UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 17-10475-GAO

RICHARD FERRARI and WILLIAM BOHR,
individually and on behalf of all others similarly situated,
Plaintiffs,

v.

VITAMIN SHOPPE, INC.,
Defendant.

OPINION AND ORDER
March 31, 2022

O'TOOLE, D.J.

The plaintiffs Richard Ferrari and William Bohr brought this putative class action alleging that the defendant Vitamin Shoppe, Inc. ("Vitamin Shoppe") placed false and misleading statements on the labels of three of its dietary supplements. The plaintiffs allege violations of Massachusetts and Illinois statutes prohibiting false advertising and deceptive business practices, as well as multiple common law torts. The defendant moved for summary judgment on the ground that the plaintiffs' claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 301, 321, 337, 343, 371, and the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. For the reasons detailed below, the defendant's motion is granted.

I. Background

Vitamin Shoppe manufactures and sells dietary supplements. Some of those supplements contain glutamine, an amino acid that exists naturally in the human body. Glutamine is believed to contribute to "anti-catabolic activity"—which reduces the breakdown of muscle proteins and

facilitates the creation of new muscle proteins—and to general immune and intestinal health. Dietary supplements containing glutamine are sometimes recommended for glutamine-deficient individuals, who often benefit from supplemental doses. In addition, glutamine supplements are marketed to, and purchased by, individuals with normal glutamine levels who want to build and maintain muscle mass through weight training. Some glutamine supplements contain only glutamine, while others combine glutamine with ingredients such as creatine, whey protein, or Branch Chain Amino Acids.[1]

This case concerns three dietary supplements ("the products") that Vitamin Shoppe manufactures and markets under the label "BodyTech": BodyTech Glutamine, BodyTech Creatine & Glutamine with Beta-Alanine, and BodyTech BCAA & Glutamine. Glutamine is the only ingredient in BodyTech Glutamine, and it is a central ingredient in the other two products. It accounts for 38% of each recommended serving of BodyTech BCAA & Glutamine, and for 31% of each recommended serving of BodyTech Creatine & Glutamine with Beta-Alanine. The labels on the products contain statements about glutamine ("the contested statements"), including that it "has been shown to possess anti-catabolic properties to help preserve muscle," "helps support muscle growth and recovery as well as immune health," and "is involved in regulating protein synthesis." (Decl. of Michael R. McDonald, Esq., Exs. B, C, D (dkt. nos. 137-2, 137-3, 137-4)).[2] Each of the respective product labels displays the following disclaimer: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." (Decl. of Michael R. McDonald, Esq., Exs. B, C, D).

[1] The DSHEA's definition of a "dietary supplement" includes "a product . . . intended to supplement the diet that bears or contains . . . an amino acid …." 21 U.S.C. § 321(ff)(1).
[2] Most of the contested statements refer simply to "glutamine," but some refer to "L-glutamine." The record reveals no scientific distinction between the two.

The plaintiffs Richard Ferrari and William Bohr are residents of Massachusetts and Illinois, respectively, and they are former customers of Vitamin Shoppe. They brought this suit under the laws of their respective states after purchasing and using the products.[3] The plaintiffs allege that the contested statements induced them to purchase the products, and that the products subsequently did not yield the results that they believe the labels promised them. For example, Bohr alleges that he purchased BodyTech BCAA & Glutamine because the label indicated that glutamine supports "muscle growth," but that he experienced no additional muscle growth after consuming the product. The plaintiffs do not claim to be glutamine-deficient; they simply sought improved results from their training regimens.

The plaintiffs claim that Vitamin Shoppe committed false advertising, misbranding, unjust enrichment, breach of express warranty, and breach of implied warranty by placing the contested statements on its product labels. The plaintiffs' claims all arise under state law. The parties have each submitted admissible expert testimony and reports on the properties of glutamine, the efficacy, or lack thereof, of Vitamin Shoppe's products, and the truth or falsity of the contested statements. The defendant moved for summary judgment on the ground that the plaintiffs' state law claims are preempted by federal law. The plaintiffs opposed the motion but did not cross-move.

[3] Richard Ferrari purchased BodyTech Creatine & Glutamine with Beta Alanine, and William Bohr purchased BodyTech Glutamine and BodyTech BCAA & Glutamine. Each plaintiff only has standing to challenge the labels of the products that he himself purchased. Downing v. Keurig Green Mountain, Inc., No. 20-cv-11673-IT, 2021 WL 2403811, at *3 n.1 (D. Mass. June 11, 2021) ("[F]or there to be a cognizable injury, the person who was the target of the misrepresentation [must have] actually acquired something in a transaction that is of less value than he was led to believe it was worth when he bargained for it." (internal citation omitted)).

II. Federal Preemption at Summary Judgment

A party seeking summary judgment must demonstrate that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. Johnson v. Johnson, 23 F.4th 136, 141 (1st Cir. 2022). The Supreme Court has held that questions of preemption are to be decided by courts at the motion to dismiss and summary judgment stages of a case. Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1680 (2019). A defendant who demonstrates that a plaintiff's state law claims are preempted by federal law is entitled to summary judgment on those claims. See In re Zofran (Ondansetron) Prod. Liab. Litig., 541 F. Supp. 3d 164, 166 n.1, 206 (D. Mass. 2021).

III. Discussion

A. Preemption Under the FDCA

The FDCA, DSHEA, and NLEA govern the branding and labeling of food, drugs, and dietary supplements. 21 U.S.C. § 343(r) "places limits on health claims that may be made on food and dietary supplement labels." Nat'l Council for Improved Health v. Shalala, 122 F.3d 878, 880 (10th Cir. 1997). To ensure nationwide uniformity in labeling standards, Congress has prohibited states from "directly or indirectly establish[ing] under any authority or continu[ing] in effect" any labeling requirement for dietary supplements that is "not identical to" the requirements articulated in § 343(r). § 343-1(a). Thus, any cause of action arising under a state statute or legal rule that purports to apply a labeling standard not found in § 343(r) is preempted by the FDCA. Kaufman v. CVS Caremark Corp., 836 F.3d 88, 92 (1st Cir. 2016).[4]

[4] The Supreme Court has held that the preemption provisions of some federal statutes do not preempt common law tort claims to the same extent that they preempt state statutory claims. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, 444–45 (2005) (Federal Insecticide, Fungicide, and Rodenticide Act); Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 525–27 (1992) (Federal Cigarette Labeling and Advertising Act). That limitation has not been extended to the FDCA. See

B. Structure/Function Claims

The FDCA broadly prohibits label statements that are "false or misleading in any particular." § 343(a). That rule applies to all statements, including those about nutritional value, health, price, taste, composition, and quality. Prior to 1994, the FDA enforced that rule by subjecting health claims on supplement labels to the same costly premarket approval processes that claims on drug labels are subject to. Lars Noah & Barbara A. Noah, A Drug by Any Other Name . . . ?: Paradoxes in Dietary Supplement Risk Regulation, 17 Stan. L. & Pol'y Rev. 165, 165–67 (2006). Dietary supplement manufacturers, looking to stimulate growth in their industry, undertook a massive lobbying effort to relax labeling regulations on their products. Id. at 166; 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, Esq., Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation, 50 Food & Drug L.J. 341, 341–42 (1995) ("[M]embers of the House of Representatives and Senate stated that they had received more mail, phone calls, and constituent pressure on [dietary supplement labeling] than on anything else . . . .").

In 1994, Congress amended the FDCA to re-classify supplements as food products and to exempt certain statements on supplement labels from premarket approval requirements. Noah,

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Mills v. Giant of Md., LLC, 441 F. Supp. 2d 104, 106–9 (D.D.C. 2006) (noting that Bates was "moored tightly to the specific preemption clause at issue" and that "nothing in Bates categorically defeats defendants' argument that plaintiffs' claims are precluded by FDCA's preemption clause"). Indeed, district courts have repeatedly held that § 343(a)(5) applies to common law claims and state statutory claims alike. Patane v. Nestlé Waters N. Am., Inc., 314 F. Supp. 3d 375, 385 (D. Conn. 2018); In re PepsiCo, Inc., Bottled Water Mktg. & Pracs. Litig., 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008); Mills, 441 F. Supp. 2d at 106–9. Accordingly, each of the plaintiffs' claims is subject to the same preemption analysis; the defendant is entitled to summary judgment on all counts as to any contested statements that are permitted by the FDCA.

supra, at 166. Those amendments, among them § 343(r)(6), "sharply limit[ed] the FDA's express authority to regulate [dietary supplement labeling]." Id. Commentators widely agree that the 1994 amendments were direct responses to the supplement industry's lobbying efforts. Id.; Cohen, supra, at 179–80; McNamara, supra, at 341–42. The result is a regime in which "[c]ompared to drugs, dietary supplements and their labels appear strikingly unregulated." Michael A. McCann, Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice, 31 Am. J.L. & Med. 215, 220 (2005).

The 1994 amendments to the FDCA articulated new rules for applying the FDCA's prohibition on false and misleading statements to health-related claims on dietary supplement labels. Congress defined two categories of permissible label statements: product-specific "disease" claims and nutrient-specific "structure/function" claims. Kroessler v. CVS Health Corp., 977 F.3d 803, 809 (9th Cir. 2020); see § 343(r)(6); 21 C.F.R. § 101.93(g). Health-related statements that do not fall into those categories are prohibited as "false or misleading." § 343(r)(6); § 101.93(g).

A label statement qualifies as a "structure/function" claim if: 1) the statement describes the general effects of a nutrient or dietary ingredient or the mechanism by which it may affect the body's structure or functions and does not claim its efficacy in the product at hand; 2) the manufacturer has evidence substantiating the statement as truthful and not misleading; 3) the statement is accompanied by a disclaimer stating that it has not been evaluated by the FDA; and 4) the statement does not claim that a nutrient or dietary ingredient diagnoses, treats, cures, or prevents a specific disease (i.e., it is not a disease claim). § 343(r)(6).[5]

[5] Disease claims assert that a product diagnoses, treats, or prevents a specific disease. § 101.93(g). Disease claims must be substantiated with evidence indicating that the product itself, and not just a particular ingredient, has the claimed effects when used as recommended by the manufacturer. Id.

Pursuant to the structure/function rule, a manufacturer may place a broad statement about the general effect of a dietary supplement ingredient on a supplement label, even if the dosage of the supplement in the product may not actually produce the described result. The statement need only be literally true as a general statement to be eligible for legitimate inclusion on a supplement label without FDA preclearance. This regime surely permits some statements that might confuse or mislead consumers about the actual effects of the products they are purchasing. See Noah, supra, at 171 (noting that "the subtleties of [the] distinctions [within structure function claims] may be lost on many consumers of supplement products"). For example, a consumer might interpret a calcium supplement label to say that the supplement itself supports bone strength, when in fact the label simply states that calcium, generally, can affect bone strength. See id. at 171 n.21. That result is not accidental. Congress intentionally authorized such generalized structure/function claims in response to advocacy from the supplement industry.

The defendant argues that the contested statements properly qualify as permitted structure/function claims and, consequently, that the plaintiffs' state law claims that purport to challenge the propriety of the statements under potentially applicable state law theories are preempted by the FDCA. Accordingly, the preemption question hinges on whether the contested statements do qualify as structure/function claims.

i. Scope of the Claims

Structure/function claims must be "narrowly focused"—they may refer only to a nutrient or ingredient within a product, and not to the product as a whole. Greenberg v. Target Corp., 985 F.3d 650, 654 (9th Cir. 2021). They typically, as here, use broad general verbs such as "improve," "promote," "regulate," and "support" to describe the properties of a nutrient, rather than promising specific results. See Regulations on Statements Made for Dietary Supplements Concerning the

Effect of the Product on the Structure or Function of the Body**,** 65 Fed. Reg. 1000-01, 1011 (Jan. 6, 2000) (codified at 21 C.F.R. pt. 101).

The plaintiffs' expert, Dr. Darren Candow, contends that the contested statements in this case improperly refer to Vitamin Shoppe's products themselves, and not to specific nutrients in a product. But the statements are literally, and intentionally, quite narrow; they state only that the product contains glutamine as a nutrient and that glutamine may have a certain property. For example, the BodyTech Glutamine label reads: "*Glutamine* . . . is involved in regulating protein synthesis and has been shown to possess anti-catabolic properties to help preserve muscle." (Decl. of Michael R. McDonald, Esq., Ex. B (emphasis added)). The BodyTech BCAA & Glutamine label similarly reads: "also added [is] *L-Glutamine* for its anti-catabolic properties[.]" (Decl. of Michael R. McDonald, Esq., Ex. D (emphasis added)). The BodyTech Creatine & Glutamine with Beta-Alanine label reads: "*Glutamine* helps support muscle growth and recovery as well as immune health." (Decl. of Michael R. McDonald, Esq., Ex. C (emphasis added)). The other contested statements are similarly carefully limited in scope and tone; they describe generally the potential impact of a specific ingredient. Notably, they make no promises about the supplement's actual efficacy in the product. They are statements of a property of glutamine generally, not of the offered product. This careful limitation in meaning may strike one as too clever by half, but it is exactly what Congress intended to authorize in DSHEA. The statements at issue here are all sufficiently narrow to qualify as structure/function claims. Cf. Greenberg, 985 F.3d at 654–56 (noting that "vitamin C boosts immunity," "calcium helps maintain bones," and "[biotin] helps support healthy hair and skin" were sufficiently narrow to be structure/function claims).

ii. Substantiation

To substantiate a structure/function claim, a manufacturer must offer reliable evidence of the general effect or function of the ingredient described on the label. See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. at 1032. The FDCA "only requires substantiation for *the ingredient's* function in the human body, not the health impact of the product as a whole." Greenberg, 985 F.3d at 656 (emphasis in original). Dietary supplement manufacturers "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." Id.; see also Kaufman, 836 F.3d at 95 ("[A]ny nutrient or ingredient that . . . the heart needs might be described as supporting heart health, even if taking the supplement form of the nutrient actually does nothing to improve the health of one's heart . . . .").

Dr. Candow conceded that the contested statements, taken literally, are true. The following exchange occurred during his deposition:

Q. So you agree that generally glutamine helps support muscle growth. Correct?

A. It's an amino acid, yes. They all have to.

Q. Does it help support muscle growth by keeping your muscles out of the catabolic state?

A. It can, yes.

Q. And turning to the same label, glutamine helps support muscle recovery, you generally agree with that statement. Is that correct?

A. It can definitely help in recovery, yes.

Q. Your only objection to that statement is that at this dosage you don't believe that glutamine helps support muscle recovery. Correct?

A. That is correct.

(Oral Dep. of Darren G. Candow, Ex. K at 195–96 (dkt. no. 137-11)).[6]

The plaintiffs argue that the contested statements, while literally true, should be deemed unsubstantiated because glutamine has not been shown to build and preserve muscle when taken in the dosages recommended on the product labels. They also argue that the defendant must substantiate the contested statements with evidence specifically about supplemental glutamine, as opposed to evidence about glutamine that exists naturally in the body. But either argument holds the defendant to a higher standard of substantiation than is required by DSHEA. See Greenberg, 985 F.3d at 656. The contested statements refer only to glutamine as an ingredient generally, and not to effective levels of dosage. As to whether there is a meaningful distinction between naturally occurring glutamine and supplemental glutamine, the record is silent. Under the structure/function framework, Vitamin Shoppe is not required to show that its products work in the recommended dosages, nor is it required to broadly prove the efficacy of supplemental glutamine.[7]

The plaintiffs also attempt to sidestep substantiation entirely, arguing that a nutrient-specific claim is "false or misleading," and therefore broadly prohibited by the FDCA, if the nutrient is not effective when consumed in the manufacturer-recommended dosages. The plaintiffs misinterpret the statutory structure. The FDCA's general prohibition on "false or misleading" statements is applied to structure/function claims via the substantiation requirement articulated in § 343(r)(6) and the related regulations. Kroessler, 977 F.3d at 809. The prohibition on misleading

[6] He made similar admissions elsewhere in his testimony: "Q. Do you agree that glutamine has anti-catabolic properties? A. It does. Q. So is anything about the back of this label false? A. I don't think so." (Oral Dep. of Darren G. Candow, Ex. K at 219 (dkt. no. 137-11)).

[7] The plaintiffs cite sub-regulatory guidance from the FDA and FTC that articulates more stringent standards for substantiation in other contexts. As previous courts have noted, those sources are off-point and non-binding. See Greenberg, 985 F.3d at 656 n.3.

statements is baked into the substantiation requirement; by definition, a properly substantiated structure/function claim is not "false or misleading." See id.; Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. at 1003 ("[§ 343(r)(6)] requires dietary supplement manufacturers to have substantiation that their statements are truthful and non-misleading."). The plaintiffs' proposal would require the same level of substantiation for two types of statements that Congress explicitly separated by eliminating the distinction between nutrient-specific structure/function claims and product-specific disease claims. See Greenberg, 985 F.3d at 656 ("[A plaintiff] cannot implicitly import a disease claim requirement—evidence showing the product's impact on the consumer's health or disease—into the structure/function claim, given the differences in the statutory requirements for each."). A rule so at odds with the statutory structure and so contrary to Congress's intent cannot carry the day. See id. (noting that the plaintiff's "reliance on the FDCA's general prohibition against false or misleading statements . . . conflicts with the FDCA's statutory language and the FDA's stated purpose for allowing structure/function claims").

The evidence in the record indicates that glutamine possesses anti-catabolic properties that generally support and relate to muscle growth, endurance, recovery, and health. The results of several observational studies bear that out, as do the expert reports. Indeed, the parties' dueling experts appear to agree about glutamine's basic properties. Dr. Candow does not dispute the literal truth of the contested statements; he merely argues that they are misleading in the context of the label-recommended dosages. His concern may be well founded, but it is irrelevant to the narrow substantiation inquiry applicable to structure/function claims. Congress intended to permit structure/function claims that offer limited information to be placed on dietary supplement labels. By failing to meaningfully dispute the truth of the contested limited statements, and by failing to

grapple with the evidence in the record supporting them, the plaintiffs have failed to demonstrate that the statements are unsubstantiated. The defendant has carried the narrow burden for substantiation that existing law has established. Cf. Greenberg, 985 F.3d at 655–57 (holding that the statement biotin helps "support healthy hair and skin" was substantiated by evidence about biotin's general role in the body, even though most consumers would not benefit from the defendant's low-dose biotin supplement).

iii. Other Requirements

The third and fourth elements are not contested by the plaintiffs. First, each contested statement is accompanied by an appropriate disclaimer as required by § 343(r)(6). Second, the contested statements do not claim to diagnose or treat any specific diseases. See generally § 101.93(g)(2). In fact, the disclaimers state that each product "is not intended to diagnose, treat, cure, or prevent any disease." (Decl. of Michael R. McDonald, Esq., Exs. B, C, D).

IV. Conclusion

The defendant has shown that the contested statements qualify as permissible structure/function claims under the FDCA. The state laws on which the plaintiffs rely would therefore impose an obligation inconsistent with the FDCA by prohibiting those statements. Accordingly, those state laws are preempted in this action by § 343(a)(5), and the plaintiffs' state law claims challenging the contested statements are barred. The defendant's Motion for Summary Judgement (dkt. no. 134) is GRANTED.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge