Docket No. 19-16699

In the

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 and
PERRIGO COMPANY OF SOUTH CAROLINA, INC.,

Defendants-Appellees.

Appeal from a Decision of the United States District Court for the Northern District of California, No. 3:17-cv-01862-RS · Honorable Richard Seeborg

BRIEF *AMICUS CURIAE* OF THE COUNCIL FOR RESPONSIBLE NUTRITION IN SUPPORT OF DEFENDANTS-APPELLEES

J. KATHLEEN BOND, ESQ.
JENNIFER M.S. ADAMS, ESQ.
AMIN TALATI WASSERMAN, LLP
100 South Wacker Drive, Suite 200
Chicago, Illinois 60606
(202) 496-4966 Telephone

Attorneys for Amicus Curiae,
The Council for Responsible Nutrition

COUNSEL PRESS · (213) 680-2300 PRINTED ON RECYCLED PAPER

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 and 29(a) of the Federal Rules of Appellate Procedure, *Amicus Curiae* The Council for Responsible Nutrition hereby states that it has no parent corporation, and no publicly held company owns 10 percent or more of its stock.

Dated: April 14, 2020

Respectfully submitted,

By: *Jennifer M.S. Adams*

J. Kathleen Bond
Jennifer M.S. Adams
AMIN TALATI WASSERMAN, LLP
100 S. Wacker Dr., Suite 200
Chicago, IL 60606
T: (312) 327-3383
jennifer@amintalati.com

Attorneys for *Amicus Curiae* The Council for Responsible Nutrition

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

COURT RULES

STATUTES

OTHER AUTHORITIES

INTEREST OF AMICUS CURIAE

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the Council for Responsible Nutrition ("CRN") files this *Amicus Curiae* brief with the consent of all parties. CRN is the leading trade association for the dietary supplement industry. CRN represents more than 160 companies worldwide selling products such as multivitamins, single ingredient vitamins and minerals (*e.g.*, vitamin C, calcium), prenatal vitamins and folic acid supplements, omega-3, and probiotics, among many others. CRN works with its members to ensure compliance with federal and state laws governing marketing, as well as manufacturing and safety. CRN's work promotes and protects responsible industry, while also helping to ensure that consumers receive high quality nutritional products.

The Plaintiff-Appellant filed a putative class action alleging that Target Corporation, International Vitamin Corporation, and Perrigo Company of South Carolina, Inc. ("Defendants") violated California law by marketing Up&Up store brand biotin supplements with label claims to support "healthy hair and skin." On August 29, 2019, the lower court properly granted Defendants' motion for summary judgement, finding that the relevant federal food and drug law expressly preempts Plaintiff-Appellant's action.

Each biotin product at issue provides from 1,000 to 10,000 micrograms of biotin, a water soluble B vitamin. Plaintiff-Appellant contends that where the Daily

Value for biotin is low, and consumers can obtain the Daily Value from food, Defendants' claims about biotin are somehow misleading.

For vitamins and minerals like biotin, federal law has established a Daily Value system intended to help consumers compare the nutritional content of different food products, including dietary supplements, and assess how a serving of a product fits into their overall daily dietary intake. Plaintiff-Appellant effectively argues that federal law requires product marketers, prior to making any nutrient benefit claim, to police whether or how a consumer might meet or exceed a nutrient's Daily Value – through a food or dietary supplement. This argument is incorrect and would add complex, novel, and misguided requirements to the existing uniform federal law that Congress carefully crafted for foods and dietary supplements.

By creating the relevant federal framework governing foods and supplements, Congress sought to encourage the dissemination of nutrition information and empower consumers to make their own choices about nutrition and dietary supplementation. Congress moreover gave the federal standards preemptive effect to avoid exactly this type of situation where a private plaintiff seeks to overhaul a carefully crafted federal system.

CRN's interest as *Amicus Curiae* is to inform the Court as to the importance of the lower court decision to industry and consumers. If the lower court decision

is reversed, companies will be obligated to follow novel and misguided requirements never contemplated in the applicable federal law.

No party or party's counsel authored this brief in whole or in part. No party or party's counsel contributed money intended to fund the preparation or submission of this brief. No person other than CRN, its members, or their counsel contributed money intended to fund this brief.

SUMMARY OF ARGUMENT

On April 4, 2017, Plaintiff-Appellant Todd Greenberg filed a putative class action alleging that Defendants violated California law by marketing Up&Up store brand biotin supplements with label claims to support "healthy hair and skin." According to the Plaintiff-Appellant, these claims are misleading where the Daily Value for biotin is set by federal standards at a low level, and consumers can obtain the Daily Value from food. On August 29, 2019, the lower court granted Defendants' motion for summary judgment, finding that the Plaintiff-Appellant failed to state a claim upon which relief may be granted. Specifically, the court held that federal law expressly preempts Plaintiff-Appellant's claims. This holding is proper and in the public interest.

The applicable law in this case creates a framework for both food and dietary supplement manufacturers to disseminate information about how nutrients affect the health and function of the body. Along with claims requirements, this federal framework mandates Daily Value disclosures on food and supplement labels to help consumers compare the nutritional content of different products and assess how a serving of a product fits into their overall daily diet. By creating the relevant federal framework, Congress sought to empower consumers to make informed choices about nutrition. Congress deliberately gave the federal standards

preemptive effect to avoid exactly the type of disruption the Plaintiff-Appellant seeks, where a private action could overhaul the carefully crafted federal system.

Plaintiff-Appellant's arguments against the lower court's decision fail to recognize that the federal law in no way requires product marketers to police whether or how a consumer might meet or exceed a nutrient's Daily Value – through a food or dietary supplement. There is no disagreement that Defendants properly label their products with the amount and percentage Daily Value of biotin. There is also no disagreement biotin, in fact, is an essential nutrient that supports hair and skin health and function. There is likewise no allegation here – nor could there be – that the level of biotin in Defendant's products presents any safety issue. In fact, there is no evidence of toxic effects from biotin in humans. As such, under the carefully crafted federal framework, the Defendants are free to tout the truthful, substantiated benefits that biotin provides, and consumers are free to obtain biotin in the manner they choose.

Plaintiff-Appellant argues throughout his brief that his position is entirely consistent with federal law and therefore escapes the express preemption provisions in the federal law governing food. Plaintiff-Appellant, however, never once identifies a single law, regulation, or enforcement action similar to the action he asks the court to undertake in this case. The federal law, for good reason, has never limited the benefit claims that may be made for nutrients based on whether

or how a consumer might meet or exceed the nutrient's Daily Value. Apart from the illogic of policing the form or level to which consumers choose to ingest essential nutrients, like biotin, there is no practical way food or dietary supplements companies could ensure that where a nutrient benefit claim is made, consumer intake of the nutrient, within the overall diet, will never exceed the recommended amount.

ARGUMENT

I. WITH THE NLEA AND DSHEA, CONGRESS CREATED A UNIFORM REGULATORY REGIME INTENDED TO PROVIDE CONSUMERS GREATER ACCESS TO DIETARY HEALTH BENEFIT INFORMATION

Under the 1990 Nutrition Labeling and Education Act ("NLEA"), Congress created new mandates and voluntary means for food and dietary supplement manufacturers to provide consumers health related information. *See* Pub. Law 101-535. Under the NLEA, companies for the first time were required to include nutrient declarations on most "foods," of which "dietary supplements" are a subset. *See id.*; *see also* 21 U.S. Code § 321(f), (ff). Specifically, the NLEA required "nutrition labeling" on most food products and directed the Food and Drug Administration ("FDA") to "issue final regulations" to ensure nutrition information is "conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." *See* Pub. Law 101-535, §2. FDA subsequently issued regulations requiring certain label declarations for various macro and micronutrients. These regulations provided (and still provide) that, where a claim is made about an essential vitamin, like biotin, the label must disclose the "quantitative amount by weight [of the vitamin] and percent of the [established] Daily Value." 21 C.F.R. § 101.9(c)(8); *see also* 21 C.F.R. § 101.93 (requiring the same nutrient declaration not only where a claim is made, but also whenever an

essential vitamin or mineral is present at more than two percent of the Daily Value).

In addition to the nutrition labeling requirements, the NLEA also created new avenues for food and dietary supplement manufacturers to make health-related labeling claims. For instance, the NLEA allowed food and dietary supplement companies to seek FDA authorization to make "health claims," defined as "claim[s] made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterize[] the relationship of any substance to a disease." 21 U.S.C. § 343(r)(1)(B).

Four years later, with the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Congress amended the Food, Drug, and Cosmetic Act ("FDCA") again, this time to expand the scope of health benefit information dietary supplement manufacturers, specifically, could provide to consumers. *See* Pub. Law 103-417. The text of DSHEA states that because "dietary supplements are safe within a broad range of intake" and "the benefits of [supplements] in health promotion and disease prevention have been documented increasingly in scientific studies," consumers "should be empowered to make choices" about taking them. *Id.* at § 2.

DSHEA for the first time allowed dietary supplement "structure/function claims," defined as statements "describ[ing] the role of a nutrient or dietary

ingredient intended to affect the structure or function in humans [or] characterize[ing] 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). Those are the types of claims at issue in this case. To support such claims, Congress required that the dietary supplement manufacturer possess "substantiation that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). Although the law is directed to dietary supplements, FDA has since allowed foods other than supplements to make structure/function claims based on the same substantiation requirement from DSHEA. *See, e.g.*, FDA, Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages, at 8 (Jan. 2004), https://www.fda.gov/media/87567/download.

Neither the NLEA, DSHEA, nor any other law or regulation governing structure/function claims or any other type of claim, for that matter, has ever required that, as a part of the substantiation obligation, food and supplement marketers must attempt to address whether or how a consumer might meet or exceed a nutrient's Daily Value – through a food or dietary supplement. Rather, according to FDA, the Daily Values shown on both "Nutrition and Supplement Facts" labels "help[] consumers understand how the amount of a nutrient that is present in a serving of a food fits into their total daily diet, and allows them to compare the nutritional value of food products." *See* FDA, Frequently Asked

Questions for Industry on Nutrition Facts Labeling Requirements, https://www.fda.gov/media/99059/downloadl; *see also* FDA, Final Rule, Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742, at 33,793 (May 27, 2016) ("[N]utrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet.").

Where FDA rules governing food and dietary supplement claims discuss at all the level of a nutrient in a product, they quite logically focus solely on ensuring that a product provides enough of a nutrient to contribute materially to obtaining the claimed benefit. For instance, FDA has authorized companies to make a health claim associating consumption of calcium and vitamin D with reduced risk of osteoporosis. *See* 21 C.F.R. § 101.72. In order to make the claim, a serving of the food or supplement must provide the levels of calcium and vitamin D that "*meet[] or exceed[]* the requirements for a 'high' level . . . as defined in § 101.54(b)). *Id.* The "high" level for calcium and vitamin D is "20 percent or more" of the Daily Value per serving for each nutrient. 21 C.F.R. § 101.54(b). Nothing in the relevant statutory or rule provisions limits how much calcium or vitamin D can be provided, nor do these provisions require manufacturers to take into account what combination of foods and dietary supplements consumers use to reach an adequate calcium and vitamin D intake.

In fact, FDA does not establish maximum limits for the amount of nutrients in products at all, but rather takes enforcement action against unsafe products. Specifically, FDA has a means of removing a dietary supplement from the market if the product "presents a significant or unreasonable risk of illness or injury." 21 U.S.C. § 342(f)(1)(A). Under this provision FDA has deemed products like ephedra and "highly concentrated caffeine" unreasonably risky. *See* FDA, Highly Concentrated Caffeine in Dietary Supplements (Apr. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements; 21 C.F.R. § 119.1 ("dietary supplements containing ephedrine alkaloids are adulterated"). Importantly for the purposes of this case, there is no "tolerable upper intake level" for biotin, meaning there is no evidence of toxic effects from biotin in humans. *See* National Academies of Science, Dietary Reference Intakes: The Essential Guide to Nutrient Requirements (2006), https://www.nap.edu/download/11537. There is no practical or rational way that the FDA could or should, as a matter of claim substantiation, require companies to anticipate how or from what source a consumer might hit the recommended Daily Value for any given nutrient.

In order to protect the complex, uniform system regulating nutrition and dietary health benefit information, Congress prohibited any state law or action that

would impose standards that are "not identical to" the federal requirements. 21 U.S.C. § 343-1(a)(5); 21 C.F.R. § 100.1(c)(4); *see also Dachauer v. NBTY, Inc.*, 913 F.3d 844, 847 (9th Cir. 2019). Plaintiff-Appellant seeks to upend this unique federal regime, imposing standards in derogation of clear intent by Congress to empower consumers with information as to how nutrients that can be ingested through either foods or dietary supplements can benefit health.

II. THE DEFENDANTS' BIOTIN CLAIMS COMPLY WITH ALL RELEVANT FEDERAL REQUIREMENTS

There is no allegation – nor could there be – that Defendants have failed to properly declare biotin on product labels in line with federal requirements. Rather, each product includes a Supplement Facts panel listing the amount of biotin per serving and the relevant percentage Daily Values – "333% DV" for 1,000 mcg tablets, "1,667% DV" for 5,000 mcg tablets, and "3,333% DV" for 10,000 tablets. *See* ECF No. 78-1, Ex. A to SAC. The parties also agree that the labels include the following structure/function claims based on the biotin content: (1) "Helps support healthy hair and skin," and (2) "Biotin plays a role in hair and skin health." *See id.* The Plaintiff-Appellant's scientific expert acknowledges that "at the cellular level," biotin is "an essential vitamin that has an effect on hair and skin as well as other metabolic related functions." Opening Brief, at 3. Thus, the parties agree that indeed biotin "[h]elps support healthy hair and skin," and "plays a role in hair and skin health." Against this background, there can be no question that Defendant's

structure/function claims are fully substantiated. As discussed in Section I, there is simply no requirement that companies anticipate how or from what source a consumer might meet or exceed the recommended Daily Value for any given nutrient.

III. THE FDCA PREEMPTS PLAINTIFF-APPELLANT'S ACTION WHERE PLAINTIFF-APPELLANT SEEKS TO IMPOSE NOVEL STANDARDS

Plaintiff-Appellant's sole argument against preemption is that Defendant's products are "misbranded" under the FDCA because Defendants' fail to possess adequate "substantiation" for their biotin structure/function claims where the Daily Value for biotin is low, and consumers can obtain the Daily Value from foods other than dietary supplements. Opening Brief, at 10, 13-14 (citing 21 U.S.C § 343(a)(1), (r)(6)). Because the products are purportedly misbranded, they in turn supposedly violate California's Unfair Competition Law (Cal. Bus. & Prof. Code § 17200) and Consumer Legal Remedies Act (Cal Civ. § 1770).

However, throughout his entire brief, Plaintiff-Appellant fails to identify a single law, regulation, or enforcement action finding that a structure/function claim is misleading if the relevant nutrient – or the nutrient plus a consumer's background diet – might exceed the recommended Daily Value of the nutrient. This is because, as discussed in Section I, no such law, regulation, or enforcement action exists.

As described below, each of the cases and snippets of non-binding federal guidance Plaintiff-Appellant cites to attempt to support his arguments of deception involve wildly different facts from the case at hand, and are entirely irrelevant.

- ***U.S. Ninety-Five Barrels More or Less of Alleged Apple Cider Vinegar*, 265 U.S. 438 (1924) (Opening Brief, at 7).** This 96 year old case involved allegations by the FDA that a product labeled "apple cider vinegar" falsely implied that the vinegar was made from apple cider when it was in fact made from dried apples. This case is wholly irrelevant.
- ***U.S. v. An Article of Food, Etc.*, 377 F. Supp. 746 (E.D.N.Y. 1974) (Opening Brief, at 7, 11, 16).** This 46 year old case involved allegations by the FDA that labeling crackers as "Diet Thins" was misleading where the crackers were no lower in caloric content than other crackers. This case is likewise irrelevant.
- ***U.S. v. An Article of Food Labeled Nuclomin*, 482 F.2d 581 (8th Cir. 1973) (Opening Brief, at 16).** This 47 year old case involved what would now be considered a dietary supplement, although the NLEA and DSHEA were still decades away. The FDA alleged that the product label and formulation deceived consumers as to what vitamins and minerals in the product were actually "among known nutritional vitamins and minerals" that could provide a health benefit. As described in Section I, the NLEA and

FDA regulations later clearly designated certain vitamins and minerals, including biotin, essential and assigned them Daily Values. Thus, this case is not only factually irrelevant, but predates the current, relevant law by about two decades.

- **Example 8, FDA, Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) (Jan. 2009) (Opening Brief, at 22).** This example from non-binding FDA guidance describes a hypothetical situation where a U.S. company considers basing a structure/function claim for a mineral on study conducted in a foreign country where the population is generally deficient in that mineral. The example indicates that the study "may not be adequate to substantiate a claim in the United States because it is confounded by the initial abnormal blood levels of the mineral." This equivocal statement from non-binding guidance in no way indicates or suggests that the hypothetical mineral at issue is one like biotin where the health benefits are so established as to the U.S. population that the vitamin has been designated essential and has an assigned Daily Value.
- **Example 5, FTC, Dietary Supplements: An Advertising Guide for Industry (1998) (Opening Brief, at 25).** This example from non-binding Federal Trade Commission ("FTC") guidance involves a hypothetical claim to "eliminate a specific mineral deficiency" and suggests that in making such

a claim the advertiser should disclose the percentage of U.S. consumers who suffer from the deficiency. No claims to eliminate a deficiency are at issue here at all. Rather, Defendants have truthfully advertised that the essential nutrient, biotin, supports hair and skin health.

In addition to the foregoing, the Plaintiff-Appellant repeatedly cites FTC guidance for the basic proposition that when determining what express or implied claims an ad or label conveys, the assessment "should not focus just on individual phrases or statements, but rather should consider the ad as a whole." Opening Brief, at 24 (citing Dietary Supplements: An Advertising Guide for Industry, at 3); *see also generally* Opening Brief, at 24-26. The assessment, as Plaintiff-Appellant further explains, should focus rather on the "net impression conveyed by all elements" including for instance "the text, product name, and depictions." *Id.* at 24. This proposition however runs counter to Plaintiff-Appellant's arguments. Plaintiff-Appellant asks the court to focus solely on the hair and skin claims without any consideration of the FDA required biotin declarations on Defendants' labels. Taking the entirety of the label into consideration, consumers are fully and truthfully apprised – as federal law intends – that biotin is an essential nutrient that supports hair and skin health, and Defendants' products are a source from which consumers can choose to derive the benefits of biotin.

CONCLUSION

For the foregoing reasons, CRN urges the Ninth Circuit to affirm the lower decision in this case and find that the FDCA preempts Plaintiff-Appellant's action.

Dated: April 14, 2020

Respectfully submitted,

By: *Jennifer M.S. Adams*

J. Kathleen Bond
Jennifer M.S. Adams
AMIN TALATI WASSERMAN, LLP
100 S. Wacker Dr., Suite 200
Chicago, IL 60606
T: (312) 327-3383
jennifer@amintalati.com

Attorneys for *Amicus Curiae* The Council for Responsible Nutrition

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Circuit Rule 32-1(a) and Federal Rules of Appellate Procedure 32(a)(5)(A). This brief uses a proportional typeface and 14-point font, and contains 3,254 words.

Dated: April 14, 2020

Respectfully submitted,

By: *Jennifer M.S. Adams*

J. Kathleen Bond
Jennifer M.S. Adams
AMIN TALATI WASSERMAN, LLP
100 S. Wacker Dr., Suite 200
Chicago, IL 60606
T: (312) 327-3383
jennifer@amintalati.com

Attorneys for *Amicus Curiae* The Council for Responsible Nutrition

CERTIFICATE OF SERVICE

I hereby certify that on April 14, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Kirstin E. Largent