Ferrari v. Vitamin Shoppe: A Favorable Ruling for a Manufacturer Facing a Challenge to Its Dietary Supplement Structure/Function Claims

by Jennifer Hill

In *Ferrari v. Vitamin Shoppe Industries LLC*, 70 F.4th 64 (1st Cir. 2023), the First Circuit became the latest U.S. Court of Appeals to analyze the appropriateness of labeling claims that emphasize the health benefits of nutrients contained in dietary supplements. With the dietary supplement industry experiencing significant growth over the past two decades,[1] it is no surprise that labeling claims have drawn close attention.

The First Circuit's decision in favor of a manufacturer reinforces that challenging dietary supplement labeling under state law can be difficult given that satisfying U.S. Food and Drug Administration (FDA) requirements preempts such a challenge.

FDA's Regulation of Dietary Supplement Labeling

FDA regulates dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA). The DSHEA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to "establish standards with respect to dietary supplements."[2] This framework permits dietary supplement manufacturers to make labeling statements commonly known as "structure/function claims." A structure/function claim is permissible when:

> (A) the statement . . . describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
>
> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
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> (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[3]

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Structure/function claims are distinguishable from "disease claims," which are claims that a product will "diagnose, mitigate, treat, cure, or prevent disease."[4] Disease claims include explicit or implicit claims that "the product . . . has an effect on a specific disease or class of diseases."[5]

Background in *Ferrari*

The plaintiffs in *Ferrari* purchased three formulations of a glutamine supplement manufactured and sold by Vitamin Shoppe under the brand name "BodyTech." Glutamine is an amino acid produced naturally by the body. Because it has been reported to have a role in supporting immune system functions and preserving muscle tissue, glutamine supplements have become a popular component of sports nutrition.[6] BodyTech glutamine supplements are one of many similar products marketed towards athletes to support muscle growth and recovery.

Dissatisfied with their own use of the BodyTech supplements, the plaintiffs brought a putative class action against Vitamin Shoppe, alleging that BodyTech's labeling was false and misleading. They sought to recover under Massachusetts and Illinois statutes governing false advertising and deceptive business practices, as well as various common law tort theories.

The district court granted summary judgment in favor of Vitamin Shoppe, finding that the challenged labeling statements were permitted under the FDCA as structure/function claims. The district court, therefore, concluded that federal law preempted all of the plaintiffs' state law claims. The plaintiffs appealed the decision to the First Circuit.

First Circuit's Decision

The arguments on appeal required the court to consider the parameters of appropriate structure/function claims under the FDCA and the type of substantiation it requires. First, the plaintiffs challenged the district court's finding that Vitamin Shoppe's statements regarding BodyTech supplements qualified as structure/function claims. According to the plaintiffs, BodyTech's labeling impermissibly made representations about the product itself (supplemental glutamine), rather than the nutrient's general effect on the body's structure or function, and described the "specific situation and usage" for the product.[7]

To support this theory, the plaintiffs pointed to specific labeling statements they said extended beyond the qualities of glutamine as an ingredient. For example, the plaintiffs took issue with the statement that "[i]ntense exercise can deplete glutamine stores, however, supplemental glutamine is thought to replenish these stores allowing for enhanced recovery."[8] The plaintiffs argued that by describing the effects of "supplemental" glutamine and the situation for which it would be useful (following "intense exercise"), the statements no longer qualified as structure/function claims.

The First Circuit disagreed, noting this statement "fits comfortably within the definition of a structure/function claim" because it explains how supplemental glutamine helps maintain glutamine stores, i.e., the mechanism by which the nutrient acts to maintain the structure or function.[9]

The plaintiffs also challenged the statement that the supplement "combines" three nutrients, each with certain health benefits, asserting that this characterization made it a disease claim. The court rejected this argument, because "merely noting that the nutrient is in the product" was not a reason to negate "an otherwise acceptable structure/function claim."[10]

Next, the plaintiffs argued that the challenged statements were still impermissible because they lacked substantiation required for structure/function claims. The plaintiffs argued that Vitamin Shoppe must have evidence substantiating its claims based on glutamine in the supplemental form, as it is delivered in the product, rather than as naturally occurring glutamine.

The court accepted this premise, given that Vitamin Shoppe made claims about "supplemental glutamine" or glutamine that was "added" to the product.[11] But, the court found this to be a distinction without a difference because the parties agreed that supplemental glutamine and naturally occurring glutamine had the same function in the human body.

The plaintiffs urged the court to adopt a broader view of substantiation, arguing that it requires a showing of the product's efficacy in supporting the structure or function of the body as claimed. According to the plaintiffs, Vitamin Shoppe did not meet this threshold because most people produce enough natural glutamine such that additional glutamine in the form of a supplement would provide no actual benefit.[12]

The court drew a careful distinction in the type of substantiation needed for structure/function claims. Relying on the plain text of the DSHEA, the court concluded that a manufacturer is only required to have substantiation of the nutrient's claimed effect on the body's structure or function.[13] According to the court, the statute did not require evidence that the product itself has the claimed benefits. In reaching its conclusion, the court contrasted Congress' treatment of dietary supplements and

drugs. New drugs require "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested."[14] While dietary supplements that make disease claims are subject to the same efficacy requirement, it is not the case for dietary supplements making structure/function claims.[15]

The plaintiffs' reliance on FDA's Guidance for Industry did not change this conclusion.[16] The court acknowledged that FDA's guidance recommends having evidence that the supplement will affect the body as claimed, under conditions similar to those described for the supplement. However, the court found no statutory ambiguity to justify deferring to FDA's nonbinding guidance.

Finally, the plaintiffs challenged the truthful and non-misleading nature of Vitamin Shoppe's structure/function claim. The plaintiffs argued, in part, that the labeling statements were misleading in that they claimed that "the actual pills in the bottle provide certain benefits,"[17] when, according to the plaintiffs, they did not. The court disagreed. A manufacturer must have substantiation for the nutrient's claimed physiological role, but it is not required to disclose whether using the product as directed will provide a health benefit to the consumer.

Having found no genuine dispute that the BodyTech labeling claims met the standards for structure/function claims under the DSHEA, the court concluded that federal law expressly preempted all of the plaintiffs' state law claims. Indeed, the FDCA prohibits any state from establishing "any requirement respecting any claim described in section 343(r)(1) . . . made in the label or labeling of food that is not identical to the requirement of section 343(r)(6)."[18]

Because structure/function claims fall within this scope, the court affirmed summary judgment in favor of Vitamin Shoppe.

Conclusion

Ferrari demonstrates that manufacturers can face aggressive legal attacks from consumers against dietary supplement labeling claims, yet still obtain a favorable ruling. As new products emerge, so too will new theories for challenges under state law. Courts will continue to be called on to define the parameters of acceptable structure/function claims and the corresponding substantiation required by federal law.

Ferrari adds to that body of law and illustrates the need for manufacturers to be vigilant of the legal requirements for making a structure/function claim. *Ferrari* also reinforces that manufacturers (and consumers considering court challenges) should focus on whether supplement labels satisfy FDA requirements, while also providing some guidance on how the FDA requirements are interpreted.

1. Amy B. Cadwallader & AMA Council on Science and Public Health, *Which Features of Dietary Supplement Industry, Product Trends, and Regulation Deserve Physicians' Attention?*, 24 AMA J. Ethics 410 (2022), doi: 10.1001/amajethics.2022.410.
2. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417 (1994).
3. 21 U.S.C. § 343(r)(6).
4. 21 C.F.R. § 101.93(g).
5. 21 C.F.R. § 101.93(g)(2)(i).
6. Audrey Yule Coqueiro, Marcelo Macedo Rogero & Julio Tirapegui, *Glutamine as an Anti-Fatigue Amino Acid in Sports Nutrition*, 11 Nutrients 863 (2019), https://doi.org/10.3390/nu11040863.
7. Ferrari v. Vitamin Shoppe Industries LLC, 70 F.4th 64, 70 (1st Cir. 2023).
8. *Id.*
9. *Id.*
10. *Id.* at 71.
11. *Id.* at 72.
12. *Ferrari v. Vitamin Shoppe Industries LLC*, Brief of Appellants, No. 22-1332 (1st Cir. Sept. 6, 2022) at 12.
13. *Ferrari*, 70 F.4th at 73.
14. 21 U.S.C. § 355(d).
15. 21 C.F.R. § 101.93(f).
16. U.S. Food & Drug Admin., Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 304 (Jan. 2009), https://www.govinfo.gov/content/pkg/FR-2009-01-05/pdf/E8-31249.pdf.
17. *Ferrari*, Br. of Appellants at 66.
18. 21 U.S.C. § 343-1(a)(5).