Docket No. 19-55739

In the

United States Court of Appeals

For the

Ninth Circuit

TATIANA KOROLSHTEYN,
on behalf of herself and all others similarly situated,

Plaintiff-Appellant,

v.

COSTCO WHOLESALE CORPORATION and NBTY, INC.,

Defendants-Appellees.

Appeal from a Decision of the United States District Court for the Southern District of California, No. 3:15-cv-00709-CAB-RBB · Honorable Cathy Ann Bencivengo

BRIEF OF *AMICUS CURIAE* COUNCIL FOR RESPONSIBLE NUTRITION IN SUPPORT OF APPELLEES COSTCO WHOLESALE CORPORATION AND NBTY, INC.

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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: June 23, 2020

Respectfully submitted,

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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, representing more than 160 companies worldwide marketing 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 in this matter filed a putative class action alleging that Costco Wholesale Corporation and NBTY, Inc. ("Defendants") have violated California law by labeling a store ginkgo biloba supplement as "support[ing] alertness and memory," "help[ing] with mental clarity," and "help[ing] maintain healthy blood flow to the brain." On June 25, 2019, the lower court properly granted Defendants' motion for summary judgment. The court held, correctly, that federal food and drug law expressly preempts Plaintiff-Appellant's claims where Plaintiff-Appellant seeks to impose a claim substantiation standard that is different from the carefully crafted federal standard and would deprive consumers of useful

nutritional information. CRN's interest as *Amicus Curiae* is to inform the Court as to existing federal law that protects consumer access to health-related information.

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. Defendant NBTY, Inc. is a CRN member, and an NBTY, Inc. employee serves on CRN's Board of Directors and Executive Committee.

SUMMARY OF ARGUMENT

On December 15, 2014, Plaintiff-Appellant Tatiana Korolshteyn filed a putative class action alleging that Defendants have violated California law by labeling a store brand dietary supplement, TruNature Ginkgo Biloba with Vinpocetine, as "support[ing] alertness and memory," "help[ing] with mental clarity," and "help[ing] maintain healthy blood flow to the brain." On June 25, 2019, the lower court granted Defendant's motion for summary judgement, finding that federal law expressly preempts Plaintiff-Appellant's claims. This holding is proper and in the public interest.

As the lower court held, the proper and long-standing federal substantiation standard for dietary supplement structure/function claims is "competent and reliable scientific evidence." Plaintiff-Appellant misconstrues the federal law and advances a novel and ill-conceived position that existing federal law imposes a strict drug-type substantiation standard. Where the substantiation standard Plaintiff-Appellant advances is "not identical" to the actual federal standard, federal law preempts Plaintiff-Appellant's state law action.

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"), an act amending the Food Drug & Cosmetic Act ("FDCA"), Congress for the first time required nutrition labeling on most foods and created new avenues for food and dietary supplement manufacturers to provide consumers health-related information. *See* Public Law 101-535. For both foods and dietary supplements, the NLEA first allowed "health claims," meaning claims that associate a food or dietary substance with reducing the risk of disease (*e.g.*, "Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life."). *See id.* at § 3; *see also* 21 U.S.C. § 343(r)(1)(B); *Whitaker v. Thompson*, 353 F.3d 947, at 952 (D.D.C. 2004); FDA, Questions and Answers on Health Claims in Food Labeling (current as of Dec. 13, 2017), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-health-claims-food-labeling. For such claims, Congress not only required FDA pre-approval, but also provided that FDA must apply a substantiation standard of "significant scientific agreement." *See* Public Law 101-535, § 3; *see also* 21 U.S.C. § 343(r)(3)(C); 21 C.F.R. § 101.14(a)(1). Under this standard, "the totality of publicly available scientific evidence (including evidence from well-designed

studies conducted in a manner which is consistent with generally recognized scientific procedures and principles)" must show "that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." *See* Public Law 101-535, § 3; *see also* 21 U.S.C. § 343(r)(3)(C); 21 C.F.R. § 101.14(a)(1).

Four years later, with the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Congress amended the 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 implemented two fundamental shifts in dietary supplement regulation. First, DSHEA exempted "dietary supplements" from either FDA drug approval or FDA food additive approval, finding both processes overly burdensome. *Id.* at § 3; *see also* 21 U.S.C. §§ 321(g)(1)(s). Second, DSHEA for the first time allowed dietary supplement "structure/function claims," defined as statements "describe[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." Pub. Law 103-417, § 6; *see also* 21 U.S.C. § 343(r)(6)(A). Rather than requiring a stringent substantiation standard of "significant scientific agreement" or anything similar, Congress simply provided that the dietary supplement marketer must possess "substantiation that such statement is truthful and not misleading." Pub. Law 103-417, § 6; *see also* 21 U.S.C. § 343(r)(6)(B).

In order to protect this unique, uniform system of dietary health benefit claims under NLEA and DSHEA, Congress prohibited any state law or action that would impose standards that are "not identical to" the federal requirements. Public Law 101-535, § 6; *see also* 21 U.S.C. § 343-1(a)(5); 21 C.F.R. § 100.1(c)(4); *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 847 (9th Cir. 2019).

II. "SUBSTANTIATION" FOR THE PURPOSES OF THE FDCA MEANS A BROAD, FLEXIBLE CARSE STANDARD

A. FTC and FDA Guidance Confirm that "Substantiation" Under the FDCA (21 U.S.C. § 343(r)(6)) Means a Broad, Flexible CARSE Standard

The FDA and FTC share overlapping jurisdiction over claims appearing in dietary supplement labeling and advertising. *See, e.g.*, 15 U.S.C. §§ 45(a)(1), 52(a); 21 U.S.C. § 331. Given its particular expertise as to advertising substantiation, the FTC for at least the past 15 years has taken the lead in regulating structure/function claim substantiation. The FDA, on the other hand, focuses primarily on product safety, review and approval of dietary supplement

"health claims" (*i.e.*, claims about reduced disease risk), and whether supplements are being promoted with unauthorized disease language, rather than allowable health claim or structure/function language.[1]

In the years following the passage of DSHEA, first the FTC then the FDA issued guidance elaborating on the "substantiation" required for dietary supplement structure/function claims. *See* FTC, Press Release, Business Guide for Dietary Supplement Industry Released by FTC Staff (Nov. 18, 1998), https://www.ftc.gov/news-events/press-releases/1998/11/business-guide-dietary-supplement-industry-released-ftc-staff; FTC, Dietary Supplements: An Advertising Guide for Industry (1998), https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf; FDA, Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) (Jan. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food.

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[1] *See, e.g.*, FTC & FDA Joint Warning Letter to Guna, Inc. (Jan. 11, 2018), https://www.ftc.gov/system/files/attachments/ftc-us-fda-warning-letters-january-2018/guna_inc_warning_letter_final_1-11-18.pdf (warning letter in which FTC challenges claims as lacking competent and reliable scientific evidence and FDA challenges claims as improper disease claims); FTC & FDA Joint Warning Letter to Jim Bakker Show (Mar. 6, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jim-bakker-show-604820-03062020 (same).

As memorialized in FTC and FDA guidance documents – and confirmed by extensive case law – "substantiation" under the FDCA requires dietary supplement structure/function claims to be supported based on a specific type of "competent and reliable scientific evidence" ("CARSE"). The FTC guidance states with absolute clarity that "the FTC has typically applied a substantiation standard of 'competent and reliable scientific evidence'" to dietary supplement structure/function claims, among other types of health-related claims. *See* Dietary Supplements: An Advertising Guide for Industry, at 9; *see also, e.g.*, *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, at 961 (N.D. Ill. 2006), aff'd 512 F.3d 858 (7th Cir. 2008) ("In other cases involving health-related claims, courts have upheld the FTC's requirement that in order to have a 'reasonable basis' to make the claim at issue, an advertiser must possess 'competent and reliable scientific evidence' to substantiate that claim."); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 299 (D. Mass. 2008) ("For health-related efficacy and safety claims, the FTC has commonly insisted on 'competent and reliable scientific evidence.'").

After identifying the CARSE standard, FTC guidance next explains that, in applying any substantiation standard, the *Pfizer* factors must be considered, first and foremost. *Id.* at 8-9. These factors are the "type of product," "the nature of the claims" at issue, the potential "benefits of a truthful claim," "the cost [and] feasibility of developing substantiation," the potential "consequences of a false

claim," and "the amount of substantiation experts in the field believe is reasonable." *Id.* at 8-9; *see also Pfizer Inc.*, 81 F.T.C. 23, 65 (1972).

Applying the *Pfizer* factors, the FTC guidance explains further that, specifically for dietary supplement structure/function claims, "[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration." Dietary Supplements: An Advertising Guide for Industry, at 10. While "well-controlled human clinical studies" are considered "the most reliable form of evidence," "all forms" of scientific evidence including, for example, epidemiologic evidence and animal or *in vitro* studies may form the basis for dietary supplement structure/function claims. *Id.* The FTC's guidance then observes that beyond considering simply the reliability of any single study, regulators will also consider the "totality of the evidence" and whether the evidence is "relevant" to the product and claims at issue – meaning for instance, whether a study population is similar to a product's target audience. *Id.* at 8-9, 14-16. The guidance also states that "a guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." *Id.*

In this context, the totality of evidence consideration is unlike a strict drug or disease claim analysis. Rather, FTC guidance advises that "[w]here there are inconsistencies in the evidence, it is important to examine whether there is a

plausible explanation for those inconsistencies" and that "[i]n some instances, for example, the differences in results are attributable to differences in dosage, the form of administration (e.g., oral or intravenous), the population tested, or other aspects of study methodology." *Id.* at 14. The guidance also states, "If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies." *Id.*

With the *Pfizer* factors, and all other factors, considered throughout the analysis, no single factor can upend this CARSE standard to require drug level testing for a dietary supplement structure/function claims. The CARSE standard applicable to dietary supplement structure/function claims "is not the drug standard." *U.S. v. Bayer Corp.*, No. 07-01(JLL), at *9 (D.N.J. Sept. 24, 2015). Throughout the analysis, all factors work together to provide context to ensure the standard "is sufficiently flexible to ensure that consumers have access [even] to information about emerging areas of science." Dietary Supplements: An Advertising Guide for Industry, at 8.

Careful application of this CARSE standard serves numerous purposes including: promoting the dissemination of potentially beneficial health-related information, as Congress intended under DSHEA; avoiding running afoul of the First Amendment; and preventing absurd outcomes like a dietary supplement structure/function claim being held to the same incredibly stringent and expensive

FDA approval standards for prescription drugs or even FDA authorization standards for "health claims" (*i.e.*, claims about reduced risk of disease). *See, e.g.*, Commissioner Robert Pitofsky, Consumer Protection and the Regulation of Advertising, 90 HARV. L. REV. 661, 671 (1977) (stating that the overall goal of evaluating claim substantiation is not "a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable competitive market process"); *QT, Inc.*, 512 F.3d at 862 ("[P]lacebo-controlled double-blind testing is not a legal requirement for consumer products. . . . A placebo-controlled, double-blind study is the best test; something less may do (for there is no point in spending $1 million to verify a claim worth only $10,000 if true).").

After the FTC issued its guidance, FDA issued its own guidance explaining that it would follow the FTC in applying the exact same broad, flexible CARSE standard in requiring "substantiation" for dietary supplement structure/function claims for the purposes of the FDCA (21 U.S.C. § 343(r)(6)(B)). *See* Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) ("We intend to apply a standard that is consistent with the FTC standard of 'competent and reliable scientific evidence' to substantiate a claim").

Against this background, there is no doubt that the lower court was absolutely correct that dietary supplement structure/function claims require the

application of the well-reasoned and well-developed federal CARSE standard. *See Korolshteyn v. Costco Wholesale Corp.*, 393 F. Supp. 3d 1019, 1023 (S.D. Cal. 2019) ("The FDCA does not define the term "substantiation," but FDA guidance advances a common sense interpretation of "substantiation," as meaning "competent and reliable scientific evidence.").

B. Courts Have Affirmed that a Broad, Flexible CARSE Standard Applies to Dietary Supplement Structure/Function Claims

In numerous litigated cases from the past several years, courts have affirmed that the FTC's broad, flexible CARSE standard applies to dietary supplement structure/function claims. *See, e.g.*, *Bayer Corp.*, No. 07-01(JLL); *FTC v. Garden of Life, Inc.*, 845 F. Supp. 2d 1328 (S.D. Fla. 2012), aff'd, 516 F. App'x 852 (11th Cir. 2013) (rejecting FTC arguments that a study supporting dietary supplement structure/function claims was "fatally flawed" where defendant "obtained competent and reliable evidence" in the form of a report from a qualified scientific expert supporting the claims; stating that finding defendant liable "solely because another well-respected expert defines 'brain development' differently or disagrees with certain aspects of a study's 'trial design' would require this Court to read additional requirements" into the CARSE standard); *Basic Research, LLC v. FTC*, No. 2:09-cv-00779-CW, 2014 U.S. Dist. LEXIS 169043, *35-36 (Nov. 25, 2014) (crediting defendant's evidence in support of its dietary supplement structure/function claims

and noting that "implicit in" FTC's application of the CARSE standard "is the expectation of reasonableness"). *Contrast, e.g.*, *Daniel Chapter One*, FTC Opinion, No. 9329, at 20 (Dec. 24, 2009) (requiring "controlled clinical studies" where defendants promoted dietary supplements with disease claims such as "'treat or cure' cancer, eliminate or shrink tumors, and/or ameliorate the adverse effects of radiation and chemotherapy").

In fact, last year, this Court reviewed a plaintiff's action challenging claims that a vitamin E supplement "'support[s] cardiovascular health' and 'promote[s] immune function,' 'immune health,' 'heart health,' and 'circulatory health.'" *Dachauer*, 913 F.3d at 846. This Court acknowledged correctly that, under the FDCA, for such structure/function claims, the defendant must possess "substantiation that the statement is truthful and not misleading." *Id.* at 846-847 (citing 21 U.S.C. § 343(r)(6)). Despite the clear non-disease, structure/function wording of the claims at issue, the plaintiff sought "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." *Id.* 848. This Court easily held that such a substantiation requirement "is not identical to the requirement of section 343(r)" (quoting 21 U.S.C.§ 343-1(a)(5)), and as such the FDCA "preempts Plaintiff's claims." *Id.*

As explained further below, the Plaintiff seeks to carve up the federal "substantiation" requirement (21 U.S.C. § 343(r)(6)) in order to impose a stringent drug-type substantiation standard that is more appropriate to disease or drug claims.

III. THE FDCA PREEMPTS PLAINTIFF-APPELLANT'S ACTION WHERE PLAINTIFF-APPELLANT SEEKS TO IMPOSE A NOVEL SUBSTANTIATION STANDARD FOR DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS

In this action, Plaintiff-Appellant alleges that Defendants have violated California false advertising and unfair competition laws (Cal. Bus. & Prof Code §§ 17200, 1770, Cal. Civ. Code § 1750) by labeling a store brand dietary supplement, TruNature Ginkgo Biloba with Vinpocetine, as "support[ing] alertness and memory," "help[ing] with mental clarity," and "help[ing] maintain healthy blood flow to the brain." Plaintiff-Appellant argues that, in assessing evidence in support of such dietary supplement structure/function claims, both government regulators and private plaintiffs must "weigh[] the totality of the evidence," absent any other practical or public health considerations. Opening Brief, at 32. According to the Plaintiff-Appellant if Defendants have failed to meet this novel, drug-type standard, they have engaged in false advertising for the purposes of California law. This ill-conceived action by Plaintiff-Appellant cannot stand. As described above in Section I, the FDCA bars actions that would impose standards that are "not identical to" the federal standards governing structure/function claims. 21 U.S.C. §

343-1(a)(5); 21 C.F.R. § 100.1(c)(4); *Dachauer*, 913 F.3d at 847. As described in Section II, federal law could not be clearer that the FDCA "substantiation" standard is most decidedly not a drug standard, or some search for absolute truth absent practical considerations that protect consumer access to health information. Federal law, rather, applies a flexible, multifaceted CARSE standard where a specific type of "totality of evidence" analysis is only one of the several important, practical considerations that must be balanced and considered. The correct federal standard undeniably requires consideration of the "type of product," "the nature of the claims" at issue, the potential "benefits of a truthful claim," "the cost [and] feasibility of developing substantiation," the potential "consequences of a false claim," and "the amount of substantiation experts in the field believe is reasonable." *See* Dietary Supplements: An Advertising Guide for Industry, at 8-9; *see also Pfizer Inc.*, 81 F.T.C. at 65.

In defending her novel and entirely different drug-type substantiation standard, Plaintiff-Appellant cites material such as a general reference manual on scientific evidence and state law cases finding that California's Unfair Competition Law and Consumer Legal Remedies Act require "consideration and weighing of evidence from both sides." Opening Brief, at 32, 32 n.9. What is glaringly absent from Plaintiff-Appellant's arguments is citation to any case, guidance document, or anything else that has ever found that, for simple non-disease structure/function

claims like those at issue here, the FDCA requires a sterile drug-type substantiation analysis absent any practical considerations such as the "type of product," "the nature of the claims" at issue, the potential "benefits of a truthful claim," "the cost [and] feasibility of developing substantiation," the potential "consequences of a false claim," and "the amount of substantiation experts in the field believe is reasonable." *See* Dietary Supplements: An Advertising Guide for Industry, at 8-9; *see also Pfizer Inc.*, 81 F.T.C. at 65. The Plaintiff-Appellant does not cite such materials because she could not.

The FDCA preempts Plaintiff-Appellant's where it seeks to impose a drug-style standard that is on its face "not identical to" the FDCA "substantiation" standard, the action. The lower court thus properly held that "Plaintiff's claims would seek to impose requirements under California law that either alters or adds to the [FDCA] requirement that the manufacturer has substantiation that structure/function claims are truthful and not misleading." *Korolshteyn*, 393 F. Supp. 3d at 1025. Therefore, Plaintiff-Appellant's "state false advertising claims are preempted." *Id.* This holding is entirely correct.

IV. UPHOLDING THE LOWER COURT DECISION WILL SERVE PUBLIC HEALTH

The courts have long held that health-related commercial speech is vital to informed consumer decision-making and that the bar for health-related claims cannot be set so high that consumers lose access to useful information. *See, e.g.*,

Virginia Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, at 765 (1976); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 227-229, 237 (S.D.N.Y. 2015); *Pearson v. Shalala*, 164 F.3d 650, 655, 659-660 (D.C. Cir. 1999). Consistent with such precedent, as described above, the CARSE standard for dietary supplement structure/function claims is *not* a strict drug-style standard.

While most government assessments of claim substantiation occur without the opportunity for public observation, the FDA's approval of "health claims" (claims associating a dietary substance with disease risk reduction) utilizes notice and comment rulemaking. *See* 21 U.S.C. § 343(r)(1)(b); 21 C.F.R. § 101.14(a)(1). The FDA's approval of a health claim for folic acid and reduced risk of neural tube defects provides an example illustrating the complex nature of nutrition science and the imperative for flexibility.

As described in Section I above, the substantiation standard for health claims is "significant scientific agreement." *See* 21 U.S.C. § 343(r)(3)(C); 21 C.F.R. § 101.14(a)(1). Thus, it is a more stringent standard than the broad, flexible CARSE standard that applies to dietary supplement structure/function claims. The example below of the process surrounding FDA's approval of a folic acid health claim nevertheless demonstrates that even under a higher substantiation standard, the analysis of the science is *not* a drug level standard or search for absolute scientific "truth."

Neural tube defects are birth defects affecting the brain, spine, or spinal cord. *See* https://medlineplus.gov/neuraltubedefects.html. The two most common types are spina bifida and anencephaly. *Id.* In determining whether to authorize a claim associating folic acid with reduced risk of neural tube defects, the FDA convened the Folic Acid Subcommittee to assist in its review, and the agency sought comments from stakeholders including other agencies, healthcare professionals, and industry. *See* 61 Fed. Reg. 8752, 8755 (Mar. 5, 1996). Only a small number of relevant studies existed: two randomized controlled studies and five observational studies. *Id.* at 8756.

The FDA received numerous comments representing divergent views on the science, and even its own convened panel did not reach consensus on authorizing a claim. "[M]embers of the Folic Acid Subcommittee who opposed a health claim cited the weakness of the data supporting the relationship, including the very small number, and observational nature, of studies relating intake of folate at levels attainable from usual diets to reduced risk of neural tube defects and the many issues associated with the interpretation of these studies." *Id.* at 8756. The FDA itself acknowledged that "there are still significant gaps in our knowledge about the etiology of neural tube defects; about how folate, either alone or in combination with other nutrients, reduces the risk of neural tube defects; about dose-response relationships between folate intake and reduction in risk of neural

tube defect-affected pregnancies; and about the role of other essential nutrients in the etiology of neural tube defects." *Id.*

Despite the divergent views, the FDA authorized a health claim for folic acid and reduced risk of neural tube defects – meaning it promulgated a rule allowing food and dietary supplements to make claims such as the following: "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect." *Id.* at 8752; 21 C.F.R. § 101.79 (rule authorizing folic acid health claim). The agency determined that enough evidence existed, and it stated that "it . . . expected that consumption of adequate folate will avert some, but not all, neural tube defects." 61 Fed. Reg. at 8780. The authorized folic acid health claim remains in place and provides a uniform standard, allowing the claim to be used in dietary supplement and food marketing.

In 1996, the same year that FDA approved the folic acid health claim, it also mandated – presumably, based on the same science that existed at the time – that enriched cereal grain products be fortified with folic acid. *See* 21 C.F.R. § 104.20. The increased awareness of and access to folic acid has no doubt impacted public health positively. Between 1995 and 2011, based on 19 population-based surveillance programs, the Centers for Disease Control reported a substantial 28 percent reduction in anencephaly and spina bifida, with an even higher 35 percent reduction among programs with prenatal ascertainment. *See* Williams, *et al.*

Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification — United States, 1995–2011 (Jan. 16, 2015), https://www.cdc.gov/MMWr/preview/mmwrhtml/mm6401a2.htm#tab.

As another example, the FDA has approved a health claim associating calcium with a reduced risk of osteoporosis, a disease that causes bones to become brittle and more prone to fracture. *See* 21 C.F.R. § 101.72. Despite this approval, the science on bone health and calcium is complex, voluminous, and ever-growing, with some studies showing, for instance, no connection between calcium and risk of bone fracture. *See, e.g.*, Bolland, *et al.* Calcium intake and risk of fracture: systematic review, *BMJ* 2015;315:h4580, https://www.bmj.com/content/bmj/351/bmj.h4580.full.pdf (meta-analysis concluding that "Dietary calcium intake is not associated with risk of fracture, and there is no clinical trial evidence that increasing calcium intake from dietary sources prevents fractures").

Against this background, if health-related science is not assessed with flexibility and a public health mindset, as required by federal law, consumers stand to lose. In this case, Plaintiff-Appellant has made absolutely no attempt to defend her case under applicable federal law as either practical or in the public interest. This omission is no surprise where there is no dispute that Plaintiff's store brand products are safe and inexpensive. The products are, at best, incredibly

helpful to consumers given the science, or even at worst, only potentially beneficial for consumers. As noted in Section I, in passing DSHEA, Congress observed that "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"; thus, consumers "should be empowered to make choices" about taking them. Pub. Law 103-417, at § 2. In order to create that empowerment to provide consumers nutritional information, Congress created the category of non-disease structure/function claims – just like those at issue here – and applied a flexible non-disease, non-drug claim substantiation standard, requiring simply "substantiation that [the claim] is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). Congress protected this carefully crafted federal claim regime with express preemption to prevent opportunistic state law cases just like this one that stand to disrupt consumer access to products and information. 21 U.S.C. § 343-1(a)(5). *See also* 21 C.F.R. § 100.1(c)(4); *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 847 (9th Cir. 2019).

In upholding the lower court decision, this Court will uphold the flexible and practical federal CARSE "substantiation" standard, which accounts for the complexities of nutrition science and allows consumers reasonable access to nutritional information and products. ***If private actors are allowed to apply a stricter substantiation standard or seize on any inconsistency or weakness that***

might be found in a complex body of research, both dietary supplement marketers – and consumers who rely on their products – stand to be harmed. Allowing a patchwork of conflicting private actor-driven decisions on any single dietary ingredient stands to discourage manufacturers from innovating in the nutrition space, or disseminating health benefit claims at all.

V. PLAINTIFF-APPELLANT INCORRECTLY ASSERTS THAT UPHOLDING THE LOWER COURT DECISION WILL THREATEN CONSUMER SAFETY

Plaintiff-Appellant posits that upholding the lower court decision in this case will present a "serious threat to consumer safety." Opening Brief, at 44. This could not be further from the truth. First, this case has nothing to do with consumer safety. Second, if the Court correctly upholds the lower court decision, the regulation of dietary supplements will continue in full force, as Congress intended. ***The FTC and FDA will continue to take enforcement action, and where state governmental or private actions align with federal law, such cases – including consumer class actions – will continue.***

The FTC, in the past three years alone, has brought over 30 public enforcement actions over dietary supplement claims, while the FDA has taken public enforcement action in over 120 instances. FTC orders against supplement sellers normally bind both corporate and individual defendants, enjoin future violations of the FTCA, and require monetary redress, often in the millions. *See,*

e.g., Order, *FTC v. Nat'l Urological Grp., Inc.*, No. 1:04-cv-03294-CAP (N.D. Ga. Oct. 10, 2017) ($40 million in consumer redress); Order, *FTC v. XXL Impression, LLC*, No. 1:17-cv-00067-NT (D. Me. Sept. 13, 2017) ($6,574,957 in consumer redress).

States likewise have and will no doubt continue to regulate dietary supplement claims. *See, e.g.*, Press Release, Alameda District Attorney's Office, District Attorney Nancy E. O'Malley Announces $800,000 Settlement (Nov. 26, 2012), http://www.acgov.org/news/pressreleases/2012-11-26SensaSettlement.pdf; Press Release, Santa Clara District Attorney's Office, Diet Supplement Distributor to Pay $2.65 Million for False Advertising and Failure to Disclose Lead Content (Feb. 2, 2011), https://www.sccgov.org/sites/da/newsroom/newsreleases/Pages/NRA2011/irwinnaturalsinc.aspx; Press Release, Oregon Dept. of Justice, AG Rosenblum Settles with Vitamin Shoppe over Dietary Supplements (March 7, 2017), https://www.doj.state.or.us/media-home/news-media-releases/ag-rosenblum-settles-with-vitamin-shoppe-over-dietary-supplements/ (announcing $545,000 settlement); Press Release, Iowa Attorney General's Office, Dietary Supplement Sellers Barred from Iowa after Allegedly False Claims to "Put an End" to Bladder Control Problems (Sept. 13, 2016), https://www.iowaattorneygeneral.gov/newsroom/dietary-supplement-sellers-barred-from-iowa-after-alleged-false-claims-to-put-an-end-to-bladder-co (announcing $30,000 settlement).

As this Court is aware, in addition government regulation, numerous private class actions have been brought against dietary supplements in recent years. There is no reason to believe such cases would be blocked simply because this Court requires that (1) private plaintiff actions align with the unique federal law applicable to dietary supplements, and (2) plaintiffs abide by California's prohibition on private actors demanding claim substantiation. This Court and California district courts routinely allow consumer class actions to proceed where allegations against dietary supplement structure/function claims are consistent with this federal and California law. *See, e.g.*, *Dachauer*, 913 F.3d at 847 (allowing one allegation to proceed where this Court found it consistent with FDCA standards); *Chavez v. Nestle, Inc.*, 511 Fed. Appx. 606, 606-607 (9th Cir. 2013); *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 893, 896 (N.D. Cal. 2016); *Racies v. Quincy Bioscience, LLC*, Case No. 15-cv-00292-HSG, 2015 U.S. Dist. LEXIS 65468, 2015 WL 2398268, at *3-4 (N.D. Cal. May 19, 2015) (allowing certain allegations to proceed to a jury where court found them consistent with FDCA standards). *See also, e.g.*, *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 543-44 (S.D.N.Y. 2013); *In re GNC*, 789 F.3d 505, 516 (4th Cir. 2015).

CONCLUSION

For the foregoing reasons, CRN urges the Ninth Circuit to affirm the lower decision in this case.

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Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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