



**BRIEFING MEMORANDUM
THE KRATOM CONSUMER PROTECTION ACT**

Kratom has been safely used for centuries in Southeast Asia by indigenous populations where kratom grows. Chewing on the leaves for an energy boost and pain relief, field workers claimed the benefits of kratom allowed them to be more productive and it provided pain relief from the rigors of daily labor work. In Southeast Asia, researchers have documented there has never been an overdose death related to the consumption of kratom.ⁱ

Kratom has become controversial due to the concerns of the U.S. Food and Drug Administration (FDA) over the past decade as they have addressed concerns about reports of deaths associated with kratom. The FDA has concluded that kratom has killed 44 people, and is a dangerous opioid just like heroin, morphine, and fentanyl.

In 2009, a cluster of nine deaths were reported in Sweden over a twelve-month period from consuming a kratom product sold in the internet known as “Krypton.” That led to the FDA sending alerts around the country, and 6 states enacted bans on kratom product sales between 2009 and 2016. In addition, the FDA imposed an Import Alert on kratom in direct response to these deaths.

However, when the nine deaths in Sweden were analyzed, researchers found those deaths were actually caused by the intentional adulteration of the kratom powder in Krypton with a toxic dose of *O*-desmethyltramadol, an opioid analgesic and the main active metabolite of tramadol.ⁱⁱ While this undermined the basis for imposing the Import Alert, the FDA has declined to withdraw it.

The FDA claims of deaths associated with kratom are essential to meet the statutory criteria under the federal Controlled Substances Act (CSA) to show that kratom poses a threat to public safety. The FDA must also prove kratom is dangerously addictive and the alkaloids in the kratom plant have no approved medical use.

Any death that occurs in the kratom consumer population is a tragedy, and there is a compelling need for appropriate regulation on what is currently the “wild west” for kratom products that are spiked with deadly adulterants that have killed people. The FDA has elected the option to classify kratom as a Schedule I narcotic that would effectively strip the freedom of the more than 16 million kratom consumers in the United States to make informed decisions on their health and well-being.

The American Kratom Association supports a more reasonable solution where the FDA would provide specific regulatory controls on the manufacturing standards for kratom products, including (1) barring the addition of any dangerous adulterant ingredient; (2) restricting any

enhancement, concentration, or synthetization of the 7-hydroxymitragynine alkaloid content greater than levels that occur in the natural plant; (3) requiring clear labeling of all ingredients; and (4) limiting the sale of kratom products to anyone under the age of 18. This is the framework of an initiative of the American Kratom Association known as the Kratom Consumer Protection Act (KCPA) that has been enacted in Utah, Georgia, and Arizona. This legislation is also under consideration in another dozen states in the current legislative session.

At the heart of the issue is adherence to good science and the dissemination of accurate information about kratom, standards which the FDA has refused to accept.

When the FDA made its claims about 44 “kratom-associated” deaths over a five-year period around the globe, it raised significant concerns of many scientists who have specialized in kratom research.

To independently evaluate the claims by the FDA, the AKA commissioned a review of each one of those 44 deaths, and the investigator found that 43 of those deaths were due to polydrug use or adulterated kratom products, not the pure kratom plant. On the remaining death, there was not sufficient information or blood work available to draw any conclusion by anyone, including the FDA.ⁱⁱⁱ

The FDA conclusions on “kratom-associated” deaths, to illustrate, in one case involved a man who was shot in the chest at close range and died from internal injuries from the bullet hitting vital organs. The coroner properly concluded it was a death from a gunshot wound. The toxicology report found, like millions of other Americans, the decedent had used kratom that same day. The FDA then called it a “kratom-associated” death.

The National Institute on Drug Abuse, known as NIDA, conducted their own review of the FDA claimed deaths. NIDA published its conclusions on September 20, 2018 finding that all of the deaths were from polydrug use or adulterated kratom products.^{iv} There was only one death where the FDA claimed was a death where kratom was implicated as the only substance in the blood report, but NIDA was unable to examine that because the FDA could not produce any records on either the toxicology data or the medical reports of the decedent.

There is also another category of kratom deaths that should be examined. There have been reports that a death was caused by kratom because no other substance was found in the blood report of the decedent.

It is critical for deaths reportedly attributed to kratom to be carefully examined in the midst of the disinformation campaign by the FDA. Family members have a right to know exactly what caused a death with the use of investigatory reports **and** adequate technology to determine the true cause of every death.

A commentary was published in the New England Journal of Medicine in January 2019 that examined reports of 15 deaths in Colorado associated with kratom -- where 4 of those deaths

were reported by medical examiners and coroners to be caused kratom toxicity given it was the only substance detected in the toxicology reports.^v A group of researchers and medical professionals examined each of those 4 deaths that purportedly were exclusively due to a kratom overdose and found that 3 of the 4 deaths actually were the result of polydrug use, and the remaining death had no blood data even available from which a valid conclusion could be drawn.

This commentary focused on the fact these medical examiners and coroners did not have the technology and/or the right kind of analytical equipment needed to accurately determine the true cause of those deaths, perhaps because of budget restraints in the jurisdictions where they worked. Outdated or inadequate technology should not be allowed to taint conclusions on the cause of any reported deaths, including kratom.

This issue was also highlighted in the recent “CDC Report on Unintentional Drug Overdose Deaths with Kratom Detected (2019).”^{vi} Contrary to most of the hyped media headlines that incorrectly highlighted a purported increase in kratom deaths, it actually revealed that documentation of postmortem toxicology testing protocols is needed to further clarify the extent to which kratom contributes to fatal overdoses.

A proper understanding of the type and number of substances detected in the postmortem toxicology screens of decedents would allow for the identification of substances that actually cause a death and, importantly, exclude substances that do not. The CDC report showed that in death cases where kratom was found in a toxicology screen, fentanyl and fentanyl analogs were listed as the “cause of death for 65.1% of kratom-positive decedents and 56.0% of kratom-involved decedents.” Heroin was the second most frequent substance listed as the cause of death in kratom-positive decedents at 32.9%; benzodiazepines at 22.4%; prescription opioids at 19.7%; and cocaine at 18.4%. Under current protocols, multiple substances can be listed as a cause of death, therefore the substances are not mutually exclusive and a primary cause need not be identified. However, the potentially deadly toxicity profiles of fentanyl, heroin, benzodiazepines, prescription opioids, and cocaine are well-documented in published literature whereas the toxicity of kratom is not.

Here are the top-line conclusions that the CDC data actually supports as set forth in a Response to the CDC report^{vii}:

- The 91 “kratom-involved” deaths found multiple substances detected in “almost all decedents,” with fentanyl and fentanyl analogs as the most frequently identified co-occurring substances. These findings support the NIDA review of the FDA-claimed 44 kratom deaths, which concluded that “most kratom associated deaths appear to have resulted from adulterated products or taking kratom along with other potent substances.” The public policy mandate from this data is that the FDA should use its existing statutory authority to interdict manufacturers and marketers who deliberately adulterate kratom products with dangerous substances that cause death.

- Medical examiners and coroners are incorrectly reporting kratom-involved deaths as deaths caused by kratom. The lack of a consistent postmortem testing protocol to accurately pinpoint the extent kratom contributes to a death has exacerbated the grossly inaccurate and overstated FDA public narrative on the potential dangers of kratom. There is a critical need for the publication of standards for postmortem toxicology testing to avoid inaccurate findings by medical examiners and coroners, such as kratom allegedly being the cause of death and comprehensively identify substances that are not detected in routine testing for drugs of abuse.
- The report accurately states that “kratom is not an opioid” and notes that nonopioid substances are included in the State Unintentional Drug Overdose Reporting System (SUDORS), but the system records all substances testing positive on postmortem toxicology testing (including those that did and did not contribute to death). In fact, kratom critically differs from conventional opioids on the two signature features of conventional opioids that contribute to the opioid epidemic: It does not cause the powerfully addicting brain rewarding effects or the lethal respiratory depressing effects of conventional “narcotic-like” opioids.”^{viii ix} However, the repeated claims by the FDA that kratom is an opioid and advisories claiming kratom has caused overdose deaths have clearly contributed to incorrect determinations by medical examiners and coroners that the presence of even the tiniest amount of kratom in postmortem toxicology screens was the cause of a death.

Former FDA Commissioner Scott Gottlieb also told the public in February 2018 that the agency had conclusive proof that kratom was dangerously addictive because it binds to the mu-opioid receptors in the brain just as classic opioids do. While kratom does bind to that same receptor, the difference between a classic opioid like fentanyl, morphine, and heroin is that they have what is characterized as having full agonist effects where they attack the respiratory system of the user. Kratom is only a partial agonist and has no measurable effects on the respiratory system. There are a number of other common and well-known substances that also bind to the mu-opioid receptors but are partial agonists like kratom, including Naloxone, the anecdote for an opioid overdose, St. John’s Wort, and cheese.

NIDA commissioned an intramural study on kratom to test the FDA’s claim that kratom had a high addiction liability, and the National Institutes of Health also issued a grant to test that claim. Both were animal studies that are the gold standard for assessing addiction liability of substances.

The NIH funded study was published in June 2018 and concluded (1) that **kratom is not dangerously addictive** and does not act in the same way as classic opioids in suppressing the respiratory system of the consumer, and (2) that the **alkaloids in kratom actually have the effect of reducing the cravings in the animals for morphine.**^x That confirmation explains why so many opioid addicts are attempting to use kratom to reduce their opioid use or wean off of opioids entirely, and why kratom shows up in tox screens of opioid overdose victims who apparently had turned to kratom for its potential benefits in fighting their opioid addictions..

The second intramural NIDA study confirmed that kratom **is not dangerously addictive** and concluded that **more research needed to be done on the value kratom could have as an alternative pain management therapy to opioids.**^{xi} A \$3.5 million grant for that purpose was issued to the University of Florida in December 2018.^{xii} NIDA is also reviewing additional grants applications to study the beneficial effects of kratom. The U.S. House of Representatives included language in its FY 2020 Appropriations Bill that specifically addresses the need for additional research on kratom as follows:

(Page 99) Barriers to Research – The Committee is concerned that restrictions associated with Schedule I of the Controlled Substances Act effectively limit the amount and type of research that can be conducted on certain Schedule I drugs, especially marijuana or its component chemicals and new synthetic drugs and analogs. At a time when we need as much information as possible on these drugs to find antidotes for their harmful effects, we should be lowering regulatory and other barriers to conducting this research. The Committee directs NIDA to provide a short report on the barriers to research the result from the classification of drugs and compounds as Schedule I substances.

(Page 100) Kratom. — The Committee requests that NIH expand research on all health impacts of kratom, including its constituent compounds, mitragynine, and 7-hydroxymitragynine. The Committee is aware of the potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids.

(Page 124) Kratom. — The Committee notes that little research has been done to date on natural products that are used by many to treat pain in place of opioids. These natural plants and substances include kratom and cannabidiol (CBD). Given the wide availability and increased use of these substances, it is imperative to know more about potential risks or benefits, and whether or not they can have a role in finding new and effective non-opioid methods to treat pain. The Committee recommends an additional \$3,000,000 for this research and directs AHRQ to make center-based grants to address research which will lead to clinical trials in geographic regions which are among the hardest hit by the opioid crisis.^{xiii}

Despite the mounting scientific and policy evidence that contradicts its position, the FDA remains resolute in its solution to have the Drug Enforcement Administration add kratom to Schedule I. The required science simply is not available to meet the evidentiary burden for proving kratom should be scheduled. The DEA withdrew the FDA's recommendation to schedule kratom 2016 when the FDA first made its request and has taken no action since October 2017 when the FDA submitted their second request.

The DEA typically acts on scheduling requests within 90 days, and the outlier might be a 120-day review. Today, more than 18 months after receiving the request, the DEA has not accepted FDA's reasoning for scheduling kratom.

The final requirement for scheduling is that kratom has no FDA approved medical use. That is because kratom is properly classified as a dietary ingredient or herbal supplement that is not subject to a new drug application procedure. It is possible that kratom's alkaloids can have potential medical benefits and this plant will be synthesized in a way where a new drug application is warranted. But in its natural state there is no basis for anyone to seek such an approval.

The framework of the Kratom Consumer Protection Act, and an appropriate FDA action to publish standards for manufacturing kratom products as it does for other similar products, would substantially reduce dangerous adulteration of kratom products and provide needed layers of protection for consumers to assure pure and safe kratom products are available to consumers.

That is the right public policy to protect consumers and balance their right to make informed decisions about dietary ingredients and herbal supplements they choose to use.

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