SENATE COMMITTEE ON HEALTH
Senator Richard Roth, Chair

BILL NO: AB 82
AUTHOR: Weber
VERSION: May 28, 2024
HEARING DATE: June 5, 2024
CONSULTANT: Vincent D. Marchand

SUBJECT: Dietary supplements for weight loss and over-the-counter diet pills

SUMMARY: Prohibits a retail establishment from selling dietary supplements for weight loss or over-the-counter (OTC) diet pills to any person under 18 years of age without a prescription, commencing January 1, 2026. Requires the California Department of Public Health to determine which dietary supplements and OTC diet pills are subject to this bill, and to develop a notice for distribution to retail establishments for posting that states that certain dietary supplements for weight loss or OTC diet pills may contribute to specified medical conditions or other serious injury, or death.

Existing state law:

1) Enacts the Sherman Food, Drug and Cosmetic Law (Sherman Law), enforced by the California Department of Public Health (CDPH), which provides broad authority for CDPH 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 CDPH is permitted, by regulation, to adopt additional food labeling regulations. [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]

3) Requires, whenever a warning label is included on any product defined as a dietary supplement pursuant to federal law, the label to be clear and conspicuous. [HSC §110422]

4) Prohibits any manufacturer, wholesaler, retailer, or other person to sell transfer, or otherwise furnish a dietary supplement containing either of following to a person under 18 years of age:

   a) A dietary supplement containing an ephedrine group alkaloid; or
   b) A dietary supplement containing any of the following: androstanediol, androstanedione, androstenedione, norandrostenediol, norandrostenedione, dehydroepiandrosterone. [HSC §110423.2]

5) Specifies that a retail establishment that sells a dietary supplement product in violation of 4) above is not guilty of the misdemeanor penalties if the retailer met certain conditions, including that every checkout clerk has completed standardized training, every programmable checkout scanner is programmed to identify dietary supplement products subject to the age requirement, and that every checkout clerk has received a written list of dietary supplement products subject to the age requirement. [HSC §110423.6]

6) Requires all persons engaging in the retail sale of tobacco products to check the identification of tobacco purchasers, to establish the age of the purchaser, if the purchaser reasonably appears to be under 21. [BPC §22956]

7) Permits an enforcing agency, as specified, to assess civil penalties against any person, firm, or corporation that sells, gives, or in any way furnishes to another person who is under 21 any tobacco product, instrument, or paraphernalia that is designed for the smoking or ingestion of tobacco products, as specified, ranging from $400 to $6,000 for a first, second, third, fourth, or fifth violation within a five-year period. [BPC §22958]

Existing federal law:

1) Establishes, through the U.S. Food and Drug Administration (FDA), various requirements for food labels under the Federal Food, Drug, and Cosmetic Act (FD&C Act), which includes the Nutritional Labeling and Education Act and the Food Allergen Labeling and Consumer Protection Act. These include requiring specified nutrition information, a listing of all ingredients, and whether a produce contains any of eight major food allergens, such as milk, eggs, shellfish, tree nuts, etc. [21 USC §301, et seq., 21 CFR §101, et seq.]

2) Defines "dietary supplement" as a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance to supplement the diet by increasing the total dietary intake; or, a concentrate, metabolite, constituent, extract, or combination of any of these ingredients. Excludes from this definition something that is represented for use as a conventional food or as a sole item of a meal or the diet. [21 USC §322(ff)]

This bill:

1) Prohibits a retail establishment from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter (OTC) diet pills to any person under 18 years of age without a prescription.

2) Defines the following terms for purposes of this bill:

   a) "Dietary supplements for weight loss" is defined as a class of dietary supplements that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss and that are under the regulation of the FD&C Act, as specified. Specifies that "dietary supplements for weight loss" includes products marketed with a Supplemental Facts panel that contain either lawful dietary ingredients or ingredients deemed adulterated, as specified, or both. Excludes dietary fiber products from this definition;

   b) "OTC diet pills" is defined as a class of drugs that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss and that are lawfully sold, transferred, or otherwise furnished without a prescription, under the FD&C Act, as specified. Specifies that "OTC diet pills" includes products marketed with a Drug Facts panel that contains either approved drug ingredients or ingredients deemed adulterated, as specified, or both; and,

   c) "Retail establishment" is defined as any vendor that, in the regular course of business, sells dietary supplements for weight loss or OTC diet pills at retail directly to the public, including, but not limited to, pharmacies, grocery stores, other retail stores, and vendors

that accept orders placed by mail, telephone, electronic mail, internet website, online catalog, or software application.

3) Requires a retail establishment, for purposes of the prohibition on selling to those under 18, to request valid identification from any person who attempts to purchase a dietary supplement for weight loss or OTC diet pill if that person reasonably appears to the retail establishment to be under 18 years of age.

4) Requires CDPH to develop a notice, for distribution to retail establishments, stating that certain dietary supplements for weight loss or OTC diet pills may contribute to gastrointestinal impairment, tachycardia, hypertension, myocardial infarction, stroke, organ failure, other serious injury, death, or severe liver injury sometimes requiring transplant or leading to death. Requires retail establishments to post this notice. Requires this notice requirement to only be implemented to the extent not in conflict with federal law.

5) Requires CDPH, in consultation with the FDA and stakeholders, including, but not limited to, representatives from the eating disorders community, to determine which dietary supplements for weight loss and OTC diet pills are subject to the provisions of this bill, in a manner consistent with the definitions in this bill, and with a finding that the supplement or pill may contribute to any of the health conditions described in 4) above.

6) Exempts 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.

7) Exempts a retail clerk from being subject to any civil penalty 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.

8) Delays implementation of this bill until January 1, 2026.

9) Includes a severability clause, so that if any provision of this bill is held invalid, that invalidity does not affect other provisions that can be given effect without the invalid provision.

FISCAL EFFECT: According to the Assembly Appropriations Committee, CDPH estimates ongoing costs of $807,000 to $834,000 per year for regulatory and enforcement workload (General Fund). CDPH would promulgate regulations to determine which items are subject to the restrictions under this bill, and because industry will continue to bring additional supplements and drugs to market after the list is published, CDPH staff would need to periodically update the list. CDPH notes enforcement would include investigating complaints, issuing notices of violation, imposing embargo of violative product, development of regulatory correspondence, preparation of civil penalty documents, assisting management during regulatory office meetings, and verification of corrective actions taken by manufacturers found in violation.

PRIOR VOTES:

Assembly Floor:	63 - 2
Assembly Appropriations Committee:	13 - 1

Assembly Judiciary Committee: 9 - 0
Assembly Health Committee: 13 - 0

COMMENTS:

1) *Author's statement.* According to the author, children are abusing OTC weight loss products without the knowledge of their parents and without the supervision of their doctors. With limited regulatory oversight, some dietary supplements are laced with banned pharmaceuticals, steroids, and other toxic ingredients. Dangerous stimulants are also often found in widely available supplements for weight loss. Due to the ease of accessibility of these products, minors take them to lose weight quickly, while ignoring the label on the bottle stating the products are not to be consumed by those under 18 years of age.

2) *FDA regulation of dietary supplements.* Under the FD&C Act, as amended in 1994 by the Dietary Supplement Health and Education Act (often referred to as DSHEA), the FDA does not have the authority to approve dietary supplements for safety and effectiveness, or to approve their labeling, before the supplements are sold to the public. Instead, dietary supplements are regulated by FDA in much the same manner as food, which means they are subject to requirements relating to good manufacturing practices, and must meet certain labeling standards, among other requirements. According to the FDA, it is the responsibility of dietary supplement companies to ensure their products meet the safety standards for dietary supplements and are not otherwise in violation of the law. Dietary supplement labels are required to have nutrition information in the form of a Supplement Facts label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. They also must have a statement on the front of the product identifying it as a "dietary supplement" or similar descriptive term (e.g., "herbal supplement" or "calcium supplement"). The FD&C Act requires that manufacturers and distributors who wish to market dietary supplements that contain a "new dietary ingredient" (NDI) to notify the FDA about these ingredients. An NDI is an ingredient that was not marketed in a dietary supplement in the U.S. prior to October 15, 1994. When notifying the FDA about an NDI, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing the NDI will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. While the FDA is not required to formally approve an NDI, it will consider a dietary supplement "adulterated" unless the NDI has been present in the food supply in the same chemical form that you plan to use in the dietary supplement, or the manufacturer has shown evidence of safety at least 75 days before being introduced or delivered for introduction into interstate commerce, including any citation to published articles.

3) *Dietary supplements for weight loss.* According to a National Institutes for Health fact sheet called "Dietary Supplements for Weight Loss" (fact sheet), dietary supplements promoted for weight loss encompass a wide variety of products and come in a variety of forms, including capsules, tablets, liquids, powders, and bars. Manufacturers market these products with various claims, including that these products reduce macronutrient absorption, appetite, body fat, and weight, and increase metabolism and thermogenesis. Weight-loss products can contain dozens of ingredients, and some contain more than 90. Common ingredients in these supplements include botanicals (herbs and other plant components), dietary fiber, caffeine, and minerals. The fact sheet cite the U.S. Government Accountability Office's report on dietary supplements for weight loss, which concluded that "little is known about whether

weight loss supplements are effective, but some supplements have been associated with the potential for physical harm." The fact sheet states that people who are considering using weight-loss supplements should talk with their healthcare provider to discuss these products' potential benefits and risks. The fact sheet states this is especially important for those who have medical conditions, yet less than one-third of adults who use weight-loss dietary supplements discuss this use with a healthcare professional. This fact sheet lists 24 common ingredients in weight loss dietary supplements: African mango, beta-glucans, bitter orange, caffeine, calcium, capsaicin, carnitine, chitosan, chromium, coleus forskohlii, conjugated linoleic acid, fucoxanthin, garcinia cambogia (hydroxycitric acid), glucomannan, green coffee bean extract, green tea, guar gum, hoodia, probiotics, pyruvate, raspberry ketone, vitamin D, white kidney bean, and yohimbe. For several of these ingredients, the fact sheet noted that "some safety concerns" were reported, and for yohimbe, the fact sheet stated that "significant safety concerns were reported, especially for yohimbine doses of 20mg or higher, with reported adverse effects including cardiac failure and death.

4) *FDA initiative against contaminated weight loss products.* According to the FDA, it has identified an emerging trend where OTC products, frequently represented as dietary supplements, contain hidden active ingredients that could be harmful. The FDA states that it cannot test and identify all weight loss products on the market that have potentially harmful contaminants in order to assure their safety, and that enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight loss products marketed to consumers on the internet and at some retail establishments. According to the FDA, its tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein.

5) *Federal regulation of OTC drugs.* There are two regulatory pathways to bring a nonprescription drug to market in the U.S.: a review using the OTC Monograph process; or, through a new drug application (NDA). The FDA publishes an OTC monograph, which establishes conditions under which an OTC drug is generally recognized as safe and effective and can be marketed without an NDA or pre-market approval, including what active ingredients are allowed, doses, labeling, and testing. If approval is sought for an OTC drug that contains active ingredients that are not part of the OTC monograph, then an NDA is required, which includes premarket approval by the FDA.

6) *There is currently only one approved OTC weight loss pill.* Orlistat, which is sold under the brand name Xenical, has been available by prescription as a weight loss aid in the U.S. since 1999. In 2007, orlistat was also approved by the FDA for nonprescription sales under the brand name of alli, at one-half the daily dose of the prescription product (60mg vs 120mg). Currently, alli is the only FDA-approved weight loss medication available over the counter. The FDA only approved alli for overweight patients ages 18 and older. Orlistat's pharmacological effect occurs through the inhibition of gastric and pancreatic lipases in the gastrointestinal tract, which prevents triglyceride hydrolysis and results in the decreased absorption of dietary fats. Alli reduces dietary fat absorption by approximately 25% at the recommended dosage. The adverse effect profile associated with orlistat predominately consists of a variety of gastrointestinal side effects such as soft stools, abdominal pain, steatorrhea, fecal urgency, flatulence, and less common side effects such as fecal incontinence.

7) *Similar law in New York subject to a lawsuit.* In 2023, legislation was signed into law in New York to ban the sale to minors of OTC diet pills and dietary supplements for weight

loss, similar to this bill, and also include dietary supplements for muscle building, with the exception of protein drinks and powders. The Counsel for Responsible Nutrition (CRN) brought a lawsuit against the bill, arguing that the law violates the First Amendment rights of supplement makers and retailers by "restricting truthful commercial speech and access to lawful products without clear scientific justification." CRN also filed for a preliminary injunction to prevent the law from going into effect pending the lawsuit, but a federal judge denied that motion, allowing the law to take effect commencing April 22, 2024.

8) *AB 1341 Workgroup report.* As described in "Prior Legislation" below, this bill is substantially similar to AB 1341 (Garcia of 2021), which was vetoed by Governor Newsom, who stated that requiring CDPH to evaluate every individual weight loss and dietary supplement product for safety is beyond the scope of CDPH's capabilities. As part of the Governor's veto message, he stated that he would direct CDPH to form a workgroup to develop policy recommendations on the best way to address this important public health challenge. In February of 2024, CDPH released a summary report on the work of the AB 1341 Workgroup. This report summarized policy recommendations from academic and medical experts that participated in the Workgroup, but did not make recommendations of its own. According to CDPH, it convened and facilitated two virtual meetings of subject matter experts on March 7 and June 8 of 2023. CDPH stated that while the report summarizes the policy ideas generated during these meetings, it did not independently evaluate or analyze the Workgroup's proposals, nor did CDPH assess the resource needs and responsible agencies for possible implementation of any of the concepts. The proposals were organized into one of four categories: Legislative Actions; Educational Initiatives and Outreach Activities; Enforcement; and, Improve Social and Economic Resources. Within the Legislative Actions category, the recommendations included: age restrictions for both dietary supplements and OTC drugs (similar to this bill); restricting access to just OTC diet pills; granting the Attorney General authority to enforce various restrictions (such as on certain ingredients or claims to promote weight loss); and, requiring manufacturers to substantiate claims with data for effectiveness and safety. Educational Initiatives recommendations included providing outreach to specific targeted populations at greatest risk with educational programs on the dangers of weight loss supplements, and including outreach within the Health Education Curriculum Framework.

9) *Double referral.* This bill is double referred. Should it pass out of this Committee, it will be referred to the Senate Judiciary Committee.

10) *Prior legislation.* AB 1341 (Christina Garcia of 2021) was substantially similar to this bill. *AB 1341 was vetoed by the Governor, who stated*: "*I commend the work of the author as this bill raises an important public health issue related to the safety of diet or weight loss pills that can result in injury. However, dietary supplements for weight loss are not considered drugs and, therefore, this measure would require CDPH to evaluate every individual weight loss and dietary supplement product for safety, which is beyond the scope of the department's capabilities. Recognizing the need to educate and protect the public-particularly California's youth-of the dangers of using dietary supplements for weight loss, I am directing CDPH to form a workgroup, inclusive of academic and medical experts, that would develop public policy recommendations on the best way to address this important public health challenge. CDPH 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 over-the-counter diet pills that do not require the state to undertake lengthy and costly pharmacological studies on the many supplements on the market today."*

SB 651 (Wieckowski of 2021) would have required food that contains synthetic dyes to have a warning label that synthetic dyes may cause or worsen behavioral problems in children. *SB 651 was not heard in the Senate Health Committee.*

AB 1178 (Quirk of 2019) would have required a manufacturer or distributor of dietary supplements that contain live microorganisms, to include the genus, species, and strain of each live microorganism in the dietary supplement on the label of the dietary supplement. *AB 1178 was held on the Senate Appropriations Committee suspense file.*

SB 347 (Monning of 2019), SB 300 (Monning of 2017), SB 203 (Monning, of 2015), and SB 1000 (Monning of 2014) all would have established the Sugar-Sweetened Beverages Health Warning Act, to be administered by CDPH, and required a safety warning on all sealed sugar-sweetened beverage containers, as specified. These bills would have required the warning label to be posted in a place that is easily visible at the point-of-purchase of an establishment where a beverage container is not filled by the consumer. *SB 347 was not heard in Assembly Health Committee. SB 300 was not heard in Senate Health Committee. SB 203 failed passage in the Senate Health Committee. SB 1000 failed passage in the Assembly Health Committee.*

SB 1381 (Evans of 2014), would have enacted "The California Right to Know Genetically Engineered Food Act" to require the labeling of all genetically engineered foods sold within California. *SB 1381 failed passage on the Senate Floor.*

11) *Support.* This bill is sponsored by the Strategic Training Initiative for the Prevention of Eating Disorders (STRIPED), which states that this bill would protect children across California by prohibiting the sale of weight-loss dietary supplements and OTC diet pills in stores or online to any person under 18 years of age. According to STRIPED, while these dietary supplements deceptively claim to promote healthy weight loss, with some using celebrity endorsers, these products are not required to demonstrate rigorous testing for safety or efficacy before entering the market, are not medically recommended, and are inadequately regulated by the FDA. Alarmingly, there are no age restrictions on the sale of these products, leaving young people, who are particularly vulnerable to deceptive marketing claims, with no protection from purchasing these dangerous products. STRIPED points out that the American Academy of Pediatrics has strongly cautioned against teens using weight-loss supplements, and argues that these supplements have been found to be laced with pesticides, heavy metals, anabolic steroids, and pharmaceuticals that can cause strokes, cancer, and severe liver injury, and that 25% of the 23,000 Americans sent to emergency rooms every year due to dietary supplements are due to weight-loss supplements. This support is joined by a number of other organizations.

12) *Opposition.* The Natural Products Association (NPA) states that supplements are natural products found in food and nature, and that prohibiting the sale of healthy, safe, and legal products to minors will do nothing to promote public health and will do more to undermine it. Restricting access to them is unfair to Californians who value health and wellness, hurts responsible retailers, and drains California's budget through lost sales taxes. NPA states that it supports efforts to stop illegal drugs masquerading as natural products, and that the federal government has vast enforcement powers and has a long track record of punishing criminals who break the law. NPA states that the FDA has found no data suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.

The American Herbal Products Association (AHPA) also opposes this bill for similar reasons, arguing that dietary supplements are already subject to well-established regulation and enforcement systems, with the FDA charged with inspecting manufacturing facilities, reviewing labeling, and monitoring products for safety. AHPA states this bill raises practical problems of enforcement, as noted in the Governor's veto of AB 1341 when he stated that it was beyond the scope of CDPH's abilities to evaluate the safety of dietary supplement products.

SUPPORT AND OPPOSITION:

Support: Academy for Eating Disorders
Alaska Eating Disorders Alliance
Alliance for Eating Disorder Awareness
Be Real, USA
Center for Science in the Public Interest
Children's Advocacy Institute
Eating Disorders Coalition
Erevna
Finxerunt Policy Institute
For You
International Socioeconomics Laboratory
Multi-Service Eating Disorders Association
National Association of Anorexia Nervosa and Associated Disorders
National Eating Disorders Association
NCARTH
Project Heal
Realize Your Beauty
Renfrew Center for Eating Disorders
Strategic Training Initiative for the Prevention of Eating Disorders
The Eating Disorder Foundation
Five individuals

Oppose: American Herbal Products Association
Natural Products Association

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