FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TODD GREENBERG, On Behalf of Himself and All Others Similarly Situated, *Plaintiff-Appellant*, v. TARGET CORPORATION, a Minnesota Corporation; INTERNATIONAL VITAMIN CORPORATION, a New Jersey Corporation; PERRIGO COMPANY OF SOUTH CAROLINA, INC., *Defendants-Appellees.*	No. 19-16699 D.C. No. 3:17-cv-01862-RS OPINION

Appeal from the United States District Court
for the Northern District of California
Richard Seeborg, District Judge, Presiding

Argued and Submitted October 16, 2020
Pasadena, California

Filed January 13, 2021

Before: Mary H. Murguia and Kenneth K. Lee, Circuit Judges, and Edward R. Korman,[*] District Judge.

Opinion by Judge Lee

SUMMARY[**]

Federal Food, Drug, and Cosmetic Act / Preemption

The panel affirmed the district court's summary judgment in favor of defendant manufacturer and distributors, and its ruling that the plaintiff's state law claims, challenging the labeling of the dietary supplement biotin, were preempted by federal law – the Federal Food, Drug, and Cosmetic Act ("FDCA").

Plaintiff bought a bottle of biotin with a label stating that Biotin "helps support healthy fair and skin." The Food and Drug Administration has limited authority under the FDCA to regulate dietary supplements, and it requires that the label be truthful and not misleading. 21 U.S.C. § 343(r)(6)(B) authorizes several categories of statements, including disease claims and structure/function claims. The FDCA includes a preemption provision to establish a national and uniform standard for certain labeling statements.

[*] The Honorable Edward R. Korman, United States District Judge for the Eastern District of New York, sitting by designation.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that the FDCA preempted plaintiff's state law claim because the challenged statement was a permissible structure/function claim. Specifically, the panel held that if defendants' biotin statement met the FDCA's three requirements for a structure/function claim, then any state law claims challenging that claim fell to the wayside. The defendants met the first requirement for its structure/function claim because it had substantiation that biotin "helps support healthy hair and skin," and that statement was truthful and not misleading. Manufacturers may make structure/function claims about a nutrients' general role on the human body without disclosing whether the product will provide a health benefit to each consumer. Second, the biotin product label had the appropriate disclosures. Third, the biotin product label did not claim to treat diseases. Because the structure/function claim about biotin met the FDCA's requirements, plaintiff's state law claims amounted to an imposition of different standards from the FDCA.

COUNSEL

Elaine A. Ryan (argued) and Carrie A. Laliberte, Bonnett Fairbourn Friedman & Balint P.C., Phoenix, Arizona; Patricia N. Syverson, Bonnett Fairbourn Friedman & Balint P.C., San Diego, California; for Plaintiff-Appellant.

Matthew R. Orr (argued), William P. Cole, and Samuel G. Brooks, Call & Jensen ACP, Newport Beach, California, for Defendants-Appellees.

J. Kathleen Bond, and Jennifer M.S. Adams, Amin Talati Wasserman LLP, Chicago, Illinois, for Amicus Curiae Council for Responsible Nutrition.

OPINION

LEE, Circuit Judge:

Millions of Americans buy dietary supplements each year. The U.S. Food and Drug Administration (FDA) does not require pre-approval of labels on these products, but it insists that the statements be truthful and not misleading. The FDA also allows the product labels to feature so-called "structure/function" claims that describe the role of a nutrient or ingredient on the structure or function of the human body. So, for example, a vitamin product can tout that "calcium supports strong bones" because scientific evidence backs that claim, even if not everyone needs or benefits from more calcium.

This case challenges a structure/function claim for a vitamin called biotin. The label for the biotin product at issue states that it "helps support healthy hair and skin." While the plaintiff agrees that biotin can promote hair and skin health, he argues that the statement is still misleading because most people obtain enough biotin from their regular diets and thus this product provides no health benefit for them.

The district court granted summary judgment to the defendants, ruling that the plaintiff's state law claims are preempted by federal law that allows the challenged structure/function claim. We affirm the district court's order because the plain language of the statute makes clear that a structure/function claim addresses only the nutrient's role in the human body, not the product's health impact on the general population. The defendants have met all of the federal requirements for making a structure/function claim, including having substantiation showing that the biotin nutrient can promote healthy hair and skin. Federal law thus

allows the defendants to make this structure/function claim and preempts the plaintiff's state law causes-of-action.

BACKGROUND

In hopes of battling his hair loss, plaintiff Todd Greenberg dabbled in a wide variety of treatments and self-medication for several years. One of his self-cure attempts included buying a 5000-mcg bottle of Up & Up biotin at a Target store in 2015 for $8.[1]

The product label states that biotin "helps support healthy hair and skin." The label also has an asterisk that points to a disclaimer below: "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." As disclosed on the Supplement Facts panel on the bottle, biotin amount in the product far exceeds the recommended daily dosage — 333% to 3,333% depending on the size of the tablet.

Greenberg claims that he thought this biotin product would stimulate hair growth. Several weeks later, however, a friend told him that the supplement does not provide any benefits. Greenberg then filed this putative class action lawsuit, alleging that the product labels are deceptive because most people do not benefit from biotin supplementation. He brought claims under California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200,

[1] The other two defendants in this case — International Vitamin Corporation, and Perrigo Company of South Carolina, Inc. — manufacture the biotin products for Target's private label brand, Up & Up.

et seq., and California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq*.

Notably, the parties agree that biotin is a nutrient that supports healthy hair and skin. Greenberg's expert, however, concluded that most people obtain all the biotin they need from their diets. Thus, according to Greenberg's expert, Biotin vitamins are superfluous for all but a tiny percentage of people who have a biotin deficiency.

The district court granted summary judgment for the defendants, ruling that federal law preempts Greenberg's state law claims. It held that the defendants' biotin statement met the statutory requirements for a structure/function claim: there was substantiation for the truthful claim, the product label included the appropriate disclosures, and it did not suggest that the product could treat diseases. It ruled that Greenberg was seeking to impose an additional disclosure requirement by claiming that the product label was deceptive, even though it complied with the federal requirements for a structure/function claim.

STANDARD OF REVIEW

We review a district court's summary judgment order de novo, examining all evidence in the light most favorable to the non-moving party. *Badgley v. United States*, 957 F.3d 969, 974 (9th Cir. 2020). We review questions of preemption de novo. *Gingery v. City of Glendale*, 831 F.3d 1222, 1226 (9th Cir. 2016) (citation omitted).

DISCUSSION

I. Federal law permits companies to make structure/function claims for dietary supplements.

The FDA has limited authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to regulate dietary supplements, which include vitamin, botanical, enzyme, and amino acid products. Unlike with drugs, the FDA does not pre-approve product labels for dietary supplements. It, however, requires that the labels be truthful and not misleading, 21 U.S.C. § 343(r)(6)(B), and authorizes several categories of statements that can be made on the product if certain requirements are met. For purposes of this case, the two relevant types of claims allowed under the FDCA are disease claims and structure/function claims.

A disease claim refers to a "statement about a *product* [that] claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21 C.F.R. § 101.93(g)(2) (emphasis added). Put another way, a disease claim refers to a statement that the product itself can cure or treat a disease.

In contrast, a structure/function claim does not purport to treat a disease or even refer to the product itself. Rather, it is a much more narrowly focused statement "that describe[s] the role of *a nutrient or dietary ingredient* intended to affect the structure or function in humans or that characterizes the documented mechanism by which *a nutrient or dietary ingredient* acts to maintain such structure or function, provided that such statements are not disease claims." 21 C.F.R. § 101.93(f) (emphasis added); *see also* 21 U.S.C. § 343(r)(6)(A) (a structure/function claim "describes the role of *a nutrient or dietary ingredient* intended to affect the

structure or function in humans") (emphasis added).[2] In other words, a structure/function claim merely describes the function or role of an ingredient or nutrient on the human body.

To make a structure/function claim, manufacturers must meet three requirements:

> 1. The manufacturer must have substantiation that the statement is truthful and not misleading;
>
> 2. The statement must contain a prominent disclaimer that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"; and
>
> 3. The statement itself may not "claim to diagnose, mitigate, treat, cure, or prevent" disease.

21 U.S.C. § 343(r)(6)(B)–(C).

In guidance published in the Federal Register, the FDA has blessed structure/function claims that use general terms such as "strengthen," "improve," and "protect," so long as the claims do not suggest disease prevention or treatment. *See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the*

[2] The relevant FDA regulation specifies that diseases resulting from essential nutrient deficiency are not "diseases" for label claims (*e.g.*, scurvy). 21 C.F.R. § 101.93(g)(1).

Structure or Function of the Body, 65 Fed. Reg. 1000-01, 1028 (Jan. 6, 2000).

The guidance also speaks to substantiation. To substantiate a claim, supplement manufacturers need only show evidence of an effect on a small aspect of the related structure/function; they need not provide evidence of an effect on the disease linked to that structure/function. *See id*. at 1012 ("For example, to substantiate the claim 'supports mood,' it is not necessary to study the effects of a substance on clinical depression."). That guidance appears consistent with the narrow nature of a structure/function claim: it refers to the ingredient's general role in the human body, not the product's impact on a person's health.

II. The FDCA preempts Greenberg's state law claims because the challenged statement is a permissible structure/function claim.

To avoid a patchwork quilt of conflicting state labeling laws, the FDCA includes a preemption provision that establishes a national and uniform standard for certain labeling statements. The statute preempts any state law that establishes "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." 21 U.S.C. § 343-1(a)(5).

The FDCA's preemption provision covers structure/function claims because its requirements appear in section 343(r)(6), which falls under the preemption provision's umbrella. *See id*. 21 U.S.C. § 343(r)(6) ("*For purposes of paragraph (r)(1)(B)*, a statement for a dietary supplement may be made if . . . .") (emphasis added). This Court has thus held that "§ 343-1(a)(5) preempts state-law

requirements for claims about dietary supplements that differ from the FDCA's requirements." *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019).

Thus, if the defendants' biotin statement meets the FDCA's three requirements for a structure/function claim, then any state law claims challenging that claim fall to the wayside. As explained below, the defendants' biotin structure/function claim meets all three requirements.

A. The biotin structure/function claim has substantiation and is accurate.

The defendants have met the first requirement for its structure/function claim because it has substantiation that biotin "helps support healthy hair and skin," and that statement is truthful and not misleading. 21 U.S.C. § 343(r)(6)(B).

Greenberg does not dispute that scientific evidence exists showing that biotin — the nutrient — supports healthy hair and skin. Instead, he argues that the structure/function claim is nevertheless deceptive and runs afoul of the FDCA's prohibition against false or misleading statements. He maintains that a mega-dosage of biotin benefits only a tiny percentage of the public with biotin deficiency. Thus, Greenberg reasons, the suggestion that the Up & Up biotin product helps support hair and skin is misleading for most people. He implies that the structure/function claim must be true not only as to the nutrient itself but the product as a whole.

But the plain language of the FDCA and its implementing regulations clarifies that a structure/function claim addresses only the general role of an ingredient/nutrient on the human body. It does not purport

to convey the product's health impact on the general population, contrary to Greenberg's assertion. The FDCA describes a structure/function claim as one that "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) (emphasis added); *see also* 21 C.F.R. § 101.93(f). In contrast, a disease claims refers to the health benefit of a product. 21 C.F.R. § 101.93(g)(2) ("A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that *the product* . . .") (emphasis added).

Greenberg's state law claims challenging the biotin product's efficacy are preempted because the statute only requires substantiation for *the ingredient*'s function on the human body, not the health impact of the product as a whole. Put differently, Congress appears to have created two classes of claims: (1) a structure/function claim that refers only to the ingredient or nutrient's role in the human body, and (2) a disease claim that speaks to the product's effect on the consumer's disease. Greenberg 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. *Cf. Dachauer*, 913 F.3d at 847 (state law claims preempted where the plaintiff tried to use evidence about supplement's inability to prevent disease to challenge a structure/function claim).

Greenberg's reliance on the FDCA's general prohibition against false or misleading statements fares no better. Under Greenberg's view, the statement that biotin "helps support healthy hair and skin" is misleading because very few people

have biotin deficiency and thus would not benefit from the product. But only a fraction of people suffers a deficiency of any nutrient. For example, according to Greenberg's reasoning, a product that bears the true statement that "vitamin C boosts immunity" would be misleading because most people are not vitamin C deficient and would not benefit from the product. Similarly, the accurate claim that "calcium helps maintain bones" would be misleading to most consumers because an extra dosage of calcium would be superfluous for them. In short, under Greenberg's logic, virtually any structure/function claim for dietary supplements would potentially be misleading to the great majority of people. Such reasoning conflicts with the FDCA's statutory language and the FDA's stated purpose for allowing structure/function claims. *Cf. 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 (noting that the final structure/function claim rule "increase[es] the amount of information available to the consumer without prior FDA review").

Simply put, 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.[3]

[3] The plaintiff cites FDA and Federal Trade Commission guidance to bolster his argument, but they are not on-point and in any event are not binding on this Court. *See, e.g.*, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*, 74 Fed. Reg. 204-01, 304 (Jan. 5, 2009) (stating that it "does not create or confer any rights for or on any person and does not operate to bind FDA or the public").

B. The biotin product label has the appropriate disclosures.

To qualify as a structure/function claim, the product must also contain a prominent disclaimer that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C.§ 343(r)(6)(C). Here, that disclosure appears twice on the label. The FDCA's second requirement for structure/function claims has thus been met.

C. The biotin product label does not claim to treat diseases.

Finally, the FDCA requires that the statement itself does not "claim to diagnose, mitigate, treat, cure, or prevent" disease. *Id.* The Up & Up biotin product label clearly disclaims: "This product is not intended to diagnose, treat, cure, or prevent any disease." And nowhere does the label imply otherwise.

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In sum, because the structure/function claim about biotin meets the FDCA's requirements, Greenberg's state law claims amount to an imposition of different standards from the FDCA. Greenberg essentially seeks to impose an additional requirement that dietary supplement labels can make structure/function claims only if consumers are likely to benefit from the product. But that requirement "is not identical to the requirement of section 343(r)." 21 U.S.C. § 343-1(a)(5). It is thus preempted.

To be sure, a structure/function claim may be misleading if it fails to disclose a harmful aspect of the nutrient. For example, in *Dachauer*, this Court held that the FDCA did

not preempt the plaintiff's claim that vitamin E increased the risk of all-cause mortality. 913 F.3d at 849. There is no such allegation here.

Likewise, if a structure/function claim is factually false or lacks substantiation, then state law claims will not be preempted. *See Kroessler v. CVS Health Corp.*, 977 F.3d 803, 812 (9th Cir. 2020) ("Kroessler alleges that CVS's glucosamine claims are false because scientific studies directly refute them."). But that is not the case here.

We thus hold that the FDCA authorizes the defendants' structure/function claim about biotin and preempts Greenberg's state law claims challenging them.

AFFIRMED.