



**FDA Death Data on Kratom Linked to Adulterated Products,  
not the Kratom Plant Itself**

**American Kratom Association Demands a Recall on Scheduling Recommendation  
and Complete FDA Re-evaluation of Kratom Science**

**WASHINGTON, DC – September 24, 2018** – The American Kratom Association (AKA) today called upon the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) to recall its recommendation to make the botanical a Schedule I drug after the National Institute on Drug Abuse (NIDA) confirmed that it is the illegal adulteration of kratom with other substances that is responsible for the deaths cited by the FDA in its recommendation. Following confirmation from NIDA last week that it is the deliberate and illegal adulteration of kratom that has resulted in the deaths claimed by FDA, [AKA requested that HHS Assistant Secretary of Health Brett Giroir, M.D.](#), immediately recall the scheduling recommendation from the U.S. Drug Enforcement Administration (DEA) and direct the FDA to implement a complete reevaluation of the science on kratom.

NIDA's conclusion came after a two-month review of the scientific data on the safety of kratom and prompted the following statement:

*“In 2017, the Food and Drug Administration (FDA) began issuing a series of warnings about kratom and now identifies at least 44 deaths related to its use, with at least one case being investigated as possible use of pure kratom. Most kratom associated deaths appear **to have resulted from adulterated products (other drugs mixed in with the kratom) or taking kratom along 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.**”* (emphasis added)

“There is not a single instance in the history of DEA scheduling where a substance was banned because it had been deliberately adulterated with a separate deadly drug,” wrote Dave Herman, Chairman of the AKA, in a letter to Assistant Secretary Giroir, calling upon HHS to formally request the recall of the kratom scheduling recommendation from the DEA. “Congress never intended for the Controlled Substances Act (CSA) to be used to ban substances that were deliberately adulterated with other toxic or deadly drugs that cause deaths, and nothing in the statute or the legislative history permits this abuse of discretion in the scheduling recommendation initiated by the FDA.”

NIDA reports the FDA claims that there is at least one case reported by the FDA that is “being investigated as possible use of pure kratom.” Herman strongly challenged this claim saying, “the FDA made that statement on its investigation into a pure kratom death on February 6, 2018, and now more than 7 months later there is not any corroborating evidence produced by the FDA to validate that claim.”

In his letter, Herman strongly objected to FDA’s public attacks against kratom and its sustained disinformation campaign alleging deaths associated with kratom. “The FDA appears to be deliberately violating the provisions of the Information Quality Act by widely disseminating incomplete, inaccurate, biased, and unreproducible information to local medical examiners and coroners, incorrectly blaming kratom for deaths that were actually caused by polydrug use or deliberately adulterated kratom products.

“In extrapolating the data to a faulty conclusion—in an effort to place kratom as a Schedule I substance under the CSA — the FDA’s logic would require the prohibition of caffeinated products, including even Coca-Cola and coffee, because someone deliberately laced those products with ‘potent substances, including illicit drugs, opioids, benzodiazepines, alcohol, gabapentin, and over-the-counter medications, such as cough syrup.’ In fact, it could be applied to anything, even broccoli, once it has been contaminated with a dangerous substance,” Herman concluded.

**NIDA’s conclusion following its extensive review of whether a person can overdose on kratom clearly documents that pure or natural kratom does not present a public health risk under the criteria for scheduling set by the CSA,** and the FDA already has ample statutory authority to seize all dangerous adulterated and counterfeit products.

[The AKA announced its recommended standards for kratom manufacturers and vendors](#) on July 18, 2018 to promote self-regulation in the kratom industry so that consumers could identify vendors who meet or exceed FDA good manufacturing processes.

#### **ABOUT AKA**

The American Kratom Association (AKA), a consumer-based non-profit organization, advocates to protect the freedom of consumers to safely consume natural kratom as a part of their personal health and well-being regimen. AKA represents the nearly 5 million Americans who consume kratom safely each year. [www.americankratom.org](http://www.americankratom.org)

#### **MEDIA CONTACT**

Benjamin May, 202-413-0119 -- [bmay@policyimpact.com](mailto:bmay@policyimpact.com)