WASHINGTON, DC – July 31, 2018 – Concerned that the National Institute on Drug Abuse (NIDA) may be under political pressure by the Food and Drug Administration (FDA) in its characterization of kratom, after NIDA removed information regarding the natural botanical’s safety from its official government website, Dave Herman, chairman of the American Kratom Association (AKA), asked NIDA Director Dr. Nora Volkow to “stand as an independent voice, basing its conclusions on science.”

In a letter sent today, Herman and the AKA expressed concern that “NIDA may be under pressure from purely political requests or demands being made by the FDA related to kratom that are not supported by the science, including research done by NIDA and its contractors.” The letter references ample research, including studies released as recently as June 14, in conjunction with The College on Problems of Drug Dependence (CPDD) at its 80th Annual Scientific Meeting in San Diego, California.

“Deviation from this body of scientific evidence to accommodate a purely political agenda by the FDA on kratom would undermine public confidence in the independence NIDA is entrusted with in protecting the integrity of the regulatory review processes,” Herman wrote. “The scientific evidence is overwhelming that adopting the FDA’s current bias against kratom will create a more dangerous safety signal where kratom users will be forced to use either more dangerously addictive and potentially deadly opioids or to turn to the black market where the adulterated kratom products will result in even more deaths.”

Herman’s letter was in reaction to NIDA’s abrupt decision on Monday, July 30 to take down information on its website that natural kratom did not lead to deadly overdoses, as suggested by the FDA. In recent months, NIDA has changed its position that, “Kratom by itself is not associated with fatal overdose, but commercial forms of the drug are sometimes laced with other compounds that have caused deaths,” to read: “Kratom by itself is not associated with fatal overdose, but some forms of the drug packaged as dietary supplements or dietary ingredients can be laced with other compounds that have caused deaths.” This information was removed suddenly after the AKA referenced NIDA’s reaffirmed and clarified position in a media release early Monday morning.
In removing the information from its website, NIDA’s public affairs office incorrectly asserted that the information referenced in the AKA media release as being updated “had not been changed since the fact sheet was developed in February 2016.” The truth, as Herman points out in his letter to Director Volkow, is that an all-new section header on NIDA’s Kratom Fact Sheet to reiterate that natural kratom has not been a cause of death was a “material change,” along with “a significant change in the language” that indicates NIDA reviewed and reaffirmed its findings that natural kratom has never been associated with deadly overdoses. According to the AKA, these changes were significantly important in light of FDA’s repeated mischaracterizations of the risks of kratom since its November 14th, 2017 Advisory.

Particularly troubling to the AKA was that in taking down the information, the NIDA Press Office referenced FDA intervention, maintaining that it “consulted with the FDA regarding the overdose information on the Fact Sheet” and reported the “FDA is concerned that there have been deaths related to kratom that could be overdoses; while acknowledging that many of the products are adulterated, and many deaths result from mixing kratom with other drugs.”

The AKA has long encouraged the FDA to enforce the law against those who lace or contaminate kratom but to allow the millions of Americans who choose to use natural kratom for health and wellness to maintain access to the natural botanical supplement.

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 comply with FDA good manufacturing processes.

ABOUT AKA

The American Kratom Association (AKA), a consumer-based non-profit organization, focuses on setting the record straight about kratom and gives a voice to those who are suffering by protecting their rights to possess and consume safe and natural kratom. AKA represents millions of Americans, each of whom has a unique story to tell about the virtues of kratom and its positive effects on their lives. www.americankratom.org.

MEDIA CONTACT

Benjamin May – bmay@policyimpact.com – 202.413.0119