AMERICAN KRATOM ASSOCIATION

STATEMENT OF MAC HADDOW, SENIOR FELLOW ON PUBLIC POLICY
Pennsylvania House of Representatives Health Committee
Informational Meeting on Unregulated Intoxicants and Psychoactive Substances
Wednesday, April 26, 2023

Chair Frankel and Chair Rapp, and Members of the Committee. Thank you for convening this Informational Meeting on Unregulated Intoxicants and Psychoactive Substances.

My name is Mac Haddow, and I serve as the Senior Fellow on Public Policy for the American Kratom Association (AKA), representing the 12 - 15 million kratom consumers in the United States, and the hundreds of thousands of Pennsylvania citizens who safely consumer kratom products.

I recommend that you visit a website dedicated to public policy makers to review the most current science and policy on kratom: www.kratomanswers.org. The AKA urges states to enact the Kratom Consumer Protection Act (KCPA) to assure consumers have needed protections when they purchase a kratom product.

The profile of the typical kratom consumer. According to surveys in the US, most consumers report are adults, aged 35-55, with jobs, and health care insurance, 75% of whom report that their consumption is primarily for health and wellbeing. This includes consumption of kratom as an alternative to caffeinated products for alertness and increased focus. About 25% report they use kratom for the self-management of pain, to improve mood, and many consumers state that kratom worked better for them, had fewer side-effects than the FDA-approved medicines that had been taken, and/or that they preferred natural products, including consumers who consider kratom as a "life-line" or a path away from opioids. They use kratom to manage opioid withdrawal and reduce or eliminate opioid use.

Research from Johns Hopkins University on adult kratom consumers showed that 87% reported that kratom reduced their withdrawal symptoms, and 35% were opioid free within a year replacing those drugs with kratom (*See* https://www.hopkinsmedicine.org/news/newsroom/news-releases/natural-herb-kratom-may-have-therapeutic-effects-and-relatively-low-potential-for-abuse-or-harm-according-to-a-user-survey)

FDA's unsupported statements about kratom not being safe. Most of the controversy surrounding kratom has been created by the FDA that has a long-standing bias against any dietary ingredient, botanical supplement, or dietary supplement that is not a chemical formulation subject to regulatory approval as a new drug. In 1994, Congress had to pass the

Dietary Supplement Health and Education Act (DHEA) to reign in the FDA's overregulation of dietary supplements FDA wanted banned on the premise they were highly addictive, being used to self-medicate without physician supervision, or were so poorly formulated these products were so dangerous they should be banned.

Today, FDA maintains the same three common objections about kratom, i.e., kratom is unsafe, is highly addictive, and has no approved medical use — and people are using it to self-medicate to withdraw from opioid addictions. Accordingly, FDA has made three specific attempts to have kratom's constituents, mitragynine and 7-hydroxymitragynine, as Schedule I substances. Based on current science, leading public health officials have reviewed the current evidence and data on kratom and made the following decisions that kratom is not a candidate for scheduling:

- October 13, 2016: The Drug Enforcement Administration (DEA) withdrew the Notice of Intent recommending the temporary scheduling of kratom and requested a full 8-Factor Analysis from the FDA.

- August 16, 2018: HHS Assistant Secretary for Health, Brett Giroir, M.D., formally withdrew the FDA scheduling recommendation for kratom that had been submitted to the DEA and called out the FDA for "disappointingly poor evidence & data and a failure to consider the overall public health."

- December 1, 2021: The Expert Committee on Drug Dependence at the World Health Organization, comprised of 12 international experts on substance safety and addiction, unanimously concluded that there was insufficient evidence to recommend a critical international scheduling review of kratom.

- March 16, 2022: Letter from HHS Secretary Becerra acknowledging "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

- December 29, 2022: President Biden signed the FY23 Omnibus 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 FDA frequently references that there is no approved medical use for kratom. That is true for tens of thousands of foods, dietary ingredients, botanical supplements, and dietary supplements that are available to consumers in the U.S., many of which are regularly used to self-medicate by consumers. Federal law provides adequate authority for the FDA to prosecute any vendors who make illegal therapeutic claims in order to induce consumers to buy their products for therapeutic uses.

Kratom Science Updates. Former Assistant for Secretary of Health, Dr. Brett Giroir, correctly cited the "disappointingly poor evidence and data and a failure to consider the overall public

health" when he formally withdrew the FDA recommendation to schedule kratom on August 16, 2018. Since 2018, there have been more than 100 new published research articles on kratom. While there are public references to off of that research, a recent presentation on new kratom science was made at the UN Commission on Narcotic Drugs Conference in Vienna on March 16, 2023 (*See* the link to the scientist's presentation at https://youtu.be/oztAWZAaxGo).

Status of States that have banned kratom. Another relevant issue on the FDA's disinformation campaign against kratom is revealed in the responses currently ongoing in the 6 states that banned kratom from 2012 to 2017: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island.

- 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."

- 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.

- The Interim Director of the Rhode Island Department of Health, Utpala Bandy, M.D., has concluded that kratom does not meet the criteria for scheduling set forth in Rhode Island statutes.

- 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. The bill has now been transmitted to the Senate for action.

- 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.

States that have passed the KCPA. As of today, nine states have passed similar versions of the KCPA: Utah, Georgia, Arizona, Nevada, Oregon, Colorado, Oklahoma, West Virginia, and Virginia – it passed unanimously in both the House and Senate in Virginia. The Texas Legislature became the 10th state to pass the KCPA last week and that legislation has just been sent to the Governor for his signature.

Additional states currently deliberating on KCPAs are Kansas, Missouri, Illinois, Michigan, Minnesota, Wisconsin, Tennessee, Ohio, New Jersey, New York, Vermont, Rhode Island, Florida, North Carolina, South Carolina, Massachusetts, Louisiana, and here in Pennsylvania.

The FDA's false claims that kratom is an opioid. While some naturally occurring substances in kratom act on opioid receptors, kratom is not a prototypical opioid based on its chemical structure, botanical origins, or law – nationally or internationally. Like many natural products it has diverse effects and mechanisms of action that contribute to these effects and the reasons people use kratom. Properly characterized as "partial agonists" some kratom constituents bind to opioid receptors and relieve pain whereas others do not. Unlike opioids which sedate and can impair mental functioning, kratom is used by many people in place of coffee for its alerting, mental focusing, and occupational performance enhancing effects. Animal and human studies, as well as neuropharmacology mechanisms of action studies, show that kratom does not carry the substantial opioid-like risks of deadly respiratory depression or powerfully addictive euphoria.

A misunderstanding of one of kratom's self-reported beneficial uses, recognized by researchers and NIDA, providing relief of opioid withdrawal, is sometimes interpreted as evidence that it must be an opioid. In fact, the nonopioid adrenergic blocking drugs developed for treating high blood pressure, clonidine and lofexidine, were prescribed for decades to treat opioid withdrawal. FDA approved lofexidine (Lucemyra) for treating opioid withdrawal in 2018. Mitragynine and other kratom constituents also produce adrenergic effects.

The FDA's false claims kratom is dangerously addictive. NIDA has conducted two specific animal studies on the addiction liability of kratom, with the following results:

- Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. "The present findings indicate that mitragynine does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal, whereas 7-

hydroxymitragynine should be considered a kratom constituent with high abuse potential that may also increase the intake of other opiates." (*See* https://pubmed.ncbi.nlm.nih.gov/29949228/)

- Abuse liability of mitragynine assessed with a self-administration procedure in rats. "These results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse. With the current prevalence of opioid abuse and misuse, it appears currently that mitragynine is deserving of more extensive exploration for its development or that of an analog as a medical treatment for opioid abuse." (*See* https://pubmed.ncbi.nlm.nih.gov/30039246/)

The available data suggest relatively low abuse potential as compared to morphine-like opioids, stimulants, and other drugs of abuse that demonstrate robust rewarding effects across all such abuse potential models. Similarly, mitragynine's (an alkaloid in kratom) potential to produce physical dependence and withdrawal appears relatively low as compared to opioids in animal models. These findings are generally consistent with human reports that mitragynine has a relatively low abuse and withdrawal potential as compared to recreationally used opioids but can reduce opioid self-administration and withdrawal.

Kratom has no significant respiratory suppression effects. It is well understood that kratom's respiratory effects are not like those of morphine-like opioids; however, studies since 2018 support the conclusion that kratom is not simply weaker than opioids with respect to respiratory depression. Specifically, mitragynine and other alkaloids in kratom act as partial agonists at opioid receptors, meaning that their maximal effects reach a ceiling beyond which higher doses produce little additional effect. This was demonstrated in several animal species (including cats, dogs, mice, and rats) with mitragynine doses increased to levels far beyond what is or can be consumed by even high intake chronic kratom consumers. The most recent study employed a sophisticated rodent model developed by FDA to compare a broad range of mitragynine doses to therapeutic and toxic oxycodone doses across blood gases and other parameters. Whereas oxycodone produced the signature dose-related plummeting blood oxygen levels and deaths, mitragynine produced no evidence of respiratory depression at any dose, and no life-threatening effects.

Can you overdose on kratom? The overall risk for kratom overdose appears at least 1,000 times lower for kratom as compared to opioids. There were no deaths in which either the FDA or CDC confirmed as appropriately categorized as due to kratom consumption. Kratom consumers should not assume that kratom is without risk, but like many common consumer products responsible use is a key safety factor. The CDC did not list kratom as a cause of any of the more than one hundred and eight thousand drug overdose deaths in 2021, or in any other year of which we are aware. In contrast, opioids were concluded by the CDC and NIDA to account for more than 80,000 overdose deaths in 2021. Overdose is possible with many readily available consumer substances, including caffeine, but kratom's most common side-effect, transient stomach upset and nausea, also limits intake and is discomforting but not seriously harmful. In February 2018, after announcing that kratom carried opioid-like death risk, the FDA noted that only one of 44 deaths occurring in kratom consumers did not involve other

respiratory depressing substances. Further investigation found that the final cause was a motor vehicle fatality involving a kratom consumer. In fact, NIDA, FDA, US DHHS, and WHO ECDD all concluded that most kratom-associated deaths involved other substances.

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.

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, and many have said that kratom has literally saved their lives.

We urge your support for KCPA legislation because it is a critical step in enacting appropriate regulations to assure kratom products sold in Pennsylvania are safe, properly manufactured, not adulterated with dangerous substances, labeled to protect consumers, and restricted for sale to minors.

My thanks for the opportunity today to provide this information on kratom and to advocate for consumer protections.

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AMERICAN KRATOM ASSOCIATION

KEY KRATOM QUESTIONS AND ANSWERS

Why does the FDA claim kratom is unsafe for consumers?

The FDA has a long-standing bias against any dietary ingredient, botanical supplement, or dietary supplement that is not a chemical formulation subject to regulatory approval as a new drug. In 1994, Congress passed the Dietary Supplement Health and Education Act (DHEA) to reign in the FDA's overregulation of dietary supplements FDA wanted banned on the premise they were highly addictive, being used to self-medicate without physician supervision, or were so poorly formulated these products posed a threat to public health requiring them to be banned.

Today, FDA maintains the same three common objections about kratom, i.e., kratom is unsafe, is highly addictive, and has no approved medical use — and people are using it to self-medicate to withdraw from opioid addictions. Accordingly, FDA has made three specific attempts to have kratom's constituents, mitragynine and 7-hydroxymitragynine, as Schedule I substances. Based on current science, leading public health officials have reviewed the current evidence and data on kratom and vigorously disagree with the FDA's assessment of kratom's addiction and safety profile. All three of the FDA's recommendations for scheduling have been rejected by the Drug Enforcement Administration; the U.S. Department of Health and Human Services (HHS); and the Expert Committee on Drug Dependence (ECDD) for the U.N. Commission on Narcotic Drugs.

The FDA claims kratom should be classified as a Schedule I substance, so why is kratom not scheduled today at the federal level?

The short answer is because the FDA is wrong on the science, and wrong on the policy. Other federal and international agencies have carefully evaluated the FDA's claims and they find they lack sufficient evidence to support the FDA claims.

- October 13, 2016: The DEA withdrew the Notice of Intent recommending the temporary scheduling of kratom and requested a full 8-Factor Analysis from the FDA.
- August 16, 2018: HHS Assistant Secretary for Health, Brett Giroir, M.D., formally withdrew the FDA scheduling recommendation for kratom that had been submitted to the DEA and called out the FDA for "disappointingly poor evidence & data and a failure to consider the overall public health."
- December 1, 2021: The Expert Committee on Drug Dependence at the World Health Organization and the U.S. Commission of Narcotic Drugs, comprised of 12 international experts on substance safety and addiction, unanimously concluded that there was insufficient evidence to recommend a critical international scheduling review of kratom.

- March 16, 2022: Letter from HHS Secretary Becerra acknowledging "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."
- December 29, 2022: President Biden signs the FY23 Omnibus 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."

Is it true there is no approved medical use for kratom?

That claim is true, but it is also true for tens of thousands of foods, dietary ingredients, botanical supplements, and dietary supplements that are available to consumers in the U.S., many of which are regularly used to self-medicate by consumers to maintain their health and well-being. Federal law provides adequate authority for the FDA to prosecute any vendors who make illegal therapeutic claims to induce consumers to buy their products for therapeutic uses. In response, the AKA has submitted 65 documented cases of kratom vendors using illegal marketing claims on some therapeutic benefits they claim are associated with kratom consumption. Despite having sufficient legal authority to protect consumers from such illegal marketing schemes, the FDA has not initiated a single prosecution against any of those violators.

How many states have enacted the Kratom Consumer Protection Act?

As of today, 9 states have passed similar versions of the KCPA: Utah, Georgia, Arizona, Nevada, Oregon, Colorado, Oklahoma, West Virginia, and Virginia.

The Texas Senate passed the KCPA on a vote of 28-2 on March 16 and is now being considered by the Texas House. Additional states currently deliberating on KCPAs are Kansas, Illinois, Indiana, Michigan, Minnesota, Tennessee, Ohio, Pennsylvania, New Jersey, New York, Florida, North Carolina, Arkansas, Louisiana, South Carolina, Vermont, Wisconsin, and Rhode Island.

What is the status of the six states that banned kratom at the request of the FDA?

The FDA has vigorously engaged in a disinformation campaign against kratom for more than a decade. Six states did enact bans from 2021 to 2017, all in good faith, and all on the premise the FDA information was accurate: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island. Now those states are starting to push back against the FDA disinformation and most are actively working to correct the mistakes made in response to the requests by the FDA.

- 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 American Kratom Association ("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."

- 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.

- The Interim Director of the Rhode Island Department of Health, Utpala Bandy, M.D., has acknowledged that kratom does not meet the criteria for scheduling set forth in Rhode Island statutes.

- 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. The bill has now been transmitted to the Senate for action.

Is the FDA claim true that kratom is an opioid?

No, kratom is not an opioid by plant genetics, by chemical structure, or by legal definition.

While some naturally occurring substances in kratom act on opioid receptors, kratom is not a prototypical opioid based on its chemical structure, botanical origins, or law – nationally or internationally. Like many natural products it has diverse effects and mechanisms of action that contribute to these effects and the reasons people use kratom.

Properly characterized as "partial agonists" some kratom constituents bind to opioid receptors and relieve pain whereas others do not. Unlike opioids which sedate and can impair mental functioning, kratom is used by many people in place of coffee for its alerting, mental focusing, and occupational performance enhancing effects.

Animal and human studies, as well as neuropharmacology mechanisms of action studies, show that kratom does not carry the substantial opioid-like risks of deadly respiratory depression or powerfully addictive euphoria. A misunderstanding of one of kratom's self-reported beneficial uses, recognized by researchers and NIDA, providing relief of opioid withdrawal, is sometimes interpreted as evidence that it must be an opioid. In fact, the nonopioid adrenergic blocking drugs developed for treating high blood pressure, clonidine and lofexidine, were prescribed for decades to treat opioid withdrawal. FDA approved lofexidine (Lucemyra) for treating opioid withdrawal in 2018. Mitragynine and other kratom constituents also produce adrenergic effects.

Is the FDA claim true that kratom is dangerously addictive?

No, the FDA is completely wrong on this point. There is a significant difference between addiction and dependency, and there is a similar significant difference between a dangerous addiction and a socially acceptable benign addiction or dependency. Caffeine is the most widely used drug in the world and it has an addiction profile that is characterized by scientists, and the FDA, as having an acceptable addiction profile.

NIDA has conducted two specific animal studies on the addiction liability of kratom, with the following results:

- Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. "The present findings indicate that MG does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal, whereas 7-HMG should be considered a kratom constituent with high abuse potential that may also increase the intake of other opiates." (*See* https://pubmed.ncbi.nlm.nih.gov/29949228/)

- Abuse liability of mitragynine assessed with a self-administration procedure in rats. "These results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse. With the current prevalence of opioid abuse and misuse, it appears currently that mitragynine is deserving of more extensive exploration for its development or that of an analog as a medical treatment for opioid abuse." (*See* https://pubmed.ncbi.nlm.nih.gov/30039246/)

The available data suggest relatively low abuse potential as compared to morphine-like opioids, stimulants, and other drugs of abuse that demonstrate robust rewarding effects across all such abuse potential models. Similarly, MG's potential to produce physical dependence and withdrawal appears relatively low, but not absent, as compared to opioids in animal models. These findings are generally consistent with human reports that MG has a relatively low abuse and withdrawal potential as compared to recreationally used opioids but can reduce opioid self-administration and withdrawal.

Is the FDA claim true that kratom is a deadly drug that people are dying from?

No, this FDA claim about deaths associated with kratom has been reviewed by experts and found to be untrue. It is well understood that kratom's respiratory effects are not like those of morphine-like opioids and peer-reviewed published studies since 2018 support the conclusion that kratom is not simply weaker than opioids with respect to respiratory depression, kratom does not cause respiratory suppression and associated overdose death.

Specifically, mitragynine and other alkaloids in kratom act as partial agonists at opioid receptors, meaning that their maximal effects reach a ceiling beyond which higher doses produce little additional effect. This was demonstrated in several animal species (including cats, dogs, mice, and rats) with mitragynine doses increased to levels far beyond what is or can be consumed by even high intake chronic kratom consumers.

The most recent study employed a sophisticated rodent model developed by FDA to compare a broad range of mitragynine doses to therapeutic and toxic oxycodone doses across blood gases and other parameters. Whereas oxycodone produced the signature dose-related plummeting blood oxygen levels and deaths, mitragynine produced no evidence of respiratory depression at any dose, and no life-threatening effects.

Why does the DEA list kratom as a "Drug of Concern"?

The DEA has appropriately listed kratom as a "Drug of Concern" based on the conflicting reports made by the FDA, particularly with the deliberate adulteration and mislabeling of kratom products by some unscrupulous vendors in the kratom marketplace. Common adulterants include fentanyl, heroin, buprenorphine, and morphine. The DEA simply maintains surveillance of kratom to review reports of adverse events to potentially identify and interdict such adulteration with dangerous substances.

Importantly, kratom has never been listed by the DEA on their National Drug Threat Assessment (NDTA) report. This report assesses the threat posed to the U.S. by the trafficking and abuse of illicit drugs.

Why does the FDA have two import alerts on kratom?

The FDA has used import alerts to create a de-facto ban on kratom since they cannot meet the requirements for scheduling under the Controlled Substances Act (CSA). While clearly an abuse of its regulatory authority, the premise of the import alerts are based entirely on the contrived and wholly inaccurate addiction and safety profile promoted by the FDA itself.

Can you overdose on kratom itself?

The overall risk for kratom overdose appears at least 1,000 times lower for kratom as compared to opioids.

There were no deaths in which either the FDA or CDC confirmed as appropriately categorized as due to kratom consumption. Kratom consumers should not assume that kratom is without risk, but like many common consumer products, responsible use is a key safety factor. The CDC did not list kratom as a cause of any of the more than 108,000 drug overdose deaths in 2021, or in any other year of which we are aware.

In contrast, opioids were concluded by the CDC and NIDA to account for more than 80,000 overdose deaths in 2021. Overdose is possible with many readily available consumer substances, including caffeine, but kratom's most common side-effect, transient stomach upset and nausea, also limits intake and is discomforting but not seriously harmful. In February 2018, after announcing that kratom carried opioid-like death risk, the FDA noted that only one of 43 deaths occurring in kratom consumers did not involve other respiratory depressing substances. Further investigation found that the final cause was a motor vehicle fatality involving a kratom consumer.

In a review of the 44th death reported by the FDA to have been caused by kratom ingestion, when the autopsy report was obtained the actual cause of death was two gunshot wounds to the chest that occurred during a drug sting operation by law enforcement. The decedent had incidentally consumed a kratom tea on the morning he was shot.

NIDA, FDA, US DHHS, and WHO ECDD all have concluded that most kratom-associated deaths involved other substances.

What is the profile of the typical kratom consumer.

According to surveys in the US, most consumers report are White adults, aged 35-55, with jobs and health care insurance, who report that their consumption is primarily for health and wellbeing. This includes consumption as an alternative to caffeinated products for alertness and increased focus, for the self-management of pain, and to improve mood.

Many consumers state that kratom worked better for them, had fewer side-effects than the FDA-approved medicines that had been taken, and/or that they preferred natural products. A smaller but especially important fraction of consumers are people who consider kratom as a "life-line" or a path away from opioids. They use kratom to manage opioid withdrawal and reduce or eliminate opioid use.

What form do kratom products use in the marketplace?

It is well known that kratom has a bitter taste, which accounts for why pure, unadulterated kratom products are not attractive to minors. Kratom is sold in powder form, which is typically brewed into a tea by adding hot water – although some consumers consume the powder orally; in capsule or pill forms that bypass the bitter taste; and in liquids much like a five-hour energy drink. Kratom critics frequently point to kratom products being sold in convenience stores or gas stations as evidence of their harm. To the contrary, the most important protection for consumers is to make certain that every kratom product offered meets the manufacturing criteria for its content; is free from dangerous adulterants; is labeled properly; and is not sold to minors.

Some kratom products are "extracted" to (1) purify to remove any microbial contaminants; and (2) to standardize the alkaloid content of each serving size recommended for use of those products. Like any other consumer product similarly extracted, including coffee, plants and fruits, and essential oils, these extracts must use approved FDA food-grade solvents to complete the extraction process safely.

Many kratom critics claim all liquid kratom products are extracts. That is not true. Extracted kratom products are across all product forms, and the key to their safety is the use of safe extraction solvents and directions on appropriate serving sizes.

What does recent science reveal about kratom?

Since 2018, there have been more than 100 new published research articles on kratom. While there are public references to that research, a recent presentation on new science on kratom was made at the UN Commission on Narcotic Drugs Conference in Vienna on March 16, 2023.

Here are links to video of presentations made by 4 of the world's leading experts on kratom at that conference:

- Here is the link to the entire presentation (about 50 minutes long): https://youtu.be/oztAWZAaxGo
- Here are individual segments from each presenter – each is about 10 minutes long.
    - Dr. Marilyn Huestis, former NIDA official now with Thomas Jefferson University:

      https://youtu.be/SbQtzs4uphQ
    - Dr. Kirsten Smith, NIDA:

      https://youtu.be/aLS-ZbV5kIk
    - Dr. Jack Henningfield, Pinney Associates and Johns Hopkins University:

      https://youtu.be/oZj9TIFF8eI

- Dr. Chris McCurdy, University of Florida:

  https://youtu.be/KBRXbRcydoE

Summary:

Kratom is safely used by consumers for a variety of purposes, chief of which is for its energy boost and increased focus effects, typically as a replacement for a cup of coffee. Research indicates kratom can act as a pain reliever for acute and chronic pain and potentially even treat opioid withdrawal. The National Institute on Drug Abuse (NIDA) has currently funded more than $30 million in kratom research studies, including several grants totaling $15 million at the University of Florida. The U.S. Congress issued Report Language in each of the last four annual budgets calling for further research to expand studies on kratom.

Pure kratom products, when used responsibly, are safe. Studies conducted by the NIDA confirm kratom has no significant addiction liability. Any deaths allegedly associated with kratom are due to adulterated kratom, polydrug use, or underlying health conditions. To protect American consumers, suitable public policy kratom solutions require appropriate regulation.

For additional information go to www.kratomanswers.org.

AMERICAN KRATOM ASSOCIATION

KRATOM FACT SHEET

LET SCIENCE DIRECT PUBLIC POLICY ON KRATOM – NOT THE FDA BIAS AGAINST ALL DIETARY AND BOTANICAL SUPPLEMENTS

Dispelling Myths and Understanding the Facts

More than 15 million Americans safely use kratom as a part of their health and well-being regimen and have done so for decades. Kratom is regulated by the U.S. Food and Drug Administration (FDA) as a dietary ingredient/supplement, and people who use kratom do so for the same reasons as people who use dietary ingredients, supplements, and who drink coffee, tea, or other caffeinated beverages. Surveys show that kratom consumers are educated, middle-income, employed, and have health insurance – they are largely the soccer moms and dads of America.

The FDA has repeatedly attempted to force kratom into Schedule I of the Controlled Substances Act by misstating the science, ignoring kratom's long history of safe use, and falsely claiming kratom has the same effects as classic opioids. The FDA's distorted record on kratom is clearly a part of the FDA's long-standing bias against dietary supplements that are safely used by millions of Americans rather than chemical drug formulations that are subject to new drug applications that have their own potential and frequently serious adverse health impacts.

Dispelling the FDA Myths	Understanding the Facts
The FDA claims there are deaths associated with kratom use and warns consumers from using it.	There has not been a single documented fatality that can be linked to use of the natural kratom plant alone. The FDA claimed deaths "associated with kratom use" are actually deaths caused by polydrug use, underlying medical conditions, or the use of adulterated kratom products laced with toxic levels of dangerous substances, including opioids. National Institutes on Drug Abuse's (NIDA) and HHS Secretary Becerra's public conclusions agree that the problem is adulterated kratom products or polydrug use..
Kratom's primary alkaloid, mitragynine (MG) and metabolite 7-hydroxymitragynine (7-HMG) are dangerous opioids and have the same effects of opioids like heroin.	MG and 7-HMG, like many other substances like Chamomile, St. John's Wort, etc., do bind to the mu-opioid receptors in the brain. Kratom's alkaloids are actually only partial agonists, with lower dependence and abuse potential. The sectors of the brain kratom impacts are pain relief and mood sectors, not the sector that produced euphoria and, most importantly, scientific evidence demonstrates that kratom does not cause respiratory depression like classic opioids, a common cause of fatal overdoses.
Kratom is highly addictive and is abused as a drug	Like coffee, tea, and other caffeinated drinks, consumers can develop a dependency on kratom, which is vastly different from an addiction. Two NIDA funded scientific studies completely debunk the FDA theory. The Hemby study in June 2018 concluded "MG does not have abuse potential and reduces morphine intake," and the Yue study in July 2018 reported "limited abuse liability and potential for mitragynine treatment to specifically reduce opioid abuse." Recent studies confirm that fact.
The kratom industry has no production standards or consumer safety protocols.	The American Kratom Association (AKA) is committed to supporting regulations that provide consumers with safe, properly manufactured kratom products. The kratom community supports adherence to FDA product testing protocols that meet or exceed Good Manufacturing Practice (GMP) guidelines set by the FDA for dietary ingredients/supplements and support appropriate age restrictions and labeling guidelines outlining responsible use. The kratom community has called upon the FDA to use its existing regulatory authority to remove adulterated kratom products from the market and prosecute individuals or companies who produce or distribute dangerous adulterated kratom products, but in more than 65 reports provided by the AKA, not a single prosecution by the FDA.

The kratom community believes public policy related to kratom should follow the science. To learn more about the science that supports the fact that kratom is a safe natural botanical, and why the FDA claims being made about kratom are just wrong, visit the following page to download and review the compelling truth about kratom use by consumers: www.kratomanswers.org

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