

7-OH Advocates Respond to HHS Scheduling Announcement

*Despite Zero Confirmed Deaths from 7-OH, Federal Officials
Push Ban While Ignoring Science and Consumer Voices*

[Washington, DC] — **Today, HHS prematurely announced their intent to schedule 7-hydroxymitragynine (7-OH), a kratom-derived compound. The announcement lacks science, disregards how 7-OH is used in the real world, and threatens thousands of American consumers who rely on 7-OH to improve their daily lives. Jeff Smith, national policy director of the Holistic Alternative Recovery Trust (HART), issued the following statement:**

“What facts drove the recommendation today from HHS?

“None. No evidence was presented at today’s press conference. Not a single study. Not one data point specific to 7-OH. The entire event focused on addiction in general, not this compound. If 7-OH posed the kind of urgent danger that would justify emergency action, evidence would have been presented. It was not. When a reporter asked if the government could attribute even a single death to 7-OH, no official was able to do so.

“While stating that doctors don’t know what 7-OH is or how to check for it, HHS also claimed that there is an epidemic of people dying from 7-OH. Where is the data showing this?

“Since today’s announcement did not reference any concrete public health data, we can only conclude that instead of public health being paramount, other interests may be driving policy decisions.

“HHS made clear that the FDA action “is not focused on natural kratom leaf products.” A quick scan of the data leads to the obvious question: Why 7OH instead of Kratom?

- According to the FDA’s own adverse event database:
 - Zero confirmed deaths from 7-OH alone and only three serious adverse events. Two of those involved incidents that happened before today’s tested and standardized products were available.
 - Conversely, the same database confirms 201 deaths from kratom leaf products and in the first quarter of 2025 alone there have been 48 serious adverse events from kratom leaf
- Preclinical studies show that 7-OH is less toxic than mitragynine (pure leaf kratom), does not cause respiratory depression at therapeutic doses, and has a lower dependence risk than opioids.

“Big kratom trade groups have spent years blaming 7-OH for harms caused by their own unregulated products, because it threatens their market share. Last week, one of these groups even paid protestors to stage a demonstration calling for a ban. Today they trotted out a consumer long affiliated with kratom industry leaders to ‘prove’ 7-OH’s harm – and

she admitted she'd never even taken 7-OH but was instead relying on third-hand gossip heard at a vape shop.

"Schedule I was suggested during the press conference. Schedule I is supposed to be reserved for substances with high abuse potential, no accepted medical use, and no safety margin. The public needs to speak up to prevent dramatic regulatory overreach. A ban will push people back toward more dangerous substances, destroy responsible businesses, and cut off access to products that many rely on, as long as they are safe, tested, and clearly labeled.

"The FDA needs to hear from researchers, toxicologists, and addiction science experts – and from the American people. Cutting off access helps no one, but it will hurt many."