Kratom: Evidence, Definitions, and Consumer Safety

Educational Briefing for Policy Makers | International Plant and Herbal Alliance | 2026

Key Scientific Findings at a Glance

1. Natural-leaf kratom, semisynthetic 7-OH products, and fully synthetic analogues are chemically distinct with different risk profiles. Any policy addressing kratom harms should distinguish between them.

2. Natural-leaf kratom does not cause opioid-type respiratory depression, the mechanism behind virtually every opioid overdose death. No fatal kratom-induced respiratory depression has been documented in the scientific literature across an estimated 15 million U.S. users.

3. Deaths attributed to kratom overwhelmingly involve multiple other substances. A 2025 systematic review (Smallets et al., Frontiers in Pharmacology) found confounding substances in 32 of 35 deaths where kratom was detected. The authors noted the 3 remaining cases had weak or inadequate toxicology testing, meaning incomplete testing rather than confirmed absence of other substances.

4. Physical dependence on natural-leaf kratom is real and documented, but addiction is rare. Less than 3% of a Johns Hopkins survey sample of 2,798 regular users met DSM-5 criteria for moderate or severe use disorder.

5. Regulation works. 21 States have enacted Kratom Consumer Protection Act (KCPA) legislation. Rhode Island overturned a kratom ban in 2025, replacing it with the strictest regulatory framework in the country

6. The FDA's own 8-factor analysis (2018 and 2021) found that natural-leaf kratom and mitragynine did not meet criteria for scheduling. The DEA withdrew its 2016 notice of intent to place kratom in Schedule I following review.

The Most Important Distinction in Any Kratom Policy Discussion

Some products sold as 'kratom' are not kratom at all -- they are synthetic or semisynthetic compounds falsely marketed under the kratom name. This distinction is central to any regulatory conversation.

Natural Leaf Kratom	Semisynthetic 7-OH Products	Fully Synthetic Products
▪ Dried/powdered leaf; capsules and plain extracts (KCPA-permitted forms)	▪ 7-OH chemically isolated or concentrated up to 98% from natural leaf	▪ Lab-created compounds not found in the plant
▪ 7-OH at trace levels (<2% of total alkaloids- KCPA limit)	▪ Higher dependence risk, more severe withdrawal	▪ Mitragynine pseudoindoxyl, MGM-15, MGM-16
▪ No opioid-type respiratory depression	▪ Respiratory depression risk in animal studies	▪ Functionally equivalent to synthetic opioids
▪ Centuries of traditional use in Southeast Asia	▪ Often still labeled as 'kratom'	▪ No traditional use history
▪ KCPA regulates and protects access	▪ KCPA prohibits these products	▪ KCPA prohibits these products
▪ FDA 8-factor analysis did not meet scheduling criteria	▪ FDA has recommended DEA schedule synthetic 7-OH	▪ IND pathway is the appropriate regulatory route

Source: McCurdy CR et al., Expert Review of Clinical Pharmacology. 2024. PMC12671409, 2025.

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