Date of Hearing: January 9, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 82 (Weber) – As Introduced December 15, 2022

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

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. Specifically, **this bill**:

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

2) Requires a retail establishment to request valid identification (ID) 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.

3) Requires a retail establishment to post the notice described in 4) below for purposes of dietary supplements for weight loss and OTC diet pills.

4) Requires DPH to develop a notice, for distribution to retail establishments to post pursuant to 3) above, 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.

5) Requires DPH, in consultation with the United States Food and Drug Administration (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 this bill, in a manner consistent with the definitions in 9) below and with a finding the supplement or pill may contribute to any of the health conditions described in 4) above.

6) Makes a person who violates this section liable for a civil penalty of no more than $1,000 for each violation, assessed and recovered in a civil action brought by the California Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction. Exempts a retail clerk from being subject to any civil penalty, or to any disciplinary action or discharge by the retail establishment, for a violation of this bill. Applies provisions of this bill to a retail clerk who is a willful participant in an ongoing conspiracy to violate this bill.

7) Requires the notice requirements described in this bill to be implemented only to the extent not in conflict with federal law.

8) Makes this bill effective on July 1, 2024 and includes severability clause.

9) Defines the following:

   a) Dietary supplements for weight loss 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 Federal Food, Drug, and Cosmetic Act (FDCA), and regulations adopted thereunder. Includes products marketed with a Supplement Facts panel, pursuant to federal regulations, that contain either lawful dietary ingredients or ingredients deemed adulterated under Section 342 of Title 21 of the United States Code (U.S.C.), or both. Exempts dietary fiber products;

   b) OTC diet pills 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 regulation of the FDCA (21 U.S.C. Sec. 301, *et seq*.), and regulations adopted thereunder. Includes products marketed with a Drug Facts panel, pursuant to federal regulations, that contain either approved drug ingredients or ingredients deemed adulterated under Section 342 of Title 21 of the U.S.C., or both; and,

   c) Retail establishment 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.

EXISTING FEDERAL LAW:

1) Establishes the FDCA which among various provisions, gives the FDA authority to oversee the safety of food, drugs, medical devices, and cosmetics. Defines under the FDCA a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. [21 U.S.C. § 301, *et seq*.]

2) Establishes the Dietary Supplement Health and Education Act of 1994 (DSHEA), administered by the FDA, which among provisions, prohibits manufacturers and distributors of dietary supplements and dietary ingredients from marketing products that are adulterated or misbranded. Establishes under DSHEA labeling requirements for dietary supplements and permits dietary supplements to make certain structure function claims, but cannot be sold for the treatment, prevention, mitigation, or cure of diseases or conditions associated with known diseases. [21 U.S.C.§ 342]

3) Establishes the Current Good Manufacturing Practice for manufacturing, packaging, labeling, and holding operations for dietary supplements. [21 U.S.C. §§ 1-99, 200-299, 300-499, 600-799, and 800-1299]

4) Establishes under the FDA, the MedWatch program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

EXISTING STATE LAW:

1) Establishes the Sherman Food, Drug, and Cosmetic Law, administered by DPH, which regulates the packaging, labeling, and advertising of drugs and devices, including dietary supplements. [Health and Safety Code (HSC) § 109875, *et. seq*.]

2) Prohibits the sale or distribution of any dietary supplement product that contains ephedrine group alkaloids unless the product contains a specified label. Permits the sale of any dietary supplement containing ephedrine if the product label clearly and conspicuously contains specified warnings, including the following:

   a) "WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using a monoamine oxidase inhibitor or any other dietary supplement, prescription drug, or OTC drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough or cold, and weight control products)."
   b) "Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects, including heart attack and stroke."
   c) "Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms."
   d) "Individuals who are sensitive to the effects of caffeine should consult a licensed health care professional before consuming this product."
   e) "KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(a)]

3) Prohibits the sale or distribution of dietary supplements containing steroid hormone precursors unless the product label for these dietary supplements clearly and conspicuously contains the following warning:

   "WARNING: NOT FOR USE BY INDIVIDUALS UNDER THE AGE OF 18 YEARS. DO NOT USE IF PREGNANT OR NURSING. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, prostate cancer, prostate enlargement, heart disease, low "good" cholesterol, or if you are using any other dietary supplement, prescription drug, or OTC drug. Do not exceed recommended serving. Exceeding recommended serving may cause serious adverse health effects. Possible side effects include acne, hair loss, hair growth on the face (in women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, blurred vision, or other similar symptoms. KEEP OUT OF REACH OF CHILDREN." [HSC § 110423(b)]

4) Requires the product label for any dietary supplement product containing ephedrine group alkaloids or steroid hormone precursors to clearly and conspicuously display the following statement: "To report any adverse events call 1-800-332-1088" [MedWatch program]. [HSC § 110423(c)]

5) Establishes the California Unfair Practices which prohibits unfair competition and any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. [Business and Professions Code (BPC) § 17500]

6) Makes it a misdemeanor to sell, furnish, give, or cause to be sold, furnished, or given away, any alcoholic beverage to any person under the age of 21 years. Makes it a misdemeanor for any person under the age of 21 years to purchase any alcoholic beverage, or to consume any alcoholic beverage, as specified. [BPC § 25658]

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

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

COMMENTS:

1) PURPOSE OF THIS 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.

2) BACKGROUND. According to the 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 FDCA was amended in 1994 by the 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.

a) 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.

b) 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:

i) A dietary supplement containing an ephedrine group alkaloid;
ii) A dietary supplement containing any of the following (forms or classes of steroids):

(1) Androstanediol;
(2) Androstanedione;
(3) Androstenedione;

(4) Norandrostenediol;
(5) Norandrostenedione; and,
(6) 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 i) and ii) 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 i) and ii) 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.

4) **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.

5) **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.

6) **PREVIOUS LEGISLATION.**

   a) AB 1341 (C. Garcia) of 2021, is substantially similar to this bill and was vetoed by Governor Newsom with the following message:

   This bill would prohibit retail establishments from selling, transferring, or providing, dietary supplements for weight loss or OTC diet pills to anyone under 18 years of age without a prescription, or valid ID prior to purchasing. The bill would also require DPH to establish a list of dietary supplements that would be subject to this bill.

   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 DPH 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 DPH 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.

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.

For these reasons, I cannot sign this bill.

b) AB 3042 (Limon) of 2019 was substantially similar to this bill but due to the shortened Legislative calendar brought on by the COVID-19 pandemic, this bill was not set for a hearing in the Assembly Health Committee.

7) AMENDMENTS. As this bill moves forward, the author may wish to amend this bill to reflect a later implementation date to 2025 as intended in the introduced version of this bill.

8) DOUBLE REFERRAL. This bill has been double-referred; upon passage of this Committee, it will be referred to the Assembly Judiciary Committee.

9) COMMENTS. In response to the Governor’s veto of AB 1341 from 2021, DPH convened a stakeholder group and according to the author, DPH has yet to publicly share the results of this work.

REGISTERED SUPPORT / OPPOSITION:

Support

Academy for Eating Disorders
Alaska Eating Disorders Alliance
Alliance for Eating Disorders Awareness
Be Real USA
Center for Science in The Public Interest
Children's Advocacy Institute
Eating Disorders Coalition
Erevna, Policy for The People
Finxerunt Policy Institute
For You
International Socioeconomic Society & Finxerunt Policy Institute
Multi-service Eating Disorders Association
National Association of Anorexia Nervosa and Associated Disorders
National Eating Disorders Association
Ncarth
Project Heal
Realize Your Beauty, INC.

Renfrew Center for Eating Disorders
Strategic Training Initiative for The Prevention of Eating Disorders
The Eating Disorder Foundation

Opposition

Natural Products Association

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