

# EXHIBIT 52



# HHS recommended that the DEA make kratom a Schedule I drug, like LSD or heroin

Nation Nov 10, 2018 12:49 PM EST

WASHINGTON — The Department of Health and Human Services has recommended a ban on the chemicals in **kratom** that would make the popular herbal supplement as illegal as heroin or LSD, according to **documents** obtained by STAT.

HHS asserted in a letter to the Drug Enforcement Administration that two chemicals in kratom should be classified as Schedule I substances, meaning that the chemicals have "a high potential for abuse" and that there is "no currently accepted medical use" for them. The letter was accompanied by a supporting analysis.

Should the DEA make such a ruling, anyone who buys, sells, or uses the substances might face steep punishments, like prison sentences, and anyone who wants to do research with the chemicals would need to obtain special permission from the the DEA. Specific penalties would depend on state and federal laws that are often related to the DEA's scheduling decisions — so possession of kratom might be treated differently than LSD, for example.

In interviews with STAT, several scientists expressed concerns that such a ban would stifle research on chemicals that could be developed into alternatives to the addictive prescription opioids that kill tens of thousands of Americans each year. They said banning kratom would harm people who are **currently using the substance**.

## READ NEXT: FDA calls kratom an 'opioid' and warns against using the supplement

People have been using kratom, a plant from Southeast Asia, to treat pain and other conditions, and to wean off opioids. It is not approved by the Food and Drug Administration, and that agency has led an aggressive crackdown on the plant, halting some imports and reprimanding companies for claiming that the substance has medical benefits.

The recommendation in the documents is in keeping with past public statements from leading federal officials, including FDA Commissioner Scott Gottlieb, but it is the first indication of the agency's position on scheduling the chemicals in kratom. Gottlieb has said that **kratom is "an opioid"** and has been "associated" with dozens of deaths.

"Kratom should not be used to treat medical conditions, nor should it be used as an alternative to prescription opioids," Gottlieb said in a statement in February. He added, "There is no evidence to indicate that kratom is safe or effective for any medical use."

Now, it's up to the DEA to decide whether or not the chemicals should be placed on Schedule 1. DEA spokesperson Katherine Pfaff declined to say when this might happen, and said the process can take "months to years." Members of the public would have some time to appeal the decision, or make comments, before the decision is finalized.

"The medical and scientific evaluation that HHS provides to DEA is a crucial document in the process," Pfaff said.

## READ NEXT: Hidden network of kratom devotees tries to keep the supplement safe — and legal

DEA spokesperson Rusty Payne declined to say whether the agency typically follows HHS recommendations like the one in the documents STAT obtained. He said it would take days to pull those statistics. But Payne said that HHS does have the power to prevent a substance from being scheduled. "If they say no, we're bound by that," Payne said.

Scientists and kratom advocates warn that banning kratom outright will only harm people, especially people who are using kratom instead of stronger painkillers.

"I have major concerns about just pulling the rug out from under tens of thousands of people who are using this to support their health, especially in the case of people who are using it to stay off of more dangerous opioids," said Andrew Kruegel, a Columbia University associate research scientist in chemistry, who has studied kratom. A Washington-based group that opposes a kratom ban, the Drug Policy Alliance, paid to fly Kruegel to D.C. twice this year to discuss this issue with Congress, he said.

Some states have already banned kratom, but it's currently legal at the federal level. It's sold in different forms, **including dry powder and capsules**. According to the American Kratom Association, millions of Americans use the substance. Pete Candland, executive director of the association, said this is the organization's "best estimate," but did not provide a specific source.

The federal government has been contemplating tougher regulation for years. In 2016, the DEA **tried to ban** the chemicals in kratom, but **reversed course** after severe backlash from kratom users and **members of Congress**. DEA then solicited the advice of the FDA on how to proceed.

STAT obtained the document through a Freedom of Information Act request sent in March to the DEA. The DEA routed the request to HHS. HHS provided a document that appears to be missing some pages but included the department's recommendation.

An HHS spokesperson declined to provide the complete document and said the original document was provided to STAT in error.

"This document was inadvertently disclosed and should have been withheld as it is part of a pre-decisional, deliberative process rightfully protected by the Freedom of Information Act and implementing regulations," said HHS spokesperson Caitlin Oakley. "That deliberative process is still ongoing, and therefore we have nothing further to add."

In the letter dated Oct. 17, 2017, HHS sent a recommendation, which, according to the letter, is supported by the FDA as well as the National Institute on Drug Abuse at the National Institutes of Health. The recommendation: put the chemicals in kratom on Schedule 1.

#### READ NEXT: Poison control centers are getting a surge of calls about 'natural' painkiller kratom

Not only would the move make it illegal to buy, sell, or use the substances, but it would also make it more difficult for researchers to study kratom, because they would need to obtain permission from the DEA to work with the substance, scientists said.

"Me and my colleagues and other collaborators who are already working on it would probably find a way to continue, but anyone new who was looking at that would probably say, 'forget it,'" Kruegel said.

Payne said that 692 scientists currently have permission to do research on Schedule 1 substances, and that about three-quarters of them are working with marijuana or related substances.

"I understand that people would rather not have to deal with bureaucracy, but it's our job to keep the public safe, and you can't just have controlled substances running around, especially Schedule 1, being handled by non-registrants with no oversight," Payne said.

Dr. Alicia Lydecker, an emergency physician at Albany Medical Center, said that it's important to keep researching kratom because the substance might be able to provide pain relief in a safer way than prescription opioids.

"Limiting research on this could be kind of limiting or restricting a potential useful therapy for a huge problem that's going on right now," Lydecker said.

Some research conducted on rats, which was published after HHS sent its memo to DEA, **provides evidence** that some of the chemicals in kratom carry little risk for addiction. Two **studies published this summer** showed that one of the chemicals in kratom that HHS recommended scheduling, mitragynine, was not abused by the rats. Both of the studies were funded in part by the NIH.

**READ NEXT: Kratom with a side of cheesesteak: A sub shop's vending machine draws customers desperate to kick opioids**

While the FDA has been clear about its opposition to kratom for some time, it has not previously publicly supported a scheduling decision.

In February, the FDA warned that kratom might kill people. They released information about some of the 44 "reported deaths" that were "associated with the use of kratom," in Gottlieb's words.

But many of those individuals were also using other drugs, according to the FDA's own data. One person fell out of a window. Another was shot, **The Huffington Post reported**.

"It's really hard to create a consistent picture of what are the causes of death," said Oliver Grundmann, a professor at the University of Florida's College of Pharmacy. He said that "kratom is not a harmless supplement" and that there are risks to using it, but that scheduling two of the chemicals in it is "not warranted, in my opinion."

Kratom advocates say that FDA is cherry-picking the science, and that evidence exists to support the idea that kratom can help patients.

"[FDA] treated essentially a lot of anecdotal evidence of harm as fact, but is not willing to consider anecdotal evidence of benefit in the same way," said Grant Smith, deputy director of national affairs at the Drug Policy Alliance, which opposes criminalizing kratom.

The scheduling of substances by DEA doesn't always match up with how users are treated by law enforcement.

For example, marijuana is also on Schedule I, but many state have passed laws decriminalizing the use or possession of small amounts.

The American Kratom Association supports regulations for kratom, and potentially a ban on a type of kratom that is modified so it becomes more potent, Candland, the executive director, said.

*This article is reproduced with permission from STAT. It was first published on Nov. 9, 2018. Find the original story [here](#).*

# A free press is a cornerstone of a healthy democracy.

Support trusted journalism and civil dialogue.

**Donate now** →

By — Ike Swetlitz, STAT

---

 @ikeswetlitz