For Immediate Release:
December 8, 2023

Contact: Mac Haddow
Senior Fellow on Public Policy
American Kratom Association
Phone: 571-294-5978
mhaddow@americankratom.org

The American Kratom Association Calls Out the FDA for Gaslighting the Tampa Bay Times Investigative Team

Setting aside the sensationalized claims in the Tampa Bay Times article on kratom, the adverse events and fatalities are properly laid at the doorstep of the FDA.

WASHINGTON, D.C., UNITED STATES, December 8, 2023 – The American Kratom Association's (AKA) advocacy work consistently relies on two specific principles: (1) Science should dictate the public policy on kratom; and (2) the FDA should do its actual job and regulate the kratom marketplace fairly.

The Tampa Bay Times has published the first in what they say is a planned series of articles on kratom, "Deadly Dose", that relies almost completely on the FDA's claims that kratom is dangerous, and the investigative team at that newspaper has fallen victim to the FDA's decade long gaslighting of the public on the important issue on whether kratom is dangerous or not. The FDA has repeatedly made official pronouncements in government documents claiming kratom is dangerous; has flooded the internet with anti-kratom claims citing how kratom is dangerous; and has misled medical examiners, law enforcement officials, addiction recovery center officials, elected officials, trial attorneys, the media, and the public with a deliberately false stream of disinformation claiming that kratom is dangerous.

"The FDA started the false narrative that kratom is dangerous in its justification for the first import alert on kratom imposed by the FDA more than a decade ago," Mac Haddow, Senior Fellow on Public Policy with the AKA, explained. "The FDA filed official documents to schedule kratom in 2016 claiming kratom products posed an imminent threat to the safety of the American public. The FDA's disinformation campaign on kratom misled respected heath websites like the Mayo Clinic, WebMD, and the Cleveland Clinic with claims that kratom was killing people by itself."

In a stunning disclosure in the United States District Court for the Southern District of California where a Federal Judge ordered the FDA to testify under oath to justify their claims that kratom is dangerous, the Department of Justice has reported to the Judge that the FDA has refused to obey

the Order because "they ["FDA"] have not made a determination regarding whether kratom is dangerous." (*see Case 3:23-cr-00179-TWR Filed 12/06/23 Page ID.1032 Exhibit 6; United States of America, Plaintiff, v. Nine2Five, LLC (1) Sebastian Guthery (2), Defendants*)

"The FDA has repeatedly stated for more than a decade a constant false narrative that kratom is dangerous and only when they are required to document that claim under oath in a Federal District Court, they refuse because they admit they never could justify their claims kratom is dangerous," Haddow concluded. "The Tampa Bay Times makes the fair point that more regulation should be put on kratom, but it is the FDA who has failed to protect the American people from adulterated kratom products that do cause adverse events and deaths. The FDA's House of Cards on kratom has collapsed and the gaslighting by the FDA on kratom has to stop now." The AKA supports the Federal Kratom Consumer Protection Act legislation now under consideration by Congress as a means to combat FDA inaction and misinformation.

WHERE THE AKA AND TAMPA BAY TIMES AGREE – AND WHERE WE DISAGREE

Where the Tampa Bay Times and the AKA Agree:

- The AKA advocates for evidence-based labeling that will inform consumers on the serving sizes that are recommended, and we support product limitations on the ingredients that should be on a label that informs consumers. The AKA is adding minimum labeling requirements to our vendor Good Manufacturing Practices program that will be published in January. Any product that is not labeled correctly, or has no labeling instructions at all, should be banned from sale. That is a clear failure of the FDA to not remove these products from the marketplace because they have existing statutory authority to do so.
- Polydrug use and adulterated kratom products are causing serious adverse events and deaths. The Tampa Bay Times correctly states there is no known toxicity level for kratom itself, but they completely ignore the science that shows it is other substances that are causing adverse events and deaths.
- Mixing prescribed medications with kratom should be supervised by medical professionals, and kratom consumers should tell their doctor about kratom use just as they do with other dietary and botanical supplements. When the FDA identifies a specific interaction between a prescription medication and kratom, the FDA requires a warning on the label. To date, the FDA has not provided a single advisory to any drug or kratom manufacturer about known interactions, and no warning labels have been required.
- No kratom vendor should be permitted to make an illegal therapeutic claim, i.e., providing "opiate withdrawal relief." It is appropriate under federal law to make general marketing statements about increasing energy or similar benefits. The FDA has failed to take any enforcement actions against vendors who make these illegal therapeutic claims. The AKA has submitted more than 85 documented complaints to the FDA on kratom vendors making these illegal therapeutic claims over the past 3 years, and not a single prosecution has resulted.

- Concentrated levels of kratom's alkaloids or metabolites that use production methods not approved by the FDA that synthetically enhance the power of these ingredients should be banned. Synthesized 7-hydroxymitragyine to enhance the "power" of a user experience should be banned from the market. Much like concentrated caffeine products – where the FDA has taken enforcement action -- kratom products manufacturing processes should follow FDA similar concentration guidance, and the AKA advocates for such limits. More importantly, the FDA should publish specific standards for manufacturing for kratom products.

Where the Tampa Bay Times and the AKA Disagree:

- Using attention-grabbing headlines that are not supported by the actual data on kratom's role in reported deaths – like the Tampa Bay Times headline "Deadly Dose" – leads readers to the false conclusion that evidence shows kratom causes deaths – when the evidence does not support that conclusion at all. A headline like "Deadly Dose from Polydrug Use and Adulterated Kratom Products" isn't as inflammatory nor will it yield more clicks, but it is the truth.
- The Tampa Bay Times concludes that there are 46 deaths that are "kratom only." Without a standardized toxicology testing protocol, that data cannot be relied upon to support the conclusion offered. An analysis of 15 kratom related deaths over an 8 year period where there were 4 "kratom only" deaths in Colorado was reported in the New England Journal of Medicine where authors determined as follows: "We further investigated the 4 deaths that appeared to be due to mitragynine only, reviewing police investigation records for all 4 and performing comprehensive toxicology screening with high-performance liquid chromatography with tandem mass spectrometry for the 3 cases for which residual blood was available. In our investigation of all 15 kratom-related deaths, we determined that 14 deaths clearly involved multiple drugs. Mitragynine levels varied widely, from 16 to 4800 ng per milliliter. Residual blood was not available for confirmatory testing in the remaining kratom-related death." (*See https://www.nejm.org/doi/full/10.1056/NEJMc1811055*)
- The Tampa Bay Times assessment of the unintentional drug overdose deaths where kratom was detected does not support any credible conclusion that kratom was either the cause or even a contributory factor in a death. If the toxicology screen were expanded, it would show dozens of substances consumers regularly ingest that are detected, including over-the-counter medications like cough syrup, loperamide products, energy drinks, etc.
- The Center for Disease Control and Prevention ("CDC") identified this very issue in its report on "Unintentional Drug Overdose Deaths with Kratom Detected – 27 States, July 2016-December 2017" where it found "Postmortem toxicology testing protocols were not documented and varied among and within states."
  (See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6459583/)
- The documentation of postmortem toxicology testing protocols is needed to further clarify the extent to which kratom contributes to fatal overdoses. The CDC recommendation was made in 2019 and no progress has yet been made on establishing standard toxicology protocols. The FDA has aggressively advocated for medical examiners

to list kratom as a cause or contributor to a fatality even if kratom is just detected in a toxicology screen.

- A proper understanding of the type and number of substances detected in the postmortem toxicology screens of decedents would allow for the identification of substances that actually cause a death and, importantly, exclude substances that do not. The CDC report showed that in death cases where kratom was found in a toxicology screen, fentanyl and fentanyl analogs were listed as the "cause of death for 65.1% of kratom-positive decedents and 56.0% of kratom-involved decedents."
- Heroin was the second most frequent substance listed as the cause of death in kratom positive decedents at 32.9%; benzodiazepines at 22.4%; prescription opioids at 19.7%; and cocaine at 18.4%.
- Under current protocols, multiple substances can be listed as a cause of death, therefore the substances are not mutually exclusive and a primary cause need not be identified. However, the potentially deadly toxicity profiles of fentanyl, heroin, benzodiazepines, prescription opioids, and cocaine are well-documented in published literature whereas the toxicity of kratom is not.

- The entire premise of the Tampa Bay Times investigation relies on the deeply flawed claims of the FDA that kratom is dangerous. Former HHS Assistant Secretary of Health Dr. Brett Giroir reviewed the FDA's petition to include kratom's constituents as Schedule I substances under the Controlled Substances Act and concluded the "FDA's recommendation was rejected b/c of embarrassingly poor evidence & data, and a failure to consider the overall public health."
  (*See https://twitter.com/DrGiroir/status/1395874443726102533*)
- The AKA believes that public policy on kratom should be set by science, not the opinions of the AKA or the FDA – or any other party who relies on the FDA's deeply flawed and embarrassingly poor evidence and data.
- The AKA advocates for responsible regulation an reiterates the call for the FDA to Do Their Actual Job!

ABOUT AKA

The American Kratom Association (AKA), a consumer-based, nonprofit organization, focuses on setting the record straight about kratom and gives a voice to those who are suffering by protecting their rights to possess and consume safe and natural kratom. AKA represents millions of Americans, each of whom has a unique story to tell about the virtues of kratom and its positive effects on their lives.

For more information, visit www.AmericanKratom.org, www.Kratomanswers.org or www.Protectkratom.org. Follow them on Twitter (@TheKratomAssn), Facebook (https://www.facebook.com/Americankratomassociation/)