Ferrari v. Vitamin Shoppe Industries LLC

United States Court of Appeals, First Circuit. | June 9, 2023 | 70 F.4th 64 | 2023 WL 3911507

Document Details

standard Citation:	Ferrari v. Vitamin Shoppe Indus. LLC, 70 F.4th 64 (1st Cir. 2023)
All Citations:	70 F.4th 64

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Outline

70 F.4th 64
United States Court of Appeals, First Circuit.

Richard FERRARI, individually and on behalf of all others similarly situated; William Bohr, individually and on behalf of all others similarly situated, Plaintiffs, Appellants,

v.

VITAMIN SHOPPE INDUSTRIES LLC f/k/a **Vitamin Shoppe** Inc., Defendant, Appellee.

No. 22-1332
|
June 9, 2023

Synopsis

Background: Consumers who had purchased dietary supplements with glutamine brought action against products' manufacturer, alleging that products' labels were false and misleading in violation of state law. The United States District Court for the District of Massachusetts, George A. O'Toole, Jr., Senior District Judge, 2022 WL 974048, granted manufacturer's summary judgment motion on preemption grounds. Consumers appealed.

Holdings: The Court of Appeals, Carreño-Coll, District Judge, sitting by designation, held that:

[1] manufacturer's statements on labels were structure/function claims;

[2] reasonable jury could not have construed contested statements as claims about products' benefits instead of claims about glutamine's effect on the human body;

[3] manufacturer sufficiently substantiated that its structure/function claims were truthful and not misleading; and

[4] fact that taking manufacturer's dietary supplements as directed did not reap benefits label attributed to glutamine was unrelated to question whether nutrient's claimed physiological role was misleading.

Affirmed.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

West Headnotes (18)

[1] **Food** Statutory and municipal regulations in general

Health Purpose and construction of statutes

The FDCA is designed to protect consumers from harmful products. Federal Food, Drug, and Cosmetic Act § 1 et seq., 21 U.S.C.A. § 301 et seq.

[2] **Health** Advertising and other representations

Under the FDCA and Dietary Supplement Health and Education Act (DSHEA), manufacturers may make so-called structure/function claims about dietary supplements, describing the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or characterizing the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(A).

[3] **Health** Preemption

States Product safety; food and drug laws

If the manufacturer's label satisfies the FDCA's requirements for dietary supplements, consumers are preempted from attacking the structure/function claim of the dietary supplement under state law. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6).

[4] **Health** Preemption

States Product safety; food and drug laws

The FDCA expressly preempts any state law that establishes labeling requirements for structure/function claims for dietary supplements that are not identical to the requirements in the FDCA. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6).

[5] **Health** Requisites and adequacy of labeling

A manufacturer of dietary supplements prevails on a state-law claim alleging false or misleading labeling if its label satisfies the requirements of FDCA concerning claims as to products' structure and function. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6).

[6] **Federal Courts** Summary judgment

Court of Appeals reviews de novo a district court's order granting summary judgment. Fed. R. Civ. P. 56.

[7] **Federal Courts** Summary judgment

On review of grant of summary judgment, Court of Appeals views the facts in the record in the light most favorable to the nonmovants, and draws all reasonable inferences in their favor. Fed. R. Civ. P. 56.

[8] **Federal Courts** Preemption in general

A district court's preemption ruling is reviewed de novo because it presents a pure question of law.

[9] **Food** State power in general

States Product safety; food and drug laws

Manufacturer's statements on labels of dietary supplements containing glutamine, explaining how supplemental glutamine helps maintain glutamine stores, which help muscles recover after intense exercise, were structure/function claims describing nutrient's effect on the human body's structure or function or explaining how the nutrient maintained that structure or function, such that consumers' state-law claims that labels were false or misleading were preempted by FDCA. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(A).

[10] **Food** State power in general

States Product safety; food and drug laws

Manufacturer's statements on labels of dietary supplements containing glutamine, that glutamine helps support muscle growth and recovery as well as immune health and has anti-catabolic properties, were structure/function claims, such that consumers' state-law claims that labels were false or misleading were preempted by FDCA, even though statements referred to manufacturer's products, not just to nutrient glutamine; statements described how glutamine affects a structure or function in the human body, and claims were substantially similar to others that Food and Drug Administration (FDA) had approved of. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6).

[11] **Food** State power in general

States Product safety; food and drug laws

Manufacturer's statements on labels of dietary supplements containing glutamine plainly made claims about what glutamine does, not about what manufacturer's products do, and thus reasonable jury could not have construed contested statements on products' labels as claims about products' benefits instead of claims about glutamine's effect on the human body, as would support finding that statements on labels were structure/function claims such that consumers' state-law claims that labels were false or misleading were preempted by FDCA. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(A).

[12] **Food** State power in general

States Product safety; food and drug laws

Evidence substantiating that manufacturer's structure/function claims on label of dietary supplements containing supplemental glutamine were truthful and not misleading was required to be about supplemental form, not the naturally occurring form, of glutamine, for purposes of determining whether consumers' state-law claims concerning allegedly false and misleading labels were preempted by FDCA. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

[13] **Health** Requisites and adequacy of labeling

To comply with FDCA's requirements for structure/function claims on labels of dietary supplements, a manufacturer must have competent and reliable scientific evidence that its structure/function claims are truthful and not misleading. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

[14] **Health** Requisites and adequacy of labeling

Plain text of FDCA requires a manufacturer to have substantiation that a nutrient's claimed effect on the human body's structure or function is truthful and not misleading, not that the product has the claimed effect; statute does not require manufacturer to show that taking the dietary supplement affects the structure or function as claimed, and had Congress wanted to add an efficacy requirement, it could have. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

[15] **Food** State power in general

States Product safety; food and drug laws

Manufacturer of dietary supplement containing supplemental glutamine sufficiently substantiated that its structure/function claims on products' labels concerning physiological role of glutamine, that glutamine supplementation supports muscle growth, recovery, and immune health, were truthful and not misleading, such that consumers' state-law claims were preempted by FDCA; dispute boiled down to recommended dose on products as consumers' expert agreed that intense exercise can deplete glutamine stores, that glutamine supplementation can help maintain these stores and enhance recovery, that supplemental glutamine is involved in regulating protein synthesis, and that supplemental glutamine can have anti-catabolic properties, which help preserve muscle tissue by preventing protein breakdown. Federal Food, Drug,

and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

[16] **Food** State power in general

States Product safety; food and drug laws

That taking manufacturer's dietary supplements containing glutamine as directed did not reap benefits label attributed to glutamine was unrelated to question whether nutrient's claimed physiological role was misleading, as would support finding that FDCA preempted consumers' state-law claims concerning allegedly misleading labels. Federal Food, Drug, and Cosmetic Act §§ 201, 403, 21 U.S.C.A. §§ 321(n), 343(r)(6)(B).

[17] **Health** Requisites and adequacy of labeling

A structure/function claim on a dietary supplement label is misleading under the FDCA if it omits a nutrient's conflicting or harmful role in affecting the human body's structure or function. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

[18] **Health** Requisites and adequacy of labeling

A structure/function claim on a dietary supplement label is untruthful under the FDCA if the nutrient does not have the claimed effect. Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.A. § 343(r)(6)(B).

***67** APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS [Hon. George A. O'Toole, Jr., U.S. District Judge]

Attorneys and Law Firms

Mark R. Sigmon, with whom Nick Suciu, III, Milberg Coleman Bryson Phillips Grossman PLLC, Charles J. LaDuca, Brendan S. Thompson, Cuneo Gilbert & LaDuca, LLP, Joseph J. Siprut, Erica C. Mirabella, Charles E. Schaffer, and Levin Sedran & Berman LLP were on brief, for appellants.

Michael R. McDonald, with whom Caroline E. Oks and Gibbons, P.C. were on brief, for appellee.

Before Montecalvo and Thompson, Circuit Judges, and Carreño-Coll, * District Judge.

Opinion

CARREÑO-COLL, District Judge.

Richard Ferrari and William Bohr purchased three dietary supplements with glutamine in the hope that the glutamine would -- as the labels said -- help their muscles grow and recover after intense exercise. When they did not see any results, they sued the products' manufacturer, **Vitamin Shoppe**, for several state torts. The district court granted summary judgment to **Vitamin Shoppe**, ruling that the plaintiffs' state law claims are preempted because the labels comply with federal law. We affirm.

I.

[1] **[2]** The Food, Drug, and Cosmetic Act ("FDCA") is designed to protect consumers from harmful products. Perham v. GlaxoSmithKline LLC (In re Zofran (Ondansetron) Prods. Liab. Litig.), 57 F.4th 327, 330 (1st Cir. 2023). Congress amended the FDCA through the Dietary Supplement Health and Education Act of 1994 ("DSHEA") to establish a uniform framework to regulate dietary supplements. ***68** Pub. L. No. 103-417, 108 Stat. 4325, 4325–26 (1994). Under the FDCA and DSHEA, manufacturers may make so-called "structure/function claims" about dietary supplements. Kaufman v. CVS Caremark Corp., 836 F.3d 88, 92 (1st Cir. 2016). A structure/function claim "describes the role of a nutrient or

dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6)(A). That a nutrient, for example, "helps promote digestion" or "supports the immune system" is a structure/function claim. 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, 1006, 1028–29 (Jan. 6, 2000) (codified at 21 C.F.R. pt. 101). To make such a claim, the manufacturer must have "substantiation that [the claim] is truthful and not misleading." § 343(r)(6)(B). And the dietary supplement's label must bear a disclaimer stating that the claim has not been evaluated by the Food and Drug Administration ("FDA") and that the "product is not intended to diagnose, treat, cure, or prevent any disease." § 343(r)(6)(C). Finally, the claim itself may not purport "to diagnose, mitigate, treat, cure, or prevent" disease. § 343(r)(6).

[3] **[4]** **[5]** If the manufacturer's label satisfies § 343(r)(6)'s requirements, consumers may not attack the structure/function claim under state law. See Kaufman, 836 F.3d at 91–92. To keep labeling requirements uniform, the FDCA expressly preempts "any requirement" under state law "respecting any claim of the type 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)." 21 U.S.C. § 343-1(a)(5). Structure/function claims under § 343(r)(6) fall within § 343(r)(1)'s ambit. See § 343(r)(6) (stating that, "[f]or purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if" the statement complies with certain requirements). So they are "claim[s] of the type described in section 343(r)(1)." And they are claims made in the labeling of food because dietary supplements are "deemed" food under the FDCA, except in limited circumstances that do not apply here. See 21 U.S.C. § 321(ff). Thus, the FDCA expressly preempts any state law that establishes labeling requirements for structure/function claims that are not identical to the requirements in § 343(r)(6). See Dachauer v. NBTY, Inc., 913 F.3d 844, 847–48 (9th Cir. 2019). The "net effect" of this is that the manufacturer "prevail[s] if its label satisfies the requirements of [§ 343(r)(6)]." Kaufman, 836 F.3d at 92.

With our statutory scaffolding in place, we turn to what happened below. The plaintiffs purchased three dietary supplements: Glutamine, Creatine & Glutamine with Beta-Alanine, and BCAA & Glutamine.[1] Glutamine is a main ingredient in all three of them. The Glutamine supplement states that glutamine "is involved in regulating protein synthesis and has been shown to possess [a]nti-[c]atabolic properties[2] to help preserve muscle" and that "[i]ntense exercise can deplete glutamine stores, however, supplemental glutamine is thought to replenish these stores allowing for enhanced recovery." The Creatine & Glutamine with Beta-Alanine supplement ***69** says that "[g]lutamine helps support muscle growth and recovery as well as immune health."[3] And the BCAA & Glutamine supplement states that glutamine has "anti-catabolic properties." The plaintiffs claimed that these statements are false and misleading under state law.

Vitamin Shoppe moved for summary judgment on the ground that the FDCA preempts the plaintiffs' state law claims because its products' labels comply with § 343(r)(6). The plaintiffs responded that the labels' statements about glutamine are claims about supplemental glutamine -- not naturally occurring glutamine (glutamine that the body produces) -- and so to comply with § 343(r)(6), **Vitamin Shoppe** needed to substantiate those claims with evidence about supplemental glutamine. Because **Vitamin Shoppe**, they asserted, substantiated its claims about supplemental glutamine with evidence about naturally occurring glutamine, the claims are not substantiated within the meaning of § 343(r)(6) and thus the FDCA does not preempt their state law claims.

The district court granted summary judgment to **Vitamin Shoppe**, ruling that the FDCA preempts the plaintiffs' state law claims. In doing so, it held that the contested statements about glutamine are

structure/function claims, that there is no "meaningful distinction" in the record between supplemental glutamine and naturally occurring glutamine, and that the parties' experts largely agreed that glutamine does what **Vitamin Shoppe's** labels claim. This appeal followed.

II.

[6] **[7]** **[8]** We review de novo the district court's order granting summary judgment. Perham, 57 F.4th at 335. Through that lens, we view the facts in the record in the light most favorable to the plaintiffs, as the nonmovants, and draw all reasonable inferences in their favor.[4] Id. The district court's preemption ruling is reviewed de novo, too, because it "presents a pure question of law." Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Hernández, 58 F.4th 5, 11 (1st Cir. 2023).

III.

The plaintiffs argue that the district court erred by holding that the FDCA preempts their state law claims because the statements about glutamine on **Vitamin Shoppe's** labels are not structure/function claims and, even if they were, **Vitamin** *70 **Shoppe** lacks substantiation that the statements are truthful and not misleading.[5] We take each argument in turn.

A.

[9] We begin with whether the statements about glutamine on **Vitamin Shoppe's** labels are structure/function claims. Recall that a structure/function claim describes a nutrient's effect on the human body's structure or function or explains how the nutrient maintains that structure or function. § 343(r)(6)(A). **Vitamin Shoppe's** statements about glutamine fit the bill.

First, the statement "[i]ntense exercise can deplete glutamine stores, however, supplemental glutamine is thought to replenish these stores allowing for enhanced recovery"[6] explains how supplemental glutamine helps maintain glutamine stores, which help our muscles recover after intense exercise. So it fits comfortably within the definition of a structure/function claim. Indeed, the FDA has approved of a substantially similar claim: "[The] FDA believes that a claim that a product is useful because it counterbalances the effects of a drug in depleting a nutrient ... would be acceptable as a structure/function [claim]." 65 Fed. Reg. at 1029. The plaintiffs assert that this statement "go[es] too far" because by referring to a "specific situation and usage," **Vitamin Shoppe** is claiming that the product itself has this beneficial effect. But their reading finds no support in the text of the statement. The statement claims that supplemental glutamine is thought to replenish glutamine stores after intense exercise -- not that taking the product will replenish glutamine stores after intense exercise. Although this distinction may be lost on consumers, it is a "form of finesse" that § 343(r)(6)(A) allows. Cf. Kaufman, 836 F.3d at 96 (stating that drawing a "distinction between the ingredient's function" and its effect on health "likely tricks many consumers," but the FDCA allows this "form of finesse").

[10] Next, the statements that glutamine "helps support muscle growth and recovery as well as immune health" and has "anti-catabolic properties" are structure/function claims, too. For each describes how glutamine affects a structure or function in the human body. And these claims are substantially similar to others that the FDA has blessed, such as "supports the immune system" and "boosts stamina, helps increase muscle size, and helps enhance muscle tone." See 65 Fed. Reg. at 1028–30.

The plaintiffs nonetheless contend that these statements are not structure/function claims because they refer to the products -- not just to the nutrient glutamine. For example, the Glutamine supplement talks about supplemental glutamine (i.e., the form of the nutrient in the product), one of the statements about glutamine is prefaced by the phrase "[a]lso added [to the product]," and one of the labels says that the product "combines" three nutrients before listing each with a description of the nutrient's physiological role. The plaintiffs' contention is rooted in some language from Greenberg v. Target Corp., 985 F.3d 650 (9th

Cir. 2021). Greenberg, in emphasizing the differences between structure/function claims and another type *71 of claim called disease claims, said that a structure/function claim does not "refer to the product itself." Id. at 654. A disease claim, in contrast, "refers to a statement that the product itself can cure or treat a disease." Id. But Greenberg did not say that merely noting that the nutrient is in the product negates an otherwise acceptable structure/function claim. See id. Nor do we see any reason why it would. After all, a structure/function claim is about a nutrient or dietary ingredient in the product. See § 343(r)(6) (listing claims that can be made "for a dietary supplement"); 65 Fed. Reg. at 1002 (stating that the FDA's "final rule establishes criteria for determining whether a statement made about a dietary supplement is acceptable as a structure/function claim under section 403(r)(6)").

[11] The plaintiffs' last line of attack is that a reasonable jury could construe the contested statements about glutamine as claims about the products' benefits instead of claims about glutamine's effect on the human body. Assuming that the jury has a role to play in deciding whether a statement is a structure/function claim, no reasonable jury would construe the contested language as discussing the products' benefits instead of glutamine's physiological role. The statements plainly make claims about what glutamine does -- not about what the products do. That a consumer might hope or infer that the product will do what the nutrient does is a far cry from a reasonable jury finding that the words "nutrient X does Y" is best construed as meaning "product Z does Y because it contains nutrient X." [7]

In sum, because the contested statements about glutamine on **Vitamin Shoppe's** labels describe glutamine's effect on the human body's structure or function or explain how glutamine maintains that structure or function, they are structure/function claims under § 343(r)(6)(A).

B.

[12] The plaintiffs argue next that the FDCA does not preempt their state law claims because **Vitamin Shoppe** failed to substantiate its products' statements about glutamine. They assert that the evidence substantiating each structure/function claim must be about the supplemental form of the nutrient. Because the district court, they say, looked at evidence about naturally occurring glutamine rather than supplemental glutamine, it did not realize that **Vitamin Shoppe's** statements about glutamine are bereft of evidentiary support.

[13] To make a structure/function claim, the manufacturer must "ha[ve] substantiation that [the claim] is truthful and not misleading." § 343(r)(6)(B). The term "substantiation" is not defined. Kaufman, 836 F.3d at 93. But the FDA's guidance defines it as "competent and reliable scientific evidence." Id. (quoting 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 Part I.B. (Dec. 2008), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm [hereinafter Guidance for Industry]). Because we have used that definition before, see id., and both parties use it, *72 we will also do so here. Thus, to comply with § 343(r)(6)(B), **Vitamin Shoppe** must have competent and reliable scientific evidence that its structure/function claims about glutamine are truthful and not misleading. Before we decide whether it has that evidence, we resolve first a dispute about which form of glutamine the evidence must be about.

The plaintiffs argue that the evidence substantiating **Vitamin Shoppe's** structure/function claims about glutamine must be about the supplemental form, not the naturally occurring form. They are right for the simple reason that **Vitamin Shoppe's** claims are about supplemental glutamine and so its substantiation must be, too. One of the labels openly talks about what "supplemental glutamine" does. On another label, the statement about glutamine is prefaced by the phrase "[a]lso added," which means that the claim is about supplemental glutamine -- the glutamine added to the product -- not naturally occurring glutamine. The statement about glutamine on the third label appears in

a list of three nutrients "combine[d]" in the product. So this statement also refers to the form of glutamine in the product. Because the structure/function claims here are about supplemental glutamine, "substantiation that [the claims are] truthful and not misleading" must be about supplemental glutamine, too.[8] See § 343(r)(6)(B).

But in the end, the distinction between naturally occurring glutamine and supplemental glutamine is, as the district court said, meaningless. At oral argument, we asked the plaintiffs if supplemental glutamine and naturally occurring glutamine play the same role in the human body. The plaintiffs conceded that, on this record, they do. Our review of the record reveals only one difference between them: The parties' experts agreed that our bodies may struggle absorbing supplemental glutamine and that therefore much of it may be lost during digestion. But some of it survives. Indeed, the plaintiffs' expert acknowledged that some people -- such as those who exercise intensely or have suffered physical trauma, severe illness, surgery, or burns -- benefit from taking supplemental glutamine. So where does that leave the disagreement between the parties? The plaintiffs contended at oral argument that **Vitamin Shoppe** loses on substantiation "if you take a pill and it does not actually affect the body's structure or function as the label claims." Section 343(r)(6)(B), they said, requires "efficacy that the product supports the body's structure or function as claimed." **Vitamin Shoppe** argues that the plaintiffs are seeking to impose a substantiation requirement above and beyond what the plain text of § 343(r)(6)(B) requires.

With the facts and arguments ironed out, this case now looks a lot like Greenberg. The issue there was whether Target had substantiation that its claim that biotin "helps support healthy hair and skin" was truthful and not misleading when the evidence showed that most people get the biotin they need through their diet and ***73** thus taking biotin is useless for all but a select few who have a biotin deficiency. Greenberg, 985 F.3d at 652–53. The appellant argued that Target's "structure/function claim must be true not only as to the nutrient itself but [also as to] the product as a whole." Id. at 655. Greenberg rejected that argument based on the plain text of the FDCA. A structure/function claim, it said, "addresses only the general role of an ingredient/nutrient on the human body," not "the product's health impact on the general population." Id. at 655–56. Thus, the manufacturer need only have substantiation that its claim about "the ingredient's function on the human body" is truthful and not misleading. Id. at 656.

[14] We agree with Greenberg that the plain text of § 343(r)(6)(B) requires a manufacturer to have substantiation that a nutrient's claimed effect on the human body's structure or function is truthful and not misleading, not that the product has the claimed effect. Section 343(r)(6)(B) requires "the manufacturer of the dietary supplement [to] ha[ve] substantiation that such statement" -- i.e., the statement that describes the nutrient's effect on the human body's structure or function -- "is truthful and not misleading." Nowhere in the text of § 343(r)(6)(B) is the manufacturer required to show that taking the dietary supplement affects the structure or function as claimed. See United States ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 35 (1st Cir. 2013) ("We will not ordinarily read requirements into a statute that 'do not appear on its face.' " (quoting Dean v. United States, 556 U.S. 568, 572, 129 S.Ct. 1849, 173 L.Ed.2d 785 (2009))).

Had Congress wanted to add an efficacy requirement to § 343(r)(6)(B), it could have. Products that are regulated as drugs have an efficacy requirement. The FDA will deny an application to sell a new drug if, among other things, "there is a lack of 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." 21 U.S.C. § 355(d); see also Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 476, 133 S.Ct. 2466, 186 L.Ed.2d 607 (2013) (describing the new-drug application and approval process). And there is a reason why structure/function claims may not purport to treat disease and why a product bearing such claims must expressly repudiate any intention of treating disease: A dietary supplement that makes a disease claim is regulated as a drug and must meet the efficacy requirement discussed above. See 21 C.F.R. § 101.93(f); § 355(d). So

Congress knows how to add an efficacy requirement when it wants to and intentionally excluded one from structure/function claims. See Guidant Corp., 718 F.3d at 35 ("[W]hen Congress includes language in one section of a statute but omits it in another, 'it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.' " (quoting Keene Corp. v. United States, 508 U.S. 200, 208, 113 S.Ct. 2035, 124 L.Ed.2d 118 (1993))).

There is more. Congress found in the DSHEA that "safety problems with [dietary] supplements are relatively rare" and that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness." § 2(14), (15)(A), 108 Stat. at 4326. It enacted the DSHEA to "ensur[e] that the Federal Government erects no barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements" and "to clarify that dietary supplements are not drugs ... [and] should not be regulated as drugs." S. Rep. No. 103-410 (1994), 1994 WL 562259, at *2. Needless to say, Congress intended dietary ***74** supplements to escape the regulatory gauntlet that drugs must go through. [9]

The plaintiffs have a back-up argument. Putting aside § 343(r)(6)(B)'s text, they contend that we must defer to the FDA's guidance about substantiation, which, they say, "requires substantiation of actual efficacy of the supplement." It is true that the FDA's guidance opines that manufacturers should have evidence that their dietary supplements affect the human body's structure or function as claimed and under the conditions of use recommended on the products' labels. Guidance for Industry, supra, Part II.B–D. But the guidance calls itself a nonbinding recommendation "unless specific regulatory or statutory requirements are cited." Id. Part I.A.; see also Greenberg, 985 F.3d at 656 n.3 (stating that this guidance is "not on-point and in any event [is] not binding"). And we see no statutory or regulatory authority backing its opinion that, for a structure/function claim to be substantiated within the meaning of § 343(r)(6)(B), the manufacturer must have evidence that the nutrient plays the physiological role claimed under the conditions of use recommended on the label. Assuming (without deciding) that the guidance is the type of agency interpretation warranting Chevron deference, see Doe v. Leavitt, 552 F.3d 75, 79–80 (1st Cir. 2009), our analysis above about why the plain text of § 343(r)(6)(B) only requires substantiation that the structure/function claim is truthful and not misleading dooms the plaintiffs' Chevron argument. See Saysana v. Gillen, 590 F.3d 7, 16 (1st Cir. 2009) ("We have concluded that the text of the statute is clear. Consequently, ... there is nothing for the agency to interpret -- no gap for it to fill -- and there is no justification for resorting to agency interpretation to address an ambiguity.").

[15] We turn now to whether **Vitamin Shoppe** has substantiation that its structure/function claims are truthful and not misleading. Recall that substantiation requires competent and reliable scientific evidence. The plaintiffs claim that **Vitamin Shoppe** put forward evidence only about how naturally occurring glutamine — not supplemental glutamine -- affects the human body's structure or function. But the record tells a different story. **Vitamin Shoppe's** expert, Dr. Hoffman, presented a myriad of studies showing that glutamine supplementation supports immune health and muscle growth and recovery; is involved in regulating protein synthesis; has anti-catabolic effects, which help preserve muscle; and may help replenish glutamine stores after intense exercise. The plaintiffs' expert, Dr. Candow, attacked these studies on several grounds, including that they used higher doses of glutamine than **Vitamin Shoppe's** labels recommend, involved different forms of administration (e.g., intravenous), incorporated other additives, used animal subjects, and used disease-state human subjects. In crafting his report, Dr. Candow evaluated **Vitamin Shoppe's** structure/function claims with respect to healthy humans at the doses recommended ***75** on the labels. And after evaluating each claim through this lens, he concluded that glutamine supplementation at the doses recommended is useless. He did, however, agree that glutamine supplementation at some dose and for some people affects the human body's structure or function as **Vitamin Shoppe's** labels claim. Because the plaintiffs assert that he was talking about naturally occurring glutamine when he said that, we will address each claim to show that there is no genuine dispute

between the experts that supplemental glutamine plays the physiological role that **Vitamin Shoppe's** labels claim.

We start with the claim that glutamine supplementation supports muscle growth and recovery and immune health. The following exchanges took place at Dr. Candow's deposition:

> Q. Now, going to the glutamine statement which says, "Glutamine helps support muscle growth and recovery as well as immune health."
>
> A. Okay.
>
> Q. Is it your opinion that this statement is false?
>
> A. Yes. Specifically to the dose that is recommended.
>
> ....
>
> [Q.] At what dosage does glutamine help support immune health?
>
> A. I believe in all the articles the minimum dose was 10 grams a day.
>
> ....
>
> Q. Has glutamine supplementation been shown to decrease the incidence of infections?
>
> A. I believe so. I believe so, yes.
>
> Q. Has glutamine been shown to improve the response of cells in the immune system?
>
> A. Yes.
>
> ....
>
> Q. And do you disagree that glutamine supplementation can cause an increase in recovery?
>
> A. It can only at a specific dosage.
>
> Q. But in general, glutamine supplementation can increase recovery in the body?
>
> A. Again, at a specific dosage. So 1 gram, no. 2 grams or the dosage here is a specific dosage.
>
> Q. What is the dosage at which glutamine ... supports recovery?
>
> A. I believe the minimal amount was 6 grams.
>
> ....
>
> Q. Glutamine supplementation can increase muscle protein synthesis [10] and prevent metabolism in certain situations. Correct?
>
> A. That's correct.

Thus, Dr. Candow's dispute with this structure/function claim comes down to the dose recommended on the product. The same is true for the other claims. As for the claim that taking supplemental glutamine after intense exercise is thought to replenish depleted glutamine stores, leading to enhanced recovery, Dr. Candow agreed that, as a general matter, intense exercise can deplete glutamine stores and that glutamine supplementation can help maintain these stores and enhance recovery. He also agreed that supplemental glutamine is involved in regulating protein ***76** synthesis. And he agreed that supplemental glutamine, in some circumstances such as in disease-state humans, [11] has anti-catabolic properties, which help preserve muscle tissue by preventing protein breakdown. Thus, there is no genuine dispute that **Vitamin Shoppe** has substantiation that its claims about supplemental glutamine's physiological role are truthful.

[16] The plaintiffs have one more arrow in their quiver. They argue that **Vitamin Shoppe's** labels are nonetheless misleading because they fail to reveal material facts about taking the supplements as recommended (i.e., that taking the supplements as recommended does nothing). Section 343 governs when food products, including dietary supplements, are misbranded. 21 U.S.C. § 343. Section 321(n) provides that when evaluating whether a product is misbranded because the labeling is misleading, we must consider, among other things:

> [T]he extent to which the labeling ... fails to reveal facts

> material in ... light of [the] representations [on the label] or material with respect to consequences which may result from the use of the [product] to which the labeling ... relates under the conditions of use prescribed in the labeling ... thereof or under such conditions of use as are customary or usual.

Id. § 321(n); see also Kaufman, 836 F.3d at 95 ("This statutory command that we consider the omission of material facts fits hand-in-glove with the mandate of section 343(r)(6)(B) that the seller's substantiation show that a [claim] is both 'truthful and not misleading.' " (quoting § 343(r)(6)(B))). The question here is whether omitting the fact that glutamine supplementation is useless at the doses prescribed on the labels renders **Vitamin Shoppe's** claims about glutamine's physiological role misleading. In Greenberg, the Ninth Circuit answered no. It reasoned that if a true claim such as "**vitamin** C boosts immunity" is misleading because most people do not need nor benefit from taking **vitamin** C, then "virtually any structure/function claim for dietary supplements would potentially be misleading to the great majority of people" because most people are not walking around with **vitamin** deficiencies. Greenberg, 985 F.3d at 656. Such an outcome, it said, would conflict with the FDCA's text and Congress's purpose in enacting a regulatory carve-out for structure/function claims. Id. We agree. Section 343(r)(6)(B) requires the manufacturer to have substantiation that its claim about a nutrient's physiological role is not misleading. That taking the product as directed does not reap the benefits the label attributes to the nutrient has nothing to do with whether the nutrient's claimed physiological role is misleading. See id. ("[M]anufacturers may make structure/function claims about a nutrient's general role on the human body without disclosing whether the product will provide a health benefit to each consumer.").

[17] **[18]** To be sure, a structure/function claim is misleading if it omits a nutrient's conflicting or harmful role in affecting the human body's structure or function. See Kaufman, 836 F.3d at 95–96 (failing to disclose the nutrient's harmful effect on the human body's structure or function plausibly renders a structure/function claim misleadingly incomplete). And a structure/function claim is untruthful if the nutrient does not have the claimed effect. See ***77** Kroessler v. CVS Health Corp., 977 F.3d 803, 812 (9th Cir. 2020) (reversing dismissal of the plaintiff's complaint on preemption grounds where the plaintiff alleged that glucosamine does not have the claimed effect on the human body's structure or function). But this is not such a case. Because the experts here agree that **Vitamin Shoppe's** claims about glutamine's physiological role are truthful and there is no contention that these claims are misleading as to that role, **Vitamin Shoppe** has complied with § 343(r)(6)(B).

IV.

The statements about glutamine on **Vitamin Shoppe's** labels are structure/function claims under § 343(r)(6). And **Vitamin Shoppe** has complied with the FDCA's requirements to make such claims. The plaintiffs' state law claims attacking those statements are therefore expressly preempted by the FDCA. The district court's judgment is **affirmed**.

All Citations

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Footnotes

* Of the District of Puerto Rico, sitting by designation.

1 Ferrari purchased Creatine & Glutamine with Beta-Alanine, and Bohr purchased Glutamine and BCAA & Glutamine. We group the products together for analytical ease.

2 An anti-catabolic substance reduces the breakdown of muscle proteins.

3 There is some sparring in the briefing about whether two additional claims on this product -- "[c]reatine helps to improve strength and performance during high intensity exercise and training" and "[b]eta-alanine helps support muscle strength, endurance and overall athletic performance" -- are at issue. **Vitamin Shoppe** contends that this appeal is limited to claims about glutamine. The plaintiffs insist that they have "always challenged" these two additional claims. But in their complaint, the plaintiffs bolded only the product's statement about glutamine, and their opposition to **Vitamin Shoppe's** motion for summary judgment did not contest the other claims. Thus, any appellate argument based on those claims is waived. See Davis v. Lucent Techs., Inc., 251 F.3d 227, 232 (1st Cir. 2001) ("[W]here a plaintiff fails to present arguments to the district court in opposition to a defendant's motion for summary judgment, we have refused to consider those arguments for the first time on appeal.").

4 The parties disagree about whether we should defer to the district court's resolution of factual disputes subsumed within the preemption question: **Vitamin Shoppe** argues that we should review the court's findings for clear error, whereas the plaintiffs imply that we should disregard its findings and view the record in the light most favorable to them as the nonmovants. Because we would affirm the district court under either standard, we view the facts in the more appellant-friendly way -- in the light most favorable to the plaintiffs.

5 The plaintiffs do not challenge the district court's conclusion that **Vitamin Shoppe** satisfied § 343(r)(6)'s other requirements. So we need not dwell on them.

6 The plaintiffs concede that the other claim on the Glutamine supplement, which says that glutamine "is involved in regulating protein synthesis and has been shown to possess [a]nti-[c]atabolic properties to help preserve muscle," is a structure/function claim.

7 In the end, the plaintiffs all but abandon their argument that the contested statements are not structure/function claims. They say in their reply brief that "the best and most consistent position may be ... that the claims here are proper-in-form structure/function claims." And at oral argument, they conceded that the statements are structure/function claims at "some level."

8 The plaintiffs' "first reason" why evidence about supplemental glutamine is required (i.e., that the claims are about supplemental glutamine) suffices here. They nonetheless ask us to go further: They ask us to hold that every structure/function claim must be substantiated by evidence about the supplemental form of the nutrient. We see no reason to set down a hardline rule in a case that does not call for one, especially given the wide array of substances in dietary supplements and the wide array of forms they take. See 21 U.S.C. § 321(ff) (defining "dietary supplement" as a product that, among other things, contains "a **vitamin**," "a mineral," "an herb or other botanical," "an amino acid," "a dietary substance for use by man to supplement the diet by increasing the total dietary intake," or "a concentrate, metabolite, constituent, extract, or combination of any ingredient described").

9 Our conclusion is bolstered by several law review articles that the district court cited. See Ferrari v. **Vitamin Shoppe**, Inc., No. 17-10475-GAO, 2022 WL 974048, at *3 (D. Mass. Mar. 31, 2022). The DSHEA appears to be the result of intense lobbying by dietary supplement manufacturers and consumers in response to proposals to heavily regulate dietary supplements. See Lars Noah & Barbara A. Noah, A Drug by Any Other Name ... ?: Paradoxes in Dietary Supplement Risk Regulation, 17 Stan. L. & Pol'y Rev. 165, 166 (2006); Peter J. Cohen, Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA, 31 Am. J.L. & Med. 175, 179–180 (2005); Stephen H. McNamara, Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation, 50 Food & Drug L.J. 341, 341 (1995).

10 Dr. Candow states in his report, "Muscle growth reflects the net balance between muscle protein synthesis and protein breakdown .... Muscle growth may be the result of a decrease in protein breakdown, an increase in protein synthesis, or both." By agreeing that glutamine supplementation increases muscle protein synthesis, he agreed that glutamine supplementation supports muscle growth.

11 Dr. Candow explained that humans might need more glutamine than we naturally produce during times of extreme physical stress, such as trauma, cancer, HIV/AIDS, surgery, burns, sepsis, radiation, chemotherapy, and intense exercise.

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