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

TESTIMONY ON HB 1056, THE SOUTH DAKOTA KRATOM REGULATIONS ACT
Senate Health and Human Services
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My name is Mac Haddow, and I serve as the Senior Fellow on Public Policy for the American Kratom Association ("AKA"), and we appreciate the opportunity to provide testimony in support of HB 1056 that will provide needed regulations on the sale of kratom products in South Dakota.

If this legislation is enacted into law, South Dakota will become the 14th state to enact protections for consumers to assure your residents can have confidence when they purchase a kratom product that meets or exceeds the requirements for market entry in the State of South Dakota.

This discussion is necessary because the U.S. Food and Drug Administration (FDA) is continuing its decades long crusade against all dietary and botanical supplements, and the current botanical they are targeting is kratom. Despite the overwhelming evidence that kratom is safe for human consumption when used responsibly, the FDA wants to strip consumers of any freedom to make informed choices about supplements they use to maintain their health and well-being.

The more than 20 million consumers in the United States report they use kratom to just generally feel better (like a replacement for a cup of coffee), reduce feelings of anxiety, and some consumers report using kratom to manage acute and chronic pain and to wean off highly addictive and potentially deadly prescription opioids or illicit drugs.

FDA asserts its biggest concern about kratom is that consumers are using kratom products to self-medicate for medical conditions rather than using prescription medications that FDA itself has approved for those conditions. The director of the National Institute on Drug Abuse (NIDA), Nora Volkow, M.D., takes a much different approach and has testified before Congress that kratom may be a valuable harm-reduction tool for some people with substance use disorders trying to wean off dangerous opioids or illicit drugs.

A person can walk into any dietary supplement store here in South Dakota and see hundreds of products consumers are using in attempt to "self-medicate" for a variety of health challenges — products that also have not been approved by FDA for any medical use. That same complaint from the FDA applies to thousands of dietary and botanical supplement products that are sold every day in America for the very purpose the FDA complains about.

Why would anyone not allow access to kratom if it helped someone wean off dangerous drugs — especially when the safety risk for kratom itself has proven dramatically lower? FDA abuses its strong bully pulpit to declare that people cannot be trusted to use kratom to self-medicate in this way.

The FDA tried a similar attack on all dietary ingredients and supplements in the 1990s, and that forced Congress to pass the Dietary Supplement Health and Education Act of 1994 (DSHEA). The law stopped FDA from imposing its self-serving agenda to ban every dietary supplement and force those products through the average multibillion-dollar and 10-year new drug application process.

Today, the FDA continues its anti-kratom crusade while NIDA, HHS, the White House Office of National Drug Control Policy, and the U.S. Congress have disagreed with that position.

A responsible regulatory pathway to protect kratom consumers

The AKA has turned to individual states to fill the safety gap that FDA has deliberately created for kratom consumers. Six states were duped early on by FDA's promise that a federal ban would be enacted. Not only was that a false promise, the assistant secretary of health for the U.S. Department of Health and Human Services (HHS) excoriated FDA's safety claims on kratom.

In a 2018 letter to the acting director of the Drug Enforcement Administration, Brett Giroir, M.D., then-assistant secretary of health for HHS, recommended that two constituents of kratom — mitragynine and 7-hydroxmitragynine (7-OH) — not be controlled either temporarily or permanently until such action is supported by scientific research.

Unfortunately, in 2025, FDA is using that same flawed evidence and data when the real science on the safety of kratom has moved well past the agency. FDA's kratom policy is not based on science. Instead, it is rooted in a long-standing bias against any consumer product that is not an FDA-approved drug — over which the agency has complete and total control and can obtain user-fee money.

The South Dakota kratom bill will require responsible manufacturing, proper labeling, and age restrictions on kratom products. The regulatory model protects consumers from improperly formulated kratom products, including adulterated 7-OH products that synthesize components and are dangerous.

Here are some of the false myths about kratom that FDA continues to promote.

Myth #1: Kratom is an opioid and is unsafe for consumer use.

FDA still publishes on its website the false statement made in 2018 by former FDA Commissioner Scott Gottlieb, M.D. The agency claimed that kratom's chemical compounds, mitragynine and 7-OH, both bind to the same mu-opioid receptors as opioid drugs.

Published research has concluded kratom's alkaloids are only "partial agonists" that do not have the same effects as classic opioids on the respiratory system of users. Other examples of substances that have activity at the opioid receptors include St. John's wort, naloxone (the anecdote or medicine for an opioid overdose) and cheese — none of which have similar effects on the respiratory system as do classic opioids.

Kratom is not an opioid by plant genetics, chemical structure or by legal definition.
In fact, FDA conducted its own safety study on kratom last year with the full expectation that the study would pound the final nail into the kratom coffin. It didn't.

The results showed that study participants only experienced some nausea, and no significant adverse events, up to a dose of 12 grams ingested in a five-minute period. That is a huge dose of plant material consumed in a short period of time. The typical dose for a kratom consumer is 2-4 grams in any setting.

FDA has publicly admitted that kratom appears to be well-tolerated at all dose levels.

Despite this evidence and data, 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,[1] following which the DEA officially withdrew the scheduling recommendation on October 17, 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.[2]

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.[3] 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

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

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)
- ". . . 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**."[4] (***emphasis added***)

Finally, in 2021 the FDA made a recommendation to the UN Commission on Narcotic Drugs (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 Controlled Substances Act (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.[5]

On March 16, 2022, in a letter from HHS Secretary Becerra,[6] the Secretary acknowledged "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

On December 29, 2022, President Biden signed the FY23 Omnibus bill[7] 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."

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

[5] 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.

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

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

Myth #2: Kratom is dangerously addictive

There is a significant difference between dangerous levels of addiction and simple dependency. Caffeine is the most widely used psychoactive drug in the world, and it has an addiction profile characterized by scientific research as having an acceptable dependency profile.

Kirsten Smith, Ph.D., with Johns Hopkins University, was the lead author on a research paper ("Ecological Momentary Assessment of Self-Reported Kratom Use, Effects, and Motivations Among US Adults") that reported:

> "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."

Myth #3: Kratom kills people

Both the FDA and NIDA websites on kratom report that kratom deaths are rare and when they do occur, they are typically associated with polydrug use or the use of dangerously adulterated products. The adage applies here: "The dose makes the poison."

Kratom leaf and properly manufactured kratom extract products are safe under the conditions of use (labeling) with the same restraints that any other consumer product offers. In short, these products are generally safe when used responsibly and consumers follow the product's serving size instructions.

But all too often, medical examiners and coroners follow the FDA narrative and mischaracterize deaths where kratom is detected in any case of a fatality. The detection of kratom in a forensic toxicology report should not be surprising — nor automatically damning — and is impetuously reported as a cause of death, or principal substance associated with the death, when it is merely detected. If someone is struggling with an addiction to a prescription opioid or an illicit drug and tries to use kratom to wean off that drug, it would not be a surprise that he or she failed in that journey. Opioids and illicit drugs have been proven to kill people.

Too many of these autopsy reports rely — wholly or at least in part — on the biased, inaccurate and incomplete information on kratom published on FDA's website. Yet, medical examiners — and other critics of kratom — frequently cite FDA's flawed data and conclusions.

The FDA adverse event reporting system (FAERS) does not require any distinction between mitragynine, 7-hydroxymitragyine or mitragynine pseudoindoxyl — or whether these compounds, if present in a toxicology screen, were adulterated or mixed with other dangerous substances. These gaps in reporting render FAERS nothing more than a "disinformation"

database. FAERS should not be a part of any evidence-based assessment in a death investigation involving kratom.

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 danger of kratom, the addiction liability, the state of the science on the pharmacological activity, and the public health impacts of scheduling kratom.

THE SCIENCE ON THE SAFETY OF KRATOM AND THE FDA'S CURRENT POSITION

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 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[8] 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 reason for that change in the FDA's 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.[9] 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

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[8] *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*

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

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.

In conclusion, our appeal is straightforward. Consumers need to be protected from adulterated or dangerous synthetic products that exploit consumers. The South Dakota kratom regulation bill will provide a needed layer of protection for South Dakota's kratom consumers.

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
- 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