FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PAUL DACHAUER, On Behalf of Himself and All Others Similarly Situated, *Plaintiff-Appellant*, v. NBTY, INC., a Delaware corporation; NATURE'S BOUNTY, INC., a Delaware corporation, *Defendants-Appellees.*	No. 17-16242 D.C. No. 3:16-cv-00216-VC OPINION

Appeal from the United States District Court
for the Northern District of California
Vince Chhabria, District Judge, Presiding

Argued and Submitted November 13, 2018
San Francisco, California

Filed January 10, 2019

Before: Sidney R. Thomas, Chief Judge, Susan P. Graber, Circuit Judge, and Leslie E. Kobayashi,[*] District Judge.

Opinion by Judge Graber

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[*] The Honorable Leslie E. Kobayashi, United States District Judge for the District of Hawaii, sitting by designation.

SUMMARY**

California Law / Federal Preemption

The panel affirmed the district court's summary judgment in favor of makers of vitamin E supplements in a plaintiff/consumer's action alleging that the labels on the supplements violated California laws against false advertising.

For dietary supplements, the Federal Food, Drug, and Cosmetic Act ("FDCA") distinguishes between "disease claims" and "structure/function claims" that manufacturers make about their products. A structure/function claim describes the role of a dietary ingredient, but may not claim to mitigate a specific disease. 21 U.S.C. § 343(r)(6). Although the FDCA requires manufacturers to have substantiation for their structure/function claims, California law does not allow private plaintiffs to demand substantiation for advertising claims.

The panel held that § 343-1(a)(5) of the FDCA expressly preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements. The panel further held that, as applied here, § 343-1(a)(5) preempted most of plaintiff's claims. Specifically, the panel held that § 343-1(a)(5) preempted plaintiff's claims to the extent that he argued that defendants' structure/function claims were false or misleading because their supplements did not prevent cardiovascular disease. The panel also held

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that because the FDCA and California law have the same labeling requirement with respect to failing to disclose an increased risk of death, § 343-1(a)(5) did not preempt this particular aspect of plaintiff's case.

The panel held that the record lacked evidence that vitamin E supplements are actually harmful, as opposed to simply useless at reducing all-cause mortality (which they do not claim to reduce). The panel concluded that, on this record, plaintiff failed to meet his burden to create a genuine issue of material fact as to whether defendants' immune-health structure/function claim was misleading.

COUNSEL

Stewart Weltman (argued), SIPRUT PC, Chicago, Illinois; Max A. Stein and Nada Djordjevic, Boodell & Domanskis, LLC, Chicago, Illinois; Patricia N. Syverson and Manfred Muecke, Bonnett, Fairbourn, Friedman & Balint, P.C., San Diego, California; Elaine Ryan, Bonnett, Fairbourn, Friedman & Balint, P.C., Phoenix, Arizona; for Plaintiff-Appellant.

Robert Andalman (argued) and Rachael Blackburn, A&G Law, LLC, Chicago, Illinois; William A. Delgado, Willenken Wilson Loh & Delgado LLP, Los Angeles, California; for Defendants-Appellees.

OPINION

GRABER, Circuit Judge:

Defendants NBTY, Inc., and Nature's Bounty, Inc., make vitamin E supplements that claim, on their labels, to "support cardiovascular health" and to "promote[] immune function," "immune health," "heart health," and "circulatory health."[1] Plaintiff Paul Dachauer purchased one bottle of the supplements for health reasons. He claims that the labels' statements violate two California laws against false advertising, because the supplements do not prevent cardiovascular disease and might increase the risk of all-cause mortality. The district court disagreed and granted Defendants' motion for summary judgment. Reviewing de novo, and viewing the evidence in the light most favorable to Plaintiff, *Albino v. Baca*, 747 F.3d 1162, 1168 (9th Cir. 2014) (en banc), we affirm.

A. *Relevant Statutes and Regulations*

Plaintiff sued under California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, and Consumers Legal Remedies Act, Cal. Civ. Code § 1770. Both statutes prohibit: (1) false advertising; and (2) advertising that is literally true, but which is "actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008) (quoting *Kasky v. Nike, Inc.*, 45 P.3d 243, 250 (Cal. 2002)). Our analysis, however, centers on the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–399i, and its implementing regulations.

[1] The Appendix includes two examples of the labels.

For dietary supplements, the FDCA distinguishes between "disease claims" and "structure/function claims" that manufacturers make about their products. 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," but "*may not* claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6) (emphasis added). A disease claim, conversely, "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly (such as by claiming that a product treats a disease's "characteristic signs or symptoms"). 21 C.F.R. § 101.93(g)(2)(ii). Structure/function claims must meet three requirements: (1) the manufacturer has substantiation that the statement is truthful and not misleading; (2) the statement contains a prominent disclaimer that the Food and Drug Administration ("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 does not "claim to diagnose, mitigate, treat, cure, or prevent" disease. 21 U.S.C. § 343(r)(6).

The FDA has published guidance in the Federal Register discussing, among other things, acceptable structure/function claims. 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 (Jan. 6, 2000). The guidance recognizes that structure/function claims may use general terms such as "strengthen," "improve," and "protect," as long as the claims "do not suggest disease prevention or treatment." *Id.* at 1028. For example, the guidance identifies the phrase "helps maintain

cardiovascular function and a healthy circulatory system" as a permissible structure/function claim. *Id.* at 1012; *see also id.* at 1029 (The "FDA does not agree that . . . 'supports the immune system'" implies disease prevention.). The guidance further explains that manufacturers of supplements can substantiate structure/function claims with evidence of an effect on a small aspect of the related structure/function, rather than with evidence of an effect on the main disease that consumers might associate with a given bodily structure or 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. Instead, it is quite possible to assess the effects of a substance on mood changes that do not constitute clinical depression.").

Although the FDCA requires manufacturers to have substantiation for their structure/function claims, California law does not allow private plaintiffs to demand substantiation for advertising claims. *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 133 Cal. Rptr. 2d 207, 213–14 (Ct. App. 2003). Instead, a private plaintiff bears the burden of producing evidence to prove that the challenged statement is false or misleading. *Id.*

B. *Preemption*

The FDCA expressly 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). Defendants argue that § 343-1(a)(5) preempts Plaintiff's claims because he seeks to impose labeling requirements under California law that differ from the FDCA's

requirements. Although the district court did not reach the issue of preemption, we may affirm on that ground because Defendants raised the issue below, and it is a threshold legal issue. *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757 (9th Cir. 2015).

The preemption provision governs claims "of the type described in section 343(r)(1)." 21 U.S.C. § 343-1(a)(5). Section 343(r)(6), which establishes the requirements for structure/function claims, falls under subsection (r)(1)'s umbrella. *See id.* § 343(r)(6) ("*For purposes of paragraph (r)(1)(B)*, a statement for a dietary supplement may be made if . . . ." (emphasis added)). So, a structure/function claim made under § 343(r)(6) is a "claim of the type described in section 343(r)(1)." Also, the FDCA classifies dietary supplements as food; indeed, § 343-1 ("National uniform nutrition labeling") and § 343 ("Misbranded food") fall under the FDCA's "Food" subchapter. Thus, a structure/function claim also constitutes a claim "made in the label or labeling of food." *Id.* § 343-1(a)(5). Accordingly, we hold that § 343-1(a)(5) preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements.

As applied here, § 343-1(a)(5) preempts most of Plaintiff's claims. We first address Defendants' structure/function claims that their supplements promote and support cardiovascular, circulatory, and heart health. Plaintiff argues that those claims are false because the supplements do not prevent cardiovascular disease.

Plaintiff's expert witness, Edgar Miller, Ph.D., M.D., offered ample evidence that vitamin E supplements, taken in the doses that Defendants sell, fail to prevent cardiovascular

disease. In Dr. Miller's view, no metric *except* the absence or presence of cardiovascular disease can measure heart health (and, accordingly, no other metric can demonstrate whether a supplement promotes or supports heart health). In essence, Dr. Miller rejects the discrete categories of claims that the FDCA establishes; by definition, structure/function claims *do not* and *may not* claim to treat or prevent disease. *Id.* § 343(r)(6); 21 C.F.R. § 101.93(g)(2). And Defendants' labels do not claim that their vitamin E supplements treat or prevent cardiovascular disease. Yet Plaintiff seeks to impose a requirement under California law that structure/function claims—at least those related to cardiovascular, circulatory, and heart health—made on a supplement's label require proof that the supplement treats or prevents cardiovascular disease.[2] That requirement "is not identical to the requirement of section 343(r)." 21 U.S.C.§ 343-1(a)(5).

On appeal, Plaintiff argues that it does not matter whether he categorizes Defendants' claims as structure/function claims or as disease claims, because he addressed the falsity of the labels' text. To the contrary, it matters very much. Plaintiff's argument would vitiate the FDCA's distinction between disease claims and structure/function claims. The FDA allows manufacturers of supplements to make general claims—such as "promotes heart health"—and to substantiate

[2] Plaintiff suggests that we should grant him leave to amend his complaint to allege that Defendants make false implied-disease claims instead of structure/function claims. But Plaintiff had a chance to raise implied-disease claims, and he expressly told the district court that he had no such claims. Moreover, Plaintiff never requested leave from the district court to amend his complaint, so his request on appeal comes too late. *See Ventura Packers, Inc. v. F/V Jeanine Kathleen*, 305 F.3d 913, 917 n.1 (9th Cir. 2002) (declining the plaintiff's request, made for the first time on appeal, for leave to amend its complaint).

them with evidence that a supplement has some structural or functional effect on a given part of the human body. 65 Fed. Reg. at 1012. Manufacturers need not also have evidence that those structural or functional effects reduce the risk of developing a certain disease. *See Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 95 (1st Cir. 2016) (rejecting the plaintiff's argument that "evidence showing a supplement does not reduce heart disease necessarily implies that the nutrient itself has no function in maintaining heart health"). Plaintiff disagrees with the federal statutory scheme for dietary supplements, but we cannot accept his invitation to upend it. We hold that § 343-1(a)(5) preempts Plaintiff's claims to the extent that he argues that Defendants' structure/function claims are false or misleading because their supplements do not prevent cardiovascular disease.

As for Defendants' structure/function claim that their supplements promote immune health, Plaintiff argues that the claim is false and misleading, either because the supplements fail to reduce all-cause mortality or because the supplements increase the risk of all-cause mortality. The FDCA does not require that manufacturers substantiate structure/function claims about immune health with proof that their supplements reduce the risk of all-cause mortality. 21 U.S.C. § 343(r)(6). (Nor do Defendants claim that their supplements reduce that risk.) Because any such requirement under California law would differ from the FDCA's labeling requirements, the FDCA preempts Plaintiff's claim to the extent that he argues that Defendants make a false structure/function claim because their supplements fail to reduce the risk of all-cause mortality.

But the FDCA does not preempt Plaintiff's claim that Defendants' structure/function claim about immune health is

misleading because their supplements *increase* the risk of all-cause mortality. FDCA regulations state that a food label "shall be deemed to be misleading if it fails to reveal facts" that are "[m]aterial with respect to consequences which may result from use of the article" under normal conditions of use or the conditions of use that the label prescribes. 21 C.F.R. § 1.21(a)(2). In other words, if a supplement's label recommends taking one capsule per day, and that dose actually causes an increased risk of death—a material fact "with respect to consequences which may result from use of the article"—the FDCA would deem it misleading not to reveal that fact on the label. *Id.*; *see also Kaufman*, 836 F.3d at 96 (noting that a structure/function claim would be misleading if it "fail[ed] to disclose the harmful aspects of the nutrient's structure/function").

Likewise, a label that omitted that fact would be misleading under California law. The associated structure/function claim would have "a capacity, likelihood or tendency to deceive or confuse the public," because a reasonable consumer would not expect to suffer an increased risk of death from taking the product. *Williams*, 552 F.3d at 938 (quoting *Kasky*, 45 P.3d at 250). Because the FDCA and California law have the same labeling requirement with respect to failing to disclose an increased risk of death, § 343-1(a)(5) does not preempt this particular aspect of Plaintiff's case. Thus, we address whether Plaintiff created a genuine issue of material fact as to whether the immune-health claim is misleading.

C. *Defendants' Immune-Health Claim*

Conceivably, evidence that a supplement endangered users by increasing their risk of death could prove that a structure/function claim that omitted the risk was misleading. But the record lacks evidence that vitamin E supplements are actually harmful, as opposed to simply useless at reducing all-cause mortality (which they do not claim to reduce).

At best, the record reveals, in Dr. Miller's words, a "small" *correlation* between high-dose vitamin E supplements (which Defendants sell) and an increased risk of all-cause mortality. Miller cited four meta-analyses[3] for this point, but none of them concluded that vitamin E supplements *caused* an increased risk of all-cause mortality. *See, e.g.*, Goran Bjelakovic et al., *Mortality in Randomized Trials of Antioxidant Supplements for Primary and Secondary Prevention*, 297 J. Am. Med. Ass'n 842, 842, 854 (2007)[4] (concluding that "vitamin E *may* increase mortality," but also stating that "[w]e are not able to determine the cause of the increased mortality" (emphasis added)). And, as the term "all-cause mortality" suggests, the record contains no evidence about the actual cause of death for any of those included in the studies. Those causes could include many things unrelated to vitamin E supplements or immune function, such as suicide or a car accident. Without more, no reasonable jury could conclude that Defendants misleadingly "fail[ed] to disclose the harmful aspects of the nutrient's structure/function." *Kaufman*, 836 F.3d at 96. In summary,

[3] A meta-analysis combines results from multiple clinical trials to draw broader conclusions about the subject under study.

[4] Available at: http://dcscience.net/bjelakovic-supplements-07.pdf.

we hold that, on this record, Plaintiff failed to meet his burden to create a genuine issue of material fact as to whether Defendants' immune-health structure/function claim is misleading.

AFFIRMED.

APPENDIX


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Vitamin E promotes immune function and helps support cardiovascular health.* Vitamin E helps fight cell-damaging free radicals in the body.* Free radicals can contribute to oxidative stress, which in turn may contribute to the premature aging of cells.*
No Artificial Color, Flavor or Sweetener, No Preservatives, No Sugar, No Starch, No Milk, No Lactose, No Gluten, No Wheat, No Yeast, No Fish. Sodium Free.
0 74312 01799 5
Nutrition Questions or Comments? Call NutraPhone® 1-800-433-2990 Mon. - Fri. 9 AM - 7 PM ET
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Pure dl-Alpha
Promotes
Immune Function
& Healthy Heart*
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RAPID RELEASE LIQUID SOFTGEL
Powerful Antioxidant Support*
60 softgels
VITAMIN SUPPLEMENT
DIRECTIONS: For adults, take one (1) softgel daily, preferably with a meal.
Supplement Facts
Serving Size 1 Softgel
Amount Per Serving %Daily Value
Vitamin E (as dl-Alpha Tocopheryl Acetate) 1,000 IU 3,333%
Other Ingredients: Gelatin, Vegetable Glycerin, Soybean Oil.
WARNING: If you are pregnant, nursing, taking any medications or planning any medical procedure, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Keep out of reach of children. Store in a cool, dry place. Do not use if seal under cap is broken or missing.
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