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SUMMARY

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# Food and Dietary Supplement Labeling Claims: FDA Regulation and Select Legal Issues

Congress has authorized the Food and Drug Administration (FDA) to regulate nutrient-related claims on food and dietary supplement labels to promote healthful eating patterns, protect the public health, and ensure that consumers have accurate information to make informed choices about the foods they consume. FDA regulates these nutrient-related claims under its authority in the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. §§ 301–399i), which prohibits the marketing of misbranded foods and dietary supplements in U.S. commerce, including products with false or misleading labels. Congress has set out more specific statutory requirements for several types of labeling claims, including (1) health claims, (2) nutrient content claims, and (3) structure/function claims.

*Health claims* characterize a relationship between a nutrient and a disease. For example, a claim asserting that consuming calcium reduces the risk of osteoporosis is a health claim. A manufacturer can use a health claim on a label only if FDA has promulgated a regulation approving the use of the claim. A manufacturer seeking to use a new claim must submit a petition for the health claim to FDA demonstrating "significant scientific agreement" substantiating the claim. *Nutrient content claims* characterize the level of a nutrient in a food or dietary supplement. For example, a claim that a milk product is "high in" calcium is a nutrient content claim. To use a nutrient content claim on a label, the manufacturer must comply with FDA's regulations pertaining to the claim. For example, for the manufacturer to make a claim on a product label that a product is an "excellent source of" or "high" or "rich" in a nutrient, the product must contain twenty percent or more of the daily reference value for that nutrient. *Structure/function claims* describe a nutrient's effect on a structure or function of the body. For example, a claim that a milk product "builds stronger bones" is a structure/function claim because it describes the effect of the nutrient on the body's structure. Of these three types of claims, structure/function claims are subject to the most basic regulation: FDA prohibits the use of structure/function claims if they are misleading.

Because the type and degree of regulation varies significantly depending on how claims are categorized, legal issues may arise when manufacturers and FDA categorize certain labeling claims. Because FDA categorizes products based on their intended use, certain kinds of labeling claims could serve as evidence that the product is intended for use as a drug. Health claims may bear a resemblance to, or even overlap with, claims that would cause a product to qualify as a drug, and drugs are subject to much more stringent requirements and testing. The definition of *drug* includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and a health claim "characterizes the relationship of any nutrient . . . to a disease or a health-related condition." A product bearing a claim that a nutrient prevents a type of cancer, for example, may be considered a drug, as it is intended to prevent a disease, and that claim may also be considered a health claim because it is linking a nutrient in the food to a disease or health-related condition. FDA interpreted these two overlapping statutory provisions such that a claim that a product may cure, mitigate, or treat a disease is a drug claim, and a claim that a food may reduce a risk of a disease is a health claim. Applying the since-overturned *Chevron* doctrine, the U.S. Court of Appeals for the D.C. Circuit determined that the statutory language is ambiguous, and therefore it deferred to FDA's interpretation, which it found to be reasonable.

Health claims and structure/function claims are sometimes similar, despite receiving significantly different treatment. A manufacturer may make a strategic choice to phrase a claim so that it is a structure/function claim and not a health claim to avoid the premarket approval requirement and the more rigorous standard associated with health claims. In other instances, it may not be clear whether a symbol, such as a heart symbol, is an implied health claim or a structure/function claim. In these instances, FDA considers the entire label to determine, on a flexible, case-by-case basis, how to categorize a particular claim.

Another legal consideration is that claims made by food and dietary supplement manufacturers on their products' labels are commercial speech, which is protected by the Free Speech Clause of the First Amendment. The Supreme Court has held that the First Amendment generally requires government regulation of commercial speech to "directly advance" a "substantial government interest," although it does permit the government to prohibit misleading commercial speech. Courts have held that FDA's regulation of health claims may conflict with the First Amendment in certain circumstances. As a result, FDA has had to ensure that its regulation of labeling claims satisfies constitutional scrutiny.

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# Introduction

The U.S. Food and Drug Administration's (FDA's) regulation of food labeling aims to promote "healthful eating patterns," protect the public health, and ensure that consumers have accurate information to make informed decisions about the foods they consume.[1] Through the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA furthers these goals through regulating the claims that food and dietary supplement manufacturers include on their products' labels.[2] The FD&C Act generally deems foods and dietary supplements with misleading labels or bearing claims that do not comply with certain applicable statutory or regulatory requirements to be misbranded.[3] These misbranded products cannot be introduced in interstate commerce in the United States.[4]

FDA regulates certain types of claims related to nutrients that food and dietary supplement manufacturers may choose to include on their products' labels. *Health claims* are claims that link the consumption of a nutrient to a disease or health-related condition.[5] *Nutrient content claims* are claims characterizing the level of a nutrient in a product.[6] *Structure/function claims* describe the effect of a nutrient on the structure or function of the body.[7] The level and type of regulatory requirements for each of these labeling claims vary and depend on the type of claim.

Health claims may bear a resemblance to, or even overlap with, claims that would cause a product to qualify as a drug, and drugs are subject to much more stringent requirements and testing.[8] FDA categorizes products based on their intended use (and the claims made on the packaging can be evidence of the product's intended use), rather than based on how the manufacturer or seller would like to categorize them.[9] If a product's packaging makes a claim that the product will diagnose, cure, mitigate, or treat a disease, FDA may consider the product to be an adulterated or

[1] Federal Food, Drug, and Cosmetic Act (FD&C Act), ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. ch. 39). *Nutrition, Food Labeling, and Critical Foods*, Food and Drug Administration (FDA) (Oct. 1, 2024), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods [https://perma.cc/EU2H-ZDGS]; *see also* 136 CONG. REC. 20414, 20419 (1990) (statement of Rep. Henry Waxman); *see also* 136 CONG. REC. 35093, 35095 (1990) (considerations of consumer fraud and public health underpin the Nutrition Labeling and Education Act of 1990 (NLEA), (Pub. L. No. 101-535, 104 Stat. 2353 (1990), which amended the FD&C Act); Pearson v. Shalala (Pearson I), 164 F.3d 650, 655–56 (D.C. Cir. 1999) (observing that FDA stated that the purpose of the health claim regulation scheme is to protect public health and prevent consumer fraud).

[2] FDA and U.S. Department of Agriculture (USDA) share responsibility for food regulation. USDA regulates certain meat, poultry, and egg products, and FDA regulates all other foods. *See Formal Agreement Between USDA and FDA Relative to Cooperation and Coordination*, FDA (Jan. 29, 2018), https://www.fda.gov/food/international-interagency-coordination/formal-agreement-between-usda-and-fda-relative-cooperation-and-coordination [https://perma.cc/HH6A-CDQF]. Information regarding USDA regulation of food claims is beyond the scope of this report. FDA regulates the labels that appear on food packaging, while the U.S. Federal Trade Commission (FTC) regulates advertising pertaining to these products. *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration*, FTC (May 1971), https://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration [https://perma.cc/M73Q-C9KY]. FTC's regulation of advertising for food and dietary supplements is also beyond the scope of this report.

[3] 21 U.S.C. § 343(a).

[4] *Id*.

[5] *Id*. § 343(r)(1)(B).

[6] *Id*. § 343(r)(1)(A).

[7] *Id*. § 343(r)(6).

[8] *See* CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Hassan Z. Sheikh (2018).

[9] *See* 21 U.S.C. § 321(g) (defining *drug* to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.").

misbranded drug, unless the manufacturer has obtained FDA approval to market the product as a drug.[10]

Labeling on products, such as nutrient-based claims on food and dietary supplements, are a form of commercial speech by the manufacturers.[11] As such, labeling claims are protected by the First Amendment's Free Speech Clause.[12] Government regulation of such claims must be consistent with the First Amendment.[13] The government can impose certain restrictions on commercial speech to serve government interests, but those restrictions are subject to scrutiny.[14] FDA's regulation of certain health claims has been successfully challenged in court on First Amendment grounds, and FDA has been required to adjust its regulation of those claims accordingly.[15]

This report begins by providing an overview of FDA's regulation of food, dietary supplements, and drugs. The report then discusses the history of FDA's regulation of nutrient-related claims on food and dietary supplement labels. It next describes the statutory and regulatory provisions that apply to the three main types of nutrient labeling claims: health claims, nutrient content claims, and structure/function claims. The report then analyzes legal issues that arise from categorizing certain claims. Because claims are treated differently depending on how they are categorized, arguments may arise concerning which category aligns with certain claims. Finally, the report discusses the First Amendment's limitation on the government's regulation of labeling claims and sets out some considerations for Congress.

# Overview of Food, Dietary Supplements, and Drugs

Enacted in 1938 and amended several times thereafter, the FD&C Act regulates food and dietary supplement safety and labeling, and it generally prohibits manufacturers, suppliers, and retailers from buying and selling adulterated or misbranded foods and dietary supplements.[16]

The FD&C Act defines a *food* as an article "used for food or drink for man or other animals."[17] The FD&C Act deems foods that contain an unsafe food additive to be adulterated and therefore prohibited.[18] A *food additive* is defined as a substance "the intended use of which [is to become a] component or otherwise affect[] the characteristics of any food."[19] These substances generally must be approved by FDA as safe before they can be added to food.[20] The FD&C Act requires food labels to contain certain information—including the name of the food,[21] the net quantity,[22]

[10] *See id*.

[11] *Pearson I*, 164 F.3d 650, 655 (D.C. Cir. 1999).

[12] *Id*.

[13] *Id*.

[14] *Id*. at 655–56.

[15] *See id*. at 661.

[16] 21 U.S.C. § 331(a). For ease of reference, this report uses the term *manufacturers* to include all of these entities.

[17] *Id*. § 321(f).

[18] *Id*. § 342(a).

[19] *Id*. §§ 321(s) (definition of *food additive*), 348(a).

[20] *Id*. §§ 321(s), 348(a). There are a number of exceptions to the definition of *food additive* (including color additives, pesticide chemicals, and substances that are generally recognized as safe) that are outside the scope of this report. *See id.* § 321(s). Unlike food additives, these excepted substances do not need FDA's preapproval under § 348(a).

[21] *Id*. § 343(g), (i).

[22] *Id*. § 343(e).

nutrition information,[23] and information relating to allergens[24]—which must be prominently displayed on the label.[25] The FD&C Act also generally prohibits marketing foods with labels that are false or misleading.[26] Foods bearing labels that do not conform with these requirements are considered misbranded and therefore cannot be marketed in the United States.[27] FDA does not need to preapprove food labels before manufacturers can use them.[28]

The FD&C Act defines a *dietary supplement* as a product that is "intended to supplement the diet that bears or contains" a vitamin, mineral, herb or other botanical, amino acid, dietary substance, or concentrate, metabolite, constituent, extract, or any combination of these dietary ingredients.[29] The product must also not be "represented for use as a conventional food" and must be "labeled as a dietary supplement."[30] Similar to conventional food labels, dietary supplement labels must contain certain information[31] and cannot contain a false or misleading statement.[32] Failure to comply with these requirements will render the dietary supplement misbranded.[33] FDA does not preapprove dietary supplement labels prior to their use to ensure they conform to these requirements.[34]

A *drug* is statutorily defined in part as an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[35] Unlike a food or a dietary supplement, a drug generally cannot be introduced into commerce unless FDA first approves it.[36] For a drug to be approved, FDA must determine that it is safe and effective for its proposed use based on "substantial evidence" from laboratory studies and clinical trials.[37] Additionally, drug labels must be submitted along with the drug's application for FDA approval because FDA must approve the label before it can be used.[38] Drug labels must contain certain information, including the name of the drug,[39] its directions for use,[40] and relevant warnings.[41]

[23] *Id.* § 343(q).

[24] *Id.* § 343(w).

[25] *Id.* § 343(f).

[26] *Id.* § 343(a).

[27] *See id.* § 343(f); *see also id.* § 331(a), (b), (c) (prohibiting the introduction, delivery, and receipt of any misbranded food in interstate commerce and prohibiting the misbranding of such products); *id.* § 333 (setting out penalties for the prohibited acts set out in 21 U.S.C. § 331).

[28] *See id.* § 343.

[29] *Id.* § 321(ff)(1).

[30] *Id.*

[31] *Id.* § 343(s).

[32] *Id.* §§ 343(a), 321(ff) ("Except for [certain purposes], a dietary supplement shall be deemed to be a food within the meaning of this chapter.").

[33] *See id.* §§ 343(s), 343(a), 321(ff).

[34] *See id.* § 343.

[35] *Id.* § 321(g)(1).

[36] *Id.* § 355(a).

[37] *Id.* § 355(b), (d).

[38] *Id.* § 355(b)(1)(A)(vi), (d).

[39] *Id.* § 352(e).

[40] *Id.* § 352(f).

[41] *Id.*

# History of Food and Dietary Supplement Labeling

The Nutrition Labeling and Education Act of 1990 (NLEA) created nutrition labeling requirements and established the framework for industry to make certain kinds of nutrient-related labeling claims.[42] Before the passage of the NLEA, inclusion of nutrition information on food labels was generally voluntary, with certain exceptions.[43]

Prior to a marketing campaign that caused a policy change in 1984, FDA did not permit food labels to bear health claims unless the product was approved as a drug.[44] FDA took the position that a claim that consuming a product would reduce one's risk of a disease rendered the product a drug.[45] For example, prior to the NLEA, a product bearing a label claiming to reduce one's risk of cancer might have been considered to be a drug because its marketing indicated that it was intended for use in the treatment of a disease, even if it otherwise might have qualified as a food under the FD&C Act. A manufacturer seeking to use this type of claim would have needed to obtain FDA approval under the rigorous process and standards required for approving drugs.[46] That process includes the submission of an application to FDA containing data from clinical trials along with information about the product, the manufacturing process, and proposed labeling for the product. FDA may approve a new drug application only upon determining that there is substantial evidence that the drug is "safe and effective" for its proposed use.[47]

A 1984 marketing campaign by the Kellogg Company became an impetus for Congress to pass the NLEA to regulate health claims.[48] Kellogg marketed a high-fiber cereal by asserting that the fiber content in its products helped to reduce the risk of several cancers.[49] In this case, FDA allowed the use of Kellogg's cancer claim because Kellogg had obtained endorsements from both the National Cancer Institute and the Federal Trade Commission to use the claim.[50] Following this decision, FDA proposed amending its rules to allow for the use of health claims if certain criteria were met.[51] Congress responded by passing the NLEA in 1990, which included new statutory requirements governing health claims on food labels.[52]

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[42] *See* NLEA, Pub. L. No. 101-535, 104 Stat. 2353.

[43] In certain cases where a manufacturer made claims about a food's nutritional content, the disclosure of the numbers of calories and amounts of certain nutrients was mandatory. *See* Nutrition Labeling, Proposed Criteria for Food Label Information Panel, 37 Fed. Reg. 6493, 6497 (Mar. 30, 1972); *see also* 21 U.S.C. § 321(n) (a food is misbranded if it "fails to reveal facts material in the light of such representations").

[44] Richard M. Cooper, Richard L. Frank, & Michael J. O'Flaherty, *The History of Health Claims Regulation,* 45 FOOD DRUG COSMETIC L. J. 665, 660–61 (1990).

[45] *Id.*

[46] *Id.*

[47] *See* 21 U.S.C. § 355.

[48] *See* Cooper *supra* note 44, at 662–63.

[49] Marian Burros, *Health Claims on Food Put F.D.A. in a Corner*, N.Y. TIMES (Feb. 19, 1986), https://www.nytimes.com/1986/02/19/garden/health-claims-on-food-put-fda-in-a-corner.html [https://perma.cc/QNU2-7LU9].

[50] *See* Cooper, *supra* note 44, at 662–63.

[51] Food Labeling, Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28843, 28845 (Aug, 4, 1987).

[52] H.R. REP. NO. 101-538, at 12 (1990) ("[D]uring the mid-1980's, companies began making health claims on foods, even though the FDA had not approved the claims through the drug approval process," which led to "unfounded health claims" in the marketplace and "[t]herefore legislation with respect to health claims is . . . both desirable and necessary."); 136 CONG. REC. 35093, 35095 (1990) (there was "a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims.").

The NLEA amended the FD&C Act to provide more specific requirements for food labeling.[53] The NLEA requires food labels to bear nutrition information, including the serving size, the number of servings per container, and the amounts of nutrients in each serving size.[54] The NLEA also set out the requirements for manufacturers to use health claims and nutrient content claims on food labels.[55] Nutrient content claims can be made only if the characterization of the nutrient level made in the claim uses terms that are defined in FDA's regulations.[56] Food manufacturers can make health claims on food labels only if the claim meets the requirements of the FDA regulation authorizing the claim.[57]

The NLEA also addressed the use of health claims on dietary supplement labels.[58] The NLEA explicitly states that its statutory requirements do not apply to dietary supplements, and it authorized FDA to establish regulations specifying the standard and procedure for health claims on dietary supplements.[59] FDA later adopted regulations that apply the same standards and procedures to dietary supplements as are set out in the FD&C Act regarding health claims for foods.[60] Although the NLEA does not specifically address the use of nutrient content claims on dietary supplement labels, it sets out the requirements for "foods intended for human consumption,"[61] which FDA later clarified via regulation includes "conventional foods and dietary supplements."[62]

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA), which created a new regulatory framework for dietary supplements and was meant to replace the "ad hoc, patchwork regulatory policy on dietary supplements" that existed prior to this legislation.[63] On top of establishing a safety standard for dietary supplements and various other requirements, DSHEA authorized structure/function claims to be made on dietary supplement labels, as long as they are not misleading.[64]

# Types of Claims

Congress has authorized FDA to regulate several types of nutrition-related claims on food and dietary supplement labels. *Health claims* are claims that link the consumption of a nutrient to a disease or health-related condition.[65] *Nutrient content claims* are claims characterizing the level of a nutrient in a product.[66] *Structure/function claims* describe the effect of a nutrient on the structure

[53] Pub. L. No. 101-535, 104 Stat. 2353 (1990).

[54] 21 U.S.C. § 343(q).

[55] *Id.* § 343(r).

[56] *Id.* § 343(r)(1)(A), (r)(2)(A).

[57] *Id.* § 343(r)(1)(B), (r)(3).

[58] *Id.* § 343(r)(5)(D).

[59] *Id.*

[60] *See* 21 C.F.R. § 101.14(a)(1) (2024) (defining *health claim* to include claims linking the relationship of any substance to a disease or health-related condition on both foods and dietary supplements, and then setting out the requirements, procedures, and standard for "health claims").

[61] 21 U.S.C. § 343(r)(1).

[62] 21 C.F.R. § 101.13(a) ("This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.").

[63] Pub. L. No. 103-417, § 2(15), 108 Stat. 4325, 4326 (1994).

[64] 21 U.S.C. § 343(r)(6).

[65] *Id.* § 343(r)(1)(B).

[66] *Id.* § 343(r)(1)(A).

or function of the body.[67] The level and type of regulatory requirements for each of these labeling claims vary and depend on the type of claim.

## Health Claims

A health claim expressly states or implies a relationship between a nutrient in a food or dietary supplement and a specific disease or health-related condition.[68] For example, a label for a product that is high in calcium (such as milk) may state that consuming the product may reduce the risk of osteoporosis. A health claim may also be implied by using symbols (such as a heart) or written statements (such as a brand name including the term "heart") that suggest that a relationship exists between a product and a disease or health-related condition.[69]

Section 403(r) of the FD&C Act permits a manufacturer to include a health claim on a food's label only when FDA has promulgated a regulation approving the health claim.[70] FDA may approve a health claim in a regulation only if it determines "based on the totality of publicly available scientific evidence" that there is "significant scientific agreement" among qualified experts that the claim is supported.[71] The FD&C Act also clarifies that a product is not a drug solely because the label contains a health claim made in accordance with the law.[72] The FD&C Act explicitly states that the statutory health claim requirements do not apply to dietary supplements and provides that these health claims will instead by subject to the procedure and standard established by FDA in regulation.[73] FDA has since promulgated regulations clarifying that it subjects health claims made on foods and dietary supplements to the same standards and procedures.[74] As a result, as with health claims on food products, manufacturers may include a health claim on a dietary supplement only if FDA has approved such a claim in its regulations based on significant scientific agreement.[75]

Any person may petition FDA to issue a regulation approving a health claim, whether for a food or for a dietary supplement.[76] FDA must issue a final decision on any such petition within 100 days of the petition's filing.[77] To date, FDA has promulgated regulations approving twelve health claims regarding the nutrients and diseases or health-related conditions listed in **Table 1**.

[67] *Id.* § 343(r)(6).

[68] *Id.* § 343(r)(1)(B); *see also* 21 C.F.R. § 101.14(a)(1).

[69] 21 C.F.R. § 101.14(a)(1).

[70] 21 U.S.C. § 343(r).

[71] *Id.*. § 343(r); *id.* § 343(r)(3)(B)(1).

[72] *Id.* § 321(g)(1) ("A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim.").

[73] *Id.* § 343(r)(5)(D).

[74] 21 C.F.R. § 101.14(a)(1) (defining *health claim* to include claims linking the relationship of any substance to a disease or health-related condition for both foods and dietary supplements, and then setting out the requirements, procedures, and standard for health claims).

[75] *Id.*

[76] 21 U.S.C. § 343(r)(3)(B).

[77] *Id.* § 343(r)(4)(A).

**Table 1. Health Claims Approved by FDA**

| Nutrient | Disease or Health Condition | Regulation |
|---|---|---|
| Calcium and vitamin D | Osteoporosis | 21 C.F.R. § 101.72 |
| Dietary lipids | Cancer | 21 C.F.R. § 101.73 |
| Sodium | Hypertension | 21 C.F.R. § 101.74 |
| Dietary saturated fat and cholesterol | Coronary heart disease | 21 C.F.R. § 101.75 |
| Fiber-containing grain products, fruits, and vegetables | Cancer | 21 C.F.R. § 101.76 |
| Fruits, vegetables, and grain products that contain fiber | Coronary heart disease | 21 C.F.R. § 101.77 |
| Fruits and vegetables | Cancer | 21 C.F.R. § 101.78 |
| Folate | Neural tube defects | 21 C.F.R. § 101.79 |
| Dietary noncarcinogenic carbohydrate sweeteners | Dental caries | 21 C.F.R. § 101.80 |
| Soluble fiber from certain foods | Coronary heart disease | 21 C.F.R. § 101.81 |
| Soy protein | Coronary heart disease | 21 C.F.R. § 101.82 |
| Plant sterol/stanol esters | Coronary heart disease | 21 C.F.R. § 101.83 |

**Source:** Compiled by CRS.

Each regulation lists the specific requirements regarding the nature of the food or dietary supplement and the language that must be used in the claim.[78] FDA has also promulgated regulations that explicitly prohibit manufacturers from making health claims linking (1) dietary fiber and cardiovascular disease and (2) zinc and immune function in the elderly.[79]

The Food and Drug Administration Modernization Act of 1997 (FDAMA) created a limited exception that permits a manufacturer to make certain health claims on food labels without FDA's preapproval.[80] A manufacturer may make a health claim on a food label without FDA preapproval when a scientific body of the U.S. government responsible for public health protection or nutrition research (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the private, nonprofit National Academies of Science, Engineering, and Medicine has published an authoritative statement about the relationship between the nutrient and the condition used in the health claim.[81] The person seeking to make the claim must submit a notice of the claim to FDA at least 120 days before marketing the product with the claim.[82] This exception applies only to food labels; it cannot be used for health claims on dietary supplement labels.[83]

[78] *See* 21 C.F.R. §§ 101.72–101.83.

[79] *Id.* § 101.71.

[80] Pub. L. No. 105-115, 111 Stat. 2296.

[81] 21 U.S.C. § 343(r)(3)(C).

[82] *Id.*

[83] FDAMA amended 21 U.S.C. § 343(r)(3), which specifies the procedure and standard by which health claims may be made for conventional foods. It did not address 21 U.S.C. § 343(r)(5)(D), which specifies that health claims with respect to dietary supplements shall not be subject to 21 U.S.C. § 343(r)(3) but rather to a procedure and standard established in FDA's regulations. FDA has stated that it "intends to propose that health claims based on authoritative (continued...)

The FD&C Act does not allow manufacturers to include health claims on food or dietary supplement products that contain nutrients in amounts that increase the risk of another disease.[84] FDA has promulgated regulations identifying fat, saturated fat, cholesterol, and sodium as the nutrients that increase the risk of another disease.[85] The regulations set forth particular amounts of each of these nutrients that, if exceeded, trigger the prohibition on health claims.[86] These amounts are 4 grams of fat, 4 grams of saturated fat, 60 milligrams of cholesterol, or 480 milligrams of sodium per reference amount.[87] If a food meets one of these "disqualifying nutrient levels," then the food label cannot include any health claim.[88] This requirement is intended to protect consumers from buying a product because it is labeled as one that may reduce the risk of a disease when that product might increase the risk of some other disease.

## Qualified Health Claim

In 1999, the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) determined that FDA's refusal to approve certain health claims due to a lack of "significant scientific agreement" violated the manufacturer's First Amendment rights.[89] In response, FDA has exercised its enforcement discretion to allow the use of qualified health claims that do not meet the statutory criteria.[90] Qualified health claims are a type of health claim that can be made with less scientific substantiation and the use of an appropriate disclaimer.[91] For example, FDA allows manufacturers to make the claim that "eating yogurt regularly may reduce the risk of type 2 diabetes" as long as the claim is followed by the disclaimer that "FDA has concluded there is limited information supporting this claim."[92] As another example, FDA allows manufacturers to make the claim that "green tea may reduce the risk of breast or prostate cancer" if accompanied by the disclaimer that "FDA has concluded that there is very little scientific evidence for this claim."[93] FDA crafted the disclaimer for the green tea health claim to reflect that there is less evidence to support that claim than there is for the yogurt health claim.[94] In approving qualified health claims, FDA seeks to

statements be permitted for dietary supplements." *Guidance for Industry: Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body, June 1998*, FDA (Sept. 9, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-notification-health-claim-or-nutrient-content-claim-based-authoritative-statement [https://perma.cc/7LB2-TJE9].

[84] 21 U.S.C. § 343(r)(3)(A).

[85] 21 C.F.R. § 101.14(a)(4).

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *See Pearson I*, 164 F.3d 650, 661 (D.C. Cir. 1999). This case is discussed in more detail *infra* pp. 16–17.

[90] *See Guidance for Industry: FDA's Implementation of Qualified Health Claims, May 2006*, FDA (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-implementation-qualified-health-claims [https://perma.cc/D5XV-JMKQ].

[91] *Id.*

[92] Letter from Claudine Kavanaugh, Director, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, to Guy H. Johnson, Johnson Nutrition Solutions LLC, on Petition for a Qualified Health Claim for Yogurt and Reduced Risk of Type 2 Diabetes Mellitus (Docket No. FDA-2019-P-1594) (Mar. 1, 2024), https://www.fda.gov/media/176608/download?attachment [https://perma.cc/CF3B-U8VY].

[93] *See Qualified Health Claims: Letters of Enforcement Discretion*, FDA (Mar. 28, 2024), https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims-letters-enforcement-discretion [https://perma.cc/7EZD-6ZER].

[94] *Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, July 2003*, FDA (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-interim-procedures-qualified-health-claims-labeling-conventional-human-food-and [https://perma.cc/H3QS-H67Y] (Table 1 compares the levels of scientific evidence required for certain qualifying language).

comply with the First Amendment and to provide current and accurate scientific information to consumers in order to empower them to make informed health decisions.[95]

FDA does not have statutory authority to approve qualified health claims. Rather, FDA allows these claims as an exercise of its enforcement discretion, declining to enforce the FD&C Act's "significant scientific agreement" standard in situations where there is some credible scientific evidence to support the claim and where the denial of the claim may raise First Amendment considerations.[96] Accordingly, qualified health claims are not authorized in regulation as other health claims are. Instead, FDA sends the manufacturer a letter of enforcement discretion that notifies the manufacturer that FDA will allow the health claim (i.e., forbear from enforcing the FD&C Act's significant scientific agreement standard) as long as the claim is accompanied by the proper disclaimer (i.e., qualified).[97] FDA publicizes these letters of enforcement discretion on its website.[98]

## Nutrient Content Claims

A nutrient content claim characterizes the level of a nutrient in a food or dietary supplement.[99] As with health claims, it can either be explicit or implicit.[100] An express nutrient content claim is a direct statement about the level of a nutrient (such as "low sodium" or "contains 100 calories").[101] An implied nutrient content claim describes the product in a manner that suggests that a nutrient is present or absent in a certain amount (such as calling a product "healthy").[102]

For a manufacturer to make a nutrient content claim on a product's label, the product must meet the requirements set out in regulations.[103] For example, for a manufacturer to make a claim on a product label that a product is an "excellent source of" or "high" or "rich" in a nutrient, the product must contain twenty percent or more of the daily reference value for that nutrient.[104] For a manufacturer to claim that a product is a "good source" of or "contains" or "provides" a nutrient, it must have between ten and nineteen percent of the daily reference value.[105] The regulations define many other terms, including "more," "fortified," "enriched," "high potency," "light," "free," and "low," and these definitions similarly limit when manufacturers can use these terms on their labels.[106] A manufacturer cannot claim that a nutrient is absent from a product unless the

[95] *Guidance for Industry: FDA's Implementation of Qualified Health Claims*, FDA, *supra* note 90.

[96] *Qualified Health Claims: Letters of Enforcement Discretion*, FDA, *supra* note 93.

[97] *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims, January 2009*, FDA (Sept. 17, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evidence-based-review-system-scientific-evaluation-health-claims#system [https://perma.cc/38S7-ZL4P].

[98] *Qualified Health Claims: Letters of Enforcement Discretion*, FDA, *supra* note 93.

[99] 21 U.S.C. § 343(r)(1)(A) (characterizing a nutrient content claim as "a claim . . . made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient"). FDA has interpreted "food intended for human consumption" to mean both food and dietary supplements. *See id.* § 343(r)(1); 21 C.F.R. § 101.13(a) ("This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.").

[100] 21 C.F.R. § 101.13(b).

[101] *Id.* § 101.13(b)(1).

[102] *Id.* § 101.13(b)(2).

[103] *Id.* §§ 101.54–101.69.

[104] *Id.* § 101.54.

[105] *Id*.

[106] *See id.* §§ 101.54–101.62.

nutrient is usually present in the product or FDA promulgates a regulation permitting such a statement on the basis that it would assist consumers in maintaining healthy dietary practices.[107]

Some terms used in implied nutrient content claims are also defined by regulation.[108] For example, the term "healthy," which implies that certain nutrients are present and others are absent, may be used on product labels only if the product meets certain criteria.[109] To label a product as "healthy," a manufacturer must ensure that the amounts of fat, saturated fat, and cholesterol in the product are below a certain level, and the product must contain certain amounts of nutrients or vitamins.[110] These requirements vary based on the type of product at issue (e.g., raw fruit or enriched cereal-grain products).[111]

As with health claims, the FDAMA created a limited exception to permit a manufacturer to make certain nutrient content claims on labels even if FDA has not defined the claim by regulation.[112] A manufacturer may make a health claim when a scientific body of the U.S. government responsible for public health protection or nutrition research (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the private, nonprofit National Academies of Science, Engineering, and Medicine has published an authoritative statement about the nutrient level to which the claim refers.[113] The person seeking to make the claim must submit a notice of the claim to FDA at least 120 days before introducing the product with labeling containing the claim into interstate commerce.[114] FDA allows manufacturers to use this exception for nutrient content claims on both food and dietary supplements.[115]

The FD&C Act does not permit manufacturers to add nutrient content claims on a product's label when the product also contains another nutrient in an amount that increases the risk of a disease or health-related condition, unless the label contains a proper disclaimer.[116] FDA identified these disqualifying nutrients and nutrient levels (13 grams of fat, 4 grams of saturated fat, 60 milligrams of cholesterol, and 480 milligrams of sodium per reference amount) in a regulation.[117] The presence of these nutrients prevents a manufacturer from including a nutrient content claim on the product's label unless the label bears a disclosure highlighting the ingredient.[118] For example, a product that is high in fat would need to include a label saying "See nutrition information for fat content," and this disclosure would need to be immediately adjacent to the nutrient content claim.[119] Similarly, a product whose label claims it to be "healthy" and high in fat

[107] 21 U.S.C. § 343(r)(2)(A)(ii).

[108] 21 C.F.R. § 101.65.

[109] *Id*.

[110] *Id*.

[111] *Id*.

[112] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[113] 21 U.S.C. § 343(r)(2)(G).

[114] *Id*.

[115] *See Guidance for Industry: Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body*, FDA, *supra* note 83.

[116] *See* 21 U.S.C. § 343(r)(3)(A); 21 C.F.R. § 101.13(h).

[117] 21 C.F.R. § 101.13(h).

[118] *Id*.

[119] *Id*.

would also need to include such a disclaimer.[120] These rules apply to nutrient content claims that are used on conventional food labels and dietary supplement labels alike.[121]

## Structure/Function Claims

A structure/function claim describes the effect that a nutrient has on a structure or function of the body.[122] For example, the claim that "fiber maintains bowel regularity" would be a structure/function claim pertaining to a bodily function. Structure/function claims on food and dietary supplement labels must be truthful and not misleading based on scientific criteria.[123] FDA has not articulated a standard for the type and quality of evidence required to make a structure/function claim that is not misleading.

The FD&C Act has not set out statutory requirements for structure/function claims in conventional foods.[124] FDA has interpreted the definition of "drug" to authorize food manufacturers to make structure/function claims on food product labels.[125] A drug is defined, in part, as "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[126] Generally, a claim that an article affects the structure or function of the body would render a product a drug and subject to regulation as a drug. The definition of "drug" explicitly carves out "food," however, and therefore permits the use of structure/function claims on food labels.[127] Because food was carved out specifically from the definition when enacted, food has never been at risk of being considered a drug if a manufacturer makes structure/function claims.[128] Structure/function claims are allowed on food labels unless they are false or misleading.[129]

The carveout for food in the "drug" definition does not apply to dietary supplements, and therefore Congress needed to enact a new law if it wanted to allow such claims on those

[120] *Id*.

[121] 21 C.F.R. § 101.13(a) (The regulations governing nutrient content claims "apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements."); *see also* 21 U.S.C. § 343(r)(2)(A), (F) (The requirement that nutrient content claims "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations . . . does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.").

[122] *Label Claims for Conventional Foods and Dietary Supplements*, FDA (Mar. 28, 2024), https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements [https://perma.cc/2RNV-T2TV].

[123] 21 U.S.C. § 343(a), (r)(6).

[124] *See id*. § 343.

[125] Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1033 (Jan. 6, 2000) ("[C]onventional foods may make structure/function claims under section 201(g)(1)(C) of the act as long as such claims are truthful, non-misleading, and derive from the nutritive value of the food."); *see also* Ackerman v. Coca-Cola Co., No. CV-09-0395 (JG), 2010 WL 2925955, at *11 n.21 (E.D.N.Y July 21, 2010) (explaining that the statutory authority for structure/function claims for food labels comes from an exception in the definition of "drug").

[125] 21 U.S.C. § 343(r)(6).

[126] *Id*. § 321(g)(1)(C) (The definition of *drug* also states that "[a] food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.").

[127] *Id*.

[128] *Id*.

[129] *Id*. § 343(a) ("A food shall be deemed to be misbranded if [ ] its labeling is false or misleading . . ."); *see also Structure/Function Claims*, FDA (Mar. 28, 2024), https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims#conventional [https://perma.cc/Q9LX-AHHZ].

products.[130] DSHEA amended the FD&C Act to explicitly permit the use of structure/function claims on dietary supplement labels.[131] Dietary supplement manufacturers may make structure/function claims if the manufacturer has "substantiation" that the claim "is truthful and not misleading."[132] The FD&C Act requires structure/function claims on dietary supplement labels to be accompanied by a disclaimer that "[t]his statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[133] A dietary supplement manufacturer marketing a product with a structure/function claim must also submit a notification to FDA no later than thirty days after marketing the product with the text of the claim.[134] The disclaimer and notification requirements do not apply to foods.[135]

Additionally, unlike for health or nutrient content claims, there are no disqualifying ingredients for structure/function claims. In other words, a manufacturer may make a structure/function claim on a product's label even if the food contains unhealthy levels of fat, saturated fat, cholesterol, or sodium.

# Legal Issues with Categorizing Claims

Legal issues may arise when manufacturers and FDA categorize certain labeling claims. In some cases, FDA has argued that certain claims a manufacturer considers to be health claims render the product bearing the claims to be a drug.[136] In other instances, a manufacturer may reword a claim to avoid categorization as a health claim and to take advantage of the less restrictive regulation that applies to structure/function claims.[137] Manufacturers and FDA may also disagree about whether certain claims are implied health claims or structure/function claims.[138]

## Drug Claims Versus Health Claims

The NLEA created a path for food and dietary supplement companies to use health claims without being required to undergo a rigorous drug approval process. Despite the creation of this new path, the similarities between the FD&C Act's definitions of drugs—that is, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"—and

[130] The definition of *dietary supplement* deems dietary supplements to be food for most purposes, except for the provision defining *drug* that sets out the structure/function claim exception. *Id.* § 321(ff) (stating that "except for purposes of paragraph (g) [and another exception], a dietary supplement shall be deemed to be a food within the meaning of this chapter."); *id.* § 321(g) (defining *drug*); *see also* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1033 (Jan. 6, 2000) (explaining that structure/function claims can be made only for conventional foods and not for dietary supplements, under 21 U.S.C. § 321(g)(1)(C), because dietary supplements are not foods for the purposes of 21 U.S.C. § 321(g)).

[131] Pub. L. No. 103-417, 108 Stat. 4325 (1994); 21 U.S.C. § 343(r)(6).

[132] 21 U.S.C. § 343(r)(6).

[133] *Id.*

[134] *Id.*; 21 C.F.R. § 101.93(a).

[135] 21 C.F.R. § 101.93(a); *see also Label Claims for Conventional Foods and Dietary Supplements*, FDA, *supra* note 122.

[136] Whitaker v. Thompson, 353 F.3d 947, 948 (D.C. Cir. 2004).

[137] *Compare* 21 U.S.C. § 343(r)(3)(B), *with id.* § 343(r)(6).

[138] Food Labeling, General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2483 (Jan. 6, 1993) ("FDA agrees that no 'bright-line' definition can be established for implied health claims. Labeling claims need to be considered in their entirety and in context to determine if the elements of a health claim are present.").

*health claims*—which "characterize[] the relationship of any nutrient . . . to a disease or a health-related condition"—continue to raise legal issues regarding how to treat certain claims that arguably fit into both categories.[139]

For example, a claim that high-fiber cereals may prevent cancer characterizes the relationship between a nutrient and a disease, and may therefore be considered a health claim.[140] The claim that high-fiber cereal may prevent cancer also indicates that the cereal is intended to prevent cancer, which means the cereal may be considered a drug.[141] As a result of this possible overlap, similar products making similar claims about what the product can do could be subject to significantly different standards and other legal consequences. If FDA were to consider the article claiming to reduce the risk of cancer as a drug, the article must undergo a rigorous approval process before it can be marketed, in which case manufacturers would need to present substantial evidence, including evidence from clinical trials, that the article is safe and effective for its proposed use.[142] If FDA were to consider the article a food, then the article itself would not be subject to preapproval, but the manufacturer would need to obtain FDA approval to use the health claim on the food's packaging.[143] As explained above, the manufacturer would need to present evidence of substantial scientific agreement for the claim to be unqualified, but FDA may approve the use of the claim with a disclaimer, even if less evidence is presented.

FDA has interpreted these two statutory definitions such that a claim that a product may cure, mitigate, or treat an existing disease is a drug claim, and a claim that a food may reduce a consumer's risk of a disease is a health claim.[144] For example, a claim that consuming a type of food may mitigate a consumer's cancer might render the food a drug under the FD&C Act, but a claim that a food may reduce the risk of a consumer getting cancer may be regulated as a health claim.

FDA's interpretation of the similar statutory definitions was challenged before the D.C. Circuit in *Whitaker v. Thompson*.[145] In that case, marketers of a plant extract filed a health claim petition requesting FDA's approval of a label stating "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia."[146] FDA denied the petition because the label indicated that the product *treated* benign prostatic hyperplasia and therefore rendered the product a drug.[147] FDA explained that claims regarding the use of a product to "prevent" disease may be "health claims,"

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[139] *See, e.g.*, Ogden v. Bumble Bee Foods, LLC, No. 5:12–CV–01828–LHK, 2014 WL 27527, at *4 (N.D. Cal. Jan. 2, 2014) (involving a consumer arguing that claims made by a seafood manufacturer are drug claims and not health claims because they go toward diagnosis, cure, mitigation, or treatment of a disease rather than prevention); *see also* 21 U.S.C. § 321(g); *id.* § 343(r)(1)(B).

[140] *See* 21 U.S.C. § 343(r)(1)(B) (providing that a health claim "characterizes the relationship of any nutrient . . . to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with [certain statutory subsections].").

[141] *Id*. § 321(g) (defining *drug* to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.").

[142] *See id*. § 355(b); *see also* Sheikh, *supra* note 8.

[143] *See* 21 U.S.C. § 343(3), (5)(D); 21 C.F.R. § 101.14(a)(1).

[144] *See Questions and Answers on Health Claims in Food Labeling*, FDA (Dec. 13, 2017), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-health-claims-food-labeling [https://perma.cc/W2JQ-URBS] (stating that health claims "are limited to claims about disease risk reduction" and "cannot be claims about the diagnosis, cure, mitigation, or treatment of disease").

[145] 353 F.3d 947, 948 (D.C. Cir. 2004).

[146] *Id.* at 948.

[147] *Id*. at 949.

but that claims that a product could "treat" a disease would always be considered drug claims.[148] The plaintiffs challenged FDA's decision, arguing that their proposed label fits within the statutory definition of a "health claim" because it links a nutrient to a disease or health-related condition.[149]

To decide the question, the court applied the since-overturned *Chevron* doctrine, in which the court would first inquire whether the statute was ambiguous, and if so, the court would defer to the agency's interpretation "so long as it [was] reasonable."[150] In *Whitaker*, the court first determined that the statutory definitions of a drug and health claim were ambiguous because they "at least partially overlap."[151] FDA's interpretation of these two seemingly overlapping provisions was to classify claims regarding a cure, mitigation, or treatment of a disease as drug claims and to classify claims that concern reducing the risk of contracting a disease as health claims.[152] The court considered this interpretation to be reasonable, and therefore deferred to this interpretation of the potentially overlapping statutory provisions.[153]

The Supreme Court overturned the *Chevron* doctrine in its decision of *Loper Bright Enterprises v. Raimondo*.[154] Under *Loper Bright*, courts no longer are to defer to an agency's reasonable interpretation of ambiguous statutes but instead are generally required to independently determine the "best reading" of a statute based on principles of statutory interpretation.[155] The Supreme Court's decision to overturn the *Chevron* framework in *Loper Bright* may have implications for courts considering FDA's interpretation going forward.[156]

## Health Claims Versus Structure/Function Claims

Certain claims making similar connections can be formulated differently to qualify as either a health claim or a structure/function claim. For example, a product that has the potential to improve bone density because it contains calcium could be marketed as either building stronger bones or reducing the risk of osteoporosis.[157] The claim "builds stronger bones" is a structure/function claim, whereas "reduces the risk of osteoporosis" is a health claim.[158] A manufacturer may strategically choose to use the structure/function claim on a food label rather than the similar health claim to avoid the premarket approval requirement and the more rigorous standard associated with health claims.[159] A manufacturer making this strategic choice may do so because the evidence for the claim does not meet the proposed standard or because it would like to market the product without waiting for FDA to approve the health claim. Similarly, a

[148] *Id*. at 948–49.

[149] *Id*.

[150] *Id.* at 950 (quoting Chevron v. Nat. Res. Def. Council, 467 U.S. 837, 842–45 (1984), *overruled by* Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024)).

[151] *Id*. at 949.

[152] *Id*. at 951.

[153] *Id*. at 950–52.

[154] Loper Bright Enter. v. Raimondo, 603 U.S. 369, 412 (2024) ("*Chevron* is overruled. Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the [Administrative Procedure Act] requires.").

[155] *Loper Bright*, 603 U.S. at 400.

[156] For more information on *Loper Bright*, see CRS Report R48320, *Loper Bright Enterprises v. Raimondo and the Future of Agency Interpretations of Law*, by Benjamin M. Barczewski (2024).

[157] *Label Claims for Conventional Foods and Dietary Supplements*, FDA, *supra* note 122.

[158] *Id*.

[159] *Compare* 21 U.S.C. § 343(r)(3)(B), *with id.* § 343(r)(6).

manufacturer seeking to advertise its cereal product that contains a significant amount of fiber may claim that the product "helps with digestion" rather than claiming that the product "reduces the risk of diverticulitis." This is because the diverticulitis claim may be considered a health claim, and the cereal product's use would require preapproval from FDA, while the digestion claim may be considered a structure/function claim, which does not need preapproval and can be used unless it is misleading.[160]

In some cases, it may not be clear whether a particular claim or symbol is a health claim or a structure/function claim, particularly when a label bears an implied health claim. An implied health claim "include[s] those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition."[161] FDA has explained that there is no "bright-line" test for these determinations, and it considers the entire label to determine on a "flexible case-by-case" basis whether the labeling constitutes a health claim or a structure/function claim within the context presented.[162] For example, a heart symbol can be categorized as either a health claim (linking a nutrient in a food to heart disease) or a structure/function claim depending on the context.[163]

# First Amendment Restrictions

The First Amendment's protection of commercial speech limits the ways in which the government can regulate claims on food and dietary supplement labels. Commercial speech is "expression related solely to the economic interests of the speaker and its audience."[164] Information on a product's labeling is considered commercial speech.[165] Commercial speech is entitled to "lesser protection" than "other constitutionally guaranteed expression," but it is still protected from "unwarranted governmental regulation."[166]

The Supreme Court established the standard that generally governs government restrictions on commercial speech in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*.[167] In that opinion, the Court said that "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity."[168] Therefore, the government can restrict commercial speech that is misleading or

[160] *Compare* 21 U.S.C. § 343(r)(3)(B), *with id.* § 343(r)(6).

[161] 21 C.F.R. § 101.14(a)(1).

[162] Food Labeling, General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2483 (Jan. 6, 1993) ("FDA agrees that no 'bright-line' definition can be established for implied health claims. Labeling claims need to be considered in their entirety and in context to determine if the elements of a health claim are present.").

[163] *Id.* (stating that FDA "believes that most of the perceptions about heart symbols fall under the regulatory regime of a health [claim]" as an implied health claim, but also explains that there is no "bright-line" test for determining what is an implied health claim.); *see also* Haggag v. Welch Foods, Inc., No. CV 13-00341-JGB OPX, 2014 WL 1246299, at *6 (C.D. Cal. Mar. 24, 2014) (determining that it could not decide whether the heart symbol and the phrase "helps support a healthy heart" on a grape juice label was a health claim or a structure/function claim because it would be inappropriate to decide the issue "without a clear indication of how the FDA would view" it in case the court's decision is "inconsistent with the FDA's regulatory scheme or later-issued guidance.").

[164] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 561 (1980).

[165] *See* Rubin v. Coors Brewing Co., 514 U.S. 476, 481 (1995) (analyzing the Federal Alcohol Administration Act's prohibition on displaying alcohol content on beers as commercial speech).

[166] *Cent. Hudson*, 447 U.S. at 561.

[167] *Id.*

[168] *Id.* at 563.

related to illegal activity.[169] The government may need to show that the regulated statements are "inherently misleading" or produce a record of consumer deception to justify a total ban on the use of those statements.[170] If the speech "is neither misleading nor related to unlawful activity," the government restriction is subject to intermediate scrutiny.[171] That is, (1) the government must prove that its interest is "substantial," (2) the restriction must "directly advance" that "substantial government interest," and (3) the restriction cannot be "more extensive than is necessary to serve that interest."[172]

No manufacturer has challenged FDA's regulation of nutrient content claims or structure/function claims on First Amendment grounds in federal court. With respect to nutrient content claims, stakeholders have argued that nutrient content claim regulations restrict at least some "truthful information"[173] and must then pass intermediate scrutiny.[174] FDA "believes that its nutrient content claim regulations are consistent with the [F]irst [A]mendment."[175] It argues that the government's interest in ensuring that consumers have access "to truthful, reliable, scientifically valid, and not misleading" nutrition information is a substantial one.[176] It also argues that the regulations directly advance that interest and are no more extensive than necessary.[177]

On the other hand, courts have held that certain FDA regulation of health claims on dietary supplement labels has run afoul of the First Amendment's commercial speech protections.[178] The D.C. Circuit, in its opinion in *Pearson v. Shalala* (*Pearson I*), determined that FDA's refusal to approve certain health claims was prohibited by the First Amendment.[179] In *Pearson I*, a dietary supplement manufacturer requested that FDA approve its use of four health claims: (1) consuming antioxidant vitamins may reduce the risk of certain kinds of cancers, (2) consuming fiber may reduce the risk of colorectal cancer, (3) consuming omega-3 fatty acids may reduce the

[169] *Id.* at 563–64.

[170] *See In re* R. M. J., 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive."); All. for Nat. Health v. Sebelius, 714 F. Supp. 2d 48, 62 (D.D.C. 2010) ("Under *Central Hudson* and *Pearson I*, the FDA may refuse to consider disclaimers for health claims (*i.e.*, prohibit their use completely) only if such health claims are inherently misleading . . . or are potentially misleading but the Agency has deemed the claim 'incurable by disclaimer.' . . . The court in *Whitaker* arguably went even further than *Pearson I*, holding that 'any complete ban of a claim would be approved only under narrow circumstances, *i.e.*, when there was almost no qualitative evidence in support of the claim *and* where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer.'") (first quoting Whitaker v. Thompson, 248 F. Supp. 2d 1, 9, 11 (D.D.C. 2002), and then quoting *Pearson I*, 164 F. 3d 650, 659 (D.C. Cir. 1999)).

[171] *Cent. Hudson*, 447 U.S. at 564.

[172] *Id*. at 564–66.

[173] Food Labeling, Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2392 (Jan. 6, 1993) ("Comments asserted that any suggestion that consumers should be screened from truthful information for their own good is the kind of paternalism rejected by the Supreme Court . . . ." (citation omitted)).

[174] *See* Edenfield v. Fane, 507 U.S. 761, 768–69 (1993) (stating that, where "truthful and nonmisleading expression will be snared along with fraudulent or deceptive commercial speech, the [government] must satisfy the remainder of the *Central Hudson* test by demonstrating that its restriction serves a substantial state interest and is designed in a reasonable way to accomplish that end.").

[175] Food Labeling, Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2392 (Jan. 6, 1993) (responding to comments regarding FDA's nutrient content claim regulations and the First Amendment).

[176] *Id.* at 2394.

[177] *Id*.

[178] *See, e.g.*, *Pearson I*, 164 F.3d 650, 659 (D.C. Cir. 1999).

[179] *Id*.

risk of coronary heart disease, and (4) 0.8 milligrams of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.[180] FDA refused to approve the use of any of these claims, determining that there was not "significant scientific agreement" to back the claims.[181] As a result, the supplement manufacturer sued FDA, claiming that FDA's refusal to approve the claims violated its First Amendment rights.[182]

The D.C. Circuit first determined that these claims were not "inherently misleading," but rather "potentially misleading" because consumers "would have difficulty in independently verifying these claims" and "might actually assume that the government has approved [them]."[183] Applying the *Central Hudson* test, the court held that the application of FDA's preapproval requirement of "significant scientific agreement" to these health claims failed intermediate scrutiny.[184] The court reasoned that while the government had substantial interests in protecting public health and preventing consumer deception, FDA could have authorized disclaimers for the manufacturer's products to address those concerns, and therefore the "significant scientific agreement" standard was not sufficiently tailored to advancing FDA's substantial interests.[185] In short, the panel determined that manufacturers are entitled to make these health claims even though they do not meet the "significant scientific agreement" standard, as long as they are accompanied by a proper disclaimer.[186] The court also recognized that when evidence supporting a health claim is outweighed by evidence against the claim, FDA could deem the claim incurable by a disclaimer and ban the health claim outright.[187]

As a result of this decision,[188] FDA has created a more flexible scheme that allows for "qualified health claims" to be made with less scientific substantiation as long as they are accompanied by an appropriate disclaimer.[189] Under this scheme, manufacturers submit health claim petitions. FDA considers these petitions on a case-by-case basis, based on the totality of publicly available evidence. If FDA decides the "significant scientific agreement" standard is met, it authorizes the use of the claim, without a disclaimer, through rulemaking.[190] If FDA determines that no credible scientific evidence supports the claim, it may deny the petition.[191] If a petition sets forth some credible scientific evidence but not enough evidence to satisfy the health claim standard, FDA

[180] The court acknowledged that this last claim was different from a traditional health claim (likely because it compared different methods of ingesting folic acid rather than simply linking folic acid to the reduction of a disease or health-related condition) but applied the same First Amendment reasoning to this claim as well. FDA concluded that the manufacturer could not make this claim because "the scientific literature does not support the superiority of any one source [of folic acid] over others." *Pearson I*, 164 F.3d at 658 (quoting Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects, 61 Fed. Reg. 8752, 8760 (Mar. 5, 1996)). The panel concluded that credible evidence supported the claim, and therefore a clarifying declaimer could have been added, such as "The evidence in support of this claim is inconclusive." *Id*.

[181] *Id.* at 651.

[182] *See id*. at 654.

[183] *Pearson I*, 164 F.3d at 655.

[184] *Id*. at 655–59.

[185] *Id*.

[186] *Id*. at 659.

[187] *Id*.

[188] *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims, January 2009, supra* note 97 ("The genesis of qualified health claims was the court of appeals decision in *Pearson v. Shalala*.").

[189] These rules are described in more detail above. *See* discussion *supra* "*Qualified Health Claim.*"

[190] *Guidance for Industry: FDA's Implementation of Qualified Health Claims*, FDA, *supra* note 90.

[191] *Id*.

may issue a letter of enforcement discretion, specifying the appropriate disclaimer that must be used with the claim.[192]

After *Pearson I*, FDA issued a decision that it would not authorize the claim that "0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form," even with a clarifying disclaimer, because it determined that the weight of scientific evidence was against the claim.[193] The plaintiffs[194] again sued FDA in *Pearson II*, the U.S. District Court for the District of Columbia determined that FDA failed to comply with the constitutional guidelines outlined in *Pearson I*.[195] The court concluded that the proposed claim was not inherently misleading because the "mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it."[196] The district court stated that "the question which must be answered under [*Pearson I*] is whether there is any 'credible evidence'" to support a claim, and if there is credible supporting evidence, the claim should not be prohibited unless such evidence was "outweighed by evidence against the claim."[197] Following the decision, FDA approved the claim with a disclaimer that includes three sentences: (1) "Your claim does not have FDA's endorsement," (2) "Public health authorities recommend a daily intake of 0.4 mg folic acid to reduce the risk of neural tube defects . . . , not the amount promoted in your claim as being more effective," (3) "Folic acid, whether provided in fortified foods or in a dietary supplement, is effective in reducing the risk of neural tube defects."[198]

Following these cases, several manufacturers sued FDA in *Alliance for National Health v. Sebelius*, challenging its decisions not to approve a health claim.[199] These manufacturers also challenged FDA's wording of the qualified health claim and its disclaimer.[200] In *Fleminger, Inc. v. U.S. Department of Health & Human Services*, a green tea manufacturer challenged FDA's refusal to approve the health claim that green tea reduces the risk of certain kinds of cancers with the manufacturer's proposed disclaimer that "FDA has concluded that there is credible evidence

[192] *Id*.

[193] Letter from Christine J. Lewis, Ph.D., Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, to Jonathan W. Emord, Esq., Emord & Associates, P.C., Regarding a Health Claim for Folic Acid and Neural Tube Defects (Docket No. 91N-100H) (Apr. 3, 2001), https://wayback.archive-it.org/7993/20171114183742/https:/www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073042.htm [https://perma.cc/7GK6-TY5Y].

[194] The plaintiffs differed slightly in this second case. *Pearson I* was filed by Durk Pearson; Sandy Shaw; the American Preventive Medical Association; Citizens for Health; and the National Health Federation. *Pearson II* was filed by Durk Pearson; Sandy Shaw; the American Preventive Medical Association; Julian M. Whitaker, M.D.; Pure Encapsulations; Inc.; and XCEL Medical Pharmacy, Ltd.

[195] Pearson v. Shalala (Pearson II), 130 F. Supp. 2d 105, 107 (D.D.C. 2001).

[196] *Id*. at 115.

[197] *Id*. at 114–15.

[198] Lewis, *supra* note 193.

[199] *See, e.g.*, All. for Nat. Health v. Sebelius (Alliance I), 714 F. Supp. 2d 48, 62–70 (D.D.C. 2010) (reversing FDA's decision not to approve health claims linking selenium intake and a reduced risk of certain kinds of cancers and remanding for FDA to consider appropriate disclaimers); All. for Nat. Health v. Sebelius (Alliance II), 786 F. Supp. 2d 1, 15 (D.D.C. 2011) (upholding FDA's decision declining to approve several health claims concerning the relationship between vitamins C and E and the risk of certain types of cancer).

[200] *See, e.g.*, *Alliance I*, 714 F. Supp. 2d at 70–72 (determining that FDA's disclaimer for the use of a health claim linking selenium to prostate cancer was too restrictive and did not adhere to the "First Amendment's preference for disclosure over suppression," and remanding to FDA to reconsider the scientific literature and to draft a new disclaimer in light of that review); *Alliance II*, 786 F. Supp. 2d at 23–24 (determining that FDA's disclaimers for health claims were too restrictive and noting that FDA provided "no explanation as to why a less restrictive approach would not be effective.").

supporting this claim although the evidence is limited."[201] FDA had instead approved the health claim with the required disclaimer that "FDA does not agree that green tea may reduce the risk because there is very little scientific evidence for the claim."[202] The U.S. District Court for the District of Connecticut first determined that FDA had substantial interests in preventing consumer confusion and protecting public health, and the main question was whether the government's means were sufficiently tailored to further those interests.[203]

The court determined that the green tea manufacturer's proposed disclaimer—that "FDA has concluded that there is credible evidence supporting this claim although the evidence is limited"—was misleading and inaccurate.[204] The court gave "deference" to FDA's assessment of the level of scientific evidence supporting the substance-disease relationship and agreed with FDA's conclusion that "'credible but limited evidence' signals to consumers a higher level of scientific support [than] is accurately reflected by a single non-replicated study whose results were undermined by two stronger studies finding no association" between green tea and breast cancer, or that is reflected by "one relatively weak and un-replicated study finding a positive association and another relatively weak study finding no association" between green tea and prostate cancer.[205]

The court also determined that "[t]he portion of the FDA's disclaimer stating there is 'very little scientific evidence' [struck] a reasonable fit between the government's ends and the means chosen to accomplish those ends" because the disclaimer accurately conveyed the strength of the scientific evidence and directly advanced FDA's interest in preventing consumer confusion and protecting the public.[206] In contrast, the court concluded that "[t]he portion of the FDA's disclaimer stating that the 'FDA does not agree that green tea may reduce that risk' [did] not strike a reasonable fit between the government's ends and the means chosen to accomplish those ends."[207] The court stated that this portion of the disclaimer had the "effect of negating any relationship between green tea and the reduction of breast or prostate cancer . . . ," and FDA's negation of the proposed health claim was an impermissible restriction on commercial speech.[208] Ultimately, and in accordance with this opinion, FDA allowed the health claim linking green tea and breast or prostate cancer when accompanied by the disclaimer that "FDA has concluded that there is very little scientific evidence for this claim."[209]

The Supreme Court has articulated a more lenient standard than the *Central Hudson* test that courts may apply when commercial disclosure requirements, rather than bans or restrictions on speech, are at issue.[210] Under this standard, called the *Zauderer* test for the case announcing it, certain disclosure requirements comply with the First Amendment if they are "reasonably related" to a sufficient government interest and not unjustified or unduly burdensome.[211] Among other criteria, the *Zauderer* test applies only to disclosures of "purely factual and uncontroversial"

[201] 854 F. Supp. 2d 192, 204–205 (D. Conn. 2012).

[202] *Id.* at 205.

[203] *Id*. at 208.

[204] *Id*. at 210–11.

[205] *Id*. at 212.

[206] *Id*. at 216.

[207] *Id*. at 217.

[208] *Id*. at 218.

[209] *See Qualified Health Claims: Letters of Enforcement Discretion*, FDA, *supra* note 93.

[210] *See* CRS Report R45700, *Assessing Commercial Disclosure Requirements under the First Amendment*, by Valerie C. Brannon (2019).

[211] Zauderer v. Off. of Disciplinary Couns., 471 U.S. 626, 651 (1985).

information about the speakers' own products.[212] Disclosure requirements that do not qualify for *Zauderer* review may receive strict or intermediate scrutiny.[213] The courts in the *Alliance* and *Fleminger* cases applied the *Central Hudson* test, possibly because the plaintiffs characterized at least some of FDA's actions as a ban or restriction on their speech.[214] Future cases involving FDA-required disclaimers may raise questions as to which First Amendment standard—*Central Hudson* or *Zauderer*—applies.

# Considerations for Congress

Nutrient-related labeling claims are subjected to different types and degrees of regulation depending on how they are categorized. Congress may consider whether the existing laws pertaining to each category align with its policy goals. Any regulation of food labels as commercial speech would necessarily be subject to the limitations of the First Amendment and may be subject to challenge.

Based on how FDA and the courts have distinguished between drugs and health claims, Congress may consider whether the dividing line between such claims is consistent with its policy goals or whether to adjust how products are classified. If Congress approves of the existing classification, it could consider codifying FDA's approach in statute. Congress may wish to consider whether to impose specific requirements for structure/function claims on food, akin to those imposed on dietary supplements. It may also consider whether to provide further clarification on how to distinguish between health claims and structure/function claims.

Congress could consider defining additional claims. Certain claims are not explicitly regulated under the FD&C Act; FDA prohibits them only if they are misleading. These claims do not have a preapproval process, and there are no standards for evaluating whether the claims are misleading. Congress may consider adding other categories of claims or directing FDA to determine the meaning of certain claims, such as "natural." Congress has introduced legislation that would require FDA to define this term.[215]

Qualified health claims are currently being used, although they are not specifically authorized in the FD&C Act. As discussed above, *Pearson I* assessed how FDA's treatment of certain health claims on dietary supplements ran afoul of the First Amendment.[216] Although the requirements for dietary supplement health claims are set out in regulation rather than statute,[217] the same First Amendment concerns may arise in the food context, and those health claim requirements are set out in statute.[218] Congress may consider whether there are First Amendment concerns arising from the statutory language that could merit modification. Congress may also consider setting specific standards for various types of disclaimers or for when qualified claims should be

[212] Nat'l Inst. of Fam. & Life Advocs. v. Becerra, 585 U.S. 755, 768 (2018).

[213] *See* CRS In Focus IF12388, *First Amendment Limitations on Disclosure Requirements*, by Valerie C. Brannon et al. (2023).

[214] *See, e.g.*, *Alliance I*, 714 F. Supp. 2d at 62 (D.D.C. 2010). *Cf.* Fleminger, Inc., v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 216 (D. Conn. 2012) (distinguishing an "outright ban" of a health claim from "the present circumstance where the government allows the health claim to be made but drafts an appropriate disclaimer to remedy the weaknesses in the proposed claim.").

[215] *See* H.R. 2901, 118th Cong. (2023); S. 1289, 118th Cong. (2023).

[216] *Pearson I*, 164 F.3d 650, 659 (D.C. Cir. 1999).

[217] 21 C.F.R. § 101.14(a)(1).

[218] 21 U.S.C. § 343(r)(3).

permitted. Congress could also leave it to FDA to determine the appropriate disclaimers to require and standards to apply.

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## Disclaimer