No. 17-56435

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; NBTY, INC.,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of California, San Diego, No. 3:15-cv-00709-CAB-RBB.
The Honorable **Cathy Ann Bencivengo**, Judge Presiding.

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

KATIE BOND
REND AL-MONDHIRY
SANJAY S. KARNIK
JENNIFER M.S. ADAMS
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 Rules 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 that no publicly held company owns more than 10% of more of its stock.

Dated: April 5, 2018

Respectfully submitted:

/s/ Jennifer M.S. Adams
Katie Bond
Rend Al-Mondhiry
Sanjay S. Karnik
Jennifer M.S. Adams
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 Counsel for Responsible Nutrition

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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. 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 appeal, given that what is at stake, in significant part, is the appropriate legal standard for private litigants bringing false advertising cases. The current, prevailing standard limits the ability of private actors to bring cases based on a lack of substantiation. This standard appropriately recognizes that government actors are uniquely positioned to consider, impartially, complex bodies of scientific literature and issue uniform pronouncements, while weighing the public health benefits. If the current standard is overturned, well-reasoned protections for advertisers – and consumers who buy

their products – will be eviscerated. A departure from this standard would impact not only Defendant-Appellees, but also the broader dietary supplement industry. CRN's interest as *Amicus Curiae* is to inform the Court on whether the District Court applied the proper standard when it granted the Defendant's motion for summary judgment.

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.

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 underlying laws governing deceptive advertising, *King Bio* held that only regulators may premise false advertising cases on an alleged lack of substantiation. Private litigants, in 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. 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. This Court should affirm the decision below, and in doing so continue to uphold *King Bio*.

If this Court were to adopt the Appellants' arguments in this case, *King Bio* would be eviscerated, allowing a patchwork of decisions driven by private litigants. Dietary supplement companies – and consumers who rely on their products – stand to be harmed.

ARGUMENT

I. THIS COURT SHOULD CONTINUE TO FOLLOW *KING BIO* AND REQUIRE PRIVATE PLAINTIFFS TO PROVE FALSITY

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 unfair competition and false advertising laws by disseminating health benefit claims that lacked a "scientific basis." *King Bio*, 107 Cal. App. 4th at 1341. 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 soundly and 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 – such as "testing, scientific literature, or anecdotal evidence" – that would affirmatively prove that advertising claims are false. *Id.* at 1348. To allow private actors to base cases on a lack of substantiation, which is the claim private actors must base their action on when they are unable to affirmatively prove falsity, 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

This Court has confirmed twice in the past year that "*King Bio*'s holding is firmly established law in California." *Kwan v. SanMedica Int'l*, 854 F.3d 1096, 1095 (9th Cir. 2017); *see also Aloudi v. Intramedic Research Grp., LLC*, No. 16-15876, 2017 U.S. App. LEXIS 25420, at *2 (9th Cir. Dec. 15, 2017) (citing *King Bio* to hold that "[u]nder California law, private litigants can bring claims alleging that an advertising representation is actually false or misleading. Cal. Bus. & Prof. Code §§ 17200, 17500. By contrast, private litigants may not sue advertisers claiming that advertising representations lack substantiation.") (affirming dismissal of complaint for failing to state an actual falsity claim).

The majority of California district courts have also followed *King Bio* and rejected private litigant's attempts to bicker about substantiation. *See, e.g.*, *Fraker v. Bayer Corp.*, No. CV F 08-1564, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009) (granting motion to dismiss in action challenging metabolism statements, where Plaintiff failed to identify any evidence that might show that the "advertising claims with respect to [the product] are actually false; not simply that they are not backed up by science."); *Kwan*, No. 15-15496, 2017 WL 1416483, at *6 (granting motion

to dismiss in action against hormone labels where plaintiff failed to identify any "specific facts pointing to actual falsehood").

Many courts in other jurisdictions have likewise followed *King Bio* for many years. For example, in *In re GNC*, the Fourth Circuit applied *King Bio*. 789 F.3d 505, 515-516 (4th Cir. 2015). Plaintiffs had challenged claims that supplements containing glucosamine and chondroitin, among other ingredients, "promote[] joint health and mobility" and "protect[] from wear and tear of exercise." *Id.* at 509-510. Plaintiffs alleged that "the vast weight of competent and reliable scientific evidence" proved that the claims were false. *Id.* at 510 (internal citation omitted). They identified multiple published studies on glucosamine and chondroitin and two studies on another ingredient. *Id.* at 510-511. The Fourth Circuit found that the plaintiffs' allegations lacked merit and granted the defendant's motion for summary judgment.

The court reasoned that the plaintiffs' own arguments revealed that the evidence "is equivocal," which simply means that the scientific evidence is open to more than one interpretation. *Id.* at 515. The court further 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.* at 515 (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 (emphasis added).

II. THE DISTRICT COURT DECISION IS ENTIRELY CONSISTENT WITH *KING BIO* AND ITS PROGENY

Drawing from *In re GNC* and other similar cases, the District Court properly rejected a minority-view case, *Mullins v. Premier Nutrition Corp.*, 178 F.Supp. 3d 867, 894 (N.D. Cal. 2016). In *Mullins*, the plaintiff challenged advertising claims for Joint Juice, a liquid dietary supplement containing glucosamine and chondroitin, among other ingredients. 178 F.Supp.3d at 875. The defendant offered expert evidence in support of its advertising claims and pointed to studies showing the beneficial effects. *Id.* at 884-886. In response, the plaintiff offered expert evidence and clinical studies that allegedly disproved the defendant's advertising claims. *Id.* at 882-886.

The court declined to grant a motion for summary judgment, holding that the plaintiff could properly show that the Joint Juice claims were misleading if she could show that "the vast weight of competent evidence establishes that the [defendant's] health claims [were] false." *Id.* at 895. The court further explained that the plaintiff had made a threshold showing by offering "principled critiques" of the studies relied upon by the defendant and its expert. *Id.* at 895-896.

The District Court properly determined that *Mullins* is irreconcilable with *King Bio*. MSJ Order at 10. The District Court also similarly disposed of an incorrect holding of *Zakaria v. Gerber Prods Co.*, Case No. LA CV15-00200 JAK(Ex), 2015 WL 4379743 (C.D. Cal. Jul. 14, 2015). *Id.* at 6-7 n.2. The District Court then properly held that "[n]o jury conclusion would change" the fact that substantiation evidence is equivocal when both a plaintiff and defendant presents admissible expert testimony that scientific studies do not or do support a challenged advertised claim, respectively. MSJ Order at 11.

This Court should affirm the decision below, and in doing so continue to uphold *King Bio*. If this Court were to adopt the Appellant's outlier interpretation of *King Bio*, the holding would be eviscerated, allowing a patchwork of decisions driven by private litigants. Dietary supplement companies – and consumers who rely on their products – stand to be harmed.

III. THE PUBLIC INTEREST IS SERVED BY *KING BIO*

The evidence underlying health benefit claims for dietary supplements and other foods is often extremely complex, with studies utilizing a variety of different designs, and sometimes yielding inconsistent results. Research studying the exact same ingredient can reach different results, in many cases because of variations in the dosage level, frequency of administration, length of administration, length of follow up, nature of the population being studied, blood levels in the subjects prior

to starting the intervention, crossover or wash-out effects, and a host of other factors. These variables often necessitate replication of trials before scientific consensus can be reached, but do not relegate these studies to confirming that claim is false. Rather, they contribute to the totality of evidence and understanding of the health effects of these ingredients. Regulators, unlike private actors, are impartial actors who are uniquely equipped with the appropriate expertise not only to assess equivocal or conflicting science, but also to consider it in the context of public health implications.

In addition to state regulators, the federal Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") share jurisdiction over advertising claims for supplements. *See* 15 U.S.C. §§ 45(a)(1), 52(a); 21 U.S.C. § 331. The approval process for FDA's health claim for folic acid provides an informative example illustrating the complexity of nutritional science and how regulators routinely reach decisions with public health considerations in mind even when the science is open to debate. While most government assessments of claim substantiation occur without the opportunity for public observation, the FDA's approval of "health claims" (claims associating a substance with disease risk

reduction) utilizes notice and comment rulemaking,[1] which allows transparency into regulators' evaluation of data that may not be completely conclusive.

In determining whether to authorize a claim associating folic acid with a reduced risk of neural tube defects, the FDA and other stakeholders carefully reviewed the science and considered the potential public health implications. *See* 61 Fed. Reg. 8752 (Mar. 5, 1996). Only a small number of relevant studies existed: two randomized controlled studies, one of which was conducted in Hungary, and five observational studies. *Id.* at 8756. In order to assist in its assessment, the FDA convened its own Folic Acid Subcommittee and reviewed comments from other Federal agencies, State entities, health care professionals, consumers, and consumer advocacy groups, among others. *Id.* at 8755.

The FDA received a wide range of comments representing divergent views, 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

[1] The FDA has the authority to authorize "health claims" which are claims that associate a dietary substance with a reduction in disease risk. 21 U.S.C. § 343(r)(1)(b); 21 C.F.R. § 101.14(a)(1).

"there are still significant gaps in our knowledge about the etiology of neural tube defects" including about "how folate . . . reduces the risk of neural tube defects" and "the role of other essential nutrients in the etiology of neural tube defects." *Id.*

Despite the divergent views, the FDA ultimately authorized a claim. *Id.* at 8752; 21 C.F.R. § 101.79. 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, providing a uniform standard that may be used in the labeling of supplements or foods. The folic acid health claim also illustrates how regulatory agencies can judiciously evaluate science – that if left to private litigants to merely allege falsity by questioning the type of substantiation used to support a claim, without having to demonstrate actual falsity – would shut down consumers' ability to learn of beneficial products and deny advancements in public health.

Given the complexities of nutrition science and the unique expertise – and public health mindset – of regulators, this discrete group of government officials should continue to be the sole arbiters in weighing substantiation in a given case. 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 authority of expert government actors and discourage manufacturers from innovating in the nutrition space.

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).

IV. CONCLUSION

For these reasons, the District Court's application of *King Bio* should be upheld.

Dated: April 5, 2018

Respectfully submitted:

/s/ Jennifer M.S. Adams
Katie Bond
Rend Al-Mondhiry
Sanjay S. Karnik
Jennifer M.S. Adams
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 Counsel for Responsible Nutrition

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed.R.App.P. 29(a)(5) and Fed.R.App.P. 32(a)(7)(B)(i) because this brief contains 2,511 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: April 5, 2018

/s/ Jennifer M.S. Adams

Katie Bond
Rend Al-Mondhiry
Sanjay S. Karnik
Jennifer M.S. Adams
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 Counsel 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 and Affirmance 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 April 5, 2018.

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: April 5, 2018

/s/ Jennifer M.S. Adams

Katie Bond
Rend Al-Mondhiry
Sanjay S. Karnik
Jennifer M.S. Adams
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 Counsel for Responsible Nutrition