

ASSEMBLY THIRD READING
AB 82 (Weber)
As Introduced December 15, 2022
Majority vote

SUMMARY

Prohibits 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. Requires the California Department of Public Health (DPH) to develop a notice stating that certain dietary supplements for weight loss or OTC diet pills may contribute to specified health conditions or death and requires retail establishments to post it. Specifies a civil penalty of no more than \$1,000 for each violation and exempts a retail clerk from any civil penalties, or disciplinary action or discharge by the retail establishment, for a violation of these provisions, except as specified. Makes the provisions of this bill operative on July 1, 2024, and includes a severability clause.

COMMENTS

According to the United States (U.S.) Food and Drug Administration (FDA), dietary supplements are regulated as food, not as drugs. The FDA notes, however, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. For these reasons, the FDA notes that it is important to consult with a health care professional before using any dietary supplement.

The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) was amended in 1994 by the Dietary Supplement Health and Education Act (DSHEA), which defined "dietary supplement" and set out FDA's authority regarding such products. 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. Under the FDCA, 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"). In general, even if a product is labeled as a dietary supplement, a product intended to treat, prevent, cure, or alleviate the symptoms of a disease is a drug, and subject to all requirements that apply to drugs.

Estimates on the revenue from vitamin and nutritional supplement production reached nearly \$31 billion in the United States in 2018 and the industry is set to add over a billion more in revenue in 2019. By 2024 the value of the U.S. dietary supplement market is expected to reach \$56.7 billion. According to research cited by the Office of Dietary Supplements, part of the National Institutes of Health, approximately 15% of U.S. adults have used a weight-loss dietary supplement at some point in their lives; more women report use (21%) than men (10%). Americans spend about \$2.1 billion a year on weight-loss dietary supplements in pill form (e.g.,

tablets, capsules, and softgels), and one of the top 20 reasons why people take dietary supplements is to lose weight.

- 1) *Health impact of weight loss or dietary supplements on children.* A 2019 study published in the *American Journal of Public Health* conducted by researchers from Harvard T.H. Chan School of Public Health and Boston Children's Hospital found that young women who use diet pills and laxatives for weight control had higher odds of receiving a subsequent first eating disorder diagnosis within one to three years than those who did not report using these products. The researchers analyzed data from 10,058 women and girls ages 14 to 36 years who participated in the U.S.-based Growing Up Today Study from 2001 to 2016. The researchers found that among participants without an eating disorder, 1.8% of those who used diet pills during the past year reported receiving a first eating disorder diagnosis during the next one to three years compared to 1% of those who did not use the products. They also found that among these participants, 4.2% of those who used laxatives for weight control received a subsequent first eating disorder diagnosis compared to 0.8% of those who did not use these products for weight control.

A 2015 article cited by the author in the *Journal of Public Health Management & Practice* states that adolescents use dietary supplements marketed for weight loss or muscle building, but these are not recommended by physicians. These products are often ineffective, adulterated, mislabeled, or have unclear dosing recommendations, and consumers have suffered injury and death as a consequence. When Congress passed the DSHEA, it stripped the FDA of its premarket authority, rendering regulatory controls too weak to adequately protect consumers. The article makes the case that state government intervention is warranted.

- 2) *Current restriction on the sale of dietary supplements to persons under 18 years of age.* Existing law makes it a misdemeanor for any manufacturer, wholesaler, retailer or other person to sell, transfer or furnish any of the following to anyone under 18 years of age:
 - a) A dietary supplement containing an ephedrine group alkaloid;
 - b) A dietary supplement containing any of the following (forms or classes of steroids):
 - i) Androstenediol;
 - ii) Androstenedione;
 - iii) Androstenedione;
 - iv) Norandrostenediol;
 - v) Norandrostenedione; and,
 - vi) Dehydroepiandrosterone.

A seller must request valid ID from any individual who attempts to purchase a dietary supplement specified in i) and ii) above if that individual reasonably appears to the seller to be under 18 years of age. A violation of the above provisions carries a penalty of \$1,000 for the first violation, \$2,000 for the second violation and \$5,000 for the third and each subsequent violation. It should be noted that a retail clerk who fails to request ID is not guilty of a misdemeanor nor is subject to any civil penalties, or any disciplinary action or discharge by his or her employer unless the retail clerk is a willful participant in a criminal conspiracy, as specified. Moreover, a retail establishment that sells, transfers, or otherwise furnishes a dietary supplement product in violation of a) and b) above is not guilty of a misdemeanor if

certain conditions are met including that the checkout clerks have fulfilled specified standardized training and checkout scanners or computers used to check out customers with purchases are programmed to identify dietary supplement products; or if every checkout clerk has received a written list of dietary supplement products subject to this article that are sold by the retail establishment that may be posted at the checkout station for easy access. This bill expands existing law that already prohibits dietary supplements with the ingredients specified in a) and b) above to also prohibit the sale of dietary supplements (to be determined by DPH) for weight loss or OTC diet pills to any person under 18 years of age without a prescription.

- 3) *Other states.* New York recently passed legislation that will ban the sale of OTC diet pills and supplements for weight loss and muscle building to minors based on studies that found these products are laced with unapproved pharmaceutical ingredients, illicit anabolic steroids, experimental and banned stimulants, and other dangerous chemicals. Supporters also note that research often demonstrates that the use of these products may be a warning sign for the presence or risk of an eating disorder. Young people who take OTC diet pills are more likely to develop an eating disorder than those who do not. More than 1.7 million, or 9% of New Yorkers, will suffer from an eating disorder throughout their lifetime. Eating disorders cause immense harm to individuals and communities, costing New York more than \$3.9 billion a year in direct medical care costs and lost productivity. More than 10,000 lose their lives each year nationally as a direct result of an eating disorder. The New York law focuses on the marketing and advertising of OTC diet pills and muscle-building supplements to minors by establishing age verification guidelines for retailers and delivery sellers.

In 2017-2018, HB 1195 was introduced in the Massachusetts legislature that would have banned the sale of weight-loss and muscle-building dietary supplements to minors, similar to this bill. HB 1195 eventually became a study bill.

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. The author concludes that 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.

Arguments in Support

Various organizations, individuals, professors and physicians write in support citing scientific study after study showing that dietary supplements pose serious health risks to consumers. In the absence of FDA prescreening, many dietary supplements on the consumer market, especially those sold for weight loss, have been found to be laced with prescription pharmaceuticals, banned substances, heavy metals, pesticides, and other dangerous chemicals. Supporters cite a study led by the FDA which tested a small selection of the tens of thousands of dietary supplements on the market and found hundreds of those sold for weight loss to be adulterated with pharmaceutical drugs and banned chemicals, which often are associated with serious health consequences. Another study found that youth using weight-loss supplements were three times more likely than those using ordinary vitamins to experience severe medical harm, including hospitalization, disability, and even death. Studies have linked weight loss supplements to organ failure, heart attacks, stroke, and death. The Centers for Disease Control and Prevention

estimates that supplement use leads to 23,000 emergency room visits every year, with a quarter due to the weight-loss category alone. The American Academy of Pediatrics recently issued a report strongly cautioning against teens using these products for any reason. Supporters note that youth who use OTC diet pills are six times more likely to be diagnosed with an eating disorder compared to nonusers.

Arguments in Opposition

The Natural Products Association (NPA) writes that supplements are natural products found in food and nature. NPA contends that its members invest significant human resources and capital to ensure their products are safe. These include good manufacturing processes, random product testing, adhering to appropriate marketing guidelines, and following every other rule and regulation that the FDA and the Federal Trade Commission have made for 25 years. NPA contends that some have incorrectly stated that the FDA does not review dietary supplements for safety before entering the market or have incorrectly lumped OTC diet pills such as Alli, as dietary supplements when in fact they are regulated as OTC drugs by the FDA, which differs to how dietary supplements are regulated. The FDCA requires manufacturers and distributors to notify the FDA about their ingredients. The notification must include information that is the basis on which the manufacturer or distributor has concluded the dietary supplement is expected to be safe under the conditions of use suggested in the labeling. NPA states that this bill will place onerous restrictions, most notably on small businesses such as local pharmacy, convenience, or health food stores, by prohibiting the sale of popular products. 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. According to NPA, no one wants consumers to use unlawful products. Still, they are already illegal by law, and the FDA uses its enforcement authority against companies that attempt to sell these products. The federal government has vast enforcement powers and has a long track record of punishing criminals who break the law and NPA supports vigorous enforcement of the law to protect consumers. The NPA concludes that the FDA, the chief regulator of dietary supplements, found no data suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.

FISCAL COMMENTS

According to the Assembly Appropriations Committee, DPH estimates ongoing costs of \$807,000 to \$834,000 per year for regulatory and enforcement workload (General Fund).

DPH 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, DPH staff would need to periodically update the list. DPH 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.

VOTES

ASM HEALTH: 13-0-3

YES: Bonta, Waldron, Aguiar-Curry, Arambula, Wendy Carrillo, Haney, Jones-Sawyer, Maienschein, McCarty, Rodriguez, Santiago, Schiavo, Weber
ABS, ABST OR NV: Flora, Vince Fong, Joe Patterson

ASM JUDICIARY: 9-0-2

YES: Kalra, Dixon, Wicks, Bryan, Connolly, Haney, Maienschein, Pacheco, McKinnor
ABS, ABST OR NV: Sanchez, Waldron

ASM APPROPRIATIONS: 13-1-2

YES: Holden, Arambula, Wood, Calderon, Connolly, Dixon, Mike Fong, Grayson, Haney, Hart, Lowenthal, Pellerin, Villapudua
NO: Ta
ABS, ABST OR NV: Sanchez, Megan Dahle

UPDATED

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FN: 0002595