For Immediate Release

AMERICAN KRATOM ASSOCIATION

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FDA CREATES AN UNAUTHORIZED "POCKET BAN" AUTHORITY ON KRATOM BY ABUSING ITS IMPORT ALERT AUTHORITY

Recent Action Puts Millions of Americans
at Risk of Immediate Public Health Consequences

WASHINGTON, DC (May 2023) -- Recent action by the U.S. Food and Drug Administration ("FDA") to initiate a seizure action on kratom products manufactured and marketed by Botanic Tonics based on "serious safety concerns" by the FDA is directly contradicted by a substantial body of current evidence and data on the safety and addiction profile of kratom.

This FDA action is targeted at a kratom community of 15 million Americans who safely and responsibly use kratom to deny consumer access to kratom products as a "pocket ban" on all kratom products in the United States because FDA has failed to justify a recommendation to classify kratom as a Schedule I substance under the federal Controlled Substances Act ("CSA").

Assistant Secretary of Health, Dr. Brett Giroir, M.D., withdrew the FDA's recommendation for scheduling of kratom with the warning that by removing kratom from the marketplace created a "significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule I." The FDA's pocket ban on kratom in the current litigation has the same effect that Dr. Giroir warned about.

The FDA used these same "serious safety concerns" cited in the current litigation in three separate failed attempts to have kratom classified as a Schedule I substance:

- October 13, 2016: when the Drug Enforcement Administration ("DEA") rejected the FDA petition for scheduling as lacking sufficient evidence required by the CSA[i];
- August 16, 2018: Assistant Secretary of Health at the U.S. Department of Health and Human Services ("HHS"), Dr. Brett Giroir, withdrew the FDA's second petition for scheduling calling it "disappointingly poor evidence and data and an overall failure to consider the public health"[ii];

- December 1, 2021: The U.N. Commission on Narcotic Drugs ("UNCND") accepted the report from the Expert Committee on Drug Dependence, comprised of 12 international experts on substance abuse and addiction who unanimously concluded there was insufficient evidence to schedule kratom internationally.[iii]

Having failed to make the case to ban kratom on statutory criteria set by Congress, and even a lesser standard that is a part of the international drug scheduling treaty of which the U.S. is a party, the FDA is now unfairly abusing the import alert authority granted by the Congress by using it as a tool to create a de-facto ban on kratom they cannot justify on the evidence and data required by the CSA. It was never the intent of the Congress for the FDA to use the import alert authority as a self-styled pocket ban on any product, including kratom.

The FDA is singling out kratom because they could not convince the DEA or HHS to schedule this botanical supplement and is asserting an excessively broad authority to classify kratom as an unapproved drug or an unregistered new dietary ingredient.

The FDA knows the Director of the National Institute on Drug Abuse ("NIDA"), Nora Volkow, M.D., testified on May 17, 2022, at a hearing of the U.S. Senate Subcommittee on Labor, Health and Human Services regarding the drug overdose crisis. When asked about overdose prevention strategies, Dr. Volkow stated: "There's also interest in the community to test other products that may serve as harm reduction. For example, *the use of kratom*, which is sold as tea and that contains a drug molecule that *has effects that are similar to a dose of buprenorphine but could be utilized also for decreasing withdrawal* or depression."[iv] This powerful statement represents the view of one of the top public health officials in the country.

Leading scientists have recognized that kratom is a potentially valuable harm reduction tool in the war on drug overdoses and a substantial body of evidence and data that shows that kratom is much safer than FDA approved drugs the FDA requires to be used by addicts seeking addiction recovery services. The FDA has publicly complained that kratom consumers are using kratom to "self-medicate" for opioid abuse. However, the American Kratom Association ("AKA") has referred more than 65 kratom vendors since 2021 to the FDA who use illegal marketing claims to market kratom products, including claims of kratom helping with opioid withdrawal, and the FDA has failed to initiate a single prosecution against companies who are marketing their products for the precise reason the FDA claims kratom should be banned.

Consumers using kratom to help with health and wellness issues is vastly different than a kratom vendor using illegal therapeutic claims to sell products, and the FDA sits silently and allows that to occur shows both their complete failure to protect the public health from the real issue: The sale of kratom products that are either adulterated or misbranded to enrich those vendors making illegal health claims.

Current HHS Secretary Xavier Becerra has publicly stated that the FDA needs to do more research on kratom before making any more recommendations related to the safety profile to justify a scheduling recommendation and stated that claims of addiction liability or fatalities claimed to be caused by kratom are caused by polydrug use or adulterated kratom products.[v]

The FDA has also exceeded its authority because it is overstepping state's rights in regard to kratom sale and usage. Kratom is legally sold and consumed in 44 states. Ten of those 44 states,

including Oklahoma where Botanic Tonics manufactures its products, have passed the Kratom Consumer Protection Act (KCPA) which requires kratom vendors to register with the state agency, label the active ingredients in their labels, age restrict consumers and work with consumers to make certain they know which vendors make their kratom products. Numerous other states are actively considering adopting the KCPA. FDA's regulatory actions undermine states' authority to protect the health, safety, and welfare of their citizens.

The FDA did use that same "disappointingly poor evidence and data" cited by Assistant Secretary of Health Giroir to convince 6 states to ban kratom between 2012 and 2017. Of those 6 states that banned kratom from 2012 to 2017: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island, 5 of those states are taking action to correct the mistakes in banning kratom because the FDA said they should:

- The Vermont Department of Health removed mitragynine and 7-hydroxymitragynine from the Regulated Drug Rule on March 1, 2023.
- The Wisconsin Controlled Substances Board approved a motion to affirm mitragynine and 7 hydroxymitragynine do not meet the required 8-factors for scheduling under Wisconsin law on March 10, 2023
- The Interim Director of the Rhode Island Department of Health, Utpala Bandy, M.D., told legislators that kratom does not meet the criteria for scheduling set forth in Rhode Island statutes on October 25, 2022.
- 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
- In Arkansas, where the Department of Health issued a ban on kratom in 2015, legislation to repeal the ban and replace it with the KCPA has been filed with the Senate Committee on Public Health, Welfare and Labor.

Based on the evidence and data about the safety and addiction profile of kratom that is available in the public realm, and that has been found by various senior government officials and other agencies tasked with protecting the public health and safety, the FDA's actions should be held as unlawful, and a Court should set the seizure action aside and vacate the lawsuit against this kratom manufacturer.

The FDA has ignored countless requests to work with the kratom industry and consumers to reach a regulatory framework that would offer consumer protection to all. In addition, the AKA has reported over 60 companies for egregious marketing and production violations which the FDA has ignored.

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About the American Kratom Association

The American Kratom Association (AKA), a consumer-based non-profit organization, gives a voice to the millions of Americans who safely consume kratom each year. Please visit www.kratomanswers.org for further details on kratom science and regulation.

[i] Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine into Schedule I, 81 Fed. Reg. 70652 (proposed Oct. 13, 2016) (to be codified at 21 C.F.R. 1308),

https://www.federalregister.gov/documents/2016/10/13/2016-24659/withdrawal-of-notice-of-intent-to-temporarily-place-mitragynine-and-7-hydroxymitragynine-into.

[ii] Letter from Brett Giroir, M.D., Assistant Secretary for Health, to Uttam Dhillon, Acting Admin. of the DEA (Aug. 16, 2018), https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/6014 5eab6df59e7e36a7cfc1/1611947693695/dhillon-8.16.2018-response-letter-from-ash-radm-giroir.pdf.

[iii] *See* World Health Organization, Commission on Narcotic Drugs: Summary of assessments, findings and recommendations of the 44th WHO's Expert Committee on Drug Dependence (2021), https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_64Reconvened/ECN72021_CRP12_V2108992.pdf.

[iv] Hearing on the FY 2023 Budget Request for the National Institute of Health Before the S. Appropriations Subcomm. On Labor, HHS, Education, and Related Agencies,117th Cong. (2022) (statement of Dr. Nora Volkow at 38:30).

[v] https://www.dropbox.com/s/m7c87cu47667ec3/TAB%2014%20HHS%20Becerra%20Letter%20Lee%20and%20Pocan.pdf?dl=0