

July 29, 2025

Dear Colleague,

I am writing to warn you about an opioid that few physicians may be aware of. It's called 7-hydroxymitragynine (7-OH).

7-OH is found in trace amounts in the kratom plant leaf. But this is not our focus. Our primary concern is the concentrated form of 7-OH. This is an important distinction. These concentrated 7-OH opioid products are far more dangerous than traditional kratom leaf products.

Concentrated 7-OH products have exploded in popularity in recent years, with vape shops, gas stations and corner stores selling pills, gummies, candies, and even eye-catching products like ice cream cones containing 7-OH. You may also see 7-OH referred to as 7-OHMG, 7-Hydroxy, 7-HMG, or 7. Additionally, some kratom leaf products marketed as "spiked" or "enhanced" may contain 7-OH at a level 500% higher than would be naturally expected in kratom leaf.

Notably, <u>one study</u> in the Journal of Medicinal Chemistry found 7-OH to be 13 times more potent than morphine. Aside from addiction, 7-OH side effects include withdrawal symptoms, insomnia and anxiety, seizures, and fatal respiratory depression. The FDA is seeing increases in adverse events and related reports to poison control and is concerned about the growth of 7-OH product sales nationwide. We have already issued warning letters to several firms for illegally distributing 7-OH products and are working alongside our partners at the DEA to move forward with adding certain 7-OH products to the controlled substances schedules.

Like many physicians, I find it painful to recall the many opioid prescriptions I wrote in the early 2000s for routine procedures, unaware of the high potential for abuse. Our recognition of the abuse potential and our delayed response as a medical community resulted in a national health crisis. Let's not get caught flat footed again. In addition to the FDA's ongoing regulatory activities and education efforts, I appreciate your vigilance on this issue.

For more information, please refer to our new report and educational resources, which can be found at www.fda.gov/7-OH.

Sincerely,

Martin A. Makary, M.D., M.P.H Commissioner of Food and Drugs

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