No. 17-55261

In the United States Court of Appeals for the Ninth Circuit

KATHLEEN SONNER, on behalf of herself and all others similarly situated,

Plaintiff-Appellant,

v.

SCHWABE NORTH AMERICA, INC.; NATURES WAY PRODUCTS, LLC,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of California, Riverside, No. 5:15-cv-01358-VAP-SP.
The Honorable **Virginia A. Phillips**, Judge Presiding.

AMICUS CURIAE BRIEF OF THE COUNCIL FOR RESPONSIBLE NUTRITION IN SUPPORT OF DEFENDANTS-APPELLEES' PETITION FOR REHEARING EN BANC

JENNIFER M.S. ADAMS
J. KATHLEEN BOND
AMIN TALATI UPADHYE, LLP
100 S. Wacker Dr., Suite 2000
Chicago, IL 60606
(312) 327-3383

Counsel for Amicus Curiae
The Council for Responsible Nutrition

COUNSEL PRESS · (866) 703-9373 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% or more of its stock.

Dated: January 22, 2019

Respectfully submitted,

By: */s/ Jennifer M.S. Adams*

Jennifer M.S. Adams
J. Kathleen Bond
AMIN TALATI UPADHYE, 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

Page(s)

Cases

Statutes and Regulations

Other Authorities

INTEREST 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 that manufacture dietary ingredients or dietary supplements, or supply services to those manufacturers. CRN members market popular national brands, as well as store brands. CRN members also include mainstream direct selling companies and companies marketing products through natural food stores.

CRN works with its members to ensure compliance with federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. As such, CRN has a special interest in this case, given that what is at stake, in significant part, is the appropriate substantive law applicable to private litigants bringing false advertising cases.

Prior to the Ninth Circuit's decision in *Sonner v. Schwabe North America, Inc.*, No. 17-55261, 2018 U.S. App. LEXIS 36460 (9th Cir. Dec. 26, 2018), prevailing law in California, and throughout much of the country, prevented private actors from challenging advertising substantiation as inadequate. Rather, under *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336 (2003), private plaintiffs could only bring deceptive advertising

cases if they could demonstrate with affirmative evidence that advertising claims were actually false. With this limitation, *King Bio* and its progeny appropriately recognized that government actors are uniquely positioned – and uniquely empowered – to consider, impartially, complex bodies of scientific literature and issue uniform pronouncements, while weighing the public health benefits.

The *Sonner* decision threatens to overturn *King Bio* by allowing private plaintiffs to attack substantiation in an identical manner as government actors. This departure impacts not only the Defendants in this case, but also the broader dietary supplement industry. CRN's interest as *Amicus Curiae* is to inform the Court as to the importance of *King Bio*, which provides well-reasoned protections not only for advertisers, but also the consumers.

No party or party's counsel authored this *Amicus Curiae* brief in whole or in part. No party or party's counsel contributed money that was intended to fund the preparation or submission of this brief. No person other than CRN, its members, or their counsel contributed money that was intended to fund the preparation or submission of this brief. Defendant Nature's Way is a member of CRN. An employee of Nature's Way serves on CRN's Board of Directors and Executive Committee.

SUMMARY OF ARGUMENT

In the landmark case, *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336 (2003), the California Court of Appeal drew a crucial distinction between private litigants and regulators who allege deceptive advertising. Based on the structure and intent of the existing laws governing deceptive advertising, *King Bio* held that only regulators may premise false advertising cases on an alleged lack of substantiation. Private litigants, by contrast, must identify facts that would affirmatively prove that an advertising claim is false or misleading.

In the fifteen years since *King Bio*, the vast majority of courts have continued to limit the role of private litigants in false advertising cases. Courts have scrutinized facts identified by private litigants and allowed cases to proceed only where the facts offered could prove *actual falsity*. Where plaintiffs have merely shown that the underlying science is weak or equivocal, courts have rejected claims by private litigants.

In considering a motion for summary judgment, a court "must not only properly consider the record on summary judgment, but must consider that record in light of the 'governing law.'" *Zetwick v. Cnty. of Yolo*, 850 F.3d 436 (9th Cir. 2017) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986)). In its recent decision in *Sonner v. Schwabe North America, Inc.*, No. 17-55261, 2018 U.S. App.

LEXIS 36460 (9th Cir. Dec. 26, 2018), the Ninth Circuit purported to consider the Defendant's motion for summary judgement in this manner, but refused to apply *King Bio*, the governing substantive law. While *King Bio* requires a private plaintiff to point to affirmative evidence that the advertising at issue is actually false, *Sonner* found – incorrectly – that this standard "elevat[es] the plaintiff's burden well beyond what is usually required to defeat summary judgment." *Sonner*, No. 17-55261, at *2, *8.

If the Ninth Circuit allows the *Sonner* decision to stand, *King Bio* could be eviscerated, allowing a patchwork of substantiation decisions driven by private litigants. Dietary supplement companies – and consumers who rely on their products – stand to be harmed. Sitting *en banc*, the Ninth Circuit should reverse the recent decision and, in doing so, continue to uphold *King Bio*.

ARGUMENT

I. THE NINTH CIRCUIT SHOULD CONTINUE TO FOLLOW *KING BIO*

A. *King Bio* Held That Private Litigants Must Offer Facts That Would Affirmatively Prove Falsity

In *King Bio*, a private litigant alleged that a seller of homeopathic remedies had violated California's false advertising laws by disseminating health benefit claims that lacked a "scientific basis." *Nat'l Council Against Health Fraud, Inc. v. King Bio*, 107 Cal. App. 4th 1336, 1341 (2003). The plaintiff offered no evidence in support of its allegations; rather, the plaintiff argued that "the burden of proof should be shifted to [the defendant] to prove its products' efficacy." *Id.* The court appropriately rejected this theory.

The court reviewed California's Unfair Competition Law ("UCL") (Bus. & Prof. Code § 17200 *et seq.*) and False Advertising Law ("FAL") (Bus. & Prof. Code § 17500 *et seq.*) and determined that the statutes clearly and expressly empower state regulators to demand "evidence of the facts on which such advertising claims are based." *Id.* at 1343 (citing Bus. & Prof. Code § 17508). The court, however, found that private plaintiffs are in no way similarly empowered. *Id.* at 1345.

The court reasoned that because government actors are uniquely empowered to demand an advertiser's substantiation, only government actors may bring false

advertising cases based on a lack of substantiation. *Id.* at 1349. Private plaintiffs, rather, must present evidence that would affirmatively prove that advertising claims are false. *Id.* at 1348. According to the court, to allow private actors to base cases on a lack of substantiation would "thwart the intent of the Legislature." *Id.* at 1345. The court observed that the distinction, embodied in the law, between private and government actors "prevents undue harassment of advertisers" and allows for "the least burdensome method of obtaining substantiation for advertising claims." *Id*.

B. *King Bio* Is Well-Established Law

In the fifteen years since *King Bio*, this court – and other courts in California and many other jurisdictions – have recognized the case as well- established law. *See, e.g.*, *Kwan v. SanMedica Int'l*, 854 F.3d 1088, 1096 (9th Cir. 2017) ("[I]t is readily apparent that *King Bio*'s holding is firmly established in California law."); *Racies v. Quincy Bioscience, LLC*, No. 15-cv-00292-HSG, 2015 WL 2398268, at *3 (N.D. Cal. May 19, 2015) ("It is well-settled that private litigants may not bring any UCL claims based on alleged lack of substantiation.").

Courts, moreover, have properly applied *King Bio*, requiring private plaintiffs to identify facts that, if proven, would demonstrate that claims are actually false. *See, e.g.*, *Kwan*, 854 F.3d at 1097 (dismissing where plaintiff failed

to identify any "specific facts pointing to actual falsehood"); *Reed v. NBTY, Inc.*, No. ED-CV-13-0142 JGB (OPx), 2014 WL 12284044, at *14-15 (C.D. Cal. Nov. 18, 2014) ("[i]nconclusive findings and unsettled science are insufficient to meet Plaintiff's burden of raising a question of fact on the issue of falsity" and "mixed evidence demonstrates at most that the science on effectiveness is inconclusive"); *Quinn v. Walgreen Co.*, 958 F.Supp.2d 533, 544 (S.D.N.Y. 2013) (private litigant must present facts that, if true, would show that advertising claims are "affirmatively false"); *Fraker v. Bayer Corp.*, No. CV 08-1564, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009) (granting motion to dismiss where Plaintiff failed to identify any evidence that might show that the "advertising claims with respect to [the product] are actually false").

For example, in *Stanley v. Bayer Healthcare LLC*, the plaintiff challenged advertising claims that a probiotic supplement "promote[s] overall digestive health" and "helps defend against" symptoms like gas and bloating. No. 3:11-cv-00862, 2012 WL 1132920, at *1-2 (S.D. Cal. Apr. 3, 2012). The plaintiffs alleged that the claims were deceptive because there were no studies on the specific blend of probiotics in the product, *id.* at *6, and "a majority of data generated in peer reviewed, double blind, placebo controlled studies relating to probiotics, largely suggests that probiotics have little effect on human digestive or immune health." *Id.* at *5.

The court reviewed the expert testimony, but ultimately determined that "none of the Plaintiff's experts opine that the claims [at issue] are actually false." *Id.* The court observed that "[i]nstead, Plaintiff's experts repeatedly assert the [advertising claims] are rendered false or misleading due to a lack of substantiation." *Id.* The court pointed to one expert's testimony that the effects of probiotics "var[y] dramatically between individuals" and that the science is "inconclusive" on whether probiotics might work for some people. *Id.* at *5-6. The court dismissed the plaintiff's allegations as inappropriately premised on a lack of substantiation. *Id.* at *5-9. It stated that "[t]he burden is upon Plaintiff to present evidence that Defendant's advertising claims are actually false or misleading." *Id.* at *9.

In *In re GNC*, the Fourth Circuit rendered a similar decision acknowledging the need to identify facts that, if true, would affirmatively disprove claims. 789 F.3d 505, 515-16 (4th Cir. 2015). In this case, plaintiffs challenged advertising claims for joint supplements that contained glucosamine and chondroitin, among other ingredients. *Id.* at 509-10. The advertising at issue claimed for instance "promote[] joint health and mobility" and "protect[] from wear and tear of exercise." *Id.* at 509. Plaintiffs alleged that "the vast weight of competent and reliable scientific evidence" proved that such claims were false. *Id.* at 510 (internal citation omitted). The plaintiffs noted multiple peer-reviewed studies on

glucosamine and chondroitin and two studies on another ingredient. *Id.* at 510-11. The Fourth Circuit found that the plaintiff's allegations lacked merit and granted the defendant's motion for summary judgment.

The court reasoned that the plaintiffs' own arguments revealed that the science "is equivocal." *Id.* at 515. The court stated that "[w]hen litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is literally false." *Id.* (internal quotation omitted). In order to state an actionable claim, the court held that the plaintiff must have alleged "that all reasonable experts in the field agree that the representations are false" and that "all of the ingredients contained in the products are incapable of providing the represented benefits." *Id.* at 516.

In contrast to cases like *Stanley* and *GNC*, courts have allowed cases to proceed where it is determined that a plaintiff could prove actual falsity. For instance, *Chavez v. Nestle, Inc.* involved claims that DHA added to a juice supports brain children's development. 511 Fed. Appx. 606, 606-607 (9th Cir. 2013). The plaintiff alleged that the juice contained only "very small amounts" and that "to obtain enough DHA . . . to promote potential brain development, young children need to consume an impractical and extremely high quantity of juice – more than a bottle's worth each day." *Id.* at 607. Where under-dosed DHA could prove the advertising claims actually false, the Ninth Circuit denied a motion for summary

judgment. *Id.*

Another case, *Murray v. Elations Co. LLC*, involved claims that a supplement "renews joint cartilage." No. 13-cv-02357-BAS, 2014 WL 3849911, at *8 (S.D. Cal. Aug. 4, 2014). A private plaintiff alleged that the claims were false and pointed to a study concluding that "adult cartilage cannot be regenerated." *Id.* Given that the study could prove the claim to "renew[] joint cartilage" actually false, the court allowed the case to proceed.

In sum, whether ending a case or allowing a case to proceed, most courts have followed *King Bio* and required plaintiffs to point to evidence that could prove actual falsity.

II. IN *SONNER*, THE NINTH CIRCUIT ERRED BY FAILING TO APPLY *KING BIO*, THE SUBSTANTIVE, GOVERNING LAW

In 2015, Kathleen Sonner filed a putative class action challenging claims that two Gingko biloba products support "mental sharpness," "memory," and "concentration." *Sonner*, No. No. 17-55261, at *4. The Defendants filed a motion for summary judgment arguing that the Plaintiff could not show falsity, as required under *King Bio*. *Id.* at 5.

In support of its arguments, the Plaintiff offered scientific studies and expert testimony suggesting that the Gingko biloba in the products has no effect on cognitive function. *Id.* The Defendants, however, offered contrary studies and

expert testimony supporting the advertising claims. *Id.* Because the Plaintiff failed, at any point, to offer "principled critiques" upon which a jury might disregard the positive studies as fatally flawed or unreliable, the district court properly dismissed the case. *Id.* at *5, *7; *see also Sonner*, 231 F. Supp. 3d 502, 509 (C.D. Cal. 2017) (citing *Mullins v. Premier Nutrition Corp.*, 178 F.Supp.3d 867, 896 (N.D. Cal. 2016)). According to the court, the Plaintiff failed to "foreclose[] any possibility that Defendants' products provide the advertised benefits" and, therefore, failed to "meet her burden to prove falsity." *Sonner*, 231 F. Supp. at 512.

In reviewing *Sonner*, the Ninth Circuit reversed the district court's decision based on a novel, incorrect analysis of the applicable standards. The Ninth Circuit refused to follow *King Bio* because it found that requiring evidence of actual falsity would "elevat[e] the plaintiff's burden well beyond what is usually required to defeat summary judgment." *Sonner*, No. No. 17-55261, at *2. *King Bio*, however, is *not* an evidentiary rule impacting the summary judgment standard and has never before been construed as such. Rather, *King Bio* is simply the substantive law that the court was obligated to consider in determining if a triable factual dispute existed.

The Ninth Circuit has long recognized that, in reviewing a summary judgment motion, the court "must not only properly consider the record on summary judgment, *but must consider that record in light of the 'governing law*.'"

Zetwick v. Cnty. of Yolo, 850 F.3d 436, 441 (9th Cir. 2017) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)) (emphasis added); *see also Fuller v. Idaho Dep't of Corr.*, 865 F.3d 1154, 1161 (9th Cir. 2017) (quoting *Ray v. Henderson*, 217 F.3d 1234, 1239-1240 (9th Cir. 2000)) ("[V]iewing the evidence in the light most favorable to the nonmoving party," the appellate court must determine "whether there are any genuine issues of material fact *and whether the [lower] court correctly applied the substantive law*."); *Soto v. Unknown Sweetman*, 882 F.3d 865, 869 (9th Cir. 2018).

The Ninth Circuit has reversed numerous summary judgment decisions where, as here, the court failed to apply the relevant, governing law in a particular case. For instance, *Mavrix Photographs v. LiveJournal, Inc.* involved allegations that a website operator engaged in copyright infringement by reposting another company's celebrity photos. 873 F.3d 1045, 1049 (9th Cir. 2017). The website operator argued that its reposting fit into an exception within Digital Millennium Copyright Act ("DMCA") for infringement resulting solely from user uploads. *Id.* at 1052. The lower court granted summary judgment in favor of the website operator. *Id.* at 1048. The Ninth Circuit, however, reversed after finding that the lower court failed to follow the correct law applicable to copyright cases in the Ninth Circuit. *Id.* at 1053. Specifically, the Ninth Circuit found that the lower court failed to apply the common law of agency to its interpretation of the DMCA

exception. *Id.* According to the Ninth Circuit, had the lower court followed the correct law, it would have found genuine disputes of material fact. *Id.*

Similarly, in *Zetwick*, the Ninth Circuit reversed a grant of summary judgment after finding that the lower court misapplied an applicable legal standard. *Zetwick*, 850 F.3d at 443. The plaintiff alleged workplace sexual harassment. *Id.* The Ninth Circuit found that the lower court in granting summary judgment had incorrectly focused on whether the defendant's alleged misconduct was "severe *and* pervasive," rather than the applicable standard, "severe *or* pervasive." *Id.* (emphasis added).

Just as the lower courts in these cases erred in failing to apply the prevailing law, the Ninth Circuit in *Sonner* erred in failing to require a private plaintiff to point to evidence that could prove claims are "actually false." *Fraker*, No. CV 08-1564, 2009 WL 5865687, at *8. By inexplicably conflating the application of the relevant substantive law with "elevating the plaintiff's burden" in a summary judgment case, the court created entirely new standards. *Sonner*, No. 17-55261, at *2. The court's holding is not only inconsistent with *King Bio*, but inconsistent with existing law as to how to apply the relevant, substantive law in summary judgment cases. CRN strongly believes that *en banc* consideration is appropriate given the novel questions and questions of exceptional importance presented in this case. *See* Fed. R. App. P. 35(b)(1)(B); Ninth Circuit Rule 29-2 (*amicus* brief in

support of *en banc* hearing is appropriate when related to novel issues).

III. THE PUBLIC INTEREST IS SERVED BY CONTINUING TO FOLLOW *KING BIO*

The evidence underlying health benefit claims for dietary supplements and other foods is often extremely complex, with studies utilizing a variety of designs and sometimes yielding inconsistent results. Regulators, however, are uniquely equipped with appropriate expertise not only to assess equivocal or conflicting science, but also consider it in the context of factors including the nature and cost of the product and potential public health implications.

In addition to state regulators, the Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") share jurisdiction over advertising claims for dietary supplements. *See* 15 U.S.C. §§ 45(a)(1), 52(a); 21 U.S.C. § 331. Courts have long acknowledged the FDA's scientific expertise regarding the broad range of products regulated by the agency. *See, e.g.*, *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) ("FDA possesses the requisite know-how to conduct such [scientific] analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information"). Courts likewise have credited the FTC's unique expertise in reviewing advertising and setting practice standards for advertisers. *See POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015) (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965)) ("The Commission 'is often in a better position than are courts to determine when a

practice is deceptive within the meaning of the [FTC] Act,' and that 'admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this field rests so heavily on inference and pragmatic judgment.'").

The courts have long held that health-related advertising 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. Virginia 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, regulators eschew a substantiation standard that requires absolute truth or unequivocal science. Regulators, rather, apply a "reasonable basis" standard that takes into consideration an array of practical factors including the "type of product," "the potential benefits of a truthful claims," "the cost of developing substantiation," and "the amount of evidence experts in the field believe is reasonable." *See* Dietary Supplements: An Advertising Guide for Industry, at 8-9; *see also* FDA, Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008). Although applying the "reasonable basis" standard requires a complex, multi-factor analysis, it helps "to ensure that consumers have access to information." Dietary Supplements: An Advertising Guide for Industry, at 8. For a

low-cost, safe product like a food, personal care product, or even a Gingko biloba supplement, the bar will not be set nearly so high as it would be, for instance, for a prescription drug or other product requiring agency preapproval.

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 ingredient with disease risk reduction) utilizes notice and comment rulemaking. 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 provides an informative example illustrating the complexity of the analysis and how regulators nevertheless routinely reach decisions with public health considerations in mind.

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 it 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 the 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 claim. *Id.* at 8752; 21 C.F.R. § 101.79 (rule authorizing folic acid health claim). The agency determined that enough consistent 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. If health-related science is *not* assessed with flexibility and a public health mindset, consumers stand to lose.

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").

Given the complexities of nutrition science and the unique expertise – and public health mindset – of regulators, this discrete group should continue to be the sole arbiters in weighing substantiation. If private actors are allowed to seize on any inconsistency or weakness that might be found in a complex body of research, both advertisers – 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 dilute the significance and authority of expert government actors and discourage manufacturers from innovating in the nutrition space, or disseminating health benefit claims at all.

King Bio properly limits the role of private litigants by requiring that they "affirmatively prove that [an advertising claim] is a false or misleading statement and not merely one that is unsubstantiated." *Scheuerman v. Nestle Healthcare Nutrition, Inc.*, No. 10-3684, 2012 WL 2916827, at *8 (D.N.J. July 16, 2012).

CONCLUSION

For the foregoing reasons, CRN urges the Ninth Circuit to rehear and reverse *Sonner*, and affirm the decision by Judge Phillips in the Central District of California.

Dated: January 22, 2019

Respectfully submitted,

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

Attorney for *Amicus Curiae* The Council for Responsible Nutrition

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of 9th Cir. R. 29-2(c)(2) because this brief contains 4,191 words, excluding the parts of the brief exempted by Fed.R.App.P. 32(f) and 9th Circuit R. 32-1(c).

In addition, this brief complies with the typeface requirements of Fed.R.App.P. 32(a)(5) and the type style requirements of Fed.R.App.P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2003, typeface of 14 points and type style of Times New Roman.

Dated: January 22, 2019

/s/ Jennifer M.S. Adams

Jennifer M.S. Adams
J. Kathleen Bond
AMIN TALATI UPADHYE, LLP
100 S. Wacker Dr., Suite 2000
Chicago, IL 60606
T: (312) 327-3383
F: (312) 884-7352

Attorneys for Amicus Curiae, The Council for Responsible Nutrition

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the Amicus Curiae Brief of The Council for Responsible Nutrition in Support of Defendants-Appellees' Petition for Rehearing En Banc with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on January 22, 2019.

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

Dated: January 22, 2019

/s/ Jennifer M.S. Adams

Jennifer M.S. Adams
J. Kathleen Bond
AMIN TALATI UPADHYE, LLP
100 S. Wacker Dr., Suite 2000
Chicago, IL 60606
T: (312) 327-3383
F: (312) 884-7352

Attorneys for Amicus Curiae, The Council for Responsible Nutrition