AMERICAN KRATOM ASSOCIATION

STATEMENT OF MAC HADDOW, SENIOR FELLOW ON PUBLIC POLICY
Ohio Senate Health Committee
SB 103, Regarding Sales of Kratom Products
Wednesday, September 27, 2023

Chair Huffman, Vice Chair Johnson, and Members of the Committee. Thank you for this opportunity to testify in support of the passage of SB 103 that will provide appropriate and needed regulations for the sales of kratom products in Ohio.

My name is Mac Haddow, and I serve as the Senior Fellow on Public Policy for the American Kratom Association (AKA), representing the more than 15 million kratom consumers in the United States, and the hundreds of thousands of Ohio citizens who safely consumer kratom products.

I recommend that you visit a website dedicated to public policy makers to review the most current science and policy on kratom: www.kratomanswers.org. The AKA urges states to enact SB 103 to assure Ohio consumers have needed protections when they purchase a kratom product.

The profile of the typical kratom consumer. According to surveys in the US, most consumers report are adults, aged 35-55, with jobs, and health care insurance, 75% of whom report that their consumption is primarily for health and wellbeing. This includes consumption of kratom as an alternative to caffeinated products for alertness and increased focus. About 25% report they use kratom for the self-management of pain, to improve mood, and many consumers state that kratom worked better for them, had fewer side-effects than the FDA-approved medicines that had been taken, and/or that they preferred natural products, including consumers who consider kratom as a "lifeline" or a path away from opioids. They use kratom to manage opioid withdrawal and reduce or eliminate opioid use.

Research from Johns Hopkins University on adult kratom consumers showed that 87% reported that kratom reduced their withdrawal symptoms, and 35% were opioid free within a year replacing those drugs with kratom (*See* https://www.hopkinsmedicine.org/news/newsroom/news-releases/natural-herb-kratom-may-have-therapeutic-effects-and-relatively-low-potential-for-abuse-or-harm-according-to-a-user-survey)

FDA's unsupported statements about kratom not being safe. Most of the controversy surrounding kratom has been created by the FDA that has a long-standing bias against any dietary ingredient, botanical supplement, or dietary supplement that is not a chemical

formulation subject to regulatory approval as a new drug. In 1994, Congress had to pass the Dietary Supplement Health and Education Act (DHEA) to reign in the FDA's overregulation of dietary supplements FDA wanted banned on the premise they were highly addictive, being used to self-medicate without physician supervision, or were so poorly formulated these products were so dangerous they should be banned.

Today, FDA maintains the same three common objections about kratom, i.e., kratom is unsafe, is highly addictive, and has no approved medical use — and people are using it to self-medicate to withdraw from opioid addictions. Accordingly, FDA has made three specific attempts to have kratom's constituents, mitragynine and 7-hydroxymitragynine, as Schedule I substances. Based on current science, leading public health officials have reviewed the current evidence and data on kratom and made the following decisions that kratom is not a candidate for scheduling:

- October 13, 2016: The Drug Enforcement Administration (DEA) withdrew the Notice of Intent recommending the temporary scheduling of kratom and requested a full 8-Factor Analysis from the FDA.

- August 16, 2018: HHS Assistant Secretary for Health, Brett Giroir, M.D., formally withdrew the FDA scheduling recommendation for kratom that had been submitted to the DEA and called out the FDA for "disappointingly poor evidence & data and a failure to consider the overall public health."

- December 1, 2021: The Expert Committee on Drug Dependence 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.

- March 16, 2022: Letter from HHS Secretary Becerra acknowledging "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

- December 29, 2022: President Biden signed the FY23 Omnibus 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."

The FDA frequently references that there is no approved medical use for kratom. That is true for tens of thousands of foods, dietary ingredients, botanical supplements, and dietary supplements that are available to consumers in the U.S., many of which are regularly used to self-medicate by consumers. Federal law provides adequate authority for the FDA to prosecute any vendors who make illegal therapeutic claims to induce consumers to buy their products for therapeutic uses.

Kratom Science Updates. Former Assistant for Secretary of Health, Dr. Brett Giroir, correctly cited the "embarrassingly poor evidence and data and a failure to consider the overall public health" when he formally withdrew the FDA recommendation to schedule kratom on August 16, 2018. Since 2018, there have been more than 120 new published research articles on kratom. While there are public references to off of that research, a recent presentation on new kratom science was made at the UN Commission on Narcotic Drugs Conference in Vienna on March 16, 2023 (*See* the link to the scientist's presentation at https://youtu.be/oztAWZAaxGo).

Status of States that have banned kratom. Another relevant issue on the FDA's disinformation campaign against kratom is revealed in the responses currently ongoing in the 6 states that banned kratom from 2012 to 2017: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island.

- 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 shortly 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."

- Wisconsin is another state that banned kratom on the recommendation of the FDA, and 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 mitragynine and 7 hydroxymitragynine do not meet the required 8-factors for scheduling under Wisconsin law.

- The Interim Director of the Rhode Island Department of Health, Utpala Bandy, M.D., has concluded that kratom does not meet the criteria for scheduling set forth in Rhode Island statutes.

- In Indiana, the House of Representatives took the first step to remove the kratom ban and enact the Kratom Consumer Protection Act in a vote of 54-30 on February 21. The bill has now been referred to a Senate study committee for recommendations.

- In Arkansas, where the Department of Health issued a ban on kratom in 2015, legislation to repeal the ban and replace it with the KCPA has been filed with the Senate Committee on Public Health, Welfare and Labor.

States that have passed the KCPA. As of today, eleven states have passed similar versions of the KCPA: Utah, Georgia, Arizona, Nevada, Oregon, Colorado, Oklahoma, West Virginia, Virginia, Florida, and Texas.

Additional states currently deliberating on KCPAs are Wisconsin, New Jersey, North Carolina, Massachusetts, and here in Ohio.

The FDA's false claims that kratom is an opioid. While some naturally occurring substances in kratom act on opioid receptors, kratom is not a prototypical opioid based on its chemical structure, botanical origins, or law – nationally or internationally. Like many natural products it has diverse effects and mechanisms of action that contribute to these effects and the reasons people use kratom. Properly characterized as "partial agonists" some kratom constituents bind to opioid receptors and relieve pain whereas others do not. Unlike opioids which sedate and can impair mental functioning, kratom is used by many people in place of coffee for its alerting, mental focusing, and occupational performance enhancing effects. Animal and human studies, as well as neuropharmacology mechanisms of action studies, show that kratom does not carry the substantial opioid-like risks of deadly respiratory depression or powerfully addictive euphoria.

A misunderstanding of one of kratom's self-reported beneficial uses, recognized by researchers and NIDA, providing relief of opioid withdrawal, is sometimes interpreted as evidence that it must be an opioid. In fact, the nonopioid adrenergic blocking drugs developed for treating high blood pressure, clonidine and lofexidine, were prescribed for decades to treat opioid withdrawal. FDA approved lofexidine (Lucemyra) for treating opioid withdrawal in 2018. Mitragynine and other kratom constituents also produce adrenergic effects.

The FDA's false claims kratom is dangerously addictive. NIDA has conducted two specific animal studies on the addiction liability of kratom, with the following results:

- Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. "The present findings indicate that mitragynine does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal, whereas 7-hydroxymitragynine should be considered a kratom constituent with high abuse

potential that may also increase the intake of other opiates." (*See* https://pubmed.ncbi.nlm.nih.gov/29949228/)

- Abuse liability of mitragynine assessed with a self-administration procedure in rats. "These results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse. With the current prevalence of opioid abuse and misuse, it appears currently that mitragynine is deserving of more extensive exploration for its development or that of an analog as a medical treatment for opioid abuse." (*See* https://pubmed.ncbi.nlm.nih.gov/30039246/)

The available data suggest relatively low abuse potential as compared to morphine-like opioids, stimulants, and other drugs of abuse that demonstrate robust rewarding effects across all such abuse potential models. Similarly, mitragynine's (an alkaloid in kratom) potential to produce physical dependence and withdrawal appears relatively low as compared to opioids in animal models. These findings are generally consistent with human reports that mitragynine has a relatively low abuse and withdrawal potential as compared to recreationally used opioids but can reduce opioid self-administration and withdrawal.

Kratom has no significant respiratory suppression effects. It is well understood that kratom's respiratory effects are not like those of morphine-like opioids; however, studies since 2018 support the conclusion that kratom is not simply weaker than opioids with respect to respiratory depression. Specifically, mitragynine and other alkaloids in kratom act as partial agonists at opioid receptors, meaning that their maximal effects reach a ceiling beyond which higher doses produce little additional effect. This was demonstrated in several animal species (including cats, dogs, mice, and rats) with mitragynine doses increased to levels far beyond what is or can be consumed by even high intake chronic kratom consumers. The most recent study employed a sophisticated rodent model developed by FDA to compare a broad range of mitragynine doses to therapeutic and toxic oxycodone doses across blood gases and other parameters. Whereas oxycodone produced the signature dose-related plummeting blood oxygen levels and deaths, mitragynine produced no evidence of respiratory depression at any dose, and no life-threatening effects.

Can you overdose on kratom? The overall risk for kratom overdose appears at least 1,000 times lower for kratom as compared to opioids. There were no deaths in which either the FDA or CDC confirmed as appropriately categorized as due to kratom consumption. Kratom consumers should not assume that kratom is without risk, but like many common consumer products responsible use is a key safety factor. The CDC did not list kratom as a cause of any of the more than one hundred and eight thousand drug overdose deaths in 2021, or in any other year of which we are aware. In contrast, opioids were concluded by the CDC and NIDA to account for more than 80,000 overdose deaths in 2021. Overdose is possible with many readily available consumer substances, including caffeine, but kratom's most common side-effect, transient stomach upset and nausea, also limits intake and is discomforting but not seriously harmful. In February 2018, after announcing that kratom carried opioid-like death risk, the FDA noted that only one of 44 deaths occurring in kratom consumers did not involve other respiratory depressing substances. Further investigation found that the final cause was a motor

vehicle fatality involving a kratom consumer. In fact, NIDA, FDA, US DHHS, and WHO ECDD all concluded that most kratom-associated deaths involved other substances.

Today, the National Institute on Drug Abuse (NIDA) has opposed the FDA on kratom, and Director Nora Volkow has testified before Congress that kratom should not be banned, like the FDA wants, but regulated appropriately and new research should be undertaken. NIDA currently has more than $30 million in grants for kratom research. NIDA researched the FDA claims that kratom caused deaths, and concluded those deaths were from polydrug use or adulterated kratom products.

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.

HHS has strongly opposed the FDA's scheduling recommendation for kratom. Current HHS Secretary Becerra has publicly stated that the FDA needs to do much more research on kratom before making any more recommendations, that claims of addiction liability or fatalities claimed to be caused by kratom are caused by polydrug use or adulterated kratom products.

When kratom consumers have the opportunity to tell their personal stories, they tell of how kratom has improved their lives, and many have said that kratom has literally saved their lives.

We urge your support for KCPA legislation because it is a critical step in enacting appropriate regulations to assure kratom products sold in Ohio are safe, properly manufactured, not adulterated with dangerous substances, labeled to protect consumers, and restricted for sale to minors.

My thanks for the opportunity today to provide this information on kratom and to advocate for consumer protections.

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