AMERICAN KRATOM ASSOCIATION

STATEMENT OF MAC HADDOW, SENIOR FELLOW ON PUBLIC POLICY
KANSAS HOUSE OF REPRESENTATIVES – HB 2084
February 1, 2023

Members of the Committee, thank you for convening this hearing today on HB 2084, the Kansas Kratom Consumer Protection Act, often referred to as the KCPA. My name is Mac Haddow, and I serve as the Senior Fellow on Public Policy for the American Kratom Association (AKA), representing the 11 - 15 million kratom consumers in the United States.

The KCPA has one purpose that we believe we all share: To protect Kansas consumers from dangerously adulterated kratom products that are currently widely available both here in Kansas, and in many other states. Seven states have enacted the KCPA in their states to protect consumers – Utah, Georgia, Arizona, Nevada, Oregon, Colorado, and Oklahoma – and we hope Kansas will join this effort to enact needed consumer protections.

These bills are law today in those seven states despite the attempts by the U.S. Food and Drug Administration (FDA) to have kratom banned at the federal level. It is part of a decades long fight by the FDA to take all dietary and herbal supplements off the market, and to expand their regulatory powers over products consumer make informed decisions to use every day.

The dietary and herbal supplement marketplace has made a huge impact on the choices of products consumers use to maintain their health and well-being, and today more than 70% of Americans use these products to make an informed decision on the health products they choose to use. The dietary and herbal supplement industry tops $60 billion annually and all of those products would be gone if the FDA had its way.

The important issue we confront today is that a Kansas consumer can purchase what they believe to be a pure kratom product and after consuming it, notice it has a different and more powerful effect. They are duped into thinking it is a better product. One that gives a more powerful "kick."

The truth is, pure kratom does not produce any reinforcing euphoric high and if you take too much of it you feel sick to your stomach.

Based on survey research, about 1/3 of kratom consumers consume kratom as a replacement for coffee for an energy boost and increased focus; another 1/3 use it to reduce anxiety or feelings of depression; and the final 1/3 use it to manage acute and chronic pain, including to wean off highly addictive and potentially deadly opioids.

Published surveys of more than 20,000 US adults and more than 23,000 comments to the DEA show that most kratom consumers use kratom for health and well-being because they find it beneficial, accessible, acceptable, tolerable, and/or effective for health reasons and self-management of health issues that they formerly addressed with conventional FDA approved medicines.

Kratom has increased in popularity, growing from a consumer population estimated in 2016 to be approximately 3-5 million, to the estimated 12-15 million kratom consumers today, and produce an economic contribution to the U.S. market of $1.5 billion.

Growing markets attract the interest of the bad actors who adulterate products like kratom with fentanyl, heroin, morphine and cocaine, the adulterants of choice. Those powerful drugs produce a euphoric high that is the signature of opioid products. A little dose of these drugs drives kratom sales to customers who just think it is a better kratom product.

Repeated evaluations by independent experts and scientists have concluded adulterated kratom leads to dangerous addictions and overdose deaths. Pure, natural, kratom is, as Jack Henningfield of Johns Hopkins University one of the leading scientists testified recently in a similar Hearing like this one and characterized kratom as a plant where "Nature got it right."

Those who argue for a ban on kratom do so at the call of the repeated disinformation circulated by the FDA about the purported dangers of kratom because the FDA falsely claims kratom is an opioid; inaccurately claims kratom has a high addiction liability; and untruthfully claims there are deaths from using pure kratom.

None of those claims are accurate or based on current science.

- That was the conclusion of the DEA in 2016 when they withdrew the FDA's first scheduling recommendation based on insufficient evidence.
- The second FDA scheduling recommendation was officially withdrawn by the HHS Assistant Secretary of Health in 2018 who concluded it was based on "disappointingly poor evidence and data."
- The FDA went forum shopping on 2021 by recommending kratom scheduling to the U.N. Commission on Narcotic Drugs. The did that for two reasons: (1) the criteria for substance scheduling internationally is substantially lower; and (2) if kratom is scheduled internationally, then the U.S. is obligated to commence scheduling of kratom here. The Expert Committee on Drug Dependence voted 12-0 on December 1, 2021, that there was insufficient evidence for kratom to be scheduled internationally.

In baseball, three strikes and you are out. But the FDA is not counting.

In fact, the FDA has refused to enforce existing laws to regulate the kratom marketplace, and that has encouraged the bad actors to continue their sales of dangerously adulterated kratom products. In addition, the FDA has ignored their statutory responsibility to enforce the

requirement that kratom vendors cannot make therapeutic claims for any product that has not received a new drug approval from the FDA.

The AKA actively monitors the marketing activities of these bad actor kratom vendors and have, over the past 24months, referred more than 64 of these kratom vendors who are violating the Food, Drug, and Cosmetic Act to the FDA, and there has no significant warning letters issued or enforcement actions taken to protect consumers by forcing those bad actor kratom vendors to be shut down.

This neglect by the FDA is not unique to kratom. The FDA has taken similar approaches to CBD and hemp, and that has compelled states to take action to protect their constituents.

Today, the National Institute on Drug Abuse (NIDA) has opposed the FDA on kratom, and Director Nora Volkow has testified before Congress that kratom should not be banned, like the FDA wants, but regulated appropriately and new research should be undertaken. NIDA currently has more than $30 million in grants for kratom research. NIDA researched the FDA claims that kratom caused deaths, and concluded those deaths were from polydrug use or adulterated kratom products.

The NIDA 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

The U.S. Congress has adopted report language in the last four appropriations bills opposing any kratom ban and encouraging more funding for research.

HHS has strongly opposed the FDA's scheduling recommendation for kratom. Current HHS Secretary Becerra has publicly stated that the FDA needs to do much more research on kratom before making any more recommendations, that claims of addiction liability or fatalities claimed to be caused by kratom are caused by polydrug use or adulterated kratom products.

When kratom consumers have the opportunity to tell their personal stories, they tell of how kratom has improved their lives, allowed them to become fully functional husbands or wives, become productive employees, and being functional parents to their children. Many have said that kratom literally saved their lives.

Johns Hopkins University published a study of 2,798 adult kratom consumers who use it to reduce reliance on more dangerous opioids. The results:

- Of those treating opioid dependence, 87% reported relief from withdrawal symptoms;
- 35% were from opioids >1 year

That Harm Reduction message is mirrored in public hearings across America. It is my hope that the Kansas Legislature will take the important step in enacting HB 2084 to protect Kansas kratom consumers.

The kratom community is grateful for this Hearing because it is a critical step in protecting Kansas kratom consumers from adulterated kratom products that are properly manufactured and labeled.

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EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

AUG 16 2018

The Honorable Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Dhillon:

Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. § 811, I am rescinding our prior recommendation dated October 17, 2017, that the substances mitragynine and 7-hydroxymitragynine be permanently controlled in Schedule I of the CSA. HHS is instead recommending that mitragynine and 7-hydroxymitragynine not be controlled at this time, either temporarily or permanently, until scientific research can sufficiently support such an action. Mitragynine and 7-OH-mitragynine are two of the constituents of the plant *Mitragyna speciosa* (*M. speciosa*), commonly referred to as *kratom*. 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. Further research, which I am proposing be undertaken, should provide additional data to better inform any subsequent scheduling decision.

Procedural History

On August 31, 2016, the Drug Enforcement Administration (DEA) issued a Notice of Intent to temporarily schedule the chemicals mitragynine and 7-hydroxymitragynine into Schedule I pursuant to the temporary scheduling provisions of the CSA, 21 U.S.C. § 811(h). *See.* 81 Fed. Reg. 59,929 (Aug. 31, 2016). In response to the Notice of Intent, the DEA received numerous comments from the public on mitragynine and 7-hydroxymitragynine, including comments offering their opinions regarding the pharmacological effects of these substances. To allow consideration of these comments, as well as others received on or before December 1, 2016, the DEA issued a Withdrawal of Notice of Intent and Solicitation of Comments on October 31, 2016.

On October 17, 2017, the then-Acting Assistant Secretary for Health of HHS wrote to then-Acting Administrator of the DEA to indicate that HHS was recommending that the substances mitragynine and 7-OH-mitragynine be permanently controlled in Schedule I of the Controlled

Substances Act. Recently, I became aware of DEA's intent to schedule mitragynine and 7-OH-mitragynine - into Schedule I.

Analysis

The Controlled Substances Act ("CSA") provides in pertinent part that the Attorney General may by rule add to Schedule I any drug or other substance if the Attorney General makes the findings prescribed by subsection (b) of section 812 of the CSA for Schedule I. *See,* 21 U.S.C. § 811(a). Such findings are:

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety or use of the drug or other substance under medical supervision.

The CSA requires that "[i]n making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter."

21 U.S.C. § 811(c).

Before scheduling a substance, though, the Attorney General must "request from the Secretary (of HHS) a scientific and medical evaluation, and his recommendation, as to whether such drug or other substance should be so controlled or removed as a controlled substance." *Id.* at § 811(b). The Secretary's evaluation should be based on factors (2), (3), (6), (7), and (8), noted above, and the scientific and medical considerations involved in factors (1), (4), and (5). Moreover, the "recommendation of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." *Id.*

The Secretary has delegated to the Assistant Secretary for Health, in consultation with the National Institute on Drug Abuse and the Food and Drug Administration, the responsibility to make a recommendation under the CSA to the Attorney General. On October 17, 2017, my

predecessor, the Acting Assistant Secretary for Health, forwarded to you his recommendation that mitragynine and 7-hydroxymitragynine be permanently controlled in Schedule I of the CSA. The recommendation included a scientific and medical evaluation prepared by the FDA of the eight factors determinative of control under the CSA. The FDA evaluation also recommended in favor of the three findings that are required for DEA to place a substance in Schedule I.

I have reviewed the Acting Assistant Secretary's earlier recommendation as well as previous and new scientific data. In light of this review, combined with concerns for unintended public health consequences, I now conclude that while mitragynine and 7-hydroxymitragynine have many properties of an opioid, scheduling these chemicals at this time in light of the underdeveloped state of the science would be premature. For example, one recently published peer reviewed animal study indicated that mitragynine does not have abuse potential and actually reduced morphine intake. As such, these new data suggest that mitragynine does not satisfy the first of the three statutory requisites for Schedule I, irrespective of broader considerations of public health. While a single study is rarely dispositive, it strongly suggests that further evaluation is warranted.

Although there remains cause for concern for 7-hydroxymitragynine and potentially mitragynine, the level of scientific data and analysis presented by the FDA and available in the literature do not meet the criteria for inclusion of *kratom* or its chemical components in Schedule I of the CSA at this time. There is still debate among reputable scientists over whether *kratom* by itself is associated with fatal overdoses. Further analysis and public input regarding *kratom* and its chemical components are needed before any scheduling should be undertaken. It is important that we have additional information to justify scheduling, such as:[1]

- A scientific assessment of how many Americans utilize *kratom*, and an understanding of the geographic and demographic distribution of these users (Factors 4, 5);
- A scientific assessment of the actual scale and degree of dependence and/or addiction of Americans utilizing *kratom* (Factors 1, 5, 7);
- A scientific determination based on data whether *kratom* actually serves as a gateway drug that promotes further use of more dangerous opioids (Factors 1, 4, 5);
- A valid prediction of how many *kratom* users will suffer adverse consequences if *kratom* is no longer available, including:
    - Intractable pain, psychological distress, risk for suicide;
    - Transition to proven deadly opioids such as prescription opioids, heroin, or fentanyl; and
    - Transition to other potent or harmful drugs (Factor 6);
- A scientifically valid assessment of causality in the current few deaths in which *kratom* was co-utilized with known lethal drugs such as fentanyl (Factors 1, 2, 3, 5 & 6).

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:

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[1] I am also concerned about the impact of scheduling *kratom* on our ability to conduct research, especially survey research and our currently inability to routinely test for *kratom* in those brought into an emergency room as a result of a possible overdose.

- 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*.

Therefore, I conclude at the current time, available evidence does not support mitragynine and 7-hydroxymitragynine being controlled in Schedule I of the Controlled Substances Act. This assessment supersedes the previous recommendation letter from Acting Assistant Secretary Wright dated October 17, 2017. In the meantime, it is recognized that *kratom* may potentially have harmful effects, especially in specific circumstances and/or when used with potent prescription or illicit drugs.

Finally, it is entirely possible that new data and evidence could support scheduling of chemicals in *kratom* at some future time. *Kratom* may have harmful effects, particularly when used with other drugs. As such, I encourage continued enforcement by the FDA against unproven claims by *kratom* manufacturers. I also support enhanced public awareness that *kratom* contains molecules that may potentially be dangerous. I also plan to work expeditiously with colleagues throughout the U.S. government to seek transparent public and scientific input, and to collect data on the critical public health considerations outlined above.

Should you have any questions regarding this recommendation, please contact my office at (202) 690-7694.

Sincerely yours,

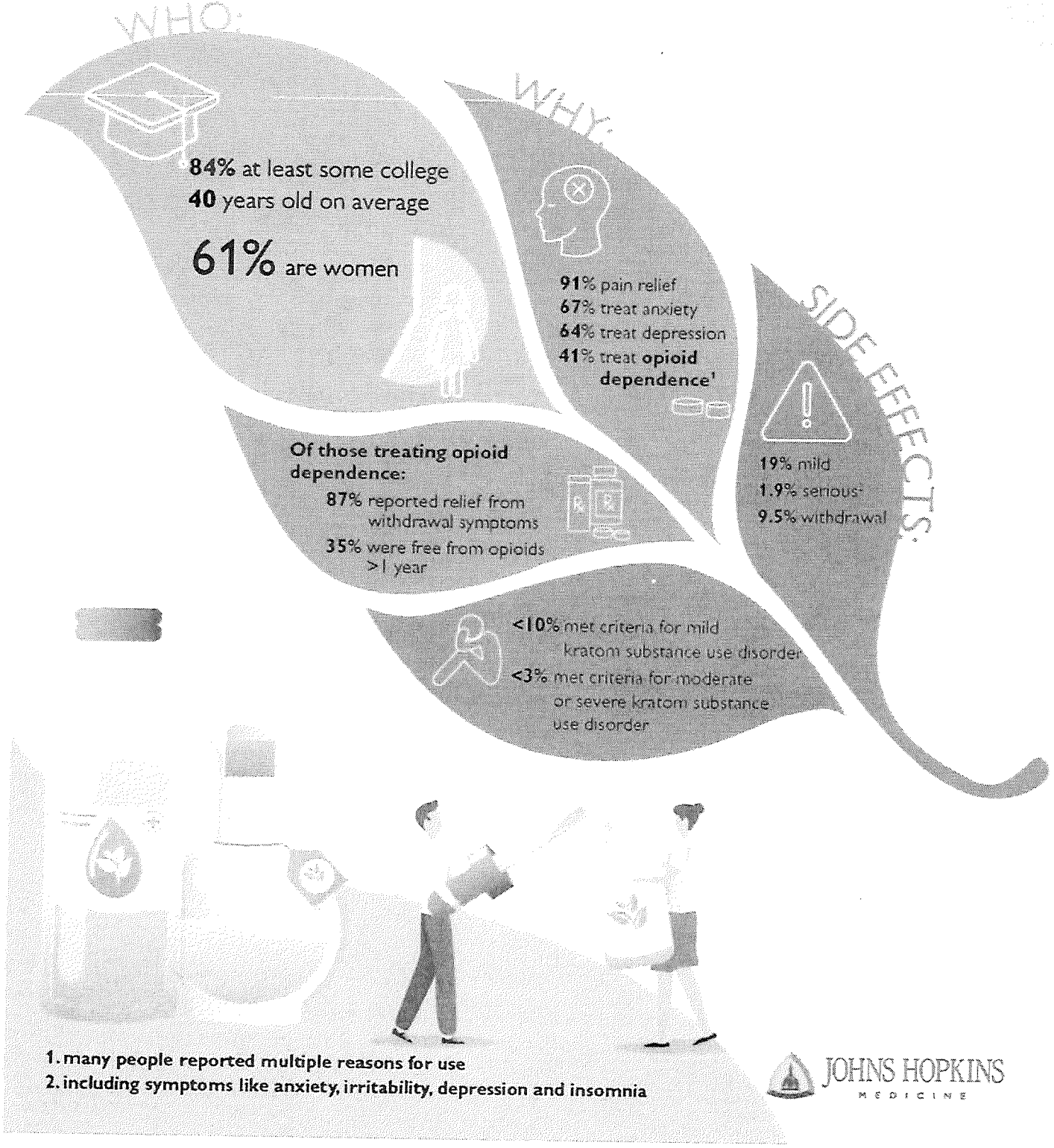
Brett P. Giroir, M.D.
ADM, U.S. Public Health Service
Assistant Secretary for Health
Senior Advisor for Opioid Policy

EXHIBIT 2

Survey of Adult Kratom Users in the U.S.

Provides Insight Into Potential for Harm or Abuse

2,798 kratom users



1. many people reported multiple reasons for use
2. including symptoms like anxiety, irritability, depression and insomnia

JOHNS HOPKINS MEDICINE