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Where is the Crisis? Six Months After FDA, HHS Announced Plans to Schedule 7-OH, Death Toll Remains at Zero

Federal Officials Push Ban While Ignoring Science and Consumer Voices

Washington, DC — Six months after the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) announced their intent to schedule 7-**hydroxymitragynine (7-OH)**, a naturally occurring alkaloid derived from kratom, **the number of confirmed deaths linked exclusively to 7-OH still remains zero**.

Despite repeated claims suggesting imminent danger, **no data has ever been presented** to show that 7-OH poses any public health threat warranting emergency scheduling. Instead, the agencies' actions appear to disregard the lived experiences of thousands of Americans who use 7-OH responsibly to manage pain, improve focus, and support overall well-being.

Jeff Smith, PhD, national policy director of the Holistic Alternative Recovery Trust (HART), issued the following statement:

“What facts drove the recommendation from HHS? None. No evidence was presented in August or over the past 6 months. Not a single independent study. Not one data point specific to 7-OH.

“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 there is an epidemic of people dying from it. Where is the data showing this?

“Let’s be clear: 7-OH is not a public health crisis. According to the Food and Drug Administration’s (FDA) [own Adverse Event Reporting System](#) (FAERS), there have been under 75 adverse events ever reported, despite well over a billion doses consumed nationwide.”

The real public-health danger is coming from unregulated products like [Feel Free](#), which combines kratom and kava into an addictive cocktail that [has caused severe physical and emotional harm to consumers](#), including intense withdrawal, depression, skin deterioration, and emotional instability.

The FDA abandoned its case against Feel Free but continues to pursue 7-OH, despite no FDA-reported deaths, fueling concerns that politics and powerful relationships, including ties to Robert F. Kennedy Jr., are outweighing real consumer protection.

“The fixation on 7-OH is a deliberate distraction from these far more dangerous products flooding the market, many of them marketed without clear warnings and readily available in convenience stores,” Smith said. “Instead of pursuing a misguided ban, regulators should focus on consumer protection through consistent, science-based standards applied equally across all kratom products.”



Smith added that HART continues to call for **evidence-based policymaking and open scientific review** before any action is taken that could harm consumers, researchers, and small businesses operating within the legal botanical products industry.

“The American people deserve transparency, scientific integrity, and consumer choice,” Smith said. “The scheduling of 7-OH is a dangerous precedent. It tells consumers their health takes a back seat to corporate lobbying. It tells researchers their work will be evaluated in the policymaking sphere based on politics, not evidence. And it tells patients seeking safer alternatives that Washington would rather push them into the shadows than allow regulated, legal access.”

About the Holistic Alternative Recovery Trust (HART)

The **Holistic Alternative Recovery Trust (HART)** is a nonprofit policy organization dedicated to advancing safe, evidence-based access to natural alternatives for recovery and wellness. HART advocates for scientific transparency, consumer safety, and regulatory accountability in emerging health and wellness industries.

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7-OH AND KRATOM IN CONTEXT (COMPARED TO REAL DRUG THREATS)

Relative comparison (approximate U.S. 2024/2025 overdose burden):

SUBSTANCE	SHARE OF U.S. OVERDOSE DEATHS (ESTIMATED)	MORTALITY SCALE
Fentanyl & analogs	60%	Catastrophic
Methamphetamine	25%	Severe
Cocaine	18%	Severe
Xylazine/Nitazenes	<10%	Growing
Designer Benzos/Tianeptine	<5%	Emerging
Kratom	<0.05%	Very low
7-OH	<0.01%	Statistically negligible

