

POLICY BRIEF

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Why Should States Enact the KCPA?

The FDA has launched a war on kratom with claims kratom can cause deaths that are the result of polydrug use or ingesting adulterated kratom products consumers presumed to be safe. Based on an analysis by the American Kratom Association (AKA) of kratom products offered for sale in the United States, the majority of adulterated products enter the supply chain because an unscrupulous vendor deliberately adulterates their products with dangerous drugs or synthesizes the natural alkaloid content of the plant in order to deliver a euphoric high that is not present in the natural plant. The transparent objective is to increase their sales revenue.

Based on the AKA's review of product supply chains, the four states where the Kratom Consumer Protection Act provisions have been enacted, Utah, Georgia, Arizona, and Nevada, the number of adulterated kratom products spiked with dangerous drugs like heroin, fentanyl, and morphine has significantly decreased. Restricting the sale of adulterated kratom products is the most powerful argument that can be made to protect the safety of consumers.

The other important issue is why consumers choose to use kratom in the first place. Kratom has been used safely for centuries in Southeast Asia and is particularly popular with laborers and field workers who find its energy-boosting and pain relief properties helps them get through long days of work in the fields. Surveys of kratom consumers in the United States show about one-third use it the same way many Americans use coffee for an energy boost, or for increased focus. Another third use kratom for its mood smoothing effects and reduced anxiety. And the final third have found that kratom, at higher levels of consumption, can relieve opioid withdrawal symptoms and help manage pain.

KEY FINDINGS

FDA's claims that kratom is harmful is actually the result of adulterated kratom products or polydrug use.

Unscrupulous vendors intentionally spike pure kratom with dangerous substances to enhance the effects and increase sales of the adulterated products.

In states where the KCPA has passed, the number of adulterated products sold to consumers has decreased.

Kratom is not addictive like classic opioids, and studies funded by NIH and NIDA demonstrate kratom does not have any significant addiction liability.

A 2020 Johns Hopkins study of adult kratom users revealed 87% of those using kratom for opioid dependence reported kratom provided relief from withdrawal symptoms, and 35% were free from opioids > 1 year.

The FDA's attempts to have kratom scheduled is the precursor to a PhRMA company filing a new drug application to cash in, but kratom would have to be banned first.

The FDA has a long-standing bias against natural products and dietary supplements, and kratom is no exception to the FDA's efforts to increase their regulatory control over the choices Americans make in their health and well-being. In fact, the claims the FDA makes about kratom associated adverse events and deaths are exclusively related to dangerously adulterated kratom products or polydrug use. Pure kratom that is not contaminated or adulterated and responsibly used is safe for consumer use.

The conflict with the FDA is explainable and transparent. When kratom is available in its natural form to millions of consumers no PhRMA company is going to be interested in submitting a new drug application (NDA). The NDA process typically requires a \$3 - \$5 billion investment and 10 years of review by the FDA, and no PhRMA company would have an interest in that investment if kratom is legally available to consumers.

In the 1990's, the FDA launched a similar attack on dietary supplements and vitamins with claims that these products were all unapproved drugs and there were significant number of adverse events and deaths resulting from the sale of these products. The FDA solution was to ban all dietary supplements and force consumers to use only FDA approved drugs to maintain their health and well-being.

At that time, the U.S. Congress intervened and stopped the broad regulatory overreach for literally hundreds of dietary supplement and vitamin products by passing the Dietary Supplement Health & Education Act (DSHEA) that today provides regulations for the safe use of dietary supplements and vitamins used by more than 85% of American consumers and accounting for \$53 billion in sales annually.

Kratom was specifically targeted by the FDA in 2009 when the FDA circulated reports out of Sweden that 9 deaths in a 12-month period were reportedly caused by the consumption of a powdered kratom product sold on the Internet known as Krypton. That cluster of deaths in such a short time frame appropriately caught the attention of every public health official in the world, including the FDA. The FDA imposed an import alert on kratom and flooded the information pipeline with shrill warnings to state and local health officials, pharmacy boards, medical examiners, and drug task forces around the country that kratom was a dangerous substance that should be banned.

In a seven-year span between 2009 and 2016, six states enacted bans on kratom — Vermont, Alabama, Indiana, Wisconsin, Arkansas, and Rhode Island. The FDA regularly points to those states as evidence of how dangerous kratom is, but what is actually surprising is that only six states enacted bans in the face of a full-throated disinformation campaign on kratom by the FDA with outrageously untrue claims about kratom being the cause of dozens of deaths.

What the FDA never told the public was that a peer-reviewed published research report on the 9 deaths in Sweden confirmed all were caused by a toxic dose of the powerful chemical O-desmethyltramadol. If that same dose of that chemical were put in a cup of coffee or glass of orange juice, the consumer would be dead within minutes. But that fact did not conform to the FDA's war on kratom, so they withheld it in the information they circulated to states to convince state legislators to ban kratom.

In August of 2016, with clear frustration that more states had not enacted more bans prompted by their war on kratom, the FDA sent a recommendation to the Drug Enforcement Administration (DEA) to classify the two primary alkaloids of the kratom plant as Schedule I dangerous substances under the Controlled Substances Act (CSA), and used a section of the CSA reserved for the most dangerous street drugs to expedite the scheduling.

After a review of the science and the submitted data, the DEA took the unprecedented step of withdrawing its scheduling notice on October 13, 2016, the first time it had done so in 82 previous

scheduling requests to remove dangerous drugs, and then required the FDA to document its claims with a full scheduling recommendation.

The FDA tried again with another scheduling recommendation on October 13, 2017 asserting the same poorly documented death claims in an attempt to meet the criteria in the CSA that kratom must be dangerous to the public; that kratom has a high addiction liability; and that kratom is an opioid.

The National Institutes on Drug Abuse (NIDA) reviewed those claims about the addiction liability^{1 2} and the claimed deaths associated with kratom and rejected them. Gold standard animal studies on the addiction liability concluded the FDA was wrong. Independent researchers reviewed the FDA's claim about kratom being an opioid and concluded those claims were also incorrect.

On each of these key criteria, the FDA was wrong on the science and wrong on the policy. Kratom does not induce any reinforcing euphoric high nor does it have any significant impact on the respiratory system as classic opioids do. When an overdose death occurs, it is because the user has literally suffocated from respiratory suppression that kratom does not cause.

Overdose deaths, euphoric highs, and addiction are the signatures of adulterated kratom, and the AKA wants to eliminate those dangerous products from the marketplace. The KCPA is needed to protect the freedom of consumers to make informed decisions on their health and well-being without the overreaching regulatory power the FDA is trying to seize.

The FDA wants kratom to be subject to its new drug application process. They want the same thing for homeopathic medicines, herbal remedies, and medical foods — all of which have been used safely by American consumers for decades. The FDA has confronted a significant disagreement about kratom at the federal level and remains alone in its call for kratom to be scheduled.

Those Agencies lined up on the other side include NIDA, who argues for more study on kratom and following a harm reduction policy to allow consumers to use pure kratom to manage acute and chronic pain as an alternative to highly addictive and potentially deadly opioid medications. NIDA has already funded more than \$15 million in research studies, and more is in the research pipeline.

The DEA is also on the other side of FDA. The DEA has the exclusive authority to schedule any dangerous substance that threatens the safety of the American people. When they receive a scheduling recommendation initiated by the FDA, they typically issue a decision within 90 days to stop any safety risk that exists. The current recommendation from the FDA to schedule kratom has been before the DEA for more than 3 years and they have taken no action to accept that scheduling recommendation. If the FDA claim were true about deaths associated with kratom, the DEA would have acted immediately because it is their duty to do so.

The U.S. Congress is also opposed to the FDA scheduling recommendation on kratom. In its FY 2020 and FY 2021 budget bills that include specific funding appropriated for new research on kratom: Report language states that a Schedule I designation interferes with research; and the bill specifically cites the

¹ <https://pubmed.ncbi.nlm.nih.gov/29949228/>

² <https://pubmed.ncbi.nlm.nih.gov/30039246/>

reports of kratom helping people reduce or stop the use of dangerously addictive and potentially deadly opioids.

Finally, the states are lining up against the FDA as well. Four states in 2019 passed the Kratom Consumer Protection Act that is being considered in numerous states in 2021: Utah, Georgia, Arizona, and Nevada.

During the 2019 legislative session that was interrupted by the COVID-19 pandemic, various versions of the Kratom Consumer Protection Act were voted on, including the Missouri House on a vote of 139-6; passed the Oregon Senate unanimously; passed the Oklahoma House unanimously; a bill file was opened on a unanimous vote by the Wisconsin Senate to replace the existing ban with the KCPA; passed the New Hampshire Senate unanimously; passed the Mississippi Senate Drug Policy Committee on a unanimous vote; and the Maryland Senate passed it unanimously.

While the FDA is virtually alone in its war on kratom among federal Agencies, they do have one powerful ally siding with them, and that is the potential for a blockbuster drug that a few big pharmaceutical companies would leap at the opportunity to exploit – if the FDA can get natural kratom banned from consumers.

To show how strong that incentive is, a Johns Hopkins University study in 2020³ reported 87% of kratom consumers using it to treat opioid dependence reported relief from withdrawal symptoms, and 35% were free from opioids in a year or less. That explains why NIDA has invested so much in research, and accounts for why there is such a big interest by some PhRMA companies who invest in pain management therapies.

The American Kratom Association advocates for states to stand up against overregulation by the FDA; stand up to the exploitation of some opportunistic PhRMA company in the pain relief market; and support consumers having the freedom to make informed decisions on safe kratom products to manage their own health and well-being.

³ Garcia-Romeu A, Cox DJ, Smith KE, Dunn KE, Griffiths RR. Kratom (*Mitragyna speciosa*): User demographics, use patterns, and implications for the opioid epidemic. *Drug Alcohol Depend.* 2020;208:107849. doi:10.1016/j.drugalcdep.2020.107849