

ARC issue brief: Unregulated kratom and tianeptine are dangerous substances and represent serious public health concerns

Background

The AMA is increasingly concerned about the unregulated use of many substances, including kratom and tianeptine. In recent years, the AMA adopted new policy that emphasizes public health harms associated with these substances and is calling for regulatory review and approval before products containing kratom or tianeptine are allowed to be marketed, purchased or prescribed to the general public.

Kratom basics

Kratom is an extract of a tropical tree (*Mitragyna speciosa*) native to Southeast Asia.¹ Kratom is often used to self-treat conditions such as pain, coughing, diarrhea, anxiety and depression, opioid use disorder, and opioid withdrawal. There are no FDA-approved prescription or over-the-counter drug products containing kratom or its known alkaloids. Kratom use raises concern during pregnancy due to risk for opioid-like neonatal abstinence syndrome. Additional adverse effects include mental and neurological symptoms (confusion, tremors and seizures), heart and lung problems (high blood pressure and slow breathing), gastrointestinal problems (nausea and vomiting) and liver problems.² Kratom sales were more than \$440 million in 2025, a 21.9 percent increase in one year.³

Of particular concern is 7-hydroxymitragynine (7-OH), a naturally occurring alkaloid in the kratom plant. Even though 7-OH comprises less than 2 percent of the total alkaloid content in natural kratom leaves, it is often concentrated in kratom products such as pills, powders, drinks, gummies and other consumer goods. An FDA assessment of 7-OH found that “7-OH produces respiratory depression, physical dependence, and withdrawal symptoms characteristic of classical opioids, such as morphine, fentanyl, oxycodone, and hydrocodone.”⁴ Studies have found that “7-OH produces respiratory depression with more than 3-fold greater potency than morphine.” FDA reports that an estimated 1.7 million Americans aged 12 and older used kratom in 2021.

Tianeptine basics

Tianeptine is an atypical tricyclic antidepressant that is not FDA-approved for any use in the United States, but is approved in some countries to treat major depressive disorder.⁵ Tianeptine is commonly referred to as “gas station heroin,” as it is regularly sold in gas stations, corner stores, bodegas, or from the Internet.⁶ The FDA has warned that tianeptine use can lead to symptoms of varying severity, including for agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma and death.⁷ The FDA reported in early 2025 that “case reports in the medical literature describe U.S. consumers ingesting daily doses on the order of 1.3 to 250 times (50 mg to 10,000 mg) the daily tianeptine dose typically recommended in labeled foreign drug products.”⁸ Tianeptine exposure resulting in calls to poison control centers has increased in recent years.⁹

AMA recommendations

The AMA recommends the safety and efficacy of kratom should be determined through research and clinical trials and subsequently evaluated by the relevant regulatory entities for its appropriateness for sale and potential oversight via the Controlled Substances Act, before it can be marketed, purchased, or prescribed.

The AMA also advocates to ban the sale of tianeptine directly to the public in the absence of research into the safety and efficacy of the substance.

State efforts to protect consumers from unregulated kratom and tianeptine products

Kratom

At least 24 states regulate kratom, but there is wide variability in the laws.¹⁰ Provisions might include:

- Restrictions on the possession, distribution, sale and manufacturing
- Labeling requirements, such as the amount of mitragynine, 7-OH, and other ingredients; health and safety disclaimer(s) (13 states)
- Age restrictions (7 states limit sales to those over the age of 18 years; 11 states limit sales to those over the age of 21 years)
- Scheduling kratom as a controlled substance (4 states schedule kratom under Schedule I)
- Allowable levels of active ingredients, mitragynine and 7-OH, vary considerably by state

Tianeptine

At least 13 states regulate tianeptine, but there is wide variability in the laws.¹¹ Provisions might include:

- Scheduling tianeptine as a controlled substance (7 states schedule tianeptine under Schedule I)
- Distinctions between individual possession and the manufacture, sale or delivery of tianeptine
- Age restrictions on the purchase of products containing tianeptine
- Labeling requirements

For more information

For more information, please contact Daniel Blaney-Koen, JD, Senior Attorney, American Medical Association at daniel.blaney-koen@ama-assn.org or Jennie Jarrett, PharmD, MS, PhD, Director, Science and Drug Policy at jennie.jarrett@ama-assn.org.

¹ The bulk of information about kratom in this issue brief is taken from “FDA and Kratom,” published by the U.S. Food and Drug Administration. September 25, 2025. Available at <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>

² National Institute on Drug Abuse. *Kratom*. March 2022. <https://nida.nih.gov/research-topics/kratom>.

³ Kratom sees impressive sales growth despite its regulatory status and stigma. *Nutritional Outlook* Vol. 28, No. 1. March 12, 2025. <https://www.nutritionaloutlook.com/view/kratom-sees-impressive-sales-growth-despite-its-regulatory-status-and-stigma>

⁴ 7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat. U.S. Food and Drug Administration. Available at <https://www.fda.gov/media/187899/download>

⁵ Edinoff AN, Sall S, Beckman SP, Koepnick AD, Gold LC, Jackson ED, Wenger DM, Cornett EM, Murnane KS, Kaye AM, Kaye AD. Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review. *Pain Ther*. 2023 Oct;12(5):1121-1134. doi: 10.1007/s40122-023-00539-5. Epub 2023 Jul 15. PMID: 37453966; PMCID: PMC10444703.

⁶ Edinoff AN, Sall S, Beckman SP, Koepnick AD, Gold LC, Jackson ED, Wenger DM, Cornett EM, Murnane KS, Kaye AM, Kaye AD. Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review. *Pain Ther*. 2023 Oct;12(5):1121-1134.

⁷ Tianeptine Products Linked to Serious Harm, Overdoses, Death. U.S. Food and Drug Administration. May 9, 2025. Available at <https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death>

⁸ FDA warns consumers not to purchase or use any tianeptine product due to serious risks. U.S. Food and Drug Administration. May 8, 2025. Available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-any-tianeptine-product-due-serious-risks>

⁹ Quadir M, Rine NI, Badeti J, Hays HL, Michaels NL, Yang J, Smith GA. Tianeptine Exposures Reported to United States Poison Centers, 2015-2023. *J Med Toxicol*. 2025 Jan;21(1):30-41. doi: 10.1007/s13181-024-01053-6. Epub 2024 Dec 26. PMID: 39724478; PMCID: PMC11706824.

¹⁰ Kratom: Summary of State Laws. Legislative Analysis and Public Policy Association. April 2025. Available at <https://legislativeanalysis.org/kratom-summary-of-state-laws/>

¹¹ Regulation of Tianeptine – State by State Overview. North Carolina General Assembly. March 11, 2025. Available at <https://webservices.ncleg.gov/ViewDocSiteFile/84838>