AMERICAN KRATOM ASSOCIATION

POLICY BRIEF

February 2024

FDA tells Federal Court it has "not yet determined if kratom is dangerous."

Judge forces the FDA to admit its evidence and data on kratom does not support multiple past and current claims the Agency has made about kratom being dangerous.

The FDA has repeatedly made claims over the past 12 years that kratom is a dangerous substance that should be classified as a Schedule I substance under the federal Controlled Substances Act ("CSA"). Yet, when called by a Federal Judge to present witnesses and testimony under oath in a case in the Southern District of California at a Hearing on February 8, 2024, on whether kratom is dangerous, the FDA refused to attend the Hearing or even provide under oath any documents or testimony to the Court.[i]
The explanation provided by the U.S. Attorney to the Court explaining the FDA's decision stated the following:

> **They [FDA] have refused to provide us with witnesses or documents to support our position . . . The reason they gave was that they have not yet made a determination regarding whether kratom is dangerous."**

The FDA has repeatedly made claims on its website and in recommendations to the Drug Enforcement Administration ("DEA") to schedule kratom's constituents as Schedule I substances. The first rejection was issued by the DEA on October 13, 2016 [ii] with a finding that the evidence and data was insufficient to justify scheduling.

Then, on August 16, 2018, the Assistant Secretary of Health at the US Department of Health and Human Services issued a scathing withdrawal letter on the FDA's second attempt to schedule kratom's constituents under the CSA.[iii] When confronted by former FDA Commissioner Scott Gottlieb on the decision. Dr. Giroir called the FDA recommendation "embarrassingly poor evidence and data".[iv]

Finally, the FDA took its crusade to ban kratom to the international stage where the standards of scheduling are less rigorous than under the federal CSA. On December 21, 2021, the WHO's Expert Committee on Drug Dependence unanimously concluded there was "insufficient evidence" to justify international scheduling of kratom and refused to even authorize a critical review.[v]

[i] Case 3:23-cr-00179-TWR Filed 12/06/23 Page ID.1032 Exhibit 6; United States of America, Plaintiff, v. Nine2Five, LLC (1) Sebastian Guthery (2), Defendants
[ii] https://www.federalregister.gov/documents/2016/10/13/2016-24659/withdrawal-of-notice-of-intent-to-temporarily-place-mitragynine-and-7-hydroxymitragynine-into
[iii] https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/60145eab6df59e7e36a7cfc1/1611947693695/dhillon8.16.2018-response-letter-from-ash-radm-giroir.pdf
[iv] https://twitter.com/DrGiroir/status/1395874443726102533
[v] Expert Comm. on Drug Dependance, Summary of Assessments, Findings, and Recommendations of the 44th ECDD (2021), available at https://cdn.who.int/media/docs/default-source/controlled-substances/44ecdd_unsg_annex1.pdf.