AMERICAN KRATOM ASSOCIATION

HB 236 PROPONENT TESTIMONY OF
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AMERICAN KRATOM ASSOCIATION

OHIO HOUSE OF REPRESENTATIVES HEALTH COMMITTEE
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Chair Lipps, Vice Chair Holmes, Ranking Member Russo, and members of the Committee, my name is David Carlucci and I serve as the Senior Advisor for External Affairs with the American Kratom Association (AKA), representing the 11 - 15 million kratom consumers in the United States. We thank you for this opportunity to testify on the kratom issue, and to address HB 236, the proposed Ohio Kratom Consumer Protection Act (KCPA).

About five years ago, when I was serving in the New York State Senate, I introduced a bill to ban kratom because of reports (largely from the FDA) that kratom was dangerously addictive and that it was killing people. Immediately I started to hear from my constituents that kratom was saving their lives, that it was not addictive as the FDA claimed, and it was helping them improve their quality of life, not endangering their lives. After more than a hundred emails like that, I took notice. When it hit the thousands, I did a deep dive into kratom and its science and concluded kratom needed to be regulated, not banned. I sponsored the KCPA in New York.

The real problem is with unscrupulous vendors that are selling kratom products spiked with dangerous controlled substances—which is fueling an addiction crisis and putting unsuspecting kratom consumers at risk for serious adverse events and even death. While this is happening, the FDA is refusing to fulfill their statutory duty to protect consumers using their current regulatory authority and have vigorously supported a total ban on kratom.

To fill this void, five states have enacted the KCPA: Utah, Georgia, Arizona, Nevada, and Oklahoma. Nearly 20 additional states are working on KCPA legislation in current legislative sessions; we hope Ohio will become the 6th state to enact this consumer protection legislation.

At the federal level, the National Institute on Drug Abuse (NIDA) agrees that kratom should be accessible to consumers, and they have committed more than $30 million in grants to conduct research on potential benefits unique to the kratom plant. The U.S. Congress has included report language in the last three Budget Bills that condemns kratom bans, encourages consumer access to kratom, and funds new research. The DEA withdrew the first scheduling recommendation made by the FDA in 2016 and requested more evidence.

The Department of Health and Human Services (HHS) conducted a review of the FDA's second recommendation in 2018 to classify kratom as a Schedule I substance, and officially withdrew

the scheduling request from the DEA with a scathing rebuke that bluntly told the FDA they had submitted disappointingly poor evidence and data.

The FDA then took their case against kratom to the UN Commission on Narcotic Drugs asking for an international ban on kratom. The review was assigned to 12 scientists appointed to the World Health Organization's Expert Committee on Drug Dependence (ECDD). That decision was published on December 1, 2021 where the ECDD ruled (11-1) that there was insufficient evidence to recommend an international ban on kratom.

Through all of this, the FDA claims kratom is dangerously addictive and it kills people. They are wrong.

NIDA reviewed FDA's addiction liability claims[1] [2] and the autopsies on the deaths FDA claimed were caused by kratom—and rejected them. Independent researchers also reviewed the FDA's claim about kratom being an opioid and concluded they were wrong. On each of these key criteria the FDA was wrong on the science and wrong on the policy. The FDA's inexplicable refusal to use its regulatory authority to properly regulate kratom puts Americans at risk, and that is why the KCPA is so important.

The AKA advocates for protections for consumers from dangerously adulterated or contaminated kratom products that are currently marketed in the United States. Most of these unregulated products enter the supply chain because an unscrupulous vendor deliberately adulterates their products with dangerous drugs or synthesizes the natural alkaloid content of the plant to deliver a euphoric high not present in the natural plant.

The important issue is why 11 – 15 million American consumers choose to use kratom in the first place. Kratom has been used safely for centuries in Southeast Asia and is particularly popular with laborers and field workers who find its energy-boosting and pain relief properties helps them get through long days of work in the fields. Surveys of kratom consumers in the United States show about one-third use it the same way many Americans use coffee for an energy boost, or for increased focus. Another third use kratom for its mood smoothing effects and reduced anxiety. And the final third have found that kratom, at higher levels of consumption, can relieve opioid withdrawal symptoms to help them wean off of dangerously addictive and potentially deadly opioids and help manage acute and chronic pain.

The FDA has a long-standing bias against natural products and dietary supplements, and kratom is no exception to the FDA's efforts to increase their regulatory control over the choices Americans make in their health and well-being. In fact, the claims the FDA makes about kratom-associated adverse events and deaths are exclusively related to dangerously adulterated kratom products or polydrug use. Pure kratom that is not contaminated or adulterated is safe when used responsibly.

[1] https://pubmed.ncbi.nlm.nih.gov/29949228/
[2] https://pubmed.ncbi.nlm.nih.gov/30039246/

Kratom does not induce any reinforcing euphoric high nor does it have any significant impact on the respiratory system as classic opioids do. When an overdose death occurs, it is because the user has literally suffocated from respiratory suppression that kratom does not cause. Overdose deaths, euphoric highs, and addiction are the signatures of adulterated kratom, and we want to eliminate those dangerous products from the marketplace.

In the mid-1990s, the FDA launched a similar attack on dietary supplements and vitamins with claims that these products were all unapproved drugs and there were significant number of adverse events and deaths resulting from their sale. The FDA solution was to ban all dietary supplements and force consumers to use only FDA approved drugs to maintain their health and well-being. At that time, the U.S. Congress intervened and stopped the broad regulatory overreach for literally hundreds of dietary supplement and vitamin products by passing the Dietary Supplement Health & Education Act that today provides regulations for the safe use of products accounting for $53 billion in sales to consumers.

That truly is why we are here today: To protect the freedom of Ohio citizens to make informed decisions on their health and well-being without the overreaching regulatory power the FDA is trying to seize. The FDA wants kratom to be subject to its new drug application process. They want the same thing for homeopathic medicines, herbal remedies, and medical foods — all of which have been used safely by American consumers for decades.

A Johns Hopkins University study in 2020[3] supports that point when reporting (1) 87% of kratom consumers using kratom to treat opioid dependence reported relief from withdrawal symptoms, and (2) 35% were free from opioids in a year or less. That explains why NIDA has invested so much of our taxpayer funds in kratom research.

The American Kratom Association asks the state of Ohio to stand up against overregulation by the FDA and protect consumers by allowing them to have the freedom to make informed decisions on safe kratom products they can responsibly use to manage their own health and well-being.

Thank you for the opportunity to testify. I would be happy to answer any questions.

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[3] Garcia-Romeu A, Cox DJ, Smith KE, Dunn KE, Griffiths RR. Kratom (Mitragyna speciosa): User demographics, use patterns, and implications for the opioid epidemic. *Drug Alcohol Depend*. 2020;208:107849. doi:10.1016/j.drugalcdep.2020.107849