Case No. 19-55671

In the

United States Court of Appeals

for the

Ninth Circuit

JAMES KROESSLER,
individually, and on behalf of all others similarly situated,
Plaintiff-Appellant,

v.

CVS HEALTH CORPORATION,
Defendant-Appellee.

Appeal from a Decision of the United States District Court for the Southern District of California, Case No. 3:19-cv-00277-CAB-JLB · Honorable Cathy Ann Bencivengo, District Judge

BRIEF OF *AMICUS CURIAE* THE COUNCIL FOR RESPONSIBLE NUTRITION IN SUPPORT OF DEFENDANT-APPELLEE AND AFFIRMANCE

J. KATHLEEN BOND
JENNIFER M.S. ADAMS
AMIN TALATI WASSERMAN, LLP
100 South Wacker Drive, Suite 200
Chicago, Illinois 60606
(312) 327-3383 Telephone
jennifer@amintalati.com

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)(4)(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: January 31, 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 ii

INTEREST AND IDENTITY OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 4

I. With the NLEA and DSHEA, Congress Created a Uniform Regulatory Regime Intended to Provide Consumers Greater Access to Dietary Health Benefit Information 4

II. The FDCA Preempts the Plaintiff-Appellant's Case Where Plaintiff-Appellant Seeks to Impose Standards Different from the Federal Law Defining "Structure/Function" Claims 6

III. The FDCA Preempts Plaintiff-Appellant's action Where Plaintiff- Appellant Seeks to Impose a New Substantiation Standard for Dietary Supplement Structure/function Claims 10

IV. Plaintiff-Appellant Incorrectly Asserts that There Is Little Federal Oversight of Dietary Supplement Advertising 15

CONCLUSION 16

CERTIFICATE OF COMPLIANCE 17

CERTIFICATE OF SERVICE 18

TABLE OF AUTHORITIES

CASES **Page(s)**

Dachauer v. NBTY, Inc.,
913 F.3d 844 (9th Cir. 2019) 6, 11

FDA v. Brown & Williamson Tobacco Corp.,
529 U.S. 120 (2000).....9

FTC v. Nat'l Urological Grp., Inc.,
No. 1:04-cv-03294-CAP (N.D. Ga. Oct. 10, 2017).....15, 16

FTC v. XXL Impression, LLC,
No. 1:17-cv-00067-NT (D. Me. Sept. 13, 2017).....16

Gallagher v. Bayer AG,
No. 14-cv-04601-WHO, 2015 U.S. Dist. LEXIS 29326
(N.D. Cal. Mar. 10, 2015).....9

Luman v. NAC Mktg. Co., LLC,
No. 2:13-cv-00656-KJM-AC, 2017 U.S. Dist. LEXIS 125498
(9th Cir. Aug. 8, 2017).....10

Pfizer Inc.,
81 F.T.C. 23 (1972) 13, 14

STATUTES

21 U.S.C. § 321(g) 9

21 U.S.C. § 321(g)(1)(s) 5, 11

21 U.S.C. § 321(h) 9

21 U.S.C. § 343(r)(1)(B).....4

21 U.S.C. § 343(r)(3)(C).....4, 5

21 U.S.C. § 343(r)(6) 7

21 U.S.C. § 343(r)(6)(A).....5

21 U.S.C. § 343(r)(6)(B).....6, 12

21 U.S.C. § 343-1(a)(5) 6, 9, 11

RULES

Fed. R. App. P. 29(a)(3) 1

REGULATIONS

21 C.F.R. § 100.1(c)(4) 6, 9, 11

21 C.F.R. § 101.14(a)(1) 4, 5, 7

21 C.F.R. § 101.93 7

21 C.F.R. § 101.93(g) 7

21 C.F.R. § 201.128 9

OTHER AUTHORITIES

65 Fed. Reg. 999 (Jan. 6, 2000) 7, 8

FDA, Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) (Jan. 2009) 12, 14

FTC, Dietary Supplements: An Advertising Guide for Industry (1998) 12, 13

Pub. Law 101-535 4

Pub. Law 103-417 ..... 5, 11

INTEREST AND IDENTITY OF AMICUS CURIAE

The Council for Responsible Nutrition ("CRN") files this *Amicus Curiae* brief pursuant to a motion for leave under Federal Rule of Appellate Procedure 29(a)(3). 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 CVS Health Corporation ("CVS") has violated California law by advertising its store brand glucosamine supplements as supporting "JOINT HEALTH" and otherwise benefitting joint function. On May 16, 2019, the lower court properly granted CVS's motion to dismiss, finding that federal food and drug law expressly preempts Plaintiff-Appellant's claims.

CRN's interest as *Amicus Curiae* is to inform the Court as to the importance of the lower court decision to responsible industry and consumers. If the lower court decision is reversed, and the nutrition space becomes beholden to an

unchecked plaintiff's bar, federal law and the authority of government actors will be diluted as a patchwork of state common law takes shape. Investing in research will become riskier than ever before in a space where there is little patent protection. Product prices will rise, or products may simply not be sold.

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 February 7, 2019, Plaintiff-Appellant James Kroessler filed a putative class action alleging that CVS violated California law by advertising its store brand glucosamine supplements as supporting "JOINT HEALTH" and otherwise benefiting joint function. On May 16, 2019, the lower court granted CVS's motion to dismiss, 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. Plaintiff-Appellant's arguments against the lower court's decision are legally incorrect and fail to recognize the invaluable role the federal government plays in protecting consumer access to health-related information.

First, Plaintiff-Appellant argues that CVS's joint health claims are unauthorized disease claims, rather than allowable dietary supplement "structure/function" claims. These arguments run counter to the federal Food, Drug, and Cosmetic Act ("FDCA"), which provides a uniform, federal regime for dietary supplement structure/function claims. Under the plain terms of the FDCA, Plaintiff cannot – and as a public health matter should not – create new and different standards that conflict with this federal law.

Second, Plaintiff-Appellant advances a novel, ill-conceived position that existing state and federal law require structure/function claims to be substantiated with a drug-type "totality of the evidence." CRN agrees with CVS that the district court did not need to consider the applicable substantiation standards and that the district court explicitly disclaimed any lack of substantiation theory by observing that California law does not allow private plaintiffs to demand advertising substantiation. CRN addresses the Plaintiff's irrelevant arguments on substantiation due only to grave concerns that his arguments could disrupt an important federal regime. For dietary supplement structure/function claims, federal law applies a broad, flexible "competent and reliable scientific evidence" standard, not a drug-type "totality of the evidence" standard.

Finally, as a policy matter, Plaintiff-Appellant argues that there is little federal oversight of dietary supplement advertising. This position ignores extensive

and stringent Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") enforcement.

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 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," 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). For such claims, Congress not only required FDA pre-approval, but also provided that FDA must apply a substantiation standard of "significant scientific agreement." 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." 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. 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." 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." 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. 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 dietary supplements can benefit health.

II. THE FDCA PREEMPTS THE PLAINTIFF-APPELLANT'S CASE WHERE PLAINTIFF-APPELLANT SEEKS TO IMPOSE STANDARDS DIFFERENT FROM THE FEDERAL LAW DEFINING "STRUCTURE/FUNCTION" CLAIMS

Plaintiff-Appellant's action is preempted insofar as he seeks to impose requirements different from the federal standards distinguishing structure/function claims from "health claims" or other disease or drug claims. As noted in Section I, the FDCA defines dietary supplement structure/function claims 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." 21 U.S.C. § 343(r)(6). Under federal law, as long as a company meets requirements for notification and "substantiation," it may promote "structure/function claims" without agency pre-approval. *See* 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93. By contrast, pre-approval is required for "health claims" or any other "claims to diagnose, mitigate, treat, cure, or prevent disease," defined as "damage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.*, cardiovascular disease), or a state of health leading to such dysfunctioning (*e.g.*, hypertension)." 21 C.F.R. § 101.93(g); 21 C.F.R. § 101.14(a)(1).

Under these federal regulatory standards, CVS's claims could not possibly be disease claims, rather than structure/function claims. CVS claims only that its products support "JOINT HEALTH" and otherwise "support," "maintain" or "help to promote" joint comfort, flexibility, and mobility. Opening Brief, at 6. These claims make no express or implied mention of any disease, and rather, do nothing more than describe the role of glucosamine products in positively affecting the function of joints.

FDA guidance and enforcement underscores this point. As to joint health, FDA guidance indicates that "*helps support cartilage and joint function*" is an acceptable structure/function claim. 65 Fed. Reg. 999, at 1013 (Jan. 6, 2000). On the other hand, guidance provides that FDA would normally consider the following

to be a disease claim indicating treatment of arthritis: "*improves joint mobility and reduces joint inflammation and pain*." *Id.*

In response to companies' structure/function claim notifications, FDA will occasionally send so-called "courtesy letters" where an FDA staff member provides his or her opinion that the agency is likely to treat a claim as a disease claim, rather than a structure/function claim. Such courtesy letters have been sent where companies used – in whole or in part – the same disease language FDA guidance identifies. For instance, Plaintiff-Appellant is correct that Nature's Bounty (formerly NBTY) received a courtesy letter objecting to the claim, "the only joint care brand with Joint Shield help . . . and improve joint mobility." ER68. NBTY heeded this informal objection and did not market a product with this claim.

Formal FDA warning letters have identified as disease claims much clearer language that lines up even more precisely with the agency's guidance. For instance, warning letters have identified as disease claims language such as "used in humans to reduce pain in bones and joints and to improve mobility" and "reduce joint swelling and stiffness." *See, e.g.*, FDA Warning Letter to VitaPurity Corp. (May 12, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vitapurity-corporation-514472-05122017); FDA Warning Letter to Baker's Best Health Products, Inc. (Apr. 25, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-

investigations/warning-letters/bakers-best-health-products-inc-544600-04252018. CVS has not made any similar claims and, accordingly, has never received an FDA warning letter or even a courtesy letter.

In arguing that CVS's claims are disease claims, Plaintiff-Appellant distorts the foregoing federal FDA standards and enforcement. Where the standards he pushes are "not identical" to the federal standards, his claims are pre-empted. 21 U.S.C. § 343-1(a)(5); 21 C.F.R. § 100.1(c)(4); *Gallagher v. Bayer AG*, No. 14-cv-04601-WHO, 2015 U.S. Dist. LEXIS 29326 (N.D. Cal. Mar. 10, 2015).

In addition to distorting the clear federal law, the Plaintiff-Appellant incorrectly relies on cases on "intended use" to argue that CVS's claims are disease claims versus structure/function claims. Opening Brief at 31-34. FDA relies on the "intended use" doctrine to determine if a product is subject to regulation under the statutory definition of a "drug" or "new drug" and thus would require additional labeling or other precautions to ensure consumer safe use of the product – not whether a claim is a disease or structure/function claim. *See* 21 U.S.C. § 321(g),(h); 21 C.F.R. § 201.128; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In fact, Plaintiff-Appellant's own description of the "intended use" doctrine highlights that it is a separate inquiry from whether a claim is an appropriate structure/function claim. Opening Brief, at 39 ("FDA may find that a dietary supplement for which *only structure/function claims are made in labeling*

may nevertheless be a drug if there is other evidence of intended use to prevent or treat disease. 65 FR 1000 at 1006.") (emphasis added). "Intended use" law is irrelevant, and in any case, determining the "intended use" of a product is within the sole primary jurisdiction of the FDA. *Luman v. NAC Mktg. Co., LLC*, No. 2:13-cv-00656-KJM-AC, 2017 U.S. Dist. LEXIS 125498, at *11-14 (9th Cir. Aug. 8, 2017) ("[B]ecause plaintiff's claims require a determination of whether defendant's product is a 'new drug,' the primary jurisdiction doctrine applies.").

The FDCA and FDA regulations precisely address what constitutes dietary supplement structure/function claims versus disease claims. As such, this law is obviously controlling and makes clear that CVS's claims are proper structure/function claims.

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

CRN agrees with CVS that the district court did not need to consider the applicable substantiation standards and that the district court explicitly disclaimed any lack of substantiation theory by stating twice that "California law does not allow private plaintiffs to demand substantiation for advertising claims.'" Answering Brief, at 33 (quoting ER 9, 11). CRN addresses the Plaintiff's irrelevant arguments on substantiation due only to grave concerns that his arguments could disrupt an important federal regime.

As stated 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. The Plaintiff-Appellant's action is thus preempted where he seeks to impose a heightened substantiation standard that federal law applies *only* to "health claims" or other disease or drug claims, rather than dietary supplement structure/function claims.

Plaintiff-Appellant vehemently argues that, in assessing substantiation for dietary supplement structure/function claims, both government regulators and private plaintiffs must "weigh the totality of the evidence using the principles of evidence-based medicine." Opening Brief, at 11. However, federal law could not be clearer that the FDCA "substantiation" standard is most decidedly not this type of drug or "medicine" standard. Federal law, rather, applies a flexible, multifaceted competent and reliable scientific evidence ("CARSE") standard where the "totality of evidence" is only one of several important factors that must be balanced and considered.

As discussed in Section I, with DSHEA, Congress exempted dietary supplements from either FDA drug approval or FDA food additive approval, finding both processes overly burdensome. Pub. Law 103-417, §§ 3(b), 10 (amending 21 U.S.C. §§ 321(g)(1)(s)). Congress also avoided imposing on dietary

supplement structure/function claims the "significant scientific agreement standard" applicable to "health claims." 21 U.S.C. § 343(r)(6)(B). Congress, instead, simply required "substantiation that such statement[s] [are] truthful and not misleading." *Id.* This background on DSHEA makes abundantly clear that "substantiation" under the FDCA could not possibly be the strict drug-type "evidence-based medicine" standard the Plaintiff-Appellant advances.

FTC and FDA guidance and enforcement further confirm that the DSHEA "substantiation" standard is a broad, flexible CARSE standard. 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* Press Release, FTC, 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.

The FTC guidance states with absolute clarity that for dietary supplement structure/function claims, the agency applies a standard of "competent and reliable scientific evidence, defined in FTC cases as 'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'" *See* Dietary Supplements: An Advertising Guide for Industry, at 9. FTC guidance elaborates that, in applying this standard, the *Pfizer* factors must be considered, first and foremost, and throughout the CARSE analysis. *Id.* at 8-9. These factors are the "type of product," "the nature of the claims" made, "the potential benefits of a truthful claims," "the cost of developing substantiation," and "the amount of evidence experts in the field believe is reasonable." *Id.* at 8-9; *see also Pfizer Inc.*, 81 F.T.C. 23, 65 (1972).

The guidance further explains that, within the context of the *Pfizer* factors, "[t]here is no fixed formula for the number or type of studies required." 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 explains 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.

With the *Pfizer* factors, and all other factors, considered throughout the analysis, no single factor – like the totality of evidence – can upend the CARSE standard to require drug level testing for a dietary supplement structure/function claims, as the Plaintiff-Appellant would have to argue. Rather, the totality of evidence is among the many important considerations for assessing science for simple, non-disease structure/function claims. Throughout the analysis, all factors work together to provide constant context to ensure the FTC's CARSE "standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access [even] to information about emerging areas of science. *Id.* at 8.

Several years after the FTC issued its guidance, FDA issued guidance explaining that it would follow the FTC, applying the exact same broad, flexible CARSE standard in requiring "substantiation" for dietary supplement structure/function claims. *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").

The Plaintiff-Appellant's case is thus clearly preempted where he seeks to apply a stringent a drug or "medicine" style "totality of the evidence" standard. If such a standard were applicable, it would necessarily lead to absurd results that are harmful for consumers. Dietary supplement structure/function claims could easily be held to the same incredibly exacting scientific standards as "health claims" or even prescription drug claims, despite DSHEA and despite the stark differences among the types of claims.

The Court should find that the Plaintiff-Appellant's action is preempted where it seeks to impose an entirely different substantiation standard than the FDCA.

IV. PLAINTIFF-APPELLANT INCORRECTLY ASSERTS THAT THERE IS LITTLE FEDERAL OVERSIGHT OF DIETARY SUPPLEMENT ADVERTISING

Plaintiff-Appellant suggests that any limit on private class actions will leave advertising for dietary supplements unregulated. Opening Brief, at 3. This could not be further from the truth. The FTC, in the past three years alone, has brought over 30 enforcement actions over dietary supplement claims, while the FDA has taken 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).

In addition to the FTC and FDA, the National Advertising Division, a well-regarding self-regulatory forum, has an entire unit devoted solely to dietary supplement cases. *See* http://asrcreviews.org/category/nad/about_nad/. As of this *Amicus Curiae*, the Council for Responsible Nutrition' s non-profit foundation – the Council for Responsible Nutrition Foundation, helps fund this unit. In the past three years, NAD has heard over 50 cases involving dietary supplement advertising.

CONCLUSION

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

Dated: January 31, 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 FRAP 32(a)(5)(A) and FRAP 29(a)(5). This brief uses a proportional typeface and 14-point font, and contains 3,248 words.

Dated: January 31, 2020

By: *Jennifer M.S. Adams*
J. Kathleen Bond
Jennifer M.S. Adams
AMIN TALATI WASSERMAN, LLP

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 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.

By: *Jennifer M.S. Adams*
J. Kathleen Bond
Jennifer M.S. Adams
AMIN TALATI WASSERMAN, LLP