Congressional Research Service
Informing the legislative debate since 1914

IN FOCUS

October 31, 2024

Health Claims on Food and Dietary Supplement Labels: FDA Regulation and Select Legal Issues

A food or dietary supplement manufacturer may seek to market a product through a statement on its product's label that suggests a link between a nutrient in that product and a disease or health-related condition. Such a statement may qualify as a "health claim" under the Federal Food Drug and Cosmetic Act (FD&C Act, 21 U.S.C. §§ 301 et seq.), which the Food and Drug Administration (FDA) administers. Generally, the FD&C Act prohibits the introduction into interstate commerce of misbranded foods and dietary supplements, which generally relates to how the product is labeled or marketed. The FD&C Act and the relevant regulations deem a product to be misbranded if it contains an unauthorized health claim.

In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA; P.L. 101-535), which amended the FD&C Act to provide specific requirements for using certain types of marketing claims on food, including health claims. Prior to the NLEA, if a product claimed a connection between a nutrient in the product and a disease or health-related condition, FDA could either regulate it as a drug, subjecting it to the rigorous drug approval process, or treat it as food and allow it to bear the claim without any preapproval. Today, the FD&C Act provides procedures and standards for FDA to regulate the use of such claims without subjecting the products to the drug approval process. The FD&C Act addresses health claims on food labels and authorizes FDA to establish standards and procedures for such claims on dietary supplements. FDA regulations apply the same standards and procedures for health claims on food to dietary supplements.

This In Focus discusses the legal framework governing health claims and certain legal issues that have arisen regarding FDA's regulation of them.

The Health Claim Regulatory Scheme

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. An example of such a claim would be stating that a product that is high in calcium (e.g., milk) may reduce the risk of osteoporosis. A health claim may also be implied by using symbols (e.g., a heart symbol) or written statements (e.g., including "heart" in the brand name) that suggest a relationship between the product and a disease or health-related condition.

Section 403(r) of the FD&C Act (21 U.S.C. § 343(r)) and the relevant regulations (21 C.F.R. §§ 101.14, 101.70–72) permit a manufacturer to include a health claim on a product's label only when FDA has promulgated a regulation approving the health claim. FDA may approve a health claim 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. Any person may petition FDA to authorize a health claim, and FDA must issue a final decision on any such petition within 100 days. To date, FDA has promulgated regulations approving 12 health claims (*see* 21 C.F.R. §§ 101.72–101.83). Each regulation lists the specific requirements a product must satisfy in order to use the approved health claim on its labeling.

Federal law prohibits including health claims on food or dietary supplement products that contain certain other nutrients in amounts that may increase the risk of another disease. If a product has a "disqualifying nutrient level" (i.e., greater than a certain level of total fat, saturated fat, cholesterol, or sodium per reference amount), then the product's label cannot include any health claim. This requirement is intended to protect a consumer from buying a product based on labeling that indicates it could reduce the risk of one disease when that product could increase the risk of some other disease.

Health Claims Versus Drug Claims

The criteria for qualifying as a health claim and the definition of *drug* under the FD&C Act are sufficiently similar that questions persist regarding when a product may be marketed as a food or dietary supplement with a health claim versus requiring premarket approval as a drug. The FD&C Act defines *drug* to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," whereas a health claim "characterize[s] the relationship of any nutrient . . . to a disease or health-related condition." In some cases, these requirements may effectively overlap. For example, a claim that a nutrient in a product treats a disease may cause the product be considered a drug while also qualifying as a product bearing a health claim that "characterize[s] the relationship" between the nutrient and disease.

FDA considered the potential overlap between these two types of claims for the first time when evaluating a petition for a health claim that saw palmetto extract may improve certain symptoms associated with mild benign prostatic hyperplasia. Prior approved health claims had claimed that the nutrient reduced the risk of a future disease rather than affected an existing disease. FDA denied the petition and concluded that the claim was a drug claim. FDA interpreted the statutory provisions such that a product marketed as diagnosing, curing, mitigating, or treating disease would generally be considered a "drug," even if it would otherwise qualify as a food or dietary supplement, and a product marketed only as reducing the risk of a disease would be considered to bear a health claim.

On review in *Whitaker v. Thompson*, the D.C. Court of Appeals for the D.C. Circuit upheld FDA's petition denial and interpretation of the statute. The court determined that the statutory provisions defining *drug* and authorizing health claims "at least partially overlap" and provide "little guidance as to how FDA should sort out claims that seem to fit both definitions." Applying the now-overturned *Chevron* framework, the court deferred to FDA's reasonable interpretation. The Supreme Court subsequently overturned the *Chevron* framework in *Loper Bright Enterprises v. Raimondo*, which may have implications for courts considering FDA's interpretation going forward. This Legal Sidebar describes the case and its potential implications. Congress may consider whether to clarify the distinction between drug claims and health claims in the FD&C Act.

Qualified Health Claims

Following a successful First Amendment challenge to FDA's rejection of certain health claims on dietary supplements, FDA has exercised its enforcement discretion to allow manufacturers to use qualified health claims. *Qualified health claims* are health claims that FDA determines are not supported by "significant scientific agreement" but may be qualified by an appropriate disclaimer to allow their use without misleading consumers.

Health claims on food and dietary supplement labels are a form of commercial speech and therefore protected by the First Amendment from unwarranted government restriction. Whether a particular restriction is unwarranted depends on the type of speech, the government's interest in restricting the speech, and the connection between the interest and the restriction. For commercial speech, any restriction generally must "directly advance" the government's "substantial" interest and must not be "more extensive than necessary to serve that interest." The Supreme Court has held that certain types of commercial speech generally may be banned entirely consistent with the First Amendment, such as prohibiting the use of misleading commercial speech or commercial speech related to illegal activity.

In 1999, the D.C. Circuit considered a First Amendment challenge to FDA's rejection of certain health claims for dietary supplements in *Pearson v. Shalala*. The court held that while FDA had a substantial interest in protecting the public health and preventing consumer confusion, FDA's outright ban of the health claims after concluding that they were not supported by "significant scientific agreement" was not sufficiently tailored to those interests. The court determined that FDA could have sufficiently served the government's substantial interests by requiring the use of disclaimers rather than prohibiting the claims outright.

Although the D.C. Circuit's ruling only addressed FDA's regulation of health claims on dietary supplements, these same constitutional concerns may be raised regarding the regulation of health claims on food because the standards and restrictions are the same for both products. FDA only has authority to unilaterally amend the requirements for dietary supplements because they are set out in regulations, whereas the requirements for health claims on food labels are set in statute and can only be amended by Congress. In light of the potential First Amendment considerations for the regulation of both types of products, FDA chose to exercise its enforcement discretion to decline to pursue certain violations of the "significant scientific agreement" standard. In the wake of *Pearson*, FDA has issued letters of enforcement discretion that allow certain qualified health claims on food and dietary supplement labels when accompanied by an appropriate disclaimer.

If FDA determines that a health claim does not meet the "significant scientific agreement" standard, it determines what disclaimer—if any—cures the health claim's potential to mislead consumers based on the level of scientific evidence that supports the claim. For example, FDA has exercised its enforcement discretion to allow manufacturers to claim that green tea reduces the risk of breast or prostate cancer as long as the claim is accompanied by the disclaimer that "there is very little scientific evidence for this claim." Meanwhile, a yogurt manufacturer may claim that eating yogurt regularly may reduce the risk of type 2 diabetes if the label also states that there is "limited information" or "limited scientific evidence" supporting the claim. The disclaimers differ because, although FDA concluded neither claim meets the "significant scientific agreement" standard, FDA determined that there is more evidence backing the yogurt claim than the green tea claim.

FDA must also comply with the First Amendment when requiring a disclaimer for a qualified health claim. For example, green tea manufacturers challenged FDA's requirement that a qualified health claim linking green tea to breast and prostate cancer include a disclaimer that stated in part that "FDA does not agree that green tea may reduce that risk." The federal district court held that, although FDA has a substantial interest in preventing consumer confusion and protecting public health, this portion of the disclaimer did not strike "a reasonable fit between the government's ends and means chosen to accomplish those ends." The court noted that this language had the "effect of negating any relationship between green tea and the reduction of breast or prostate cancer" and was therefore overly burdensome. As a result, the court remanded the matter to FDA to consider alternative qualified health claim language that would strike an appropriate balance consistent with the First Amendment. Although not relied upon by the court in the green tea litigation, the Supreme Court has articulated a more lenient standard that courts may apply when assessing commercial *disclosure* requirements (i.e., compelled commercial speech) rather than restrictions on speech. Future cases involving FDA-required disclaimers may raise questions as to which First Amendment standard applies.

In light of the potential First Amendment implications for the statutory framework for health claims, Congress may consider whether to amend the FD&C Act to address the court's concerns in *Pearson*. Congress could consider adopting an approach similar to FDA's qualified health claims framework or a superseding framework. Any restrictions on speech or compelled disclaimers would be subject to First Amendment scrutiny.

Dorothy C. Kafka, Legislative Attorney

IF12801

Disclaimer