrates an important point: Receptor interaction alone has never been used as the basis for retail restrictions. Despite interaction with μ-opioid receptors, these products are not treated like controlled substances because:

- Receptor interaction alone does not determine abuse potential.
- Most have weak or peripheral activity.
- They have long histories of safe consumer use.
- They do not produce the rapid central nervous system effects typical of opioids like morphine or fentanyl.

In pharmacology, many natural compounds influence opioid receptors without producing the risks associated with opioid drugs.

DISTINGUISHING NATURAL KRATOM FROM ADULTERATED OR SYNTHETIC PRODUCTS

A growing concern among toxicologists and regulators is the emergence of chemically manipulated compounds falsely marketed as kratom, including:

- high-concentration 7-OH products, and
- synthetic derivatives such as pseudoindoxyl and MGM 15/16.

These compounds behave pharmacologically very differently from natural kratom leaf and can be dramatically more potent.

During the Rhode Island hearing, examples of these chemically manufactured products were presented and explained as the type of products that have raised legitimate safety concerns.

Federal regulators have increasingly focused their concern on these types of chemically manipulated products, not on traditional kratom leaf. On July 29, 2025, FDA Commissioner Makary made the following statement:

> "The FDA is specifically targeting 7-OH, a concentrated byproduct of the kratom plant; it is not focused on natural kratom leaf products. 7-OH is increasingly recognized as having potential for abuse because of its ability to bind to opioid receptors." [9]

RHODE ISLAND SHOULD FOCUS ON ACCURATE SCIENCE

[9] https://www.fda.gov/news-events/press-announcements/fda-takes-steps-restrict-7-oh-opioid-products-threatening-american-consumers

The Rhode Island Kratom Act already reflects this scientific distinction.

The law:

- prohibits adulterated products,
- requires labeling and manufacturing standards, and
- protects consumers from unsafe formulations.

Policy discussions should therefore be grounded in the actual findings of federal health authorities, which consistently show that:

- kratom-related deaths are rare,
- nearly all cases involve multiple drugs, and
- the most serious risks arise from adulterated or chemically manipulated products.

Mischaracterizing “kratom-positive” toxicology reports as proof that kratom caused a death risks misleading policymakers and undermining evidence-based consumer protection policy.

CONCLUSION

The federal government’s own public-health agencies are clear: deaths directly attributable to kratom are rare, and when fatalities occur they almost always involve polydrug use or contaminated products.

At the same time, addiction researchers recognize that many individuals report using kratom as a harm-reduction tool to move away from far more dangerous opioids.

The appropriate policy response is therefore to focus enforcement and regulatory attention on dangerous synthetic or chemically manipulated products falsely marketed as kratom, while preserving access to regulated natural kratom products under the Rhode Island Kratom Consumer Protection Act.

Thank you for the opportunity to provide this clarification to the Committee.