

Date of Hearing: April 29, 2025

Chief Counsel: Andrew Ironside

ASSEMBLY COMMITTEE ON PUBLIC SAFETY

Nick Schultz, Chair

AB 634 (Jeff Gonzalez) – As Introduced February 13, 2025

SUMMARY: Makes tianeptine a Schedule I controlled substance under California’s Uniform Controlled Substances Act (UCSA).

EXISTING LAW:

- 1) Lists controlled substances in five “schedules” - intended to list drugs in decreasing order of harm and increasing medical utility or safety - and provides penalties for possession of and commerce in controlled substances. Schedule I includes the most serious and heavily controlled substances, with Schedule V being the least serious and most lightly controlled substances. (Health & Saf. Code, §§ 11054-11058.)
- 2) Makes possession of most Schedule I controlled substances a misdemeanor, except that a person with at least one prior conviction for a serious or violent felony, or a crime requiring sex offender registration, is guilty of a felony punishable by 16 months, two years, or three years. (Health & Saf. Code, § 11350.)
- 3) Makes possession of a Schedule I controlled substance when the person has two or more prior convictions of specified drug crimes, including possession, an alternate felony/misdemeanor punishable by up to one year in county jail or by 16 months, two years, or three years. (Health & Saf. Code, § 11395, subd. (b)(1).)
- 4) Makes a second or subsequent conviction of the above punishable in state prison if a felony. (Health & Saf. Code, § 11395, subd. (b)(2).)
- 5) Makes the possession for sale or purchase for purposes of sale of most Schedule I controlled substances punishable by two, three, or four years. (Health & Saf. Code, § 11351.)
- 6) Makes transporting, importing into the state, selling, furnishing, administering, or giving away, or attempting to import into this state or to transport, most Schedule I controlled substances a felony punishable by imprisonment for three, four, or five years. (Health & Saf. Code, § 11352.)
- 7) Provides that every person 18 years of age or over, who hires, employs, or uses a minor to unlawfully transport, carry, sell, give away, prepare for sale, or peddle most Schedule I controlled substances, or who unlawfully sells, furnishes, administers, gives, or offers to sell, furnish, administer, or give, any such controlled substance to a minor, shall be punished by imprisonment in the state prison for three, six, or nine years. (Health & Saf. Code, § 11353.)
- 8) Provides that any person 18 years of age or over who is convicted specified violations related to, among other acts, the sale, transport, or furnishing of most Schedule I controlled

substances, or of a conspiracy to commit one of those offenses, where the violation takes place upon the grounds of, or within 1,000 feet of, a public or private elementary, vocational, junior high, or high school during hours that the school is open for classes or school-related programs, or at any time when minors are using the facility where the offense occurs, shall receive an additional punishment of three, four, or five years at the court's discretion. (Health & Saf. Code, § 11353.6, subd. (a).)

- 9) Any person 18 years of age or older who is convicted of the above violation which involves a minor who is at least four years younger than that person, as a full and separately served enhancement to that provided above, shall be punished by imprisonment for three, four, or five years at the court's discretion. (Health & Saf. Code, § 11353.6, subd. (b).)
- 10) Enacts the Sherman Law, enforced by Department of Public Health, which provides broad authority for DPH to enforce food safety requirements, including that food is not adulterated, misbranded, or falsely advertised. Food labeling requirements generally adopt federal food labeling laws as the state requirement, including nutrition labeling and allergen labeling, but DPH is permitted, by regulation, to adopt additional food labeling regulations. (Health & Saf. Code, § 109875, et seq.)
- 11) Prohibits any person from engaging in the manufacturing, packing, or holding of any processed food unless the person has a valid registration as a food processing facility from the DPH under the Sherman Law. (Health & Saf. Code, § 110460.)
- 12) Establishes penalties for violations of the Sherman Law, including a fine of up to \$1,000, or up to \$10,000 for repeated violations. (Health & Saf. Code, § 111825.)
- 13) Prohibits any manufacturer, wholesaler, retailer, or other person from selling, transferring, or otherwise furnishing specified dietary supplements. (Health & Saf. Code, § 110423.2.)

FISCAL EFFECT: Unknown

COMMENTS:

- 1) **Author's Statement:** According to the author, "AB 634 aims to combat the growing threat posed by Tianeptine, also known as "gas station heroin." This legislation will add Tianeptine to the Schedule 1 list of controlled substances in California. Tianeptine has been increasingly misused, particularly by individuals seeking an opioid-like effect, despite its unregulated status and the severe risks it poses to the public. The opioid epidemic continues to ravage communities across the nation, and Tianeptine has become a disturbing new threat in this ongoing crisis. This Bill seeks to address this emerging danger and prevent further harm to vulnerable populations, especially those already at risk due to the opioid crisis. With AB 641, California will strengthen its response to the opioid epidemic by closing a dangerous loophole and taking decisive action to safeguard public health and safety."
- 2) **Tianeptine:** Tianeptine is an antidepressant approved for use to treat major depressive disorder in countries in Asia, Europe, and Latin America but has been not approved for use in

the United States.¹ “[It] has shown potential benefits in addressing anxiety and irritable bowel disease” as well.² In the United States, it is generally sold online or at convenient stores as a powder, a pill, or a liquid. At high doses, it can produce a high and feelings of euphoria.³ Misuse can lead to dependence and, in rare cases, death.⁴

According to the Drug Enforcement Administration:

In August 2018, CDC published an analysis of the tianeptine-related calls to the NPDS between 2000 and 2017. During the first 14 years of the study period (2000–2013), NPDS reported a total of 11 tianeptine exposure calls. From 2014 through 2017, NPDS reported 207 calls [2014 (5 calls); 2015 (38); 2016 (83); 2017 (81)]. In addition, NPDS reported 29 withdrawal-associated calls, of which 21 (72.4%) calls involved tianeptine only. Among these withdrawal-associated calls, the most commonly reported adverse effects included agitation, nausea, vomiting, tachycardia, hypertension, diarrhea, tremor, and diaphoresis.⁵

According to the FDA, between 2015 and 2022, “Two deaths were reported [nationwide] as a result of tianeptine use.”⁶ In 2024, the CDC issued a report after tianeptine exposure calls in New Jersey increased to 20 calls from 17 patients, up from two or fewer cases per year.⁷ Six of the patients reported “coingesting [tianeptine with] other substances.”⁸ Seven of the patients required intubation, although the report does not state how many of those patients were among the coingesting group.⁹ Fourteen patients reported consuming a brand of tianeptine that contained kava, another unregulated substance.¹⁰ Notably, analyses of samples of that brand of tianeptine also found synthetic weed, which is illegal to sell in California.¹¹ (See Health & Saf., § 11357.5) None of the exposures resulted in death.¹²

¹ Edinoff et al., *Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review* (Jul. 15, 2023) <<https://pmc.ncbi.nlm.nih.gov/articles/PMC10444703/>> [last visited Apr. 25, 2025].

² *Ibid.*

³ Tianeptine: Is safe use possible? Mayo Clinic <[⁴ *Ibid.*](https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/tianeptine-is-safe-use-possible/art-20562252#:~:text=When%20taken%20in%20small%20doses,of%20tianeptine%20can%20be%20fatal.> [last visited Apr. 25, 2025].</p>
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⁵ DEA, Tianeptine (Apr. 2025) <https://www.deadiversion.usdoj.gov/drug_chem_info/tianeptine.pdf> [last visited Apr. 25, 2025].

⁶ Hoffman-Pennesi et al., Tianeptine Product Adverse Event Reports from FDA CFSAN Adverse Event Reporting System (CAERS), 2015-2022, FDA; see also, Musa, Some tianeptine products recalled as CDC links drug to ‘cluster of severe illness’, CNN.com (Feb. 1, 2024) <<https://www.cnn.com/2024/02/01/health/tianeptine-illness-recall/index.html>> [last visited Apr. 25, 2025].

⁷ Hoffman-Pennesi, *supra*.

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ Musa, *supra*.

¹¹ *Ibid.*

¹² Counts et al, Notes from the Field: *Cluster of Severe Illness from Neptune’s Fix Tianeptine Linked to Synthetic Cannabinoids—New Jersey, June-November 2023*, CDC (Feb. 1, 2024) https://www.cdc.gov/mmwr/volumes/73/wr/mm7304a5.htm?s_cid=mm7304a5_e&ACSTrackingID=USCDC_921DM121333&ACSTrackingLabel=This%20Week%20in%20MMWR%3A%20Vol.%2073%2C%20February%201%2C%202024&deliveryName=USCDC_921-DM121333 [last visited Apr. 25, 2025].

- 3) **The California Uniform Controlled Substances Act:** In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act, which established a framework for federal regulation of controlled substances. Title II of the act is the Controlled Substances Act (CSA), which placed controlled substances in one of five “schedules.”

The schedule on which a controlled substance is placed determines the level of restriction imposed on its production, distribution, and possession, as well as the penalties applicable to any improper handling of the substance... [W]hen DEA places substances under control by regulation, the agency assigns each controlled substance to a schedule based on its medical utility and its potential for abuse and dependence.¹³

Substances are added to or removed from schedules through agency action or by legislation.¹⁴

State laws generally follow the federal scheduling decisions, and “they are relatively uniform across jurisdictions because almost all states have adopted a version of a model statute called the Uniform Controlled Substances Act (UCSA).”¹⁵ California adopted the UCSA in 1972. (Stats. 1972, ch. 1407, § 3.)

With few exceptions, California generally has aligned its Uniform Controlled Substances Act (UCSA) with the federal government’s scheduling decisions. (See *People v. Ward* (2008) 167 Cal.App.4th 252, 259 [“In the California Uniform Controlled Substances Act, California adopted the five schedules of controlled substances used in federal law and in the Uniform Controlled Substances Act”]; *Williamson v. Bd. Of Medical Quality Assurance* (1990) 271 Cal.App.3d 1343, 1352, fn. 1. [“Effective January 1, 1985, Schedules I through V of the California Uniform Controlled Substances Act were revised so as to generally parallel the five schedules contained in the Federal Controlled Substances Act.”].) The federal government has not listed tianeptine on any of the five schedule under the CSA.

- 4) **Effect of the Bill:** This bill would make tianeptine a Schedule I controlled substance under the UCSA. By placing it on Schedule I, this bill would create significant criminal penalties for such conduct. In most cases, possession of a Schedule I controlled substance generally is a misdemeanor. (Health & Saf. Code, § 11350.) However, after the passage of Prop 36, the possession of a Schedule I controlled substance when the person has two or more prior convictions of specified drug crimes, including possession, is an alternate felony/misdemeanor punishable by up to one year in county jail or by imprisonment for up to three years, generally in county jail. (Health & Saf. Code, § 11395, subd. (b)(1).) A second or subsequent conviction of the above is punishable in state prison if a felony. (Health & Saf. Code, § 11395, subd. (b)(2).)

Possession for sale or purchase for purposes of sale of most Schedule I controlled substances is punishable by imprisonment for two, three, or four years. (Health & Saf. Code, § 11351.) Transporting, importing into the state, selling, furnishing, administering, or giving away, or attempting to import into this state or to transport, a Schedule I controlled substance is

¹³ The Controlled Substances ACT (CSA): A Legal Overview for the 118th Congress, Congressional Research Service (Jan. 19, 2023) p. 2 <<https://crsreports.congress.gov/product/pdf/r/r45948>> [last visited Mar. 28, 2024].

¹⁴ *Id.* at p. 9.

¹⁵ *Id.* at 4.

punishable by imprisonment for three, four, or five years. (Health & Saf. Code, § 11352.) A person 18 years of age or over who is convicted specified violations related to, among other acts, the sale, transport, or furnishing of a Schedule I, or of a conspiracy to commit one of those offenses, where the violation takes place upon the grounds of, or within 1,000 feet of, a public or private elementary, vocational, junior high, or high school during hours that the school is open for classes or school-related programs, or at any time when minors are using the facility where the offense occurs, could receive an additional punishment of up to five years. (Health & Saf. Code, § 11353.6, subd. (a).)

Currently, there are no existing criminal penalties for tianeptine-related conduct. As such, this bill would take a currently legal substance and apply the most serious criminal penalties to conduct related to that substance. The author may wish to consider a more modest approach.

For example, like Tianeptine, Kratom is a legal substance with effects similar to those of opioids. Per the United States Drug Enforcement Administration (DEA), consumption of kratom tree leaves produces a stimulant effect in low doses, and a sedative effect in high doses. Consumption of kratom in high doses can also lead to psychotic symptoms, and psychological and physiological dependence. According to the DEA, the abuse of kratom has increased markedly in recent years. Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion. And Kratom has resulted in fatal overdoses.¹⁶ Yet Kratom has not been placed on any schedule under the federal Controlled Substances Act.

Unlike this bill, however, AB 1088 (Bains) would add kratom products to the Sherman Food, Drug, and Cosmetic Law, prescribe specified quantities of alkaloids present in kratom products, prohibits the sale of kratom products to those under 21 years of age, require the packaging of kratom products to be child resistant, and prohibit the sale and manufacture of a kratom product that is attractive to children. This approach may better achieve the goal of reducing harmful public health outcomes without burdening the state and law enforcement with increased incarceration and enforcement costs.

- 5) **Criminal Penalties and Drug Use:** Ample research on the impact of increasing penalties for drug offenses on criminal behavior has called into question the effectiveness of such measures. In a report examining the relationship between prison terms and drug misuse, PEW Charitable Trusts found “[n]o relationship between drug imprisonment rates and states’ drug problems,” finding that “high rates of drug imprisonment did not translate into lower rates of drug use, arrests, or overdose deaths.”¹⁷ According to PEW, “[A] large body of prior

¹⁶ Freund et al., *Hundreds died using kratom in Florida. It was touted as safe*. Tampa Bay Times (Dec. 7, 2023) <<https://project.tampabay.com/investigations/deadly-dose/kratom-overdose-deaths-florida-mitragynine-testing/>> [last visited Apr. 25, 2025].

¹⁷ PEW, *More Imprisonment Does Not Reduce State Drug Problems* (Mar. 2018) p. 5 <https://www.pewtrusts.org/-/media/assets/2018/03/pspp_more_imprisonment_does_not_reduce_state_drug_problems.pdf> [last viewed Feb. 6, 2023]; see generally, Przybylski, *Correctional and Sentencing Reform for Drug Offenders* (Sept. 2009) <http://www.ccjrc.org/wp-content/uploads/2016/02/Correctional_and_Sentencing_Reform_for_Drug_Offenders.pdf> [last visited Mar. 20, 2023].

research...cast[s] doubt on the theory that stiffer prison terms deter drug misuse, distribution, and other drug-law violations.”¹⁸ PEW concludes:

Putting more drug-law violators behind bars for longer periods of time has generated enormous costs for taxpayers, but it has not yielded a convincing public safety return on those investments. Instead, more imprisonment for drug offenders has meant limited funds are siphoned away from programs, practices, and policies that have been proved to reduce drug use and crime.¹⁹

Based on this research, one might reasonably question whether creating stiff penalties for tianeptine would meaningfully impact the drug’s availability or the number of people who use it.

- 4) **Argument in Support:** According to *California Narcotic Officers’ Association*, “U.S. poison control centers are reporting a dramatic spike in cases involving tianeptine — a drug that isn’t FDA approved, and poses overdose and dependency risks. Tianeptine, however, doesn’t just bind to the mu opioid receptor, It actually activates the receptor like other opioids do, like morphine or like oxycodone or like fentanyl.

“It’s currently illegal to market or sell tianeptine *as a drug*, but it’s also *not* on the list of federally controlled substances. As a result, it is widely available at gas stations, vape shops and online as a ‘supplement.’ The FDA refers to tianeptine as ‘an unapproved drug associated with serious health risks and even death.’

“Tianeptine has never been cleared by the U.S. Food and Drug Administration for medical use, so it’s sold in the U.S. as a nootropic, a substance promising to enhance users’ mood and cognitive function.

“Experts warn that it’s dangerous to consume any unapproved drug, particularly one that poses the risk of dependency, withdrawal, respiratory depression and even death as does tianeptine. It’s often packaged in colorful, shot-sized bottles, containing the drug in varying concentrations without proper disclosures to the public about the true contents. Many tianeptine products have been found to include dangerous synthetic cannabinoids as well.

“Lack of a federal ban on tianeptine has forced states to act on their own. In 2018, Michigan became the first state to ban sales of the drug, classifying it as a Schedule II controlled substance, the same category as drugs like cocaine and fentanyl. The FDA says at least 12 states have enacted similar bans to protect their residents. California should do the same. Tianeptine is a dangerous, addictive and unregulated product that should not be made available for sale in our state.”

- 5) **Argument in Opposition:** According to the *Drug Policy Alliance*, “**We all want our loved ones and communities to be safe, but criminalizing tianeptine and other commonly-available substances will not effectively protect or improve the health of those seeking such substances, and instead will cause other harms.** It will result in increased criminalization of people who use drugs, exposing them to additional criminal charges and

¹⁸ PEW, *supra*. See generally, Przybylski, *Correctional and Sentencing Reform for Drug Offenders* (Sept. 2009)

¹⁹ *Ibid.*

potentially increased sentences, and have the unintentional consequence of fostering an illicit market for such substances and substantially similar chemical compounds.

“Tianeptine is an antidepressant drug approved for the treatment of major depressive disorder in some countries outside of the United States. It has been shown to have potential benefits in addressing anxiety, irritable bowel disease, and declines mental cognition.^{1,2} Tianeptine has been shown to be comparable with fluoxetine, or ‘Prozac’ in a number of studies on its efficacy as an antidepressant and been shown to treat Major depressive disorder (MDD), one of the most common mental disorders in the United States, which can lead to severe impairments that interfere with one’s ability to carry out major life activities.^{3,4} Patients without access to “first-line antidepressant treatments” tend to have a more severe course of illness and are at an increased risk of suicide.

“At this time, however, tianeptine is not approved for any use by the United States Federal Drug Administration (FDA) and is not regulated in many states. As a result, manufacturers and distributors of products containing the substance are not subject to controls on product marketing, concentrations, testing, age verification, requirements for bundling naloxone with the product, or per-consumer quantity limits.

“One of the consequences with scheduling substances on Schedule I, the most strictly controlled category, designates them as having no medical use and subject to the highest penalties. Criminalizing certain formulations simply incentivizes more innovation so that suppliers will produce new and different molecular compounds to avoid criminalization. This could actually lead to the development and dissemination of more potent or risky drugs.

“Scheduling tianeptine, particularly on Schedule I, will also create barriers to critically needed research on the drug at a time when we need more research to understand its effects and uses. Scheduling drugs makes them more difficult for researchers to access and procure for research purposes, and can have a chilling effect on research for fear of legal repercussions or barriers to Institutional Review Board (IRB) approval. There is still a great amount of information that is not well understood about Tianeptine, including how various doses act in the body, potential interaction with medications and other drugs, how to treat and manage withdrawal among dependent users, medication treatments for people who are addicted to these drugs, and also potential novel medical uses.

“The schedules of controlled substances in California and elsewhere are generally designed to weigh the “potential for abuse”, accepted medical use, and public health risks of a drug. Adding Tianeptine as a controlled substance without conducting scientific and medical evaluations that are necessary in the drug scheduling process undermines the process for scheduling drugs and imposing criminal penalties. It remains uncertain how the classification of Tianeptine on Schedule I could be justified without additional research.

“Instead of hastily criminalizing tianeptine as a controlled substance, policymakers should focus on health-centered approaches: improving access to mental health services, expanding overdose-prevention and harm-reduction services (including community-based drug checking programs), peer-led outreach and street-medicine programs, strengthening our good samaritan statute, and increasing access to Medically Assisted Treatment (i.e. methadone and buprenorphine), and expanding access to and training around naloxone, and evidence-based drug education and voluntary treatment.

“Overdose deaths are preventable, but expanded criminalization causes more harm and stands in the way of saving lives. Criminalization creates instability, blocks access to jobs and housing, increases overdose risk, and leads to more dangerous substances. A vast body of evidence has found that adding criminal penalties does not reduce overdose rates or the supply of drugs.⁵ Instead, it creates a dangerous cycle that exposes people who use drugs to newer and potentially more dangerous alternatives from unknown sources. Criminalizing tianeptine will likely lead to the emergence of other, potentially more deadly substances in the illicit drug supply. Effective solutions center support, not punishment.”

6) Related Legislation:

- a) AB 1088 (Bains) would, among other things add kratom and other specified products to the Sherman Food, Drug, and Cosmetic Law (Sherman Law), prohibit the sale of those products to persons under 21 years of age, and require the packaging of those products to be child resistant. AB 1088 is pending a hearing in the Assembly Appropriations committee.
- b) SB 6 (Ashby) would make xylazine also known as “tranq,” a Schedule III drug under UCSA.

7) Prior Legislation:

- a) AB 2018 (Rodriguez), Chapter 98, Statutes of 2024, removed fenfluramine as a controlled substance under the UCSA.
- b) AB 2217 (Weber), of the 2023-2024 Legislative Session, would have provided that, commencing on January 1, 2027, no person or entity may manufacture, sell deliver, distribute, hold, or offer for sale, in commerce a food product for human consumption that contains tianeptine, subject to civil penalties of between \$5,000 and \$10,000 for each violation. The hearing on AB 2217 was canceled at the request of the author.
- c) AB 2365 (Haney), of the 2023-2024 Legislative Session, would have established the Kratom Consumer Protection Program to provide a regulatory structure for kratom products, as provided. AB 2365 was held on the Senate Appropriations Committee suspense file.
- d) AB 3029 (Bains) would make xylazine, also known as “tranq,” a Schedule III drug under California’s UCSA, contingent on the federal government adding xylazine to Schedule III of the federal CSA. AB 3029 was held in suspense in the Senate Appropriations Committee.
- e) SB 1502 (Ashby), of the 2023-2024 Legislative Session, would have made xylazine also known as “tranq,” a Schedule III drug under UCSA. AB 1502 failed passage in this committee.

REGISTERED SUPPORT / OPPOSITION:

Support

California District Attorneys Association
California Narcotic Officers' Association
California State Sheriffs' Association
Union Station Homeless Services

Oppose

ACLU California Action
California Public Defenders Association (CPDA)
Californians United for a Responsible Budget
Drug Policy Alliance
Ella Baker Center for Human Rights
Initiate Justice Action
Justice2jobs Coalition
LA Defensa
San Francisco Public Defender
Smart Justice California, a Project of Tides Advocacy
Universidad Popular

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