

Date of Hearing: January 13, 2026

ASSEMBLY COMMITTEE ON HEALTH

Mia Bonta, Chair

AB 634 (Jeff Gonzalez) – As Amended January 5, 2026

SUBJECT: Tianeptine.

SUMMARY: Prohibits the sale of tianeptine. Specifically, **this bill:**

- 1) Prohibits a person or entity from manufacturing, selling, delivering, distributing, holding, or offering for sale in commerce a product that contains tianeptine.
- 2) Makes a person or entity that violates 1) liable for a civil penalty not to exceed \$5,000 for the first violation and not to exceed \$10,000, upon an action brought by the Attorney General, city attorney, county counsel, or district attorney.
- 3) Provides this bill does not impair or impede any other rights, causes of action, claims, or defenses available under any other law.
- 4) Provides that remedies provided by this bill are cumulative with any other remedies available under any other law.

EXISTING FEDERAL LAW:

- 1) Establishes the Federal Food, Drug and Cosmetic Act (FDCA) which among various provisions, gives the United States (U.S.) Food and Drug Administration (FDA) authority to oversee the safety of food, drugs, medical devices, and cosmetics. [21 United States Code (U.S.C.) § 301, *et seq.*]
- 2) Defines a "food additive" as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized as safe under the conditions of its intended use, as specified. [21 U.S.C. § 321]
- 3) Provides that a substance added to food is unsafe unless the substance conforms to the terms of an exemption for investigational use, or unless the substance is in conformance with a regulation describing the conditions under which the substance may be safely used. [21 U.S.C. § 348]
- 4) Deems a food adulterated if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe, as specified. [21 U.S.C. § 342]

EXISTING STATE LAW:

- 1) Enacts the Sherman Food, Drug, and Cosmetic (Sherman) Law, enforced by the State Department of Public Health (DPH), which provides broad authority for DPH to enforce food safety requirements. [Health and Safety Code (HSC) § 109875, *et seq.*]
- 2) Establishes penalties for violations of the Sherman Law, including a fine of up to \$1,000, or up to \$10,000 for repeated violations. [HSC § 111825]

FISCAL EFFECT: Unknown. This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, this bill aims to combat the growing threat posed by tianeptine, also known as "gas station heroin." The author states that this bill will restrict the commercial manufacturing, selling, delivering, distributing, and holding of tianeptine in California. The author continues that 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 author contends that the opioid epidemic continues to ravage communities across the nation, and tianeptine has become a disturbing new threat in this ongoing crisis. The author asserts that 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. The author concludes that this bill will strengthen California's response to the opioid epidemic by closing a dangerous loophole and taking decisive action to safeguard public health and safety.

- 2) **BACKGROUND.**

- a) **What is tianeptine?** Tianeptine is an antidepressant drug approved for the treatment of major depressive disorder in various countries within Europe, Asia, and Latin America. It is not approved for any use in the United States (U.S.) by the FDA.

According to a 2023 article published in *Pain and Therapy* titled "Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review," tianeptine is an opioid receptor agonist. Tianeptine's opioid-like actions can induce euphoric effects.

- b) **Legal status of tianeptine.** Tianeptine, also known as "gas station heroin," is not approved by the FDA for medical use. Pursuant to existing federal law above, tianeptine is considered an unsafe food additive, making its sale illegal in the U.S. As part of its post-market surveillance of food ingredients, the FDA developed an inventory of certain food ingredients deemed unsafe because they are unapproved food additives that are not generally recognized as safe when used as intended. The FDA released this inventory to the public on July 12, 2023. Tianeptine is included in this inventory. The FDA has taken actions on tianeptine including: issuing multiple consumer advisories and warnings about products with tianeptine as being linked to serious harm, overdose, and death; issuing warning letters to companies distributing and selling unlawful tianeptine products as dietary supplements and unapproved drugs; and, issuing import alerts to help detain tianeptine shipments at U.S. borders.

Despite this, tianeptine continues to be sold in convenience stores and gas stations in both powder and pill form claiming to treat conditions such as anxiety, depression, pain, and enhance the users' mood and cognitive function. Tianeptine can be obtained online from independent vendors without a prescription. According to a *National Public Radio* article titled, "8 things to know about the drug known as 'gas station heroin'," these products are often packaged in colorful, shot-sized bottles, containing tianeptine in varying concentrations and have also been found to include dangerous synthetic cannabinoids.

A March 2024 publication by the North Carolina General Assembly titled "Regulation of Tianeptine – State by State Overview" shows that at least 13 states regulate tianeptine. Seven states have listed it as a Schedule I drug, including Alabama, Florida, Georgia, Indiana, Kentucky, Ohio and Virginia. Michigan and Tennessee have listed tianeptine as a Schedule II drug. Mississippi state law has listed tianeptine as a Schedule III drug.

In California, the Sherman Law gives DPH the broad regulatory authority to oversee food, drug, and medical device safety and makes violators subject to penalties. The Food and Drug Branch (FDB) of DPH is responsible for complaints regarding commercially processed foods, drugs, medical devices, cosmetics, and certain consumer products affecting Californians. The FDB investigates complaints about products like tianeptine and shares findings with relevant authorities, including local health jurisdictions. Local environmental health agencies can request stores to voluntarily remove products containing tianeptine and can impound such products. Local environmental health agencies also provide materials about risks of these substances.

- c) **Impacts of tianeptine.** According to the FDA, reports of severe side effects involving tianeptine are increasing. Poison control center cases involving tianeptine exposure have increased nationwide, from 11 total cases between 2000 and 2013 to 151 cases in 2020 alone.

The FDA has identified cases in which people experienced other serious harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and anti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.

- d) **How would this bill change how tianeptine is regulated?** It is already illegal to market and sell tianeptine in California, and DPH already has authority to address the illegal sale of tianeptine under the Sherman Law. This bill expressly prohibits the manufacture, sale, delivery, distribution, holding, or offer for sale of tianeptine in commerce and creates an additional civil penalty structure upon action by the Attorney General, city attorney, county counsel or district attorney.

- 3) **SUPPORT.** This bill is sponsored by the California Narcotic Officers' Association (CNOA), who writes in support, tianeptine inhabits a murky space in U.S. drug regulation. CNOA states that it is illegal to market or sell the drug, but it is also not on the list of federally controlled substances. CNOA continues that while tianeptine is in products sold at gas stations and other stores, it is also available to buy online. CNOA continues that from a law-enforcement and public-safety perspective, tianeptine presents several acute concerns. First, CNOA flags high abuse and addiction potential. CNOA notes that tianeptine acts on opioid

receptors and produces opioid-like effects, including euphoria, dependence, and severe withdrawal symptoms. CNOA continues that emergency departments across the country have reported increasing numbers of tianeptine-related overdoses, poisonings, and hospitalizations. Second, CNOA highlights deceptive marketing and easy access. CNOA asserts that products containing tianeptine are often labeled as supplements, energy boosters, or mood enhancers, creating a false perception of safety and enabling access by minors and vulnerable populations. Third, CNOA flags strain on first responders and emergency services. CNOA notes that law-enforcement officers, firefighters, and Emergency Medical Services (EMS) personnel are increasingly encountering individuals suffering from tianeptine intoxication, withdrawal, or polysubstance abuse, diverting critical resources from other public-safety priorities. Fourth, CNOA contends there is a regulatory gap under current law and absent clear scheduling, enforcement agencies face challenges in removing these dangerous substances from circulation or holding distributors accountable.

4) RELATED LEGISLATION.

- a) AB 1088 (Bains) of 2025 adds kratom products and products containing 7-hydroxymitragynine (7-OH products), as defined, to the Sherman Law. Prescribes specified quantities of alkaloids present in kratom products and 7-OH products. Prohibits the sale of kratom products and 7-OH products to those under 21 years of age. Requires the packaging of kratom products and 7-OH products to be child resistant and prohibits the sale and manufacture of a kratom product or 7-OH product that is attractive to children. AB 1088 is a two-year bill in Senate Health Committee.

5) PREVIOUS LEGISLATION.

- a) AB 2217 (Weber) of 2024 would have, commencing January 1, 2027, prohibited a person or entity from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains tianeptine. Would have made a violation of these provisions punishable by a civil penalty not to exceed \$5,000 for a first violation and not to exceed \$10,000 for each subsequent violation, upon an action brought by the Attorney General, a city attorney, a county counsel, or a district attorney. AB 2217 was not heard in the Assembly Health Committee.
- b) AB 2365 (Haney) of 2024 would have added kratom products, as defined, to the Sherman Law and required processors of kratom products to register with DPH. Would have authorized DPH to establish an annual fee for processors and would have authorized the fee to be based on certain criteria, including annual sales in California. AB 2635 would have prescribed specified quantities of alkaloids present in kratom products and would have established labeling and packaging requirements. The bill would have required that kratom products be registered with DPH annually, which would include certification by a laboratory specifying that the product meets certain qualifications. Additionally, the bill would have prohibited the sale of kratom leaf and kratom products to those under 21 years of age and would have prohibited the sale and manufacture of a kratom product that is attractive to children or an inhalable kratom product. AB 2365 also would have authorized DPH to take various enforcement actions, including executing interagency agreements for the implementation of these provisions, among others. AB 2635 was held on the Senate Appropriations Committee's suspense file.

- c) AB 418 (Gabriel), Chapter 328, Statutes of 2023 prohibits a person or entity, commencing January 1, 2027, from manufacturing, selling, delivering, distributing, holding, or offering for sale, in commerce a food product for human consumption that contains any of the following substances: Brominated vegetable oil (BVO); Potassium bromate; Propylparaben; or, Red dye 3. Makes a violation of these provisions punishable by a civil penalty not to exceed \$5,000 for a first violation and not to exceed \$10,000 for each subsequent violation, upon an action brought by the Attorney General, a city attorney, a county counsel, or a district attorney.
- d) AB 82 (Weber) of 2024 would have prohibited a retail establishment from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter (OTC) diet pills, as defined, to any person under 18 years of age without a prescription. Would have required DPH to determine which dietary supplements and OTC diet pills would be subject to AB 82, in a manner consistent with specified criteria. Would have exempted a violation of this bill from existing penalties provisions that subjects violations of the Sherman Law to misdemeanor penalties and instead provides for a civil penalty for violations of this bill of up to \$250, assessed in a civil action brought by the Attorney General or any district attorney, county counsel, or city attorney in any court of competent jurisdiction. Would have exempted a retail clerk from any civil penalty for a violation of AB 82 but specifies that this exemption does not apply to a retail clerk who is a willful participant in an ongoing conspiracy to violate the provisions of AB 82. Would have made the provisions of this bill operative on January 1, 2026, and included a severability clause. AB 82 was held on the Senate Appropriations Committee's suspense file.
- e) AB 1341 (C. Garcia) of 2021 was substantially similar to AB 82 and would have also required DPH to develop a notice stating that certain dietary supplements or OTC diet pills may contribute to specified health conditions or death and required a retail establishment to post this notice, and additionally exempted a retail clerk from being subject to disciplinary action or discharge by the retail establishment, for a violation of this bill, but specifies that this exemption does not apply to a retail clerk who is a willful participant in an ongoing conspiracy to violate the provisions of this bill. AB 1341 was vetoed by Governor Newsom who stated in part:

“DPH is prepared to work with the legislature next session to address sales age limits and other potential legislative actions to address the responsible sale of dietary supplements for weight loss and OTC diet pills that do not require the state to undertake lengthy and costly pharmacological studies on the many supplements on the market today.”

- 6) **DOUBLE REFERRAL.** This bill has been double-referred; upon passage of this Committee, it will be referred to the Assembly Judiciary Committee.
- 7) **POLICY COMMENT.** In addition to the penalties specified under the Sherman Law, this bill creates a civil penalty for a person who manufactures, sells, delivers, distributes, holds, or offers tianeptine for sale. Previous legislation, which would have created similar civil penalties for diet pills, included an exemption for retail clerks, as described in **5) d)** and **e)** above. The author may wish to consider working with stakeholders to ensure that retail clerks are not subject to civil penalty or retaliation when a retailer is illegally selling tianeptine.

REGISTERED SUPPORT / OPPOSITION:

Support

California Narcotics Officers' Association

Opposition

None on file

Analysis Prepared by: Eliza Brooks / HEALTH / (916) 319-2097