

POLICY BRIEF

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The FDA Bias Against Dietary Supplements and Botanicals (and Kratom)

The FDA has waged a regulatory war on dietary supplements and botanical products for decades. In 1994, the FDA lobbied the Congress to ban dietary supplements and vitamins claiming huge numbers of adverse medical events and dozens of deaths from the use of dietary supplements and vitamins.

The FDA solution: Ban all dietary supplements and botanicals and force each of those products to be subject to the new drug application process (a process that takes an average of 10 years and costs as much as \$5 billion).

In response, the U.S. Congress rejected the FDA's claims against these products and unanimously voted to enact the Dietary Supplement Health & Education Act (DSHEA) in 1994 that severely limited the FDA's regulatory control over dietary supplements, dietary ingredients, and vitamins.

Research demonstrates the supportive role micronutrients like vitamins A, C, & D, and zinc can play in reducing the risk of acute infection and/or enhancing the body's response to vaccinations, and, when supplemented in an individual's diet, potentially shortening the duration and severity of disease.ⁱ

Recent surveys show that as consumers continue to confront the devastating public health effects of COVID-19, Americans are focused more than ever on their overall health and well-being. As evidenced in the survey, dietary supplements continue to play a critical role in the lives of most Americans, and even more so in light of the ongoing health crisis. More than three quarters of Americans report taking dietary supplements

KEY FINDINGS

Congress had to reign in the FDA in 1994 when the Agency claimed dietary supplements and vitamins were causing adverse medical events and deaths. The DSHEA Act imposed significant restraints on the FDA's regulatory authority on those products.

Dietary supplements and vitamins play an important role, particularly during the pandemic, in helping consumers maintain their health and well-being.

FDA has waged a regulatory war against kratom filled with inaccurate, distorted, and false information since 2012, and that has led to 6 states banning kratom.

Big Pharma has little interest in developing a kratom drug unless the FDA can ban consumer access to the natural plant.

The FDA's propaganda campaign against kratom has misled state and local government jurisdictions in an effort to enact local bans. Regulation is needed to protect consumers from adulterated kratom products, not a ban.

and the overwhelming majority of supplement users, 83 percent, believe these products play an important role in helping to support health and wellness during COVID-19.ⁱⁱ

Despite this clear acceptance by consumers of these kinds of products, the FDA remains hostile to the dietary supplement industry and uses every tool it can to create barriers to consumer access.

Kratom is the latest target of the Agency to ban consumer access and force this plant to be synthesized into a chemical formulation for submission as a new drug. The FDA knows there is economic interest by pharmaceutical companies to aggressively pursue a kratom new drug application (NDA) as long as consumers can easily access natural kratom products.

The FDA does not make scheduling decisions on any substance, the Controlled Substances Act (CSA) reserves that authority exclusively for the Drug Enforcement Administration (DEA). The DEA has refused to approve multiple scheduling recommendations for kratom made by the FDA, the most recent of which was submitted in November 2017, more than 3 years ago. If there was a significant safety risk to the American public from the use of kratom, the DEA would have scheduled kratom immediately.

The Impact of the FDA's War on Kratom:

The FDA started a broad-based disinformation campaign against kratom in 2012 to support its overreach of statutory authority by imposing an import alert on all kratom being imported into the United States – an authority granted by Congress to restrict specific importers of contaminated or adulterated products. Between 2012 and 2016, six states reacted to the FDA propaganda campaign against kratom by enacting bans (Indiana, Arkansas, Wisconsin, Vermont, Rhode Island, and Alabama).

The FDA has continued to disseminate inaccurate, outdated, incomplete, and completely false information about kratom to internet health information services (WebMD, Mayo Clinic, HealthLine, etc.), state pharmacy boards, state health departments, medical associations, coroners and medical examiners, addiction recovery providers, and anti-drug advocacy groups.

The FDA falsely claims kratom is an opioid despite the fact the plant is from the coffee family, has no significant addiction liability, its alkaloids do not act as opioids, does not produce a euphoric reinforcing high like opioids, and does not cause overdose deaths.

Conclusion:

While the FDA attempts to ban consumer access to kratom products, it is saving lives. In the midst of the pandemic, where social isolation, increased depression, and spiking opioid overdoses plague us, the FDA should be doing everything it can to encourage products that reduce harm.

It is critically important for states to enact the Kratom Consumer Protection Act that stops dangerous adulteration, bans synthesizing kratom's alkaloids; requires labeling so consumers know what is in a kratom product; and sets an appropriate age limit to purchase kratom products.

ⁱ <https://www.crnusa.org/newsroom/updated-noted-physician-touts-nutritious-critical-role-supporting-immune-health-congressional>

ⁱⁱ <https://www.crnusa.org/newsroom/dietary-supplement-usage-dramatically-during-pandemic-new-ipsos-crn-survey-shows>