SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2021-2022 Regular Session

AB 1341 (Cristina Garcia)
Version: June 8, 2022
Hearing Date: June 21, 2022
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 (DPH) to determine which dietary supplements and over-the-counter (OTC) diet pills are subject to the prohibition, 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, other serious injury, or death. 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 8 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. The bill is opposed by the Natural Products Association.

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 (DPH). (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) 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.
   a) Requires retail establishments to post this notice.
   b) Specifies this notice requirement is to be implemented only to the extent it's not in conflict with federal law.

4) 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 $1,000, assessed in a civil action brought by the Attorney General or any district attorney, county counsel, or city attorney.

5) Exempts a retail clerk from being subject to any penalty, or to any disciplinary action or discharge by the retail establishment, 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.

6) Delays implementation of its provisions until July 1, 2023.

7) Includes a severability clause.

COMMENTS

1. Stated need for the bill

The author writes:

> Teens use dietary supplements for weight loss and muscle building even though doctors say they shouldn't. 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.
>
> Accordingly, research shows that health inequities exist across race/ethnicity, gender, and socioeconomic status:
> - Women are two times more likely to use weight loss supplements and over the counter (OTC) diet pills than men.
> - African American & Latinx adults are at a higher risk of using weight loss supplements than white adults.
> - People in households with annual income less than $40,000 are more likely to use dietary supplements for weight loss than those with higher incomes.
> - Latinx teens are 40% more likely to use OTC diet pills than white teens.

To limit the harmful impact OTC diet pills have on our youth, AB 1341 would ban retail establishments from selling these products to minors under the age of 18.

2. 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").[1]"

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.)

In the Assembly Judiciary Committee, amendments were taken to ensure that a minor could be sold a dietary supplement or OTC diet pill if they have a valid prescription. As noted by the Assembly Judiciary Committee, 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.[2] (Health & Saf. Code §§ 11110-11111.) The FDA has approved at least one weight loss drug for over-the-counter sale.[3] This exception safeguards against claims that bill is somehow an obstacle to the federal law.

c. Notice provisions in the bill

The bill requires DPH to determine which dietary supplements and over-the-counter (OTC) diet pills are subject to the prohibition, and to develop a notice for distribution to

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[1] 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.
[2] Asm. Judiciary Com. Analysis Asm. Bill 1321 (2021-2022 Reg. Sess.) as amended Apr. 15, 2022, at p. 4-5.
[3] *Id*.

retail establishments for posting that states that certain dietary supplements for weight loss or OTC diet pills may contribute to specified medical conditions, other serious injury, or death. The bill specifically requires the notice to say: 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.

The notice requirement implicates the First Amendment as it is compelled speech. Courts have generally found that certain types of commercial speech, such as state and federal statutes regarding food labeling requirements and prescription drug warnings, are not in violation of the First Amendment.[4] The U.S. Supreme Court has held that the content of any compelled disclosure must be limited to "purely factual and uncontroversial information.[5]" (Zauderer, supra, 471 U.S. at 651.) It is unclear whether the notice that this bill requires DPH to develop meets this standard. The bill requires DPH, in consultation with the FDA and other stakeholders, to determine which dietary supplements for weight loss and over-the-counter diet pills are to be subject to the bill with a finding that the supplement or pill may contribute to any of the health conditions specified in the notice.

Additionally, the FDCA expressly preempts state laws addressing the labeling of food, which a dietary supplement is under that law, but specifically allows for labeling that provides a warning concerning safety. (21 U.S.C. Section 343-1 (a); Nutrition Labeling and Education Act, Pub. L. 101-535, Section 6 (c)(2), 104 Stat. 2353, 2364 (uncodified) (1990).) The notice under this bill likely falls within this exception. The FDCA also establishes labeling requirements for drugs, which include over-the-counter diet pills, and forbids states from establishing "any requirement…that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDA and other federal labeling laws. (21 U.S.C. Section 379r(a).) Labeling," includes both the labels on drug containers and wrappers, and "other written, printed, or graphic matters…accompanying [the drugs]." (21 U.S.C. Section 321 (k), (m).) No savings clause is provided for these provisions. The notice required by this bill may be sufficiently detached from the OTC diet pill as to not be preempted since it's not required to be on the pill itself or material accompanying the pill.

In light of these issues the bill specifically provides that the notice requirements described in the bill are to be implemented only to the extent they are not in conflict with federal law.

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[4] *Zauderer v. Office of Disciplinary Counsel of Supreme Court* (1985) 471 U.S. 626, 651.
[5] *Id*. at 651.

d. Dormant Commerce Clause

The United States Constitution's commerce clause provides that Congress has paramount authority to regulate commerce with "foreign Nations, and among the several States." (U.S. Const. Art. I, § 8, Cl 3.) However, inherent in this clause is a limitation on the states' ability to engage in conduct that unduly burdens interstate commerce. This latter principle is referred to as the dormant commerce clause:

> "It has long been accepted that the Commerce Clause not only grants Congress the authority to regulate commerce among the States, but also directly limits the power of the States to discriminate against interstate commerce." *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 273, 100 L. Ed. 2d 302, 108 S. Ct. 1803 (1988). This limitation on state power is the so-called "dormant commerce clause." It "prohibits economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 273-74.[6]

The United States Supreme Court has further explained:

> As we have long recognized, the "negative" or "dormant" aspect of the Commerce Clause prohibits States from "advancing their own commercial interests by curtailing the movement of articles of commerce, either into or out of the state." *H. P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 535, 93 L. Ed. 865, 69 S. Ct. 657 (1949). A state statute that clearly discriminates against interstate commerce is therefore unconstitutional "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism." *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 274, 100 L. Ed. 2d 302, 108 S. Ct. 1803 (1988).[7]

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. Additionally, the rationale for the bill is to ensure the health and safety of minors, which is a valid exercise of the state's police powers.[8]

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[6] *Big Country Foods, Inc. v. Board of Educ. of Anchorage School Dist.* (9th Cir. 1992) 952 F.2d 1173, 1177.
[7] *Fort Gratiot Sanitary Landfill v. Michigan Dep't of Natural Resources* (1992) 504 U.S. 353, 359.
[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].

e. *Enforcement*

The bill provides 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.

3. Statements in support

STRIPED, the sponsor of the bill, writes in support:

> […] this important legislation would protect children across California by prohibiting the sale of weight-loss dietary supplements and over-the-counter (OTC) diet pills in stores or online to any person under 18 years of age. This bill would also ensure that health-related notices regarding these dangerous products are conspicuously posted at each purchase counter in stores.
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> While these dietary supplements deceptively claim to promote healthy weight loss – 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 U.S. Food and Drug Administration (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.

4. Statements in opposition

The Natural Products Association writes in opposition to this bill with various concerns including: it is either unnecessary and imprudent, arguing, there is inadequate evidence to support its provisions; the FDA and the Federal Trade Commission (FTC) already have adequate authority to ensure product safety in this area; concerns with the civil penalty amount; and argue that the industry employs practices that ensure product quality and safety. They write:

> The proposal under consideration today would place onerous restrictions, most notably on small businesses such as your local pharmacy, convenience, or health food store, 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. Nobody wins. We support efforts to stop illegal drugs masquerading as natural products. Of course, no one wants consumers to use unlawful products like Selective

Androgen Receptor Modulators (SARMs) or Selective Estrogen Receptor Modulators (SERMs). 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. We support vigorous enforcement of the law to protect consumers. Still, 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.

SUPPORT

Strategic Training Initiative for The Prevention of Eating Disorders (sponsor)
Academy for Eating Disorders
Alliance for Eating Disorders Awareness
Be Real USA
Center for Science in the Public Interest
Eating Disorders Coalition
Finxerunt Policy Institute
For Her
International Socioeconomic Lab
National Eating Disorders Association
Renfrew Center for Eating Disorders
Over 100 individuals

OPPOSITION

Natural Products Association

RELATED LEGISLATION

Pending Legislation: 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.

Prior Legislation:

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 8, Noes 0)
Assembly Floor (Ayes 53, Noes 13)
Assembly Appropriations Committee (Ayes 12, Noes 2)
Assembly Judiciary Committee (Ayes 8, Noes 3)
Assembly Health Committee (Ayes 11, Noes 1)

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