AMERICAN KRATOM ASSOCIATION

September 19, 2019

Steve Ehlmann
County Executive
St. Charles County
100 N. Third Street, Suite 318
St. Charles, MO 63301

Mr. Ehlmann:

The American Kratom Association (AKA) applauds the St. Charles County Council for their passage of Amended Substitute Bill 4721 that provides needed consumer protections for the citizens of St. Charles County to protect them from dangerously adulterated kratom products, and empowers kratom consumers to make informed decisions based on accurate labeling of kratom products offered for sale in your jurisdiction. This action joins the states of Utah, Georgia, Arizona, and Nevada in enacting similar consumer protections to ban dangerously adulterated kratom products from sale. There are currently 16 other states in the process of considering the framework for the Kratom Consumer Protection Act.

The AKA is deeply disappointed in your September 12, 2019 memorandum to the County Council, and its release to the public, wherein you express the concern that the public may misconstrue the provisions of this Bill to believe that St. Charles County has "determined Kratom is safe to use."

Our specific concern is that your memorandum may inadvertently mislead St. Charles County citizens in an equally or greater manner that suggests pure unadulterated kratom is unsafe for consumption. That assumption would contradict hundreds of years of kratom's safe use by consumers in Southeast Asia, and the decades of safe kratom use in the United States where today more than 15 million consumers regularly and safely use unadulterated kratom products. Your memorandum appears to rely on the conclusion that the FDA alone is "responsible for protecting public health by regulating drugs for humans" and their judgment on this issue should be the final word, and therein lies the fundamental conflict in our positions.

In fact, kratom is not a drug and is a dietary ingredient/supplement for which there is no current application before the FDA seeking approval for any product formulation of a drug that would require FDA approval. The attempts by the FDA to require kratom to be classified as an unapproved new drug defies the accepted science on the kratom plant and is arguably a clear overreach of the regulatory powers granted to the FDA by statute.

The FDA has a well-known and long-standing bias against dietary supplements and vitamins that dates back to the early 1970s, and that culminated in a legislative battle in the U.S. Congress precipitated by the claims of the FDA then that dietary supplements and vitamins were dangerous, unsafe, and killing consumers and should be banned. The FDA then asserted that any of those products that manufacturers wanted to market to consumers should be required to submit new drug applications.

The U.S. Congress rejected those claims by the FDA and then enacted the Dietary Supplement Health and Education Act (DSHEA) in 1994 that sharply limited the FDA's authority to ban dietary ingredients/supplements and vitamins as they had sought to do. That is the statute that kratom falls under and the FDA should be administering kratom with the same consumer protection framework that is embodied in the St. Charles County consumer protections in Amended Substitute Bill 4721. To date, the FDA has opted to seek a Schedule I ban on kratom rather than appropriately regulate kratom from adulteration and contamination.

The FDA does have the primary responsibility for regulating drugs, but kratom is a dietary ingredient/supplement that is not subject to new drug application (NDA) regulations until and if a sponsor elects to seek an approval of a product that has synthesized or chemically altered the primary alkaloids in the kratom plant that are, in their natural state, known to have a mild pain relief or energy boosting effect as hundreds of other dietary ingredients/supplement do that are marketed to consumers. This DEA scheduling authority is distinctly different from the FDA's responsibility to establish standards for the manufacturing and marketing of dietary ingredients/supplements that the agency has abdicated in their zeal to mischaracterize kratom as a "drug" that should be banned.

In fact, the only role the FDA has under the Controlled Substances Act (CSA) is to make a recommendation, in conjunction with the National Institute on Drug Abuse (NIDA), to the Drug Enforcement Administration (DEA). The DEA is the agency designated to make the decision on the dangers of any substance that meets the criteria for scheduling under the criteria set in the CSA.

On August 30, 2016 the DEA published a Federal Register Notice accepting the FDA's recommendation to schedule two alkaloids in kratom, mitragynine (MG) and 7-hydroxymitragynine (7-HMG), into Schedule I of the CSA under the emergency powers provisions of the CSA. This Notice marked the 82nd time this provision was used for scheduling of dangerous substances, and in each case the named substance was added to Schedule I of the CSA.

However, in an unprecedented move by the DEA, the Notice to schedule kratom's alkaloids was rescinded on October 14, 2016, and was returned to the FDA with the request for an expedited full analysis of the basis for a scheduling recommendation – known as an 8-Factor Analysis (8-FA) to be filed by December 1, 2016. The FDA failed to meet that deadline, but the AKA commissioned the production of the required 8-FA from one of the world's leading experts on addiction liability and safety of substances, Jack Henningfield, Ph.D., who worked for 17 years at NIDA and who has extensive experience in developing 8-FA analyses.

Dr. Henningfield's 8-FA was accepted for a peer-reviewed publication and made the critical argument that banning of kratom products would force those currently using kratom as an alternative to dangerously addictive and potentially deadly opioids that have a far higher safety signal (by many magnitudes) than unadulterated kratom. Equally important was the conclusion by Dr. Henningfield that a ban might also expand consumer reliance on black-market kratom products that are known to be adulterated and terribly unsafe for consumers.

In November 2017 the FDA did submit its 8-FA to the DEA once again recommending the scheduling of kratom's alkaloids. Despite nearly two years of review by the DEA, that agency has declined to take any action to schedule kratom despite the claims by the FDA that kratom poses and imminent threat to the health and safety of the American people. The FDA makes three foundational arguments in their overzealous effort and, to date, the unconvincing arguments to have the DEA accept its recommended ban on kratom:

1. **Kratom is an opioid.**

The kratom plant does not have the pharmacologic properties of an opioid. The available science is clear that kratom, although having effects on opioid receptors in the brain, is distinct from classical opioids (e.g. morphine, heroin, oxycodone, etc.) in its chemistry, biological effects, and origin (kratom is a tree in the coffee family, not the opium poppy family). Kratom does not result in the lethal respiratory depressing effects of classical opioids.

2. **Kratom is dangerously addictive.**

As commonly used in raw plant form, kratom does not appear to produce the highly addictive euphoria or lethal respiratory depressing effects of classical opioids. Equally important, four surveys indicate that kratom is presently serving as a lifeline away from strong, often dangerous opioids for many of the millions of Americans who use kratom.

NIDA funded two independent animal studies – which are widely recognized as the "gold standard" for addiction liability assessments for substances, and the conclusions were peer-reviewed and published documenting the FDA is wrong on its claim kratom as dangerously addictive as opioids.

The Hemby study results speak conclusively to the addiction issue:

> "The present finding indicate that MG does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal, whereas 7-HMG should be considered a kratom constituent with high abuse potential that may also increase the intake of other opiates." [1]

The study results are encapsulated in the statement by Dr. Hemby himself:

> "We stood on our heads to get them to self-administer," Hemby said, adding that his team tried upping the doses of MG several times. "It just wasn't working. It was almost like it was innocuous."[2]

The concern about the addiction potential for 7-HMG was found to be mitigated by the low levels of that alkaloid that are present in the natural kratom plant, and Dr. Hemby specifically concluded that it's the adulterated "purified extracts of 7-HMG [that] are available on the internet and consumed for their euphoric effects."

Dr. Henningfield provided this assessment of the implications on kratom from the Hemby study:

> "This is an important study that addresses the addictiveness of kratom," says Jack E. Henningfield, Ph.D., at Pinney Associates, a health consulting firm. "It

[1] Hemby et al. "Abuse liability and therapeutic potential of the Mitragyna speciosa
Hemby et al. "Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine," Addiction Biology, 27 June 2018, doi: 10.1111/abd.12629.
[2] Business Insider, A mysterious supplement has a viral following of people who take it for addiction – and researchers say it's too compelling to ignore, Erin Brodwin, July 2, 2018, https://www.businessinsider.com/kratom-research-opioid-addiction-2018-6

> shows that the major naturally occurring constituent responsible for the health-related effects of kratom, mitragynine, is of very low abuse potential. A second substance, 7-HMG, which naturally occurs at such low levels in kratom that it might be of minimal health consequence, has higher abuse potential. This has at least two regulatory implications. First, the findings do not support the FDA's claim that kratom is a narcotic-like opioid. Second, in regulating kratom products, the FDA could set standards to ensure that no kratom product contain levels of 7-HMG exceeding those that are commonly present in kratom leaves and products."[3]

A second animal study, this one conducted by NIDA as in intramural research project, reported as follows:

> **"Conclusions**: 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."[4]

Banning kratom, or its placement into Schedule I at the federal level, will potentially increase the number of deaths of Americans caused by opioids because many people who have found kratom to be their lifeline away from strong opioids will be vulnerable to resumption of that opioid use, whether their prior opioid use was for relief of pain or due to opioid addiction. This opinion is supported by four national surveys conducted in the past two years, as well as decades of studies in the US and in Southeast Asia, where kratom has been used as a safer alternative to opioids for management of acute or chronic pain for more than a century.

In fact, publicly available research documents that kratom has a long history of acceptably safe consumer use, and, when used as an alternative pain management therapy, kratom provides a far more favorable safety profile for consumers compared to more dangerously addictive and potentially deadly classical opioid medications. Current scientific research suggests that kratom provides some pain relief activity on the pain centers in the brain without the dangerous and potentially deadly respiratory suppression induced by classical opioid medications. The federal government should be encouraging additional research

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[3] High Point University, *Professor's Research Shows Therapeutic Potential for Kratom,* June 29, 2018, http://www.highpoint.edu/ blog/2018/06/professors-research-shows-therapeutic-potential-for-kratom/

[4] Yue K, Kopajtic, Katz, Abuse liability of mitragynine assessed with a self-administration procedure in rats, Psychopharmacology, 2018, https://www.ncbi.nlm.nih.gov/pubmed/30039246

into the potential benefits of kratom, as well as the possibility that extracts of kratom and/or new medicines that are similar to kratom's active ingredients might serve as breakthroughs in pain relieving medicines that are so desperately needed.

3. **Kratom kills people.**

The FDA claims on 44 kratom "associated deaths" have been completely debunked. Each of those deaths for which medical and autopsy reports are available, show that the deaths were caused by polydrug use or adulterated kratom products, not the natural kratom plant. NIDA did their own assessment of the FDA claims on kratom deaths, and published their own damning condemnation of the FDA claims as published on their website on September 20, 2018:

> *"In 2017, the Food and Drug Administration (FDA) began issuing a series of warnings about kratom and now identifies at least 44 deaths related to its use, with at least one case being investigated as possible use of pure kratom. Most kratom associated deaths appear* ***to have resulted from adulterated products (other drugs mixed in with the kratom) or taking kratom along with other potent substances, including illicit drugs, opioids, benzodiazepines, alcohol, gabapentin, and over-the-counter medications, such as cough syrup.*** *Also, there have been some reports of kratom packaged as dietary supplements or dietary ingredients that were* ***laced with other compounds that caused deaths****." (emphasis added)*

In conclusion, we understand your expressed concern for the safety of consumers in St. Charles County, and the AKA shares that concern as it relates to the sale of adulterated kratom products. In fact, like hundreds of other dietary ingredients/supplements and vitamins, kratom is widely and safely used by millions of consumers despite the disinformation campaign by the FDA. I would specifically direct your attention to the report language approved by the US House of Representatives in their FY 2020 Appropriations bill that I have attached for your review.

The FDA is presently the outlier in the public policy discussions about kratom with NIDA and the U.S. House of Representatives, along with four states with many more looking to join in the effort endorsed by the AKA to enact real consumer protections by banning adulterated kratom products, all clearly support the scientific basis for kratom remaining available to the public. The AKA supports the conclusion of numerous leading scientists who have researched kratom and told the White House and the DEA that "placing kratom into Schedule I will potentially increase the number of deaths of Americans caused by opioids

because many people who have found kratom to be their lifeline away from strong opioids will be vulnerable to resumption of that opioid use, whether their prior opioid use was for relief of pain or due to opioid addiction."

We welcome the opportunity for further dialogue with you and your staff on this important issue.

Sincerely,

C.M. Haddow
Senior Fellow on Public Policy
American Kratom Association

cc: St. Charles County Council