

EXHIBIT 48



Herbal drug kratom faces uncertain legal future, despite public outpouring

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Kratom, a leafy-green herbal supplement used by an estimated 3 to 5 million Americans, has inspired tens of thousands of responses in a public comment period over its possible controlled substance designation by the Drug Enforcement Agency.

The substance is derived from a Southeast Asian plant that belongs to the same family as coffee. It's ground down into an earthy-green powder and then put inside capsules or mixed into a liquid and sipped like tea. Depending on how much is ingested, it can act as a stimulant or a painkiller.

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Kratom has been used for hundreds of years in places like Thailand, but only within the last few years has it become popular in the U.S. It is widely available online and in convenience stores.

It grabbed the attention of the DEA when calls to poison control centers increased ten-fold from 2010 to 2015. Most callers complained about effects such as increased heart rate, agitation, drowsiness, nausea, and hypertension. One death was reported in a person who was also on an antidepressant and a mood stabilizer. So far, in 2016, the American Association of Poison Control Centers has received around 480 calls about kratom. (For context, critics cite that the center has received more than 10,000 calls just this year for laundry detergent pods.)

In Illinois, where earlier this year the federal government confiscated hundreds of thousands of dollars of kratom, the state's poison control center has received 24 calls so far this year, in comparison with five in 2015. For perspective, there have been 1,772 calls for prescription opioids in 2016 so far.

Michael Wahl, the medical director of the Illinois Poison Center said most of the calls came from hospital emergency centers where users experienced more serious effects like hallucinations, seizures, and withdrawal from the plant.

In August, in response to the uptick in calls to poison control centers, the DEA announced emergency scheduling of the legal drug, which would have temporarily made kratom a Schedule I substance like heroin, banning the substance and bypassing the normal process.

However, pushback from the public and members of Congress resulted in an unprecedented reversal. The DEA **withdrew the immediate scheduling**, and opened a public comment period that ended Dec. 1.

The DEA **received some 23,210 comments** online, an abnormally high amount, according to DEA spokesperson Melvin Patterson. He said all comments will be taken into consideration in the search to find out which benefits, if any, kratom provides. Personal stories offered by commenters could help the DEA make a decision despite a lack of research on and knowledge of the drug's effects.

Dr. Richard Clark of U.C. San Diego's toxicology department says our lack of knowledge is exactly why we should be cautious. "The most educated way to approaching it is, if we don't know much, we ought to be careful, and maybe banning it is the right way to go so it doesn't hit the streets full force," Clark said.

Clark is concerned about how the herb affects our brain, and in particular how it interacts with our brain's opioid receptors. "We know that most drugs that affect those receptors can build up tolerance and dependence, and there are a couple cases that I've seen that suggest that people can get dependent and addicted on kratom."

Andrew Turner, a Maryland resident who became active in efforts to keep kratom legal, will be personally affected by the DEA's decision. He spent more than nine years in the U.S. military, serving in Iraq, Jordan, and South Korea. His experience landed him a long list of ailments like severe PTSD, cluster headaches and degenerative disc disease.

"All these things work against me, and it makes life hard to deal with,"Turner said.

He received painkillers and other pharmaceuticals from the Department of Veterans Affairs, but found that the prescription drugs did not help him, and the side effects were damaging.

After finding kratom about two years ago he hasn't taken anything else for his pain, aside from the occasional Tylenol.

"Kratom doesn't fix the symptoms but it gives me an overall sense of well-being," Turner said. "The ticks go away, my speech is much more eased. It'd be awesome if it were a magical cure; it isn't, but it helps."

Along with the comments, the DEA will receive analysis from the FDA, which will assess the drug based on eight factors. Patterson says the decision will be largely dependent on this analysis.

An advocacy group called the American Kratom Association conducted a study using the same eight-factor analysis, headed by a researcher previously with the National Institute on Drug Abuse (NIDA). It concluded that there was "insufficient evidence for the U.S. Drug Enforcement Administration (DEA) to ban or otherwise restrict the coffee-like herb kratom under the Controlled Substances Act."

Once the DEA receives the FDA assessment and goes through the public comments, there are a couple of possible outcomes: it could return to emergency scheduling putting kratom into Schedule I immediately; the DEA could go through routine scheduling opening up another public comment period; or scheduling could not be pursued at all.

Turner, the military veteran, knows kratom has to go through the DEA's process and welcomes regulation, but he doesn't believe it's being given a fair assessment.

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