AMERICAN KRATOM ASSOCIATION
13575 Heathcote Blvd STE 320
Gainesville, VA 20155
www.americankratom.org

MEMORANDUM

January 10, 2025

TO: North Dakota House Judiciary Committee

FROM: Mac Haddow, Senior Fellow on Public Policy
American Kratom Association

RE: HB 1101, A BILL for an Act to amend and reenact subsection 3 of section 19-03.1-05 of the North Dakota Century Code, relating to the scheduling of mitragynine as a schedule I controlled substance.

The American Kratom Association ("AKA"), on behalf of the estimated 20 million kratom consumers in the United States and the tens of thousands of North Dakota residents who are kratom consumers, strongly opposes HB 1101 that would classify kratom's compounds, mitragynine and 7-hydroxymitragynine, as a Schedule I controlled substance in the state of North Dakota.

In 2016, the U.S. Food and Drug Administration ("FDA") put out a nationwide alert to every state to schedule kratom on the claim kratom would be scheduled at the federal level. Six states did respond to that request and took action to schedule kratom,[1] but the FDA was unable to justify a scheduling recommendation under the 8-factors required under the Controlled Substances Act ("CSA"). No states have banned kratom since Rhode Island followed the FDA directive in 2017.

Starting in 2019, 13 states have enacted model legislation known as the Kratom Consumer Protection Act (KCPA) – Utah, Georgia, Arizona, Oregon, Nevada, Colorado, Oklahoma, Kentucky, Virginia, West Virginia, Maryland, Florida, and Texas.

KCPA legislation fills the gap in the failure of the FDA to protect consumers, and requires kratom manufacturers to safely manufacture, label and distribute compliant products for kratom pure leaf and properly extract products marketed in the state where the KCPA is enacted. These states have established needed consumer protections to limit risks from adulterated, mislabeled, and contaminated kratom products. These laws also establish age restrictions on the sale and use of kratom.

[1] Vermont, Rhode Island, Wisconsin, Indiana, Arkansas, and Alabama scheduled kratom at the request of the FDA.

First and foremost, it is important to understand that kratom helps people. That is illustrated in the letter received from Congressman Jack Bergman (R-MICH), who is a former Lt. General in the U.S. Marine Corps where he advocates for veterans who benefit from access to kratom [see Exhibit 1]:

> "My specific concern is for the health and welfare of many of our nation's servicemembers and Veterans that I served with and others who returned from their service with injuries and chronic pain. Many of those Veterans have received treatments with dangerous opioids that lead to severe addictions and expose them to the unacceptable risk they will end up as another of the more than 80,000 opioid overdose deaths per year in the United States.
>
> **One of the tools and resources many Veterans have used to quit their opioid dependence, manage pain, improve mood and focus, and get their lives back on track has been through controlled use of a pure, unmodified kratom product. For many, it has been a miracle solution keeping them from a downward spiral of addiction and destruction."** (emphasis added)

KRATOM IS NOT A CANDIDATE FOR SCHEDULING BECAUSE MITRAGYNINE AND 7-HYDROXYMITRAGYNINE DO NOT MEET THE 8-FACTOR CRITERIA FOR SCHEDULING UNDER NORTH DAKOTA 19-03.1-02. AUTHORITY TO CONTROL

The criteria for scheduling under North Dakota CHAPTER 19-03.1, UNIFORM CONTROLLED SUBSTANCES ACT[2] match the 8-Factor criteria in the federal Controlled Substances Act (CSA), Section 201 (c), [21 U.S.C. § 811 (c)].[3]

Federal CSA Scheduling Criteria	State of North Dakota Scheduling Criteria
(1) Its actual or relative potential for abuse.	a. The actual or relative potential for abuse;
(2) Scientific evidence of its pharmacological effect, if known.	b. The scientific evidence of its pharmacological effect, if known;
(3) The state of current scientific knowledge regarding the drug or other substance.	c. The state of current scientific knowledge regarding the substance;
(4) Its history and current pattern of abuse.	d. The history and current pattern of abuse;
(5) The scope, duration, and significance of abuse.	e. The scope, duration, and significance of abuse;
(6) What, if any, risk there is to the public health.	f. The risk to the public health;
(7) Its psychic or physiological dependence liability.	g. The potential of the substance to produce psychic or physiological dependence liability; and

[2] https://ndlegis.gov/cencode/t19c03-1.pdf

[3] https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section811&num=0&edition=prelim

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.	h. Whether the substance is an immediate precursor of a substance already controlled under this chapter

The criteria for federal scheduling of kratom matches the North Dakota requirements and HB 1101 simply circumvents the statutory requirements for banning substances. The Legislature must consider if the evidence and data exist to justify classifying kratom as a Schedule I substance.

THE FDA HAS FAILED IN THREE ATTEMPTS TO HAVE KRATOM CLASSIFIED AS A SCHEDULE I SUBSTANCE BECAUSE THEY DO NOT HAVE SUFFICIENT EVIDENCE TO JUSTIFY SCHEDULING UNDER THE SAME 8-FACTORS REQUIRED BY NORTH DAKOTA STATUTES

The FDA has made three specific attempts to have kratom's constituents, mitragynine and 7-hydroxymitragynine, classified as Schedule I substances, two recommendations under the federal CSA and a third recommendation for international scheduling by the UN Commission on Narcotic Drugs (UNCND) that has a lower scientific standard in its scheduling criteria, but the U.S. would have been obligated to commence scheduling under the CSA if the UNCND had approved the scheduling of mitragynine and 7-hydroxymitragynine.

The FDA's initial recommendation to schedule kratom was published in the Federal Register on August 31, 2016,[4] following which the DEA officially withdrew the scheduling recommendation on October 13, 2016, based on questions raised about the validity of the FDA's evidence and safety data. The DEA then requested that the FDA expedite its scientific and medical evaluation and scheduling recommendation for these substances.[5]

The FDA then submitted a second scheduling recommendation for kratom on October 17, 2017 and, after a comprehensive review by the Assistant Secretary of Health (ASH) at the U.S. Department of Health and Human Services (HHS) of the FDA's 8-factor analysis on the alleged safety and addiction liability of kratom, the ASH formally withdrew the FDA's recommendation from the DEA on August 18, 2018.[6] The reasons for the rescission are directly relevant to any consideration or decision to schedule kratom that relies in whole or in part on the evidence provided by the FDA. Here are some excerpts from the ASH letter explaining why the FDA had failed to meet its burden of proof:

- "This decision is based on many factors, in part on new data, and in part on the relative lack of evidence, combined with an unknown and potentially substantial risk to public health if these chemicals were scheduled at this time." (Page 1)

[4] https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into
[5] https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1013.htm
[6] https://www.dropbox.com/s/ljo3rxvgn4em2ub/dhillon-8.16.2018-response-letter-from-ash-radm-giroir%282%29.pdf?dl=0

- ". . . one recently published peer reviewed animal study indicated that mitragynine does not have abuse potential and actually reduced morphine intake." (Page 3)
- "Furthermore, there is a significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule I . . ." (Page 3)

In response to criticism by former FDA Commissioner Gottlieb on his decision to rescind the FDA recommendation for scheduling of kratom's alkaloids, HHS Assistant Secretary of Health Dr. Giroir made the following statement:

> "FDA doesn't schedule; it only recommends. **FDA's recommendation was rejected because of embarrassingly poor evidence and data, and a failure to consider overall public health**."[7] (***emphasis added***)

Finally, in 2021 the FDA made a recommendation to the UNCND to schedule kratom internationally, submitting their best evidence and data to support their recommendation under a far less rigorous standard that is required under the CSA in the United States. The UNCND ordered a comprehensive review by the Expert Committee on Drug Dependence (ECDD) comprised of 12 independent international experts on addiction and safety of substances. In a unanimous decision on December 1, 2021, the ECDD declared there was "insufficient evidence" to recommend scheduling of kratom by the UNCND.[8]

On December 29, 2022, President Biden signed the FY23 Omnibus bill[9] 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 reason kratom is not scheduled at the federal or international level is straightforward: The FDA has failed to meet its burden of proof to document the addiction liability, the state of the science on the pharmacological activity, and the public health impacts of scheduling kratom.

INACCURATE REPORTS OF KRATOM ASSOCIATED ADVERSE EVENTS AND DEATHS

Some anti-kratom advocates disseminate inaccurate and, in some cases, deliberately false claims on kratom adverse events and deaths. The evidence on reports of kratom associated adverse events and deaths are directly addressed by the FDA, NIDA, and the HHS Secretary of Health.

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[7] https://twitter.com/DrGiroir/status/1395874443726102533

[8] Expert Comm. on Drug Dependance, Summary of Assessments, Findings, and Recommendations of the 44th ECDD (2021), available at https://cdn.who.int/media/docs/default-source/controlled-substances/44ecdd_unsg_annex1.pdf.

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

NIDA Report on Kratom:[10] "Rare but serious effects have been reported in people who use kratom, including psychiatric, cardiovascular, gastrointestinal and respiratory problems.[11] [12] 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**. (*emphasis added*)"[13] [14] [15] [16] [17]

FDA Report on Kratom:[18] "In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. **However, in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear**. (*emphasis added*)"

HHS Secretary Becerra on Kratom Deaths, March 16, 2022:[19] "To your final point regarding kratom safety and consumer protections, I agree with your concerns describing safety concerns associated with kratom, including death. **Many kratom-involved deaths have occurred after use of adulterated kratom products or taking kratom with other substances**. (*emphasis added*)"

THE SCIENCE ON THE SAFETY OF KRATOM DIRECTLY REFUTES THE FDA'S CLAIM KRATOM IS DANGEROUS

While the FDA has previously maintained the position that kratom poses a danger to the public, the agency refused to participate in a hearing ordered by a federal judge scheduled on February 8, 2024, in the Southern District of California to provide witnesses and documents to prove the validity of the FDA's claims that kratom is a dangerous substance. This case was initiated by the FDA against an importer who had falsely identified kratom raw materials on the shipping

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[10] https://nida.nih.gov/research-topics/kratom

[11] United Nations, Commission on Narcotic Drugs. Summary of assessments, findings and recommendations of the 44th World Health Organization's (WHO) Expert Committee on Drug Dependence (ECDD), 11–15 October 2021. Vienna; 9-10 December 2021. Report No. E/CN.7/2021/CRP.12

[12] Leong Bin Abdullah MFI, Singh D. The adverse cardiovascular effects and cardiotoxicity of kratom (*Mitragyna speciosa* korth.): A comprehensive review. *Front Pharmacol*. 2021;12:726003. Published 2021 Sep 27. doi:10.3389/fphar.2021.726003

[13] Post S, Spiller HA, Chounthirath T, Smith GA. Kratom exposures reported to United States poison control centers: 2011-2017. *Clin Toxicol (Phila)*. 2019;57(10):847-854. doi:10.1080/15563650.2019.1569236

[14] Kronstrand R, Roman M, Thelander G, Eriksson A. Unintentional fatal intoxications with mitragynine and O-desmethyltramadol from the herbal blend Krypton. *J Anal Toxicol*. 2011;35(4):242-247. doi:10.1093/anatox/35.4.242

[15] Henningfield JE, Grundmann O, Babin JK, Fant RV, Wang DW, Cone EJ. Risk of death associated with kratom use compared to opioids. *Prev Med*. 2019;128:105851. doi:10.1016/j.ypmed.2019.105851

[16] United Nations, Expert Committee on Drug Dependence. Pre-review report: Kratom (*Mytragyna speciosa*), mitragynine, and 7-hydroxymitragynine. 11–15 October 2021. Geneva.

[17] Leong Bin Abdullah MFI, Singh D, Swogger MT, Rahim AA, Vicknasingam B. The prevalence of psychotic symptoms in kratom (*Mitragyna speciosa* korth) users in Malaysia. *Asian J Psychiatr*. 2019;43:197-201. doi:10.1016/j.ajp.2019.07.008

[18] https://www.fda.gov/news-events/public-health-focus/fda-and-kratom

[19] https://kratomanswers.org/wp-content/uploads/2022/07/TAB-14-HHS-Becerra-Letter-Lee-and-Pocan.pdf

manifest documents which resulted in a guilty plea. In the sentencing phase of the case, the Judge wanted more information from the FDA on their claims on the danger of kratom. In an email from the Assistant U.S. Attorney[20] the following explanation was provided to the Court on why the FDA refused to participate in the Hearing:

> "They [FDA] have refused to provide us with witnesses or documents to support our position . . . The reason they gave was that **they have not yet made a determination regarding whether kratom is dangerous." (*emphasis added*)**

The FDA's admission that the Agency lacked the evidence to make a determination on whether kratom is dangerous exposed its gross regulatory overreach when it made the following contradictory statement in the August 31, 2016, Federal Register Notice in Factor 6:[21]

> **"Factor 6. What, if Any, Risk There Is to the Public Health**
>
> The use of kratom and associated products, which contains the main active alkaloids mitragynine and 7-hydroxymitragine, pose an imminent hazard to public safety."

The reason for the FDA's dramatic change in position reportedly is because the FDA had recently completed a Single Ascending Dose ("SAD") study on whether kratom can be safely consumed by humans, and an abstract of the results of that study were reported at the 3rd International Kratom Symposium in Orlando, Florida on February 16, 2024. This study concluded that "***kratom appears to be well tolerated in humans at all dose levels***." (*emphasis added*)

This key finding cleared the solicitation by the FDA for proposals to conduct a Human Abuse Potential ("HAP") study to determine whether kratom use results in dependency or addiction, and the severity if indicated. The notice for solicitation for the HAP study was issued on January 16, 2024.[22] This study is expected to be completed in two to four years.

In the SAD study, the FDA found that only two human subjects of the 40 participants experienced nausea only after the consumption of 12 grams of kratom, 24 capsules, within five minutes. The response was the same for both the kratom cohort and the placebo cohort demonstrating the nausea was related to consuming a high volume of plant material in a five-minute period. None of the subjects reached the study's "stopping criteria" that would have resulted in termination of the study, but the FDA stopped the study because it concluded that kratom is well tolerated even at extremely high levels.

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[20] 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

[21] https://www.govinfo.gov/content/pkg/FR-2016-08-31/pdf/2016-20803.pdf, Factor 6, page 59932.

[22] https://grants.gov/search-results-detail/351644

THE SCIENCE ON THE SAFETY OF KRATOM DIRECTLY REFUTES CLAIMS KRATOM IS DANGEROUSLY ADDICTIVE

The addiction recovery industry is strongly opposed to kratom, based largely on the misinformation disseminated by the FDA that has a strong bias against all dietary and botanical supplements.

One of the leading kratom researchers to focuses on kratom addiction and dependence, Kirsten Smith, PhD, with Johns Hopkins University, was the lead author on a research paper entitled "Ecological Momentary Assessment of Self-Reported Kratom Use, Effects, and Motivations Among US Adults"[23] that reported as follows:

> "Among the 357 kratom consumers surveyed using ecological momentary assessment in this cross-sectional study, most reported using kratom daily to relieve pain, improve mood, or increase productivity, and some used it as an opioid substitute. Most participants reported improvements in daily living and productivity; more frequent use was associated with tolerance, withdrawal, and craving but not with social or functional impairment."

The 8-factors in the CSA account for the difference between a dangerous addiction and a dependency. Jack Henningfield, PhD, led a research project to evaluate, among other of the 8-factors in the CSA, the addiction liability of kratom entitled "Kratom Abuse Potential 2021: An Updated Eight Factor Analysis**"** and provided the following conclusion:

> "Survey data from the US and field studies in Southeast Asia (SEA) showed most kratom use was for health-related benefits, and to facilitate occupational performance. **Data indicated that problem abuse and addiction were not common and was generally more tolerable and readily self-manageable as compared to opioids**. A frequent reason for use was as an opioid substitute for pain and self-management of opioid, alcohol, and other drug dependence. (emphasis added)"

HB 1101, IF PASSED, WILL UNJUSTIFIABLY CRIMINALIZE NORTH DAKOTA CITIZENS WHO SELL OR POSSESS KRATOM

Kratom is not a federally scheduled substance, but HB 1101 will make kratom a Schedule I substance in North Dakota, and will impose the following penalties:

> 19-03.1-22.3. Ingesting a controlled substance - Venue for violation – Penalty, provides that the consumption of a Schedule I substance is guilty of a Class A misdemeanor.

[23] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2814305

> 19-03.1-23. Prohibited acts – Penalties, provides that the manufacture, delivery, or possession of a Schedule I substance is guilty of a Class B or Class C felony, depending on specific circumstances.

There are more than 300 retail outlets that sell kratom in North Dakota, and they provide products to tens of thousands of local consumers of kratom.

When evaluating the impact of a similar bill filed in South Dakota in 2020, the Legislative Research Council produced a report on the fiscal impact of incarceration of individuals who would be convicted of distribution or possession of kratom if it were classified as a Schedule I substance.[24]

Their findings included the following:

- Based on that percentage, and the estimated 8,100 kratom users in South Dakota, LRC estimates that approximately 107 people will be convicted of kratom offenses over the next ten years.
- Based on conviction data for the past year for non-meth related charges, LRC estimates 95%, or approximately 102 of those charged, will be convicted for ingestion or possession charges, which are Class 5 felonies. These charges qualify for presumptive probation. In FY18, 64.7% of those convicted of this type of crime completed presumptive probation, thus serving no prison or jail time. Over this ten year period, approximately 31 would serve time for the Class 5 felony of possession or ingestion of Kratom (29 in prison, two in jail), while five would serve time in prison for the Class 4 felony of distribution of a Schedule I or II controlled substance
- The estimated prison and jail costs over the next ten years are as follows:
  - 10-Year Prison Cost: $396,289
  - 10-Year Jail Cost: $7,741

KRATOM BANS PUT CONSUMERS AT GREATER RISK AND POTENTIALLY CREATE DANGEROUS BLACK MARKETS

On August 16, 2018, HHS Assistant Secretary of Health, Brett Giroir, MD, an appointee of President Donald J. Trump, highlighted the dangers of bans on kratom in his formal withdrawal letter of the FDA's second scheduling recommendation made to the Drug Enforcement Administration ("DEA"):[25]

> "Furthermore, there is a significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule I, such as:

[24] https://mylrc.sdlegislature.gov/api/Documents/FiscalImpact/63243.pdf?Year=2020
[25] https://images.go02.informamarkets.com/Web/Informa02/%7b548e6d56-2ea4-4da4-9404-0348b56e9a88%7d_dhillon-8.16.2018-response-letter-from-ash-radm-giroir.pdf

- Suffering with intractable pain;
- Kratom users switching to highly lethal opioids, including potent and deadly prescription opioids, heroin, and/or fentanyl, risking thousands of deaths from overdoses and infectious diseases associated with IV drug use;
- Inhibition of patients discussing kratom use with their primary care physicians leading to more harm, and enhancement of stigma thereby decreasing desire for treatment, because of individual users now being guilty of a crime by virtue of their possession or use of kratom
- The stifling effect of classification in Schedule I on critical research needed on the complex and potentially useful chemistry of components of kratom."

Christina Dent, founder of "End It For Good", a conservative nonprofit advocating for heath-centered approaches to drugs, made the following observation in an Op-Ed addressing a proposed bill that would have scheduled kratom in Mississippi (a bill that did not pass):[26]

> "First, banning a popular substance does not make it disappear. It simply transfers the substance from a legal market, where we have the option to regulate it, to the black market where we have zero regulation. This market transfer increases crime by providing a revenue stream that entices people to break the law to get a share of the profits. This decreases public safety.
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> Second, criminalizing a substance makes it more available to our children. In a regulated market, we can set age limits for purchasing. Certainly some youth find their way around that, but most legal retailers are checking IDs. On the street corner, no one is. A 13-year-old and a 33-year-old have the same access to prohibited substances, and those substances are available on the streets of every town in America today. This decreases our children's safety."

THE FDA HAS SUFFICIENT LEGAL AUTHORITY TO REGULATE ADULTERATED AND CONTAMINATED KRATOM PRODUCTS – THEY JUST REFUSE TO DO SO IN ORDER TO BUILD THE CASE FOR SCHEDULING

The 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

[26] https://www.clarionledger.com/story/opinion/columnists/2019/05/06/stopping-opioid-use-banning-kratom-do-more-harm-than-good/3646002002/

illness or injury under the conditions of use recommended or suggested in labeling."[27] If the 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.[28]

The FDA regulates a product based on its intended use as evidenced by the product's labeling and claims.[29] Kratom, like other products intended to be a food, dietary supplement, or cosmetic, do not require FDA approval.[30] The FDA has acknowledged it "does not have premarket approval of food products."[31] Instead, the FDA can approve certain ingredients before they are used in foods such as food or color additives.[32] As such, kratom that is intended to be a food, and not a food or color additive, is not a product that the FDA approves.[33] Therefore, it can be legally marketed as such. In addition, when intended for use as a food, it is immaterial that kratom does not have any "approved uses," since food products are not "approved."[34]

Kratom can be lawfully marketed and sold as a food. The FDA does not preapprove food products. Although the FDA has taken enforcement action against kratom manufacturers and vendors whose products are intended to be used for other purposes such as an unapproved new drug, the agency has never adequately established all kratom is adulterated under required rulemaking subject to public comment. To the contrary, kratom has been lawfully and safely consumed as a food by American consumers for decades. Millions of Americans eat or drink kratom every day to improve their well-being. Kratom can be legally sold under the FDA's laws, rules, and guidance.

Much of the discussion on kratom among policy makers focuses on the webpage the FDA has published, "FDA and Kratom" on its Internet site without notice to the public where the FDA determined in the webpage that all kratom—in raw leaf and processed, extract forms—is categorically adulterated under the FDCA and therefore not marketable anywhere in the United

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[27] 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.

[28] *See generally Compliance & Enforcement (Food)*, FDA.gov, available at https://www.fda.gov/food/compliance-enforcement-food.

[29] *See Small Entity Compliance Guide on Structure/Function Claims,* 67 Fed. Reg. 1225, Jan. 9, 2002, available at https://www.federalregister.gov/documents/2002/01/09/02-451/small-entity-compliance-guide-structurefunction-claims-availability.

[30] Unlike those products, FDA requires premarket approval of drugs and many medical devices.

[31] *Is it really "FDA Approved?",* FDA.gov, January 2017, available at https://www.fda.gov/consumers/consumer-updates/it-really-fda approved#:~:text=FDA%20approves%20food%20additives%20in,to%20food%2C%20and%20color%20additives.

[32] *Id.*

[33] A food additive includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly … in its becoming a component or otherwise affecting the characteristics of any food." 21 C.F.R. § 570.3. Food means "articles used for food or drink for man." 21 U.S.C. § 321. Kratom does not meet an additive definition, because kratom is itself the food, not the additive.

[34] Although premarket approval is not required, food products are regulated by FDA. For example, manufacturers at a minimum must meet Good Manufacturing Practices, have proper labeling, and register as a food facility.

States. The FDA itself characterizes these conclusions only as "guidance" for consumers and they have not conducted required rulemaking under federal law.

Additionally, the FDA now acknowledges the potential for science to help understand both the safety and addiction liability where they now correctly viewed through the lens of product forms and intended use in the consumption of kratom products. This is a dramatic shift from the FDA's initial 2016 position where they were calling for a total ban. Here is the excerpt from the FDA and Kratom webpage on this issue:

> "If a new drug application (NDA) is submitted for kratom (or one of its components) to treat a specific medical condition, FDA will review the scientific data to determine if a drug product containing kratom (or its components) is safe and effective to treat that specific medical condition. Consistent with FDA's practice with unapproved substances, until the agency scientists can evaluate the safety and effectiveness of kratom (or its components) in the treatment of any medical conditions, FDA will continue to warn the public against the use of kratom for medical treatment. The agency will also continue to monitor emerging data trends to better understand the substance and its components."[35]

THE NATIONAL INSTITUTE ON DRUG ABUSE (NIDA) POSITION ON KRATOM

National Institute on Drug Abuse (NIDA) Director Nora Volkow has testified before Congress that kratom should not be banned but rather regulated appropriately and new research should be undertaken. NIDA currently has funded more than $100 million in grants for kratom research. NIDA researched the FDA claims that kratom caused deaths and concluded those deaths were largely from polydrug use or adulterated kratom products.

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's blog and offered the following assessment of kratom on January 24, 2020:[36]

> "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

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

> 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."[37]

Researchers at Johns Hopkins University concluded that 87% of adult consumers using kratom to treat opioid dependence reported relief from withdrawal symptoms, and 35% were free from opioids within a year. The researchers concluded that serious adverse events are uncommon even at high consumption rates.[38] [See Exhibit 2]

NIDA's 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 that pure and unadulterated kratom is not dangerous to consumers.

CURRENT REGULATORY STATUS OF KRATOM

The FDA's recommendation to schedule kratom under the CSA has been rejected on two separate occasions. Kratom is legal for sale in all but six states, all of which enacted bans on kratom between 2015-2017 at the encouragement of the FDA based on the claim kratom would be scheduled under the CSA, which did not occur.

Thirteen states have now passed legislation known as the "Kratom Consumer Protection Act ("KCPA")" setting product standards to ensure kratom products are not adulterated and limiting sales to minors: Utah, Georgia, Arizona, Nevada, Oregon, Colorado, Oklahoma, West Virginia, Virginia, Florida, Kentucky, Maryland, and Texas.

Today, kratom is legal for sale in every other state.

The Federal Kratom Consumer Protection Act ("KCPA")[39], sponsored by Senator Mike Lee (R-UT), Senator Corey Booker (D-NJ), Congressman Mark Pocan (D-WI), and Congressman Jack Bergman (R-MI), will require the FDA to develop appropriate regulatory standards for the manufacturing and marketing of kratom products to consumers.

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

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

[39] *Federal Kratom Consumer Protection Act (S. 3039 and H.R.5905)*

THE DEA'S DESIGNATION AS A DRUG OF CONCERN

The DEA designated kratom as a drug of concern following the rejection of the recommendation by the FDA to classify kratom as a Schedule I substance in 2016. That designation is appropriate for the role the DEA plays in monitoring substances of concern in the United States. It is important to note the DEA has never designated kratom in any of the National Drug Threat Assessment ("NDTA") reports.

The NDTA is a comprehensive strategic assessment of the threat posed to the United States by domestic and international drug trafficking and the abuse of both licit and illicit drugs. The report combines federal, state, local, and tribal law enforcement reporting; public health data; open-source reporting; and intelligence from other government agencies to determine which substances and criminal organizations represent the greatest threat to the United States.

Kratom does not now, nor has it ever, met the criteria for inclusion in the DEA's NDTA report.

STATUS OF U.S. STATES THAT HAVE BANNED KRATOM.

Based on early recommendations by the FDA, six states banned kratom from 2012 to 2017: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island. Since then, five of those six states have begun the process of rescinding those bans and replacing them with a rational regulatory framework.

- 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." That rulemaking is currently ongoing.

- 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 and they recommended the Legislature address the issue with regulations if they chose to lift the scheduling.

- 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, 2023. The bill is now under review with the Senate Health Committee.

- In Arkansas, where the Department of Health issued a ban on kratom in 2015, legislation to challenge the ban and replace it with the KCPA has been filed with the Senate Committee on Public Health, Welfare and Labor the Interim Study Committee completed its Hearing on October 7, 2024, with a favorable motion to pass.

THE POSITION OF THE U.S. CONGRESS ON KRATOM

First, please consider the views of Representative Jack Bergman (R-MICH.) that he expressed in an Op-Ed piece in The Hill on July 28, 2023[40] where he made the following point:

> "In their relentless campaign to get kratom reclassified as a dangerous drug, the FDA has relied on three fallacious and thoroughly debunked objections to its widespread use: that kratom is unsafe, that it is highly addictive, and that it has no approved medical use. Even former HHS Assistant Secretary for Health Brett Giroir felt compelled to call out the FDA for relying on "disappointingly poor evidence and data and a failure to consider the overall public health" in coming to such a baseless conclusion. It is rare for a top-ranking HHS official to criticize the FDA for biased, shoddy work, but in this case the unsupported conclusions were so egregious that Giroir felt it necessary to publicly criticize them. Likewise, current HHS Secretary Xavier Becerra acknowledged substantial "knowledge gaps" regarding kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

[40] https://thehill.com/opinion/congress-blog/4125241-lets-prevent-the-feds-from-jeopardizing-veteran-addiction-recovery/

Congress itself spoke clearly in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, FY2022, in its Report approved on July 15, 2021[41] including the following positions on kratom:

> **PAGE 134:**
>
> Kratom. — The Committee recognizes that NIDA-funded research has contributed to the continued understanding of the health impacts of kratom, including its constituent compounds, mitragynine and 7-hydroxymitragynine. The Committee is aware of the potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids and of research investigating the use of kratom's constituent compounds for opioid use disorder. The Committee directs NIDA to continue to invest in this important research, especially considering the increase in overdose deaths during the COVID–19 pandemic.
>
> **PAGE 187:**
>
> Kratom. — The Committee directs the Secretary to maintain current Agency policy to not recommend that the substances mitragynine and 7-hydroxymitragynine, known as kratom, be permanently controlled in Schedule I of the Controlled Substances Act, either temporarily or permanently, until scientific research can sufficiently support such an action. The Committee encourages AHRQ to continue to fund research on natural products that are used by many to treat pain in place of opioids, including kratom. Given the wide availability and increased use of these substances, it is imperative to know more about potential risks or benefits, and whether they can have a role in finding new and effective non-opioid methods to treat pain. The Committee recommends an additional $3,000,000 for this research and directs AHRQ to make center based grants to address research which will lead to clinical trials in geographic regions which are among the hardest hit by the opioid crisis.

BACKGROUND ON KRATOM AND ITS SAFETY PROFILE

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.

[41] https://docs.house.gov/meetings/AP/AP00/20210715/113908/HMKP-117-AP00-20210715-SD003.pdf

The existing science on kratom does not justify its scheduling under the CSA, nor for kratom to be added to any local or state Controlled Substances list that would effectively remove it from consumer access. Here are references to peer-reviewed, published scientific articles addressing the addiction and safety profile for use of kratom by consumers supporting the position that scheduling is not appropriate:

- Patterns of Kratom use and health impact in the US-Results from an online survey, Grundmann et al.[42]
- The abuse potential of kratom according the 8-factors of the controlled substances act: implications for regulation and research, Henningfield et al.[43]
- The medicinal chemistry and neuropharmacology of Kratom: A preliminary discussion of a promising medicinal plant and analysis of its potential for abuse, Grundmann and Kruegel[44]
- Kratom use and mental health: A systematic review, Swogger and Walsh[45]

These studies and other independent peer reviewed evaluations published in scientific and medical journals provide the profile of a substance that is largely used safely to the benefit of the estimated 20+ million Americans.

RECOMMENDATION TO DEFEAT HB 1101 THAT WOULD CLASSIFY KRATOM AS A SCHEDULE I SUBSTANCE AND, AS AN ALTERNATIVE, PASS THE KRATOM CONSUMER PROTECTION ACT

The evidence and data currently available in peer-reviewed published literature documents the evidence on the safety profile for kratom that supports a regulatory framework as provided in the Kratom Consumer Protection Act, not scheduling as is proposed in HB 1101.

The AKA recommends consideration of a North Dakota Kratom Consumer Protection Act (KCPA) that will directly provide consumer protections from adulterated, mislabeled, and contaminated products and provide restrictions on access to kratom products by minors.

SUPPLEMENTAL MATERIALS

The following documents are available by clicking on this link: https://www.dropbox.com/scl/fo/bvjt936xdqs9hr530baai/ABgRoBlzTzeSFqMVaNAr0s0?rlkey=nmvaa6kmyqmprcjz8rpsakxov&e=1&st=xs0twilb&dl=0 .

- AKA Policy Brief on FDA Shift on Kratom and CBD
- AKA Policy Brief on Kratom Dose Finding Study
- AKA Policy Brief on FDA Admission on Kratom Danger

[42] https://pubmed.ncbi.nlm.nih.gov/28521200/
[43] https://pubmed.ncbi.nlm.nih.gov/29273821/
[44] https://pubmed.ncbi.nlm.nih.gov/28830758/
[45] https://pubmed.ncbi.nlm.nih.gov/29248691/

- AKA Kratom Science Update
- Letter from Congressman Jack Bergman on FDA Mistake on Kratom
- Scheduling Withdrawal Letter from HHS Asst. Secretary of Health, August 16, 2018
- FDA Admission in Court Filing on Danger of Kratom is not Determined
- Kratom Safety and Toxicology – Dr. Jack Henningfield
- Updated 8-Factor Analysis on Kratom, 2022
- Key Kratom Questions and Answers
- Kratom Science Update 2024
- Scientist Statement on Science and Kratom Products
- UN Commission on Narcotic Drugs Finding on Kratom, December 1, 2021

Contact Information:

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

EXHIBIT 1

JACK BERGMAN
1ST DISTRICT, MICHIGAN

COMMITTEE ON ARMED SERVICES
COMMITTEE ON VETERANS' AFFAIRS

Congress of the United States
House of Representatives
Washington, DC 20515–2201

March 12, 2024

Congressman Matt Salmon (Ret.)
Chairman, American Kratom Association
13575 Heathcote Boulevard, Suite 320
Gainesville, VA 20155

Dear Matt:

My purpose is writing today is to provide my perspective on the reports from state and local jurisdictions who are proposing bans on kratom, many of which are based on well-intentioned but misplaced concerns by law enforcement and public health officials. Simply put, these proposed bans will create far more harm than any potential benefit kratom critics believe will result from a ban.

My specific concern is for the health and welfare of many of our nation's servicemembers and Veterans that I served with and others who returned from their service with injuries and chronic pain. Many of those Veterans have received treatments with dangerous opioids that lead to severe addictions and expose them to the unacceptable risk they will end up as another of the more than 80,000 opioid overdose deaths per year in the United States.

One of the tools and resources many Veterans have used to quit their opioid dependence, manage pain, improve mood and focus, and get their lives back on track has been through controlled use of a pure, unmodified kratom product. For many, it has been a miracle solution keeping them from a downward spiral of addiction and destruction.

I am certain you have seen during your time in Congress what I see clearly today. The common opponent in our effort to facilitate the recovery of millions of Veterans is the U.S. Food and Drug Administration (FDA). Three times in the last decade, the FDA has attempted to force kratom into Schedule 1 of the Controlled Substances Act, a drastic action that would essentially criminalize the use of the supplement nationwide and harm countless Americans who have benefited from kratom for decades. The FDA, which has a long-standing bias against any supplement that is not a pharmaceutical that can profit Big Pharma and their own budget, has pushed for kratom to be labelled a Controlled Substance by misstating the science, ignoring kratom's long history of safe use, and falsely claiming kratom has the same effects as classic opioids.

In their campaign to get kratom reclassified as a dangerous drug, the FDA has relied on three false and thoroughly debunked objections to its widespread use: that kratom is unsafe, that it is highly addictive, and that it has no approved medical use. Even former HHS Assistant Secretary for Health Brett Giroir felt compelled to call out the FDA for relying on "disappointingly poor evidence and data and a failure to consider the overall public health" in coming to such a baseless conclusion. It is rare for a top-ranking HHS official to criticize the FDA for biased, shoddy work, but in this case the unsupported conclusions were so egregious that Giroir felt it

WASHINGTON, DC OFFICE
566 CANNON HOUSE OFFICE BLDG
WASHINGTON, DC 20515
(202) 225-4735

TRAVERSE CITY OFFICE
1396 DOUGLAS DR, STE 22B
TRAVERSE CITY, MI 49696
(231) 944-7633

GWINN OFFICE
125 G AVE, STE B-119
GWINN, MI 49841
(906) 273-2227

MANISTIQUE OFFICE
7876W CO RD 442, STE B
MANISTIQUE, MI 49854
(906) 286-4191

necessary to publicly criticize them. Likewise, current HHS Secretary Xavier Becerra acknowledged substantial "knowledge gaps" regarding kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

While the FDA continues to spread its propaganda about kratom, the Agency itself just concluded a human safety study on kratom that showed that kratom "appears to be well tolerated at all dose levels" (presented by the FDA at the 3rd Annual International Kratom Symposium in Orlando, Florida, February 2024). The study showed that two of the 40 participants experienced nausea after ingesting 12 grams of kratom in 24 capsules in a five minute period. No significant adverse events occurred. That study has now cleared the way for a Human Abuse Potential study to assess what level of dependence or addiction that kratom may cause, if any. That research will take another two years or more to complete.

Equally significant is the FDA's refusal to comply with an order by a federal judge in the United States District Court for the Southern District of California to provide witnesses and documents on the FDA's position that kratom is dangerous. The judge called the hearing in a case the FDA itself initiated against a kratom importer. The U.S. Attorney stunningly informed the Court that the FDA "refused to provide us with witnesses or documents . . . [and] the reason they gave was that they have not yet made a determination regarding whether kratom is dangerous."

Yet, the FDA continues to mislead state and local officials on the safety profile of kratom, including with false statements that remain on the FDA's website today. Any state or locality that proposes to criminalize the sale and consumption of kratom needs to look at the science on kratom, not the gaslighting the FDA continues to engage in.

There is no doubt that kratom needs to be regulated to protect consumers from improperly manufactured or deliberately adulterated kratom products, and that is why there are eleven states who have taken that step, with many more currently considering state Kratom Consumer Protection Acts in their states. Senator Mike Lee (R-UT) and I are conservatives, and we have joined with our progressive colleagues, Senator Cory Booker (D-NJ) and Congressman Mark Pocan (D-WI), to lead a bipartisan effort to protect Veterans and the public with a federal Kratom Consumer Protection Act.

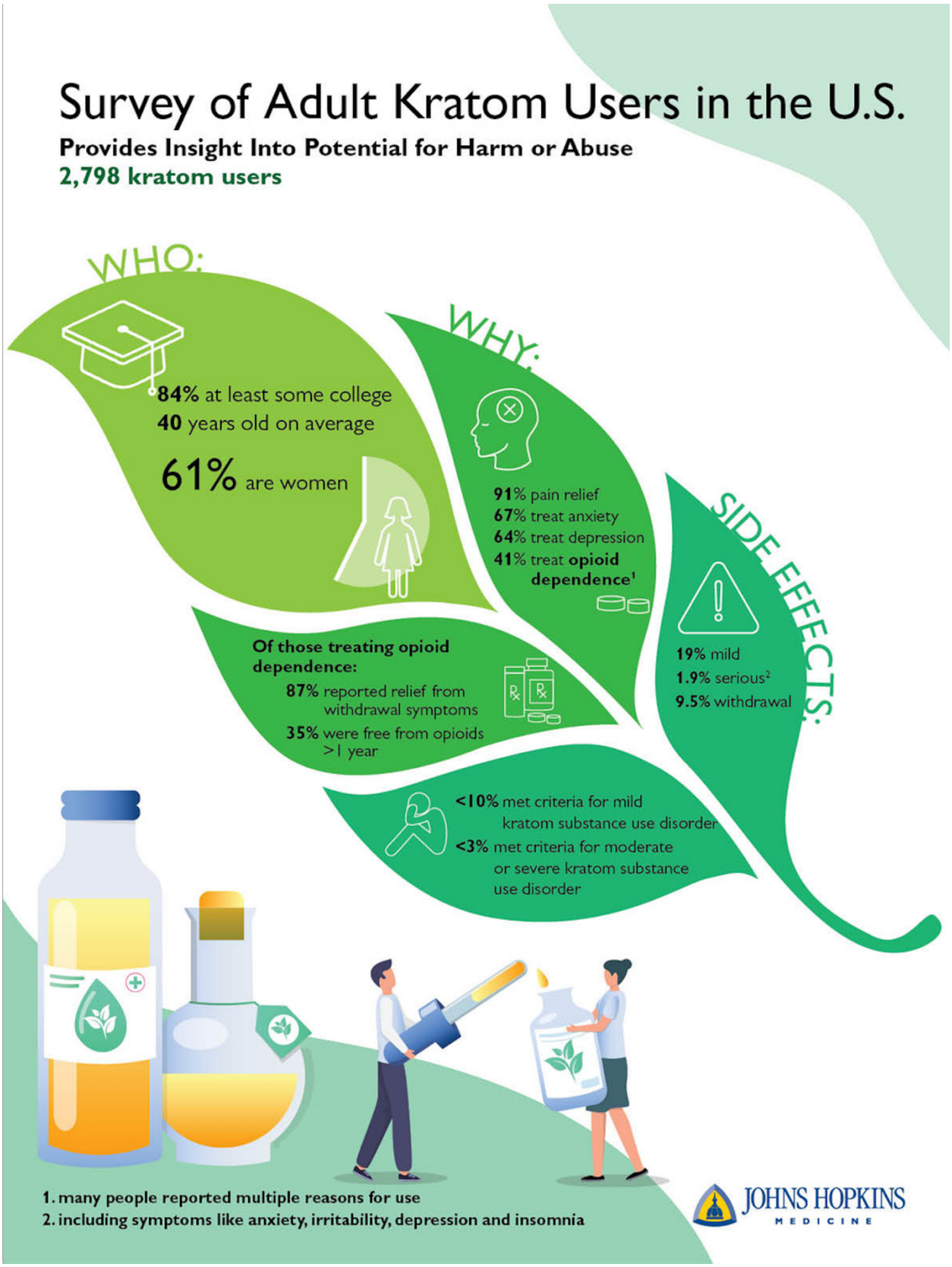
Please let me know how I can provide additional assistance to you in your efforts as the Chair of the American Kratom Association in the effort to protect all consumers with responsible regulations on kratom.

If you have any questions, please notify my staff, Amelia Burns at amelia.burns@mail.house.gov. Thank you for your prompt attention.

Kind regards,

Jack Bergman
Member of Congress

EXHIBIT 2


Survey of Adult Kratom Users in the U.S.
Provides Insight Into Potential for Harm or Abuse
2,798 kratom users
WHO:
84% at least some college
40 years old on average
61% are women
WHY:
91% pain relief
67% treat anxiety
64% treat depression
41% treat opioid dependence[1]
Of those treating opioid dependence:
87% reported relief from withdrawal symptoms
35% were free from opioids >1 year
SIDE EFFECTS:
19% mild
1.9% serious[2]
9.5% withdrawal
<10% met criteria for mild kratom substance use disorder
<3% met criteria for moderate or severe kratom substance use disorder
1. many people reported multiple reasons for use
2. including symptoms like anxiety, irritability, depression and insomnia
JOHNS HOPKINS
MEDICINE