Date of Hearing: January 11, 2024

# ASSEMBLY COMMITTEE ON JUDICIARY Brian Maienschein, Chair B 82 (Wahar) As Introduced December 15, 2020

AB 82 (Weber) – As Introduced December 15, 2022

**SUBJECT**: DIETARY SUPPLEMENTS FOR WEIGHT LOSS AND OVER-THE-COUNTER DIET PILLS

**KEY ISSUE**: SHOULD A RETAIL ESTABLISHMENT BE PROHIBITED FROM SELLING DIETARY SUPPLEMENTS FOR WEIGHT LOSS AND OVER-THE-COUNTER DIET PILLS TO MINORS, UNLESS THEY ARE PRESCRIBED TO THE MINOR BY A PHYSICIAN?

#### **SYNOPSIS**

According to the author and supporters of this bill, although some over-the-counter diet pills and weight loss supplements contain substances which may be harmful to minors, such products are easily purchased by children and teens without parental or physician approval. This bill, therefore, would prohibit a retailer from selling such products to minors, unless the minor has a physician's prescription. The bill also requires the California Department of Public Health (DPH), in consultation with the federal Food and Drug Administration (FDA), to determine which dietary and weight loss products are to be subject to this bill and to develop a notice specifying known risks associated with use of these products. The bill would require the retailer to post this notice at their establishment.

The bill is virtually identical to the final version of AB 1341 (C. Garcia, 2021), which was vetoed by Governor Newsom. The Governor's veto message applauded the intent of AB 1341, but noted that he feared that the bill 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." As an alternative, the Governor directed DPH to form a working group to promote educational efforts and, if necessary, recommend legislation. As of this writing, DPH has still not developed those recommendations, though they are reportedly imminent. The author has indicated an intent to amend the bill in the Senate, if necessary, to incorporate working group recommendations if and when they become available.

This author-sponsored bill is supported by several individuals and groups, especially those concerned with childhood eating disorders. Supporters contend that social and cultural pressures lead many young people to use, and sometimes abuse, diet pills and weight loss supplements. While these products may also harm adults, the author contends that adults have more capacity to assess risks and make informed decisions. The bill is opposed by the Natural Products Association (NPA), a natural products trade association, because, they claim, it would place onerous restrictions on retailers and would unfairly restrict access to safe and healthy products. They claim that there is insufficient evidence linking these products to childhood eating disorders, and that existing state and federal law already provides for the removal of truly harmful products from the market. The bill recently passed out of the Assembly Health Committee by a vote of thirteen to zero.

**SUMMARY**: Seeks to reduce the risks posed to consumers by dietary supplements for weight loss and over-the-counter diet pills by regulating their sale by retailers. Specifically, **this bill**:

- 1) Defines the following for purposes of the bill:
  - a) "Dietary supplements for weight loss" means 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).
  - b) "Over-the-the-counter diet pills" means 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.
  - c) "Retail establishment" means any vendor that, in the regular course of business, sells dietary supplements for weight loss or over-the-counter 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.
- 2) Prohibits retail establishments from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter diet pills to any person under 18 years of age without a prescription.
- 3) Requires the California Department of Public Health (DPH) to develop a notice for distribution to retail establishments to post stating that certain dietary supplements for weight loss or over-the-counter 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, and would further require the DPH, in collaboration with the federal Food and Drug Administration (FDA) and stakeholders, to determine which dietary supplements for weight loss and over-the-counter diet pills will be subject to the provisions of this bill.
- 4) Requires retail establishments to post the notice described in (3) above.
- 5) Imposes a civil penalty of no more than \$1,000 for each individual violation of (2) or (3) above.
- 6) Exempts a retail clerk from the civil penalty in (5) above, as well as from any disciplinary action or discharge by the retail establishment for a violation of (2) or (3) above.

#### **EXISTING LAW:**

- 1) Grants the FDA authority to oversee the safety of food, drugs, medical devices, and cosmetics, and defines a dietary supplement as a vitamin; mineral; herb or other botanical; amino acid; or other substance for used 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. Section 301, *et seq.*)
- 2) Establishes under federal law the Dietary Supplement Health and Education Act (DSHEA), administered by the FDA, which among other things, regulates the manufacture, distribution, and labeling of dietary supplements and prohibits marketing products that are adulterated or misbranded. (21 U.S.C. Section 342.)

- 3) Establishes the state Sherman Food, Drug, and Cosmetic Law, administered by DPH, which regulates the packaging, labeling, and advertising of drugs and devices, including dietary supplements. (Health & Safety Code Section 109875 *et. seq.*)
- 4) Regulates the sale or distribution of any dietary supplement that contains ephedrine group alkaloids and makes it a misdemeanor to sell such products to persons under 18 years of age. Requires the seller of such products to request a valid identification of any prospective purchaser that reasonably appears to be under 18 years of age. Requires a label to contain specified warnings, including a warning that such products should not be used by persons under 18 years of age. (Health & Safety Code Sections 110423 and 110423.2.)
- 5) Prohibits unfair competition and any unlawful, unfair or fraudulent business act or practice, including any unfair, deceptive, untrue or misleading advertising. (Business and Professions Code Sections 17200 and 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 21 years of age. 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. (Business & Professions Code Section 25658.)
- 7) Requires all persons engaging in the retail sale of tobacco products to check the ID of prospective tobacco purchasers in order to determine their age, if the purchaser reasonably appears to be under 21 years of age. (Business & Professions Code Section 22956.)

**FISCAL EFFECT**: As currently in print this bill is keyed fiscal.

**COMMENTS**: According to the author, children and teens "are abusing over the counter 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." The author has submitted several studies suggesting that some of dietary supplements, which are not rigorously evaluated by the FDA or other regulatory agencies, may present health risks to children and young adults, especially those who suffer from, or display behaviors associated with, eating disorders. Notwithstanding these risks, the author claims that more than 30 percent of children and adolescents take dietary supplements of some sort on a regular basis, and 11 percent of teens report using dietary supplements specifically for weight loss.

This bill seeks to reduce the risk posed to children and teens by regulating the sale of dietary supplements for weight loss and over-the-counter diet pills in two ways. First, the bill would prohibit a retailer from selling such products, without a prescription, to consumers under 18 years of age, and it would require the retailer to request proof of age from any person that reasonably appears to be under 18 years of age. Second, the bill requires DPH to develop and distribute a notice identifying the risks of the regulated products and require that the notice be posted in retail establishments that sell covered products. The notice must state that *certain* dietary supplements for weight loss and the over-the-counter diet pills may contribute to specified ailments and medical conditions. The bill also requires DPH, in consultation with FDA, to determine *which* products are to be subject to the bill's provisions, based upon a finding that the supplement or pill contributes to one of the specified conditions. As to enforcement, the bill subjects any person who violates the bill's provisions to a civil penalty of no more than \$1,000

for each violation, to be recovered in a civil action brought by the California Attorney General, a district attorney, or a city or county counsel.

The bill specifies that only the retail establishment, rather than the retail clerk employee, would be subject to the penalty. The same provision of the bill, however, also provides that no retail clerk shall be subject to "any disciplinary action or discharge by the retail establishment" for a violation of the bill's provisions. As noted in the "Arguments in Opposition" section below, the California Chamber of Commerce submitted a late letter opposing this specific provision, claiming that if an employer cannot take *any* internal disciplinary action they will have no way to comply the bill's provisions.

Existing restrictions on over-the-counter supplements and the ability of minors to consent. By definition, "over-the-counter" products do not require a prescription and thus, with few exceptions, there is no barrier on who may purchase them. One notable exception includes the regulation and sale of over-the-counter products that contain ephedrine. Although no prescription is required for an adult, retailers must keep such products in a secure location, check the IDs of all purchasers, and refrain from selling the product to anyone under 18 years of age. However, regulations of ephedrine had less to do with protecting minors, per se, than with regulating a product that is used in the production of methamphetamine.

Other prohibitions on the sale of harmful products to a minor – most notably alcohol and tobacco products – are rooted in the age-old presumption (whether justified or not) that minors have less capacity than adults to make rational decisions about their health. As a general rule, for example, a minor cannot consent to medical treatments or procedures without parental consent. In recent years, the legislature has made notable exceptions to this general rule when it comes to reproductive care, some mental health counseling, and certain substance abuse treatments. However, those exceptions represent unique situations in which requiring parental consent could pose a risk to the minor that is greater than the risk posed by the medical treatment or procedure. Under this bill, however, denying minors the right to purchase potentially harmful weight loss supplements or diet pills without a prescription does not pose any health risk to the minor.

To which supplements would the bill apply? This prohibits a retailer from selling "dietary supplements for weight loss" or "over-the-counter diet pills" to a minor, unless the minor has a prescription. While the bill defines each of these terms (see the definitions in the bill summary above), but the distinction between them is not entirely clear; both involve products that are marketed for the purpose of achieving weight loss that may otherwise be purchased without a prescription under FDA regulations. However, the provision of the bill requiring DPH to develop a notice for posting at the retail establishment also requires DPH, in consultation with FDA, to "determine which dietary supplements for weight loss and over-the-counter diet pills" contribute to a list of specified medical conditions. The bill specifies that only those products determined by DPH to cause such ailments shall be "subject to this section" ("the section" being the entire contents of the bill). According to information provided to the Committee, it is the author's intent that the bill will not apply to all dietary supplements for weight loss and over-the-counter diet pills, but it will only apply to those products which DPH determines to contribute to one of the listed conditions.

As noted above, AB 1341 (2021), in its final forms, was virtually identical to this bill and was vetoed by the Governor. In his veto message, the Governor stated that he would direct DPH to convene a working group to prepare a report on the issue and to make legislative

recommendations, if necessary. Because DPH is currently preparing recommendations pursuant to the Governor's directive, the Committee is not asking the author to take specific amendments at this time. The author's office, however, has informed the Committee of its intention to amend the bill as necessary when the DPH recommendations become available. If the bill passes out of this Committee, the author may wish to clarify that the bill only applies to products for which DPH has made a determination that the product contributes to one of listed ailments. The author may also wish to consult with DPH on a reasonable timeline for DPH to make such determinations. The author may also wish to consider the reasonable argument made by the California Chamber of Commerce – that prohibiting an employer from taking "any" disciplinary action against a retail clerk who fails to check ID to verify the age of the consumer will hamper a retailer's ability to comply with the law—and allow employers to discipline employees who, for example, violate store policies.

ARGUMENTS IN SUPPORT: According to a coalition of childhood health advocates and medical professionals, especially those concerned with childhood eating disorders, several studies and reports document the dangers of dietary supplements to all consumers. For example, the proponents of this bill claim that "weight-loss supplements have been found to be laced with pesticides, heavy metals, anabolic steroids, and pharmaceuticals that can cause strokes, cancer, and severe liver damage, which sometimes require transplants or cause death." Notwithstanding these dangers, promotional materials for these products "deceptively claim to promote healthy weight loss" even though such products are not rigorously tested "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 protections from purchasing these dangerous products." The proponents maintain that this bill is necessary to "protect children and other vulnerable consumers in the state from these harmful products," and they contend that this approach is consistent with age restrictions placed upon the purchase of other harmful products, such as tobacco and ephedrine.

ARGUMENTS IN OPPOSITION: According to the Natural Products Association (NPA), a trade association, this bill is a "solution in search of a problem" that will ultimately "undermine public health." NPA raises a number of objections to this bill. First, NPA notes the FDA already enforces several federal statutes that seek a "balanced and informed approach to protecting consumer health and access to dietary supplements." They point out that FDA already has the power remove products from the market if the product, or an ingredient within it, represents an actual harm. In addition, dietary supplements that are allowed to be sold over-the-counter must still meet manufacturing, distribution, and labeling requirements. Moreover, NPA questions claims that dietary supplements are routinely "laced" with dangerous substances, claiming that the products sold by their members contain "natural products contained in food and nature." These products may help consumers who struggle with obesity, which "is a complex, multifactorial health issue that requires a comprehensive approach." Obesity, the proponents note, is "the second leading preventable cause of death in the United States and is associated with many comorbid conditions." NPA concludes that this bill would place onerous restrictions on retailers and restrict consumer access to safe and healthy products without any corresponding benefit.

The California Chamber of Commerce (Cal Chamber) supports the overall intent of this bill; however, it opposes the language providing that no retail clerk shall be subject to "any disciplinary action or discharge" for a violation. Cal Chamber concludes that, "we do not oppose protecting California's youth from diet pills by verifying identification – but when employers are

facing monetary fines if their employees fail to comply with state law, that employer must be able to discipline employees for that failure."

**Prior related legislation**. AB 1341 (C. Garcia, 2021) would have similarly prohibited the sale of dietary supplements for weight loss and over-the-counter diet pills to minors without a prescription, and it would have required DPH to create a prescribed notice. This bill was vetoed for the reasons stated in the analysis.

AB 3042 (Limon, 2019) was substantially similar to this bill and AB 1341, except that it would have additionally required retailers to limit physical access to products, as specified. This bill died in the Assembly Health Committee.

#### **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
FINIXERUNT 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**

California Chamber of Commerce Natural Products Association

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