AMERICAN KRATOM ASSOCIATION

POLICY BRIEF

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Is Kratom Safe?

The FDA claims that kratom is the cause of deaths is not supported by any creditable data that would justify scheduling.

The responsibility for protecting Americans from dangerous substances is delegated by Congress to the Drug Enforcement Administration (DEA), not the FDA.

The Controlled Substances Act (CSA) requires the DEA to apply a strict criterion in classifying substances to appropriate scheduling levels. The FDA's powers are strictly limited and require coordination with the National Institutes on Drug Abuse (NIDA), in making recommendations on substances they deem to be appropriate for scheduling.

The FDA has made two specific recommendations to the DEA to schedule kratom as a Schedule I substance, thereby banning consumer access to kratom products. The first recommendation made on December 31, 2016 was initially accepted by the DEA, but after a review of the data supplied by the FDA supporting the recommendation, the DEA took the unprecedented action of withdrawing the scheduling recommendation for kratom on October 13, 2016.

A second scheduling recommendation was submitted by the FDA in November 2017, but the DEA has declined to act on that recommendation in the more than 3 years since it was filed. The DEA typically acts within 90 days on such recommendations, and usually within just a few days if the public safety threat is real and properly documented. The DEA has a stellar record for acting to protect the public when the CSA criteria for scheduling is fully met and documented.

The FDA has attempted to bypass the statutory requirements for scheduling at the federal level by using its vast public information resources to demonize kratom using a coordinated disinformation campaign with a variety of state public health agencies, law enforcement departments, and coroners and medical examiners to create de-facto ban on kratom at state and local levels.

KEY FINDINGS

The FDA does not have the authority to schedule or ban kratom, only the DEA holds that power under the CSA.

The DEA has refused to take any action to schedule kratom despite two attempts by the FDA in the 4 years that have elapsed since the first recommendation was made.

Independent reviews of the FDA data claiming deaths associated with kratom have shown to have no credibility in meeting the burden for scheduling.

Research funded by NIDA has directly contradicted the FDA claims that kratom has a high addiction liability (one of the key factors required for scheduling).

The NIDA research also shows that kratom offers real potential to replace more dangerous treatment options like opioids for acute and chronic pain management.

The FDA knowingly uses false "kratom associated" death claims to advocate for kratom bans at the federal, state, and local government levels.

The US Congress has recognized the potential value of kratom in fighting opioid use disorder.

In addition, since the 2017 FDA recommendation to schedule kratom, there have been a significant number of credible peer-reviewed research articles published that further undermine the claims made by the FDA against kratom, including NIDA funded research projects that directly refute the FDA's claims that kratom has a dangerous addiction liability.

The DEA's withdrawal of the initial scheduling recommendation by the FDA for kratom's two primary alkaloids, mitragynine and 7-hydroxymitragynine, was based on "numerous comments from members of the public challenging the scheduling action[i]" that included bi-partisan letters signed by 51 members of the United States House of Representatives and 13 members of the United States Senate objecting to the DEA's scheduling notice.

In FDA initially claimed kratom "directly or indirectly"[ii] was involved in 33 deaths. Following a review of those claims, the DEA withdrew the scheduling recommendation, in part, because the data did not meet the criteria required under the CSA for scheduling. The FDA resubmitted its second scheduling recommendation for kratom in November 2017 and increased the number of deaths "associated" with kratom to 44.

An independent review of the autopsy and medical reports of the 44 deaths resulted in the following conclusion:

> "The key evidence the FDA has offered on the dangers of kratom as the basis for placing it in Schedule I are case reports on 44 deaths over a nine-year period world-wide associated with the use of kratom. However, the FDA did not independently verify or perform any due diligence on the death reports, and worse, FDA's own documents indicate that every reported case involved other factors. With no direct investigation by the FDA, and a clearly unprofessional review, those case reports are riddled with significant credibility issues. In addition, there are serious errors and omissions between the source reports and the data entered into the FDA FAERS database by FDA that are either deliberate, or so incredibly unskilled as to call into question the validity of any conclusions made by the FDA."[iii]

A significant finding also involved the single FDA reported death where the FDA redacted all of the data on a 14-page autopsy report.[iv] The explanation from the FDA for denying the FOIA request on this death was an objection raised by the family on disclosing private data. However, a reporter from Huffington Post found a completely unredacted autopsy report on a separate FDA database with no restriction on its release. That autopsy report revealed that the decedent had Citalopram, Hydrobromide, Chlordiazepoxide (all antidepressants and anti-anxiety medications), and mitragynine in his system at the time of death, but none at a toxic level. The Medical Examiner listed the cause of death as "Death by Homicide" resulting from gunshot wounds to the chest. This is an illustration of the lengths the FDA will go to mislead the public in its campaign to demonize kratom.

The FDA also uses reports of 9 deaths over a 12-month period in 2009 that occurred in Sweden that were reported to have resulted from a powdered kratom product sold on the internet known as "Krypton." These deaths are a part of the DEA submissions recommending scheduling of kratom. However, what the FDA fails to report is that a peer-reviewed published paper found that all of those deaths were caused by an adulterant, *O*-desmethyltramadol, a powerful chemical opioid used in the production of the opioid Tramadol. The FDA is fully aware that then natural kratom powder would not have resulted in those deaths, but the Agency continues to promote its false reports to support its unjustified case to schedule kratom by continually referring to these deaths as associated with kratom.

NIDA funded two research projects to determine if kratom's alkaloids meet the CSA scheduling factor for a "high potential for abuse" (also commonly referred to as addiction liability) to be classified as a Schedule I substance. Some examples of Schedule I drugs are heroin, LSD, marijuana, Ecstasy, methaqualone, and peyote.[v] The Hemby study concluded that "MG (kratom) does not have abuse potential and reduces morphine intake"[vi], and the Yue study concluded that its results "suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse."[vii]

These published research reports not only directly dispute the FDA's claims about kratom's addiction liability, both studies show that there is a credible basis for those using kratom for management of acute and chronic pain to reduce or eliminate more dangerous treatment options like opioids. The federal health policy should be about harm reduction, not stoking false fears to promote its own expansive regulatory agenda.

In addition, NIDA has reviewed all of the autopsies and medical records of the deaths associated with kratom submitted by the FDA to support its scheduling recommendations and clarified that the "FDA reports note that many of the kratom-associated deaths appeared to have resulted from adulterated products or taking kratom with other potent substances, including illicit drugs, opioids, benzodiazepines, alcohol, gabapentin, and over-the-counter medications, such as cough syrup. Also, there have been some reports of kratom packaged as dietary supplements or dietary ingredients that were laced with other compounds that caused deaths."

The CSA does not allow for scheduling of a substance that has been adulterated or mixed with other dangerous substances, and the FDA's disingenuous attempt to conflate pure kratom with the effects of adulteration with dangerous drugs like fentanyl, heroin, and morphine shows how biased the FDA is on this issue.

The US Congress recognized the potential for kratom FY2021 U.S. House of Representatives Committee on Appropriations, Report 116-450, 116th Congress, 2nd Session, pages 120, with the following Report Language:

> *Kratom*. – The Committee encourages NIDA to expand research on all health impacts of kratom, including its constituent compounds, mitragynine and 7-hydroxymitragynine. The Committee is aware of the potential promise of kratom-derived compounds for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids.

The FDA is isolated at the federal level in its war on kratom. FDA has lost the support of NIDA and the US Congress on scheduling kratom, and the growing body of research shows the responsible use of pure unadulterated kratom is safe.

Conclusion:

The sole authority for scheduling of dangerous substances is held by the DEA. The FDA can only make recommendations for scheduling, and even then, the Agency is required to provide documentation on 8 specific factors specified by the CSA. The DEA has, over the past 4 years, taken no action on two separate scheduling recommendations clearly because the FDA has failed to meet its burden to conclusively justify the scheduling of kratom.

NIDA research has directly contradicted the FDA claims on kratom having an abuse potential required by the CSA. NIDA has also agreed with an independent review of the FDA's alleged kratom death that they were actually caused by adulterated kratom products or an underlying medical condition, neither of which supports classifying kratom as a Schedule I substance.

The research also shows that kratom offers a real potential for helping individuals who struggle with the management of acute and chronic pain to replace more dangerous opioids with kratom. The potential for kratom helping with opioid use disorder was recognized by the U.S. Congress in its FY2021 Appropriations legislation.

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[i] https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1013.htm
[ii] https://www.govinfo.gov/content/pkg/FR-2016-08-31/pdf/2016-20803.pdf
[iii] https://www.americankratom.org/images/10_FDA_Fails_to_Follow_the_Science_-_Babin_-_August_2018.pdf
[iv] See pages 74-87: https://www.fda.gov/files/drugs/published/Adverse-event-reports-for-Kratom-involoving-death.pdf
[v] https://www.dea.gov/drug-scheduling
[vi] https://pubmed.ncbi.nlm.nih.gov/29949228/
[vii] https://pubmed.ncbi.nlm.nih.gov/30039246/