SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

AB 82 (Weber)
Version: May 28, 2024
Hearing Date: June 25, 2024
Fiscal: Yes
Urgency: No
AM

SUBJECT

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

DIGEST

This bill prohibits a retail establishment from selling dietary supplements for weight loss or over-the-counter diet pills to any person under 18 years of age without a prescription. Requires the California Department of Public Health (CDPH) to determine which dietary supplements and over-the-counter (OTC) diet pills are subject to the prohibition. The bill provides that a person who violates this section is liable for a civil penalty of no more than $1,000 for each violation to be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction.

EXECUTIVE SUMMARY

This bill's author and sponsor of the bill argue that dietary supplements and OTC diet pills pose a serious risk to children, noting that the American Academy of Pediatrics has strongly cautioned against teens using weight-loss supplements. In light if these concerns, the bill prohibits a retail establishment from selling dietary supplements for weight loss or OTC diet pills to any person under 18 years of age without a prescription. This bill was previously analyzed by the Senate Health Committee—where it passed by a vote of 9 to 0—regarding issues relating to the public health implications of the bill's provisions. This analysis, however, is limited to the issues within the Committee's jurisdiction—namely, the enforcement and potential legal issues implicated by the bill's provisions. The bill is sponsored by the Strategic Training Initiative for the Prevention of Eating Disorders (STRIPED). The bill is supported by various organizations and a few individuals. The bill is opposed by the American Herbal Products Association, Natural Products Association, Unilever, and Vytalogy Wellness. This bill passed out of the Senate Health Committee on a vote of 9 to 0.

PROPOSED CHANGES TO THE LAW

Existing federal law:

1) Establishes the Federal Food, Drug, and Cosmetics Act (FDCA), which, among other things, grants the Food and Drug Administration (FDA) authority to oversee the safety of food, drugs, medical devices, and cosmetics. (21 U.S.C. Sections 301 – 399i.)

2) Establishes the Nutrition Labeling and Education Act, which amends the FDCA to prescribe requirements for nutrition labeling. (Pub. L. 101-535, 104 Stat. 2353.)

3) Establishes the Dietary Supplement Health and Education Act, which amends the FDCA to regulate dietary supplements. (Pub. L. No. 103-417, 108 Stat. 4325.)

4) Establishes various requirements for food labels including 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. (*Id.*; 21 C.F.R. §101, et seq.)

Existing state law:

1) Establishes the Sherman Food, Drug, and Cosmetic Law (Sherman Law), which regulates the packaging, labeling, and advertising of food, drugs, medical devices, and cosmetics and is administered by the California Department of Public Health (CDPH). (Health & Safe. Code §§ 109875-111915.)

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.
    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 FDCA 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.

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.

2) 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 reasonable appears to the retail establishment to be under 18 years of age.

3) Exempts a violation of this bill from existing penalty 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.

4) 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.

5) Delays implementation of its provisions until January 1, 2026.

6) Includes a severability clause.

COMMENTS

1. Stated need for the bill

The author writes:

> Children 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. 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. This is a re-introduction of AB 1341 (Cristina Garcia, 2022)

This bill is substantially similar to AB 1341 (Cristina Garcia, 2022), which passed this Committee on a vote of 9 to 2 but was ultimately vetoed by Governor Newsom. The main differences are: (1) the penalty was lowered to $250 for each violation, (2) removes the requirement that CDPH create a specified notice regarding the dangers of dietary supplements and that a retail establishment post said notice, and (3) removes limitation that a retail clerk is not subject to discipline by the retail establishment for violating the bill's provisions. In the Governor's veto message of AB 1341, he wrote:

> 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.

The California Department of Public Health established an AB 1341 Workgroup in response to the Governor's veto to address the potential risks associated with the use of dietary supplements for weight loss and over-the-counter (OTC) diet pills by youth. The Workgroup came up with various policy recommendations; however, the recommendations did not represent a position of the California Health and Human Services Agency, the California Department of Health, or the Governor's Office. Some of the Legislative proposals included:

- restricting the sale of OTC diet pills and weight loss dietary supplements to adults 18-years-old and over;
- mandating these products are kept behind the counter; and
- restricting access to OTC diet pills carrying drug facts panel to adults 18-years-old and over, but do not restrict access to dietary supplements.[1]

[1] Cal. Dept. of Pub. Health, *AB 1341 Workgroup Report*, (Feb. 2024), p. 2.

3. Legal issues raised by the bill and enforcement

a. FDCA and dietary supplements

Under the FDCA, the FDA does not have pre-market approval like it does for drugs. Dietary supplements are regulated by FDA in a similar manner as food, meaning they are subject to requirements relating to food 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").[2]"

b. Federal preemption

The courts have held that when Congress acts under its constitutional powers, it may preempt state laws by one of the following means: (1) an express preemption provision that "withdraw[s] specified powers from the States"; (2) field preemption that "precludes [States] from regulating conduct in a field that Congress . . . has determined must be regulated by its exclusive governance"; or (3) conflict preemption, which occurs when either "compliance with both federal and state regulations is a physical impossibility," or the "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Arizona v. United States* (2012) 567 U.S. 387, 399 [internal quotation marks omitted].)

On the other hand, courts also apply a strong presumption against federal preemption of state law, particularly with respect to matters within states' traditional police powers. "[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." (*Gonzales v. Oregon* (2006) 546 U.S. 243, 270 [internal quotation marks omitted].) "[Police] regulations may validly be imposed if they constitute a reasonable exertion of governmental authority for the public good." (*In re Fuller* (1940) 15 Cal. 2d 425, 428.) Ensuring the safety of minors by prohibiting the sale of dietary supplements and drugs to minors is at least presumptively within the state's power to regulate for the "protection of the lives, limbs, health, comfort, and quiet of all persons." (*Gonzales v. Oregon*, *supra,* at 270.)

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[2] Food and Drug Administration, *FDA 101: Dietary Supplement* (Jun 2, 2022), available at https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements#:~:text=Under%20the%20FD%26C%20Act%2C%20it,in%20violation%20of%20the%20law.

The bill ensures that a minor could be sold a dietary supplement or OTC diet pill if they have a valid prescription. As noted in this Committee's analysis of AB 1321, existing state law bars the sale of FDA-approved OTC drugs to minors that contain any quantity of dextromethorphan without a prescription, as well as 16 other states, and that none of these laws have been struck down by courts as federally preempted. (Health & Saf. Code §§ 11110-11111.) The FDA has approved at least one weight loss drug for over-the-counter sale. This exception aids against claims that bill is somehow an obstacle to the federal law.

c. Dormant Commerce Clause

Section 8 of Article I of the United States Constitution grants the United States Congress the power to regulate interstate commerce.[3] The converse proposition—that states may not usurp Congress's express power to regulate interstate commerce—is known as the Dormant Commerce Clause—"the [Commerce] Clause also contains a further, negative command, one effectively forbidding the enforcement of certain state economic regulations even when Congress has failed to legislate on the subject."[4] The United States Supreme Court recently affirmed that the dormant Commerce Clause generally does not prohibit a state from regulating commerce within its borders, even if the prohibition affects out-of-state sellers, unless the prohibition acts to discriminate against out-of-state interests for the benefit of in-state commerce.[5] The Court has held that "[s]tate laws that 'regulat[e] even-handedly [across all in-state and out-of-state businesses] to effectuate a legitimate local public interest…will be upheld unless the burden imposed upon such commerce is clearly excessive in relation to the putative local benefits.' "[6]

This bill's prohibition on the sale of specified weight loss products to minors does not implicate the dormant Commerce Clause as the bill's provisions apply equally to all retailers that sell to Californians, regardless of whether they are physically located within the state. There is no implication that the bill benefits in-state retailers over out-of-state retailers. A statute may also violate the dormant Commerce Clause, even if it "regulates even handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental" and the burden imposed on commerce "is clearly excessive in relation to the putative local benefits" or substantially burdens interstate commerce.[7] (*Pike v. Bruce Church, Inc.* (1970) 397 U.S. 137, 142.) As the rationale for the bill is to ensure the health and safety of minors, which is a valid

[3] U.S. Const., art. I, § 8, cl. 3.
[4] *National Pork Producers Council v. Ross* (2023) 143 S.Ct. 1142, 1152 (internal quotation marks and alterations omitted).
[5] *Id.* at pp. 1152-1153.
[6] *South Dakota v. Wayfair, Inc.* (2018) 138 S.Ct. 2080, 2091.
[7] *Pike v. Bruce Church, Inc.* (1970) 397 U.S. 137, 142; *National Pork Producers Council* supra at fn. 6 at pp. 1162-1163.

exercise of the state's police powers, this bill would likely not be found to substantially burden interstate commerce in violation of the Dormant Commerce Clause.[8]

d. *Enforcement*

The bill provides a person who violates this section is liable for a civil penalty of no more than $250 for each violation to be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction.

4. Statements in support

STRIPED, the sponsor of the bill, and a coalition of other organizations write in support, stating:

> We must take action now to protect the children of California by making it harder for children to be targeted by the empty promises of under-regulated weight-loss supplements. These products pose a serious risk to children of all ethnicity groups, genders, and ages across the state. The American Academy of Pediatrics has strongly cautioned against teens using these products. The Food and Drug Administration has yet to approve any over-the-counter weight-loss products for children.
>
> Restricting access puts California's public health approach in line with physician recommendations. We, the undersigned, urge your support of AB-82 to protect young people in California from these dangerous products.

5. Statements in opposition

The Animal Herbal Products Association writes in opposition stating:

> […] AHPA has addressed legislation similar to AB 82 in several states, where it has consistently raised problems of practical enforcement. As with AB 1341, AB 82 would require that the California Department of Public Health (CDPH) evaluate the composition, labeling, marketing, and all other representations of products on the market, as well as evaluate the potential health effects of their individual ingredients, to determine whether such products are subject to the notice and restriction requirements of the proposed law. As Governor Newsom noted in his veto memo for AB 1341, it is "beyond the scope of the department's abilities" to evaluate the safety of all dietary supplement products according to the dictates of the bill, a problem which raises further resource questions regarding the expense of consistently

[8] *Gonzales v. Oregon* (2006) 546 U.S. 243, 270; "the structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." [internal quotation marks omitted].

determining how all such products are "labeled, marketed, or otherwise represented."

SUPPORT

Strategic Training Initiative for the Prevention of Eating Disorders (STRIPED) (sponsor)
Academy for Eating Disorders
Alaska Eating Disorders Alliance
Alliance for Eating Disorder Awareness
Awareness
Be Real, USA
Center for Science in the Public Interest
Children's Advocacy Institute
Eating Disorders Coalition
Eating Disorder Foundation
Erevna
Finxerunt Policy Institute
For You
iCure Health International
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
Five individuals

OPPOSITION

American Herbal Products Association
Natural Products Association
Unilever
Vytalogy Wellness

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

AB 1341 (Cristina Garcia) was substantially similar to this bill and was vetoed by Governor Newsom. *See* Comment 2 for Governor's veto message.

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 Senate Health Committee.

AB 1178 (Quirk, 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, 2019) 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. 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 (Monning, 2017), SB 203 (Monning, 2015), and SB 1000 (Monning, 2014) were all substantially similar to SB 347. SB 300 was not heard in the Senate Health Committee, SB 203 failed passage in the Senate Health Committee, and 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.

PRIOR VOTES

Senate Health Committee (Ayes 9, Noes 0)
Assembly Floor (Ayes 63, Noes 2)
Assembly Appropriations Committee (Ayes 13, Noes 1)
Assembly Judiciary Committee (Ayes 9, Noes 0)
Assembly Health Committee (Ayes 13, Noes 0)

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